Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Finerenon (KERENDIA®)

Bayer Vital GmbH

Modul 4B, Anhang 4-I

Erwachsene mit chronischer Nierenerkrankung (Stadium 1 und 2 mit Albuminurie) und Diabetes mellitus Typ II

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 22.02.2023

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4.2 Disposition

Table 4.2 / 1: Subject disposition (all enrolled Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			13911
Screening failures			8177
Randomized	217	223	440
GCP VIOLATIONS	6	2	8
Full analysis set	211 (100.0%)	221 (100.0%)	432 (100.0%)
Study drug never administered	1 (0.5%)	0	1 (0.2%)
Treated	210 (99.5%)	221 (100.0%)	431 (99.8%)
Did not complete study	0	1 (0.5%)	1 (0.2%)
WITHDRAWN CONSENT	0	1 (0.5%)	1 (0.2%)
LOST TO FOLLOW-UP	0	0	0
Completed study	211 (100.0%)	220 (99.5%)	431 (99.8%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
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Table 4.2 / 2: Disposition: End of treatment (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Completed epoch	164 (77.7%)	169 (76.5%)	333 (77.1%)
Not completed	47 (22.3%)	52 (23.5%)	99 (22.9%)
Primary reason			
ADVERSE EVENT	16 (7.6%)	18 (8.1%)	34 (7.9%)
DEATH	12 (5.7%)	8 (3.6%)	20 (4.6%)
WITHDRAWAL BY SUBJECT	12 (5.7%)	13 (5.9%)	25 (5.8%)
LOST TO FOLLOW-UP	0	1 (0.5%)	1 (0.2%)
NON-COMPLIANCE WITH STUDY DRUG	0	1 (0.5%)	1 (0.2%)
PHYSICIAN DECISION	2 (0.9%)	7 (3.2%)	9 (2.1%)
TECHNICAL PROBLEMS	3 (1.4%)	3 (1.4%)	6 (1.4%)
PROTOCOL DEVIATION	1 (0.5%)	1 (0.5%)	2 (0.5%)
OTHER	1 (0.5%)	0	1 (0.2%)

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4.3 Demographic characteristics

Table 4.3 / 1: Demographics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Race (N)			
WHITE	140 (66.4%)	152 (68.8%)	292 (67.6%)
BLACK OR AFRICAN AMERICAN	10 (4.7%)	9 (4.1%)	19 (4.4%)
ASIAN	39 (18.5%)	44 (19.9%)	83 (19.2%)
AMERICAN INDIAN OR ALASKA NATIVE	11 (5.2%)	12 (5.4%)	23 (5.3%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	2 (0.9%)	0	2 (0.5%)
NOT REPORTED	0	1 (0.5%)	1 (0.2%)
MULTIPLE	9 (4.3%)	3 (1.4%)	12 (2.8%)
Sex (N)			
Male	153 (72.5%)	154 (69.7%)	307 (71.1%)
Female	58 (27.5%)	67 (30.3%)	125 (28.9%)
Age (YEARS)			
n	211	221	432
Mean	63.85	64.09	63.97
SD	7.86	9.88	8.94
Min	40.0	28.0	28.0
Q1	59.00	58.00	59.00
Median	65.00	65.00	65.00
Q3	69.00	71.00	70.00
Max	82.0	86.0	86.0
Run-in age group (years) category (N)			
18 - 44 years	5 (2.4%)	9 (4.1%)	14 (3.2%)
45 - 64 years	94 (44.5%)	87 (39.4%)	181 (41.9%)
65 - 74 years	101 (47.9%)	96 (43.4%)	197 (45.6%)
>= 75 years	11 (5.2%)	29 (13.1%)	40 (9.3%)
Age group (years) category 3 (N)			
< 65 years	99 (46.9%)	96 (43.4%)	195 (45.1%)
>= 65 years	112 (53.1%)	125 (56.6%)	237 (54.9%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	179 (84.8%)	184 (83.3%)	363 (84.0%)
HISPANIC OR LATINO	30 (14.2%)	37 (16.7%)	67 (15.5%)
NOT REPORTED	2 (0.9%)	0	2 (0.5%)

Table 4.3 / 1: Demographics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Region (N)			
Europe	104 (49.3%)	112 (50.7%)	216 (50.0%)
North America	42 (19.9%)	40 (18.1%)	82 (19.0%)
Asia	39 (18.5%)	41 (18.6%)	80 (18.5%)
Latin America	21 (10.0%)	24 (10.9%)	45 (10.4%)
Others	5 (2.4%)	4 (1.8%)	9 (2.1%)
Baseline Weight (kg)			
n	210	221	431
Mean	88.14	88.55	88.35
SD	19.37	20.52	19.94
Min	52.5	50.0	50.0
Q1	75.10	74.10	74.90
Median	86.25	85.40	85.70
Q3	97.20	99.80	98.50
Max	163.3	156.0	163.3
Baseline weight (kg) category (N)			
missing	1 (0.5%)	0	1 (0.2%)
< 60 kg	10 (4.7%)	12 (5.4%)	22 (5.1%)
60 - < 90 kg	114 (54.0%)	116 (52.5%)	230 (53.2%)
>= 90 kg	86 (40.8%)	93 (42.1%)	179 (41.4%)
Baseline Height (cm)			
n	211	221	432
Mean	167.90	168.49	168.20
SD	9.65	10.49	10.08
Min	143.0	141.0	141.0
Q1	161.00	161.30	161.15
Median	169.00	169.00	169.00
Q3	175.10	176.00	175.65
Max	189.0	193.0	193.0

Table 4.3 / 1: Demographics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline Body Mass Index (kg/m2)			
n	210	221	431
Mean	31.18	30.99	31.08
SD	5.77	5.55	5.65
Min	21.5	19.7	19.7
Q1	27.10	27.20	27.10
Median	30.30	30.50	30.40
Q3	34.00	34.20	34.10
Max	55.6	51.3	55.6
Baseline BMI (kg/m2) category 2 (N)			
missing	1 (0.5%)	0	1 (0.2%)
< 30 kg/m2	95 (45.0%)	98 (44.3%)	193 (44.7%)
>= 30 kg/m2	115 (54.5%)	123 (55.7%)	238 (55.1%)
Baseline BMI (kg/m2) category 3 (N)			
missing	1 (0.5%)	0	1 (0.2%)
< 20 kg/m2	0	2 (0.9%)	2 (0.5%)
20 - < 25 kg/m2	21 (10.0%)	26 (11.8%)	47 (10.9%)
25 - < 30 kg/m2	74 (35.1%)	70 (31.7%)	144 (33.3%)
30 - < 35 kg/m2	71 (33.6%)	76 (34.4%)	147 (34.0%)
>= 35 kg/m2	44 (20.9%)	47 (21.3%)	91 (21.1%)
Baseline Hip Circumference (cm)			
n	211	220	431
Mean	106.83	106.78	106.81
SD	13.74	13.22	13.46
Min	50.0	53.5	50.0
Q1	99.00	99.00	99.00
Median	104.00	105.20	105.00
Q3	113.50	115.05	114.00
Max	164.0	156.0	164.0

Table 4.3 / 1: Demographics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline waist circumference (cm)			
n	211	220	431
Mean	106.53	106.96	106.75
SD	14.61	14.63	14.61
Min	51.0	76.4	51.0
Q1	97.00	96.00	96.50
Median	105.00	106.45	106.00
Q3	114.00	116.00	115.00
Max	157.5	154.0	157.5
Baseline waist circumf. (cm) cat. (N)			
missing	0	1 (0.5%)	1 (0.2%)
normal	19 (9.0%)	26 (11.8%)	45 (10.4%)
increased	49 (23.2%)	42 (19.0%)	91 (21.1%)
substantially increased	143 (67.8%)	152 (68.8%)	295 (68.3%)
Baseline waist-hip ratio (N)			
n	211	220	431
Mean	1.00	1.01	1.00
SD	0.12	0.12	0.12
Min	0.7	0.7	0.7
Q1	0.94	0.94	0.94
Median	1.00	1.00	1.00
Q3	1.04	1.05	1.05
Max	2.1	2.1	2.1
Smoking History (N)			
NEVER	100 (47.4%)	105 (47.5%)	205 (47.5%)
FORMER	74 (35.1%)	84 (38.0%)	158 (36.6%)
CURRENT	37 (17.5%)	32 (14.5%)	69 (16.0%)

Table 4.3 / 1: Demographics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Alcohol Use (N)			
ABSTINENT	126 (59.7%)	120 (54.3%)	246 (56.9%)
LIGHT	76 (36.0%)	85 (38.5%)	161 (37.3%)
MODERATE	8 (3.8%)	14 (6.3%)	22 (5.1%)
HEAVY	1 (0.5%)	2 (0.9%)	3 (0.7%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
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4.4 Baseline characteristics

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline potassium (mmol/L)			
n	211	221	432
Arithm. Mean	4.34	4.32	4.33
Arithm. SD	0.45	0.45	0.45
Min	3.0	3.0	3.0
Q1	4.00	4.00	4.00
Median	4.30	4.30	4.30
Q3	4.60	4.60	4.60
Max	5.7	5.9	5.9
Baseline ser. potassium (mmol/L) cat.(N)			
<= 4.5 mmol/L	144 (68.2%)	158 (71.5%)	302 (69.9%)
> 4.5 mmol/L	67 (31.8%)	63 (28.5%)	130 (30.1%)
Base. ser. potassium (mmol/L) cat.10 (N)			
<=4.8 mmol/L	187 (88.6%)	201 (91.0%)	388 (89.8%)
>4.8 to <=5.0 mmol/L	13 (6.2%)	8 (3.6%)	21 (4.9%)
>5.0 mmol/L	11 (5.2%)	12 (5.4%)	23 (5.3%)
Basel. potass (mmol/L) median FAS (N)			
<= 4.30 mmol/L (median in FAS)	106 (50.2%)	118 (53.4%)	224 (51.9%)
> 4.30 mmol/L (median in FAS)	105 (49.8%)	103 (46.6%)	208 (48.1%)
Basel. potass (mmol/L) quartiles FAS (N)			
<=4.1 mmol/L (<= Q1 in FAS)	71 (33.6%)	81 (36.7%)	152 (35.2%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	35 (16.6%)	37 (16.7%)	72 (16.7%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	53 (25.1%)	57 (25.8%)	110 (25.5%)
>4.6 mmol/L (>Q3 in FAS)	52 (24.6%)	46 (20.8%)	98 (22.7%)
Baseline Systolic Blood Pressure (mmHg)			
n	211	221	432
Arithm. Mean	137.28	139.44	138.38
Arithm. SD	13.74	13.41	13.60
Min	92.0	93.3	92.0
Q1	128.33	130.00	129.17
Median	138.00	139.00	138.50
Q3	146.33	148.00	147.50
Max	185.3	188.0	188.0

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline SBP (mmHg) category (N)			
< 130 mmHg	64 (30.3%)	54 (24.4%)	118 (27.3%)
130 - < 160 mmHg	138 (65.4%)	156 (70.6%)	294 (68.1%)
>= 160 mmHg	9 (4.3%)	11 (5.0%)	20 (4.6%)
Baseline SBP (mmHg) median for FAS (N)			
<= 137.00 mmHg (median in FAS)	99 (46.9%)	95 (43.0%)	194 (44.9%)
> 137.00 mmHg (median in FAS)	112 (53.1%)	126 (57.0%)	238 (55.1%)
Baseline Diastolic Blood Pressure (mmHg)			
n	211	221	432
Arithm. Mean	77.52	77.75	77.64
Arithm. SD	9.70	9.48	9.57
Min	39.7	54.0	39.7
Q1	71.67	70.67	71.00
Median	78.33	78.00	78.17
Q3	83.33	84.67	84.00
Max	103.3	102.7	103.3
Baseline Heart Rate (BEATS/MIN)			
n	211	221	432
Arithm. Mean	72.31	72.50	72.41
Arithm. SD	11.02	10.20	10.60
Min	44.7	49.7	44.7
Q1	64.33	65.00	65.00
Median	73.00	72.00	72.50
Q3	80.00	78.67	79.67
Max	102.3	104.3	104.3
Baseline eGFR (mL/min/1.73m2)			
n	211	221	432
Arithm. Mean	65.15	64.72	64.93
Arithm. SD	9.57	9.75	9.65
Min	29.0	29.3	29.0
Q1	59.30	59.60	59.50
Median	65.70	64.40	65.00
Q3	70.30	70.40	70.35
Max	91.9	104.2	104.2

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline eGFR (mL/min/1.73m2) cat.(N)			
25 - < 45 mL/min/1.73m2	4 (1.9%)	5 (2.3%)	9 (2.1%)
45 - < 60 mL/min/1.73m2	57 (27.0%)	57 (25.8%)	114 (26.4%)
>= 60 mL/min/1.73m2	150 (71.1%)	159 (71.9%)	309 (71.5%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
< 30 mL/min/1.73m2	2 (0.9%)	1 (0.5%)	3 (0.7%)
30 - < 60 mL/min/1.73m2	59 (28.0%)	61 (27.6%)	120 (27.8%)
60 - < 90 mL/min/1.73m2	149 (70.6%)	157 (71.0%)	306 (70.8%)
>= 90 mL/min/1.73m2	1 (0.5%)	2 (0.9%)	3 (0.7%)
Screening eGFR (mL/min/1.73m2)			
n	210	221	431
Arithm. Mean	66.59	66.54	66.56
Arithm. SD	4.43	4.99	4.72
Min	60.1	60.0	60.0
Q1	62.80	62.40	62.60
Median	66.15	65.90	66.00
Q3	70.10	69.50	69.70
Max	80.8	100.8	100.8
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	1 (0.5%)	0	1 (0.2%)
>= 60 mL/min/1.73m2	210 (99.5%)	221 (100.0%)	431 (99.8%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	1 (0.5%)	0	1 (0.2%)
60 - < 90 mL/min/1.73m2	210 (99.5%)	220 (99.5%)	430 (99.5%)
>= 90 mL/min/1.73m2	0	1 (0.5%)	1 (0.2%)
Baseline UACR (mg/g)			
n	211	221	432
Geom. Mean	812.71	814.90	813.83
Geom. SD	2.26	2.15	2.20
Min	50.1	51.3	50.1
Q1	464.64	470.85	468.42
Median	798.00	758.37	781.61
Q3	1406.73	1388.84	1396.24
Max	4902.9	5924.9	5924.9

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline albuminuria (mg/g) cat. (N)			
High albuminuria (30 mg/g - < 300 mg/g)	19 (9.0%)	12 (5.4%)	31 (7.2%)
Very high albuminuria (>= 300 mg/g)	192 (91.0%)	209 (94.6%)	401 (92.8%)
Baseline UACR (mg/g) cat. median fas (N)			
<= 514.7 mg/g (median in FAS)	63 (29.9%)	70 (31.7%)	133 (30.8%)
> 514.7 mg/g (median in FAS)	148 (70.1%)	151 (68.3%)	299 (69.2%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
NO	210 (99.5%)	218 (98.6%)	428 (99.1%)
YES	1 (0.5%)	3 (1.4%)	4 (0.9%)
Baseline Creatinine (mg/dL)			
n	211	221	432
Arithm. Mean	1.12	1.12	1.12
Arithm. SD	0.21	0.21	0.21
Min	0.7	0.6	0.6
Q1	1.00	0.99	0.99
Median	1.12	1.14	1.13
Q3	1.23	1.23	1.23
Max	2.1	2.2	2.2
Baseline Albumin (g/dL) in Serum			
n	211	221	432
Arithm. Mean	4.16	4.17	4.17
Arithm. SD	0.33	0.36	0.34
Min	2.9	2.0	2.0
Q1	4.00	4.00	4.00
Median	4.20	4.20	4.20
Q3	4.40	4.40	4.40
Max	5.0	5.3	5.3

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Baseline Hemoglobin (g/dL) in Blood			
n	211	221	432
Arithm. Mean	13.55	13.64	13.60
Arithm. SD	1.57	1.47	1.52
Min	6.6	9.4	6.6
Q1	12.60	12.60	12.60
Median	13.60	13.60	13.60
Q3	14.60	14.70	14.60
Max	18.0	17.1	18.0
Baseline Hemoglobin A1C (%)			
n	211	221	432
Arithm. Mean	7.76	7.76	7.76
Arithm. SD	1.38	1.29	1.33
Min	4.9	5.2	4.9
Q1	6.70	6.80	6.75
Median	7.60	7.60	7.60
Q3	8.70	8.60	8.70
Max	12.2	10.6	12.2
Basel. Hemoglobin A1C % cat. 2 (N)			
<= 7.5%	104 (49.3%)	110 (49.8%)	214 (49.5%)
> 7.5%	107 (50.7%)	111 (50.2%)	218 (50.5%)
Basel. HBA1C (%) quartiles FAS (N)			
<=6.7 % (<= Q1 in FAS)	53 (25.1%)	55 (24.9%)	108 (25.0%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	51 (24.2%)	55 (24.9%)	106 (24.5%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	47 (22.3%)	54 (24.4%)	101 (23.4%)
>8.5 % (>Q3 in FAS)	60 (28.4%)	57 (25.8%)	117 (27.1%)
Baseline C Reactive Protein (mg/L)			
n	210	220	430
Arithm. Mean	4.23	4.98	4.61
Arithm. SD	8.34	13.14	11.05
Min	0.1	0.1	0.1
Q1	0.96	0.98	0.97
Median	2.09	1.87	1.99
Q3	5.05	4.27	4.72
Max	106.0	163.0	163.0

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Basel. C Reactive Protein Quartiles (N)			
missing	1 (0.5%)	1 (0.5%)	2 (0.5%)
<=0.95 % (<= Q1 in FAS)	51 (24.2%)	53 (24.0%)	104 (24.1%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	58 (27.5%)	66 (29.9%)	124 (28.7%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	50 (23.7%)	58 (26.2%)	108 (25.0%)
>5.13 % (>Q3 in FAS)	51 (24.2%)	43 (19.5%)	94 (21.8%)
Stratification factor 3 (N)			
CVD present	88 (41.7%)	89 (40.3%)	177 (41.0%)
CVD absent	123 (58.3%)	132 (59.7%)	255 (59.0%)
Hyperkalemia (based on MLG) in MH (N)			
NO	210 (99.5%)	220 (99.5%)	430 (99.5%)
YES	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hepatic impairment in medical history(N)			
NO	180 (85.3%)	186 (84.2%)	366 (84.7%)
YES	31 (14.7%)	35 (15.8%)	66 (15.3%)
Child Pugh (N)			
likely Child Pugh A	204 (96.7%)	211 (95.5%)	415 (96.1%)
likely Child Pugh B	7 (3.3%)	9 (4.1%)	16 (3.7%)
certain Child Pugh B	0	1 (0.5%)	1 (0.2%)
Duration of diabetes (in years) (N)			
n	211	220	431
Arithm. Mean	15.33	15.56	15.45
Arithm. SD	7.88	8.34	8.11
Min	0.4	0.3	0.3
Q1	9.33	10.00	9.91
Median	14.29	15.22	15.13
Q3	20.30	20.70	20.30
Max	41.1	41.1	41.1
ACEI use (N)			
NO	125 (59.2%)	129 (58.4%)	254 (58.8%)
YES	86 (40.8%)	92 (41.6%)	178 (41.2%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
ARB use (N)			
NO	86 (40.8%)	92 (41.6%)	178 (41.2%)
YES	125 (59.2%)	129 (58.4%)	254 (58.8%)
Beta blocker use at baseline (N)			
NO	114 (54.0%)	114 (51.6%)	228 (52.8%)
YES	97 (46.0%)	107 (48.4%)	204 (47.2%)
Diuretic use at baseline (N)			
NO	108 (51.2%)	105 (47.5%)	213 (49.3%)
YES	103 (48.8%)	116 (52.5%)	219 (50.7%)
Statins use at baseline (N)			
NO	68 (32.2%)	67 (30.3%)	135 (31.3%)
YES	143 (67.8%)	154 (69.7%)	297 (68.8%)
Anti-diabetic use at baseline (N)			
NO	2 (0.9%)	1 (0.5%)	3 (0.7%)
YES	209 (99.1%)	220 (99.5%)	429 (99.3%)
Insul. and analo. use at baseline (N)			
NO	78 (37.0%)	91 (41.2%)	169 (39.1%)
YES	133 (63.0%)	130 (58.8%)	263 (60.9%)
Dip pep 4 inhibitors use at baseline (N)			
NO	165 (78.2%)	172 (77.8%)	337 (78.0%)
YES	46 (21.8%)	49 (22.2%)	95 (22.0%)
GLP1 agonists use at baseline (N)			
NO	192 (91.0%)	202 (91.4%)	394 (91.2%)
YES	19 (9.0%)	19 (8.6%)	38 (8.8%)
SGLT-2 inhib. use at baseline (N)			
NO	190 (90.0%)	203 (91.9%)	393 (91.0%)
YES	21 (10.0%)	18 (8.1%)	39 (9.0%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Biguanides use at baseline (N)			
NO	67 (31.8%)	53 (24.0%)	120 (27.8%)
YES	144 (68.2%)	168 (76.0%)	312 (72.2%)
Sulfonamides use at baseline (N)			
NO	156 (73.9%)	167 (75.6%)	323 (74.8%)
YES	55 (26.1%)	54 (24.4%)	109 (25.2%)
Alpha gluc. inhib. use at baseline (N)			
NO	198 (93.8%)	212 (95.9%)	410 (94.9%)
YES	13 (6.2%)	9 (4.1%)	22 (5.1%)
Meglitinides use at baseline (N)			
NO	201 (95.3%)	215 (97.3%)	416 (96.3%)
YES	10 (4.7%)	6 (2.7%)	16 (3.7%)
Thiazolidinediones use at baseline (N)			
NO	199 (94.3%)	213 (96.4%)	412 (95.4%)
YES	12 (5.7%)	8 (3.6%)	20 (4.6%)
Potassium supplement use at baseline (N)			
NO	208 (98.6%)	214 (96.8%)	422 (97.7%)
YES	3 (1.4%)	7 (3.2%)	10 (2.3%)
Potassium lowering use at baseline (N)			
NO	210 (99.5%)	221 (100.0%)	431 (99.8%)
YES	1 (0.5%)	0	1 (0.2%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	0	4 (1.8%)	4 (0.9%)
unclassified	2 (0.9%)	4 (1.8%)	6 (1.4%)
moderate	8 (3.8%)	3 (1.4%)	11 (2.5%)
weak	119 (56.4%)	132 (59.7%)	251 (58.1%)
none	82 (38.9%)	78 (35.3%)	160 (37.0%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Potency CYP3A4 inducer at baseline (N)			
strong	1 (0.5%)	2 (0.9%)	3 (0.7%)
weak	9 (4.3%)	9 (4.1%)	18 (4.2%)
none	201 (95.3%)	210 (95.0%)	411 (95.1%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:25
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4.5 Medical History

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Number (%) of subjects with at least one medical history finding	211 (100.0%)	221 (100.0%)	432 (100.0%)
Blood and lymphatic system disorders	15 (7.1%)	19 (8.6%)	34 (7.9%)
Anaemia	8 (3.8%)	12 (5.4%)	20 (4.6%)
Anaemia macrocytic	0	1 (0.5%)	1 (0.2%)
Anaemia vitamin B12 deficiency	1 (0.5%)	0	1 (0.2%)
Iron deficiency anaemia	2 (0.9%)	3 (1.4%)	5 (1.2%)
Nephrogenic anaemia	0	1 (0.5%)	1 (0.2%)
Normochromic normocytic anaemia	0	1 (0.5%)	1 (0.2%)
Polycythaemia	0	1 (0.5%)	1 (0.2%)
Splenomegaly	3 (1.4%)	0	3 (0.7%)
Thrombocytopenia	1 (0.5%)	0	1 (0.2%)
Cardiac disorders	95 (45.0%)	95 (43.0%)	190 (44.0%)
Acute myocardial infarction	0	1 (0.5%)	1 (0.2%)
Angina pectoris	8 (3.8%)	5 (2.3%)	13 (3.0%)
Angina unstable	0	3 (1.4%)	3 (0.7%)
Aortic valve disease	1 (0.5%)	2 (0.9%)	3 (0.7%)
Aortic valve incompetence	2 (0.9%)	2 (0.9%)	4 (0.9%)
Aortic valve stenosis	1 (0.5%)	0	1 (0.2%)
Arrhythmia	0	2 (0.9%)	2 (0.5%)
Arrhythmia supraventricular	0	1 (0.5%)	1 (0.2%)
Arteriosclerosis coronary artery	2 (0.9%)	4 (1.8%)	6 (1.4%)
Atrial fibrillation	17 (8.1%)	15 (6.8%)	32 (7.4%)
Atrial flutter	0	2 (0.9%)	2 (0.5%)
Atrial thrombosis	0	1 (0.5%)	1 (0.2%)
Atrioventricular block complete	0	1 (0.5%)	1 (0.2%)
Atrioventricular block first degree	3 (1.4%)	3 (1.4%)	6 (1.4%)
Atrioventricular block second degree	0	2 (0.9%)	2 (0.5%)
Bundle branch block left	2 (0.9%)	4 (1.8%)	6 (1.4%)
Bundle branch block right	6 (2.8%)	2 (0.9%)	8 (1.9%)
Cardiac disorder	1 (0.5%)	0	1 (0.2%)
Cardiac failure	2 (0.9%)	2 (0.9%)	4 (0.9%)
Cardiac failure chronic	4 (1.9%)	5 (2.3%)	9 (2.1%)
Cardiac failure congestive	4 (1.9%)	0	4 (0.9%)
Cardiac valve disease	0	1 (0.5%)	1 (0.2%)
Cardiomyopathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Coronary artery disease	59 (28.0%)	61 (27.6%)	120 (27.8%)
Defect conduction intraventricular	0	1 (0.5%)	1 (0.2%)
Diastolic dysfunction	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Extrasystoles	0	1 (0.5%)	1 (0.2%)
Hypertensive heart disease	4 (1.9%)	3 (1.4%)	7 (1.6%)
Ischaemic cardiomyopathy	1 (0.5%)	0	1 (0.2%)
Left atrial enlargement	0	1 (0.5%)	1 (0.2%)
Left ventricular dysfunction	0	1 (0.5%)	1 (0.2%)
Left ventricular hypertrophy	3 (1.4%)	6 (2.7%)	9 (2.1%)
Mitral valve disease	0	2 (0.9%)	2 (0.5%)
Mitral valve incompetence	3 (1.4%)	1 (0.5%)	4 (0.9%)
Mitral valve prolapse	0	1 (0.5%)	1 (0.2%)
Myocardial infarction	26 (12.3%)	25 (11.3%)	51 (11.8%)
Myocardial ischaemia	10 (4.7%)	8 (3.6%)	18 (4.2%)
Palpitations	0	1 (0.5%)	1 (0.2%)
Prinzmetal angina	0	1 (0.5%)	1 (0.2%)
Right atrial enlargement	0	1 (0.5%)	1 (0.2%)
Sinus bradycardia	3 (1.4%)	0	3 (0.7%)
Sinus node dysfunction	0	1 (0.5%)	1 (0.2%)
Sinus tachycardia	1 (0.5%)	0	1 (0.2%)
Supraventricular extrasystoles	0	1 (0.5%)	1 (0.2%)
Tachyarrhythmia	1 (0.5%)	0	1 (0.2%)
Tachycardia	0	1 (0.5%)	1 (0.2%)
Tricuspid valve disease	0	1 (0.5%)	1 (0.2%)
Tricuspid valve incompetence	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ventricular extrasystoles	3 (1.4%)	0	3 (0.7%)
Congenital, familial and genetic disorders	11 (5.2%)	9 (4.1%)	20 (4.6%)
Adenomatous polyposis coli	1 (0.5%)	0	1 (0.2%)
Congenital myopia	0	1 (0.5%)	1 (0.2%)
Congenital renal cyst	1 (0.5%)	1 (0.5%)	2 (0.5%)
Corneal dystrophy	0	1 (0.5%)	1 (0.2%)
Hydrocele	1 (0.5%)	0	1 (0.2%)
Myocardial bridging	0	1 (0.5%)	1 (0.2%)
Phimosis	2 (0.9%)	0	2 (0.5%)
Renal aplasia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Sickle cell trait	0	1 (0.5%)	1 (0.2%)
Type IIa hyperlipidaemia	0	1 (0.5%)	1 (0.2%)
Type V hyperlipidaemia	5 (2.4%)	3 (1.4%)	8 (1.9%)
Ear and labyrinth disorders	7 (3.3%)	9 (4.1%)	16 (3.7%)
Auditory disorder	0	1 (0.5%)	1 (0.2%)
Cerumen impaction	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Deafness	4 (1.9%)	2 (0.9%)	6 (1.4%)
Deafness bilateral	0	1 (0.5%)	1 (0.2%)
Deafness neurosensory	2 (0.9%)	0	2 (0.5%)
Deafness unilateral	0	1 (0.5%)	1 (0.2%)
Hypoacusis	0	1 (0.5%)	1 (0.2%)
Tinnitus	2 (0.9%)	1 (0.5%)	3 (0.7%)
Vertigo	0	3 (1.4%)	3 (0.7%)
Vertigo positional	1 (0.5%)	0	1 (0.2%)
Vestibular ataxia	0	1 (0.5%)	1 (0.2%)
Endocrine disorders	37 (17.5%)	38 (17.2%)	75 (17.4%)
Autoimmune hypothyroidism	1 (0.5%)	0	1 (0.2%)
Autoimmune thyroiditis	3 (1.4%)	2 (0.9%)	5 (1.2%)
Basedow's disease	3 (1.4%)	0	3 (0.7%)
Goitre	5 (2.4%)	7 (3.2%)	12 (2.8%)
Hyperparathyroidism secondary	1 (0.5%)	0	1 (0.2%)
Hyperthyroidism	2 (0.9%)	3 (1.4%)	5 (1.2%)
Hypogonadism	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypogonadism male	0	1 (0.5%)	1 (0.2%)
Hypopituitarism	0	1 (0.5%)	1 (0.2%)
Hypothyroidism	21 (10.0%)	17 (7.7%)	38 (8.8%)
Primary hypothyroidism	1 (0.5%)	2 (0.9%)	3 (0.7%)
Thyroid mass	2 (0.9%)	7 (3.2%)	9 (2.1%)
Thyroiditis	0	1 (0.5%)	1 (0.2%)
Thyroiditis chronic	1 (0.5%)	0	1 (0.2%)
Toxic nodular goitre	0	1 (0.5%)	1 (0.2%)
Eye disorders	104 (49.3%)	124 (56.1%)	228 (52.8%)
Arteriosclerotic retinopathy	0	1 (0.5%)	1 (0.2%)
Astigmatism	1 (0.5%)	1 (0.5%)	2 (0.5%)
Blepharitis	1 (0.5%)	0	1 (0.2%)
Blindness unilateral	2 (0.9%)	0	2 (0.5%)
Borderline glaucoma	1 (0.5%)	2 (0.9%)	3 (0.7%)
Cataract	27 (12.8%)	31 (14.0%)	58 (13.4%)
Cataract cortical	1 (0.5%)	0	1 (0.2%)
Cataract nuclear	1 (0.5%)	0	1 (0.2%)
Conjunctivitis allergic	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diabetic retinal oedema	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diabetic retinopathy	79 (37.4%)	96 (43.4%)	175 (40.5%)
Dry age-related macular degeneration	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Dry eye	2 (0.9%)	6 (2.7%)	8 (1.9%)
Eye disorder	0	1 (0.5%)	1 (0.2%)
Eye pruritus	1 (0.5%)	0	1 (0.2%)
Glaucoma	9 (4.3%)	16 (7.2%)	25 (5.8%)
Heerfordt's syndrome	0	1 (0.5%)	1 (0.2%)
Hypermetropia	0	1 (0.5%)	1 (0.2%)
Keratitis	0	1 (0.5%)	1 (0.2%)
Macular degeneration	1 (0.5%)	1 (0.5%)	2 (0.5%)
Macular oedema	1 (0.5%)	1 (0.5%)	2 (0.5%)
Maculopathy	0	3 (1.4%)	3 (0.7%)
Myopia	2 (0.9%)	2 (0.9%)	4 (0.9%)
Neovascular age-related macular degeneration	0	1 (0.5%)	1 (0.2%)
Ocular hypertension	0	1 (0.5%)	1 (0.2%)
Optic ischaemic neuropathy	0	1 (0.5%)	1 (0.2%)
Posterior capsule opacification	0	1 (0.5%)	1 (0.2%)
Presbyopia	2 (0.9%)	2 (0.9%)	4 (0.9%)
Pterygium	1 (0.5%)	0	1 (0.2%)
Refraction disorder	0	1 (0.5%)	1 (0.2%)
Retinal artery embolism	1 (0.5%)	0	1 (0.2%)
Retinal artery occlusion	1 (0.5%)	0	1 (0.2%)
Retinal degeneration	1 (0.5%)	1 (0.5%)	2 (0.5%)
Retinal detachment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Retinal disorder	0	1 (0.5%)	1 (0.2%)
Retinal haemorrhage	1 (0.5%)	3 (1.4%)	4 (0.9%)
Retinal vascular disorder	1 (0.5%)	0	1 (0.2%)
Retinal vascular thrombosis	0	1 (0.5%)	1 (0.2%)
Retinal vein occlusion	0	1 (0.5%)	1 (0.2%)
Retinopathy	0	1 (0.5%)	1 (0.2%)
Retinopathy hypertensive	2 (0.9%)	2 (0.9%)	4 (0.9%)
Strabismus	0	1 (0.5%)	1 (0.2%)
Visual acuity reduced	2 (0.9%)	0	2 (0.5%)
Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)
Vitreous haemorrhage	2 (0.9%)	2 (0.9%)	4 (0.9%)
Vitreous opacities	0	1 (0.5%)	1 (0.2%)
Gastrointestinal disorders	61 (28.9%)	75 (33.9%)	136 (31.5%)
Abdominal distension	1 (0.5%)	0	1 (0.2%)
Abdominal hernia	2 (0.9%)	1 (0.5%)	3 (0.7%)
Abdominal pain upper	0	1 (0.5%)	1 (0.2%)
Change of bowel habit	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Chronic gastritis	7 (3.3%)	9 (4.1%)	16 (3.7%)
Colitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Constipation	3 (1.4%)	9 (4.1%)	12 (2.8%)
Dental caries	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diarrhoea	3 (1.4%)	6 (2.7%)	9 (2.1%)
Diverticulum	2 (0.9%)	4 (1.8%)	6 (1.4%)
Diverticulum intestinal	2 (0.9%)	1 (0.5%)	3 (0.7%)
Dry mouth	1 (0.5%)	0	1 (0.2%)
Duodenal ulcer	3 (1.4%)	4 (1.8%)	7 (1.6%)
Duodenitis	2 (0.9%)	0	2 (0.5%)
Duodenogastric reflux	0	1 (0.5%)	1 (0.2%)
Dyspepsia	1 (0.5%)	4 (1.8%)	5 (1.2%)
Dysphagia	0	1 (0.5%)	1 (0.2%)
Erosive duodenitis	0	1 (0.5%)	1 (0.2%)
Gastric disorder	1 (0.5%)	0	1 (0.2%)
Gastric ulcer	4 (1.9%)	0	4 (0.9%)
Gastritis	7 (3.3%)	8 (3.6%)	15 (3.5%)
Gastritis erosive	1 (0.5%)	5 (2.3%)	6 (1.4%)
Gastroduodenal ulcer	2 (0.9%)	0	2 (0.5%)
Gastrointestinal motility disorder	1 (0.5%)	0	1 (0.2%)
Gastrointestinal polyp	0	1 (0.5%)	1 (0.2%)
Gastrointestinal scarring	0	2 (0.9%)	2 (0.5%)
Gastrooesophageal reflux disease	17 (8.1%)	21 (9.5%)	38 (8.8%)
Haematochezia	0	1 (0.5%)	1 (0.2%)
Haemorrhoids	5 (2.4%)	3 (1.4%)	8 (1.9%)
Hiatus hernia	3 (1.4%)	2 (0.9%)	5 (1.2%)
Impaired gastric emptying	1 (0.5%)	1 (0.5%)	2 (0.5%)
Inguinal hernia	2 (0.9%)	0	2 (0.5%)
Intestinal obstruction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intestinal polyp	0	2 (0.9%)	2 (0.5%)
Irritable bowel syndrome	3 (1.4%)	5 (2.3%)	8 (1.9%)
Large intestinal obstruction	0	1 (0.5%)	1 (0.2%)
Large intestine polyp	2 (0.9%)	5 (2.3%)	7 (1.6%)
Mouth ulceration	0	1 (0.5%)	1 (0.2%)
Nausea	0	2 (0.9%)	2 (0.5%)
Pancreatitis	0	1 (0.5%)	1 (0.2%)
Pancreatitis acute	1 (0.5%)	0	1 (0.2%)
Pancreatitis chronic	3 (1.4%)	1 (0.5%)	4 (0.9%)
Peptic ulcer	0	3 (1.4%)	3 (0.7%)
Periodontal disease	3 (1.4%)	10 (4.5%)	13 (3.0%)
Toothache	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Umbilical hernia	2 (0.9%)	3 (1.4%)	5 (1.2%)
Vomiting	1 (0.5%)	1 (0.5%)	2 (0.5%)
General disorders and administration site conditions	13 (6.2%)	26 (11.8%)	39 (9.0%)
Asthenia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Chest discomfort	1 (0.5%)	0	1 (0.2%)
Chills	0	1 (0.5%)	1 (0.2%)
Cyst	0	1 (0.5%)	1 (0.2%)
Drug intolerance	0	3 (1.4%)	3 (0.7%)
Fatigue	1 (0.5%)	3 (1.4%)	4 (0.9%)
Generalised oedema	0	1 (0.5%)	1 (0.2%)
Hernia	1 (0.5%)	0	1 (0.2%)
Oedema	4 (1.9%)	4 (1.8%)	8 (1.9%)
Oedema peripheral	5 (2.4%)	16 (7.2%)	21 (4.9%)
Pain	1 (0.5%)	0	1 (0.2%)
Peripheral swelling	0	1 (0.5%)	1 (0.2%)
Temperature intolerance	1 (0.5%)	0	1 (0.2%)
Xerosis	0	1 (0.5%)	1 (0.2%)
Hepatobiliary disorders	33 (15.6%)	38 (17.2%)	71 (16.4%)
Biliary dyskinesia	0	1 (0.5%)	1 (0.2%)
Cholecystitis	3 (1.4%)	3 (1.4%)	6 (1.4%)
Cholecystitis acute	1 (0.5%)	0	1 (0.2%)
Cholecystitis chronic	2 (0.9%)	0	2 (0.5%)
Cholelithiasis	11 (5.2%)	7 (3.2%)	18 (4.2%)
Chronic hepatitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gallbladder cholesterolosis	0	1 (0.5%)	1 (0.2%)
Gallbladder polyp	0	3 (1.4%)	3 (0.7%)
Hepatic cyst	0	2 (0.9%)	2 (0.5%)
Hepatic steatosis	20 (9.5%)	28 (12.7%)	48 (11.1%)
Hepatitis	0	1 (0.5%)	1 (0.2%)
Liver disorder	2 (0.9%)	0	2 (0.5%)
Non-alcoholic steatohepatitis	1 (0.5%)	0	1 (0.2%)
Nonalcoholic fatty liver disease	0	1 (0.5%)	1 (0.2%)
Primary biliary cholangitis	1 (0.5%)	0	1 (0.2%)
Steatohepatitis	0	1 (0.5%)	1 (0.2%)
Immune system disorders	10 (4.7%)	16 (7.2%)	26 (6.0%)
Allergy to vaccine	0	1 (0.5%)	1 (0.2%)
Anaphylactic shock	1 (0.5%)	0	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Contrast media reaction	0	1 (0.5%)	1 (0.2%)
Drug hypersensitivity	4 (1.9%)	6 (2.7%)	10 (2.3%)
Dust allergy	0	1 (0.5%)	1 (0.2%)
Food allergy	1 (0.5%)	0	1 (0.2%)
Hypersensitivity	0	1 (0.5%)	1 (0.2%)
Iodine allergy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Multiple allergies	2 (0.9%)	2 (0.9%)	4 (0.9%)
Reaction to food additive	0	1 (0.5%)	1 (0.2%)
Rubber sensitivity	0	1 (0.5%)	1 (0.2%)
Seasonal allergy	2 (0.9%)	11 (5.0%)	13 (3.0%)
Selective IgA immunodeficiency	0	1 (0.5%)	1 (0.2%)
Infections and infestations	37 (17.5%)	53 (24.0%)	90 (20.8%)
Abscess limb	1 (0.5%)	0	1 (0.2%)
Acarodermatitis	0	1 (0.5%)	1 (0.2%)
Appendicitis	0	4 (1.8%)	4 (0.9%)
Arthritis bacterial	0	1 (0.5%)	1 (0.2%)
Aspergilloma	1 (0.5%)	0	1 (0.2%)
Bacteraemia	1 (0.5%)	0	1 (0.2%)
Body tinea	0	1 (0.5%)	1 (0.2%)
Bronchitis	2 (0.9%)	1 (0.5%)	3 (0.7%)
Candida infection	1 (0.5%)	0	1 (0.2%)
Cellulitis	0	2 (0.9%)	2 (0.5%)
Chronic hepatitis B	1 (0.5%)	1 (0.5%)	2 (0.5%)
Chronic sinusitis	0	2 (0.9%)	2 (0.5%)
Conjunctivitis	1 (0.5%)	2 (0.9%)	3 (0.7%)
Cystitis	1 (0.5%)	0	1 (0.2%)
Dermatophytosis of nail	0	1 (0.5%)	1 (0.2%)
Diabetic gangrene	1 (0.5%)	0	1 (0.2%)
Diverticulitis	1 (0.5%)	0	1 (0.2%)
Echinococciasis	1 (0.5%)	0	1 (0.2%)
Erysipelas	0	1 (0.5%)	1 (0.2%)
Fungal skin infection	0	1 (0.5%)	1 (0.2%)
Gangrene	0	1 (0.5%)	1 (0.2%)
Gastroenteritis	0	1 (0.5%)	1 (0.2%)
Genital herpes	0	1 (0.5%)	1 (0.2%)
HIV infection	1 (0.5%)	0	1 (0.2%)
Helicobacter infection	0	1 (0.5%)	1 (0.2%)
Hepatitis B	2 (0.9%)	1 (0.5%)	3 (0.7%)
Hepatitis C	4 (1.9%)	0	4 (0.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Herpes simplex	0	1 (0.5%)	1 (0.2%)
Herpes zoster	1 (0.5%)	1 (0.5%)	2 (0.5%)
Influenza	2 (0.9%)	3 (1.4%)	5 (1.2%)
Localised infection	1 (0.5%)	1 (0.5%)	2 (0.5%)
Malaria	1 (0.5%)	0	1 (0.2%)
Nasopharyngitis	0	1 (0.5%)	1 (0.2%)
Onychomycosis	3 (1.4%)	3 (1.4%)	6 (1.4%)
Orchitis	0	1 (0.5%)	1 (0.2%)
Osteomyelitis	4 (1.9%)	1 (0.5%)	5 (1.2%)
Otitis externa	1 (0.5%)	0	1 (0.2%)
Pilonidal cyst	0	1 (0.5%)	1 (0.2%)
Pneumonia	2 (0.9%)	2 (0.9%)	4 (0.9%)
Pulmonary tuberculosis	0	3 (1.4%)	3 (0.7%)
Pyelonephritis	0	1 (0.5%)	1 (0.2%)
Pyelonephritis chronic	0	5 (2.3%)	5 (1.2%)
Pyuria	0	1 (0.5%)	1 (0.2%)
Rhinitis	0	1 (0.5%)	1 (0.2%)
Salpingo-oophoritis	0	1 (0.5%)	1 (0.2%)
Sepsis	0	1 (0.5%)	1 (0.2%)
Sinusitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Skin infection	1 (0.5%)	0	1 (0.2%)
Tinea infection	0	1 (0.5%)	1 (0.2%)
Tinea pedis	1 (0.5%)	2 (0.9%)	3 (0.7%)
Tinea versicolour	0	1 (0.5%)	1 (0.2%)
Tonsillitis	2 (0.9%)	0	2 (0.5%)
Upper respiratory tract infection	1 (0.5%)	6 (2.7%)	7 (1.6%)
Urinary tract infection	3 (1.4%)	6 (2.7%)	9 (2.1%)
Urosepsis	0	1 (0.5%)	1 (0.2%)
Viral hepatitis carrier	0	1 (0.5%)	1 (0.2%)
Vulvovaginal mycotic infection	0	1 (0.5%)	1 (0.2%)
Injury, poisoning and procedural complications	12 (5.7%)	15 (6.8%)	27 (6.3%)
Airway burns	0	1 (0.5%)	1 (0.2%)
Ankle fracture	0	1 (0.5%)	1 (0.2%)
Cartilage injury	0	1 (0.5%)	1 (0.2%)
Cervical vertebral fracture	0	1 (0.5%)	1 (0.2%)
Clavicle fracture	0	1 (0.5%)	1 (0.2%)
Concussion	0	1 (0.5%)	1 (0.2%)
Epicondylitis	1 (0.5%)	0	1 (0.2%)
Exposure to communicable disease	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Eye injury	1 (0.5%)	0	1 (0.2%)
Face injury	0	1 (0.5%)	1 (0.2%)
Foot fracture	1 (0.5%)	0	1 (0.2%)
Foreign body in eye	1 (0.5%)	0	1 (0.2%)
Intervertebral disc injury	1 (0.5%)	1 (0.5%)	2 (0.5%)
Joint injury	0	1 (0.5%)	1 (0.2%)
Ligament sprain	0	1 (0.5%)	1 (0.2%)
Limb injury	0	1 (0.5%)	1 (0.2%)
Meniscus injury	2 (0.9%)	0	2 (0.5%)
Penetrating abdominal trauma	0	1 (0.5%)	1 (0.2%)
Post procedural hypothyroidism	0	1 (0.5%)	1 (0.2%)
Post-traumatic pain	1 (0.5%)	0	1 (0.2%)
Rib fracture	1 (0.5%)	0	1 (0.2%)
Snake bite	0	1 (0.5%)	1 (0.2%)
Stab wound	0	1 (0.5%)	1 (0.2%)
Testicular injury	0	1 (0.5%)	1 (0.2%)
Thermal burn	1 (0.5%)	0	1 (0.2%)
Upper limb fracture	2 (0.9%)	0	2 (0.5%)
Wrist fracture	0	2 (0.9%)	2 (0.5%)
Investigations	21 (10.0%)	25 (11.3%)	46 (10.6%)
Alanine aminotransferase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Angiocardiogram	0	1 (0.5%)	1 (0.2%)
Arthroscopy	0	1 (0.5%)	1 (0.2%)
Aspartate aminotransferase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Biopsy breast	0	1 (0.5%)	1 (0.2%)
Blood cholesterol increased	2 (0.9%)	4 (1.8%)	6 (1.4%)
Blood creatine phosphokinase increased	5 (2.4%)	2 (0.9%)	7 (1.6%)
Blood creatinine increased	1 (0.5%)	0	1 (0.2%)
Blood magnesium decreased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Blood pressure increased	2 (0.9%)	0	2 (0.5%)
Blood sodium decreased	0	1 (0.5%)	1 (0.2%)
Blood testosterone decreased	0	1 (0.5%)	1 (0.2%)
Blood triglycerides increased	0	2 (0.9%)	2 (0.5%)
Blood uric acid increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Body mass index increased	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bone density decreased	0	1 (0.5%)	1 (0.2%)
Catheterisation cardiac	0	1 (0.5%)	1 (0.2%)
ECG signs of myocardial infarction	1 (0.5%)	0	1 (0.2%)
Electrocardiogram ST-T change	1 (0.5%)	0	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Electrocardiogram ST-T segment abnormal	0	1 (0.5%)	1 (0.2%)
Electrocardiogram T wave abnormal	1 (0.5%)	0	1 (0.2%)
Electrocardiogram T wave amplitude decreased	1 (0.5%)	0	1 (0.2%)
Electrocardiogram T wave inversion	1 (0.5%)	0	1 (0.2%)
Electrocardiogram abnormal	1 (0.5%)	0	1 (0.2%)
Electrocardiogram repolarisation abnormality	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gamma-glutamyltransferase increased	1 (0.5%)	3 (1.4%)	4 (0.9%)
Heart sounds abnormal	0	1 (0.5%)	1 (0.2%)
Muscle enzyme increased	1 (0.5%)	0	1 (0.2%)
Myocardial strain	0	1 (0.5%)	1 (0.2%)
Peripheral pulse decreased	0	1 (0.5%)	1 (0.2%)
QRS axis abnormal	2 (0.9%)	3 (1.4%)	5 (1.2%)
Transaminases increased	1 (0.5%)	0	1 (0.2%)
Metabolism and nutrition disorders	211 (100.0%)	221 (100.0%)	432 (100.0%)
Central obesity	1 (0.5%)	2 (0.9%)	3 (0.7%)
Dyslipidaemia	53 (25.1%)	65 (29.4%)	118 (27.3%)
Gout	12 (5.7%)	13 (5.9%)	25 (5.8%)
Haemochromatosis	1 (0.5%)	0	1 (0.2%)
Hypercalcaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypercholesterolaemia	24 (11.4%)	35 (15.8%)	59 (13.7%)
Hyperglycaemia	1 (0.5%)	0	1 (0.2%)
Hyperkalaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hyperlipidaemia	67 (31.8%)	58 (26.2%)	125 (28.9%)
Hyperphosphataemia	0	1 (0.5%)	1 (0.2%)
Hypertriglyceridaemia	5 (2.4%)	4 (1.8%)	9 (2.1%)
Hyperuricaemia	29 (13.7%)	30 (13.6%)	59 (13.7%)
Hypoalbuminaemia	1 (0.5%)	0	1 (0.2%)
Hypocholesterolaemia	0	1 (0.5%)	1 (0.2%)
Hypokalaemia	2 (0.9%)	1 (0.5%)	3 (0.7%)
Hypomagnesaemia	1 (0.5%)	0	1 (0.2%)
Hyponatraemia	1 (0.5%)	0	1 (0.2%)
Iron deficiency	0	1 (0.5%)	1 (0.2%)
Lipid metabolism disorder	0	1 (0.5%)	1 (0.2%)
Magnesium deficiency	0	1 (0.5%)	1 (0.2%)
Metabolic acidosis	0	2 (0.9%)	2 (0.5%)
Metabolic syndrome	2 (0.9%)	3 (1.4%)	5 (1.2%)
Obesity	71 (33.6%)	91 (41.2%)	162 (37.5%)
Overweight	2 (0.9%)	3 (1.4%)	5 (1.2%)
Type 2 diabetes mellitus	211 (100.0%)	221 (100.0%)	432 (100.0%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Vitamin B12 deficiency	1 (0.5%)	6 (2.7%)	7 (1.6%)
Vitamin C deficiency	1 (0.5%)	0	1 (0.2%)
Vitamin D deficiency	15 (7.1%)	16 (7.2%)	31 (7.2%)
Musculoskeletal and connective tissue disorders	79 (37.4%)	68 (30.8%)	147 (34.0%)
Arthralgia	9 (4.3%)	7 (3.2%)	16 (3.7%)
Arthritis	4 (1.9%)	1 (0.5%)	5 (1.2%)
Back disorder	1 (0.5%)	0	1 (0.2%)
Back pain	18 (8.5%)	8 (3.6%)	26 (6.0%)
Bone metabolism disorder	1 (0.5%)	1 (0.5%)	2 (0.5%)
Bursitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Cervical spinal stenosis	1 (0.5%)	0	1 (0.2%)
Chondrocalcinosis	0	1 (0.5%)	1 (0.2%)
Chronic kidney disease-mineral and bone disorder	0	1 (0.5%)	1 (0.2%)
Diastasis recti abdominis	0	1 (0.5%)	1 (0.2%)
Enthesopathy	0	1 (0.5%)	1 (0.2%)
Exostosis	0	1 (0.5%)	1 (0.2%)
Fibromyalgia	0	1 (0.5%)	1 (0.2%)
Flank pain	1 (0.5%)	0	1 (0.2%)
Foot deformity	1 (0.5%)	4 (1.8%)	5 (1.2%)
Gouty arthritis	1 (0.5%)	0	1 (0.2%)
Intervertebral disc degeneration	0	1 (0.5%)	1 (0.2%)
Intervertebral disc disorder	1 (0.5%)	1 (0.5%)	2 (0.5%)
Intervertebral disc protrusion	6 (2.8%)	3 (1.4%)	9 (2.1%)
Lumbar spinal stenosis	2 (0.9%)	1 (0.5%)	3 (0.7%)
Muscle spasms	9 (4.3%)	5 (2.3%)	14 (3.2%)
Musculoskeletal stiffness	1 (0.5%)	0	1 (0.2%)
Myalgia	3 (1.4%)	2 (0.9%)	5 (1.2%)
Neck pain	2 (0.9%)	2 (0.9%)	4 (0.9%)
Neuropathic arthropathy	3 (1.4%)	0	3 (0.7%)
Osteoarthritis	23 (10.9%)	30 (13.6%)	53 (12.3%)
Osteochondrosis	4 (1.9%)	3 (1.4%)	7 (1.6%)
Osteopenia	0	2 (0.9%)	2 (0.5%)
Osteoporosis	2 (0.9%)	6 (2.7%)	8 (1.9%)
Pain in extremity	3 (1.4%)	2 (0.9%)	5 (1.2%)
Periarthritis	1 (0.5%)	3 (1.4%)	4 (0.9%)
Plantar fascial fibromatosis	0	1 (0.5%)	1 (0.2%)
Plantar fasciitis	1 (0.5%)	0	1 (0.2%)
Psoriatic arthropathy	0	2 (0.9%)	2 (0.5%)
Rhabdomyolysis	1 (0.5%)	0	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Rheumatic fever	1 (0.5%)	0	1 (0.2%)
Rheumatoid arthritis	1 (0.5%)	4 (1.8%)	5 (1.2%)
Rotator cuff syndrome	1 (0.5%)	3 (1.4%)	4 (0.9%)
Scoliosis	0	1 (0.5%)	1 (0.2%)
Sjogren's syndrome	0	2 (0.9%)	2 (0.5%)
Spinal osteoarthritis	6 (2.8%)	6 (2.7%)	12 (2.8%)
Spinal pain	1 (0.5%)	1 (0.5%)	2 (0.5%)
Spinal stenosis	0	2 (0.9%)	2 (0.5%)
Spondylitis	1 (0.5%)	0	1 (0.2%)
Spondylolisthesis	2 (0.9%)	0	2 (0.5%)
Synovial cyst	1 (0.5%)	2 (0.9%)	3 (0.7%)
Systemic lupus erythematosus	0	1 (0.5%)	1 (0.2%)
Tenosynovitis stenosans	0	1 (0.5%)	1 (0.2%)
Torticollis	0	1 (0.5%)	1 (0.2%)
Trigger finger	2 (0.9%)	0	2 (0.5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	23 (10.9%)	14 (6.3%)	37 (8.6%)
Acrochordon	2 (0.9%)	0	2 (0.5%)
B-cell lymphoma	1 (0.5%)	0	1 (0.2%)
Basal cell carcinoma	3 (1.4%)	0	3 (0.7%)
Benign lung neoplasm	1 (0.5%)	0	1 (0.2%)
Benign neoplasm of skin	0	1 (0.5%)	1 (0.2%)
Benign neoplasm of thyroid gland	1 (0.5%)	0	1 (0.2%)
Bladder cancer	1 (0.5%)	0	1 (0.2%)
Bladder neoplasm	1 (0.5%)	0	1 (0.2%)
Bladder papilloma	2 (0.9%)	0	2 (0.5%)
Bone neoplasm	1 (0.5%)	0	1 (0.2%)
Breast cancer	1 (0.5%)	1 (0.5%)	2 (0.5%)
Colon adenoma	0	1 (0.5%)	1 (0.2%)
Colon cancer	1 (0.5%)	0	1 (0.2%)
Colon cancer stage I	1 (0.5%)	0	1 (0.2%)
Enchondromatosis	1 (0.5%)	0	1 (0.2%)
Extragonadal primary non-seminoma	0	1 (0.5%)	1 (0.2%)
Gastric cancer	0	1 (0.5%)	1 (0.2%)
Gastrointestinal tract adenoma	1 (0.5%)	0	1 (0.2%)
Langerhans' cell histiocytosis	0	1 (0.5%)	1 (0.2%)
Large intestine benign neoplasm	0	1 (0.5%)	1 (0.2%)
Lipoma	1 (0.5%)	0	1 (0.2%)
Liposarcoma	1 (0.5%)	0	1 (0.2%)
Myelodysplastic syndrome	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Prostate cancer	1 (0.5%)	2 (0.9%)	3 (0.7%)
Prostatic adenoma	1 (0.5%)	0	1 (0.2%)
Renal neoplasm	1 (0.5%)	0	1 (0.2%)
Seborrhoeic keratosis	0	1 (0.5%)	1 (0.2%)
Squamous cell carcinoma	2 (0.9%)	0	2 (0.5%)
Squamous cell carcinoma of skin	1 (0.5%)	0	1 (0.2%)
Thyroid cancer	0	2 (0.9%)	2 (0.5%)
Uterine leiomyoma	2 (0.9%)	1 (0.5%)	3 (0.7%)
Waldenstrom's macroglobulinaemia	0	1 (0.5%)	1 (0.2%)
Nervous system disorders	99 (46.9%)	114 (51.6%)	213 (49.3%)
Amnesia	1 (0.5%)	0	1 (0.2%)
Areflexia	0	1 (0.5%)	1 (0.2%)
Balance disorder	1 (0.5%)	0	1 (0.2%)
Carotid arteriosclerosis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Carotid artery disease	0	1 (0.5%)	1 (0.2%)
Carotid artery stenosis	3 (1.4%)	4 (1.8%)	7 (1.6%)
Carpal tunnel syndrome	3 (1.4%)	3 (1.4%)	6 (1.4%)
Central nervous system vasculitis	0	1 (0.5%)	1 (0.2%)
Cerebral arteriosclerosis	1 (0.5%)	2 (0.9%)	3 (0.7%)
Cerebral atrophy	0	2 (0.9%)	2 (0.5%)
Cerebral infarction	2 (0.9%)	0	2 (0.5%)
Cerebral ischaemia	2 (0.9%)	1 (0.5%)	3 (0.7%)
Cerebrospinal fluid circulation disorder	0	1 (0.5%)	1 (0.2%)
Cerebrovascular accident	1 (0.5%)	4 (1.8%)	5 (1.2%)
Cerebrovascular disorder	5 (2.4%)	3 (1.4%)	8 (1.9%)
Cervicobrachial syndrome	0	1 (0.5%)	1 (0.2%)
Cognitive disorder	0	1 (0.5%)	1 (0.2%)
Dementia	0	1 (0.5%)	1 (0.2%)
Diabetic encephalopathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Diabetic mononeuropathy	0	1 (0.5%)	1 (0.2%)
Diabetic neuropathy	60 (28.4%)	67 (30.3%)	127 (29.4%)
Dizziness	2 (0.9%)	3 (1.4%)	5 (1.2%)
Dysarthria	0	1 (0.5%)	1 (0.2%)
Epilepsy	0	1 (0.5%)	1 (0.2%)
Facial paralysis	3 (1.4%)	1 (0.5%)	4 (0.9%)
Haemorrhagic stroke	0	1 (0.5%)	1 (0.2%)
Headache	3 (1.4%)	0	3 (0.7%)
Hydrocephalus	1 (0.5%)	0	1 (0.2%)
Hypertensive encephalopathy	0	2 (0.9%)	2 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Hypoaesthesia	1 (0.5%)	2 (0.9%)	3 (0.7%)
IIIrd nerve paralysis	1 (0.5%)	0	1 (0.2%)
Ischaemic stroke	19 (9.0%)	23 (10.4%)	42 (9.7%)
Lacunar infarction	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lumbar radiculopathy	0	1 (0.5%)	1 (0.2%)
Lumbosacral radiculopathy	1 (0.5%)	0	1 (0.2%)
Migraine	1 (0.5%)	2 (0.9%)	3 (0.7%)
Neuralgia	1 (0.5%)	0	1 (0.2%)
Neuromuscular pain	1 (0.5%)	0	1 (0.2%)
Neuropathy peripheral	10 (4.7%)	12 (5.4%)	22 (5.1%)
Normal pressure hydrocephalus	0	1 (0.5%)	1 (0.2%)
Orthostatic intolerance	1 (0.5%)	0	1 (0.2%)
Paraesthesia	2 (0.9%)	1 (0.5%)	3 (0.7%)
Parkinson's disease	1 (0.5%)	0	1 (0.2%)
Parosmia	0	1 (0.5%)	1 (0.2%)
Peripheral nerve paresis	0	1 (0.5%)	1 (0.2%)
Peroneal nerve palsy	1 (0.5%)	0	1 (0.2%)
Polyneuropathy	5 (2.4%)	4 (1.8%)	9 (2.1%)
Post herpetic neuralgia	1 (0.5%)	0	1 (0.2%)
Radiculopathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Restless legs syndrome	2 (0.9%)	0	2 (0.5%)
Sciatica	3 (1.4%)	3 (1.4%)	6 (1.4%)
Seizure	1 (0.5%)	0	1 (0.2%)
Sleep deficit	1 (0.5%)	0	1 (0.2%)
Syncope	2 (0.9%)	0	2 (0.5%)
Transient ischaemic attack	1 (0.5%)	5 (2.3%)	6 (1.4%)
Trigeminal neuralgia	0	1 (0.5%)	1 (0.2%)
Vascular encephalopathy	2 (0.9%)	2 (0.9%)	4 (0.9%)
Psychiatric disorders	28 (13.3%)	36 (16.3%)	64 (14.8%)
Alcohol use disorder	1 (0.5%)	0	1 (0.2%)
Alcoholism	1 (0.5%)	0	1 (0.2%)
Anxiety	4 (1.9%)	4 (1.8%)	8 (1.9%)
Anxiety disorder	0	1 (0.5%)	1 (0.2%)
Bipolar disorder	0	1 (0.5%)	1 (0.2%)
Depression	12 (5.7%)	13 (5.9%)	25 (5.8%)
Drug abuse	2 (0.9%)	0	2 (0.5%)
Insomnia	10 (4.7%)	17 (7.7%)	27 (6.3%)
Major depression	1 (0.5%)	0	1 (0.2%)
Mixed anxiety and depressive disorder	0	2 (0.9%)	2 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Neurosis	0	1 (0.5%)	1 (0.2%)
Persistent depressive disorder	1 (0.5%)	0	1 (0.2%)
Sleep disorder	2 (0.9%)	0	2 (0.5%)
Tobacco abuse	2 (0.9%)	1 (0.5%)	3 (0.7%)
Renal and urinary disorders	211 (100.0%)	221 (100.0%)	432 (100.0%)
Albuminuria	7 (3.3%)	17 (7.7%)	24 (5.6%)
Bladder spasm	0	1 (0.5%)	1 (0.2%)
Bladder ulcer	0	1 (0.5%)	1 (0.2%)
Calculus urinary	2 (0.9%)	1 (0.5%)	3 (0.7%)
Chronic kidney disease	211 (100.0%)	221 (100.0%)	432 (100.0%)
Diabetic nephropathy	19 (9.0%)	24 (10.9%)	43 (10.0%)
Dysuria	0	1 (0.5%)	1 (0.2%)
Glomerulonephritis chronic	0	1 (0.5%)	1 (0.2%)
Glomerulonephritis membranous	0	1 (0.5%)	1 (0.2%)
Haematuria	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hydronephrosis	1 (0.5%)	0	1 (0.2%)
Hypertensive nephropathy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypertonic bladder	1 (0.5%)	3 (1.4%)	4 (0.9%)
IgA nephropathy	0	1 (0.5%)	1 (0.2%)
Kidney enlargement	1 (0.5%)	0	1 (0.2%)
Microalbuminuria	1 (0.5%)	6 (2.7%)	7 (1.6%)
Micturition urgency	1 (0.5%)	0	1 (0.2%)
Nephritic syndrome	0	1 (0.5%)	1 (0.2%)
Nephritis	1 (0.5%)	0	1 (0.2%)
Nephroangiosclerosis	1 (0.5%)	0	1 (0.2%)
Nephrolithiasis	12 (5.7%)	10 (4.5%)	22 (5.1%)
Oedematous kidney	1 (0.5%)	0	1 (0.2%)
Oliguria	1 (0.5%)	0	1 (0.2%)
Pollakiuria	2 (0.9%)	0	2 (0.5%)
Polyuria	1 (0.5%)	0	1 (0.2%)
Proteinuria	16 (7.6%)	21 (9.5%)	37 (8.6%)
Renal artery stenosis	0	1 (0.5%)	1 (0.2%)
Renal atrophy	1 (0.5%)	0	1 (0.2%)
Renal colic	4 (1.9%)	0	4 (0.9%)
Renal cyst	9 (4.3%)	7 (3.2%)	16 (3.7%)
Stress urinary incontinence	0	1 (0.5%)	1 (0.2%)
Ureterolithiasis	1 (0.5%)	0	1 (0.2%)
Urethral stenosis	0	2 (0.9%)	2 (0.5%)
Urinary hesitation	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Urinary incontinence	4 (1.9%)	3 (1.4%)	7 (1.6%)
Reproductive system and breast disorders	41 (19.4%)	43 (19.5%)	84 (19.4%)
Balanoposthitis	1 (0.5%)	0	1 (0.2%)
Benign prostatic hyperplasia	25 (11.8%)	21 (9.5%)	46 (10.6%)
Colpocele	1 (0.5%)	0	1 (0.2%)
Cystocele	1 (0.5%)	1 (0.5%)	2 (0.5%)
Erectile dysfunction	11 (5.2%)	17 (7.7%)	28 (6.5%)
Menopausal symptoms	0	1 (0.5%)	1 (0.2%)
Organic erectile dysfunction	0	1 (0.5%)	1 (0.2%)
Ovarian cyst ruptured	1 (0.5%)	0	1 (0.2%)
Polycystic ovaries	0	2 (0.9%)	2 (0.5%)
Prostatic calcification	0	1 (0.5%)	1 (0.2%)
Prostatic disorder	1 (0.5%)	0	1 (0.2%)
Prostatism	0	1 (0.5%)	1 (0.2%)
Prostatitis	3 (1.4%)	1 (0.5%)	4 (0.9%)
Prostatomegaly	0	2 (0.9%)	2 (0.5%)
Uterine haemorrhage	0	1 (0.5%)	1 (0.2%)
Uterine polyp	0	1 (0.5%)	1 (0.2%)
Vaginal prolapse	0	1 (0.5%)	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	32 (15.2%)	46 (20.8%)	78 (18.1%)
Adenoidal hypertrophy	0	1 (0.5%)	1 (0.2%)
Asthma	5 (2.4%)	8 (3.6%)	13 (3.0%)
Atelectasis	1 (0.5%)	0	1 (0.2%)
Bronchiectasis	0	1 (0.5%)	1 (0.2%)
Bronchitis chronic	2 (0.9%)	3 (1.4%)	5 (1.2%)
Catarrh	0	1 (0.5%)	1 (0.2%)
Chronic obstructive pulmonary disease	6 (2.8%)	11 (5.0%)	17 (3.9%)
Chronic respiratory disease	0	1 (0.5%)	1 (0.2%)
Cough	2 (0.9%)	3 (1.4%)	5 (1.2%)
Dyspnoea	4 (1.9%)	1 (0.5%)	5 (1.2%)
Dyspnoea exertional	1 (0.5%)	0	1 (0.2%)
Emphysema	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hypoxia	0	1 (0.5%)	1 (0.2%)
Obstructive airways disorder	1 (0.5%)	0	1 (0.2%)
Pleural effusion	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pneumonitis	1 (0.5%)	0	1 (0.2%)
Pulmonary embolism	0	1 (0.5%)	1 (0.2%)
Pulmonary fibrosis	0	1 (0.5%)	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Pulmonary mass	1 (0.5%)	2 (0.9%)	3 (0.7%)
Pulmonary oedema	1 (0.5%)	0	1 (0.2%)
Respiratory alkalosis	1 (0.5%)	0	1 (0.2%)
Rhinitis allergic	1 (0.5%)	8 (3.6%)	9 (2.1%)
Rhinorrhoea	0	1 (0.5%)	1 (0.2%)
Sinus congestion	0	1 (0.5%)	1 (0.2%)
Sleep apnoea syndrome	11 (5.2%)	10 (4.5%)	21 (4.9%)
Vocal cord polyp	0	1 (0.5%)	1 (0.2%)
Wheezing	0	1 (0.5%)	1 (0.2%)
Skin and subcutaneous tissue disorders	22 (10.4%)	27 (12.2%)	49 (11.3%)
Acne	0	1 (0.5%)	1 (0.2%)
Actinic keratosis	1 (0.5%)	0	1 (0.2%)
Decubitus ulcer	0	1 (0.5%)	1 (0.2%)
Dermal cyst	0	1 (0.5%)	1 (0.2%)
Dermatitis	3 (1.4%)	0	3 (0.7%)
Dermatitis allergic	0	2 (0.9%)	2 (0.5%)
Dermatitis atopic	0	2 (0.9%)	2 (0.5%)
Dermatitis contact	0	1 (0.5%)	1 (0.2%)
Diabetic foot	4 (1.9%)	4 (1.8%)	8 (1.9%)
Dry skin	1 (0.5%)	1 (0.5%)	2 (0.5%)
Eczema	4 (1.9%)	4 (1.8%)	8 (1.9%)
Hirsutism	0	1 (0.5%)	1 (0.2%)
Hyperkeratosis	0	3 (1.4%)	3 (0.7%)
Leukoderma	0	1 (0.5%)	1 (0.2%)
Onychalgia	1 (0.5%)	0	1 (0.2%)
Pityriasis rosea	0	1 (0.5%)	1 (0.2%)
Pruritus	2 (0.9%)	1 (0.5%)	3 (0.7%)
Psoriasis	2 (0.9%)	4 (1.8%)	6 (1.4%)
Rosacea	2 (0.9%)	0	2 (0.5%)
Skin dystrophy	0	1 (0.5%)	1 (0.2%)
Skin ulcer	4 (1.9%)	2 (0.9%)	6 (1.4%)
Solar dermatitis	0	1 (0.5%)	1 (0.2%)
Stasis dermatitis	0	1 (0.5%)	1 (0.2%)
Urticaria	1 (0.5%)	0	1 (0.2%)
Vitiligo	1 (0.5%)	0	1 (0.2%)
Social circumstances	11 (5.2%)	18 (8.1%)	29 (6.7%)
Caffeine consumption	1 (0.5%)	0	1 (0.2%)
Menopause	7 (3.3%)	10 (4.5%)	17 (3.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Postmenopause	3 (1.4%)	7 (3.2%)	10 (2.3%)
Tobacco user	1 (0.5%)	1 (0.5%)	2 (0.5%)
Surgical and medical procedures	74 (35.1%)	87 (39.4%)	161 (37.3%)
Abdominal hernia repair	0	1 (0.5%)	1 (0.2%)
Abscess drainage	1 (0.5%)	0	1 (0.2%)
Angioplasty	1 (0.5%)	0	1 (0.2%)
Ankle operation	1 (0.5%)	0	1 (0.2%)
Aortic aneurysm repair	0	1 (0.5%)	1 (0.2%)
Aortic bypass	0	1 (0.5%)	1 (0.2%)
Aortic valve replacement	1 (0.5%)	1 (0.5%)	2 (0.5%)
Appendicectomy	7 (3.3%)	11 (5.0%)	18 (4.2%)
Arthrodesis	0	1 (0.5%)	1 (0.2%)
Bladder catheter temporary	1 (0.5%)	0	1 (0.2%)
Caesarean section	0	2 (0.9%)	2 (0.5%)
Cardiac pacemaker insertion	2 (0.9%)	4 (1.8%)	6 (1.4%)
Cardiopulmonary bypass	1 (0.5%)	0	1 (0.2%)
Cardioversion	0	1 (0.5%)	1 (0.2%)
Carotid endarterectomy	1 (0.5%)	2 (0.9%)	3 (0.7%)
Carpal tunnel decompression	0	2 (0.9%)	2 (0.5%)
Cataract operation	3 (1.4%)	13 (5.9%)	16 (3.7%)
Cholecystectomy	13 (6.2%)	12 (5.4%)	25 (5.8%)
Cholesteatoma removal	0	1 (0.5%)	1 (0.2%)
Circumcision	0	1 (0.5%)	1 (0.2%)
Colectomy	0	1 (0.5%)	1 (0.2%)
Coronary angioplasty	0	3 (1.4%)	3 (0.7%)
Coronary arterial stent insertion	9 (4.3%)	4 (1.8%)	13 (3.0%)
Coronary artery bypass	5 (2.4%)	11 (5.0%)	16 (3.7%)
Cox-Maze procedure	0	1 (0.5%)	1 (0.2%)
Female sterilisation	0	1 (0.5%)	1 (0.2%)
Foot amputation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Gastrectomy	0	1 (0.5%)	1 (0.2%)
Gastric banding	1 (0.5%)	0	1 (0.2%)
Glaucoma surgery	1 (0.5%)	0	1 (0.2%)
Haemorrhoid operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Heart valve replacement	1 (0.5%)	0	1 (0.2%)
Hernia repair	1 (0.5%)	2 (0.9%)	3 (0.7%)
Hip arthroplasty	1 (0.5%)	3 (1.4%)	4 (0.9%)
Hysterectomy	6 (2.8%)	6 (2.7%)	12 (2.8%)
Hysterosalpingo-oophorectomy	1 (0.5%)	0	1 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Implantable defibrillator insertion	0	1 (0.5%)	1 (0.2%)
Inguinal hernia repair	3 (1.4%)	1 (0.5%)	4 (0.9%)
Intervertebral disc operation	1 (0.5%)	0	1 (0.2%)
Intestinal polypectomy	0	1 (0.5%)	1 (0.2%)
Intraocular lens implant	0	5 (2.3%)	5 (1.2%)
Knee arthroplasty	2 (0.9%)	2 (0.9%)	4 (0.9%)
Knee operation	2 (0.9%)	1 (0.5%)	3 (0.7%)
Large intestinal polypectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Large intestine anastomosis	0	1 (0.5%)	1 (0.2%)
Leg amputation	1 (0.5%)	2 (0.9%)	3 (0.7%)
Lithotripsy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Lung lobectomy	0	1 (0.5%)	1 (0.2%)
Lymphadenectomy	0	1 (0.5%)	1 (0.2%)
Mass excision	0	1 (0.5%)	1 (0.2%)
Mitral valve repair	0	1 (0.5%)	1 (0.2%)
Muscle operation	1 (0.5%)	0	1 (0.2%)
Nephrectomy	1 (0.5%)	3 (1.4%)	4 (0.9%)
Ovarian cystectomy	0	1 (0.5%)	1 (0.2%)
Percutaneous coronary intervention	0	2 (0.9%)	2 (0.5%)
Perineoplasty	0	1 (0.5%)	1 (0.2%)
Peripheral artery angioplasty	2 (0.9%)	1 (0.5%)	3 (0.7%)
Peripheral artery bypass	3 (1.4%)	2 (0.9%)	5 (1.2%)
Peripheral artery stent insertion	0	1 (0.5%)	1 (0.2%)
Peripheral endarterectomy	1 (0.5%)	0	1 (0.2%)
Peripheral revascularisation	0	1 (0.5%)	1 (0.2%)
Phlebectomy	2 (0.9%)	1 (0.5%)	3 (0.7%)
Photocoagulation	0	1 (0.5%)	1 (0.2%)
Pituitary tumour removal	0	1 (0.5%)	1 (0.2%)
Prostatectomy	1 (0.5%)	0	1 (0.2%)
Prosthesis implantation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Pterygium operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Renal artery stent placement	0	1 (0.5%)	1 (0.2%)
Renal stone removal	2 (0.9%)	1 (0.5%)	3 (0.7%)
Retinal laser coagulation	0	4 (1.8%)	4 (0.9%)
Retinal operation	1 (0.5%)	1 (0.5%)	2 (0.5%)
Salpingo-oophorectomy bilateral	0	1 (0.5%)	1 (0.2%)
Sinus operation	0	1 (0.5%)	1 (0.2%)
Small intestinal anastomosis	0	1 (0.5%)	1 (0.2%)
Spinal decompression	1 (0.5%)	0	1 (0.2%)
Spinal fusion surgery	1 (0.5%)	1 (0.5%)	2 (0.5%)
Spinal operation	1 (0.5%)	2 (0.9%)	3 (0.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Stent placement	2 (0.9%)	1 (0.5%)	3 (0.7%)
Synovial cyst removal	0	1 (0.5%)	1 (0.2%)
Tenoplasty	0	1 (0.5%)	1 (0.2%)
Thyroid adenoma removal	0	1 (0.5%)	1 (0.2%)
Thyroidectomy	3 (1.4%)	1 (0.5%)	4 (0.9%)
Toe amputation	2 (0.9%)	4 (1.8%)	6 (1.4%)
Tonsillectomy	4 (1.9%)	6 (2.7%)	10 (2.3%)
Tooth extraction	0	1 (0.5%)	1 (0.2%)
Transurethral bladder resection	1 (0.5%)	0	1 (0.2%)
Transurethral prostatectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Tricuspid valve repair	0	1 (0.5%)	1 (0.2%)
Umbilical hernia repair	1 (0.5%)	1 (0.5%)	2 (0.5%)
Ureterolithotomy	0	1 (0.5%)	1 (0.2%)
Urinary bladder suspension	0	1 (0.5%)	1 (0.2%)
Uterine polypectomy	0	1 (0.5%)	1 (0.2%)
Varicose vein operation	0	2 (0.9%)	2 (0.5%)
Vasectomy	0	3 (1.4%)	3 (0.7%)
Ventriculo-peritoneal shunt	0	1 (0.5%)	1 (0.2%)
Vitrectomy	1 (0.5%)	4 (1.8%)	5 (1.2%)
Vocal cord polypectomy	1 (0.5%)	1 (0.5%)	2 (0.5%)
Wisdom teeth removal	0	1 (0.5%)	1 (0.2%)
Vascular disorders	203 (96.2%)	217 (98.2%)	420 (97.2%)
Aortic aneurysm	2 (0.9%)	0	2 (0.5%)
Aortic arteriosclerosis	3 (1.4%)	1 (0.5%)	4 (0.9%)
Aortic dilatation	0	1 (0.5%)	1 (0.2%)
Aortic stenosis	3 (1.4%)	1 (0.5%)	4 (0.9%)
Arteriosclerosis	1 (0.5%)	6 (2.7%)	7 (1.6%)
Arteritis	0	1 (0.5%)	1 (0.2%)
Deep vein thrombosis	0	3 (1.4%)	3 (0.7%)
Diabetic microangiopathy	1 (0.5%)	0	1 (0.2%)
Diabetic vascular disorder	6 (2.8%)	1 (0.5%)	7 (1.6%)
Essential hypertension	8 (3.8%)	7 (3.2%)	15 (3.5%)
Extremity necrosis	1 (0.5%)	0	1 (0.2%)
Hypertension	191 (90.5%)	208 (94.1%)	399 (92.4%)
Hypertensive angiopathy	2 (0.9%)	1 (0.5%)	3 (0.7%)
Intermittent claudication	2 (0.9%)	4 (1.8%)	6 (1.4%)
Lymphoedema	0	1 (0.5%)	1 (0.2%)
Microangiopathy	0	1 (0.5%)	1 (0.2%)
Peripheral arterial occlusive disease	34 (16.1%)	29 (13.1%)	63 (14.6%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Peripheral artery aneurysm	0	1 (0.5%)	1 (0.2%)
Peripheral artery stenosis	0	2 (0.9%)	2 (0.5%)
Peripheral ischaemia	0	1 (0.5%)	1 (0.2%)
Peripheral vascular disorder	4 (1.9%)	0	4 (0.9%)
Peripheral venous disease	4 (1.9%)	5 (2.3%)	9 (2.1%)
Thrombophlebitis	1 (0.5%)	1 (0.5%)	2 (0.5%)
Thrombosis	1 (0.5%)	0	1 (0.2%)
Varicose vein	5 (2.4%)	11 (5.0%)	16 (3.7%)
White coat hypertension	0	1 (0.5%)	1 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 26JAN2023 15:25
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4.6 Concomitant medication

Table 4.6 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	157 (74.4%)	167 (75.6%)	324 (75.0%)
ACEI	32 (15.2%)	26 (11.8%)	58 (13.4%)
ARB	48 (22.7%)	51 (23.1%)	99 (22.9%)
RAS-inhibitors	72 (34.1%)	71 (32.1%)	143 (33.1%)
Beta-blocker	52 (24.6%)	55 (24.9%)	107 (24.8%)
Diuretics	68 (32.2%)	79 (35.7%)	147 (34.0%)
Loop diuretics	38 (18.0%)	55 (24.9%)	93 (21.5%)
Thiazide diuretics	27 (12.8%)	28 (12.7%)	55 (12.7%)
Potassium supplements	10 (4.7%)	13 (5.9%)	23 (5.3%)
Potassium lowering agents (including binders)	14 (6.6%)	3 (1.4%)	17 (3.9%)
Alpha blocking agents	56 (26.5%)	60 (27.1%)	116 (26.9%)
Calcium channel blockers	60 (28.4%)	68 (30.8%)	128 (29.6%)
Centrally acting antihypertensives	11 (5.2%)	14 (6.3%)	25 (5.8%)
Strong CYP3A4 inhibitors	12 (5.7%)	12 (5.4%)	24 (5.6%)
Moderate CYP3A4 inhibitors	25 (11.8%)	27 (12.2%)	52 (12.0%)
Weak CYP3A4 inhibitors	75 (35.5%)	81 (36.7%)	156 (36.1%)
Unclassified CYP3A4 inhibitors	12 (5.7%)	6 (2.7%)	18 (4.2%)
Strong CYP3A4 inducers	1 (0.5%)	3 (1.4%)	4 (0.9%)
Moderate CYP3A4 inducers	15 (7.1%)	13 (5.9%)	28 (6.5%)
Weak CYP3A4 inducers	9 (4.3%)	8 (3.6%)	17 (3.9%)
Unclassified CYP3A4 inducers	6 (2.8%)	7 (3.2%)	13 (3.0%)
Oral anticoagulants	17 (8.1%)	14 (6.3%)	31 (7.2%)
Acetylsalycylic acid and its salts	35 (16.6%)	39 (17.6%)	74 (17.1%)
Statins	58 (27.5%)	65 (29.4%)	123 (28.5%)
Erythropoeitin stimulating agents	2 (0.9%)	7 (3.2%)	9 (2.1%)
NSAIDS (excluding acetylsalicylic acid)	43 (20.4%)	58 (26.2%)	101 (23.4%)
ARNIs	2 (0.9%)	2 (0.9%)	4 (0.9%)
Potassium-sparing diuretics	16 (7.6%)	17 (7.7%)	33 (7.6%)
Platelet aggregation inhibitors (excluding heparin)	47 (22.3%)	56 (25.3%)	103 (23.8%)
Trimethoprim and derivatives	6 (2.8%)	7 (3.2%)	13 (3.0%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=211 (100%)	Placebo N=221 (100%)	Total N=432 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	123 (58.3%)	133 (60.2%)	256 (59.3%)
Insulins and analogues	88 (41.7%)	94 (42.5%)	182 (42.1%)
Dipeptidyl peptidase 4 inhibitors	30 (14.2%)	24 (10.9%)	54 (12.5%)
Glucagon-like peptide-1(GLP1) agonists	21 (10.0%)	23 (10.4%)	44 (10.2%)
SGLT-2 inhibitors	25 (11.8%)	27 (12.2%)	52 (12.0%)
Biguanides	56 (26.5%)	52 (23.5%)	108 (25.0%)
Sulfonylureas	29 (13.7%)	23 (10.4%)	52 (12.0%)
Alpha glucosidase inhibitors	8 (3.8%)	10 (4.5%)	18 (4.2%)
Meglitinides	9 (4.3%)	5 (2.3%)	14 (3.2%)
Thiazolidinediones	4 (1.9%)	5 (2.3%)	9 (2.1%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
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1.2.1 Study duration

Table 1.2.1 / 1: Study duration (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

		BAY 94-8862 (N=211)	Placebo (N=221)	Total (N=432)
Study duration (months)	n	211	221	432
	Nmiss	0	0	0
	Mean	35.960	35.684	35.819
	SD	8.394	9.190	8.801
	Min	1.35	1.48	1.35
	Median	35.680	35.975	35.696
	Max	50.37	49.54	50.37

Study duration is defined as time from randomization to the EOS visit (or to last contact date if no EOS visit took place).
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1.2.2 Time-to-event analyses

Table 1.2.2 / 1: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	17 (8.1%)	14 (6.3%)
Number (%) of subjects censored	194 (91.9%)	207 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.28 [0.63; 2.60]	
two-sided p-value from stratified logrank test	0.4902	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	17 (8.1%)	14 (6.3%)
Number (%) of subjects censored	194 (91.9%)	207 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.27 [0.62; 2.57]	
two-sided p-value from unstratified logrank test	0.5102	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	34 (16.1%)	36 (16.3%)
Number (%) of subjects censored	177 (83.9%)	185 (83.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.61; 1.56]	
two-sided p-value from stratified logrank test	0.9187	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 4: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	7 (3.3%)	16 (7.2%)
Number (%) of subjects censored	204 (96.7%)	205 (92.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.43 [0.18; 1.05]	
two-sided p-value from stratified logrank test	0.0564	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 5: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	7 (3.3%)	16 (7.2%)
Number (%) of subjects censored	204 (96.7%)	205 (92.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.44 [0.18; 1.07]	
two-sided p-value from unstratified logrank test	0.0638	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 6: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	7 (3.3%)	11 (5.0%)
Number (%) of subjects censored	204 (96.7%)	210 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.24; 1.57]	
two-sided p-value from stratified logrank test	0.3008	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 7: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	2 (0.9%)	8 (3.6%)
Number (%) of subjects censored	209 (99.1%)	213 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.25 [0.05; 1.20]	
two-sided p-value from stratified logrank test	0.0621	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 8: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	2 (0.9%)	8 (3.6%)
Number (%) of subjects censored	209 (99.1%)	213 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.25 [0.05; 1.18]	
two-sided p-value from unstratified logrank test	0.0575	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 9: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	2 (0.9%)	2 (0.9%)
Number (%) of subjects censored	209 (99.1%)	219 (99.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.13; 6.70]	
two-sided p-value from stratified logrank test	0.9541	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 10: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	1 (0.5%)	5 (2.3%)
Number (%) of subjects censored	210 (99.5%)	216 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.21 [0.02; 1.81]	
two-sided p-value from stratified logrank test	0.1176	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 11: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	1 (0.5%)	6 (2.7%)
Number (%) of subjects censored	210 (99.5%)	215 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.17 [0.02; 1.43]	
two-sided p-value from stratified logrank test	0.0641	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 12: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	6 (2.8%)	16 (7.2%)
Number (%) of subjects censored	205 (97.2%)	205 (92.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.37 [0.14; 0.95]	
two-sided p-value from stratified logrank test	0.0309	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 13: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects censored	211 (100.0%)	221 (100.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	[;]	
two-sided p-value from stratified logrank test		

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 14: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	11 (5.2%)	18 (8.1%)
Number (%) of subjects censored	200 (94.8%)	203 (91.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.62 [0.29; 1.31]	
two-sided p-value from stratified logrank test	0.2039	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 15: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	34 (16.1%)	33 (14.9%)
Number (%) of subjects censored	177 (83.9%)	188 (85.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.08 [0.67; 1.75]	
two-sided p-value from stratified logrank test	0.7397	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 16: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	34 (16.1%)	33 (14.9%)
Number (%) of subjects censored	177 (83.9%)	188 (85.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.08 [0.67; 1.74]	
two-sided p-value from unstratified logrank test	0.7547	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 17: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	32 (15.2%)	26 (11.8%)
Number (%) of subjects censored	179 (84.8%)	195 (88.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.24 [0.74; 2.08]	
two-sided p-value from stratified logrank test	0.4135	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 18: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	13 (6.2%)	12 (5.4%)
Number (%) of subjects censored	198 (93.8%)	209 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.52; 2.52]	
two-sided p-value from stratified logrank test	0.7286	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 19: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	8 (3.8%)	9 (4.1%)
Number (%) of subjects censored	203 (96.2%)	212 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.36; 2.41]	
two-sided p-value from stratified logrank test	0.8758	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 20: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	8 (3.8%)	11 (5.0%)
Number (%) of subjects censored	203 (96.2%)	210 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.31; 1.91]	
two-sided p-value from stratified logrank test	0.5721	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 21: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	9 (4.3%)	13 (5.9%)
Number (%) of subjects censored	202 (95.7%)	208 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.31; 1.68]	
two-sided p-value from stratified logrank test	0.4423	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 22: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	9 (4.3%)	10 (4.5%)
Number (%) of subjects censored	202 (95.7%)	211 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.38; 2.33]	
two-sided p-value from stratified logrank test	0.8999	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 23: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	9 (4.3%)	10 (4.5%)
Number (%) of subjects censored	202 (95.7%)	211 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.39; 2.34]	
two-sided p-value from unstratified logrank test	0.9140	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 24: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	7 (3.3%)	9 (4.1%)
Number (%) of subjects censored	204 (96.7%)	212 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.29; 2.10]	
two-sided p-value from stratified logrank test	0.6255	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 25: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	12 (5.7%)	12 (5.4%)
Number (%) of subjects censored	199 (94.3%)	209 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.47; 2.35]	
two-sided p-value from stratified logrank test	0.8952	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
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Table 1.2.2 / 26: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	12 (5.7%)	12 (5.4%)
Number (%) of subjects censored	199 (94.3%)	209 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.47; 2.31]	
two-sided p-value from unstratified logrank test	0.9269	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 27: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	11 (5.2%)	10 (4.5%)
Number (%) of subjects censored	200 (94.8%)	211 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.12 [0.47; 2.63]	
two-sided p-value from stratified logrank test	0.8026	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 28: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	9 (4.3%)	13 (5.9%)
Number (%) of subjects censored	202 (95.7%)	208 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.31; 1.68]	
two-sided p-value from stratified logrank test	0.4423	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 29: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	9 (4.3%)	13 (5.9%)
Number (%) of subjects censored	202 (95.7%)	208 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.30; 1.66]	
two-sided p-value from unstratified logrank test	0.4273	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 30: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	8 (3.8%)	8 (3.6%)
Number (%) of subjects censored	203 (96.2%)	213 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.37; 2.66]	
two-sided p-value from stratified logrank test	0.9952	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 31: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	87 (41.2%)	94 (42.5%)
Number (%) of subjects censored	124 (58.8%)	127 (57.5%)
Median Time to event (month) [95 % CI]	47.433 [n.c.]	45.833 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.70; 1.26]	
two-sided p-value from stratified logrank test	0.6623	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 32: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	87 (41.2%)	94 (42.5%)
Number (%) of subjects censored	124 (58.8%)	127 (57.5%)
Median Time to event (month) [95 % CI]	47.433 [n.c.]	45.833 [n.c.]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.71; 1.28]	
two-sided p-value from unstratified logrank test	0.7533	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 33: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	211 (100.0%)	221 (100.0%)
Number (%) of subjects with event	82 (38.9%)	89 (40.3%)
Number (%) of subjects censored	129 (61.1%)	132 (59.7%)
Median Time to event (month) [95 % CI]	47.433 [n.c.]	45.000 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.68; 1.24]	
two-sided p-value from stratified logrank test	0.5624	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s2.sas 06FEB2023 15:10
End of table

Table 1.2.2 / 34: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.73; 1.39]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.9567

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 06FEB2023 15:14
End of table

Figure 1.2.2 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

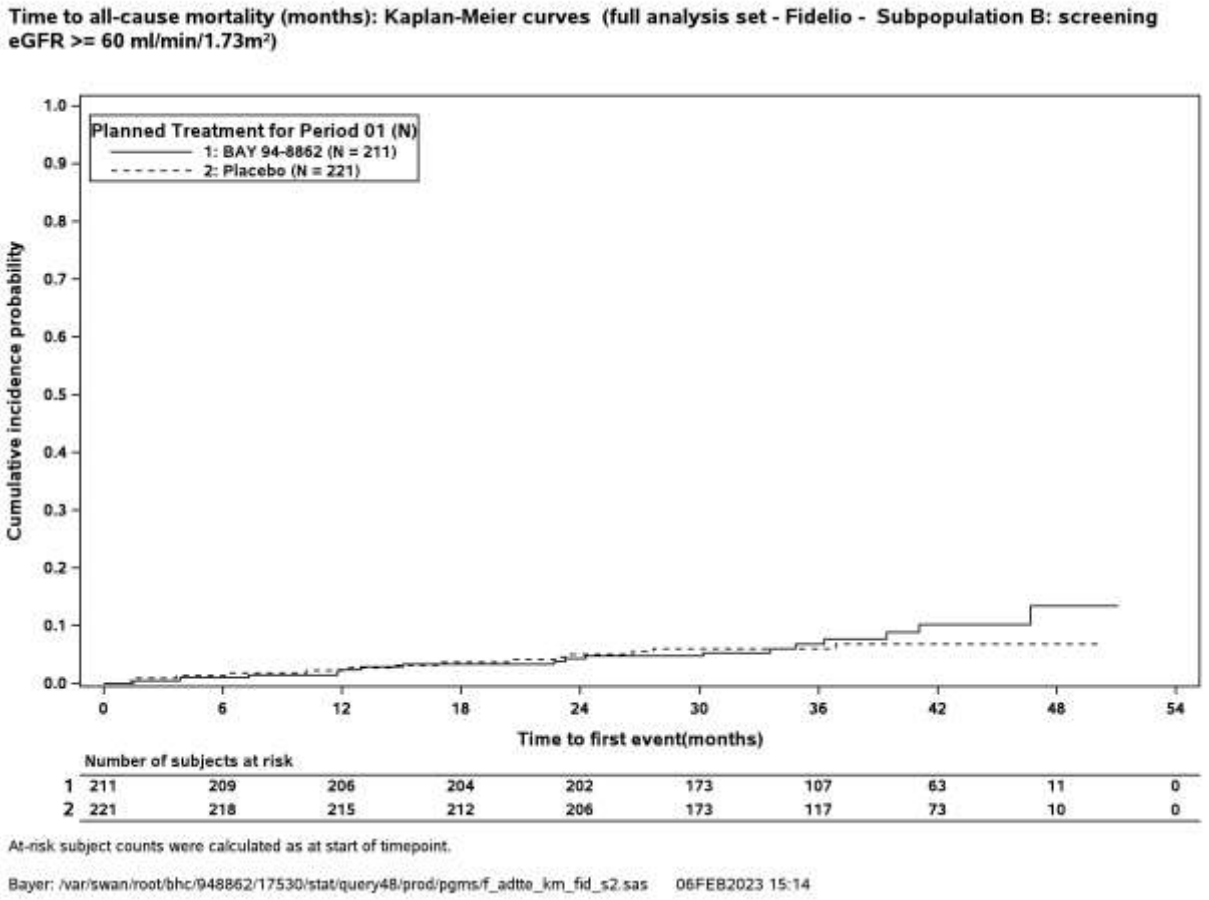


Figure 1.2.2 / 2: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

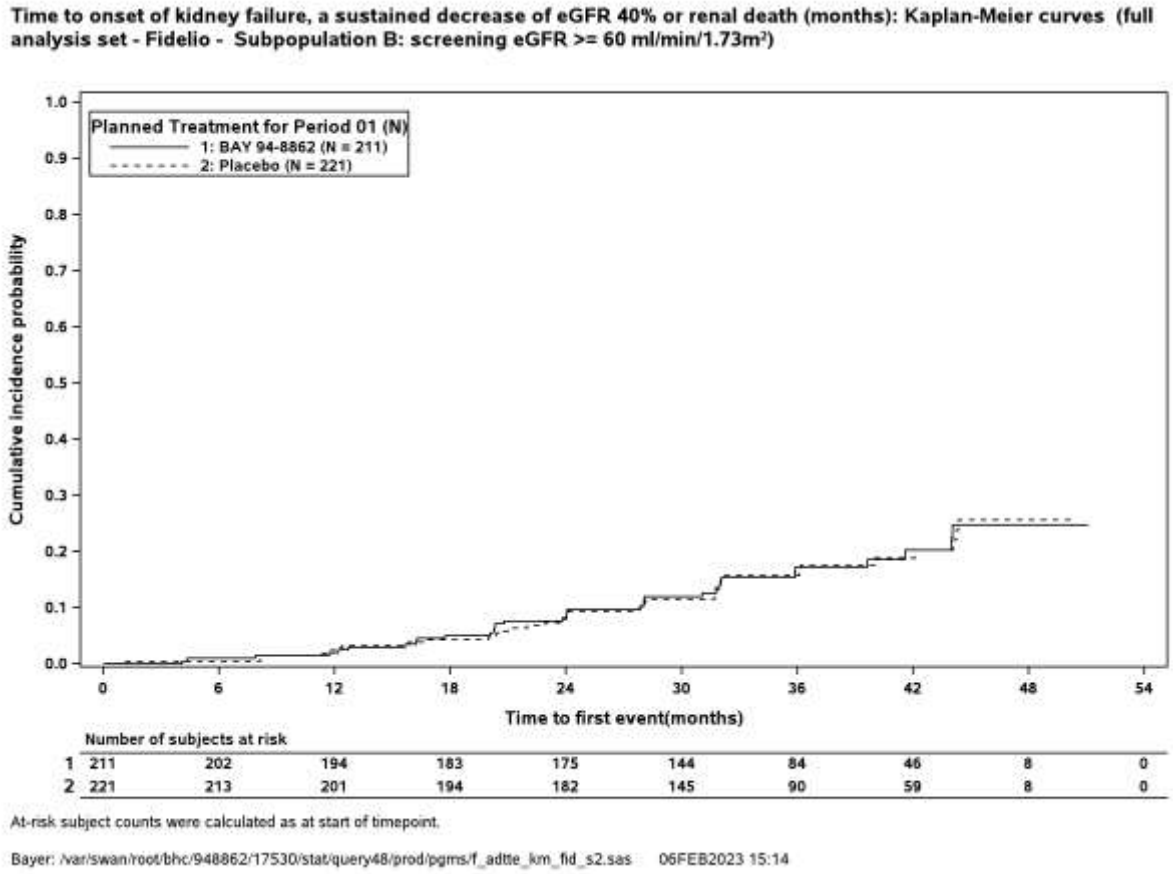


Figure 1.2.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

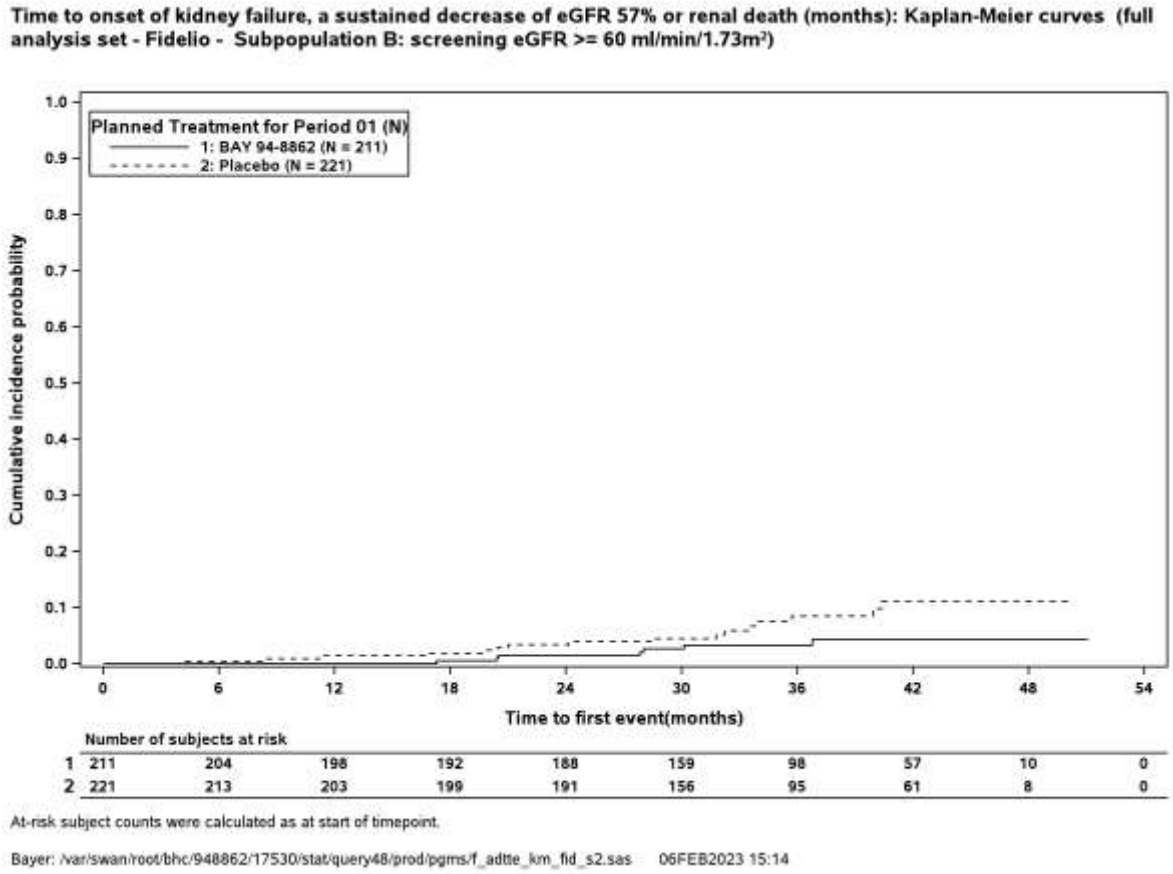


Figure 1.2.2 / 4: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

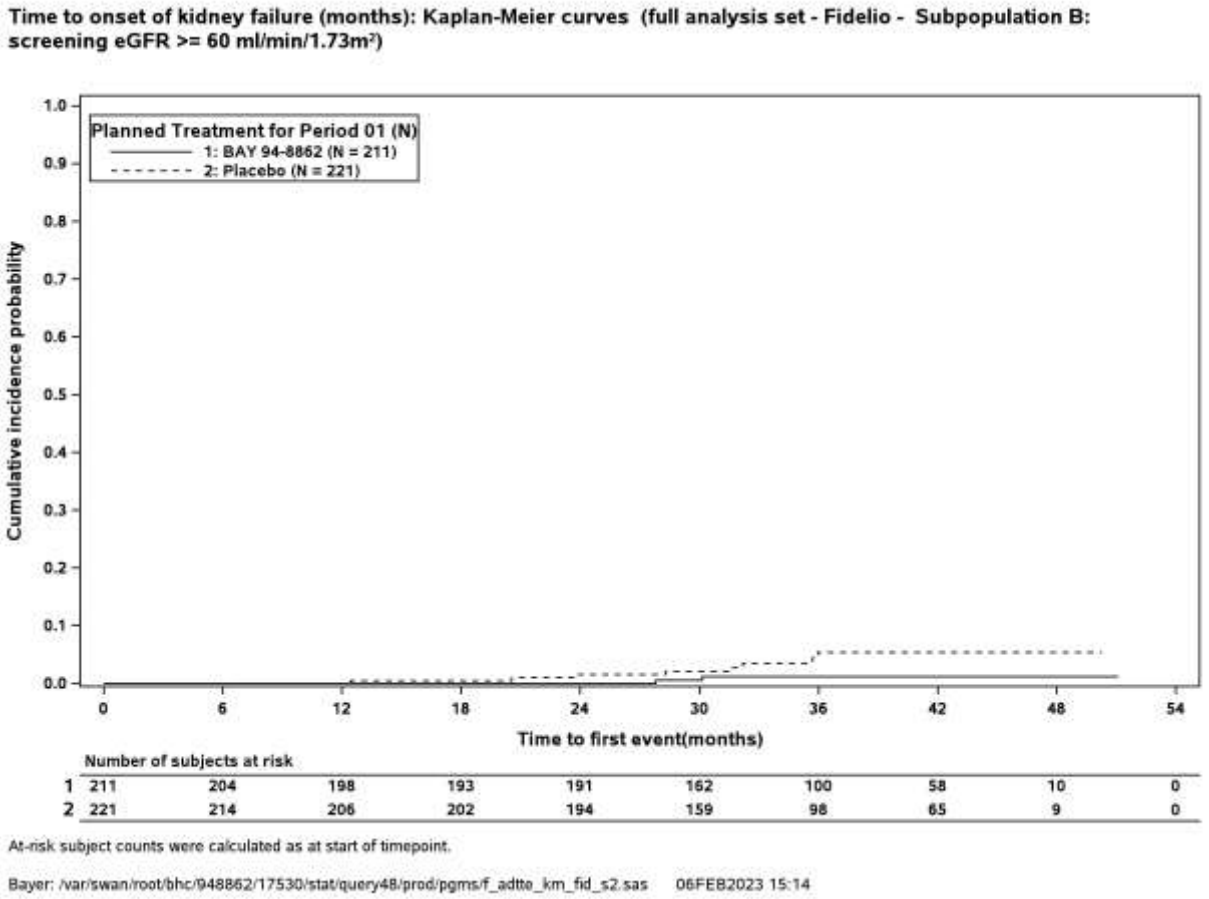


Figure 1.2.2 / 5: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

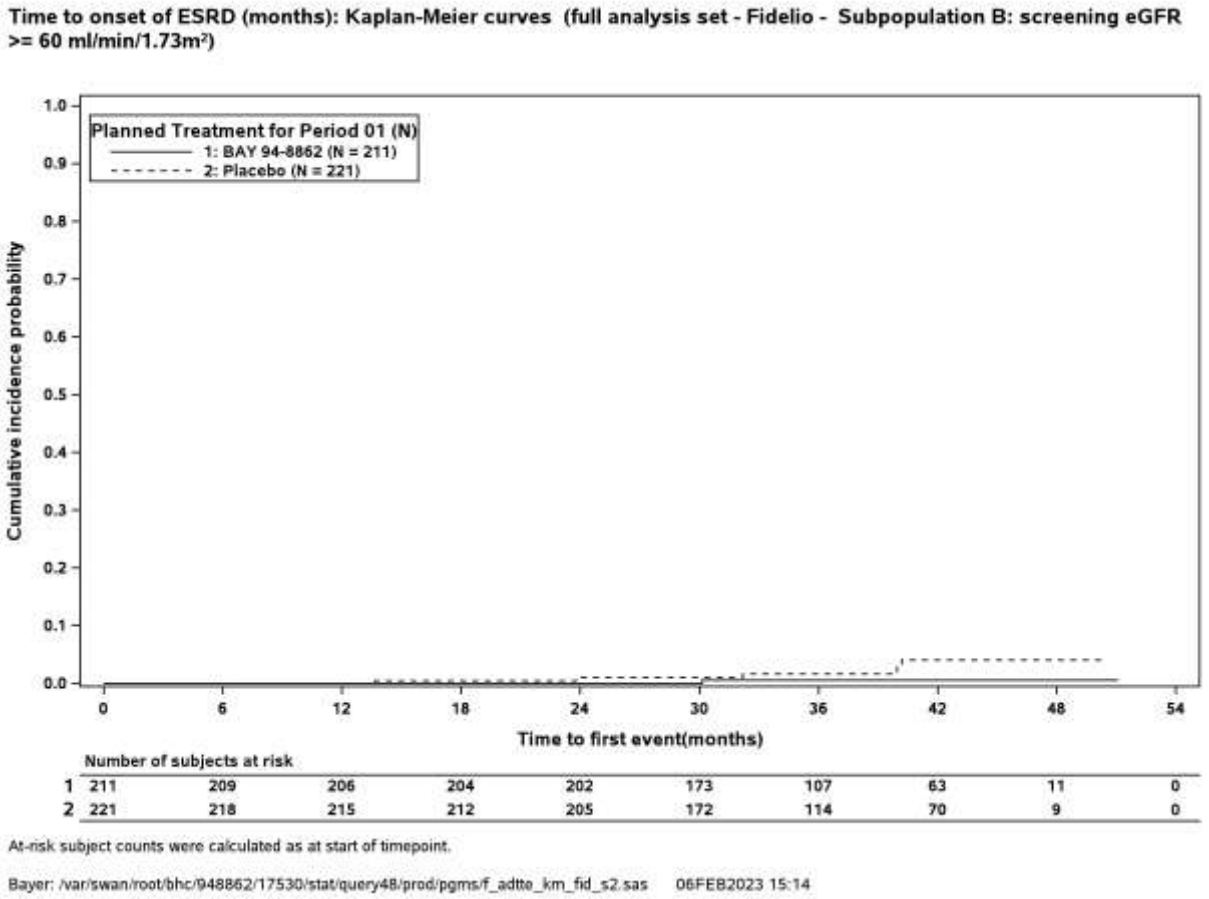


Figure 1.2.2 / 6: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

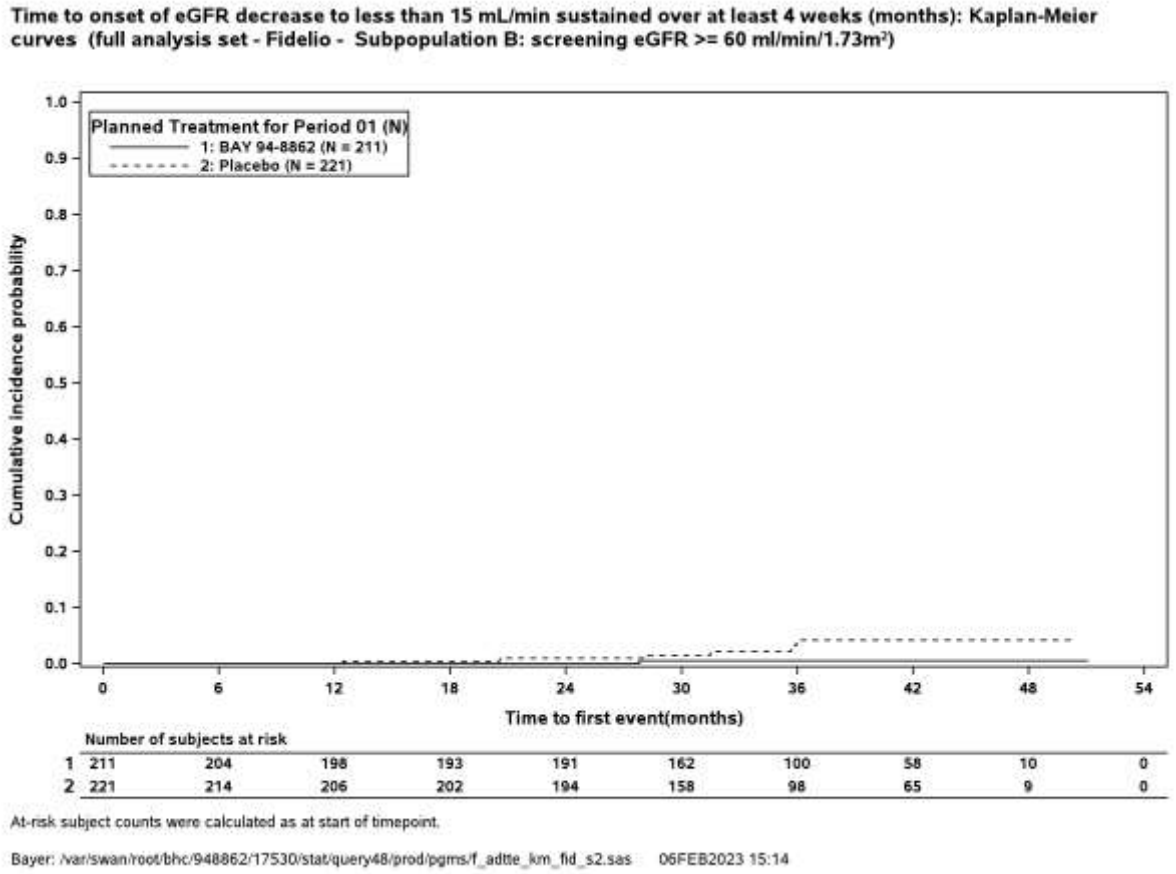


Figure 1.2.2 / 7: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

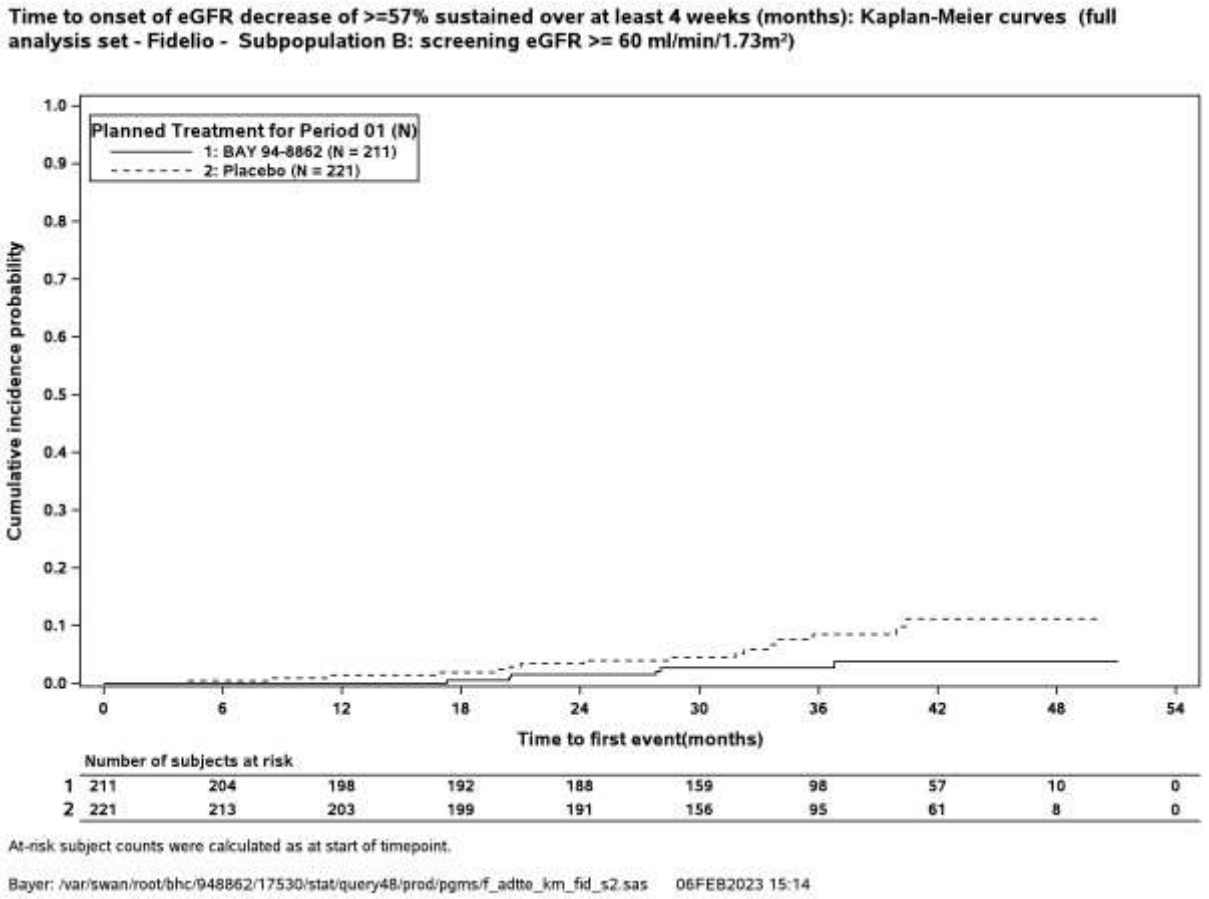


Figure 1.2.2 / 8: Time to renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

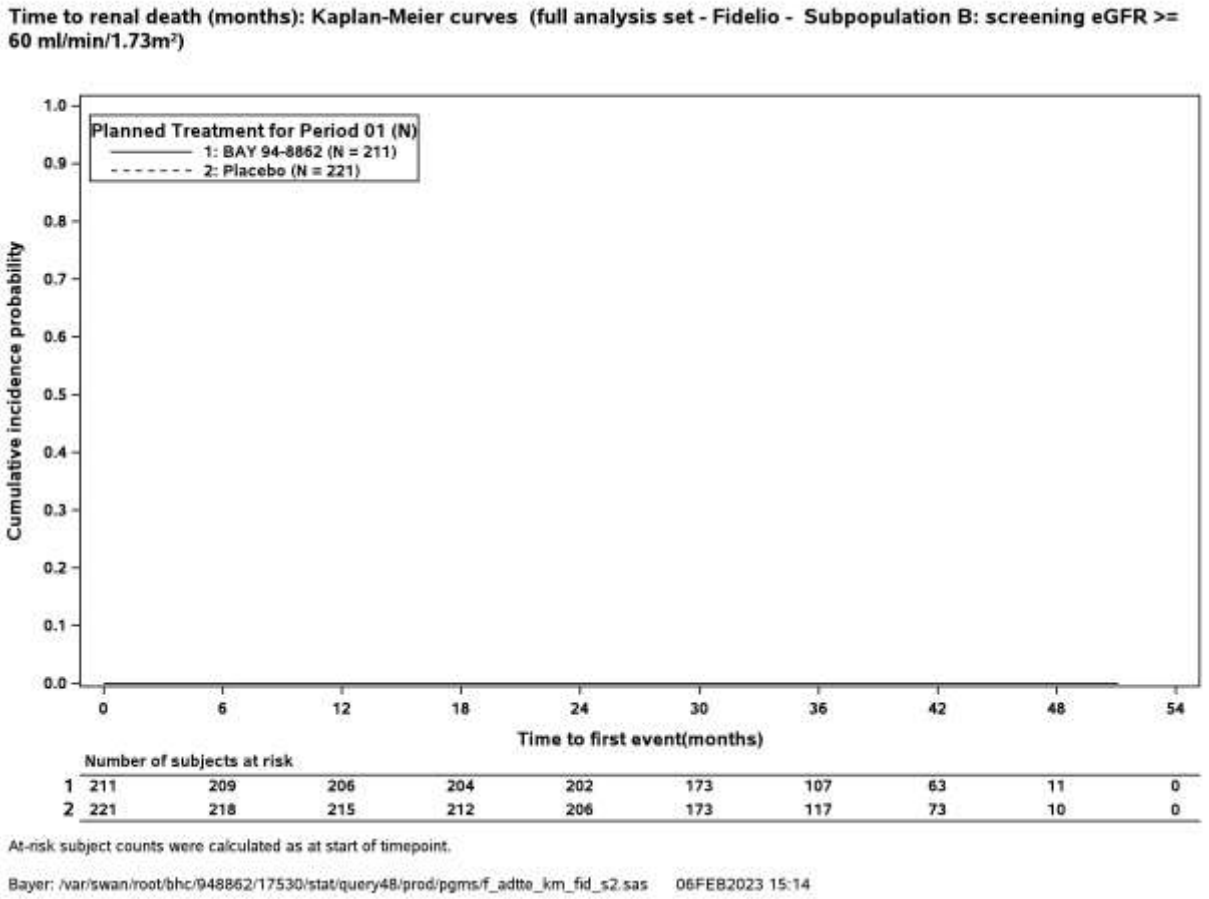


Figure 1.2.2 / 9: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

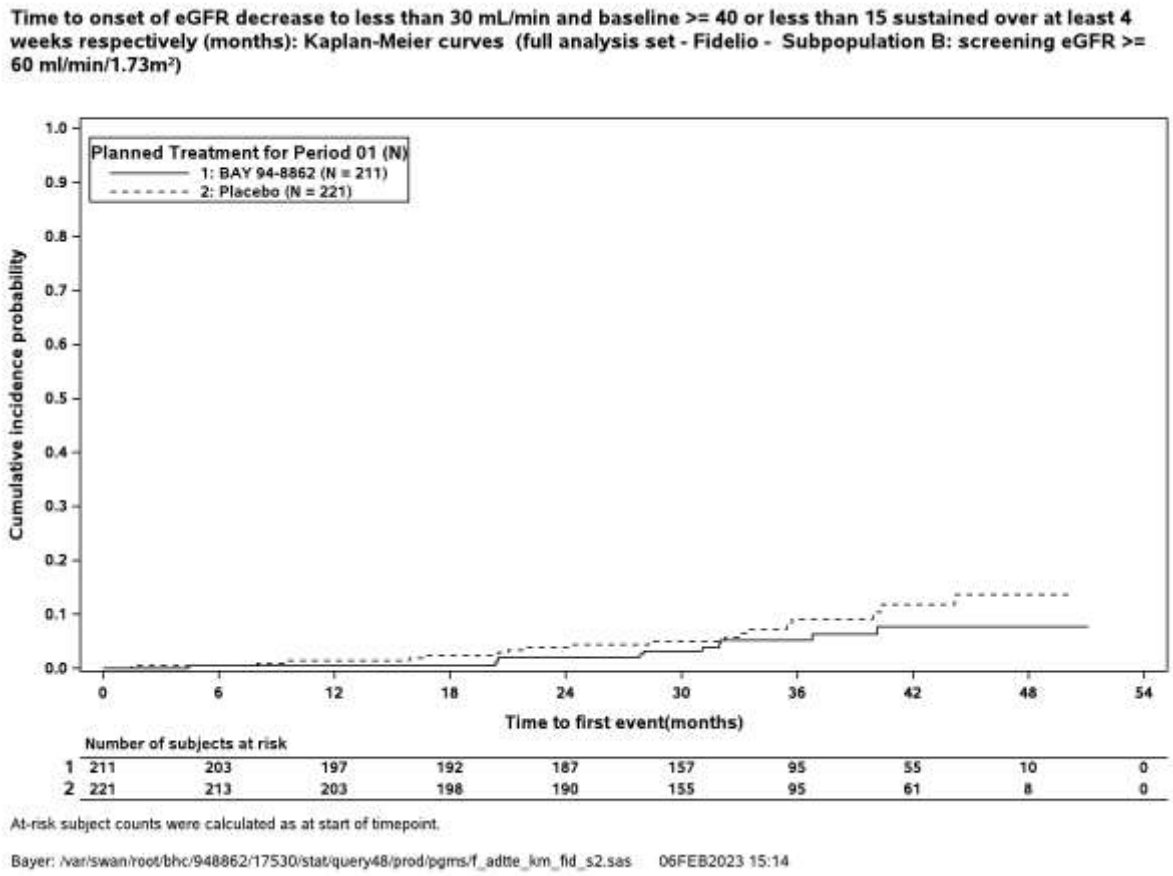


Figure 1.2.2 / 10: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

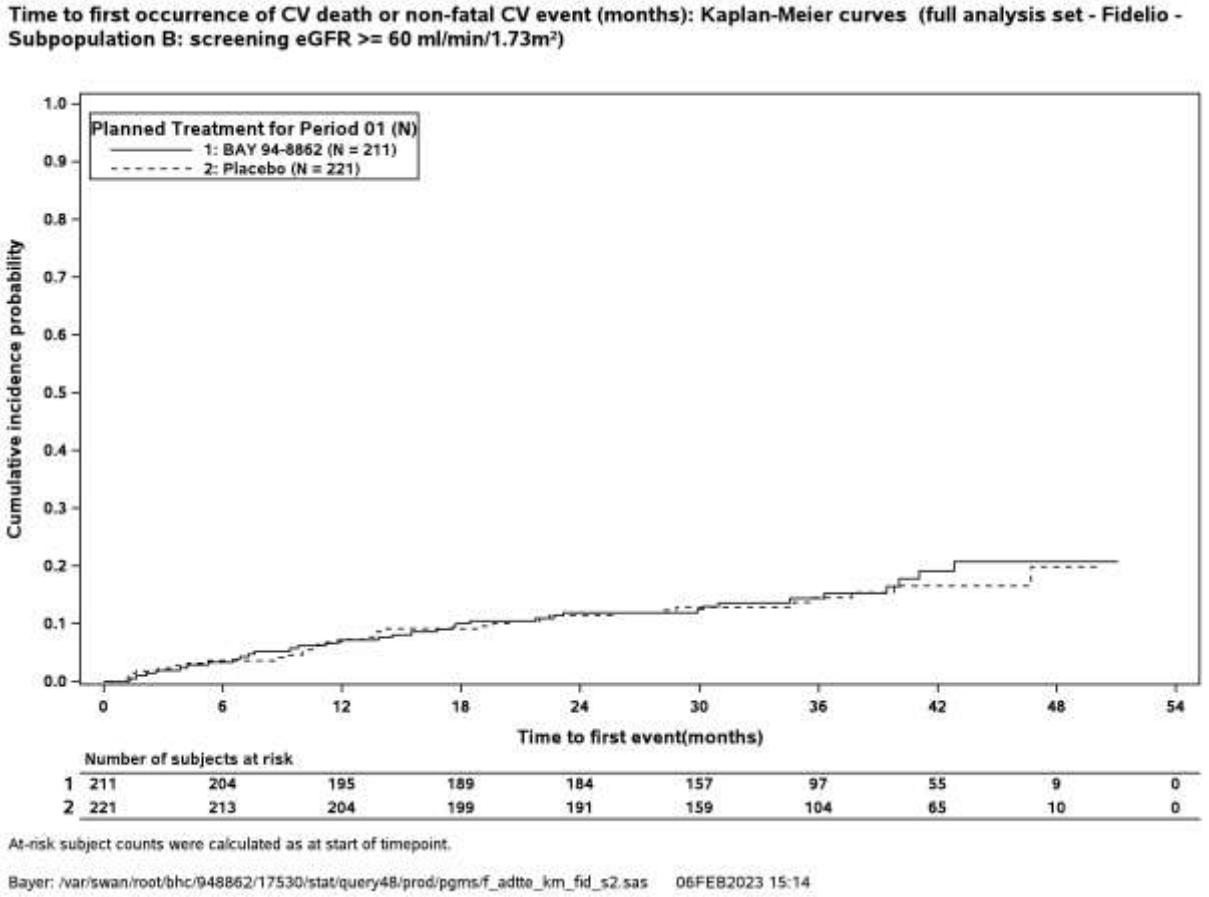


Figure 1.2.2 / 11: Time to CV death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

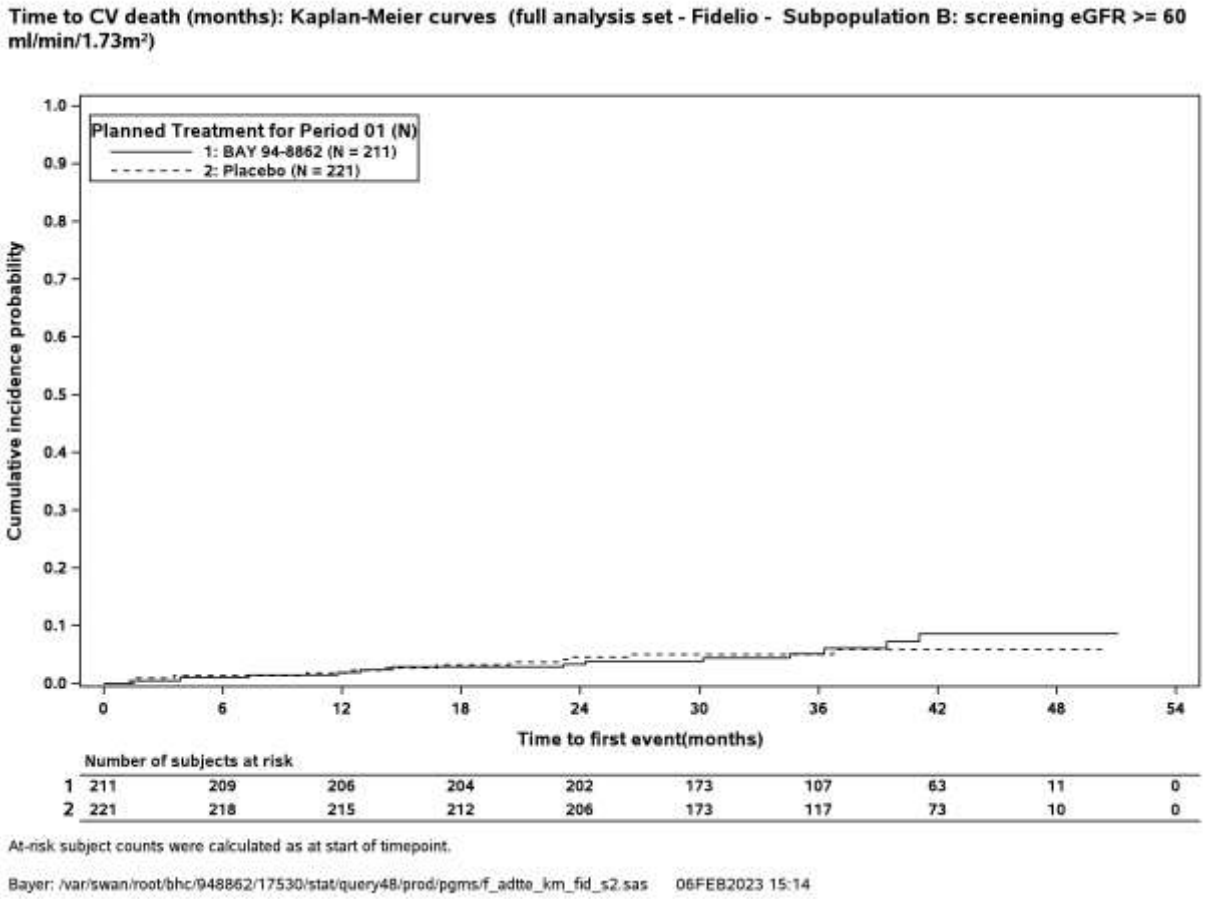


Figure 1.2.2 / 12: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

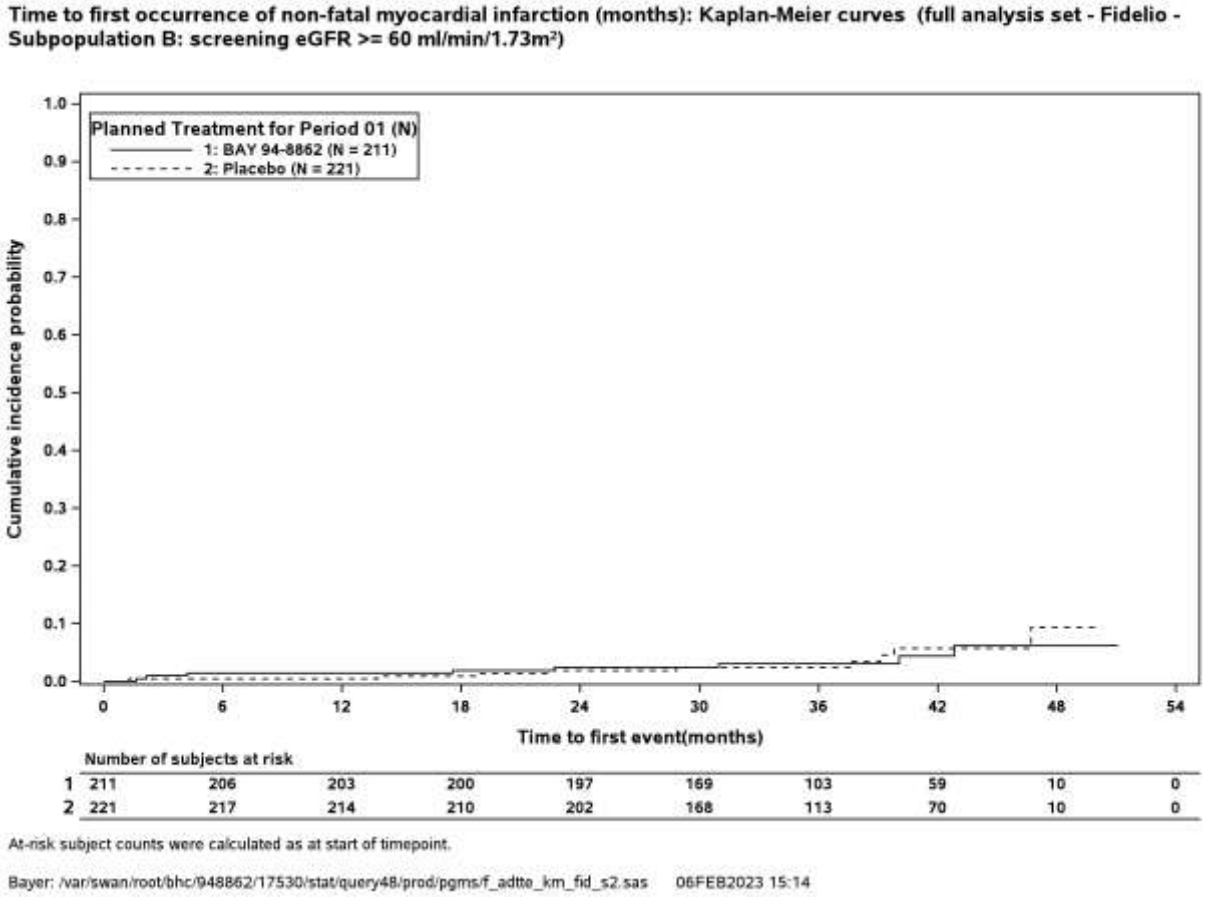


Figure 1.2.2 / 13: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

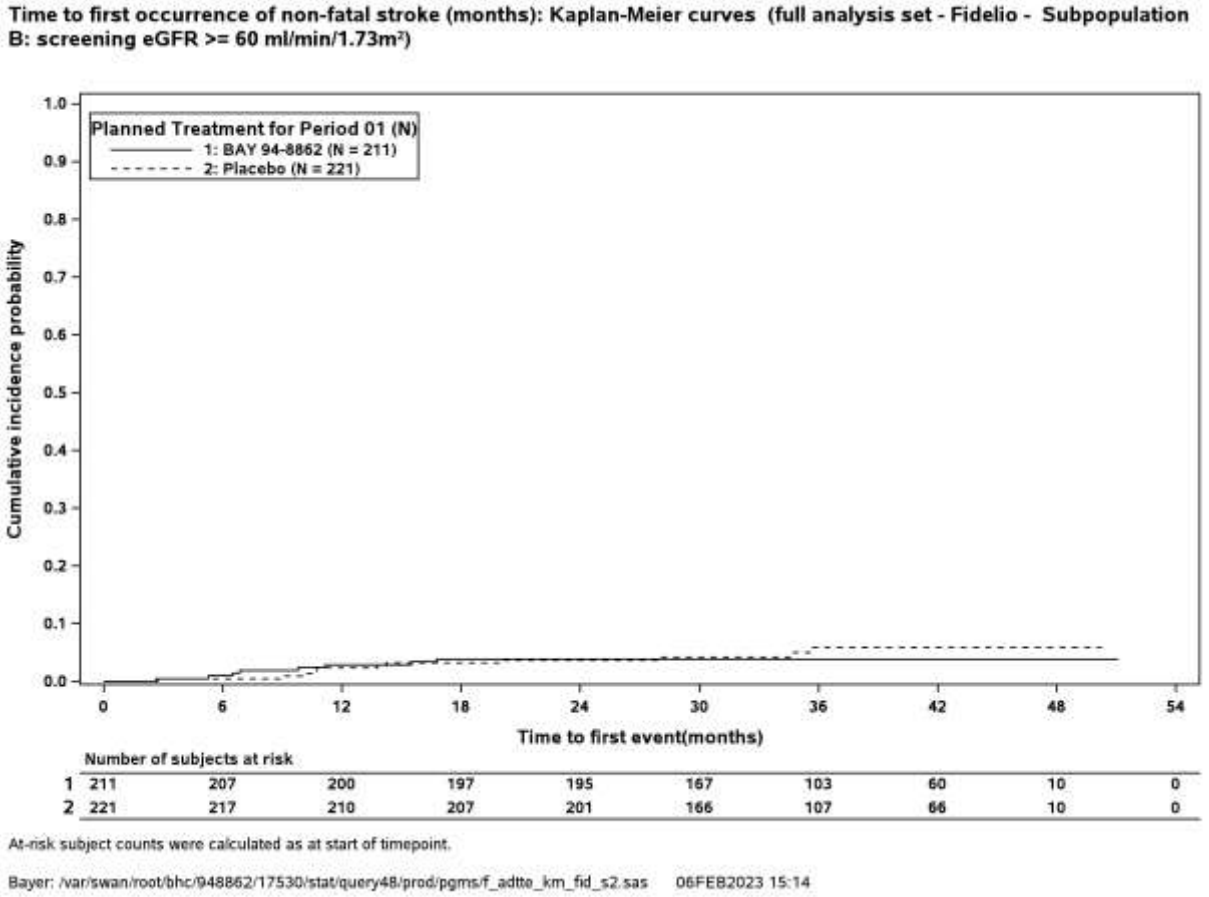


Figure 1.2.2 / 14: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

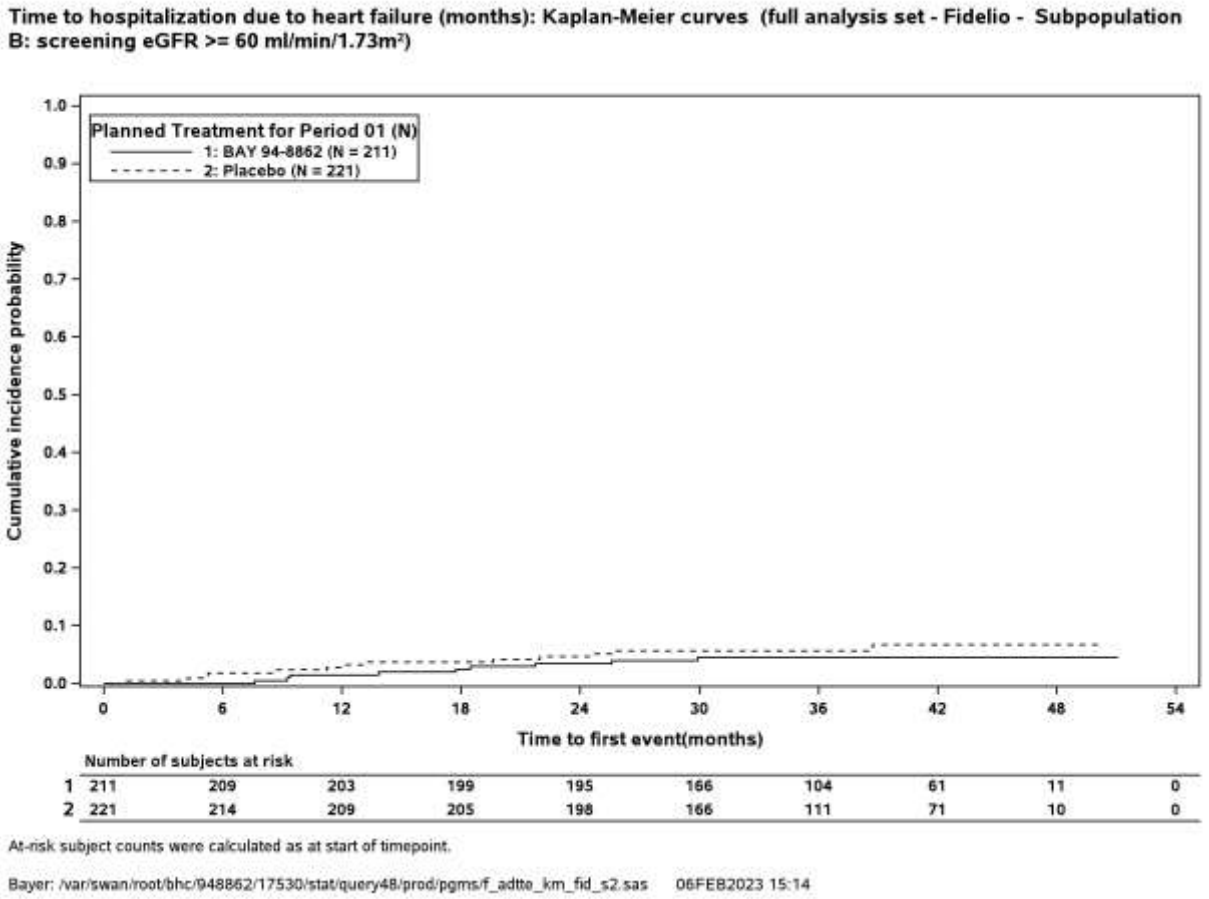


Figure 1.2.2 / 15: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

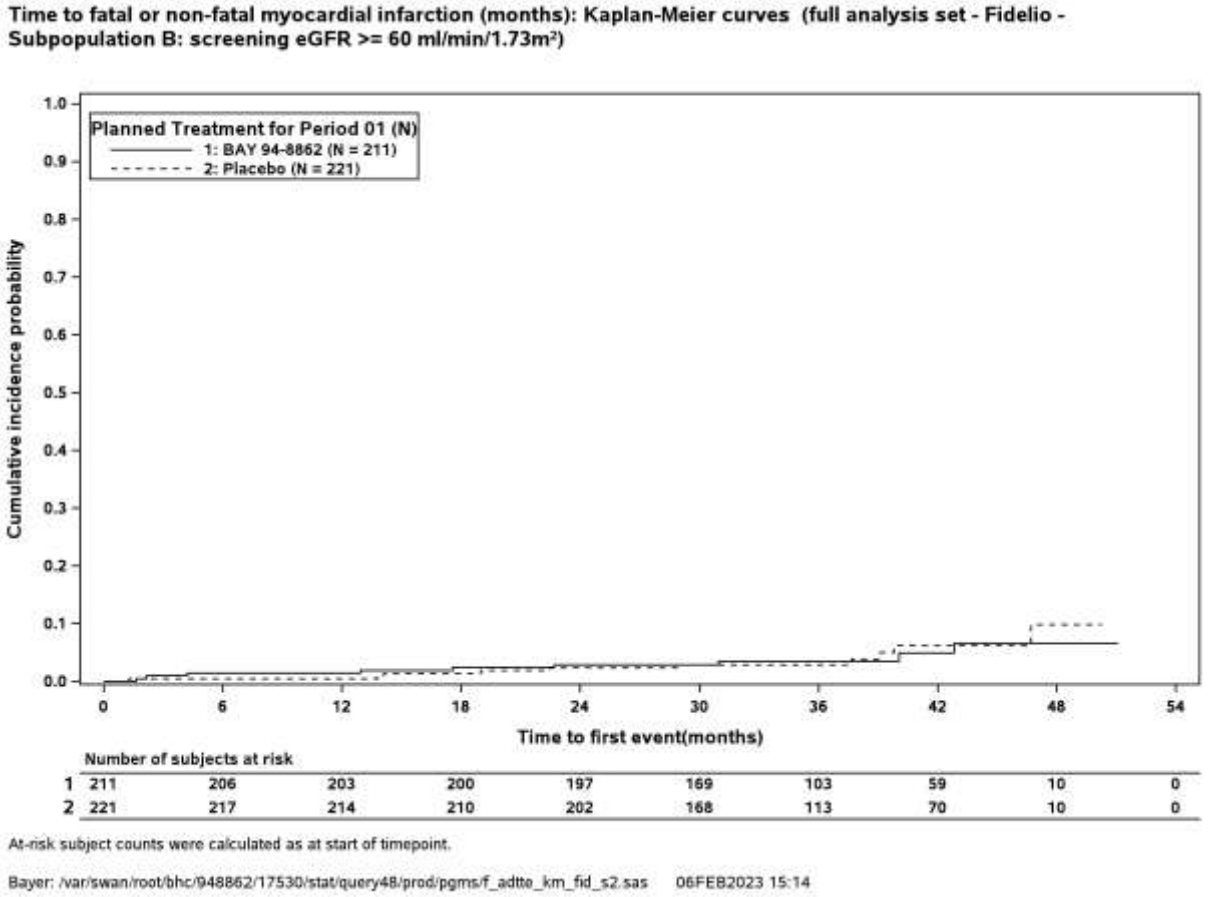


Figure 1.2.2 / 16: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

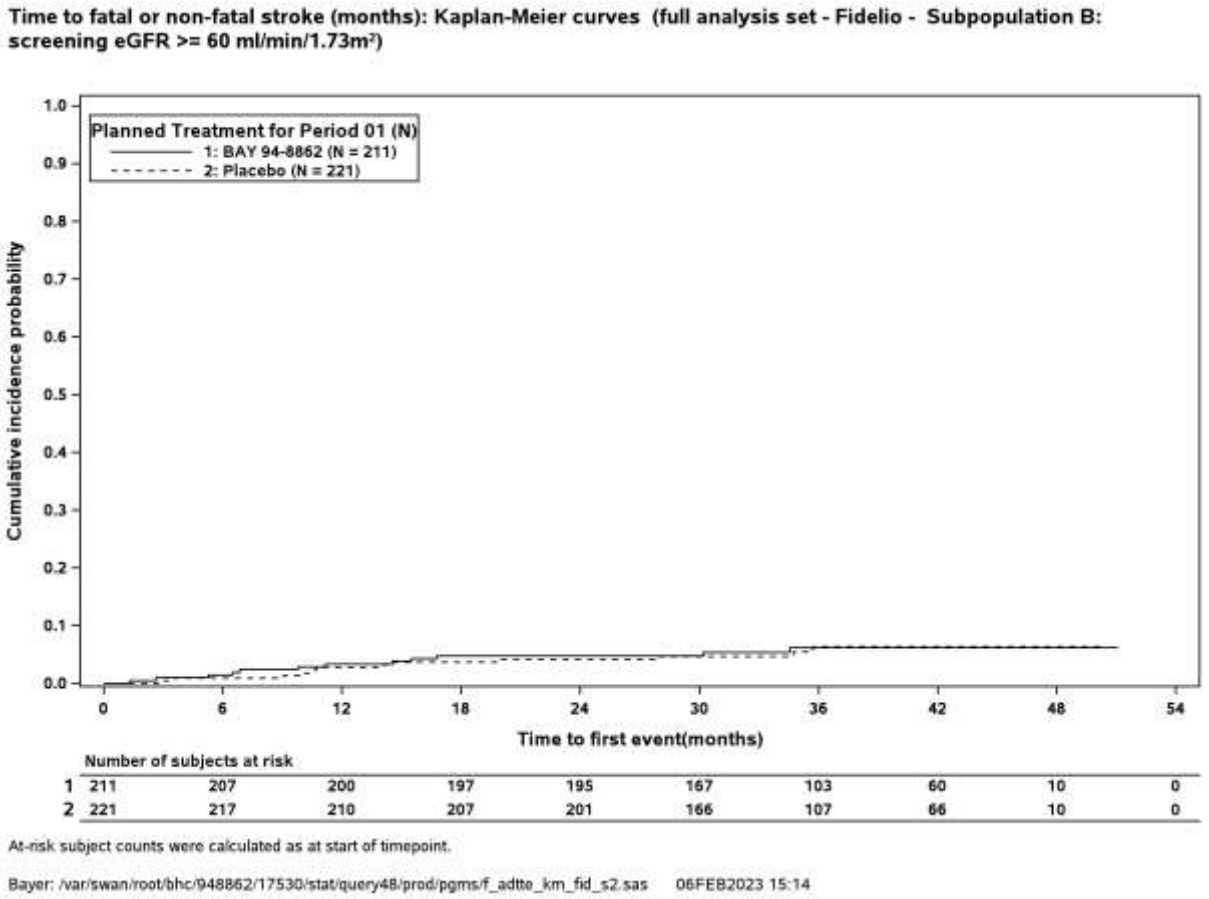


Figure 1.2.2 / 17: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

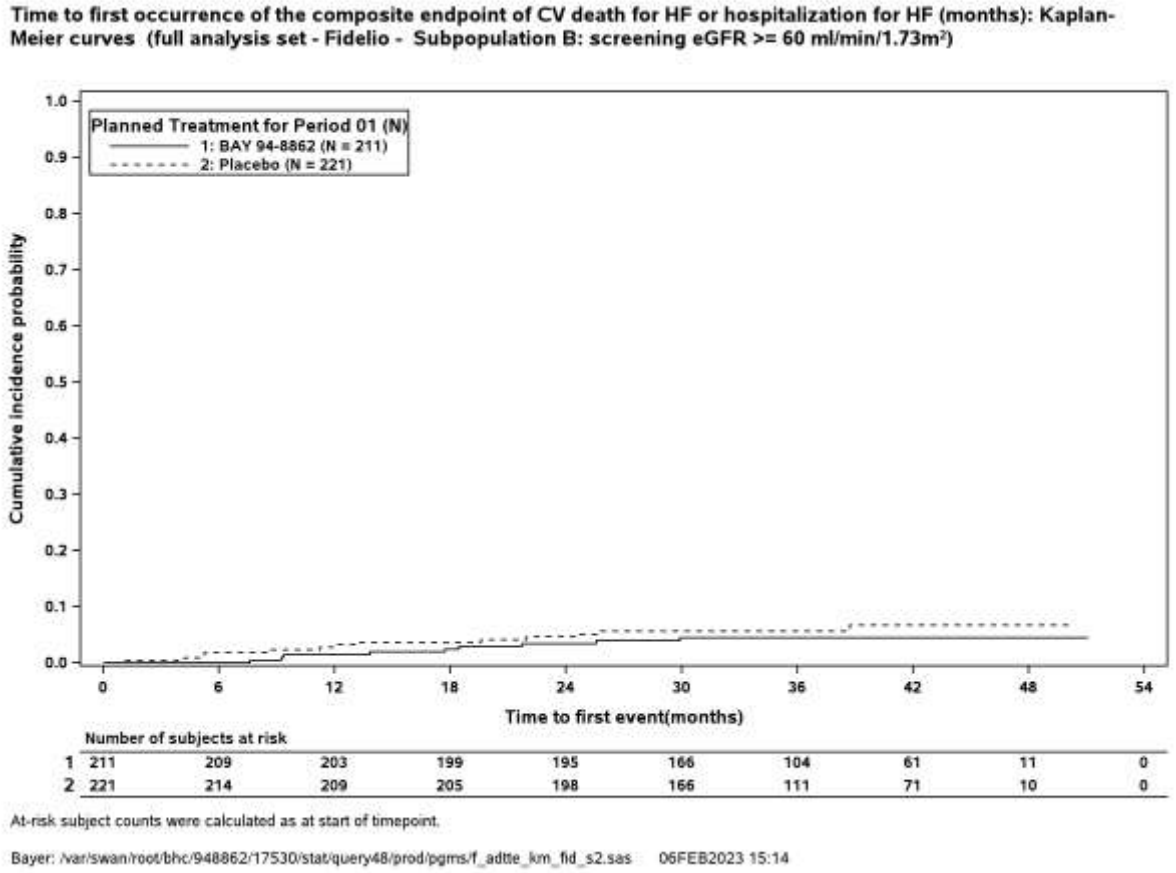


Figure 1.2.2 / 18: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

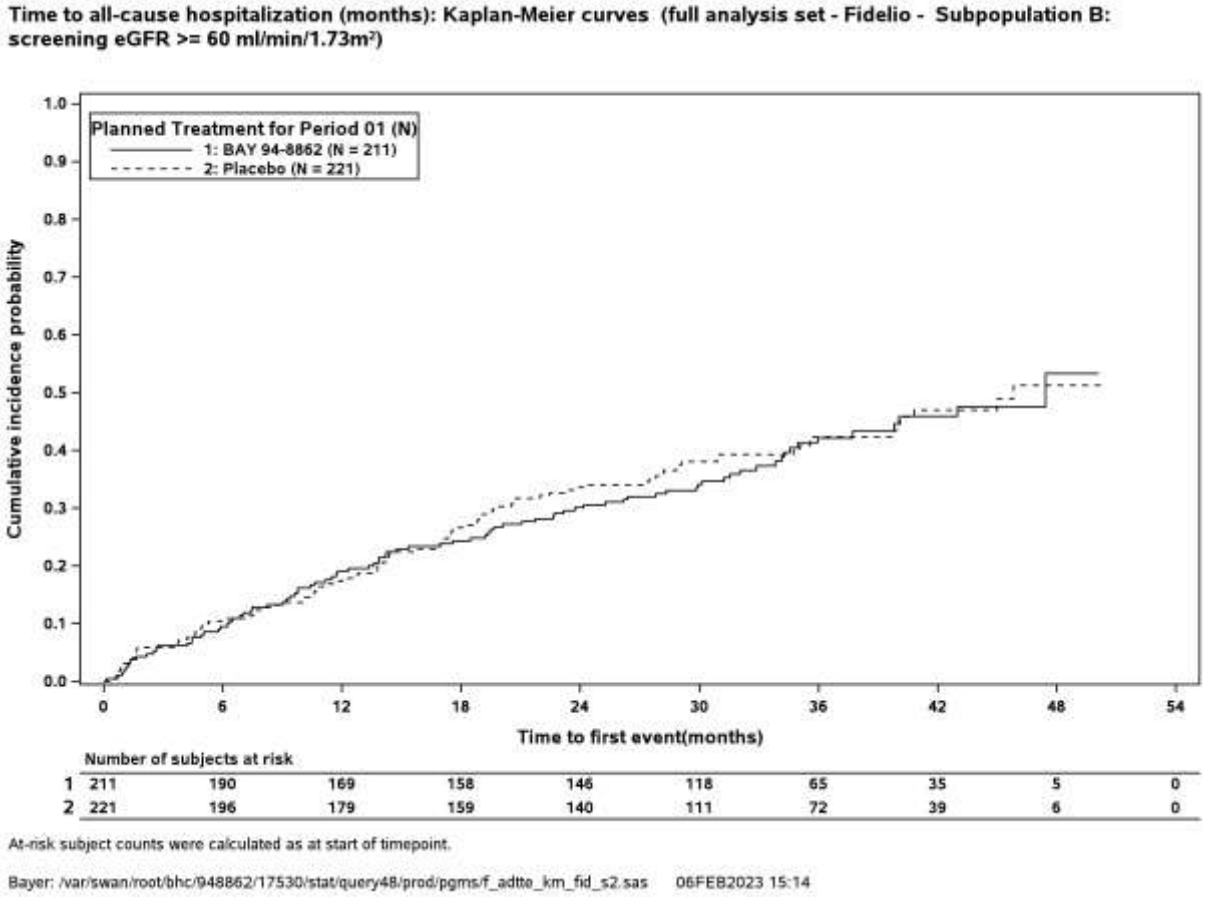


Table B3.1.1: EQ-5D VAS - Return Rate - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	207	211	98.1%	221	221	100.0%	428	432	99.1%
Baseline	207	211	98.1%	221	221	100.0%	428	432	99.1%
Visit 5	193	211	91.5%	205	221	92.8%	398	432	92.1%
Visit 8	187	211	88.6%	191	221	86.4%	378	432	87.5%
Visit 11	90	211	42.7%	91	221	41.2%	181	432	41.9%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	195	221	88.2%	384	432	88.9%
Premature discontinuation	8	211	3.8%	12	221	5.4%	20	432	4.6%
End of Study Visit	167	211	79.1%	174	221	78.7%	341	432	78.9%

Abbreviations: eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, VAS=Visual analog scale.

Table B3.1.2: KDQoL-36 - Return Rate of Physical Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	205	211	97.2%	219	221	99.1%	424	432	98.1%
Baseline	205	211	97.2%	219	221	99.1%	424	432	98.1%
Visit 5	192	211	91.0%	203	221	91.9%	395	432	91.4%
Visit 8	187	211	88.6%	188	221	85.1%	375	432	86.8%
Visit 11	90	211	42.7%	89	221	40.3%	179	432	41.4%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	194	221	87.8%	383	432	88.7%
Premature discontinuation	8	211	3.8%	12	221	5.4%	20	432	4.6%
End of Study Visit	167	211	79.1%	172	221	77.8%	339	432	78.5%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.

Table B3.1.3: KDQoL-36 - Return Rate of Mental Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	205	211	97.2%	219	221	99.1%	424	432	98.1%
Baseline	205	211	97.2%	219	221	99.1%	424	432	98.1%
Visit 5	192	211	91.0%	203	221	91.9%	395	432	91.4%
Visit 8	187	211	88.6%	188	221	85.1%	375	432	86.8%
Visit 11	90	211	42.7%	89	221	40.3%	179	432	41.4%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	194	221	87.8%	383	432	88.7%
Premature discontinuation	8	211	3.8%	12	221	5.4%	20	432	4.6%
End of Study Visit	167	211	79.1%	172	221	77.8%	339	432	78.5%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.

Table B3.1.4: KDQoL-36 - Return Rate of Burden of Kidney Disease - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	208	211	98.6%	221	221	100.0%	429	432	99.3%
Baseline	208	211	98.6%	221	221	100.0%	429	432	99.3%
Visit 5	193	211	91.5%	205	221	92.8%	398	432	92.1%
Visit 8	187	211	88.6%	189	221	85.5%	376	432	87.0%
Visit 11	90	211	42.7%	91	221	41.2%	181	432	41.9%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	195	221	88.2%	384	432	88.9%
Premature discontinuation	7	211	3.3%	12	221	5.4%	19	432	4.4%
End of Study Visit	168	211	79.6%	173	221	78.3%	341	432	78.9%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.

Table B3.1.5: KDQoL-36 - Return Rate of Symptoms and Problems - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	208	211	98.6%	221	221	100.0%	429	432	99.3%
Baseline	208	211	98.6%	221	221	100.0%	429	432	99.3%
Visit 5	193	211	91.5%	205	221	92.8%	398	432	92.1%
Visit 8	187	211	88.6%	190	221	86.0%	377	432	87.3%
Visit 11	90	211	42.7%	91	221	41.2%	181	432	41.9%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	195	221	88.2%	384	432	88.9%
Premature discontinuation	7	211	3.3%	12	221	5.4%	19	432	4.4%
End of Study Visit	168	211	79.6%	173	221	78.3%	341	432	78.9%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.

Table B3.1.6: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	207	211	98.1%	221	221	100.0%	428	432	99.1%
Baseline	207	211	98.1%	221	221	100.0%	428	432	99.1%
Visit 5	192	211	91.0%	204	221	92.3%	396	432	91.7%
Visit 8	187	211	88.6%	190	221	86.0%	377	432	87.3%
Visit 11	89	211	42.2%	91	221	41.2%	180	432	41.7%
Visit 14	6	211	2.8%	8	221	3.6%	14	432	3.2%
Last on-treatment	189	211	89.6%	195	221	88.2%	384	432	88.9%
Premature discontinuation	8	211	3.8%	12	221	5.4%	20	432	4.6%
End of Study Visit	168	211	79.6%	173	221	78.3%	341	432	78.9%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.

Table B3.1.7: EQ-5D VAS - Return Rate (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	207	211	98.1%	221	221	100.0%	428	432	99.1%
Visit 5	193	199	97.0%	205	211	97.2%	398	410	97.1%
Visit 8	187	194	96.4%	191	201	95.0%	378	395	95.7%
Visit 11	90	95	94.7%	91	101	90.1%	181	196	92.3%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	8	12	66.7%	12	14	85.7%	20	26	76.9%
End of Study Visit	167	187	89.3%	174	199	87.4%	341	386	88.3%

Abbreviations: eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, VAS=Visual analog scale.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.8: KDQoL-36 - Return Rate of Physical Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	205	211	97.2%	219	221	99.1%	424	432	98.1%
Visit 5	192	199	96.5%	203	211	96.2%	395	410	96.3%
Visit 8	187	194	96.4%	188	201	93.5%	375	395	94.9%
Visit 11	90	95	94.7%	89	101	88.1%	179	196	91.3%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	8	12	66.7%	12	14	85.7%	20	26	76.9%
End of Study Visit	167	187	89.3%	172	199	86.4%	339	386	87.8%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.9: KDQoL-36 - Return Rate of Mental Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	205	211	97.2%	219	221	99.1%	424	432	98.1%
Visit 5	192	199	96.5%	203	211	96.2%	395	410	96.3%
Visit 8	187	194	96.4%	188	201	93.5%	375	395	94.9%
Visit 11	90	95	94.7%	89	101	88.1%	179	196	91.3%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	8	12	66.7%	12	14	85.7%	20	26	76.9%
End of Study Visit	167	187	89.3%	172	199	86.4%	339	386	87.8%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.10: KDQoL-36 - Return Rate of Burden of Kidney Disease (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	208	211	98.6%	221	221	100.0%	429	432	99.3%
Visit 5	193	199	97.0%	205	211	97.2%	398	410	97.1%
Visit 8	187	194	96.4%	189	201	94.0%	376	395	95.2%
Visit 11	90	95	94.7%	91	101	90.1%	181	196	92.3%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	7	12	58.3%	12	14	85.7%	19	26	73.1%
End of Study Visit	168	187	89.8%	173	199	86.9%	341	386	88.3%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.11: KDQoL-36 - Return Rate of Symptoms and Problems (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	208	211	98.6%	221	221	100.0%	429	432	99.3%
Visit 5	193	199	97.0%	205	211	97.2%	398	410	97.1%
Visit 8	187	194	96.4%	190	201	94.5%	377	395	95.4%
Visit 11	90	95	94.7%	91	101	90.1%	181	196	92.3%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	7	12	58.3%	12	14	85.7%	19	26	73.1%
End of Study Visit	168	187	89.8%	173	199	86.9%	341	386	88.3%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.12: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	207	211	98.1%	221	221	100.0%	428	432	99.1%
Visit 5	192	199	96.5%	204	211	96.7%	396	410	96.6%
Visit 8	187	194	96.4%	190	201	94.5%	377	395	95.4%
Visit 11	89	95	93.7%	91	101	90.1%	180	196	91.8%
Visit 14	6	6	100.0%	8	8	100.0%	14	14	100.0%
Premature discontinuation	8	12	66.7%	12	14	85.7%	20	26	76.9%
End of Study Visit	168	187	89.8%	173	199	86.9%	341	386	88.3%

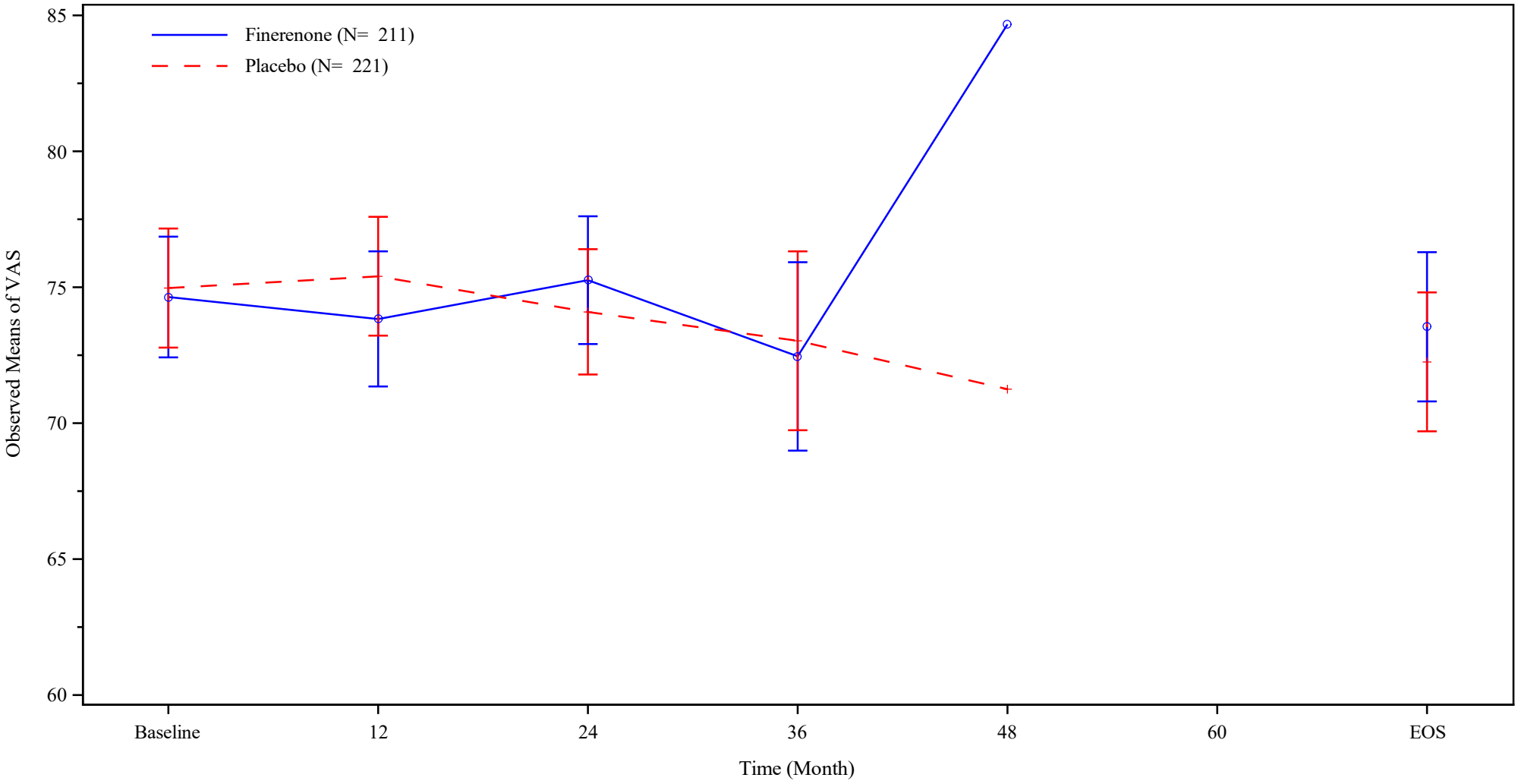
Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.2.1: EQ-5D VAS - Observed Means and Change from Baseline - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	207	74.64(16.19)	(72.42, 76.86)	80.00	(20.0, 100.0)	221	74.97(16.50)	(72.78, 77.16)	80.00	(20.0, 100.0)
Baseline	207	74.64(16.19)	(72.42, 76.86)	80.00	(20.0, 100.0)	221	74.97(16.50)	(72.78, 77.16)	80.00	(20.0, 100.0)
Visit 5	193	73.83(17.51)	(71.35, 76.32)	80.00	(10.0, 100.0)	205	75.40(15.87)	(73.22, 77.59)	80.00	(5.0, 100.0)
Visit 8	187	75.26(16.27)	(72.91, 77.61)	80.00	(20.0, 100.0)	191	74.09(16.15)	(71.79, 76.40)	75.00	(30.0, 100.0)
Visit 11	90	72.46(16.56)	(68.99, 75.92)	72.50	(20.0, 100.0)	91	73.03(15.80)	(69.74, 76.32)	75.00	(35.0, 100.0)
Visit 14	6	84.67(7.92)	(76.36, 92.97)	85.00	(70.0, 93.0)	8	71.25(12.46)	(60.83, 81.67)	72.50	(55.0, 90.0)
Last On-Treatment	189	74.01(16.47)	(71.65, 76.37)	75.00	(20.0, 100.0)	195	73.47(17.25)	(71.04, 75.91)	75.00	(5.0, 100.0)
Premature Discontinuation	8	76.25(12.17)	(66.07, 86.43)	80.00	(50.0, 90.0)	12	74.58(19.94)	(61.92, 87.25)	77.50	(30.0, 100.0)
End Of Study Visit	167	73.54(17.97)	(70.80, 76.29)	80.00	(10.0, 100.0)	174	72.25(17.09)	(69.70, 74.81)	75.00	(20.0, 100.0)
Change from Baseline										
Visit 5	191	-1.86(16.39)	(-4.20, 0.48)	0.00	(-90.0, 40.0)	205	0.27(13.83)	(-1.64, 2.17)	0.00	(-40.0, 40.0)
Visit 8	185	-0.60(16.84)	(-3.04, 1.84)	0.00	(-70.0, 70.0)	191	-1.45(14.07)	(-3.45, 0.56)	0.00	(-45.0, 40.0)
Visit 11	90	-4.41(15.41)	(-7.64, -1.18)	-4.00	(-55.0, 35.0)	91	-2.82(15.54)	(-6.06, 0.41)	0.00	(-45.0, 50.0)
Visit 14	6	3.33(14.02)	(-11.38, 18.05)	0.00	(-10.0, 30.0)	8	-3.75(12.17)	(-13.93, 6.43)	-2.50	(-20.0, 15.0)
Last On-Treatment	187	-1.67(16.68)	(-4.07, 0.74)	0.00	(-55.0, 50.0)	195	-1.97(15.55)	(-4.17, 0.23)	0.00	(-55.0, 40.0)
Premature Discontinuation	8	-5.00(17.53)	(-19.65, 9.65)	-5.00	(-35.0, 20.0)	12	5.00(18.59)	(-6.81, 16.81)	0.00	(-15.0, 50.0)
End Of Study Visit	165	-1.58(18.05)	(-4.35, 1.20)	0.00	(-70.0, 50.0)	174	-2.36(15.51)	(-4.68, -0.04)	0.00	(-65.0, 40.0)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation, VAS=Visual analog scale.

Figure B3.2.1: EQ-5D VAS - Time Profile Curve
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, EQ-5D=EuroQOL group 5-dimension, N=number of patients, VAS=Visual analog scale.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

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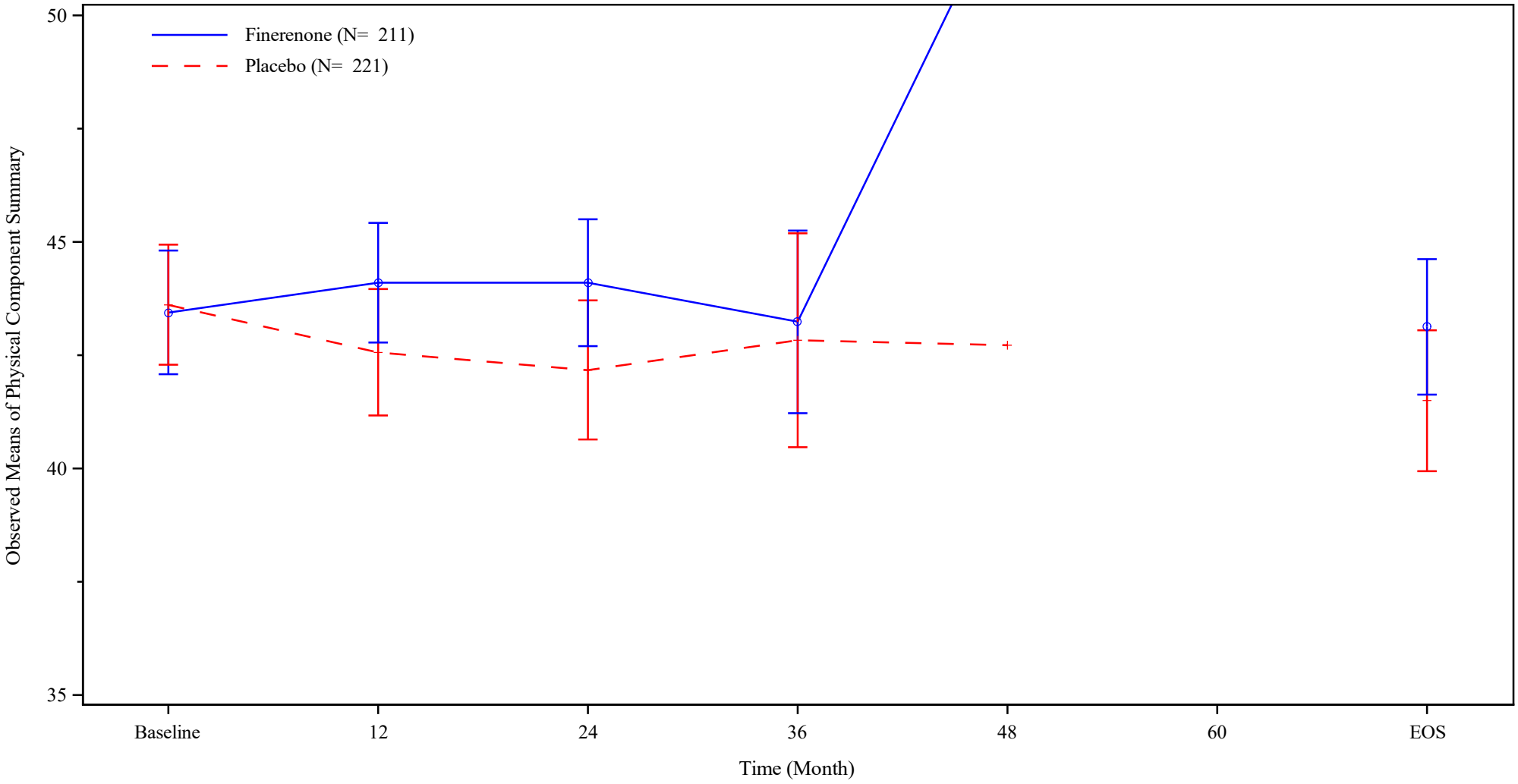
Table B3.2.2: KDQoL-36 - Observed Means and Change from Baseline of Physical Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	205	43.44(9.92)	(42.08, 44.81)	45.37	(12.1, 60.9)	219	43.61(9.94)	(42.29, 44.94)	45.84	(14.0, 60.8)
Baseline	205	43.44(9.92)	(42.08, 44.81)	45.37	(12.1, 60.9)	219	43.61(9.94)	(42.29, 44.94)	45.84	(14.0, 60.8)
Visit 5	192	44.10(9.26)	(42.78, 45.42)	45.03	(12.7, 58.9)	203	42.56(10.08)	(41.17, 43.96)	44.13	(19.9, 64.5)
Visit 8	187	44.10(9.69)	(42.70, 45.50)	44.70	(17.4, 60.7)	188	42.17(10.65)	(40.64, 43.71)	42.69	(18.9, 61.2)
Visit 11	90	43.24(9.62)	(41.22, 45.25)	44.19	(15.1, 59.9)	89	42.83(11.20)	(40.47, 45.19)	46.52	(14.1, 57.8)
Visit 14	6	52.77(3.11)	(49.50, 56.04)	52.83	(48.5, 56.9)	8	42.72(9.32)	(34.92, 50.51)	44.65	(25.5, 52.7)
Last On-Treatment	189	43.75(9.69)	(42.36, 45.14)	43.80	(18.2, 62.3)	194	42.21(10.43)	(40.73, 43.68)	43.64	(11.7, 61.2)
Premature Discontinuation	8	41.98(11.15)	(32.66, 51.30)	39.98	(23.0, 58.9)	12	40.24(11.67)	(32.83, 47.66)	41.18	(21.9, 55.7)
End Of Study Visit	167	43.13(9.77)	(41.63, 44.62)	42.33	(20.5, 62.3)	172	41.50(10.34)	(39.94, 43.05)	42.26	(11.7, 60.3)
Change from Baseline										
Visit 5	189	0.28(7.91)	(-0.85, 1.42)	0.00	(-26.8, 25.8)	201	-1.17(7.84)	(-2.26, -0.07)	-0.65	(-23.4, 25.5)
Visit 8	184	0.04(9.13)	(-1.29, 1.37)	0.50	(-29.8, 24.2)	186	-1.86(9.23)	(-3.19, -0.52)	-0.64	(-28.1, 20.4)
Visit 11	89	-2.42(9.74)	(-4.48, -0.37)	-1.48	(-34.6, 17.4)	88	-2.01(10.72)	(-4.28, 0.26)	-0.25	(-31.4, 20.7)
Visit 14	6	7.30(8.64)	(-1.76, 16.37)	5.00	(-0.5, 22.2)	8	-3.42(8.25)	(-10.32, 3.48)	-1.55	(-16.0, 7.8)
Last On-Treatment	186	-0.21(9.49)	(-1.58, 1.16)	0.15	(-34.6, 25.8)	192	-1.72(9.74)	(-3.11, -0.34)	-0.59	(-35.4, 20.8)
Premature Discontinuation	7	-2.96(14.02)	(-15.93, 10.00)	0.94	(-34.0, 7.7)	12	-3.16(4.67)	(-6.13, -0.19)	-1.54	(-15.1, 1.3)
End Of Study Visit	165	-0.71(10.31)	(-2.29, 0.88)	-0.05	(-32.3, 31.2)	170	-2.05(10.10)	(-3.58, -0.52)	-0.72	(-35.4, 20.8)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.

Figure B3.2.2: KDQoL-36 - Time Profile Curve of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



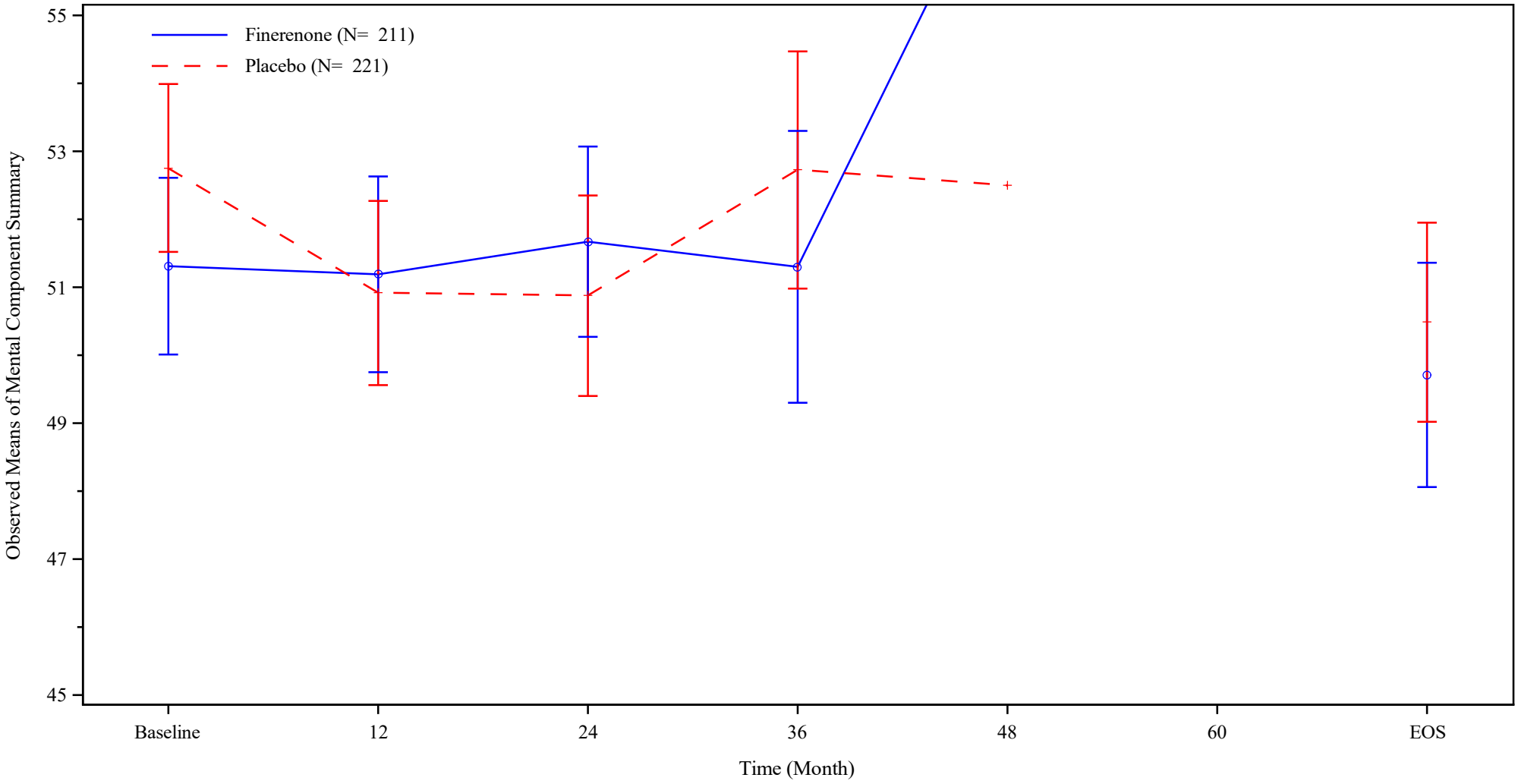
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.3: KDQoL-36 - Observed Means and Change from Baseline of Mental Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	205	51.31(9.44)	(50.01, 52.61)	54.33	(16.1, 65.2)	219	52.75(9.26)	(51.52, 53.99)	55.04	(18.0, 67.0)
Baseline	205	51.31(9.44)	(50.01, 52.61)	54.33	(16.1, 65.2)	219	52.75(9.26)	(51.52, 53.99)	55.04	(18.0, 67.0)
Visit 5	192	51.19(10.12)	(49.75, 52.63)	53.87	(22.8, 65.8)	203	50.92(9.80)	(49.56, 52.27)	54.08	(25.0, 67.3)
Visit 8	187	51.67(9.68)	(50.27, 53.07)	54.77	(25.9, 70.4)	188	50.88(10.26)	(49.40, 52.35)	54.16	(19.1, 68.5)
Visit 11	90	51.30(9.55)	(49.30, 53.30)	54.48	(24.4, 64.1)	89	52.73(8.28)	(50.98, 54.47)	54.65	(25.0, 65.2)
Visit 14	6	57.57(4.41)	(52.93, 62.20)	59.66	(51.1, 61.2)	8	52.50(10.78)	(43.48, 61.51)	53.44	(31.5, 63.8)
Last On-Treatment	189	50.12(10.61)	(48.60, 51.64)	53.73	(25.8, 68.1)	194	50.57(9.54)	(49.22, 51.92)	52.92	(21.3, 67.2)
Premature Discontinuation	8	48.82(7.34)	(42.68, 54.96)	45.84	(40.5, 58.9)	12	46.01(9.52)	(39.96, 52.06)	48.34	(29.7, 58.5)
End Of Study Visit	167	49.71(10.79)	(48.06, 51.36)	52.40	(25.4, 68.1)	172	50.49(9.72)	(49.02, 51.95)	52.79	(24.1, 70.5)
Change from Baseline										
Visit 5	189	-0.21(10.04)	(-1.65, 1.23)	0.00	(-32.5, 28.0)	201	-2.13(8.96)	(-3.38, -0.89)	-0.56	(-36.1, 19.6)
Visit 8	184	0.25(9.47)	(-1.13, 1.63)	-0.08	(-26.8, 39.9)	186	-2.24(9.59)	(-3.63, -0.85)	-1.52	(-32.0, 29.2)
Visit 11	89	-0.32(11.27)	(-2.69, 2.06)	0.00	(-33.3, 32.8)	88	-1.50(8.47)	(-3.29, 0.30)	-0.16	(-23.6, 18.6)
Visit 14	6	-1.59(6.04)	(-7.92, 4.75)	-2.83	(-8.8, 9.2)	8	-0.15(8.84)	(-7.54, 7.24)	1.04	(-13.3, 12.9)
Last On-Treatment	186	-1.46(11.03)	(-3.06, 0.13)	-0.05	(-31.0, 37.7)	192	-2.38(9.47)	(-3.73, -1.03)	-1.68	(-34.8, 28.7)
Premature Discontinuation	7	-1.16(5.87)	(-6.59, 4.26)	-1.82	(-8.2, 8.3)	12	-2.61(10.93)	(-9.55, 4.34)	-1.99	(-24.7, 19.6)
End Of Study Visit	165	-1.98(11.95)	(-3.81, -0.14)	-0.26	(-31.0, 37.7)	170	-2.40(9.75)	(-3.88, -0.93)	-1.57	(-28.9, 28.7)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.

Figure B3.2.3: KDQoL-36 - Time Profile Curve of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

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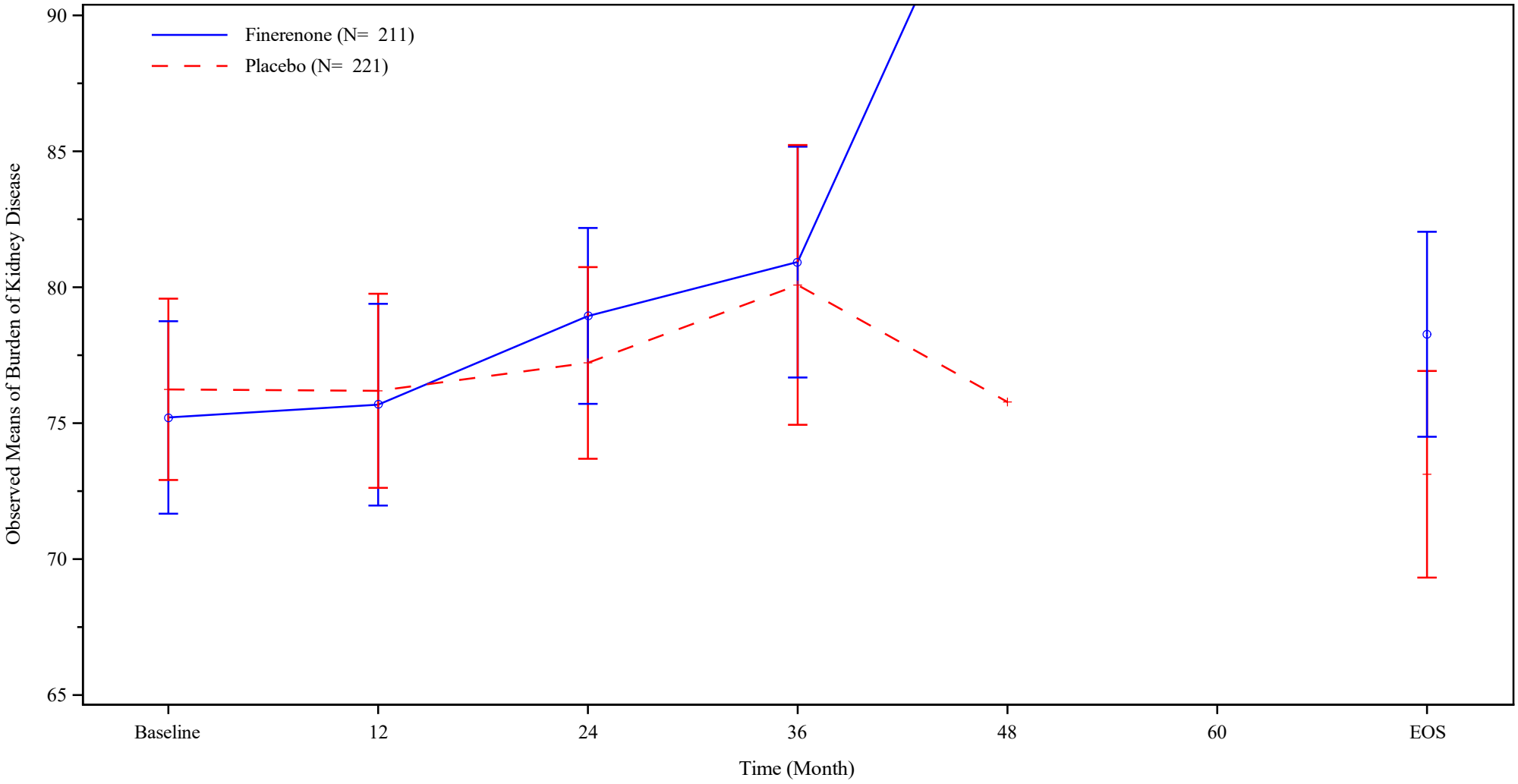
Table B3.2.4: KDQoL-36 - Observed Means and Change from Baseline of Burden of Kidney Disease - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	208	75.21(25.87)	(71.67, 78.75)	81.25	(6.3, 100.0)	221	76.24(25.13)	(72.91, 79.58)	81.25	(0.0, 100.0)
Baseline	208	75.21(25.87)	(71.67, 78.75)	81.25	(6.3, 100.0)	221	76.24(25.13)	(72.91, 79.58)	81.25	(0.0, 100.0)
Visit 5	193	75.68(26.16)	(71.97, 79.39)	81.25	(0.0, 100.0)	205	76.19(25.92)	(72.62, 79.76)	81.25	(0.0, 100.0)
Visit 8	187	78.94(22.45)	(75.71, 82.18)	87.50	(12.5, 100.0)	189	77.22(24.58)	(73.69, 80.74)	87.50	(0.0, 100.0)
Visit 11	90	80.93(20.29)	(76.68, 85.17)	84.38	(25.0, 100.0)	91	80.08(24.70)	(74.94, 85.23)	87.50	(0.0, 100.0)
Visit 14	6	97.92(5.10)	(92.56, 103.27)	100.00	(87.5, 100.0)	8	75.78(21.51)	(57.80, 93.76)	84.38	(37.5, 100.0)
Last On-Treatment	189	76.59(26.23)	(72.82, 80.35)	87.50	(6.3, 100.0)	195	73.72(25.89)	(70.06, 77.38)	75.00	(0.0, 100.0)
Premature Discontinuation	7	67.86(24.85)	(44.87, 90.84)	75.00	(18.8, 93.8)	12	60.42(26.96)	(43.29, 77.55)	56.25	(25.0, 100.0)
End Of Study Visit	168	78.27(24.76)	(74.50, 82.04)	87.50	(6.3, 100.0)	173	73.12(25.34)	(69.32, 76.92)	75.00	(0.0, 100.0)
Change from Baseline										
Visit 5	191	0.46(22.78)	(-2.79, 3.71)	0.00	(-100.0, 75.0)	205	-0.06(22.81)	(-3.20, 3.08)	0.00	(-75.0, 68.8)
Visit 8	185	3.61(22.78)	(0.31, 6.92)	0.00	(-50.0, 87.5)	189	1.26(25.50)	(-2.40, 4.91)	0.00	(-75.0, 81.3)
Visit 11	90	1.34(28.42)	(-4.61, 7.29)	0.00	(-75.0, 87.5)	91	0.96(23.53)	(-3.94, 5.86)	0.00	(-81.3, 68.8)
Visit 14	6	19.79(34.10)	(-15.99, 55.58)	6.25	(0.0, 87.5)	8	0.78(13.95)	(-10.88, 12.44)	0.00	(-18.8, 25.0)
Last On-Treatment	187	1.34(26.59)	(-2.50, 5.17)	0.00	(-93.8, 87.5)	195	-2.98(25.17)	(-6.54, 0.57)	0.00	(-100.0, 75.0)
Premature Discontinuation	7	-10.71(10.65)	(-20.57, -0.86)	-6.25	(-25.0, 0.0)	12	-10.94(23.86)	(-26.09, 4.22)	-6.25	(-56.3, 18.8)
End Of Study Visit	166	2.45(28.44)	(-1.91, 6.81)	0.00	(-93.8, 93.8)	173	-4.34(25.05)	(-8.09, -0.58)	0.00	(-100.0, 68.8)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.

Figure B3.2.4: KDQoL-36 - Time Profile Curve of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



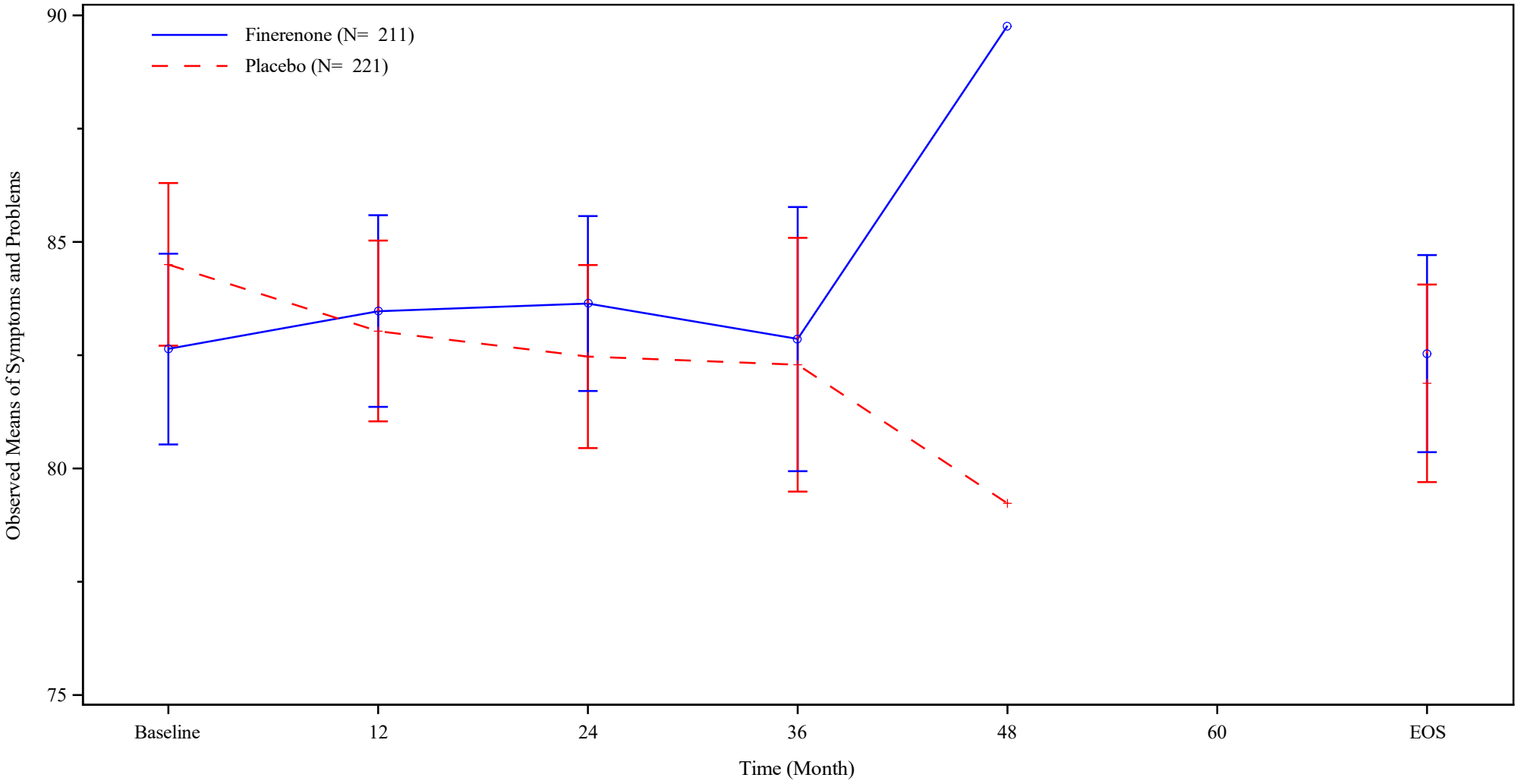
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.5: KDQoL-36 - Observed Means and Change from Baseline of Symptoms and Problems - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	208	82.64(15.40)	(80.53, 84.74)	86.36	(11.4, 100.0)	221	84.50(13.57)	(82.71, 86.30)	88.64	(36.4, 100.0)
Baseline	208	82.64(15.40)	(80.53, 84.74)	86.36	(11.4, 100.0)	221	84.50(13.57)	(82.71, 86.30)	88.64	(36.4, 100.0)
Visit 5	193	83.47(14.90)	(81.36, 85.59)	86.36	(9.1, 100.0)	205	83.03(14.47)	(81.04, 85.03)	86.36	(13.6, 100.0)
Visit 8	187	83.64(13.39)	(81.71, 85.57)	86.36	(34.1, 100.0)	190	82.47(14.13)	(80.45, 84.49)	86.36	(29.5, 100.0)
Visit 11	90	82.86(13.91)	(79.94, 85.77)	85.23	(25.0, 100.0)	91	82.29(13.44)	(79.49, 85.09)	84.09	(38.6, 100.0)
Visit 14	6	89.77(9.93)	(79.35, 100.20)	93.18	(72.7, 100.0)	8	79.23(14.21)	(67.35, 91.11)	84.09	(47.5, 90.9)
Last On-Treatment	189	83.52(14.31)	(81.46, 85.57)	86.36	(34.1, 100.0)	195	82.44(13.74)	(80.50, 84.38)	84.09	(29.5, 100.0)
Premature Discontinuation	7	84.09(10.41)	(74.46, 93.72)	88.64	(68.2, 95.5)	12	80.68(9.95)	(74.36, 87.01)	82.95	(61.4, 95.5)
End Of Study Visit	168	82.54(14.27)	(80.36, 84.71)	84.09	(38.6, 100.0)	173	81.88(14.53)	(79.70, 84.06)	84.09	(29.5, 100.0)
Change from Baseline										
Visit 5	191	0.48(9.27)	(-0.84, 1.80)	0.00	(-29.5, 40.9)	205	-1.19(12.24)	(-2.88, 0.49)	0.00	(-86.4, 36.4)
Visit 8	185	0.88(12.06)	(-0.87, 2.63)	0.00	(-31.8, 70.5)	190	-1.89(11.66)	(-3.56, -0.22)	0.00	(-65.9, 29.5)
Visit 11	90	-1.64(14.76)	(-4.73, 1.45)	-2.27	(-36.4, 65.9)	91	-3.18(11.16)	(-5.50, -0.85)	-2.27	(-29.5, 29.5)
Visit 14	6	2.65(8.31)	(-6.07, 11.37)	2.27	(-6.8, 15.9)	8	-6.85(12.02)	(-16.90, 3.20)	-4.55	(-27.5, 9.1)
Last On-Treatment	187	0.53(14.03)	(-1.50, 2.55)	0.00	(-36.4, 70.5)	195	-2.16(11.98)	(-3.85, -0.47)	0.00	(-45.5, 36.4)
Premature Discontinuation	7	-4.22(10.28)	(-13.73, 5.29)	-2.27	(-22.7, 11.4)	12	0.57(15.75)	(-9.44, 10.58)	-2.27	(-15.9, 36.4)
End Of Study Visit	166	0.03(15.22)	(-2.30, 2.36)	0.00	(-36.4, 65.9)	173	-2.45(13.04)	(-4.41, -0.50)	0.00	(-45.5, 47.7)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.

Figure B3.2.5: KDQoL-36 - Time Profile Curve of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



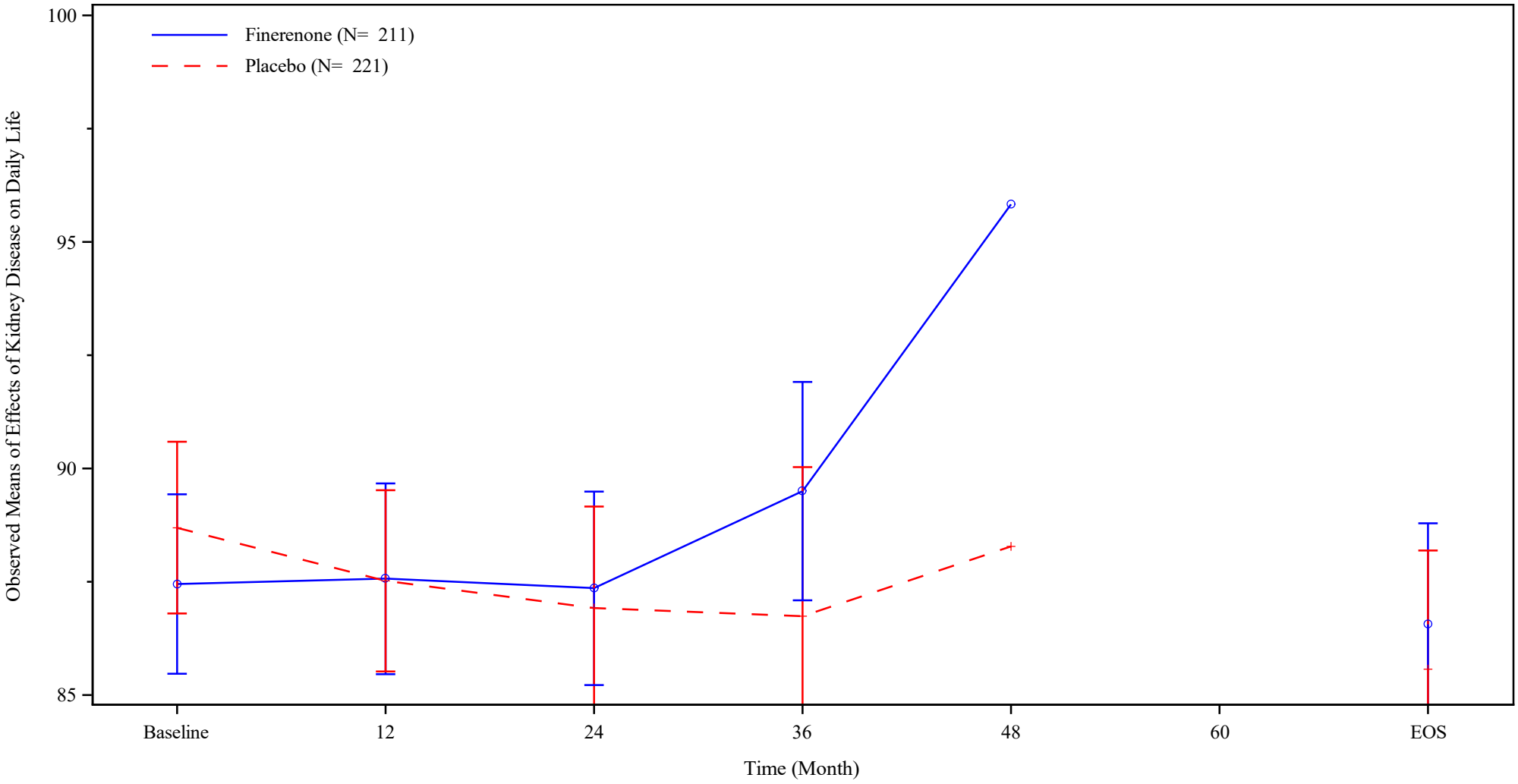
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.6: KDQoL-36 - Observed Means and Change from Baseline of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)					Placebo (N=221)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	207	87.45(14.47)	(85.47, 89.43)	93.75	(3.1, 100.0)	221	88.69(14.31)	(86.80, 90.59)	93.75	(31.3, 100.0)
Baseline	207	87.45(14.47)	(85.47, 89.43)	93.75	(3.1, 100.0)	221	88.69(14.31)	(86.80, 90.59)	93.75	(31.3, 100.0)
Visit 5	192	87.57(14.79)	(85.46, 89.67)	93.75	(34.4, 100.0)	204	87.52(14.51)	(85.52, 89.52)	93.75	(37.5, 100.0)
Visit 8	187	87.36(14.78)	(85.22, 89.49)	93.75	(25.0, 100.0)	190	86.92(15.66)	(84.68, 89.16)	93.75	(0.0, 100.0)
Visit 11	89	89.50(11.44)	(87.09, 91.91)	93.75	(46.9, 100.0)	91	86.74(15.76)	(83.46, 90.03)	93.75	(28.1, 100.0)
Visit 14	6	95.83(5.10)	(90.48, 101.19)	96.88	(87.5, 100.0)	8	88.28(11.78)	(78.43, 98.13)	90.63	(75.0, 100.0)
Last On-Treatment	189	86.45(15.09)	(84.28, 88.61)	90.63	(37.5, 100.0)	195	85.50(16.21)	(83.21, 87.79)	90.63	(34.4, 100.0)
Premature Discontinuation	8	92.58(11.07)	(83.32, 101.83)	96.88	(68.8, 100.0)	12	84.11(19.01)	(72.04, 96.19)	89.06	(40.6, 100.0)
End Of Study Visit	168	86.56(14.68)	(84.32, 88.79)	90.63	(43.8, 100.0)	173	85.57(17.47)	(82.95, 88.19)	90.63	(0.0, 100.0)
Change from Baseline										
Visit 5	190	0.07(10.74)	(-1.47, 1.60)	0.00	(-46.9, 43.8)	204	-1.37(11.74)	(-2.99, 0.25)	0.00	(-46.9, 46.9)
Visit 8	185	-0.31(13.21)	(-2.22, 1.61)	0.00	(-68.8, 75.0)	190	-2.21(12.63)	(-4.02, -0.40)	0.00	(-59.4, 37.5)
Visit 11	89	-0.37(11.65)	(-2.83, 2.08)	0.00	(-34.4, 37.5)	91	-4.57(12.94)	(-7.26, -1.87)	0.00	(-65.6, 25.0)
Visit 14	6	0.52(4.15)	(-3.84, 4.88)	0.00	(-6.3, 6.3)	8	-5.08(13.77)	(-16.59, 6.43)	-3.13	(-21.9, 12.5)
Last On-Treatment	187	-0.91(13.30)	(-2.83, 1.01)	0.00	(-37.5, 75.0)	195	-3.57(13.66)	(-5.50, -1.64)	0.00	(-50.0, 37.5)
Premature Discontinuation	8	-1.56(3.34)	(-4.36, 1.23)	0.00	(-9.4, 0.0)	12	-4.17(13.01)	(-12.43, 4.10)	-4.69	(-28.1, 28.1)
End Of Study Visit	166	-1.34(13.49)	(-3.41, 0.73)	0.00	(-37.5, 40.6)	173	-3.90(14.21)	(-6.03, -1.77)	0.00	(-75.0, 37.5)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.

Figure B3.2.6: KDQoL-36 - Time Profile Curve of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.3.1: EQ-5D VAS - Summary and MMRM of Change from Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	191	-1.82	[-3.95 , 0.31]	205	0.27	[-1.43 , 1.96]	-2.09	[-4.80 , 0.62]	0.1306
Visit 8	185	-0.35	[-2.42 , 1.72]	191	-1.62	[-3.42 , 0.19]	1.27	[-1.47 , 4.01]	0.3631
Visit 11	90	-3.56	[-6.27 , -0.84]	91	-3.98	[-6.75 , -1.22]	0.43	[-3.41 , 4.26]	0.8265
Overall	194	0.12	[-2.22 , 2.45]	205	0.04	[-2.10 , 2.19]	0.07	[-2.28 , 2.43]	0.9516
Hedges' g							0.00	[-0.19 , 0.20]	0.9640

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects, VAS=Visual Analogue Scale.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.

Table B3.3.2: KDQoL-36 - Summary and MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	189	0.30	[-0.73 , 1.33]	201	-1.20	[-2.22 , -0.18]	1.49	[0.05 , 2.94]	0.0427
Visit 8	184	0.07	[-1.09 , 1.23]	186	-1.83	[-3.04 , -0.62]	1.90	[0.22 , 3.57]	0.0264
Visit 11	89	-2.18	[-3.79 , -0.58]	88	-3.29	[-5.11 , -1.46]	1.11	[-1.30 , 3.51]	0.3663
Overall	193	-0.44	[-1.68 , 0.81]	202	-2.24	[-3.59 , -0.89]	1.80	[0.37 , 3.24]	0.0140
Hedges' g							0.19	[0.00 , 0.39]	0.0559

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
The Physical Component Summary uses items 1 to 12 of the KDQOL-36.

Table B3.3.3: KDQoL-36 - Summary and MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	189	-0.17	[-1.45 , 1.12]	201	-2.13	[-3.28 , -0.99]	1.97	[0.25 , 3.68]	0.0249
Visit 8	184	0.26	[-0.97 , 1.49]	186	-2.24	[-3.50 , -0.97]	2.50	[0.74 , 4.25]	0.0055
Visit 11	89	-0.80	[-2.56 , 0.96]	88	-2.69	[-4.15 , -1.23]	1.89	[-0.37 , 4.15]	0.1013
Overall	193	-0.28	[-1.67 , 1.12]	202	-1.37	[-2.72 , -0.01]	1.09	[-0.36 , 2.55]	0.1405
Hedges' g							0.11	[-0.09 , 0.31]	0.2706

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
The Mental Component Summary uses items 1 to 12 of the KDQOL-36.

Table B3.3.4: KDQoL-36 - Summary and MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	191	0.45	[-2.47 , 3.37]	205	-0.06	[-2.91 , 2.79]	0.51	[-3.55 , 4.57]	0.8052
Visit 8	185	3.50	[0.85 , 6.16]	189	0.52	[-2.62 , 3.65]	2.99	[-1.11 , 7.08]	0.1524
Visit 11	90	0.70	[-3.35 , 4.76]	91	-0.94	[-5.49 , 3.61]	1.65	[-4.40 , 7.69]	0.5918
Overall	194	4.24	[1.11 , 7.37]	205	2.88	[-0.49 , 6.24]	1.37	[-2.05 , 4.78]	0.4322
Hedges' g							0.06	[-0.14 , 0.26]	0.5610

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
Burden of Kidney Disease uses items 13 to 16 of the KDQOL-36.

Table B3.3.5: KDQoL-36 - Summary and MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	191	0.52	[-0.74 , 1.77]	205	-1.19	[-2.76 , 0.38]	1.71	[-0.29 , 3.71]	0.0939
Visit 8	185	0.96	[-0.51 , 2.42]	190	-1.91	[-3.45 , -0.37]	2.87	[0.75 , 4.99]	0.0082
Visit 11	90	-1.06	[-3.55 , 1.42]	91	-4.06	[-6.14 , -1.99]	3.00	[-0.21 , 6.21]	0.0664
Overall	194	-0.19	[-1.82 , 1.45]	205	-2.25	[-3.97 , -0.53]	2.06	[0.24 , 3.88]	0.0266
Hedges' g							0.17	[-0.03 , 0.37]	0.0900

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
Symptoms and Problems uses items 17 to 28 b of the KDQOL-36.

Table B3.3.6: KDQoL-36 - Summary and MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=211)			Placebo (N=221)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	190	0.11	[-1.35 , 1.57]	204	-1.43	[-2.91 , 0.06]	1.54	[-0.54 , 3.61]	0.1469
Visit 8	185	-0.19	[-1.93 , 1.54]	190	-2.38	[-4.11 , -0.65]	2.19	[-0.26 , 4.63]	0.0795
Visit 11	89	-0.94	[-3.08 , 1.20]	91	-5.99	[-8.57 , -3.41]	5.05	[1.74 , 8.36]	0.0030
Overall	194	0.62	[-1.11 , 2.34]	205	-1.72	[-3.62 , 0.18]	2.34	[0.36 , 4.31]	0.0205
Hedges' g							0.18	[-0.02 , 0.38]	0.0755

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQOL-36.

Table B3.4.1: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		67 (31.8%)	82 (37.1%)	149 (34.5%)
Number of subjects without events		144 (68.2%)	139 (62.9%)	283 (65.5%)
Odds Ratio [a]				
OR, 95% CI	0.786 [0.526, 1.174]			
p-value	0.2393			
Relative Risk [b]				
RR, 95% CI	0.860 [0.663, 1.115]			
p-value	0.2540			
Risk Difference [c]				
RD, 95% CI	-0.055 [-0.143, 0.034]			
p-value	0.2255			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, VAS=Visual Analogue Scale.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.2: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		50 (23.7%)	44 (19.9%)	94 (21.8%)
Number of subjects without events		161 (76.3%)	177 (80.1%)	338 (78.2%)
Odds Ratio [a]				
OR, 95% CI	1.261 [0.796, 1.996]			
p-value	0.3230			
Relative Risk [b]				
RR, 95% CI	1.203 [0.841, 1.720]			
p-value	0.3119			
Risk Difference [c]				
RD, 95% CI	0.041 [-0.038, 0.120]			
p-value	0.3130			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, VAS=Visual Analogue Scale.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.3: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		68 (32.2%)	82 (37.1%)	150 (34.7%)
Number of subjects without events		143 (67.8%)	139 (62.9%)	282 (65.3%)
Odds Ratio [a]				
OR, 95% CI	0.802 [0.538, 1.196]			
p-value	0.2788			
Relative Risk [b]				
RR, 95% CI	0.856 [0.661, 1.110]			
p-value	0.2418			
Risk Difference [c]				
RD, 95% CI	-0.047 [-0.137, 0.042]			
p-value	0.2975			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.4: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		64 (30.3%)	79 (35.7%)	143 (33.1%)
Number of subjects without events		147 (69.7%)	142 (64.3%)	289 (66.9%)
Odds Ratio [a]				
OR, 95% CI	0.783 [0.523, 1.173]			
p-value	0.2355			
Relative Risk [b]				
RR, 95% CI	0.835 [0.638, 1.094]			
p-value	0.1911			
Risk Difference [c]				
RD, 95% CI	-0.050 [-0.138, 0.039]			
p-value	0.2697			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.5: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		69 (32.7%)	91 (41.2%)	160 (37.0%)
Number of subjects without events		142 (67.3%)	130 (58.8%)	272 (63.0%)
Odds Ratio [a]				
OR, 95% CI	0.696 [0.470, 1.032]			
p-value	0.0715			
Relative Risk [b]				
RR, 95% CI	0.795 [0.618, 1.022]			
p-value	0.0737			
Risk Difference [c]				
RD, 95% CI	-0.085 [-0.176, 0.006]			
p-value	0.0673			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.6: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		37 (17.5%)	53 (24.0%)	90 (20.8%)
Number of subjects without events		174 (82.5%)	168 (76.0%)	342 (79.2%)
Odds Ratio [a]				
OR, 95% CI	0.673 [0.420, 1.077]			
p-value	0.0988			
Relative Risk [b]				
RR, 95% CI	0.727 [0.500, 1.059]			
p-value	0.0967			
Risk Difference [c]				
RD, 95% CI	-0.064 [-0.141, 0.013]			
p-value	0.1024			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.7: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		48 (22.7%)	61 (27.6%)	109 (25.2%)
Number of subjects without events		163 (77.3%)	160 (72.4%)	323 (74.8%)
Odds Ratio [a]				
OR, 95% CI	0.769 [0.494, 1.197]			
p-value	0.2447			
Relative Risk [b]				
RR, 95% CI	0.826 [0.598, 1.140]			
p-value	0.2450			
Risk Difference [c]				
RD, 95% CI	-0.043 [-0.127, 0.041]*			
p-value	0.3188			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.8: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		54 (25.6%)	39 (17.6%)	93 (21.5%)
Number of subjects without events		157 (74.4%)	182 (82.4%)	339 (78.5%)
Odds Ratio [a]				
OR, 95% CI	1.642 [1.022, 2.640]			
p-value	0.0405			
Relative Risk [b]				
RR, 95% CI	1.499 [1.050, 2.140]			
p-value	0.0257			
Risk Difference [c]				
RD, 95% CI	0.064 [-0.017, 0.146]*			
p-value	0.1202			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.9: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		54 (25.6%)	34 (15.4%)	88 (20.4%)
Number of subjects without events		157 (74.4%)	187 (84.6%)	344 (79.6%)
Odds Ratio [a]				
OR, 95% CI	1.910 [1.181, 3.091]			
p-value	0.0084			
Relative Risk [b]				
RR, 95% CI	1.678 [1.143, 2.462]			
p-value	0.0082			
Risk Difference [c]				
RD, 95% CI	0.099 [0.023, 0.174]			
p-value	0.0109			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.10: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		68 (32.2%)	66 (29.9%)	134 (31.0%)
Number of subjects without events		143 (67.8%)	155 (70.1%)	298 (69.0%)
Odds Ratio [a]				
OR, 95% CI	1.112 [0.735, 1.682]			
p-value	0.6152			
Relative Risk [b]				
RR, 95% CI	1.109 [0.842, 1.461]			
p-value	0.4618			
Risk Difference [c]				
RD, 95% CI	0.014 [-0.072, 0.099]			
p-value	0.7573			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.11: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		31 (14.7%)	25 (11.3%)	56 (13.0%)
Number of subjects without events		180 (85.3%)	196 (88.7%)	376 (87.0%)
Odds Ratio [a]				
OR, 95% CI	1.366 [0.770, 2.423]			
p-value	0.2863			
Relative Risk [b]				
RR, 95% CI	1.340 [0.825, 2.175]			
p-value	0.2365			
Risk Difference [c]				
RD, 95% CI	0.023 [-0.048, 0.095]*			
p-value	0.5208			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.12: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=211)	Placebo (N=221)	Total (N=432)
Number of subjects at risk		211 (100.0%)	221 (100.0%)	432 (100.0%)
Number of subjects with events		30 (14.2%)	23 (10.4%)	53 (12.3%)
Number of subjects without events		181 (85.8%)	198 (89.6%)	379 (87.7%)
Odds Ratio [a]				
OR, 95% CI	1.428 [0.796, 2.561]			
p-value	0.2324			
Relative Risk [b]				
RR, 95% CI	1.391 [0.838, 2.307]			
p-value	0.2016			
Risk Difference [c]				
RD, 95% CI	0.026 [-0.035, 0.087]			
p-value	0.4003			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group and region.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Any TEAE	181(86.2%)	178(80.5%)
Infections And Infestations	88(41.9%)	90(40.7%)
Nasopharyngitis	14(6.7%)	18(8.1%)
Urinary tract infection	14(6.7%)	15(6.8%)
Upper respiratory tract infection	11(5.2%)	18(8.1%)
Influenza	11(5.2%)	10(4.5%)
Pneumonia	10(4.8%)	6(2.7%)
Bronchitis	5(2.4%)	8(3.6%)
Sinusitis	5(2.4%)	4(1.8%)
Periodontitis	4(1.9%)	4(1.8%)
Cellulitis	4(1.9%)	3(1.4%)
Respiratory tract infection	4(1.9%)	3(1.4%)
Viral infection	3(1.4%)	2(0.9%)
Diverticulitis	3(1.4%)	0
Gastroenteritis	2(1.0%)	5(2.3%)
Conjunctivitis	2(1.0%)	4(1.8%)
Pharyngitis	2(1.0%)	4(1.8%)
Herpes zoster	2(1.0%)	3(1.4%)
Osteomyelitis	2(1.0%)	3(1.4%)
Ear infection	2(1.0%)	1(0.5%)
Helicobacter gastritis	2(1.0%)	1(0.5%)
Otitis media	2(1.0%)	1(0.5%)
Candida infection	2(1.0%)	0
Infected skin ulcer	2(1.0%)	0
Rhinitis	2(1.0%)	0
Fungal skin infection	1(0.5%)	3(1.4%)
Tooth infection	1(0.5%)	3(1.4%)
Sepsis	1(0.5%)	2(0.9%)
Skin infection	1(0.5%)	2(0.9%)
Alveolar osteitis	1(0.5%)	1(0.5%)
Cystitis	1(0.5%)	1(0.5%)
Tooth abscess	1(0.5%)	1(0.5%)
Tracheitis	1(0.5%)	1(0.5%)
Urosepsis	1(0.5%)	1(0.5%)
Acute sinusitis	1(0.5%)	0
Chest wall abscess	1(0.5%)	0
Encephalitis viral	1(0.5%)	0
Endophthalmitis	1(0.5%)	0
Febrile infection	1(0.5%)	0
Folliculitis	1(0.5%)	0
Gastroenteritis viral	1(0.5%)	0
Gastrointestinal viral infection	1(0.5%)	0
Genitourinary tract infection	1(0.5%)	0
Helicobacter infection	1(0.5%)	0
Infection	1(0.5%)	0
Laryngitis	1(0.5%)	0
Lower respiratory tract infection	1(0.5%)	0
Orchitis	1(0.5%)	0
Penile infection	1(0.5%)	0
Purulent discharge	1(0.5%)	0
Pyelonephritis	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Soft tissue infection	1(0.5%)	0
Tracheobronchitis	1(0.5%)	0
Tuberculosis	1(0.5%)	0
Vulval abscess	1(0.5%)	0
Erysipelas	0	4(1.8%)
Otitis externa	0	3(1.4%)
Respiratory tract infection viral	0	3(1.4%)
Pyelonephritis acute	0	2(0.9%)
Vulvovaginal mycotic infection	0	2(0.9%)
Abscess limb	0	1(0.5%)
Acarodermatitis	0	1(0.5%)
Bacteraemia	0	1(0.5%)
Diabetic foot infection	0	1(0.5%)
Eczema impetiginous	0	1(0.5%)
Gingivitis	0	1(0.5%)
Hepatitis A	0	1(0.5%)
Hepatitis viral	0	1(0.5%)
Herpes simplex	0	1(0.5%)
Hordeolum	0	1(0.5%)
Infected bite	0	1(0.5%)
Infective exacerbation of bronchiectasis	0	1(0.5%)
Localised infection	0	1(0.5%)
Mastoiditis	0	1(0.5%)
Mycoplasma infection	0	1(0.5%)
Paronychia	0	1(0.5%)
Pharyngotonsillitis	0	1(0.5%)
Pneumonia bacterial	0	1(0.5%)
Root canal infection	0	1(0.5%)
Tinea cruris	0	1(0.5%)
Tinea pedis	0	1(0.5%)
Tonsillitis	0	1(0.5%)
Urethritis	0	1(0.5%)
Viral pharyngitis	0	1(0.5%)
Viral upper respiratory tract infection	0	1(0.5%)
Wound infection	0	1(0.5%)
Metabolism And Nutrition Disorders	74(35.2%)	64(29.0%)
Hyperkalaemia	18(8.6%)	13(5.9%)
Hyperuricaemia	14(6.7%)	8(3.6%)
Hyperlipidaemia	9(4.3%)	3(1.4%)
Hypoglycaemia	8(3.8%)	17(7.7%)
Diabetes mellitus	7(3.3%)	5(2.3%)
Hyperglycaemia	7(3.3%)	5(2.3%)
Type 2 diabetes mellitus	5(2.4%)	4(1.8%)
Dehydration	5(2.4%)	2(0.9%)
Iron deficiency	5(2.4%)	2(0.9%)
Vitamin D deficiency	4(1.9%)	5(2.3%)
Gout	4(1.9%)	3(1.4%)
Dyslipidaemia	4(1.9%)	2(0.9%)
Diabetes mellitus inadequate control	3(1.4%)	9(4.1%)
Diabetic metabolic decompensation	3(1.4%)	3(1.4%)
Hypertriglyceridaemia	2(1.0%)	3(1.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Hypokalaemia	2(1.0%)	3(1.4%)
Fluid overload	2(1.0%)	0
Hyponatraemia	2(1.0%)	0
Hypomagnesaemia	1(0.5%)	2(0.9%)
Obesity	1(0.5%)	2(0.9%)
Abnormal loss of weight	1(0.5%)	0
Decreased appetite	1(0.5%)	0
Folate deficiency	1(0.5%)	0
Food aversion	1(0.5%)	0
Hypovolaemia	1(0.5%)	0
Metabolic acidosis	1(0.5%)	0
Hypercholesterolaemia	0	2(0.9%)
Magnesium deficiency	0	1(0.5%)
Malnutrition	0	1(0.5%)
Gastrointestinal Disorders	54(25.7%)	45(20.4%)
Diarrhoea	14(6.7%)	8(3.6%)
Constipation	7(3.3%)	7(3.2%)
Nausea	7(3.3%)	4(1.8%)
Abdominal pain upper	6(2.9%)	1(0.5%)
Vomiting	4(1.9%)	6(2.7%)
Gastritis	4(1.9%)	3(1.4%)
Dyspepsia	4(1.9%)	2(0.9%)
Gastrointestinal haemorrhage	4(1.9%)	1(0.5%)
Gastric ulcer	4(1.9%)	0
Abdominal pain	3(1.4%)	3(1.4%)
Oesophagitis	3(1.4%)	3(1.4%)
Chronic gastritis	2(1.0%)	2(0.9%)
Dysphagia	2(1.0%)	1(0.5%)
Hiatus hernia	2(1.0%)	1(0.5%)
Inguinal hernia	2(1.0%)	1(0.5%)
Large intestine polyp	2(1.0%)	1(0.5%)
Diverticulum intestinal	2(1.0%)	0
Gastrooesophageal reflux disease	1(0.5%)	4(1.8%)
Abdominal discomfort	1(0.5%)	2(0.9%)
Toothache	1(0.5%)	2(0.9%)
Duodenitis	1(0.5%)	1(0.5%)
Flatulence	1(0.5%)	1(0.5%)
Gastritis erosive	1(0.5%)	1(0.5%)
Pancreatitis chronic	1(0.5%)	1(0.5%)
Rectal polyp	1(0.5%)	1(0.5%)
Abdominal pain lower	1(0.5%)	0
Colitis ischaemic	1(0.5%)	0
Dental caries	1(0.5%)	0
Diverticulum	1(0.5%)	0
Dry mouth	1(0.5%)	0
Duodenal polyp	1(0.5%)	0
Enteritis	1(0.5%)	0
Gastric polyps	1(0.5%)	0
Haemorrhoids	1(0.5%)	0
Pancreatitis acute	1(0.5%)	0
Tooth loss	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Varices oesophageal	1(0.5%)	0
Abdominal distension	0	2(0.9%)
Anal fissure	0	1(0.5%)
Anal rash	0	1(0.5%)
Bowel movement irregularity	0	1(0.5%)
Cheilitis	0	1(0.5%)
Colitis	0	1(0.5%)
Gingival pain	0	1(0.5%)
Haematochezia	0	1(0.5%)
Hypoaesthesia oral	0	1(0.5%)
Intestinal metaplasia	0	1(0.5%)
Lip oedema	0	1(0.5%)
Melaena	0	1(0.5%)
Mesenteric panniculitis	0	1(0.5%)
Noninfective gingivitis	0	1(0.5%)
Oesophageal ulcer	0	1(0.5%)
Small intestinal obstruction	0	1(0.5%)
Musculoskeletal And Connective Tissue Disorders	53(25.2%)	51(23.1%)
Back pain	15(7.1%)	12(5.4%)
Arthralgia	12(5.7%)	11(5.0%)
Osteoarthritis	6(2.9%)	8(3.6%)
Muscle spasms	6(2.9%)	5(2.3%)
Pain in extremity	4(1.9%)	5(2.3%)
Myalgia	4(1.9%)	3(1.4%)
Periarthritis	4(1.9%)	0
Muscular weakness	3(1.4%)	0
Musculoskeletal chest pain	3(1.4%)	0
Osteopenia	3(1.4%)	0
Lumbar spinal stenosis	2(1.0%)	1(0.5%)
Neck pain	2(1.0%)	1(0.5%)
Rotator cuff syndrome	2(1.0%)	1(0.5%)
Spinal pain	2(1.0%)	0
Bursitis	1(0.5%)	3(1.4%)
Spinal osteoarthritis	1(0.5%)	3(1.4%)
Joint swelling	1(0.5%)	2(0.9%)
Musculoskeletal pain	1(0.5%)	2(0.9%)
Chondropathy	1(0.5%)	1(0.5%)
Osteoporosis	1(0.5%)	1(0.5%)
Limb mass	1(0.5%)	0
Muscle atrophy	1(0.5%)	0
Muscle rigidity	1(0.5%)	0
Musculoskeletal stiffness	1(0.5%)	0
Osteolysis	1(0.5%)	0
Synovial cyst	1(0.5%)	0
Arthritis	0	3(1.4%)
Costochondritis	0	2(0.9%)
Intervertebral disc protrusion	0	2(0.9%)
Chest wall cyst	0	1(0.5%)
Chondrocalcinosis	0	1(0.5%)
Exostosis	0	1(0.5%)
Fibromyalgia	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Flank pain	0	1(0.5%)
Gouty arthritis	0	1(0.5%)
Intervertebral disc disorder	0	1(0.5%)
Muscle tightness	0	1(0.5%)
Osteitis	0	1(0.5%)
Osteochondrosis	0	1(0.5%)
Plantar fasciitis	0	1(0.5%)
Polymyalgia rheumatica	0	1(0.5%)
Psoriatic arthropathy	0	1(0.5%)
Spondylitis	0	1(0.5%)
Spondyloarthropathy	0	1(0.5%)
Trigger finger	0	1(0.5%)
Vascular Disorders	52(24.8%)	45(20.4%)
Hypertension	18(8.6%)	24(10.9%)
Hypotension	13(6.2%)	2(0.9%)
Peripheral arterial occlusive disease	4(1.9%)	7(3.2%)
Intermittent claudication	4(1.9%)	1(0.5%)
Aortic arteriosclerosis	2(1.0%)	2(0.9%)
Hypertensive crisis	2(1.0%)	2(0.9%)
Orthostatic hypotension	2(1.0%)	2(0.9%)
Haematoma	2(1.0%)	1(0.5%)
Peripheral artery stenosis	2(1.0%)	1(0.5%)
Deep vein thrombosis	2(1.0%)	0
Aortic aneurysm	1(0.5%)	1(0.5%)
Arteriosclerosis	1(0.5%)	1(0.5%)
Peripheral vascular disorder	1(0.5%)	1(0.5%)
Aortic dissection	1(0.5%)	0
Aortic stenosis	1(0.5%)	0
Arterial disorder	1(0.5%)	0
Collateral circulation	1(0.5%)	0
Hypertensive emergency	1(0.5%)	0
Internal haemorrhage	1(0.5%)	0
Labile hypertension	1(0.5%)	0
Lymphoedema	1(0.5%)	0
Phlebitis	1(0.5%)	0
Thrombosis	1(0.5%)	0
Varicose vein	1(0.5%)	0
Circulatory collapse	0	1(0.5%)
Giant cell arteritis	0	1(0.5%)
Hypovolaemic shock	0	1(0.5%)
Microangiopathy	0	1(0.5%)
Peripheral coldness	0	1(0.5%)
Peripheral venous disease	0	1(0.5%)
Investigations	51(24.3%)	52(23.5%)
Glomerular filtration rate decreased	12(5.7%)	7(3.2%)
Blood potassium increased	9(4.3%)	3(1.4%)
Blood creatine phosphokinase increased	8(3.8%)	8(3.6%)
Blood creatinine increased	4(1.9%)	5(2.3%)
C-reactive protein increased	4(1.9%)	5(2.3%)
Gamma-glutamyltransferase increased	2(1.0%)	4(1.8%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Glycosylated haemoglobin increased	2(1.0%)	3(1.4%)
Weight increased	2(1.0%)	3(1.4%)
Blood glucose increased	2(1.0%)	2(0.9%)
Blood pressure increased	2(1.0%)	2(0.9%)
Blood triglycerides increased	2(1.0%)	1(0.5%)
Weight decreased	2(1.0%)	1(0.5%)
Blood uric acid increased	2(1.0%)	0
Protein urine present	1(0.5%)	1(0.5%)
Transaminases increased	1(0.5%)	1(0.5%)
Alanine aminotransferase increased	1(0.5%)	0
Angiocardiogram	1(0.5%)	0
Aspartate aminotransferase increased	1(0.5%)	0
Biopsy liver	1(0.5%)	0
Blood potassium decreased	1(0.5%)	0
Bone density decreased	1(0.5%)	0
Brain natriuretic peptide increased	1(0.5%)	0
Carcinoembryonic antigen increased	1(0.5%)	0
Colonoscopy	1(0.5%)	0
Electrocardiogram PR prolongation	1(0.5%)	0
Electrocardiogram ST segment depression	1(0.5%)	0
Liver function test increased	1(0.5%)	0
Red blood cell count decreased	1(0.5%)	0
Rheumatoid factor increased	1(0.5%)	0
Vitamin D decreased	1(0.5%)	0
White blood cell count increased	1(0.5%)	0
Haemoglobin decreased	0	3(1.4%)
Hepatic enzyme increased	0	2(0.9%)
Alpha 1 foetoprotein increased	0	1(0.5%)
Biopsy	0	1(0.5%)
Biopsy kidney	0	1(0.5%)
Blood alkaline phosphatase increased	0	1(0.5%)
Blood calcium increased	0	1(0.5%)
Blood creatine phosphokinase MB increased	0	1(0.5%)
Blood creatine phosphokinase abnormal	0	1(0.5%)
Blood pressure decreased	0	1(0.5%)
Blood thyroid stimulating hormone decreased	0	1(0.5%)
Carbohydrate antigen 19-9 increased	0	1(0.5%)
Cardiac murmur	0	1(0.5%)
Gastrin-releasing peptide precursor increased	0	1(0.5%)
Haematocrit abnormal	0	1(0.5%)
Haemoglobin abnormal	0	1(0.5%)
Heart rate decreased	0	1(0.5%)
Influenza B virus test positive	0	1(0.5%)
Laboratory test abnormal	0	1(0.5%)
Prostatic specific antigen increased	0	1(0.5%)
QRS axis abnormal	0	1(0.5%)
Reticulocyte count increased	0	1(0.5%)
Transferrin saturation decreased	0	1(0.5%)
Urinary occult blood positive	0	1(0.5%)
Urine albumin/creatinine ratio increased	0	1(0.5%)
Urine protein/creatinine ratio increased	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Nervous System Disorders	41(19.5%)	33(14.9%)
Dizziness	9(4.3%)	4(1.8%)
Diabetic neuropathy	7(3.3%)	5(2.3%)
Headache	3(1.4%)	7(3.2%)
Syncope	3(1.4%)	5(2.3%)
Carpal tunnel syndrome	3(1.4%)	1(0.5%)
Balance disorder	2(1.0%)	1(0.5%)
Carotid arteriosclerosis	2(1.0%)	1(0.5%)
Hypoaesthesia	2(1.0%)	1(0.5%)
Sciatica	2(1.0%)	1(0.5%)
Tremor	2(1.0%)	1(0.5%)
Cerebral ischaemia	2(1.0%)	0
Neuropathy peripheral	2(1.0%)	0
Carotid artery stenosis	1(0.5%)	3(1.4%)
Cognitive disorder	1(0.5%)	2(0.9%)
Head discomfort	1(0.5%)	1(0.5%)
Paraesthesia	1(0.5%)	1(0.5%)
Allodynia	1(0.5%)	0
Brain oedema	1(0.5%)	0
Cerebral infarction	1(0.5%)	0
Cubital tunnel syndrome	1(0.5%)	0
Migraine without aura	1(0.5%)	0
Orthostatic intolerance	1(0.5%)	0
Parkinson's disease	1(0.5%)	0
Polyneuropathy	1(0.5%)	0
Poor quality sleep	1(0.5%)	0
Vertebral artery occlusion	1(0.5%)	0
Anosmia	0	1(0.5%)
Arachnoid cyst	0	1(0.5%)
Carotid artery occlusion	0	1(0.5%)
Cerebral arteriosclerosis	0	1(0.5%)
Cerebral artery stenosis	0	1(0.5%)
Cerebral atrophy	0	1(0.5%)
Cerebral vascular occlusion	0	1(0.5%)
Dementia Alzheimer's type	0	1(0.5%)
Facial paralysis	0	1(0.5%)
Hemiparesis	0	1(0.5%)
Lethargy	0	1(0.5%)
Parkinsonism	0	1(0.5%)
Vascular dementia	0	1(0.5%)
General Disorders And Administration Site Conditions	31(14.8%)	36(16.3%)
Oedema peripheral	11(5.2%)	16(7.2%)
Pyrexia	6(2.9%)	4(1.8%)
Fatigue	5(2.4%)	5(2.3%)
Chest pain	5(2.4%)	2(0.9%)
Asthenia	4(1.9%)	2(0.9%)
Gait disturbance	2(1.0%)	1(0.5%)
Influenza like illness	2(1.0%)	0
Oedema	1(0.5%)	4(1.8%)
Malaise	1(0.5%)	1(0.5%)
Hernia	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Inflammation	1(0.5%)	0
Medical device pain	1(0.5%)	0
Peripheral swelling	0	2(0.9%)
Chest discomfort	0	1(0.5%)
Generalised oedema	0	1(0.5%)
Impaired healing	0	1(0.5%)
Medical device site pain	0	1(0.5%)
Non-cardiac chest pain	0	1(0.5%)
Sensation of foreign body	0	1(0.5%)
Respiratory, Thoracic And Mediastinal Disorders	30(14.3%)	39(17.6%)
Cough	8(3.8%)	12(5.4%)
Chronic obstructive pulmonary disease	5(2.4%)	2(0.9%)
Asthma	3(1.4%)	1(0.5%)
Pulmonary embolism	3(1.4%)	0
Dyspnoea	2(1.0%)	5(2.3%)
Nasal congestion	2(1.0%)	3(1.4%)
Sleep apnoea syndrome	2(1.0%)	1(0.5%)
Respiratory disorder	2(1.0%)	0
Rhinitis allergic	1(0.5%)	4(1.8%)
Acute respiratory failure	1(0.5%)	1(0.5%)
Epistaxis	1(0.5%)	1(0.5%)
Respiratory failure	1(0.5%)	1(0.5%)
Dyspnoea exertional	1(0.5%)	0
Pneumonia aspiration	1(0.5%)	0
Small airways disease	1(0.5%)	0
Pleural effusion	0	3(1.4%)
Dysphonia	0	2(0.9%)
Pulmonary mass	0	2(0.9%)
Sinus pain	0	2(0.9%)
Atelectasis	0	1(0.5%)
Catarrh	0	1(0.5%)
Increased bronchial secretion	0	1(0.5%)
Oropharyngeal pain	0	1(0.5%)
Productive cough	0	1(0.5%)
Pulmonary hypertension	0	1(0.5%)
Reflux laryngitis	0	1(0.5%)
Rhinorrhoea	0	1(0.5%)
Rhonchi	0	1(0.5%)
Injury, Poisoning And Procedural Complications	30(14.3%)	30(13.6%)
Limb injury	4(1.9%)	4(1.8%)
Ligament sprain	3(1.4%)	2(0.9%)
Lumbar vertebral fracture	3(1.4%)	0
Contusion	2(1.0%)	2(0.9%)
Meniscus injury	2(1.0%)	1(0.5%)
Radius fracture	2(1.0%)	1(0.5%)
Rib fracture	2(1.0%)	1(0.5%)
Head injury	2(1.0%)	0
Procedural pain	2(1.0%)	0
Fall	1(0.5%)	4(1.8%)
Muscle strain	1(0.5%)	4(1.8%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Skin abrasion	1(0.5%)	2(0.9%)
Ankle fracture	1(0.5%)	1(0.5%)
Arthropod bite	1(0.5%)	1(0.5%)
Burns second degree	1(0.5%)	1(0.5%)
Accident	1(0.5%)	0
Bone contusion	1(0.5%)	0
Chest injury	1(0.5%)	0
Foreign body in throat	1(0.5%)	0
Humerus fracture	1(0.5%)	0
Inflammation of wound	1(0.5%)	0
Joint injury	1(0.5%)	0
Reactive gastropathy	1(0.5%)	0
Seroma	1(0.5%)	0
Skin wound	1(0.5%)	0
Vaccination complication	1(0.5%)	0
Road traffic accident	0	3(1.4%)
Epicondylitis	0	2(0.9%)
Tendon rupture	0	2(0.9%)
Thoracic vertebral fracture	0	2(0.9%)
Craniocerebral injury	0	1(0.5%)
Exposure to communicable disease	0	1(0.5%)
Facial bones fracture	0	1(0.5%)
Ligament rupture	0	1(0.5%)
Mouth injury	0	1(0.5%)
Nail avulsion	0	1(0.5%)
Neck injury	0	1(0.5%)
Post-traumatic pain	0	1(0.5%)
Procedural hypertension	0	1(0.5%)
Spinal fracture	0	1(0.5%)
Thermal burn	0	1(0.5%)
Tongue injury	0	1(0.5%)
Wound haemorrhage	0	1(0.5%)
Renal And Urinary Disorders	30(14.3%)	29(13.1%)
Renal impairment	7(3.3%)	3(1.4%)
Acute kidney injury	6(2.9%)	5(2.3%)
Dysuria	3(1.4%)	4(1.8%)
Urinary retention	3(1.4%)	2(0.9%)
Pollakiuria	2(1.0%)	2(0.9%)
Nephrolithiasis	2(1.0%)	1(0.5%)
Nocturia	2(1.0%)	1(0.5%)
Urinary incontinence	2(1.0%)	0
Haematuria	1(0.5%)	4(1.8%)
Renal cyst	1(0.5%)	4(1.8%)
Urethral stenosis	1(0.5%)	1(0.5%)
Bladder dilatation	1(0.5%)	0
Chronic kidney disease	1(0.5%)	0
End stage renal disease	1(0.5%)	0
Micturition disorder	1(0.5%)	0
Nephropathy toxic	1(0.5%)	0
Renal failure	1(0.5%)	0
Renal infarct	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Renal injury	1(0.5%)	0
Urinary tract obstruction	1(0.5%)	0
Proteinuria	0	2(0.9%)
Calculus urinary	0	1(0.5%)
Diabetic nephropathy	0	1(0.5%)
Glomerulonephritis chronic	0	1(0.5%)
Hypertonic bladder	0	1(0.5%)
Lower urinary tract symptoms	0	1(0.5%)
Polyuria	0	1(0.5%)
Pyelocaliectasis	0	1(0.5%)
Subcapsular renal haematoma	0	1(0.5%)
Tubulointerstitial nephritis	0	1(0.5%)
Ureterolithiasis	0	1(0.5%)
Urine odour abnormal	0	1(0.5%)
Skin And Subcutaneous Tissue Disorders	28(13.3%)	33(14.9%)
Rash	7(3.3%)	0
Skin ulcer	6(2.9%)	7(3.2%)
Pruritus	3(1.4%)	4(1.8%)
Diabetic foot	2(1.0%)	3(1.4%)
Decubitus ulcer	2(1.0%)	1(0.5%)
Eczema	1(0.5%)	2(0.9%)
Urticaria	1(0.5%)	1(0.5%)
Blister	1(0.5%)	0
Dermal cyst	1(0.5%)	0
Ecchymosis	1(0.5%)	0
Eczema nummular	1(0.5%)	0
Hyperhidrosis	1(0.5%)	0
Hyperkeratosis	1(0.5%)	0
Nail dystrophy	1(0.5%)	0
Night sweats	1(0.5%)	0
Pigmentation disorder	1(0.5%)	0
Rosacea	1(0.5%)	0
Skin hypertrophy	1(0.5%)	0
Actinic keratosis	0	3(1.4%)
Dermatitis	0	3(1.4%)
Dermatitis allergic	0	2(0.9%)
Dermatitis contact	0	2(0.9%)
Psoriasis	0	2(0.9%)
Skin discolouration	0	2(0.9%)
Alopecia	0	1(0.5%)
Diabetic ulcer	0	1(0.5%)
Dry skin	0	1(0.5%)
Erythema	0	1(0.5%)
Hand dermatitis	0	1(0.5%)
Lipodystrophy acquired	0	1(0.5%)
Lipohypertrophy	0	1(0.5%)
Rash macular	0	1(0.5%)
Rash pruritic	0	1(0.5%)
Stasis dermatitis	0	1(0.5%)
Cardiac Disorders	26(12.4%)	20(9.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Coronary artery disease	4(1.9%)	2(0.9%)
Left ventricular hypertrophy	3(1.4%)	0
Cardiac failure	2(1.0%)	3(1.4%)
Arteriosclerosis coronary artery	2(1.0%)	1(0.5%)
Atrioventricular block first degree	2(1.0%)	1(0.5%)
Atrioventricular block second degree	2(1.0%)	0
Palpitations	2(1.0%)	0
Bradycardia	1(0.5%)	2(0.9%)
Ventricular extrasystoles	1(0.5%)	2(0.9%)
Atrial flutter	1(0.5%)	1(0.5%)
Extrasystoles	1(0.5%)	1(0.5%)
Left ventricular dysfunction	1(0.5%)	1(0.5%)
Sinus tachycardia	1(0.5%)	1(0.5%)
Tachycardia	1(0.5%)	1(0.5%)
Tricuspid valve incompetence	1(0.5%)	1(0.5%)
Aortic valve calcification	1(0.5%)	0
Aortic valve stenosis	1(0.5%)	0
Atrial fibrillation	1(0.5%)	0
Bundle branch block left	1(0.5%)	0
Coronary artery occlusion	1(0.5%)	0
Diabetic cardiomyopathy	1(0.5%)	0
Left atrial dilatation	1(0.5%)	0
Left atrial enlargement	1(0.5%)	0
Left ventricular failure	1(0.5%)	0
Mitral valve calcification	1(0.5%)	0
Mitral valve disease	1(0.5%)	0
Mitral valve incompetence	1(0.5%)	0
Mitral valve stenosis	1(0.5%)	0
Sinus bradycardia	1(0.5%)	0
Ventricular hypertrophy	1(0.5%)	0
Cardiac failure chronic	0	3(1.4%)
Angina pectoris	0	2(0.9%)
Acute left ventricular failure	0	1(0.5%)
Atrial tachycardia	0	1(0.5%)
Cardiac septal hypertrophy	0	1(0.5%)
Cardiogenic shock	0	1(0.5%)
Conduction disorder	0	1(0.5%)
Congestive cardiomyopathy	0	1(0.5%)
Coronary artery insufficiency	0	1(0.5%)
Diastolic dysfunction	0	1(0.5%)
Ischaemic mitral regurgitation	0	1(0.5%)
Mitral valve prolapse	0	1(0.5%)
Nodal rhythm	0	1(0.5%)
Supraventricular extrasystoles	0	1(0.5%)
Ventricular tachycardia	0	1(0.5%)
Eye Disorders	23(11.0%)	33(14.9%)
Cataract	10(4.8%)	10(4.5%)
Diabetic retinopathy	5(2.4%)	9(4.1%)
Retinal detachment	2(1.0%)	1(0.5%)
Glaucoma	2(1.0%)	0
Visual impairment	1(0.5%)	2(0.9%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Vitreous haemorrhage	1(0.5%)	1(0.5%)
Dry eye	1(0.5%)	0
Eye pain	1(0.5%)	0
Macular degeneration	1(0.5%)	0
Macular fibrosis	1(0.5%)	0
Periorbital swelling	1(0.5%)	0
Pupils unequal	1(0.5%)	0
Retinopathy	1(0.5%)	0
Vision blurred	1(0.5%)	0
Vitreoretinal traction syndrome	1(0.5%)	0
Diplopia	0	2(0.9%)
Macular oedema	0	2(0.9%)
Retinal haemorrhage	0	2(0.9%)
Blepharitis	0	1(0.5%)
Conjunctivitis allergic	0	1(0.5%)
Eye pruritus	0	1(0.5%)
Halo vision	0	1(0.5%)
Ocular hyperaemia	0	1(0.5%)
Retinal artery occlusion	0	1(0.5%)
Retinoschisis	0	1(0.5%)
Visual acuity reduced	0	1(0.5%)
Vitreous detachment	0	1(0.5%)
Vitreous floaters	0	1(0.5%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	17(8.1%)	15(6.8%)
Prostate cancer	3(1.4%)	0
Basal cell carcinoma	1(0.5%)	3(1.4%)
Adenocarcinoma of colon	1(0.5%)	1(0.5%)
Melanocytic naevus	1(0.5%)	1(0.5%)
Adrenal adenoma	1(0.5%)	0
Benign neoplasm of thyroid gland	1(0.5%)	0
Bladder cancer recurrent	1(0.5%)	0
Colorectal cancer	1(0.5%)	0
Gastrointestinal stromal tumour	1(0.5%)	0
Hepatocellular carcinoma	1(0.5%)	0
Lipoma	1(0.5%)	0
Rectal adenocarcinoma	1(0.5%)	0
Rectal cancer metastatic	1(0.5%)	0
Renal neoplasm	1(0.5%)	0
Sarcoma	1(0.5%)	0
Seborrhoeic keratosis	1(0.5%)	0
Skin papilloma	1(0.5%)	0
Tonsil cancer	1(0.5%)	0
Bowen's disease	0	2(0.9%)
Cholesteatoma	0	2(0.9%)
Squamous cell carcinoma of skin	0	2(0.9%)
Benign lung neoplasm	0	1(0.5%)
Colon adenoma	0	1(0.5%)
Lentigo maligna	0	1(0.5%)
Lung neoplasm	0	1(0.5%)
Lung neoplasm malignant	0	1(0.5%)
Monoclonal gammopathy	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Neoplasm	0	1(0.5%)
Oropharyngeal cancer	0	1(0.5%)
Pancreatic neoplasm	0	1(0.5%)
Blood And Lymphatic System Disorders	16(7.6%)	18(8.1%)
Anaemia	9(4.3%)	10(4.5%)
Iron deficiency anaemia	2(1.0%)	2(0.9%)
Nephrogenic anaemia	1(0.5%)	2(0.9%)
Lymphadenopathy mediastinal	1(0.5%)	1(0.5%)
Microcytic anaemia	1(0.5%)	1(0.5%)
Immune thrombocytopenia	1(0.5%)	0
Leukocytosis	1(0.5%)	0
Lymphadenopathy	1(0.5%)	0
Normochromic normocytic anaemia	1(0.5%)	0
Polycythaemia	0	1(0.5%)
Thrombocytopenia	0	1(0.5%)
Reproductive System And Breast Disorders	13(6.2%)	16(7.2%)
Benign prostatic hyperplasia	8(3.8%)	9(4.1%)
Erectile dysfunction	3(1.4%)	2(0.9%)
Atrophic vulvovaginitis	1(0.5%)	0
Postmenopausal haemorrhage	1(0.5%)	0
Prostatic calcification	1(0.5%)	0
Prostatism	1(0.5%)	0
Genital lesion	0	1(0.5%)
Gynaecomastia	0	1(0.5%)
Pelvic cyst	0	1(0.5%)
Prostatitis	0	1(0.5%)
Prostatomegaly	0	1(0.5%)
Hepatobiliary Disorders	12(5.7%)	11(5.0%)
Cholelithiasis	4(1.9%)	3(1.4%)
Hepatic cirrhosis	3(1.4%)	0
Hepatic steatosis	2(1.0%)	1(0.5%)
Hepatic function abnormal	1(0.5%)	2(0.9%)
Cholecystitis chronic	1(0.5%)	1(0.5%)
Hepatic lesion	1(0.5%)	1(0.5%)
Gallbladder polyp	0	2(0.9%)
Cholecystitis acute	0	1(0.5%)
Nonalcoholic fatty liver disease	0	1(0.5%)
Steatohepatitis	0	1(0.5%)
Surgical And Medical Procedures	9(4.3%)	11(5.0%)
Cataract operation	4(1.9%)	2(0.9%)
Acrochordon excision	1(0.5%)	0
Lymphadenectomy	1(0.5%)	0
Mole excision	1(0.5%)	0
Retinal laser coagulation	1(0.5%)	0
Spinal decompression	1(0.5%)	0
Cardiac ablation	0	1(0.5%)
Cardiac pacemaker insertion	0	1(0.5%)
Cardiac rehabilitation therapy	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Cholecystectomy	0	1(0.5%)
Dental implantation	0	1(0.5%)
Foot amputation	0	1(0.5%)
Insertion of ambulatory peritoneal catheter	0	1(0.5%)
Tooth extraction	0	1(0.5%)
Varicose vein operation	0	1(0.5%)
Psychiatric Disorders	9(4.3%)	9(4.1%)
Depression	4(1.9%)	2(0.9%)
Anxiety	1(0.5%)	3(1.4%)
Insomnia	1(0.5%)	3(1.4%)
Delirium	1(0.5%)	0
Middle insomnia	1(0.5%)	0
Nervousness	1(0.5%)	0
Restlessness	1(0.5%)	0
Sleep disorder	1(0.5%)	0
Depressed mood	0	1(0.5%)
Generalised anxiety disorder	0	1(0.5%)
Ear And Labyrinth Disorders	9(4.3%)	8(3.6%)
Vertigo	6(2.9%)	4(1.8%)
Tinnitus	1(0.5%)	2(0.9%)
Ear pruritus	1(0.5%)	0
Excessive cerumen production	1(0.5%)	0
Ear pain	0	2(0.9%)
Ear discomfort	0	1(0.5%)
Hypoacusis	0	1(0.5%)
Mixed deafness	0	1(0.5%)
Sudden hearing loss	0	1(0.5%)
Endocrine Disorders	5(2.4%)	9(4.1%)
Hypothyroidism	1(0.5%)	2(0.9%)
Thyroid mass	1(0.5%)	1(0.5%)
Basedow's disease	1(0.5%)	0
Goitre	1(0.5%)	0
Hyperthyroidism	1(0.5%)	0
Hyperparathyroidism secondary	0	2(0.9%)
Hypogonadism	0	2(0.9%)
Hyperparathyroidism	0	1(0.5%)
Hyperplasia adrenal	0	1(0.5%)
Testicular failure	0	1(0.5%)
Immune System Disorders	5(2.4%)	2(0.9%)
Drug hypersensitivity	2(1.0%)	0
Hypersensitivity	1(0.5%)	1(0.5%)
Seasonal allergy	1(0.5%)	1(0.5%)
Sarcoidosis	1(0.5%)	0
Congenital, Familial And Genetic Disorders	4(1.9%)	2(0.9%)
Phimosis	2(1.0%)	1(0.5%)
Adenomatous polyposis coli	1(0.5%)	0
Hypertrophic cardiomyopathy	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Tornwaldt cyst	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Any TEAE	65(31.0%)	67(30.3%)
Infections And Infestations	16(7.6%)	15(6.8%)
Pneumonia	5(2.4%)	2(0.9%)
Urinary tract infection	3(1.4%)	1(0.5%)
Osteomyelitis	2(1.0%)	3(1.4%)
Diverticulitis	2(1.0%)	0
Infected skin ulcer	2(1.0%)	0
Urosepsis	1(0.5%)	1(0.5%)
Chest wall abscess	1(0.5%)	0
Endophthalmitis	1(0.5%)	0
Febrile infection	1(0.5%)	0
Lower respiratory tract infection	1(0.5%)	0
Pyelonephritis	1(0.5%)	0
Erysipelas	0	3(1.4%)
Cellulitis	0	1(0.5%)
Hepatitis viral	0	1(0.5%)
Infective exacerbation of bronchiectasis	0	1(0.5%)
Pyelonephritis acute	0	1(0.5%)
Sepsis	0	1(0.5%)
Upper respiratory tract infection	0	1(0.5%)
Wound infection	0	1(0.5%)
Metabolism And Nutrition Disorders	13(6.2%)	8(3.6%)
Diabetes mellitus	3(1.4%)	2(0.9%)
Type 2 diabetes mellitus	3(1.4%)	2(0.9%)
Hyperkalaemia	2(1.0%)	0
Diabetes mellitus inadequate control	1(0.5%)	3(1.4%)
Diabetic metabolic decompensation	1(0.5%)	2(0.9%)
Dehydration	1(0.5%)	0
Fluid overload	1(0.5%)	0
Hypoglycaemia	1(0.5%)	0
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	11(5.2%)	7(3.2%)
Prostate cancer	3(1.4%)	0
Adenocarcinoma of colon	1(0.5%)	1(0.5%)
Colorectal cancer	1(0.5%)	0
Gastrointestinal stromal tumour	1(0.5%)	0
Hepatocellular carcinoma	1(0.5%)	0
Lipoma	1(0.5%)	0
Rectal adenocarcinoma	1(0.5%)	0
Rectal cancer metastatic	1(0.5%)	0
Sarcoma	1(0.5%)	0
Tonsil cancer	1(0.5%)	0
Basal cell carcinoma	0	1(0.5%)
Bowen's disease	0	1(0.5%)
Lentigo maligna	0	1(0.5%)
Lung neoplasm	0	1(0.5%)
Lung neoplasm malignant	0	1(0.5%)
Neoplasm	0	1(0.5%)
Oropharyngeal cancer	0	1(0.5%)
Pancreatic neoplasm	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Squamous cell carcinoma of skin	0	1(0.5%)
Renal And Urinary Disorders	8(3.8%)	5(2.3%)
Acute kidney injury	3(1.4%)	1(0.5%)
Urinary retention	1(0.5%)	1(0.5%)
End stage renal disease	1(0.5%)	0
Renal impairment	1(0.5%)	0
Urethral stenosis	1(0.5%)	0
Urinary incontinence	1(0.5%)	0
Dysuria	0	1(0.5%)
Haematuria	0	1(0.5%)
Proteinuria	0	1(0.5%)
Tubulointerstitial nephritis	0	1(0.5%)
Vascular Disorders	7(3.3%)	5(2.3%)
Hypotension	1(0.5%)	1(0.5%)
Aortic dissection	1(0.5%)	0
Hypertension	1(0.5%)	0
Hypertensive emergency	1(0.5%)	0
Intermittent claudication	1(0.5%)	0
Peripheral vascular disorder	1(0.5%)	0
Thrombosis	1(0.5%)	0
Giant cell arteritis	0	1(0.5%)
Hypertensive crisis	0	1(0.5%)
Hypovolaemic shock	0	1(0.5%)
Peripheral arterial occlusive disease	0	1(0.5%)
Gastrointestinal Disorders	7(3.3%)	4(1.8%)
Gastrointestinal haemorrhage	3(1.4%)	0
Large intestine polyp	2(1.0%)	1(0.5%)
Duodenal polyp	1(0.5%)	0
Gastric polyps	1(0.5%)	0
Pancreatitis acute	1(0.5%)	0
Varices oesophageal	1(0.5%)	0
Inguinal hernia	0	1(0.5%)
Melaena	0	1(0.5%)
Small intestinal obstruction	0	1(0.5%)
General Disorders And Administration Site Conditions	6(2.9%)	2(0.9%)
Oedema peripheral	2(1.0%)	1(0.5%)
Chest pain	2(1.0%)	0
Asthenia	1(0.5%)	0
Fatigue	1(0.5%)	0
Gait disturbance	1(0.5%)	0
Generalised oedema	0	1(0.5%)
Eye Disorders	5(2.4%)	6(2.7%)
Retinal detachment	2(1.0%)	0
Cataract	1(0.5%)	2(0.9%)
Vitreous haemorrhage	1(0.5%)	1(0.5%)
Macular fibrosis	1(0.5%)	0
Diabetic retinopathy	0	3(1.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Retinal artery occlusion	0	1(0.5%)
Nervous System Disorders	5(2.4%)	4(1.8%)
Syncope	1(0.5%)	1(0.5%)
Balance disorder	1(0.5%)	0
Brain oedema	1(0.5%)	0
Carotid artery stenosis	1(0.5%)	0
Vertebral artery occlusion	1(0.5%)	0
Cerebral vascular occlusion	0	1(0.5%)
Dizziness	0	1(0.5%)
Hemiparesis	0	1(0.5%)
Hepatobiliary Disorders	4(1.9%)	1(0.5%)
Cholelithiasis	3(1.4%)	0
Hepatic lesion	1(0.5%)	0
Cholecystitis acute	0	1(0.5%)
Injury, Poisoning And Procedural Complications	3(1.4%)	4(1.8%)
Ankle fracture	1(0.5%)	1(0.5%)
Chest injury	1(0.5%)	0
Head injury	1(0.5%)	0
Lumbar vertebral fracture	1(0.5%)	0
Rib fracture	1(0.5%)	0
Craniocerebral injury	0	1(0.5%)
Spinal fracture	0	1(0.5%)
Thoracic vertebral fracture	0	1(0.5%)
Surgical And Medical Procedures	3(1.4%)	3(1.4%)
Cataract operation	1(0.5%)	0
Lymphadenectomy	1(0.5%)	0
Spinal decompression	1(0.5%)	0
Cardiac rehabilitation therapy	0	1(0.5%)
Cholecystectomy	0	1(0.5%)
Foot amputation	0	1(0.5%)
Blood And Lymphatic System Disorders	3(1.4%)	2(0.9%)
Anaemia	2(1.0%)	1(0.5%)
Lymphadenopathy	1(0.5%)	0
Iron deficiency anaemia	0	1(0.5%)
Respiratory, Thoracic And Mediastinal Disorders	3(1.4%)	2(0.9%)
Pulmonary embolism	2(1.0%)	0
Chronic obstructive pulmonary disease	1(0.5%)	1(0.5%)
Acute respiratory failure	0	1(0.5%)
Musculoskeletal And Connective Tissue Disorders	2(1.0%)	9(4.1%)
Lumbar spinal stenosis	1(0.5%)	1(0.5%)
Osteoarthritis	1(0.5%)	0
Costochondritis	0	2(0.9%)
Arthritis	0	1(0.5%)
Back pain	0	1(0.5%)
Bursitis	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Intervertebral disc protrusion	0	1(0.5%)
Pain in extremity	0	1(0.5%)
Polymyalgia rheumatica	0	1(0.5%)
Investigations	2(1.0%)	5(2.3%)
Blood potassium increased	1(0.5%)	0
Colonoscopy	1(0.5%)	0
Biopsy kidney	0	1(0.5%)
Blood creatine phosphokinase MB increased	0	1(0.5%)
Blood creatinine increased	0	1(0.5%)
Glomerular filtration rate decreased	0	1(0.5%)
Protein urine present	0	1(0.5%)
Cardiac Disorders	2(1.0%)	1(0.5%)
Atrial flutter	1(0.5%)	0
Mitral valve disease	1(0.5%)	0
Ischaemic mitral regurgitation	0	1(0.5%)
Skin And Subcutaneous Tissue Disorders	1(0.5%)	3(1.4%)
Skin ulcer	1(0.5%)	0
Diabetic foot	0	2(0.9%)
Actinic keratosis	0	1(0.5%)
Ear And Labyrinth Disorders	1(0.5%)	1(0.5%)
Vertigo	1(0.5%)	1(0.5%)
Reproductive System And Breast Disorders	1(0.5%)	1(0.5%)
Benign prostatic hyperplasia	1(0.5%)	1(0.5%)
Congenital, Familial And Genetic Disorders	1(0.5%)	0
Phimosis	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Any TEAE	35(16.7%)	38(17.2%)
Infections And Infestations	8(3.8%)	6(2.7%)
Pneumonia	2(1.0%)	1(0.5%)
Osteomyelitis	1(0.5%)	1(0.5%)
Bronchitis	1(0.5%)	0
Chest wall abscess	1(0.5%)	0
Diverticulitis	1(0.5%)	0
Encephalitis viral	1(0.5%)	0
Infected skin ulcer	1(0.5%)	0
Urinary tract infection	1(0.5%)	0
Erysipelas	0	2(0.9%)
Cellulitis	0	1(0.5%)
Urosepsis	0	1(0.5%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	7(3.3%)	6(2.7%)
Prostate cancer	3(1.4%)	0
Adenocarcinoma of colon	1(0.5%)	1(0.5%)
Rectal adenocarcinoma	1(0.5%)	0
Sarcoma	1(0.5%)	0
Tonsil cancer	1(0.5%)	0
Basal cell carcinoma	0	1(0.5%)
Bowen's disease	0	1(0.5%)
Lentigo maligna	0	1(0.5%)
Lung neoplasm	0	1(0.5%)
Lung neoplasm malignant	0	1(0.5%)
Oropharyngeal cancer	0	1(0.5%)
Squamous cell carcinoma of skin	0	1(0.5%)
Renal And Urinary Disorders	5(2.4%)	3(1.4%)
Acute kidney injury	2(1.0%)	1(0.5%)
Renal impairment	1(0.5%)	1(0.5%)
End stage renal disease	1(0.5%)	0
Urinary retention	1(0.5%)	0
Hypertonic bladder	0	1(0.5%)
Gastrointestinal Disorders	4(1.9%)	2(0.9%)
Gastrointestinal haemorrhage	2(1.0%)	0
Duodenal polyp	1(0.5%)	0
Pancreatitis acute	1(0.5%)	0
Large intestine polyp	0	1(0.5%)
Small intestinal obstruction	0	1(0.5%)
Metabolism And Nutrition Disorders	4(1.9%)	0
Hyperkalaemia	2(1.0%)	0
Dehydration	1(0.5%)	0
Diabetes mellitus	1(0.5%)	0
Vascular Disorders	3(1.4%)	7(3.2%)
Hypertension	1(0.5%)	3(1.4%)
Aortic dissection	1(0.5%)	0
Hypertensive emergency	1(0.5%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Arteriosclerosis	0	1(0.5%)
Giant cell arteritis	0	1(0.5%)
Hypertensive crisis	0	1(0.5%)
Hypovolaemic shock	0	1(0.5%)
Peripheral arterial occlusive disease	0	1(0.5%)
Cardiac Disorders	3(1.4%)	2(0.9%)
Aortic valve stenosis	1(0.5%)	0
Coronary artery disease	1(0.5%)	0
Mitral valve calcification	1(0.5%)	0
Mitral valve disease	1(0.5%)	0
Conduction disorder	0	1(0.5%)
Ischaemic mitral regurgitation	0	1(0.5%)
Mitral valve prolapse	0	1(0.5%)
Respiratory, Thoracic And Mediastinal Disorders	3(1.4%)	1(0.5%)
Pulmonary embolism	2(1.0%)	0
Chronic obstructive pulmonary disease	1(0.5%)	0
Acute respiratory failure	0	1(0.5%)
General Disorders And Administration Site Conditions	3(1.4%)	0
Chest pain	2(1.0%)	0
Oedema peripheral	1(0.5%)	0
Nervous System Disorders	2(1.0%)	3(1.4%)
Brain oedema	1(0.5%)	0
Diabetic neuropathy	1(0.5%)	0
Carpal tunnel syndrome	0	1(0.5%)
Dizziness	0	1(0.5%)
Hemiparesis	0	1(0.5%)
Surgical And Medical Procedures	2(1.0%)	1(0.5%)
Cataract operation	1(0.5%)	0
Lymphadenectomy	1(0.5%)	0
Foot amputation	0	1(0.5%)
Eye Disorders	2(1.0%)	0
Cataract	1(0.5%)	0
Retinal detachment	1(0.5%)	0
Hepatobiliary Disorders	1(0.5%)	2(0.9%)
Cholelithiasis	1(0.5%)	0
Cholecystitis acute	0	1(0.5%)
Hepatic lesion	0	1(0.5%)
Blood And Lymphatic System Disorders	0	3(1.4%)
Anaemia	0	2(0.9%)
Iron deficiency anaemia	0	1(0.5%)
Musculoskeletal And Connective Tissue Disorders	0	3(1.4%)
Costochondritis	0	1(0.5%)
Osteoarthritis	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Polymyalgia rheumatica	0	1(0.5%)
Injury, Poisoning And Procedural Complications	0	2(0.9%)
Craniocerebral injury	0	1(0.5%)
Spinal fracture	0	1(0.5%)
Investigations	0	2(0.9%)
Blood triglycerides increased	0	1(0.5%)
Glomerular filtration rate decreased	0	1(0.5%)
Skin And Subcutaneous Tissue Disorders	0	2(0.9%)
Actinic keratosis	0	1(0.5%)
Diabetic foot	0	1(0.5%)
Psychiatric Disorders	0	1(0.5%)
Depression	0	1(0.5%)
Reproductive System And Breast Disorders	0	1(0.5%)
Benign prostatic hyperplasia	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N= 210)	Placebo (N= 221)
Any TEAE	10(4.8%)	11(5.0%)
Investigations	3(1.4%)	1(0.5%)
Blood potassium increased	2(1.0%)	0
Glomerular filtration rate decreased	1(0.5%)	1(0.5%)
Metabolism And Nutrition Disorders	2(1.0%)	2(0.9%)
Hyperkalaemia	2(1.0%)	2(0.9%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	1(0.5%)	3(1.4%)
Renal neoplasm	1(0.5%)	0
Adenocarcinoma of colon	0	1(0.5%)
Lung neoplasm	0	1(0.5%)
Pancreatic neoplasm	0	1(0.5%)
General Disorders And Administration Site Conditions	1(0.5%)	1(0.5%)
Asthenia	1(0.5%)	0
Malaise	0	1(0.5%)
Renal And Urinary Disorders	1(0.5%)	1(0.5%)
Urinary retention	1(0.5%)	0
Tubulointerstitial nephritis	0	1(0.5%)
Vascular Disorders	1(0.5%)	1(0.5%)
Hypertension	1(0.5%)	0
Peripheral arterial occlusive disease	0	1(0.5%)
Hepatobiliary Disorders	1(0.5%)	0
Hepatic cirrhosis	1(0.5%)	0
Gastrointestinal Disorders	0	1(0.5%)
Diarrhoea	0	1(0.5%)
Musculoskeletal And Connective Tissue Disorders	0	1(0.5%)
Fibromyalgia	0	1(0.5%)
Nervous System Disorders	0	1(0.5%)
Paraesthesia	0	1(0.5%)
Skin And Subcutaneous Tissue Disorders	0	1(0.5%)
Dermatitis allergic	0	1(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N= 210)	Placebo (N= 221)	Total (N= 431)
Treatment duration (months)			
n	210	221	431
Mean	32.6	31.0	31.8
SD	11.42	12.66	12.08
Median	34.3	32.8	33.2
Q1-Q3	28.3 - 40.7	26.8 - 40.2	27.6 - 40.7
Range	0.33 - 50.37	0.59 - 49.54	0.33 - 50.37

Abbreviations: eGFR=estimated glomerular filtration rate, N=number of subjects, n=number of subjects with non-missing values in category, Q1=first quartile, Q3=third quartile, SD=standard deviation.
Note: Treatment duration is defined as the time from start of study drug to permanent stop of study drug (in months).

Table B2.1.1: Effect Measures of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		181 (86.2%)	178 (80.5%)	359 (83.3%)
Number of subjects without events		29 (13.8%)	43 (19.5%)	72 (16.7%)
Odds Ratio [a]				
OR, 95% CI	1.508 [0.901, 2.522]			
p-value	0.1177			
Relative Risk [b]				
RR, 95% CI	1.070 [0.983, 1.164]			
p-value	0.1157			
Risk Difference [c]				
RD, 95% CI	0.056 [-0.014, 0.126]			
p-value	0.1139			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.2: Effect Measures of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		176 (83.8%)	177 (80.1%)	353 (81.9%)
Number of subjects without events		34 (16.2%)	44 (19.9%)	78 (18.1%)
Odds Ratio [a]				
OR, 95% CI	1.287 [0.785, 2.108]			
p-value	0.3169			
Relative Risk [b]				
RR, 95% CI	1.046 [0.958, 1.143]			
p-value	0.3155			
Risk Difference [c]				
RD, 95% CI	0.037 [-0.035, 0.110]			
p-value	0.3146			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.3: Effect Measures of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		65 (31.0%)	67 (30.3%)	132 (30.6%)
Number of subjects without events		145 (69.0%)	154 (69.7%)	299 (69.4%)
Odds Ratio [a]				
OR, 95% CI	1.030 [0.684, 1.552]			
p-value	0.8862			
Relative Risk [b]				
RR, 95% CI	1.021 [0.768, 1.357]			
p-value	0.8862			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.081, 0.093]			
p-value	0.8862			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.4: Effect Measures of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		64 (30.5%)	65 (29.4%)	129 (29.9%)
Number of subjects without events		146 (69.5%)	156 (70.6%)	302 (70.1%)
Odds Ratio [a]				
OR, 95% CI	1.052 [0.697, 1.589]			
p-value	0.8094			
Relative Risk [b]				
RR, 95% CI	1.036 [0.776, 1.383]			
p-value	0.8094			
Risk Difference [c]				
RD, 95% CI	0.011 [-0.076, 0.097]			
p-value	0.8094			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.5: Effect Measures of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		35 (16.7%)	38 (17.2%)	73 (16.9%)
Number of subjects without events		175 (83.3%)	183 (82.8%)	358 (83.1%)
Odds Ratio [a]				
OR, 95% CI	0.963 [0.582, 1.594]			
p-value	0.8839			
Relative Risk [b]				
RR, 95% CI	0.969 [0.638, 1.473]			
p-value	0.8839			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.076, 0.066]			
p-value	0.8838			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.6: Effect Measures of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		35 (16.7%)	37 (16.7%)	72 (16.7%)
Number of subjects without events		175 (83.3%)	184 (83.3%)	359 (83.3%)
Odds Ratio [a]				
OR, 95% CI	0.995 [0.599, 1.650]			
p-value	0.9833			
Relative Risk [b]				
RR, 95% CI	0.995 [0.653, 1.518]			
p-value	0.9833			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.071, 0.070]			
p-value	0.9833			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.7: Effect Measures of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		10 (4.8%)	11 (5.0%)	21 (4.9%)
Number of subjects without events		200 (95.2%)	210 (95.0%)	410 (95.1%)
Odds Ratio [a]				
OR, 95% CI	0.955 [0.397, 2.297]			
p-value	0.9173			
Relative Risk [b]				
RR, 95% CI	0.957 [0.415, 2.206]			
p-value	0.9173			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.043, 0.038]			
p-value	0.9172			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.8: Effect Measures of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		16 (7.6%)	18 (8.1%)	34 (7.9%)
Number of subjects without events		194 (92.4%)	203 (91.9%)	397 (92.1%)
Odds Ratio [a]				
OR, 95% CI	0.930 [0.461, 1.876]			
p-value	0.8396			
Relative Risk [b]				
RR, 95% CI	0.935 [0.490, 1.785]			
p-value	0.8397			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.056, 0.046]			
p-value	0.8395			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.9: Effect Measures of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		9 (4.3%)	10 (4.5%)	19 (4.4%)
Number of subjects without events		201 (95.7%)	211 (95.5%)	412 (95.6%)
Odds Ratio [a]				
OR, 95% CI	0.945 [0.376, 2.373]			
p-value	0.9038			
Relative Risk [b]				
RR, 95% CI	0.947 [0.393, 2.285]			
p-value	0.9038			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.041, 0.036]			
p-value	0.9037			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.10: Effect Measures of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		26 (12.4%)	20 (9.0%)	46 (10.7%)
Number of subjects without events		184 (87.6%)	201 (91.0%)	385 (89.3%)
Odds Ratio [a]				
OR, 95% CI	1.420 [0.767, 2.630]			
p-value	0.2647			
Relative Risk [b]				
RR, 95% CI	1.368 [0.788, 2.375]			
p-value	0.2653			
Risk Difference [c]				
RD, 95% CI	0.033 [-0.025, 0.092]			
p-value	0.2639			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.11: Effect Measures of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		23 (11.0%)	33 (14.9%)	56 (13.0%)
Number of subjects without events		187 (89.0%)	188 (85.1%)	375 (87.0%)
Odds Ratio [a]				
OR, 95% CI	0.701 [0.396, 1.238]			
p-value	0.2210			
Relative Risk [b]				
RR, 95% CI	0.733 [0.446, 1.207]			
p-value	0.2223			
Risk Difference [c]				
RD, 95% CI	-0.040 [-0.103, 0.023]			
p-value	0.2170			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.12: Effect Measures of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		10 (4.8%)	10 (4.5%)	20 (4.6%)
Number of subjects without events		200 (95.2%)	211 (95.5%)	411 (95.4%)
Odds Ratio [a]				
OR, 95% CI	1.055 [0.430, 2.589]			
p-value	0.9069			
Relative Risk [b]				
RR, 95% CI	1.052 [0.447, 2.477]			
p-value	0.9069			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.037, 0.042]			
p-value	0.9070			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.13: Effect Measures of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		54 (25.7%)	45 (20.4%)	99 (23.0%)
Number of subjects without events		156 (74.3%)	176 (79.6%)	332 (77.0%)
Odds Ratio [a]				
OR, 95% CI	1.354 [0.863, 2.124]			
p-value	0.1875			
Relative Risk [b]				
RR, 95% CI	1.263 [0.892, 1.788]			
p-value	0.1882			
Risk Difference [c]				
RD, 95% CI	0.054 [-0.026, 0.133]			
p-value	0.1867			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.14: Effect Measures of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		14 (6.7%)	8 (3.6%)	22 (5.1%)
Number of subjects without events		196 (93.3%)	213 (96.4%)	409 (94.9%)
Odds Ratio [a]				
OR, 95% CI	1.902 [0.781, 4.631]			
p-value	0.1569			
Relative Risk [b]				
RR, 95% CI	1.842 [0.789, 4.300]			
p-value	0.1581			
Risk Difference [c]				
RD, 95% CI	0.030 [-0.011, 0.072]			
p-value	0.1528			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.15: Effect Measures of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		31 (14.8%)	36 (16.3%)	67 (15.5%)
Number of subjects without events		179 (85.2%)	185 (83.7%)	364 (84.5%)
Odds Ratio [a]				
OR, 95% CI	0.890 [0.528, 1.500]			
p-value	0.6618			
Relative Risk [b]				
RR, 95% CI	0.906 [0.583, 1.409]			
p-value	0.6620			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.084, 0.053]			
p-value	0.6613			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.16: Effect Measures of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		11 (5.2%)	16 (7.2%)	27 (6.3%)
Number of subjects without events		199 (94.8%)	205 (92.8%)	404 (93.7%)
Odds Ratio [a]				
OR, 95% CI	0.708 [0.321, 1.564]			
p-value	0.3933			
Relative Risk [b]				
RR, 95% CI	0.724 [0.344, 1.523]			
p-value	0.3939			
Risk Difference [c]				
RD, 95% CI	-0.020 [-0.066, 0.026]			
p-value	0.3891			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.17: Effect Measures of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		12 (5.7%)	11 (5.0%)	23 (5.3%)
Number of subjects without events		198 (94.3%)	210 (95.0%)	408 (94.7%)
Odds Ratio [a]				
OR, 95% CI	1.157 [0.499, 2.682]			
p-value	0.7339			
Relative Risk [b]				
RR, 95% CI	1.148 [0.518, 2.545]			
p-value	0.7339			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.035, 0.050]			
p-value	0.7341			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.18: Effect Measures of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		88 (41.9%)	90 (40.7%)	178 (41.3%)
Number of subjects without events		122 (58.1%)	131 (59.3%)	253 (58.7%)
Odds Ratio [a]				
OR, 95% CI	1.050 [0.715, 1.541]			
p-value	0.8035			
Relative Risk [b]				
RR, 95% CI	1.029 [0.822, 1.289]			
p-value	0.8034			
Risk Difference [c]				
RD, 95% CI	0.012 [-0.081, 0.105]			
p-value	0.8035			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.19: Effect Measures of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		11 (5.2%)	10 (4.5%)	21 (4.9%)
Number of subjects without events		199 (94.8%)	211 (95.5%)	410 (95.1%)
Odds Ratio [a]				
OR, 95% CI	1.166 [0.485, 2.806]			
p-value	0.7312			
Relative Risk [b]				
RR, 95% CI	1.158 [0.502, 2.669]			
p-value	0.7313			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.034, 0.048]			
p-value	0.7314			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.20: Effect Measures of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		14 (6.7%)	18 (8.1%)	32 (7.4%)
Number of subjects without events		196 (93.3%)	203 (91.9%)	399 (92.6%)
Odds Ratio [a]				
OR, 95% CI	0.806 [0.390, 1.664]			
p-value	0.5591			
Relative Risk [b]				
RR, 95% CI	0.819 [0.418, 1.603]			
p-value	0.5594			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.064, 0.035]			
p-value	0.5574			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.21: Effect Measures of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		10 (4.8%)	6 (2.7%)	16 (3.7%)
Number of subjects without events		200 (95.2%)	215 (97.3%)	415 (96.3%)
Odds Ratio [a]				
OR, 95% CI	1.792 [0.639, 5.020]			
p-value	0.2673			
Relative Risk [b]				
RR, 95% CI	1.754 [0.649, 4.741]			
p-value	0.2681			
Risk Difference [c]				
RD, 95% CI	0.020 [-0.015, 0.056]			
p-value	0.2637			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.22: Effect Measures of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		11 (5.2%)	18 (8.1%)	29 (6.7%)
Number of subjects without events		199 (94.8%)	203 (91.9%)	402 (93.3%)
Odds Ratio [a]				
OR, 95% CI	0.623 [0.287, 1.353]			
p-value	0.2321			
Relative Risk [b]				
RR, 95% CI	0.643 [0.311, 1.329]			
p-value	0.2333			
Risk Difference [c]				
RD, 95% CI	-0.029 [-0.076, 0.018]			
p-value	0.2254			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.23: Effect Measures of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		14 (6.7%)	15 (6.8%)	29 (6.7%)
Number of subjects without events		196 (93.3%)	206 (93.2%)	402 (93.3%)
Odds Ratio [a]				
OR, 95% CI	0.981 [0.461, 2.085]			
p-value	0.9601			
Relative Risk [b]				
RR, 95% CI	0.982 [0.486, 1.985]			
p-value	0.9601			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.049, 0.046]			
p-value	0.9601			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.24: Effect Measures of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		30 (14.3%)	30 (13.6%)	60 (13.9%)
Number of subjects without events		180 (85.7%)	191 (86.4%)	371 (86.1%)
Odds Ratio [a]				
OR, 95% CI	1.061 [0.615, 1.831]			
p-value	0.8312			
Relative Risk [b]				
RR, 95% CI	1.052 [0.658, 1.683]			
p-value	0.8312			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.058, 0.073]			
p-value	0.8313			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.25: Effect Measures of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		51 (24.3%)	52 (23.5%)	103 (23.9%)
Number of subjects without events		159 (75.7%)	169 (76.5%)	328 (76.1%)
Odds Ratio [a]				
OR, 95% CI	1.042 [0.669, 1.623]			
p-value	0.8540			
Relative Risk [b]				
RR, 95% CI	1.032 [0.737, 1.446]			
p-value	0.8540			
Risk Difference [c]				
RD, 95% CI	0.008 [-0.073, 0.088]			
p-value	0.8540			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.26: Effect Measures of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		12 (5.7%)	7 (3.2%)	19 (4.4%)
Number of subjects without events		198 (94.3%)	214 (96.8%)	412 (95.6%)
Odds Ratio [a]				
OR, 95% CI	1.853 [0.715, 4.800]			
p-value	0.2042			
Relative Risk [b]				
RR, 95% CI	1.804 [0.724, 4.495]			
p-value	0.2052			
Risk Difference [c]				
RD, 95% CI	0.025 [-0.014, 0.064]			
p-value	0.2002			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.27: Effect Measures of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		74 (35.2%)	64 (29.0%)	138 (32.0%)
Number of subjects without events		136 (64.8%)	157 (71.0%)	293 (68.0%)
Odds Ratio [a]				
OR, 95% CI	1.335 [0.890, 2.003]			
p-value	0.1631			
Relative Risk [b]				
RR, 95% CI	1.217 [0.923, 1.604]			
p-value	0.1637			
Risk Difference [c]				
RD, 95% CI	0.063 [-0.025, 0.151]			
p-value	0.1622			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.28: Effect Measures of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		18 (8.6%)	13 (5.9%)	31 (7.2%)
Number of subjects without events		192 (91.4%)	208 (94.1%)	400 (92.8%)
Odds Ratio [a]				
OR, 95% CI	1.500 [0.716, 3.143]			
p-value	0.2828			
Relative Risk [b]				
RR, 95% CI	1.457 [0.732, 2.899]			
p-value	0.2834			
Risk Difference [c]				
RD, 95% CI	0.027 [-0.022, 0.076]			
p-value	0.2816			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.29: Effect Measures of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		14 (6.7%)	8 (3.6%)	22 (5.1%)
Number of subjects without events		196 (93.3%)	213 (96.4%)	409 (94.9%)
Odds Ratio [a]				
OR, 95% CI	1.902 [0.781, 4.631]			
p-value	0.1569			
Relative Risk [b]				
RR, 95% CI	1.842 [0.789, 4.300]			
p-value	0.1581			
Risk Difference [c]				
RD, 95% CI	0.030 [-0.011, 0.072]			
p-value	0.1528			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.30: Effect Measures of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		8 (3.8%)	17 (7.7%)	25 (5.8%)
Number of subjects without events		202 (96.2%)	204 (92.3%)	406 (94.2%)
Odds Ratio [a]				
OR, 95% CI	0.475 [0.201, 1.126]			
p-value	0.0910			
Relative Risk [b]				
RR, 95% CI	0.495 [0.218, 1.123]			
p-value	0.0926			
Risk Difference [c]				
RD, 95% CI	-0.039 [-0.082, 0.005]			
p-value	0.0812			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.31: Effect Measures of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		53 (25.2%)	51 (23.1%)	104 (24.1%)
Number of subjects without events		157 (74.8%)	170 (76.9%)	327 (75.9%)
Odds Ratio [a]				
OR, 95% CI	1.125 [0.724, 1.750]			
p-value	0.6003			
Relative Risk [b]				
RR, 95% CI	1.094 [0.782, 1.529]			
p-value	0.6003			
Risk Difference [c]				
RD, 95% CI	0.022 [-0.059, 0.102]			
p-value	0.6004			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.32: Effect Measures of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		12 (5.7%)	11 (5.0%)	23 (5.3%)
Number of subjects without events		198 (94.3%)	210 (95.0%)	408 (94.7%)
Odds Ratio [a]				
OR, 95% CI	1.157 [0.499, 2.682]			
p-value	0.7339			
Relative Risk [b]				
RR, 95% CI	1.148 [0.518, 2.545]			
p-value	0.7339			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.035, 0.050]			
p-value	0.7341			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.33: Effect Measures of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		15 (7.1%)	12 (5.4%)	27 (6.3%)
Number of subjects without events		195 (92.9%)	209 (94.6%)	404 (93.7%)
Odds Ratio [a]				
OR, 95% CI	1.340 [0.612, 2.934]			
p-value	0.4645			
Relative Risk [b]				
RR, 95% CI	1.315 [0.631, 2.744]			
p-value	0.4648			
Risk Difference [c]				
RD, 95% CI	0.017 [-0.029, 0.063]			
p-value	0.4644			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.34: Effect Measures of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		17 (8.1%)	15 (6.8%)	32 (7.4%)
Number of subjects without events		193 (91.9%)	206 (93.2%)	399 (92.6%)
Odds Ratio [a]				
OR, 95% CI	1.210 [0.588, 2.489]			
p-value	0.6051			
Relative Risk [b]				
RR, 95% CI	1.193 [0.611, 2.326]			
p-value	0.6052			
Risk Difference [c]				
RD, 95% CI	0.013 [-0.037, 0.063]			
p-value	0.6053			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.35: Effect Measures of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		41 (19.5%)	33 (14.9%)	74 (17.2%)
Number of subjects without events		169 (80.5%)	188 (85.1%)	357 (82.8%)
Odds Ratio [a]				
OR, 95% CI	1.382 [0.836, 2.286]			
p-value	0.2076			
Relative Risk [b]				
RR, 95% CI	1.308 [0.861, 1.985]			
p-value	0.2083			
Risk Difference [c]				
RD, 95% CI	0.046 [-0.025, 0.117]			
p-value	0.2068			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.36: Effect Measures of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		30 (14.3%)	29 (13.1%)	59 (13.7%)
Number of subjects without events		180 (85.7%)	192 (86.9%)	372 (86.3%)
Odds Ratio [a]				
OR, 95% CI	1.103 [0.637, 1.911]			
p-value	0.7255			
Relative Risk [b]				
RR, 95% CI	1.089 [0.678, 1.749]			
p-value	0.7255			
Risk Difference [c]				
RD, 95% CI	0.012 [-0.053, 0.077]			
p-value	0.7256			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.37: Effect Measures of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		13 (6.2%)	16 (7.2%)	29 (6.7%)
Number of subjects without events		197 (93.8%)	205 (92.8%)	402 (93.3%)
Odds Ratio [a]				
OR, 95% CI	0.845 [0.396, 1.803]			
p-value	0.6641			
Relative Risk [b]				
RR, 95% CI	0.855 [0.422, 1.734]			
p-value	0.6642			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.058, 0.037]			
p-value	0.6632			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.38: Effect Measures of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		30 (14.3%)	39 (17.6%)	69 (16.0%)
Number of subjects without events		180 (85.7%)	182 (82.4%)	362 (84.0%)
Odds Ratio [a]				
OR, 95% CI	0.778 [0.463, 1.306]			
p-value	0.3423			
Relative Risk [b]				
RR, 95% CI	0.810 [0.523, 1.253]			
p-value	0.3431			
Risk Difference [c]				
RD, 95% CI	-0.034 [-0.103, 0.035]			
p-value	0.3399			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.39: Effect Measures of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		8 (3.8%)	12 (5.4%)	20 (4.6%)
Number of subjects without events		202 (96.2%)	209 (94.6%)	411 (95.4%)
Odds Ratio [a]				
OR, 95% CI	0.690 [0.276, 1.723]			
p-value	0.4264			
Relative Risk [b]				
RR, 95% CI	0.702 [0.293, 1.682]			
p-value	0.4270			
Risk Difference [c]				
RD, 95% CI	-0.016 [-0.056, 0.023]			
p-value	0.4218			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.40: Effect Measures of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		28 (13.3%)	33 (14.9%)	61 (14.2%)
Number of subjects without events		182 (86.7%)	188 (85.1%)	370 (85.8%)
Odds Ratio [a]				
OR, 95% CI	0.876 [0.509, 1.509]			
p-value	0.6343			
Relative Risk [b]				
RR, 95% CI	0.893 [0.560, 1.424]			
p-value	0.6345			
Risk Difference [c]				
RD, 95% CI	-0.016 [-0.082, 0.050]			
p-value	0.6336			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.41: Effect Measures of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		9 (4.3%)	11 (5.0%)	20 (4.6%)
Number of subjects without events		201 (95.7%)	210 (95.0%)	411 (95.4%)
Odds Ratio [a]				
OR, 95% CI	0.855 [0.347, 2.107]			
p-value	0.7332			
Relative Risk [b]				
RR, 95% CI	0.861 [0.364, 2.036]			
p-value	0.7333			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.047, 0.033]			
p-value	0.7325			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.42: Effect Measures of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		52 (24.8%)	45 (20.4%)	97 (22.5%)
Number of subjects without events		158 (75.2%)	176 (79.6%)	334 (77.5%)
Odds Ratio [a]				
OR, 95% CI	1.287 [0.818, 2.025]			
p-value	0.2749			
Relative Risk [b]				
RR, 95% CI	1.216 [0.856, 1.728]			
p-value	0.2754			
Risk Difference [c]				
RD, 95% CI	0.044 [-0.035, 0.123]			
p-value	0.2745			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.43: Effect Measures of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		18 (8.6%)	24 (10.9%)	42 (9.7%)
Number of subjects without events		192 (91.4%)	197 (89.1%)	389 (90.3%)
Odds Ratio [a]				
OR, 95% CI	0.770 [0.405, 1.463]			
p-value	0.4243			
Relative Risk [b]				
RR, 95% CI	0.789 [0.441, 1.411]			
p-value	0.4249			
Risk Difference [c]				
RD, 95% CI	-0.023 [-0.079, 0.033]			
p-value	0.4217			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.44: Effect Measures of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		13 (6.2%)	2 (0.9%)	15 (3.5%)
Number of subjects without events		197 (93.8%)	219 (99.1%)	416 (96.5%)
Odds Ratio [a]				
OR, 95% CI	7.226 [1.611, 32.419]			
p-value	0.0098			
Relative Risk [b]				
RR, 95% CI	6.840 [1.562, 29.950]			
p-value	0.0107			
Risk Difference [c]				
RD, 95% CI	0.053 [0.018, 0.088]			
p-value	0.0030			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.45: Effect Measures of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		16 (7.6%)	15 (6.8%)	31 (7.2%)
Number of subjects without events		194 (92.4%)	206 (93.2%)	400 (92.8%)
Odds Ratio [a]				
OR, 95% CI	1.133 [0.545, 2.353]			
p-value	0.7385			
Relative Risk [b]				
RR, 95% CI	1.123 [0.569, 2.213]			
p-value	0.7385			
Risk Difference [c]				
RD, 95% CI	0.008 [-0.041, 0.057]			
p-value	0.7387			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.46: Effect Measures of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		13 (6.2%)	8 (3.6%)	21 (4.9%)
Number of subjects without events		197 (93.8%)	213 (96.4%)	410 (95.1%)
Odds Ratio [a]				
OR, 95% CI	1.757 [0.713, 4.329]			
p-value	0.2206			
Relative Risk [b]				
RR, 95% CI	1.710 [0.723, 4.042]			
p-value	0.2215			
Risk Difference [c]				
RD, 95% CI	0.026 [-0.015, 0.067]			
p-value	0.2174			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.47: Effect Measures of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=210)	Placebo (N=221)	Total (N=431)
Number of subjects at risk		210 (100.0%)	221 (100.0%)	431 (100.0%)
Number of subjects with events		11 (5.2%)	7 (3.2%)	18 (4.2%)
Number of subjects without events		199 (94.8%)	214 (96.8%)	413 (95.8%)
Odds Ratio [a]				
OR, 95% CI	1.690 [0.642, 4.445]			
p-value	0.2876			
Relative Risk [b]				
RR, 95% CI	1.654 [0.653, 4.186]			
p-value	0.2884			
Risk Difference [c]				
RD, 95% CI	0.021 [-0.017, 0.059]			
p-value	0.2850			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

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4.2 Disposition

Table 4.2 / 1: Subject disposition (all enrolled Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			19381
Screening failures			11944
Randomized	2346	2333	4679
GCP VIOLATIONS	19	29	48
Full analysis set	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Study drug never administered	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Treated	2326 (>99.9%)	2302 (>99.9%)	4628 (>99.9%)
Did not complete treatment due COVID-19	17 (0.7%)	23 (1.0%)	40 (0.9%)
Subject decision: COVID-19 pandemic related	13 (0.6%)	14 (0.6%)	27 (0.6%)
Physician decision: COVID-19 pandemic related	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Logistical reason: COVID-19 pandemic related	3 (0.1%)	7 (0.3%)	10 (0.2%)
Did not complete study	3 (0.1%)	6 (0.3%)	9 (0.2%)
WITHDRAWN CONSENT	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
LOST TO FOLLOW-UP	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Completed study	2324 (99.9%)	2298 (99.7%)	4622 (99.8%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
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Table 4.2 / 2: Disposition: End of treatment (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Completed epoch	1773 (76.2%)	1714 (74.4%)	3487 (75.3%)
Not completed	554 (23.8%)	590 (25.6%)	1144 (24.7%)
Primary reason			
ADVERSE EVENT	129 (5.5%)	144 (6.3%)	273 (5.9%)
DEATH	111 (4.8%)	156 (6.8%)	267 (5.8%)
WITHDRAWAL BY SUBJECT	157 (6.7%)	127 (5.5%)	284 (6.1%)
LOST TO FOLLOW-UP	1 (<0.1%)	0	1 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	6 (0.3%)	6 (0.3%)	12 (0.3%)
PHYSICIAN DECISION	76 (3.3%)	75 (3.3%)	151 (3.3%)
TECHNICAL PROBLEMS	34 (1.5%)	37 (1.6%)	71 (1.5%)
DETERIORATION OF GENERAL CONDITIONS	0	1 (<0.1%)	1 (<0.1%)
PROTOCOL DEVIATION	9 (0.4%)	11 (0.5%)	20 (0.4%)
SITE TERMINATED BY SPONSOR	3 (0.1%)	3 (0.1%)	6 (0.1%)
SUBJECT DECISION	3 (0.1%)	2 (<0.1%)	5 (0.1%)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	13 (0.6%)	14 (0.6%)	27 (0.6%)
PHYSICIAN DECISION: COVID-19 PANDEMIC RELATED	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
LOGISTICAL REASON: COVID-19 PANDEMIC RELATED	3 (0.1%)	7 (0.3%)	10 (0.2%)
OTHER	8 (0.3%)	5 (0.2%)	13 (0.3%)

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4.3 Demographic characteristics

Table 4.3 / 1: Demographics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Race (N)			
WHITE	1659 (71.3%)	1613 (70.0%)	3272 (70.7%)
BLACK OR AFRICAN AMERICAN	70 (3.0%)	74 (3.2%)	144 (3.1%)
ASIAN	464 (19.9%)	486 (21.1%)	950 (20.5%)
AMERICAN INDIAN OR ALASKA NATIVE	58 (2.5%)	58 (2.5%)	116 (2.5%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	14 (0.6%)	8 (0.3%)	22 (0.5%)
NOT REPORTED	6 (0.3%)	3 (0.1%)	9 (0.2%)
MULTIPLE	56 (2.4%)	62 (2.7%)	118 (2.5%)
Sex (N)			
Male	1611 (69.2%)	1640 (71.2%)	3251 (70.2%)
Female	716 (30.8%)	664 (28.8%)	1380 (29.8%)
Age (YEARS)			
n	2327	2304	4631
Mean	61.19	60.92	61.05
SD	9.45	9.73	9.59
Min	27.0	23.0	23.0
Q1	55.00	54.00	55.00
Median	62.00	62.00	62.00
Q3	68.00	68.00	68.00
Max	88.0	86.0	88.0
Run-in age group (years) category (N)			
18 - 44 years	121 (5.2%)	117 (5.1%)	238 (5.1%)
45 - 64 years	1295 (55.7%)	1304 (56.6%)	2599 (56.1%)
65 - 74 years	755 (32.4%)	724 (31.4%)	1479 (31.9%)
>= 75 years	156 (6.7%)	159 (6.9%)	315 (6.8%)
Age group (years) category 3 (N)			
< 65 years	1416 (60.9%)	1421 (61.7%)	2837 (61.3%)
>= 65 years	911 (39.1%)	883 (38.3%)	1794 (38.7%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	1860 (79.9%)	1854 (80.5%)	3714 (80.2%)
HISPANIC OR LATINO	459 (19.7%)	449 (19.5%)	908 (19.6%)
NOT REPORTED	8 (0.3%)	1 (<0.1%)	9 (0.2%)

Table 4.3 / 1: Demographics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Region (N)			
Europe	1114 (47.9%)	1111 (48.2%)	2225 (48.0%)
North America	292 (12.5%)	277 (12.0%)	569 (12.3%)
Asia	522 (22.4%)	523 (22.7%)	1045 (22.6%)
Latin America	322 (13.8%)	316 (13.7%)	638 (13.8%)
Others	77 (3.3%)	77 (3.3%)	154 (3.3%)
Baseline Weight (kg)			
n	2323	2300	4623
Mean	89.49	89.47	89.48
SD	20.67	20.14	20.41
Min	35.5	37.3	35.5
Q1	74.30	75.60	75.00
Median	87.00	87.50	87.30
Q3	102.00	101.00	101.60
Max	190.4	172.7	190.4
Baseline weight (kg) category (N)			
missing	4 (0.2%)	4 (0.2%)	8 (0.2%)
< 60 kg	108 (4.6%)	110 (4.8%)	218 (4.7%)
60 - < 90 kg	1182 (50.8%)	1145 (49.7%)	2327 (50.2%)
>= 90 kg	1033 (44.4%)	1045 (45.4%)	2078 (44.9%)
Baseline Height (cm)			
n	2325	2301	4626
Mean	167.95	168.24	168.09
SD	9.98	9.59	9.79
Min	118.0	121.0	118.0
Q1	161.00	162.00	162.00
Median	168.00	169.00	168.65
Q3	175.00	175.00	175.00
Max	198.0	206.0	206.0

Table 4.3 / 1: Demographics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline Body Mass Index (kg/m2)			
n	2321	2299	4620
Mean	31.59	31.49	31.54
SD	6.22	6.06	6.14
Min	16.7	15.9	15.9
Q1	27.20	27.20	27.20
Median	30.80	30.70	30.80
Q3	35.00	34.70	34.80
Max	83.9	56.3	83.9
Baseline BMI (kg/m2) category 2 (N)			
missing	6 (0.3%)	5 (0.2%)	11 (0.2%)
< 30 kg/m2	1012 (43.5%)	1026 (44.5%)	2038 (44.0%)
>= 30 kg/m2	1309 (56.3%)	1273 (55.3%)	2582 (55.8%)
Baseline BMI (kg/m2) category 3 (N)			
missing	6 (0.3%)	5 (0.2%)	11 (0.2%)
< 20 kg/m2	14 (0.6%)	21 (0.9%)	35 (0.8%)
20 - < 25 kg/m2	256 (11.0%)	247 (10.7%)	503 (10.9%)
25 - < 30 kg/m2	742 (31.9%)	758 (32.9%)	1500 (32.4%)
30 - < 35 kg/m2	728 (31.3%)	721 (31.3%)	1449 (31.3%)
>= 35 kg/m2	581 (25.0%)	552 (24.0%)	1133 (24.5%)
Baseline Hip Circumference (cm)			
n	2318	2300	4618
Mean	107.56	107.41	107.49
SD	14.17	13.83	14.00
Min	48.4	40.6	40.6
Q1	98.80	99.00	99.00
Median	106.00	106.00	106.00
Q3	115.00	115.00	115.00
Max	199.0	161.0	199.0

Table 4.3 / 1: Demographics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline waist circumference (cm)			
n	2319	2300	4619
Mean	107.14	106.96	107.05
SD	15.38	14.93	15.16
Min	57.0	51.0	51.0
Q1	96.50	97.00	97.00
Median	106.00	106.00	106.00
Q3	117.00	116.00	116.80
Max	240.0	166.0	240.0
Baseline waist circumf. (cm) cat. (N)			
missing	8 (0.3%)	4 (0.2%)	12 (0.3%)
normal	288 (12.4%)	263 (11.4%)	551 (11.9%)
increased	406 (17.4%)	424 (18.4%)	830 (17.9%)
substantially increased	1625 (69.8%)	1613 (70.0%)	3238 (69.9%)
Baseline waist-hip ratio (N)			
n	2318	2298	4616
Mean	1.00	1.00	1.00
SD	0.11	0.12	0.11
Min	0.6	0.4	0.4
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.05	1.05
Max	2.7	2.3	2.7
Smoking History (N)			
NEVER	1109 (47.7%)	1020 (44.3%)	2129 (46.0%)
FORMER	714 (30.7%)	763 (33.1%)	1477 (31.9%)
CURRENT	504 (21.7%)	521 (22.6%)	1025 (22.1%)

Table 4.3 / 1: Demographics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Alcohol Use (N)			
missing	2 (<0.1%)	0	2 (<0.1%)
ABSTINENT	1372 (59.0%)	1337 (58.0%)	2709 (58.5%)
LIGHT	792 (34.0%)	796 (34.5%)	1588 (34.3%)
MODERATE	150 (6.4%)	159 (6.9%)	309 (6.7%)
HEAVY	11 (0.5%)	12 (0.5%)	23 (0.5%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
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4.4 Baseline characteristics

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline potassium (mmol/L)			
n	2327	2303	4630
Arithm. Mean	4.31	4.31	4.31
Arithm. SD	0.42	0.43	0.42
Min	2.8	2.6	2.6
Q1	4.10	4.00	4.00
Median	4.30	4.30	4.30
Q3	4.60	4.60	4.60
Max	6.0	5.9	6.0
Baseline ser. potassium (mmol/L) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.5 mmol/L	1719 (73.9%)	1680 (72.9%)	3399 (73.4%)
> 4.5 mmol/L	608 (26.1%)	623 (27.0%)	1231 (26.6%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.8 mmol/L	2120 (91.1%)	2091 (90.8%)	4211 (90.9%)
>4.8 to <=5.0 mmol/L	119 (5.1%)	118 (5.1%)	237 (5.1%)
>5.0 mmol/L	88 (3.8%)	94 (4.1%)	182 (3.9%)
Basel. potass (mmol/L) median FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1278 (54.9%)	1251 (54.3%)	2529 (54.6%)
> 4.30 mmol/L (median in FAS)	1049 (45.1%)	1052 (45.7%)	2101 (45.4%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	800 (34.4%)	797 (34.6%)	1597 (34.5%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	478 (20.5%)	454 (19.7%)	932 (20.1%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	600 (25.8%)	598 (26.0%)	1198 (25.9%)
>4.6 mmol/L (>Q3 in FAS)	449 (19.3%)	454 (19.7%)	903 (19.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	2327	2304	4631
Arithm. Mean	136.62	136.41	136.51
Arithm. SD	13.52	13.72	13.62
Min	82.7	94.7	82.7
Q1	127.67	127.33	127.67
Median	136.67	136.67	136.67
Q3	145.67	146.00	146.00
Max	208.0	200.0	208.0
Baseline SBP (mmHg) category (N)			
< 130 mmHg	693 (29.8%)	700 (30.4%)	1393 (30.1%)
130 - < 160 mmHg	1561 (67.1%)	1525 (66.2%)	3086 (66.6%)
>= 160 mmHg	73 (3.1%)	79 (3.4%)	152 (3.3%)
Baseline SBP (mmHg) median for FAS (N)			
<= 137.00 mmHg (median in FAS)	1209 (52.0%)	1202 (52.2%)	2411 (52.1%)
> 137.00 mmHg (median in FAS)	1118 (48.0%)	1102 (47.8%)	2220 (47.9%)
Baseline Diastolic Blood Pressure (mmHg)			
n	2327	2304	4631
Arithm. Mean	78.36	78.68	78.52
Arithm. SD	8.94	8.95	8.95
Min	45.3	47.7	45.3
Q1	72.33	73.00	72.67
Median	79.00	79.33	79.33
Q3	84.67	84.33	84.33
Max	112.3	108.0	112.3
Baseline Heart Rate (BEATS/MIN)			
n	2327	2304	4631
Arithm. Mean	75.34	75.14	75.24
Arithm. SD	10.82	11.29	11.05
Min	37.0	41.7	37.0
Q1	68.00	67.00	67.67
Median	75.00	74.67	75.00
Q3	82.00	82.33	82.33
Max	115.7	144.0	144.0

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	2327	2304	4631
Arithm. Mean	80.14	80.74	80.44
Arithm. SD	15.54	15.47	15.50
Min	24.7	29.9	24.7
Q1	68.40	69.10	68.70
Median	79.00	79.70	79.50
Q3	91.70	91.90	91.80
Max	137.1	131.5	137.1
Baseline eGFR (mL/min/1.73m2) cat.(N)			
< 25 mL/min/1.73m2	1 (<0.1%)	0	1 (<0.1%)
25 - < 45 mL/min/1.73m2	23 (1.0%)	10 (0.4%)	33 (0.7%)
45 - < 60 mL/min/1.73m2	170 (7.3%)	175 (7.6%)	345 (7.4%)
>= 60 mL/min/1.73m2	2133 (91.7%)	2119 (92.0%)	4252 (91.8%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
< 30 mL/min/1.73m2	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
30 - < 60 mL/min/1.73m2	192 (8.3%)	184 (8.0%)	376 (8.1%)
60 - < 90 mL/min/1.73m2	1481 (63.6%)	1467 (63.7%)	2948 (63.7%)
>= 90 mL/min/1.73m2	652 (28.0%)	652 (28.3%)	1304 (28.2%)
Screening eGFR (mL/min/1.73m2)			
n	2325	2301	4626
Arithm. Mean	81.56	81.70	81.63
Arithm. SD	14.10	14.31	14.20
Min	40.3	45.4	40.3
Q1	70.20	70.00	70.10
Median	79.50	79.90	79.70
Q3	91.40	91.80	91.60
Max	147.0	135.0	147.0
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	2 (<0.1%)	3 (0.1%)	5 (0.1%)
25 - < 45 mL/min/1.73m2	2 (<0.1%)	0	2 (<0.1%)
45 - < 60 mL/min/1.73m2	8 (0.3%)	9 (0.4%)	17 (0.4%)
>= 60 mL/min/1.73m2	2315 (99.5%)	2292 (99.5%)	4607 (99.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	2 (<0.1%)	3 (0.1%)	5 (0.1%)
30 - < 60 mL/min/1.73m2	10 (0.4%)	9 (0.4%)	19 (0.4%)
60 - < 90 mL/min/1.73m2	1678 (72.1%)	1649 (71.6%)	3327 (71.8%)
>= 90 mL/min/1.73m2	637 (27.4%)	643 (27.9%)	1280 (27.6%)
Baseline UACR (mg/g)			
n	2327	2302	4629
Geom. Mean	524.44	525.59	525.01
Geom. SD	2.93	2.98	2.95
Min	6.2	1.8	1.8
Q1	303.36	320.47	311.41
Median	567.29	563.75	565.52
Q3	1102.71	1112.35	1106.15
Max	7630.5	5642.5	7630.5
Baseline albuminuria (mg/g) cat. (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	22 (0.9%)	26 (1.1%)	48 (1.0%)
High albuminuria (30 mg/g - < 300 mg/g)	548 (23.5%)	504 (21.9%)	1052 (22.7%)
Very high albuminuria (>= 300 mg/g)	1757 (75.5%)	1772 (76.9%)	3529 (76.2%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<= 514.7 mg/g (median in FAS)	1068 (45.9%)	1072 (46.5%)	2140 (46.2%)
> 514.7 mg/g (median in FAS)	1259 (54.1%)	1230 (53.4%)	2489 (53.7%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
NO	2316 (99.5%)	2298 (99.7%)	4614 (99.6%)
YES	11 (0.5%)	5 (0.2%)	16 (0.3%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Baseline Creatinine (mg/dL)			
n	2327	2304	4631
Arithm. Mean	0.94	0.94	0.94
Arithm. SD	0.22	0.21	0.21
Min	0.4	0.4	0.4
Q1	0.79	0.79	0.79
Median	0.93	0.93	0.93
Q3	1.07	1.07	1.07
Max	2.5	2.2	2.5
Baseline Albumin (g/dL) in Serum			
n	2326	2303	4629
Arithm. Mean	4.24	4.22	4.23
Arithm. SD	0.32	0.33	0.33
Min	2.4	2.4	2.4
Q1	4.10	4.00	4.00
Median	4.30	4.20	4.30
Q3	4.50	4.50	4.50
Max	5.3	5.4	5.4
Baseline Hemoglobin (g/dL) in Blood			
n	2321	2302	4623
Arithm. Mean	13.88	13.87	13.87
Arithm. SD	1.63	1.63	1.63
Min	8.3	5.8	5.8
Q1	12.80	12.90	12.90
Median	13.90	13.90	13.90
Q3	15.00	14.90	15.00
Max	19.4	19.6	19.6
Baseline Hemoglobin A1C (%)			
n	2325	2301	4626
Arithm. Mean	7.83	7.83	7.83
Arithm. SD	1.43	1.43	1.43
Min	4.7	4.5	4.5
Q1	6.80	6.70	6.80
Median	7.60	7.60	7.60
Q3	8.70	8.80	8.70
Max	14.5	12.6	14.5

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	2 (<0.1%)	3 (0.1%)	5 (0.1%)
<= 7.5%	1123 (48.3%)	1115 (48.4%)	2238 (48.3%)
> 7.5%	1202 (51.7%)	1186 (51.5%)	2388 (51.6%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	2 (<0.1%)	3 (0.1%)	5 (0.1%)
<=6.7 % (<= Q1 in FAS)	555 (23.9%)	581 (25.2%)	1136 (24.5%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	568 (24.4%)	534 (23.2%)	1102 (23.8%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	551 (23.7%)	527 (22.9%)	1078 (23.3%)
>8.5 % (>Q3 in FAS)	651 (28.0%)	659 (28.6%)	1310 (28.3%)
Baseline C Reactive Protein (mg/L)			
n	2327	2301	4628
Arithm. Mean	5.01	4.63	4.82
Arithm. SD	12.19	9.46	10.92
Min	0.1	0.1	0.1
Q1	0.95	0.96	0.95
Median	2.14	2.23	2.18
Q3	4.96	5.09	5.04
Max	311.0	212.0	311.0
Basel. C Reactive Protein Quartiles (N)			
missing	0	3 (0.1%)	3 (<0.1%)
<=0.95 % (<= Q1 in FAS)	587 (25.2%)	574 (24.9%)	1161 (25.1%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	608 (26.1%)	572 (24.8%)	1180 (25.5%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	571 (24.5%)	586 (25.4%)	1157 (25.0%)
>5.13 % (>Q3 in FAS)	561 (24.1%)	569 (24.7%)	1130 (24.4%)
Stratification factor 3 (N)			
CVD present	811 (34.9%)	803 (34.9%)	1614 (34.9%)
CVD absent	1516 (65.1%)	1501 (65.1%)	3017 (65.1%)
Hyperkalemia (based on MLG) in MH (N)			
NO	2314 (99.4%)	2292 (99.5%)	4606 (99.5%)
YES	13 (0.6%)	12 (0.5%)	25 (0.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Hepatic impairment in medical history(N)			
NO	1911 (82.1%)	1865 (80.9%)	3776 (81.5%)
YES	416 (17.9%)	439 (19.1%)	855 (18.5%)
Child Pugh (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
likely Child Pugh A	2263 (97.2%)	2231 (96.8%)	4494 (97.0%)
likely Child Pugh B	62 (2.7%)	70 (3.0%)	132 (2.9%)
certain Child Pugh B	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duration of diabetes (in years) (N)			
n	2325	2301	4626
Arithm. Mean	13.65	13.48	13.56
Arithm. SD	7.93	7.81	7.87
Min	0.2	0.2	0.2
Q1	7.61	7.73	7.70
Median	12.30	12.41	12.32
Q3	18.20	18.13	18.16
Max	52.1	47.7	52.1
ACEI use (N)			
NO	1307 (56.2%)	1290 (56.0%)	2597 (56.1%)
YES	1020 (43.8%)	1014 (44.0%)	2034 (43.9%)
ARB use (N)			
NO	1021 (43.9%)	1016 (44.1%)	2037 (44.0%)
YES	1306 (56.1%)	1288 (55.9%)	2594 (56.0%)
Beta blocker use at baseline (N)			
NO	1343 (57.7%)	1307 (56.7%)	2650 (57.2%)
YES	984 (42.3%)	997 (43.3%)	1981 (42.8%)
Diuretic use at baseline (N)			
NO	1357 (58.3%)	1335 (57.9%)	2692 (58.1%)
YES	970 (41.7%)	969 (42.1%)	1939 (41.9%)
Statins use at baseline (N)			
NO	826 (35.5%)	743 (32.2%)	1569 (33.9%)
YES	1501 (64.5%)	1561 (67.8%)	3062 (66.1%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Anti-diabetic use at baseline (N)			
NO	30 (1.3%)	28 (1.2%)	58 (1.3%)
YES	2297 (98.7%)	2276 (98.8%)	4573 (98.7%)
Insul. and analo. use at baseline (N)			
NO	1042 (44.8%)	1049 (45.5%)	2091 (45.2%)
YES	1285 (55.2%)	1255 (54.5%)	2540 (54.8%)
Dip pep 4 inhibitors use at baseline (N)			
NO	1808 (77.7%)	1827 (79.3%)	3635 (78.5%)
YES	519 (22.3%)	477 (20.7%)	996 (21.5%)
GLP1 agonists use at baseline (N)			
NO	2136 (91.8%)	2150 (93.3%)	4286 (92.6%)
YES	191 (8.2%)	154 (6.7%)	345 (7.4%)
SGLT-2 inhib. use at baseline (N)			
NO	2096 (90.1%)	2080 (90.3%)	4176 (90.2%)
YES	231 (9.9%)	224 (9.7%)	455 (9.8%)
Biguanides use at baseline (N)			
NO	482 (20.7%)	531 (23.0%)	1013 (21.9%)
YES	1845 (79.3%)	1773 (77.0%)	3618 (78.1%)
Sulfonamides use at baseline (N)			
NO	1687 (72.5%)	1636 (71.0%)	3323 (71.8%)
YES	640 (27.5%)	668 (29.0%)	1308 (28.2%)
Alpha gluc. inhib. use at baseline (N)			
NO	2217 (95.3%)	2187 (94.9%)	4404 (95.1%)
YES	110 (4.7%)	117 (5.1%)	227 (4.9%)
Meglitinides use at baseline (N)			
NO	2270 (97.6%)	2255 (97.9%)	4525 (97.7%)
YES	57 (2.4%)	49 (2.1%)	106 (2.3%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Thiazolidinediones use at baseline (N)			
NO	2244 (96.4%)	2225 (96.6%)	4469 (96.5%)
YES	83 (3.6%)	79 (3.4%)	162 (3.5%)
Potassium supplement use at baseline (N)			
NO	2274 (97.7%)	2254 (97.8%)	4528 (97.8%)
YES	53 (2.3%)	50 (2.2%)	103 (2.2%)
Potassium lowering use at baseline (N)			
NO	2315 (99.5%)	2293 (99.5%)	4608 (99.5%)
YES	12 (0.5%)	11 (0.5%)	23 (0.5%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	18 (0.8%)	19 (0.8%)	37 (0.8%)
unclassified	26 (1.1%)	39 (1.7%)	65 (1.4%)
moderate	43 (1.8%)	43 (1.9%)	86 (1.9%)
weak	1247 (53.6%)	1244 (54.0%)	2491 (53.8%)
none	993 (42.7%)	959 (41.6%)	1952 (42.2%)
Potency CYP3A4 inducer at baseline (N)			
strong	2 (<0.1%)	5 (0.2%)	7 (0.2%)
unclassified	6 (0.3%)	6 (0.3%)	12 (0.3%)
moderate	2 (<0.1%)	6 (0.3%)	8 (0.2%)
weak	77 (3.3%)	72 (3.1%)	149 (3.2%)
none	2240 (96.3%)	2215 (96.1%)	4455 (96.2%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:15
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4.5 Medical History

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Number (%) of subjects with at least one medical history finding	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Blood and lymphatic system disorders	199 (8.6%)	193 (8.4%)	392 (8.5%)
Anaemia	110 (4.7%)	118 (5.1%)	228 (4.9%)
Anaemia megaloblastic	0	1 (<0.1%)	1 (<0.1%)
Anaemia of chronic disease	0	2 (<0.1%)	2 (<0.1%)
Aplasia pure red cell	1 (<0.1%)	0	1 (<0.1%)
Blood loss anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coagulopathy	1 (<0.1%)	0	1 (<0.1%)
Deficiency anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eosinophilia	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic diathesis	1 (<0.1%)	0	1 (<0.1%)
Hypercoagulation	2 (<0.1%)	0	2 (<0.1%)
Hyperfibrinogenaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	0	2 (<0.1%)
Immune thrombocytopenia	0	1 (<0.1%)	1 (<0.1%)
Increased tendency to bruise	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	25 (1.1%)	25 (1.1%)	50 (1.1%)
Leukocytosis	11 (0.5%)	8 (0.3%)	19 (0.4%)
Leukopenia	0	4 (0.2%)	4 (<0.1%)
Lymphadenitis	1 (<0.1%)	0	1 (<0.1%)
Lymphadenopathy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Lymphadenopathy mediastinal	0	1 (<0.1%)	1 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Macrocytosis	0	2 (<0.1%)	2 (<0.1%)
Microcytic anaemia	2 (<0.1%)	0	2 (<0.1%)
Microcytosis	0	1 (<0.1%)	1 (<0.1%)
Nephrogenic anaemia	8 (0.3%)	4 (0.2%)	12 (0.3%)
Normochromic normocytic anaemia	0	2 (<0.1%)	2 (<0.1%)
Normocytic anaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pancytopenia	0	1 (<0.1%)	1 (<0.1%)
Pernicious anaemia	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Polycythaemia	8 (0.3%)	7 (0.3%)	15 (0.3%)
Spleen disorder	0	1 (<0.1%)	1 (<0.1%)
Splenic infarction	1 (<0.1%)	0	1 (<0.1%)
Splenic lesion	1 (<0.1%)	0	1 (<0.1%)
Splenitis	0	1 (<0.1%)	1 (<0.1%)
Splenomegaly	9 (0.4%)	6 (0.3%)	15 (0.3%)
Thrombocytopenia	11 (0.5%)	13 (0.6%)	24 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Thrombocytosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Cardiac disorders	1006 (43.2%)	984 (42.7%)	1990 (43.0%)
Acute coronary syndrome	0	2 (<0.1%)	2 (<0.1%)
Acute myocardial infarction	7 (0.3%)	5 (0.2%)	12 (0.3%)
Angina pectoris	116 (5.0%)	116 (5.0%)	232 (5.0%)
Angina unstable	21 (0.9%)	20 (0.9%)	41 (0.9%)
Aortic valve calcification	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Aortic valve disease	0	3 (0.1%)	3 (<0.1%)
Aortic valve incompetence	14 (0.6%)	9 (0.4%)	23 (0.5%)
Aortic valve sclerosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Aortic valve stenosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Aortic valve thickening	0	1 (<0.1%)	1 (<0.1%)
Arrhythmia	18 (0.8%)	21 (0.9%)	39 (0.8%)
Arrhythmia supraventricular	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Arteriosclerosis coronary artery	41 (1.8%)	36 (1.6%)	77 (1.7%)
Atrial conduction time prolongation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrial enlargement	2 (<0.1%)	0	2 (<0.1%)
Atrial fibrillation	139 (6.0%)	148 (6.4%)	287 (6.2%)
Atrial flutter	19 (0.8%)	11 (0.5%)	30 (0.6%)
Atrial tachycardia	1 (<0.1%)	0	1 (<0.1%)
Atrial thrombosis	1 (<0.1%)	0	1 (<0.1%)
Atrioventricular block	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Atrioventricular block complete	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Atrioventricular block first degree	18 (0.8%)	34 (1.5%)	52 (1.1%)
Atrioventricular block second degree	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Bradyarrhythmia	1 (<0.1%)	0	1 (<0.1%)
Bradycardia	6 (0.3%)	6 (0.3%)	12 (0.3%)
Bundle branch block bilateral	0	2 (<0.1%)	2 (<0.1%)
Bundle branch block left	23 (1.0%)	41 (1.8%)	64 (1.4%)
Bundle branch block right	45 (1.9%)	44 (1.9%)	89 (1.9%)
Cardiac aneurysm	3 (0.1%)	0	3 (<0.1%)
Cardiac arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiac asthma	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	1 (<0.1%)	0	1 (<0.1%)
Cardiac dysfunction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac failure	35 (1.5%)	36 (1.6%)	71 (1.5%)
Cardiac failure acute	1 (<0.1%)	0	1 (<0.1%)
Cardiac failure chronic	100 (4.3%)	80 (3.5%)	180 (3.9%)
Cardiac failure congestive	15 (0.6%)	16 (0.7%)	31 (0.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Cardiac hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac septal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Cardiac valve disease	3 (0.1%)	4 (0.2%)	7 (0.2%)
Cardiac valve sclerosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiomegaly	8 (0.3%)	9 (0.4%)	17 (0.4%)
Cardiomyopathy	14 (0.6%)	7 (0.3%)	21 (0.5%)
Cardiovascular disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiovascular insufficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic left ventricular failure	5 (0.2%)	5 (0.2%)	10 (0.2%)
Congestive cardiomyopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Cor pulmonale	1 (<0.1%)	0	1 (<0.1%)
Cor pulmonale chronic	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Coronary artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Coronary artery disease	566 (24.3%)	531 (23.0%)	1097 (23.7%)
Coronary artery insufficiency	1 (<0.1%)	0	1 (<0.1%)
Coronary artery occlusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Coronary artery stenosis	2 (<0.1%)	7 (0.3%)	9 (0.2%)
Coronary artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Defect conduction intraventricular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Degenerative aortic valve disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Diastolic dysfunction	8 (0.3%)	10 (0.4%)	18 (0.4%)
Dilatation atrial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dressler's syndrome	0	1 (<0.1%)	1 (<0.1%)
Extrasystoles	4 (0.2%)	6 (0.3%)	10 (0.2%)
Heart valve calcification	0	1 (<0.1%)	1 (<0.1%)
Heart valve incompetence	0	1 (<0.1%)	1 (<0.1%)
Hypertensive cardiomyopathy	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Hypertensive heart disease	20 (0.9%)	28 (1.2%)	48 (1.0%)
Ischaemic cardiomyopathy	6 (0.3%)	7 (0.3%)	13 (0.3%)
Left atrial dilatation	4 (0.2%)	4 (0.2%)	8 (0.2%)
Left atrial enlargement	4 (0.2%)	6 (0.3%)	10 (0.2%)
Left atrial hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Left ventricular dysfunction	6 (0.3%)	6 (0.3%)	12 (0.3%)
Left ventricular enlargement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular failure	5 (0.2%)	4 (0.2%)	9 (0.2%)
Left ventricular hypertrophy	53 (2.3%)	62 (2.7%)	115 (2.5%)
Low cardiac output syndrome	0	1 (<0.1%)	1 (<0.1%)
Malignant hypertensive heart disease	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Metabolic cardiomyopathy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Mitral valve calcification	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mitral valve disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mitral valve incompetence	29 (1.2%)	22 (1.0%)	51 (1.1%)
Mitral valve sclerosis	1 (<0.1%)	0	1 (<0.1%)
Mitral valve stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Myocardial fibrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Myocardial infarction	315 (13.5%)	299 (13.0%)	614 (13.3%)
Myocardial ischaemia	103 (4.4%)	94 (4.1%)	197 (4.3%)
Myocardial necrosis	0	1 (<0.1%)	1 (<0.1%)
Myocarditis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodal rhythm	1 (<0.1%)	0	1 (<0.1%)
Palpitations	7 (0.3%)	7 (0.3%)	14 (0.3%)
Pericardial cyst	1 (<0.1%)	0	1 (<0.1%)
Pericardial effusion	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Pericarditis	3 (0.1%)	0	3 (<0.1%)
Pericarditis constrictive	0	1 (<0.1%)	1 (<0.1%)
Prinzmetal angina	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pulmonary valve incompetence	1 (<0.1%)	0	1 (<0.1%)
Rheumatic heart disease	1 (<0.1%)	0	1 (<0.1%)
Right ventricular dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular dysfunction	0	1 (<0.1%)	1 (<0.1%)
Right ventricular hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Silent myocardial infarction	0	1 (<0.1%)	1 (<0.1%)
Sinus arrhythmia	6 (0.3%)	4 (0.2%)	10 (0.2%)
Sinus bradycardia	9 (0.4%)	21 (0.9%)	30 (0.6%)
Sinus node dysfunction	4 (0.2%)	3 (0.1%)	7 (0.2%)
Sinus tachycardia	5 (0.2%)	9 (0.4%)	14 (0.3%)
Supraventricular extrasystoles	17 (0.7%)	11 (0.5%)	28 (0.6%)
Supraventricular tachycardia	9 (0.4%)	4 (0.2%)	13 (0.3%)
Systolic dysfunction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tachyarrhythmia	0	1 (<0.1%)	1 (<0.1%)
Tachycardia	7 (0.3%)	4 (0.2%)	11 (0.2%)
Tachycardia induced cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Tachycardia paroxysmal	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Tricuspid valve disease	0	2 (<0.1%)	2 (<0.1%)
Tricuspid valve incompetence	21 (0.9%)	16 (0.7%)	37 (0.8%)
Tricuspid valve sclerosis	1 (<0.1%)	0	1 (<0.1%)
Trifascicular block	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Ventricular extrasystoles	15 (0.6%)	17 (0.7%)	32 (0.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Ventricular fibrillation	0	2 (<0.1%)	2 (<0.1%)
Ventricular hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Ventricular hypokinesia	1 (<0.1%)	0	1 (<0.1%)
Ventricular remodelling	1 (<0.1%)	0	1 (<0.1%)
Ventricular tachycardia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Wolff-Parkinson-White syndrome	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Congenital, familial and genetic disorders	107 (4.6%)	91 (3.9%)	198 (4.3%)
Accessory spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adenomatous polyposis coli	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Albinism	1 (<0.1%)	0	1 (<0.1%)
Arnold-Chiari malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cone dystrophy	0	1 (<0.1%)	1 (<0.1%)
Congenital cystic kidney disease	0	1 (<0.1%)	1 (<0.1%)
Congenital ectopic pancreas	0	1 (<0.1%)	1 (<0.1%)
Congenital hearing disorder	1 (<0.1%)	0	1 (<0.1%)
Congenital hydronephrosis	0	1 (<0.1%)	1 (<0.1%)
Congenital hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Congenital musculoskeletal anomaly	1 (<0.1%)	0	1 (<0.1%)
Congenital myopia	1 (<0.1%)	0	1 (<0.1%)
Congenital nose malformation	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	7 (0.3%)	4 (0.2%)	11 (0.2%)
Congenital spinal fusion	0	1 (<0.1%)	1 (<0.1%)
Congenital ureteric anomaly	1 (<0.1%)	0	1 (<0.1%)
Corneal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Craniofacial deformity	1 (<0.1%)	0	1 (<0.1%)
Cryptorchism	0	1 (<0.1%)	1 (<0.1%)
Dermoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Developmental hip dysplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dolichocolon	0	2 (<0.1%)	2 (<0.1%)
Ectopic kidney	5 (0.2%)	0	5 (0.1%)
Exomphalos	1 (<0.1%)	0	1 (<0.1%)
Familial hypertriglyceridaemia	1 (<0.1%)	0	1 (<0.1%)
Familial mediterranean fever	0	1 (<0.1%)	1 (<0.1%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	2 (<0.1%)	0	2 (<0.1%)
Gitelman's syndrome	1 (<0.1%)	0	1 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Haemoglobinopathy	1 (<0.1%)	0	1 (<0.1%)
Heart disease congenital	1 (<0.1%)	0	1 (<0.1%)
Hepatic hamartoma	0	1 (<0.1%)	1 (<0.1%)
Hereditary motor and sensory neuropathy	1 (<0.1%)	0	1 (<0.1%)
Homocystinaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Homocystinuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrocele	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Hypertrophic cardiomyopathy	4 (0.2%)	8 (0.3%)	12 (0.3%)
Kidney duplex	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Kimmerle's anomaly	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	2 (<0.1%)	2 (<0.1%)
Klippel-Feil syndrome	1 (<0.1%)	0	1 (<0.1%)
Multiple endocrine neoplasia Type 1	1 (<0.1%)	0	1 (<0.1%)
Muscular dystrophy	1 (<0.1%)	0	1 (<0.1%)
Myotonic dystrophy	1 (<0.1%)	0	1 (<0.1%)
Patent ductus arteriosus	0	1 (<0.1%)	1 (<0.1%)
Phimosis	6 (0.3%)	4 (0.2%)	10 (0.2%)
Protein C deficiency	0	1 (<0.1%)	1 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Renal fusion anomaly	1 (<0.1%)	0	1 (<0.1%)
Retinopathy congenital	1 (<0.1%)	0	1 (<0.1%)
Sickle cell trait	2 (<0.1%)	0	2 (<0.1%)
Spinal muscular atrophy	1 (<0.1%)	0	1 (<0.1%)
Strabismus congenital	1 (<0.1%)	0	1 (<0.1%)
Synostosis	1 (<0.1%)	0	1 (<0.1%)
Thalassaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thalassaemia alpha	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Thalassaemia beta	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Thalassaemia minor	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Thyroglossal cyst	1 (<0.1%)	0	1 (<0.1%)
Type IIa hyperlipidaemia	4 (0.2%)	6 (0.3%)	10 (0.2%)
Type IIb hyperlipidaemia	3 (0.1%)	4 (0.2%)	7 (0.2%)
Type V hyperlipidaemia	29 (1.2%)	23 (1.0%)	52 (1.1%)
Ventricular septal defect	0	1 (<0.1%)	1 (<0.1%)
Ear and labyrinth disorders	124 (5.3%)	105 (4.6%)	229 (4.9%)
Allergic otitis media	0	1 (<0.1%)	1 (<0.1%)
Auditory disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Aural polyp	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Conductive deafness	1 (<0.1%)	0	1 (<0.1%)
Deafness	19 (0.8%)	15 (0.7%)	34 (0.7%)
Deafness bilateral	7 (0.3%)	8 (0.3%)	15 (0.3%)
Deafness neurosensory	12 (0.5%)	6 (0.3%)	18 (0.4%)
Deafness unilateral	4 (0.2%)	7 (0.3%)	11 (0.2%)
Ear discomfort	1 (<0.1%)	0	1 (<0.1%)
Ear pain	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Eustachian tube disorder	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	1 (<0.1%)	0	1 (<0.1%)
Eustachian tube stenosis	0	1 (<0.1%)	1 (<0.1%)
Excessive cerumen production	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exostosis of external ear canal	0	1 (<0.1%)	1 (<0.1%)
Hypoacusis	15 (0.6%)	11 (0.5%)	26 (0.6%)
Labyrinthine fistula	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Middle ear disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Middle ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	1 (<0.1%)	0	1 (<0.1%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	0	2 (<0.1%)	2 (<0.1%)
Otosclerosis	3 (0.1%)	0	3 (<0.1%)
Presbyacusis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sudden hearing loss	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tinnitus	23 (1.0%)	12 (0.5%)	35 (0.8%)
Tympanic membrane perforation	0	4 (0.2%)	4 (<0.1%)
Vertigo	26 (1.1%)	29 (1.3%)	55 (1.2%)
Vertigo positional	6 (0.3%)	6 (0.3%)	12 (0.3%)
Vestibular ataxia	5 (0.2%)	3 (0.1%)	8 (0.2%)
Vestibular disorder	5 (0.2%)	3 (0.1%)	8 (0.2%)
Endocrine disorders	315 (13.5%)	296 (12.8%)	611 (13.2%)
Acromegaly	0	1 (<0.1%)	1 (<0.1%)
Adrenal cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adrenal mass	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Androgen deficiency	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Autoimmune hypothyroidism	2 (<0.1%)	0	2 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	0	1 (<0.1%)
Autoimmune thyroiditis	21 (0.9%)	19 (0.8%)	40 (0.9%)
Basedow's disease	5 (0.2%)	3 (0.1%)	8 (0.2%)
Cushing's syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Endocrine disorder	0	1 (<0.1%)	1 (<0.1%)
Goitre	85 (3.7%)	68 (3.0%)	153 (3.3%)
Hyperaldosteronism	0	4 (0.2%)	4 (<0.1%)
Hyperparathyroidism	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Hyperparathyroidism primary	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hyperparathyroidism secondary	0	2 (<0.1%)	2 (<0.1%)
Hyperplasia adrenal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperprolactinaemia	2 (<0.1%)	0	2 (<0.1%)
Hyperthyroidism	12 (0.5%)	14 (0.6%)	26 (0.6%)
Hypogonadism	6 (0.3%)	5 (0.2%)	11 (0.2%)
Hypogonadism male	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypopituitarism	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypothalamo-pituitary disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypothyroidism	152 (6.5%)	148 (6.4%)	300 (6.5%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	0	1 (<0.1%)	1 (<0.1%)
Oestrogen deficiency	1 (<0.1%)	0	1 (<0.1%)
Primary hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary hypothyroidism	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Secondary hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Testicular failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Thyroid calcification	2 (<0.1%)	0	2 (<0.1%)
Thyroid cyst	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Thyroid disorder	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Thyroid mass	34 (1.5%)	23 (1.0%)	57 (1.2%)
Thyroiditis chronic	0	1 (<0.1%)	1 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Toxic nodular goitre	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Eye disorders	1088 (46.8%)	1053 (45.7%)	2141 (46.2%)
Age-related macular degeneration	3 (0.1%)	3 (0.1%)	6 (0.1%)
Amaurosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Amaurosis fugax	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amblyopia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amblyopia strabismic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angle closure glaucoma	0	1 (<0.1%)	1 (<0.1%)
Arcus lipoides	1 (<0.1%)	0	1 (<0.1%)
Arteriosclerotic retinopathy	8 (0.3%)	8 (0.3%)	16 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Asthenopia	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Astigmatism	12 (0.5%)	12 (0.5%)	24 (0.5%)
Atrophy of globe	1 (<0.1%)	0	1 (<0.1%)
Blepharitis	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Blepharitis allergic	0	1 (<0.1%)	1 (<0.1%)
Blepharochalasis	1 (<0.1%)	0	1 (<0.1%)
Blindness	6 (0.3%)	1 (<0.1%)	7 (0.2%)
Blindness unilateral	9 (0.4%)	6 (0.3%)	15 (0.3%)
Borderline glaucoma	3 (0.1%)	4 (0.2%)	7 (0.2%)
Cataract	288 (12.4%)	282 (12.2%)	570 (12.3%)
Cataract cortical	1 (<0.1%)	0	1 (<0.1%)
Cataract diabetic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cataract nuclear	9 (0.4%)	7 (0.3%)	16 (0.3%)
Cataract subcapsular	2 (<0.1%)	0	2 (<0.1%)
Chorioretinal atrophy	2 (<0.1%)	0	2 (<0.1%)
Choroidal neovascularisation	1 (<0.1%)	0	1 (<0.1%)
Conjunctival haemorrhage	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Conjunctival hyperaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conjunctivitis allergic	12 (0.5%)	6 (0.3%)	18 (0.4%)
Corneal degeneration	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	1 (<0.1%)	0	1 (<0.1%)
Corneal erosion	0	2 (<0.1%)	2 (<0.1%)
Corneal leukoma	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	0	1 (<0.1%)	1 (<0.1%)
Dacryolith	1 (<0.1%)	0	1 (<0.1%)
Dacryostenosis acquired	1 (<0.1%)	0	1 (<0.1%)
Dermatochalasis	0	1 (<0.1%)	1 (<0.1%)
Diabetic eye disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinal oedema	14 (0.6%)	6 (0.3%)	20 (0.4%)
Diabetic retinopathy	806 (34.6%)	734 (31.9%)	1540 (33.3%)
Diplopia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dry age-related macular degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dry eye	18 (0.8%)	22 (1.0%)	40 (0.9%)
Eales' disease	0	1 (<0.1%)	1 (<0.1%)
Ectropion	1 (<0.1%)	0	1 (<0.1%)
Eczema eyelids	1 (<0.1%)	0	1 (<0.1%)
Endocrine ophthalmopathy	0	1 (<0.1%)	1 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye allergy	0	1 (<0.1%)	1 (<0.1%)
Eye disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye haemorrhage	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye oedema	1 (<0.1%)	0	1 (<0.1%)
Eye opacity	0	1 (<0.1%)	1 (<0.1%)
Eyelid oedema	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eyelid pain	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	5 (0.2%)	4 (0.2%)	9 (0.2%)
Eyelid skin dryness	1 (<0.1%)	0	1 (<0.1%)
Flat anterior chamber of eye	1 (<0.1%)	0	1 (<0.1%)
Glaucoma	99 (4.3%)	104 (4.5%)	203 (4.4%)
Hypermetropia	15 (0.6%)	20 (0.9%)	35 (0.8%)
Idiopathic orbital inflammation	1 (<0.1%)	0	1 (<0.1%)
Iridocyclitis	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Iris adhesions	0	1 (<0.1%)	1 (<0.1%)
Keratitis	3 (0.1%)	0	3 (<0.1%)
Keratoconus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	1 (<0.1%)	0	1 (<0.1%)
Lacrimal disorder	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lacrimation increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lenticular opacities	0	1 (<0.1%)	1 (<0.1%)
Macular cyst	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	13 (0.6%)	12 (0.5%)	25 (0.5%)
Macular fibrosis	7 (0.3%)	4 (0.2%)	11 (0.2%)
Macular hole	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	16 (0.7%)	15 (0.7%)	31 (0.7%)
Macular scar	0	1 (<0.1%)	1 (<0.1%)
Maculopathy	9 (0.4%)	5 (0.2%)	14 (0.3%)
Meibomianitis	1 (<0.1%)	0	1 (<0.1%)
Metamorphopsia	0	1 (<0.1%)	1 (<0.1%)
Myopia	34 (1.5%)	32 (1.4%)	66 (1.4%)
Myopic chorioretinal degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-proliferative retinopathy	0	3 (0.1%)	3 (<0.1%)
Normal tension glaucoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ocular discomfort	2 (<0.1%)	0	2 (<0.1%)
Ocular hyperaemia	0	1 (<0.1%)	1 (<0.1%)
Ocular hypertension	4 (0.2%)	8 (0.3%)	12 (0.3%)
Open angle glaucoma	7 (0.3%)	5 (0.2%)	12 (0.3%)
Ophthalmoplegia	2 (<0.1%)	0	2 (<0.1%)
Optic atrophy	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Optic disc haemorrhage	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Optic ischaemic neuropathy	0	4 (0.2%)	4 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Pathologic myopia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Periorbital fat herniation	1 (<0.1%)	0	1 (<0.1%)
Posterior capsule opacification	0	2 (<0.1%)	2 (<0.1%)
Presbyopia	29 (1.2%)	38 (1.6%)	67 (1.4%)
Pseudopapilloedema	0	1 (<0.1%)	1 (<0.1%)
Pterygium	5 (0.2%)	13 (0.6%)	18 (0.4%)
Punctate keratitis	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	6 (0.3%)	7 (0.3%)	13 (0.3%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery spasm	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Retinal cyst	1 (<0.1%)	0	1 (<0.1%)
Retinal degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal detachment	12 (0.5%)	12 (0.5%)	24 (0.5%)
Retinal disorder	1 (<0.1%)	0	1 (<0.1%)
Retinal drusen	0	2 (<0.1%)	2 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	6 (0.3%)	9 (0.4%)	15 (0.3%)
Retinal oedema	1 (<0.1%)	0	1 (<0.1%)
Retinal pigment epitheliopathy	2 (<0.1%)	0	2 (<0.1%)
Retinal scar	0	1 (<0.1%)	1 (<0.1%)
Retinal tear	0	1 (<0.1%)	1 (<0.1%)
Retinal vascular disorder	10 (0.4%)	13 (0.6%)	23 (0.5%)
Retinal vascular thrombosis	1 (<0.1%)	0	1 (<0.1%)
Retinal vein occlusion	7 (0.3%)	0	7 (0.2%)
Retinal vein thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinopathy	5 (0.2%)	4 (0.2%)	9 (0.2%)
Retinopathy hypertensive	25 (1.1%)	34 (1.5%)	59 (1.3%)
Retinopathy proliferative	2 (<0.1%)	0	2 (<0.1%)
Retinoschisis	1 (<0.1%)	0	1 (<0.1%)
Scintillating scotoma	0	1 (<0.1%)	1 (<0.1%)
Scleritis	0	2 (<0.1%)	2 (<0.1%)
Strabismus	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Swelling of eyelid	0	1 (<0.1%)	1 (<0.1%)
Trichiasis	0	1 (<0.1%)	1 (<0.1%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	0	1 (<0.1%)	1 (<0.1%)
Vision blurred	4 (0.2%)	4 (0.2%)	8 (0.2%)
Visual acuity reduced	3 (0.1%)	5 (0.2%)	8 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Visual impairment	4 (0.2%)	7 (0.3%)	11 (0.2%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	5 (0.2%)	0	5 (0.1%)
Vitreous detachment	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Vitreous fibrin	0	1 (<0.1%)	1 (<0.1%)
Vitreous floaters	0	2 (<0.1%)	2 (<0.1%)
Vitreous haemorrhage	20 (0.9%)	10 (0.4%)	30 (0.6%)
Vitreous opacities	2 (<0.1%)	0	2 (<0.1%)
Vogt-Koyanagi-Harada disease	0	1 (<0.1%)	1 (<0.1%)
Xanthopsia	0	1 (<0.1%)	1 (<0.1%)
Xerophthalmia	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	727 (31.2%)	737 (32.0%)	1464 (31.6%)
Abdominal discomfort	0	1 (<0.1%)	1 (<0.1%)
Abdominal distension	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Abdominal hernia	6 (0.3%)	8 (0.3%)	14 (0.3%)
Abdominal pain	4 (0.2%)	4 (0.2%)	8 (0.2%)
Abdominal pain lower	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Abdominal pain upper	6 (0.3%)	11 (0.5%)	17 (0.4%)
Abnormal faeces	0	1 (<0.1%)	1 (<0.1%)
Acid peptic disease	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Acquired oesophageal web	2 (<0.1%)	0	2 (<0.1%)
Aerophagia	1 (<0.1%)	0	1 (<0.1%)
Alcoholic pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Anal fistula	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Anal haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Anal incontinence	3 (0.1%)	0	3 (<0.1%)
Anal polyp	0	1 (<0.1%)	1 (<0.1%)
Anal pruritus	0	1 (<0.1%)	1 (<0.1%)
Anal skin tags	0	1 (<0.1%)	1 (<0.1%)
Aphthous ulcer	0	1 (<0.1%)	1 (<0.1%)
Appendicitis noninfective	0	1 (<0.1%)	1 (<0.1%)
Aptyalism	1 (<0.1%)	0	1 (<0.1%)
Ascites	1 (<0.1%)	0	1 (<0.1%)
Barrett's oesophagus	6 (0.3%)	5 (0.2%)	11 (0.2%)
Cardiospasm	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	67 (2.9%)	87 (3.8%)	154 (3.3%)
Coeliac disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colitis	9 (0.4%)	8 (0.3%)	17 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Colitis ulcerative	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Colon dysplasia	1 (<0.1%)	0	1 (<0.1%)
Constipation	80 (3.4%)	55 (2.4%)	135 (2.9%)
Crohn's disease	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Dental caries	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Dental cyst	0	1 (<0.1%)	1 (<0.1%)
Diabetic enteropathy	1 (<0.1%)	0	1 (<0.1%)
Diabetic gastroparesis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Diabetic gastropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic hernia	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Diarrhoea	26 (1.1%)	32 (1.4%)	58 (1.3%)
Diverticulum	11 (0.5%)	22 (1.0%)	33 (0.7%)
Diverticulum intestinal	24 (1.0%)	11 (0.5%)	35 (0.8%)
Dry mouth	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Duodenal polyp	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Duodenal ulcer	13 (0.6%)	14 (0.6%)	27 (0.6%)
Duodenal ulcer haemorrhage	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Duodenitis	4 (0.2%)	6 (0.3%)	10 (0.2%)
Duodenogastric reflux	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dyspepsia	34 (1.5%)	37 (1.6%)	71 (1.5%)
Dysphagia	6 (0.3%)	4 (0.2%)	10 (0.2%)
Ectopic gastric mucosa	0	1 (<0.1%)	1 (<0.1%)
Enteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterocolitis	1 (<0.1%)	0	1 (<0.1%)
Enterovesical fistula	1 (<0.1%)	0	1 (<0.1%)
Epigastric discomfort	0	2 (<0.1%)	2 (<0.1%)
Erosive duodenitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Erosive oesophagitis	2 (<0.1%)	0	2 (<0.1%)
Fistula of small intestine	0	1 (<0.1%)	1 (<0.1%)
Flatulence	4 (0.2%)	3 (0.1%)	7 (0.2%)
Food poisoning	0	1 (<0.1%)	1 (<0.1%)
Functional gastrointestinal disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallstone ileus	1 (<0.1%)	0	1 (<0.1%)
Gastric disorder	3 (0.1%)	0	3 (<0.1%)
Gastric haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	0	2 (<0.1%)	2 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	9 (0.4%)	9 (0.4%)	18 (0.4%)
Gastric ulcer	23 (1.0%)	27 (1.2%)	50 (1.1%)
Gastric ulcer haemorrhage	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Gastric ulcer perforation	1 (<0.1%)	0	1 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastritis	76 (3.3%)	66 (2.9%)	142 (3.1%)
Gastritis erosive	11 (0.5%)	6 (0.3%)	17 (0.4%)
Gastritis haemorrhagic	0	1 (<0.1%)	1 (<0.1%)
Gastroduodenal ulcer	0	3 (0.1%)	3 (<0.1%)
Gastrointestinal angiectasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal angiodysplasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorder	4 (0.2%)	5 (0.2%)	9 (0.2%)
Gastrointestinal dysplasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal haemorrhage	5 (0.2%)	4 (0.2%)	9 (0.2%)
Gastrointestinal hypomotility	0	2 (<0.1%)	2 (<0.1%)
Gastrointestinal inflammation	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal motility disorder	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal polyp	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal polyp haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal scarring	0	1 (<0.1%)	1 (<0.1%)
Gastrooesophageal reflux disease	176 (7.6%)	179 (7.8%)	355 (7.7%)
Gingival bleeding	1 (<0.1%)	0	1 (<0.1%)
Gingival hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gingival pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematochezia	0	2 (<0.1%)	2 (<0.1%)
Haemorrhagic erosive gastritis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoidal haemorrhage	3 (0.1%)	0	3 (<0.1%)
Haemorrhoids	42 (1.8%)	49 (2.1%)	91 (2.0%)
Hernial eventration	0	2 (<0.1%)	2 (<0.1%)
Hiatus hernia	24 (1.0%)	29 (1.3%)	53 (1.1%)
Ileus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Impaired gastric emptying	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Incarcerated umbilical hernia	1 (<0.1%)	0	1 (<0.1%)
Inflammatory bowel disease	0	2 (<0.1%)	2 (<0.1%)
Inguinal hernia	10 (0.4%)	30 (1.3%)	40 (0.9%)
Internal hernia	0	1 (<0.1%)	1 (<0.1%)
Intestinal ischaemia	2 (<0.1%)	0	2 (<0.1%)
Intestinal metaplasia	0	1 (<0.1%)	1 (<0.1%)
Intestinal obstruction	0	4 (0.2%)	4 (<0.1%)
Intestinal perforation	3 (0.1%)	0	3 (<0.1%)
Intestinal polyp	3 (0.1%)	3 (0.1%)	6 (0.1%)
Irritable bowel syndrome	14 (0.6%)	21 (0.9%)	35 (0.8%)
Large intestinal haemorrhage	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Large intestinal stenosis	0	1 (<0.1%)	1 (<0.1%)
Large intestine polyp	25 (1.1%)	35 (1.5%)	60 (1.3%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lip disorder	1 (<0.1%)	0	1 (<0.1%)
Lip swelling	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Lumbar hernia	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Melaena	0	3 (0.1%)	3 (<0.1%)
Mouth cyst	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	0	1 (<0.1%)
Nausea	10 (0.4%)	13 (0.6%)	23 (0.5%)
Odynophagia	0	1 (<0.1%)	1 (<0.1%)
Oesophageal dilatation	0	1 (<0.1%)	1 (<0.1%)
Oesophageal disorder	1 (<0.1%)	0	1 (<0.1%)
Oesophageal obstruction	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophagitis	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Oesophagitis ulcerative	0	1 (<0.1%)	1 (<0.1%)
Oral disorder	0	1 (<0.1%)	1 (<0.1%)
Pancreatic atrophy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic cyst	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Pancreatic failure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pancreatic necrosis	0	1 (<0.1%)	1 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	2 (<0.1%)	0	2 (<0.1%)
Pancreatitis	12 (0.5%)	9 (0.4%)	21 (0.5%)
Pancreatitis acute	13 (0.6%)	9 (0.4%)	22 (0.5%)
Pancreatitis chronic	32 (1.4%)	37 (1.6%)	69 (1.5%)
Pancreatitis necrotising	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatitis relapsing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatolithiasis	0	1 (<0.1%)	1 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer	15 (0.6%)	12 (0.5%)	27 (0.6%)
Periodontal disease	123 (5.3%)	112 (4.9%)	235 (5.1%)
Peristalsis visible	1 (<0.1%)	0	1 (<0.1%)
Poor dental condition	1 (<0.1%)	0	1 (<0.1%)
Presbyoesophagus	1 (<0.1%)	0	1 (<0.1%)
Proctitis	0	1 (<0.1%)	1 (<0.1%)
Rectal fissure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal haemorrhage	3 (0.1%)	5 (0.2%)	8 (0.2%)
Rectal polyp	2 (<0.1%)	3 (0.1%)	5 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Rectal prolapse	1 (<0.1%)	0	1 (<0.1%)
Salivary gland disorder	0	1 (<0.1%)	1 (<0.1%)
Short-bowel syndrome	1 (<0.1%)	0	1 (<0.1%)
Spigelian hernia	1 (<0.1%)	0	1 (<0.1%)
Splenic artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Stomatitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tongue dysplasia	0	1 (<0.1%)	1 (<0.1%)
Tongue oedema	0	1 (<0.1%)	1 (<0.1%)
Tooth disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth loss	2 (<0.1%)	0	2 (<0.1%)
Toothache	3 (0.1%)	3 (0.1%)	6 (0.1%)
Ulcerative gastritis	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	23 (1.0%)	33 (1.4%)	56 (1.2%)
Upper gastrointestinal haemorrhage	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varices oesophageal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vomiting	3 (0.1%)	6 (0.3%)	9 (0.2%)
General disorders and administration site conditions	197 (8.5%)	166 (7.2%)	363 (7.8%)
Asthenia	3 (0.1%)	7 (0.3%)	10 (0.2%)
Axillary pain	1 (<0.1%)	0	1 (<0.1%)
Calcinosis	1 (<0.1%)	0	1 (<0.1%)
Chest discomfort	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chest pain	18 (0.8%)	14 (0.6%)	32 (0.7%)
Chronic fatigue syndrome	0	1 (<0.1%)	1 (<0.1%)
Cyst	6 (0.3%)	5 (0.2%)	11 (0.2%)
Disease susceptibility	0	1 (<0.1%)	1 (<0.1%)
Drug ineffective	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	8 (0.3%)	6 (0.3%)	14 (0.3%)
Face oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial discomfort	0	1 (<0.1%)	1 (<0.1%)
Facial pain	1 (<0.1%)	0	1 (<0.1%)
Fatigue	13 (0.6%)	12 (0.5%)	25 (0.5%)
Feeling cold	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	3 (0.1%)	4 (0.2%)	7 (0.2%)
Generalised oedema	2 (<0.1%)	0	2 (<0.1%)
Gravitational oedema	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Hernia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Illness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Impaired healing	2 (<0.1%)	0	2 (<0.1%)
Inflammation	4 (0.2%)	3 (0.1%)	7 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Influenza like illness	2 (<0.1%)	0	2 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Malaise	2 (<0.1%)	0	2 (<0.1%)
Nodule	0	1 (<0.1%)	1 (<0.1%)
Non-cardiac chest pain	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oedema	20 (0.9%)	14 (0.6%)	34 (0.7%)
Oedema peripheral	89 (3.8%)	81 (3.5%)	170 (3.7%)
Pain	12 (0.5%)	12 (0.5%)	24 (0.5%)
Peripheral swelling	6 (0.3%)	4 (0.2%)	10 (0.2%)
Polyp	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Pyrexia	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Secretion discharge	1 (<0.1%)	0	1 (<0.1%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Temperature intolerance	1 (<0.1%)	0	1 (<0.1%)
Tissue infiltration	0	1 (<0.1%)	1 (<0.1%)
Treatment noncompliance	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Xerosis	0	1 (<0.1%)	1 (<0.1%)
Hepatobiliary disorders	482 (20.7%)	487 (21.1%)	969 (20.9%)
Acute hepatic failure	1 (<0.1%)	0	1 (<0.1%)
Alcoholic liver disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Autoimmune hepatitis	0	2 (<0.1%)	2 (<0.1%)
Bile duct stone	3 (0.1%)	3 (0.1%)	6 (0.1%)
Biliary colic	2 (<0.1%)	0	2 (<0.1%)
Biliary dilatation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biliary dyskinesia	5 (0.2%)	0	5 (0.1%)
Cholangitis	1 (<0.1%)	0	1 (<0.1%)
Cholangitis acute	1 (<0.1%)	0	1 (<0.1%)
Cholangitis chronic	1 (<0.1%)	0	1 (<0.1%)
Cholangitis sclerosing	2 (<0.1%)	0	2 (<0.1%)
Cholecystitis	15 (0.6%)	15 (0.7%)	30 (0.6%)
Cholecystitis acute	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cholecystitis chronic	21 (0.9%)	29 (1.3%)	50 (1.1%)
Cholelithiasis	108 (4.6%)	98 (4.3%)	206 (4.4%)
Cholestasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Chronic hepatitis	8 (0.3%)	6 (0.3%)	14 (0.3%)
Cirrhosis alcoholic	0	1 (<0.1%)	1 (<0.1%)
Diabetic hepatopathy	11 (0.5%)	5 (0.2%)	16 (0.3%)
Drug-induced liver injury	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Fatty liver alcoholic	0	1 (<0.1%)	1 (<0.1%)
Gallbladder cholesterolosis	1 (<0.1%)	0	1 (<0.1%)
Gallbladder disorder	4 (0.2%)	0	4 (<0.1%)
Gallbladder enlargement	2 (<0.1%)	0	2 (<0.1%)
Gallbladder hypofunction	1 (<0.1%)	0	1 (<0.1%)
Gallbladder polyp	10 (0.4%)	18 (0.8%)	28 (0.6%)
Granulomatous liver disease	0	1 (<0.1%)	1 (<0.1%)
Hepatic calcification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic cirrhosis	7 (0.3%)	4 (0.2%)	11 (0.2%)
Hepatic cyst	7 (0.3%)	11 (0.5%)	18 (0.4%)
Hepatic fibrosis	1 (<0.1%)	0	1 (<0.1%)
Hepatic function abnormal	6 (0.3%)	10 (0.4%)	16 (0.3%)
Hepatic lesion	0	2 (<0.1%)	2 (<0.1%)
Hepatic mass	0	1 (<0.1%)	1 (<0.1%)
Hepatic steatosis	300 (12.9%)	326 (14.1%)	626 (13.5%)
Hepatitis	3 (0.1%)	10 (0.4%)	13 (0.3%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Hepatocellular injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatomegaly	11 (0.5%)	8 (0.3%)	19 (0.4%)
Hepatotoxicity	1 (<0.1%)	0	1 (<0.1%)
Hydrocholecystis	0	1 (<0.1%)	1 (<0.1%)
Hyperbilirubinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperplastic cholecystopathy	0	2 (<0.1%)	2 (<0.1%)
Hypertransaminasaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Jaundice	0	2 (<0.1%)	2 (<0.1%)
Liver disorder	11 (0.5%)	17 (0.7%)	28 (0.6%)
Liver injury	3 (0.1%)	0	3 (<0.1%)
Non-alcoholic steatohepatitis	7 (0.3%)	7 (0.3%)	14 (0.3%)
Nonalcoholic fatty liver disease	28 (1.2%)	18 (0.8%)	46 (1.0%)
Post cholecystectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Sphincter of Oddi dysfunction	0	1 (<0.1%)	1 (<0.1%)
Steatohepatitis	6 (0.3%)	8 (0.3%)	14 (0.3%)
Immune system disorders	96 (4.1%)	105 (4.6%)	201 (4.3%)
Allergy to animal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Allergy to arthropod sting	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Allergy to chemicals	3 (0.1%)	0	3 (<0.1%)
Allergy to metals	0	2 (<0.1%)	2 (<0.1%)
Alloimmunisation	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Anaphylactic reaction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaphylactic shock	0	1 (<0.1%)	1 (<0.1%)
Autoimmune disorder	0	1 (<0.1%)	1 (<0.1%)
Contrast media allergy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cryofibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Drug hypersensitivity	32 (1.4%)	45 (2.0%)	77 (1.7%)
Dust allergy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Food allergy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Graft versus host disease	0	1 (<0.1%)	1 (<0.1%)
Hypersensitivity	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immune system disorder	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Mite allergy	3 (0.1%)	0	3 (<0.1%)
Multiple allergies	4 (0.2%)	3 (0.1%)	7 (0.2%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	1 (<0.1%)	1 (<0.1%)
Rubber sensitivity	1 (<0.1%)	0	1 (<0.1%)
Sarcoidosis	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Seasonal allergy	42 (1.8%)	41 (1.8%)	83 (1.8%)
Infections and infestations	528 (22.7%)	496 (21.5%)	1024 (22.1%)
Abdominal abscess	1 (<0.1%)	0	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	0	1 (<0.1%)
Abscess	0	1 (<0.1%)	1 (<0.1%)
Abscess limb	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Abscess neck	0	1 (<0.1%)	1 (<0.1%)
Abscess oral	1 (<0.1%)	0	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	0	2 (<0.1%)
American trypanosomiasis	0	2 (<0.1%)	2 (<0.1%)
Anal abscess	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Antibiotic associated colitis	0	1 (<0.1%)	1 (<0.1%)
Appendicitis	11 (0.5%)	9 (0.4%)	20 (0.4%)
Appendicitis perforated	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	0	1 (<0.1%)	1 (<0.1%)
Arthritis infective	0	1 (<0.1%)	1 (<0.1%)
Aspergillus infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	0	1 (<0.1%)	1 (<0.1%)
Atypical mycobacterial pneumonia	1 (<0.1%)	0	1 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Bacteraemia	0	1 (<0.1%)	1 (<0.1%)
Bacterial disease carrier	0	1 (<0.1%)	1 (<0.1%)
Bacterial infection	1 (<0.1%)	0	1 (<0.1%)
Bacterial sepsis	1 (<0.1%)	0	1 (<0.1%)
Balanitis candida	2 (<0.1%)	0	2 (<0.1%)
Balanoposthitis infective	1 (<0.1%)	0	1 (<0.1%)
Body tinea	2 (<0.1%)	0	2 (<0.1%)
Bone tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Borrelia infection	1 (<0.1%)	0	1 (<0.1%)
Bronchiolitis	1 (<0.1%)	0	1 (<0.1%)
Bronchitis	20 (0.9%)	32 (1.4%)	52 (1.1%)
Bronchitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Brucellosis	0	2 (<0.1%)	2 (<0.1%)
Campylobacter colitis	0	1 (<0.1%)	1 (<0.1%)
Candida infection	1 (<0.1%)	0	1 (<0.1%)
Carbuncle	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cellulitis	26 (1.1%)	16 (0.7%)	42 (0.9%)
Cellulitis of male external genital organ	1 (<0.1%)	0	1 (<0.1%)
Chancroid	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis infective	2 (<0.1%)	0	2 (<0.1%)
Chorioretinitis	1 (<0.1%)	0	1 (<0.1%)
Chronic hepatitis B	5 (0.2%)	6 (0.3%)	11 (0.2%)
Chronic hepatitis C	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Chronic sinusitis	19 (0.8%)	11 (0.5%)	30 (0.6%)
Chronic tonsillitis	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Conjunctivitis	20 (0.9%)	10 (0.4%)	30 (0.6%)
Conjunctivitis viral	1 (<0.1%)	0	1 (<0.1%)
Cystitis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dengue fever	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Dermatophytosis of nail	6 (0.3%)	11 (0.5%)	17 (0.4%)
Diabetic foot infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Diabetic gangrene	3 (0.1%)	4 (0.2%)	7 (0.2%)
Diarrhoea infectious	1 (<0.1%)	0	1 (<0.1%)
Disseminated tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Disseminated varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Diverticulitis	10 (0.4%)	13 (0.6%)	23 (0.5%)
Ear infection	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Eczema impetiginous	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Eczema infected	0	2 (<0.1%)	2 (<0.1%)
Emphysematous cystitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	0	2 (<0.1%)	2 (<0.1%)
Endocarditis bacterial	0	1 (<0.1%)	1 (<0.1%)
Epididymitis	3 (0.1%)	0	3 (<0.1%)
Epiglottitis	0	1 (<0.1%)	1 (<0.1%)
Epstein-Barr virus infection	0	1 (<0.1%)	1 (<0.1%)
Erysipelas	11 (0.5%)	7 (0.3%)	18 (0.4%)
Eye infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye infection toxoplasmal	1 (<0.1%)	0	1 (<0.1%)
Folliculitis	4 (0.2%)	3 (0.1%)	7 (0.2%)
Fournier's gangrene	1 (<0.1%)	0	1 (<0.1%)
Fungal infection	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Fungal skin infection	11 (0.5%)	2 (<0.1%)	13 (0.3%)
Furuncle	5 (0.2%)	3 (0.1%)	8 (0.2%)
Gallbladder abscess	1 (<0.1%)	0	1 (<0.1%)
Gangrene	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Gastroenteritis	4 (0.2%)	6 (0.3%)	10 (0.2%)
Gastroenteritis viral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Genital herpes	0	1 (<0.1%)	1 (<0.1%)
Genital infection fungal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gingivitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Groin abscess	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
HIV infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Helicobacter gastritis	0	1 (<0.1%)	1 (<0.1%)
Helicobacter infection	4 (0.2%)	6 (0.3%)	10 (0.2%)
Hepatic echinococciasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis A	10 (0.4%)	3 (0.1%)	13 (0.3%)
Hepatitis B	16 (0.7%)	10 (0.4%)	26 (0.6%)
Hepatitis C	7 (0.3%)	15 (0.7%)	22 (0.5%)
Herpes dermatitis	0	1 (<0.1%)	1 (<0.1%)
Herpes ophthalmic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Herpes simplex	0	1 (<0.1%)	1 (<0.1%)
Herpes virus infection	0	1 (<0.1%)	1 (<0.1%)
Herpes zoster	13 (0.6%)	6 (0.3%)	19 (0.4%)
Human T-cell lymphocytic virus type II infection	0	1 (<0.1%)	1 (<0.1%)
Human T-cell lymphotropic virus type I infection	0	1 (<0.1%)	1 (<0.1%)
Infected bite	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	0	1 (<0.1%)	1 (<0.1%)
Infection	1 (<0.1%)	0	1 (<0.1%)
Infectious pleural effusion	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Infective spondylitis	0	1 (<0.1%)	1 (<0.1%)
Influenza	12 (0.5%)	10 (0.4%)	22 (0.5%)
Intervertebral discitis	0	2 (<0.1%)	2 (<0.1%)
Klebsiella bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Labyrinthitis	5 (0.2%)	0	5 (0.1%)
Laryngitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Legionella infection	1 (<0.1%)	0	1 (<0.1%)
Leprosy	3 (0.1%)	0	3 (<0.1%)
Liver abscess	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Localised infection	5 (0.2%)	6 (0.3%)	11 (0.2%)
Lower respiratory tract infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lower respiratory tract infection viral	0	1 (<0.1%)	1 (<0.1%)
Lung abscess	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Lyme disease	0	1 (<0.1%)	1 (<0.1%)
Lymphangitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Mastoiditis	1 (<0.1%)	0	1 (<0.1%)
Mediastinal abscess	0	1 (<0.1%)	1 (<0.1%)
Mediastinitis	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	1 (<0.1%)	0	1 (<0.1%)
Meningitis	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Meningitis tuberculous	1 (<0.1%)	0	1 (<0.1%)
Muscle abscess	0	1 (<0.1%)	1 (<0.1%)
Myringitis	1 (<0.1%)	0	1 (<0.1%)
Nail candida	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	15 (0.6%)	17 (0.7%)	32 (0.7%)
Necrotising fasciitis	0	2 (<0.1%)	2 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Onychomycosis	37 (1.6%)	26 (1.1%)	63 (1.4%)
Oophoritis	0	1 (<0.1%)	1 (<0.1%)
Opisthorchiasis	0	1 (<0.1%)	1 (<0.1%)
Oral candidiasis	0	2 (<0.1%)	2 (<0.1%)
Oral fungal infection	0	1 (<0.1%)	1 (<0.1%)
Oral herpes	0	3 (0.1%)	3 (<0.1%)
Osteomyelitis	10 (0.4%)	14 (0.6%)	24 (0.5%)
Osteomyelitis chronic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Otitis externa	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Otitis media	3 (0.1%)	4 (0.2%)	7 (0.2%)
Otitis media chronic	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Otosalpingitis	0	1 (<0.1%)	1 (<0.1%)
Pancreas infection	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Pancreatic abscess	0	1 (<0.1%)	1 (<0.1%)
Paronychia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Parotitis	4 (0.2%)	0	4 (<0.1%)
Penile infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Periodontitis	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Peritonsillar abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	4 (0.2%)	9 (0.4%)	13 (0.3%)
Pharyngotonsillitis	1 (<0.1%)	0	1 (<0.1%)
Pilonidal cyst	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	28 (1.2%)	24 (1.0%)	52 (1.1%)
Pneumonia bacterial	0	1 (<0.1%)	1 (<0.1%)
Pneumonia legionella	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonia pseudomonal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia viral	1 (<0.1%)	0	1 (<0.1%)
Poliomyelitis	5 (0.2%)	3 (0.1%)	8 (0.2%)
Post procedural infection	1 (<0.1%)	0	1 (<0.1%)
Postoperative wound infection	2 (<0.1%)	0	2 (<0.1%)
Pulmonary tuberculoma	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	8 (0.3%)	7 (0.3%)	15 (0.3%)
Pulpitis dental	0	1 (<0.1%)	1 (<0.1%)
Pustule	0	1 (<0.1%)	1 (<0.1%)
Pyelonephritis	6 (0.3%)	11 (0.5%)	17 (0.4%)
Pyelonephritis acute	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Pyelonephritis chronic	42 (1.8%)	35 (1.5%)	77 (1.7%)
Pyoderma	1 (<0.1%)	0	1 (<0.1%)
Pyuria	1 (<0.1%)	0	1 (<0.1%)
Renal abscess	0	1 (<0.1%)	1 (<0.1%)
Respiratory tract infection	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Respiratory tract infection viral	1 (<0.1%)	0	1 (<0.1%)
Retroperitoneal abscess	0	1 (<0.1%)	1 (<0.1%)
Rhinitis	9 (0.4%)	10 (0.4%)	19 (0.4%)
Scrotal infection	0	1 (<0.1%)	1 (<0.1%)
Sepsis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Septic arthritis staphylococcal	1 (<0.1%)	0	1 (<0.1%)
Septic shock	1 (<0.1%)	0	1 (<0.1%)
Sialoadenitis	0	1 (<0.1%)	1 (<0.1%)
Sinusitis	12 (0.5%)	18 (0.8%)	30 (0.6%)
Skin candida	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Skin infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Staphylococcal infection	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal sepsis	0	1 (<0.1%)	1 (<0.1%)
Streptococcal endocarditis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	3 (0.1%)	3 (0.1%)	6 (0.1%)
Syphilis	2 (<0.1%)	0	2 (<0.1%)
Systemic candida	1 (<0.1%)	0	1 (<0.1%)
Tinea capitis	0	2 (<0.1%)	2 (<0.1%)
Tinea cruris	6 (0.3%)	2 (<0.1%)	8 (0.2%)
Tinea infection	3 (0.1%)	5 (0.2%)	8 (0.2%)
Tinea pedis	18 (0.8%)	28 (1.2%)	46 (1.0%)
Tinea versicolour	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tonsillitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tonsillitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Tooth abscess	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tooth infection	1 (<0.1%)	0	1 (<0.1%)
Tracheitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tuberculosis	9 (0.4%)	8 (0.3%)	17 (0.4%)
Tuberculous pleurisy	2 (<0.1%)	0	2 (<0.1%)
Tubo-ovarian abscess	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	27 (1.2%)	21 (0.9%)	48 (1.0%)
Urethritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary tract infection	29 (1.2%)	40 (1.7%)	69 (1.5%)
Urinary tract infection bacterial	0	1 (<0.1%)	1 (<0.1%)
Urosepsis	0	1 (<0.1%)	1 (<0.1%)
Vaginal infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicella	1 (<0.1%)	0	1 (<0.1%)
Vascular device infection	1 (<0.1%)	0	1 (<0.1%)
Vestibular neuronitis	0	1 (<0.1%)	1 (<0.1%)
Viral hepatitis carrier	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Viral infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vulvitis	0	1 (<0.1%)	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginitis	0	1 (<0.1%)	1 (<0.1%)
Wound infection	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Zika virus infection	1 (<0.1%)	0	1 (<0.1%)
Injury, poisoning and procedural complications	201 (8.6%)	179 (7.8%)	380 (8.2%)
Abdominal injury	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Accident	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Anastomotic ulcer	0	1 (<0.1%)	1 (<0.1%)
Animal bite	1 (<0.1%)	0	1 (<0.1%)
Ankle fracture	13 (0.6%)	8 (0.3%)	21 (0.5%)
Aortic injury	1 (<0.1%)	0	1 (<0.1%)
Arthropod sting	1 (<0.1%)	0	1 (<0.1%)
Asbestosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blindness traumatic	2 (<0.1%)	0	2 (<0.1%)
Bone contusion	0	1 (<0.1%)	1 (<0.1%)
Breast injury	1 (<0.1%)	0	1 (<0.1%)
Burns second degree	1 (<0.1%)	0	1 (<0.1%)
Burns third degree	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cartilage injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chest injury	0	4 (0.2%)	4 (<0.1%)
Chillblains	0	1 (<0.1%)	1 (<0.1%)
Clavicle fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Concussion	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Contusion	6 (0.3%)	1 (<0.1%)	7 (0.2%)
Corneal abrasion	0	2 (<0.1%)	2 (<0.1%)
Coronary bypass stenosis	0	1 (<0.1%)	1 (<0.1%)
Craniocerebral injury	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Electric injury	1 (<0.1%)	0	1 (<0.1%)
Endotracheal intubation complication	1 (<0.1%)	0	1 (<0.1%)
Epicondylitis	11 (0.5%)	5 (0.2%)	16 (0.3%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye contusion	1 (<0.1%)	0	1 (<0.1%)
Eye injury	0	2 (<0.1%)	2 (<0.1%)
Eye laser scar	1 (<0.1%)	0	1 (<0.1%)
Eyeball avulsion	0	1 (<0.1%)	1 (<0.1%)
Face injury	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Facial bones fracture	1 (<0.1%)	0	1 (<0.1%)
Fall	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Femoral neck fracture	1 (<0.1%)	0	1 (<0.1%)
Femur fracture	5 (0.2%)	6 (0.3%)	11 (0.2%)
Fibula fracture	4 (0.2%)	4 (0.2%)	8 (0.2%)
Foot fracture	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Forearm fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body	0	1 (<0.1%)	1 (<0.1%)
Foreign body in eye	1 (<0.1%)	0	1 (<0.1%)
Fracture	0	1 (<0.1%)	1 (<0.1%)
Fracture of penis	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Fractured coccyx	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastrointestinal anastomotic leak	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	1 (<0.1%)	0	1 (<0.1%)
Hand fracture	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Head injury	4 (0.2%)	3 (0.1%)	7 (0.2%)
Hip fracture	0	1 (<0.1%)	1 (<0.1%)
Humerus fracture	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Iliotibial band syndrome	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia	6 (0.3%)	7 (0.3%)	13 (0.3%)
Injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injury corneal	0	2 (<0.1%)	2 (<0.1%)
Intentional overdose	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc injury	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Iris injury	1 (<0.1%)	0	1 (<0.1%)
Jaw fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Joint dislocation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint injury	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Ligament injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament rupture	5 (0.2%)	6 (0.3%)	11 (0.2%)
Ligament sprain	6 (0.3%)	5 (0.2%)	11 (0.2%)
Limb injury	11 (0.5%)	11 (0.5%)	22 (0.5%)
Limb traumatic amputation	3 (0.1%)	5 (0.2%)	8 (0.2%)
Lower limb fracture	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Lumbar vertebral fracture	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Median nerve injury	0	1 (<0.1%)	1 (<0.1%)
Meniscus injury	15 (0.6%)	9 (0.4%)	24 (0.5%)
Multiple fractures	1 (<0.1%)	0	1 (<0.1%)
Multiple injuries	1 (<0.1%)	0	1 (<0.1%)
Muscle injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Muscle rupture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Muscle strain	4 (0.2%)	0	4 (<0.1%)
Patella fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic bone injury	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Persistent corneal epithelial defect	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	2 (<0.1%)	0	2 (<0.1%)
Post concussion syndrome	1 (<0.1%)	0	1 (<0.1%)
Post laminectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypothyroidism	7 (0.3%)	7 (0.3%)	14 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Post procedural swelling	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic neck syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post-traumatic pain	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Postoperative adhesion	1 (<0.1%)	0	1 (<0.1%)
Procedural intestinal perforation	1 (<0.1%)	0	1 (<0.1%)
Procedural pain	0	3 (0.1%)	3 (<0.1%)
Radiation skin injury	1 (<0.1%)	0	1 (<0.1%)
Radius fracture	6 (0.3%)	3 (0.1%)	9 (0.2%)
Rib fracture	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Road traffic accident	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Scar	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Silicosis	1 (<0.1%)	0	1 (<0.1%)
Skin abrasion	1 (<0.1%)	0	1 (<0.1%)
Skin laceration	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Skin wound	1 (<0.1%)	0	1 (<0.1%)
Skull fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Soft tissue injury	2 (<0.1%)	0	2 (<0.1%)
Spinal column injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal compression fracture	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Spinal cord injury	0	1 (<0.1%)	1 (<0.1%)
Spinal cord injury thoracic	0	1 (<0.1%)	1 (<0.1%)
Spinal fracture	0	2 (<0.1%)	2 (<0.1%)
Spleen contusion	1 (<0.1%)	0	1 (<0.1%)
Splenic rupture	0	2 (<0.1%)	2 (<0.1%)
Stoma site irritation	0	1 (<0.1%)	1 (<0.1%)
Stomal hernia	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	0	1 (<0.1%)
Subdural haematoma	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Synovial rupture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tendon injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tendon rupture	6 (0.3%)	2 (<0.1%)	8 (0.2%)
Thermal burn	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thermal burns of eye	0	1 (<0.1%)	1 (<0.1%)
Thoracic vertebral fracture	1 (<0.1%)	0	1 (<0.1%)
Tibia fracture	3 (0.1%)	4 (0.2%)	7 (0.2%)
Tobacco poisoning	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth fracture	0	2 (<0.1%)	2 (<0.1%)
Toxicity to various agents	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthritis	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthrosis	2 (<0.1%)	0	2 (<0.1%)
Traumatic fracture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Traumatic haemothorax	0	2 (<0.1%)	2 (<0.1%)
Traumatic renal injury	1 (<0.1%)	0	1 (<0.1%)
Traumatic ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ulna fracture	0	1 (<0.1%)	1 (<0.1%)
Upper limb fracture	5 (0.2%)	5 (0.2%)	10 (0.2%)
Wound dehiscence	0	1 (<0.1%)	1 (<0.1%)
Wound necrosis	2 (<0.1%)	0	2 (<0.1%)
Wrist fracture	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Investigations	242 (10.4%)	249 (10.8%)	491 (10.6%)
Alanine aminotransferase increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Albumin urine present	0	1 (<0.1%)	1 (<0.1%)
Angiocardiogram	21 (0.9%)	15 (0.7%)	36 (0.8%)
Angiogram	4 (0.2%)	4 (0.2%)	8 (0.2%)
Angiogram cerebral	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Antinuclear antibody positive	2 (<0.1%)	0	2 (<0.1%)
Aortic bruit	0	2 (<0.1%)	2 (<0.1%)
Arthroscopy	5 (0.2%)	10 (0.4%)	15 (0.3%)
Aspartate aminotransferase increased	2 (<0.1%)	0	2 (<0.1%)
Aspiration pleural cavity	1 (<0.1%)	0	1 (<0.1%)
Autoantibody positive	0	1 (<0.1%)	1 (<0.1%)
Biopsy kidney	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Biopsy prostate	0	1 (<0.1%)	1 (<0.1%)
Biopsy thyroid gland	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	0	1 (<0.1%)	1 (<0.1%)
Blood bicarbonate decreased	1 (<0.1%)	0	1 (<0.1%)
Blood calcium increased	0	1 (<0.1%)	1 (<0.1%)
Blood cholesterol increased	32 (1.4%)	47 (2.0%)	79 (1.7%)
Blood creatine phosphokinase abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood creatine phosphokinase increased	30 (1.3%)	40 (1.7%)	70 (1.5%)
Blood creatinine increased	0	2 (<0.1%)	2 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood lactate dehydrogenase increased	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Blood magnesium decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood potassium decreased	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	1 (<0.1%)	0	1 (<0.1%)
Blood pressure increased	0	2 (<0.1%)	2 (<0.1%)
Blood sodium decreased	2 (<0.1%)	0	2 (<0.1%)
Blood testosterone decreased	3 (0.1%)	0	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Blood thyroid stimulating hormone normal	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	6 (0.3%)	6 (0.3%)	12 (0.3%)
Blood uric acid abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood uric acid increased	4 (0.2%)	7 (0.3%)	11 (0.2%)
Body mass index increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bone density decreased	0	1 (<0.1%)	1 (<0.1%)
Borrelia test positive	0	1 (<0.1%)	1 (<0.1%)
Breath sounds abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	14 (0.6%)	7 (0.3%)	21 (0.5%)
Carcinoembryonic antigen increased	1 (<0.1%)	0	1 (<0.1%)
Cardiac function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Cardiac murmur	14 (0.6%)	9 (0.4%)	23 (0.5%)
Cardiac stress test normal	0	1 (<0.1%)	1 (<0.1%)
Carotid bruit	1 (<0.1%)	0	1 (<0.1%)
Carotid intima-media thickness increased	0	1 (<0.1%)	1 (<0.1%)
Catheterisation cardiac	9 (0.4%)	6 (0.3%)	15 (0.3%)
Catheterisation cardiac normal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cystoscopy	2 (<0.1%)	0	2 (<0.1%)
ECG electrically inactive area	2 (<0.1%)	0	2 (<0.1%)
Ejection fraction decreased	0	1 (<0.1%)	1 (<0.1%)
Ejection fraction normal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram PR shortened	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QRS complex abnormal	2 (<0.1%)	0	2 (<0.1%)
Electrocardiogram QT interval abnormal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Electrocardiogram QT prolonged	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram ST segment abnormal	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Electrocardiogram ST segment depression	0	3 (0.1%)	3 (<0.1%)
Electrocardiogram ST segment elevation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram ST-T change	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram ST-T segment abnormal	0	2 (<0.1%)	2 (<0.1%)
Electrocardiogram T wave abnormal	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Electrocardiogram T wave amplitude decreased	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Electrocardiogram T wave inversion	3 (0.1%)	5 (0.2%)	8 (0.2%)
Electrocardiogram abnormal	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Electrocardiogram repolarisation abnormality	2 (<0.1%)	4 (0.2%)	6 (0.1%)
False positive investigation result	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Forced expiratory volume decreased	0	1 (<0.1%)	1 (<0.1%)
Gamma-glutamyltransferase increased	14 (0.6%)	13 (0.6%)	27 (0.6%)
Gastric pH decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glycosylated haemoglobin increased	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin decreased	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin increased	0	2 (<0.1%)	2 (<0.1%)
Heart rate decreased	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	2 (<0.1%)	0	2 (<0.1%)
Helicobacter test positive	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Hepatic enzyme abnormal	0	2 (<0.1%)	2 (<0.1%)
Hepatic enzyme increased	7 (0.3%)	5 (0.2%)	12 (0.3%)
Hepatitis B antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B core antibody positive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis B surface antibody positive	1 (<0.1%)	0	1 (<0.1%)
Hepatitis B surface antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	0	2 (<0.1%)
Hepatitis C antibody positive	0	1 (<0.1%)	1 (<0.1%)
Human papilloma virus test negative	1 (<0.1%)	0	1 (<0.1%)
Hysteroscopy	0	1 (<0.1%)	1 (<0.1%)
Intraocular pressure increased	4 (0.2%)	3 (0.1%)	7 (0.2%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)
Left ventricular end-diastolic pressure increased	0	1 (<0.1%)	1 (<0.1%)
Lipids abnormal	0	2 (<0.1%)	2 (<0.1%)
Lipoprotein (a) increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipoprotein abnormal	0	1 (<0.1%)	1 (<0.1%)
Liver function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Liver function test increased	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Liver scan abnormal	1 (<0.1%)	0	1 (<0.1%)
Low density lipoprotein increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mean cell volume increased	0	1 (<0.1%)	1 (<0.1%)
Muscle enzyme increased	0	1 (<0.1%)	1 (<0.1%)
Occult blood positive	2 (<0.1%)	0	2 (<0.1%)
Oxygen consumption increased	1 (<0.1%)	0	1 (<0.1%)
Peripheral arteriogram	2 (<0.1%)	0	2 (<0.1%)
Physical examination	0	1 (<0.1%)	1 (<0.1%)
Platelet count decreased	0	1 (<0.1%)	1 (<0.1%)
Prostatic specific antigen increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Protein urine present	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary imaging procedure abnormal	2 (<0.1%)	0	2 (<0.1%)
Pulse absent	1 (<0.1%)	0	1 (<0.1%)
QRS axis abnormal	12 (0.5%)	12 (0.5%)	24 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Red blood cell sedimentation rate increased	0	1 (<0.1%)	1 (<0.1%)
Scan myocardial perfusion	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test normal	1 (<0.1%)	0	1 (<0.1%)
Transaminases increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Treponema test positive	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Troponin increased	2 (<0.1%)	0	2 (<0.1%)
Ultrasound Doppler abnormal	0	1 (<0.1%)	1 (<0.1%)
Ultrasound kidney abnormal	0	1 (<0.1%)	1 (<0.1%)
Ureteroscopy	1 (<0.1%)	0	1 (<0.1%)
Urinary occult blood positive	0	1 (<0.1%)	1 (<0.1%)
Urine albumin/creatinine ratio increased	0	2 (<0.1%)	2 (<0.1%)
Urogram	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	0	2 (<0.1%)	2 (<0.1%)
Vitamin D decreased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Vitamin E decreased	0	1 (<0.1%)	1 (<0.1%)
Weight decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Weight increased	0	2 (<0.1%)	2 (<0.1%)
White blood cell count increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Metabolism and nutrition disorders	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Abnormal loss of weight	1 (<0.1%)	0	1 (<0.1%)
Acidosis	1 (<0.1%)	0	1 (<0.1%)
Acquired mixed hyperlipidaemia	0	2 (<0.1%)	2 (<0.1%)
Calcium deficiency	1 (<0.1%)	0	1 (<0.1%)
Central obesity	13 (0.6%)	18 (0.8%)	31 (0.7%)
Decreased appetite	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Dehydration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus	2 (<0.1%)	0	2 (<0.1%)
Diabetes mellitus inadequate control	5 (0.2%)	8 (0.3%)	13 (0.3%)
Diabetic dyslipidaemia	0	3 (0.1%)	3 (<0.1%)
Diabetic ketoacidosis	0	5 (0.2%)	5 (0.1%)
Diabetic ketosis	0	3 (0.1%)	3 (<0.1%)
Dyslipidaemia	778 (33.4%)	796 (34.5%)	1574 (34.0%)
Fluid retention	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Folate deficiency	3 (0.1%)	5 (0.2%)	8 (0.2%)
Fructose intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	0	1 (<0.1%)	1 (<0.1%)
Gout	107 (4.6%)	124 (5.4%)	231 (5.0%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Haemochromatosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyper HDL cholesterolaemia	1 (<0.1%)	0	1 (<0.1%)
Hypercalcaemia	7 (0.3%)	5 (0.2%)	12 (0.3%)
Hypercholesterolaemia	264 (11.3%)	258 (11.2%)	522 (11.3%)
Hyperferritinaemia	0	2 (<0.1%)	2 (<0.1%)
Hyperglycaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperhomocysteinaemia	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Hyperinsulinaemic hypoglycaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperkalaemia	12 (0.5%)	12 (0.5%)	24 (0.5%)
Hyperlipidaemia	532 (22.9%)	549 (23.8%)	1081 (23.3%)
Hyperphosphataemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypertriglyceridaemia	63 (2.7%)	56 (2.4%)	119 (2.6%)
Hyperuricaemia	200 (8.6%)	182 (7.9%)	382 (8.2%)
Hypervolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypo HDL cholesterolaemia	1 (<0.1%)	0	1 (<0.1%)
Hypoalbuminaemia	0	1 (<0.1%)	1 (<0.1%)
Hypocalcaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hypoglycaemia	12 (0.5%)	12 (0.5%)	24 (0.5%)
Hypokalaemia	23 (1.0%)	18 (0.8%)	41 (0.9%)
Hypomagnesaemia	8 (0.3%)	7 (0.3%)	15 (0.3%)
Hyponatraemia	10 (0.4%)	6 (0.3%)	16 (0.3%)
Hypoproteinaemia	4 (0.2%)	6 (0.3%)	10 (0.2%)
Hypovitaminosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Impaired fasting glucose	0	2 (<0.1%)	2 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iodine deficiency	0	1 (<0.1%)	1 (<0.1%)
Iron deficiency	15 (0.6%)	14 (0.6%)	29 (0.6%)
Iron overload	0	1 (<0.1%)	1 (<0.1%)
Ketosis	0	1 (<0.1%)	1 (<0.1%)
Lactose intolerance	0	2 (<0.1%)	2 (<0.1%)
Lipid metabolism disorder	7 (0.3%)	6 (0.3%)	13 (0.3%)
Lipomatosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipoprotein deficiency	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Metabolic acidosis	0	1 (<0.1%)	1 (<0.1%)
Metabolic alkalosis	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metabolic syndrome	20 (0.9%)	19 (0.8%)	39 (0.8%)
Obesity	1012 (43.5%)	1015 (44.1%)	2027 (43.8%)
Overweight	20 (0.9%)	22 (1.0%)	42 (0.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Purine metabolism disorder	0	1 (<0.1%)	1 (<0.1%)
Type 2 diabetes mellitus	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Vitamin B complex deficiency	4 (0.2%)	6 (0.3%)	10 (0.2%)
Vitamin B12 deficiency	28 (1.2%)	19 (0.8%)	47 (1.0%)
Vitamin D deficiency	119 (5.1%)	98 (4.3%)	217 (4.7%)
Musculoskeletal and connective tissue disorders	753 (32.4%)	764 (33.2%)	1517 (32.8%)
Acquired claw toe	1 (<0.1%)	0	1 (<0.1%)
Ankylosing spondylitis	3 (0.1%)	7 (0.3%)	10 (0.2%)
Arthralgia	79 (3.4%)	95 (4.1%)	174 (3.8%)
Arthritis	28 (1.2%)	25 (1.1%)	53 (1.1%)
Arthritis reactive	0	1 (<0.1%)	1 (<0.1%)
Arthropathy	4 (0.2%)	3 (0.1%)	7 (0.2%)
Autoimmune arthritis	1 (<0.1%)	0	1 (<0.1%)
Back disorder	5 (0.2%)	10 (0.4%)	15 (0.3%)
Back pain	120 (5.2%)	151 (6.6%)	271 (5.9%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	0	1 (<0.1%)	1 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone infarction	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	1 (<0.1%)	0	1 (<0.1%)
Bone loss	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	1 (<0.1%)	0	1 (<0.1%)
Bone pain	1 (<0.1%)	0	1 (<0.1%)
Bone swelling	1 (<0.1%)	0	1 (<0.1%)
Bursitis	12 (0.5%)	9 (0.4%)	21 (0.5%)
Cervical spinal stenosis	5 (0.2%)	7 (0.3%)	12 (0.3%)
Chondrocalcinosis pyrophosphate	2 (<0.1%)	0	2 (<0.1%)
Chondromalacia	0	2 (<0.1%)	2 (<0.1%)
Chondropathy	0	1 (<0.1%)	1 (<0.1%)
Chronic kidney disease-mineral and bone disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Clubbing	0	1 (<0.1%)	1 (<0.1%)
Coccydynia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Collagen disorder	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	1 (<0.1%)	0	1 (<0.1%)
Connective tissue inflammation	0	1 (<0.1%)	1 (<0.1%)
Costochondritis	1 (<0.1%)	0	1 (<0.1%)
Crowned dens syndrome	1 (<0.1%)	0	1 (<0.1%)
Crystal arthropathy	1 (<0.1%)	0	1 (<0.1%)
Dactylitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Diastasis recti abdominis	1 (<0.1%)	6 (0.3%)	7 (0.2%)
Diffuse idiopathic skeletal hyperostosis	0	1 (<0.1%)	1 (<0.1%)
Dupuytren's contracture	10 (0.4%)	4 (0.2%)	14 (0.3%)
Enthesopathy	3 (0.1%)	0	3 (<0.1%)
Exostosis	7 (0.3%)	8 (0.3%)	15 (0.3%)
Facet joint syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fasciitis	0	2 (<0.1%)	2 (<0.1%)
Fibromyalgia	6 (0.3%)	4 (0.2%)	10 (0.2%)
Finger deformity	0	1 (<0.1%)	1 (<0.1%)
Fistula	1 (<0.1%)	0	1 (<0.1%)
Flank pain	3 (0.1%)	0	3 (<0.1%)
Foot deformity	13 (0.6%)	12 (0.5%)	25 (0.5%)
Gouty arthritis	13 (0.6%)	7 (0.3%)	20 (0.4%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)
Haemarthrosis	0	1 (<0.1%)	1 (<0.1%)
Inclusion body myositis	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc compression	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc degeneration	23 (1.0%)	21 (0.9%)	44 (1.0%)
Intervertebral disc disorder	27 (1.2%)	19 (0.8%)	46 (1.0%)
Intervertebral disc displacement	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc protrusion	56 (2.4%)	72 (3.1%)	128 (2.8%)
Jaw cyst	1 (<0.1%)	0	1 (<0.1%)
Joint deposit	1 (<0.1%)	0	1 (<0.1%)
Joint effusion	0	2 (<0.1%)	2 (<0.1%)
Joint range of motion decreased	1 (<0.1%)	0	1 (<0.1%)
Joint stiffness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint swelling	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Knee deformity	1 (<0.1%)	0	1 (<0.1%)
Kyphosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Limb asymmetry	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Limb deformity	0	1 (<0.1%)	1 (<0.1%)
Limb discomfort	2 (<0.1%)	0	2 (<0.1%)
Lumbar spinal stenosis	16 (0.7%)	11 (0.5%)	27 (0.6%)
Metatarsalgia	1 (<0.1%)	0	1 (<0.1%)
Muscle atrophy	0	1 (<0.1%)	1 (<0.1%)
Muscle contracture	2 (<0.1%)	0	2 (<0.1%)
Muscle fatigue	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	41 (1.8%)	43 (1.9%)	84 (1.8%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscle twitching	0	1 (<0.1%)	1 (<0.1%)
Muscular weakness	2 (<0.1%)	3 (0.1%)	5 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Musculoskeletal chest pain	1 (<0.1%)	0	1 (<0.1%)
Musculoskeletal discomfort	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Musculoskeletal pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Musculoskeletal stiffness	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Myalgia	29 (1.2%)	26 (1.1%)	55 (1.2%)
Myofascial pain syndrome	0	2 (<0.1%)	2 (<0.1%)
Myopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Myositis	2 (<0.1%)	0	2 (<0.1%)
Neck mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neck pain	20 (0.9%)	19 (0.8%)	39 (0.8%)
Neuropathic arthropathy	9 (0.4%)	11 (0.5%)	20 (0.4%)
Oligoarthritis	1 (<0.1%)	0	1 (<0.1%)
Osteitis	3 (0.1%)	0	3 (<0.1%)
Osteoarthritis	240 (10.3%)	246 (10.7%)	486 (10.5%)
Osteoarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteochondritis	1 (<0.1%)	0	1 (<0.1%)
Osteochondrosis	31 (1.3%)	35 (1.5%)	66 (1.4%)
Osteomalacia	1 (<0.1%)	0	1 (<0.1%)
Osteonecrosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Osteopenia	20 (0.9%)	13 (0.6%)	33 (0.7%)
Osteoporosis	50 (2.1%)	44 (1.9%)	94 (2.0%)
Osteoporosis postmenopausal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Osteosclerosis	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	30 (1.3%)	28 (1.2%)	58 (1.3%)
Patellofemoral pain syndrome	0	3 (0.1%)	3 (<0.1%)
Pathological fracture	1 (<0.1%)	0	1 (<0.1%)
Periarthritis	25 (1.1%)	9 (0.4%)	34 (0.7%)
Perthes disease	1 (<0.1%)	0	1 (<0.1%)
Plantar fascial fibromatosis	0	1 (<0.1%)	1 (<0.1%)
Plantar fasciitis	6 (0.3%)	4 (0.2%)	10 (0.2%)
Polyarthritis	4 (0.2%)	5 (0.2%)	9 (0.2%)
Polymyalgia rheumatica	0	2 (<0.1%)	2 (<0.1%)
Psoriatic arthropathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Rhabdomyolysis	0	1 (<0.1%)	1 (<0.1%)
Rheumatic disorder	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Rheumatic fever	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Rheumatoid arthritis	19 (0.8%)	12 (0.5%)	31 (0.7%)
Rotator cuff syndrome	24 (1.0%)	27 (1.2%)	51 (1.1%)
Sacroiliitis	2 (<0.1%)	0	2 (<0.1%)
Scleroderma	0	1 (<0.1%)	1 (<0.1%)
Scoliosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Sjogren's syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Soft tissue disorder	1 (<0.1%)	0	1 (<0.1%)
Spinal deformity	3 (0.1%)	0	3 (<0.1%)
Spinal disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Spinal fusion acquired	1 (<0.1%)	0	1 (<0.1%)
Spinal instability	1 (<0.1%)	0	1 (<0.1%)
Spinal ligament ossification	0	2 (<0.1%)	2 (<0.1%)
Spinal osteoarthritis	91 (3.9%)	89 (3.9%)	180 (3.9%)
Spinal pain	14 (0.6%)	12 (0.5%)	26 (0.6%)
Spinal retrolisthesis	2 (<0.1%)	0	2 (<0.1%)
Spinal stenosis	13 (0.6%)	9 (0.4%)	22 (0.5%)
Spondylitis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Spondyloarthropathy	4 (0.2%)	4 (0.2%)	8 (0.2%)
Spondylolisthesis	6 (0.3%)	6 (0.3%)	12 (0.3%)
Sympathetic posterior cervical syndrome	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	9 (0.4%)	2 (<0.1%)	11 (0.2%)
Synovitis	0	2 (<0.1%)	2 (<0.1%)
Systemic lupus erythematosus	1 (<0.1%)	0	1 (<0.1%)
Temporomandibular joint syndrome	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Tendon calcification	1 (<0.1%)	0	1 (<0.1%)
Tendon disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tendonitis	12 (0.5%)	6 (0.3%)	18 (0.4%)
Tenosynovitis	5 (0.2%)	8 (0.3%)	13 (0.3%)
Tenosynovitis stenosans	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Trigger finger	5 (0.2%)	9 (0.4%)	14 (0.3%)
Vertebral foraminal stenosis	0	4 (0.2%)	4 (<0.1%)
Vertebral lesion	1 (<0.1%)	0	1 (<0.1%)
Vertebral osteophyte	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	225 (9.7%)	223 (9.7%)	448 (9.7%)
Acoustic neuroma	0	1 (<0.1%)	1 (<0.1%)
Acrochordon	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Acute myeloid leukaemia	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma	2 (<0.1%)	0	2 (<0.1%)
Adenocarcinoma of colon	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenoma benign	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Adrenal adenoma	6 (0.3%)	9 (0.4%)	15 (0.3%)
Adrenal neoplasm	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyolipoma	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Basal cell carcinoma	11 (0.5%)	9 (0.4%)	20 (0.4%)
Basosquamous carcinoma	1 (<0.1%)	0	1 (<0.1%)
Benign abdominal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign breast neoplasm	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Benign duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Benign hepatobiliary neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign lung neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Benign neoplasm of adrenal gland	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of cornea	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of eyelid	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of skin	0	2 (<0.1%)	2 (<0.1%)
Benign neoplasm of thyroid gland	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Benign ovarian tumour	0	1 (<0.1%)	1 (<0.1%)
Benign pancreatic neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Bladder cancer	4 (0.2%)	6 (0.3%)	10 (0.2%)
Bladder neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder papilloma	2 (<0.1%)	0	2 (<0.1%)
Bladder transitional cell carcinoma	0	2 (<0.1%)	2 (<0.1%)
Bowen's disease	0	2 (<0.1%)	2 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Breast adenoma	1 (<0.1%)	0	1 (<0.1%)
Breast cancer	9 (0.4%)	9 (0.4%)	18 (0.4%)
Breast cancer metastatic	0	1 (<0.1%)	1 (<0.1%)
Breast fibroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast neoplasm	0	1 (<0.1%)	1 (<0.1%)
Carcinoid tumour of the stomach	1 (<0.1%)	0	1 (<0.1%)
Cerebellopontine angle tumour	1 (<0.1%)	0	1 (<0.1%)
Cerebral haemangioma	0	1 (<0.1%)	1 (<0.1%)
Cervix carcinoma	0	3 (0.1%)	3 (<0.1%)
Chronic lymphocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)
Clear cell renal cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Colon adenoma	7 (0.3%)	6 (0.3%)	13 (0.3%)
Colon cancer	6 (0.3%)	6 (0.3%)	12 (0.3%)
Colon cancer stage 0	1 (<0.1%)	0	1 (<0.1%)
Colon neoplasm	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cutaneous lymphoma	1 (<0.1%)	0	1 (<0.1%)
Duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Endometrial cancer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Epiglottic cancer	1 (<0.1%)	0	1 (<0.1%)
Erythroplasia	1 (<0.1%)	0	1 (<0.1%)
Essential thrombocythaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye naevus	0	2 (<0.1%)	2 (<0.1%)
Fibroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibrous histiocytoma	0	2 (<0.1%)	2 (<0.1%)
Focal nodular hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Gallbladder adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallbladder cancer	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Gastrointestinal carcinoma	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal submucosal tumour	2 (<0.1%)	0	2 (<0.1%)
Haemangioma	2 (<0.1%)	0	2 (<0.1%)
Haemangioma of bone	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemangioma of liver	5 (0.2%)	9 (0.4%)	14 (0.3%)
Haemangioma of spleen	1 (<0.1%)	0	1 (<0.1%)
Hepatic adenoma	0	1 (<0.1%)	1 (<0.1%)
Hepatic cancer	0	1 (<0.1%)	1 (<0.1%)
Hepatocellular carcinoma	0	2 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	1 (<0.1%)	0	1 (<0.1%)
Intraductal papillary mucinous neoplasm	1 (<0.1%)	0	1 (<0.1%)
Iris neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine benign neoplasm	1 (<0.1%)	0	1 (<0.1%)
Laryngeal cancer	0	2 (<0.1%)	2 (<0.1%)
Laryngeal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Laryngeal papilloma	1 (<0.1%)	0	1 (<0.1%)
Leiomyosarcoma	0	1 (<0.1%)	1 (<0.1%)
Lipoma	11 (0.5%)	8 (0.3%)	19 (0.4%)
Lipoma of breast	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malignant melanoma	6 (0.3%)	2 (<0.1%)	8 (0.2%)
Malignant neoplasm of conjunctiva	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eye	1 (<0.1%)	0	1 (<0.1%)
Malignant palate neoplasm	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	4 (0.2%)	6 (0.3%)	10 (0.2%)
Meningioma	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Meningioma benign	1 (<0.1%)	0	1 (<0.1%)
Metastases to lymph nodes	1 (<0.1%)	0	1 (<0.1%)
Monoclonal gammopathy	0	2 (<0.1%)	2 (<0.1%)
Myelodysplastic syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Nasopharyngeal neoplasm benign	1 (<0.1%)	0	1 (<0.1%)
Neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neoplasm prostate	0	2 (<0.1%)	2 (<0.1%)
Neoplasm skin	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-secretory adenoma of pituitary	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ocular lymphoma	1 (<0.1%)	0	1 (<0.1%)
Osteochondroma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian adenoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	0	2 (<0.1%)	2 (<0.1%)
Paget's disease of nipple	1 (<0.1%)	0	1 (<0.1%)
Pancreatic neuroendocrine tumour	0	1 (<0.1%)	1 (<0.1%)
Papillary cystadenoma lymphomatosum	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Papillary thyroid cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Parathyroid tumour benign	1 (<0.1%)	0	1 (<0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	5 (0.2%)	6 (0.3%)	11 (0.2%)
Pleomorphic adenoma	0	1 (<0.1%)	1 (<0.1%)
Polycythaemia vera	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary myelofibrosis	1 (<0.1%)	0	1 (<0.1%)
Prolactin-producing pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Prostate cancer	15 (0.6%)	14 (0.6%)	29 (0.6%)
Prostatic adenoma	7 (0.3%)	10 (0.4%)	17 (0.4%)
Rectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Rectal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Renal cancer	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal cell carcinoma	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Renal hamartoma	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Renal neoplasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal oncocytoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland adenoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland neoplasm	1 (<0.1%)	0	1 (<0.1%)
Schwannoma	0	1 (<0.1%)	1 (<0.1%)
Seborrhoeic keratosis	7 (0.3%)	8 (0.3%)	15 (0.3%)
Seminoma	1 (<0.1%)	0	1 (<0.1%)
Skin cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin papilloma	5 (0.2%)	3 (0.1%)	8 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Small cell lung cancer	0	1 (<0.1%)	1 (<0.1%)
Spinal meningioma benign	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma	0	5 (0.2%)	5 (0.1%)
Squamous cell carcinoma of skin	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma of the tongue	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testis cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thyroid adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thyroid cancer	5 (0.2%)	4 (0.2%)	9 (0.2%)
Tongue neoplasm malignant stage unspecified	0	1 (<0.1%)	1 (<0.1%)
Tonsil cancer	1 (<0.1%)	0	1 (<0.1%)
Transitional cell cancer of the renal pelvis and ureter	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	0	2 (<0.1%)	2 (<0.1%)
Urinary bladder adenoma	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Uterine leiomyoma	27 (1.2%)	26 (1.1%)	53 (1.1%)
Vulvovaginal warts	1 (<0.1%)	0	1 (<0.1%)
Waldenstrom's macroglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Nervous system disorders	1195 (51.4%)	1145 (49.7%)	2340 (50.5%)
Acoustic neuritis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Akinesia	1 (<0.1%)	0	1 (<0.1%)
Amnesia	6 (0.3%)	3 (0.1%)	9 (0.2%)
Anaesthesia	1 (<0.1%)	0	1 (<0.1%)
Anosmia	1 (<0.1%)	0	1 (<0.1%)
Arachnoid cyst	2 (<0.1%)	0	2 (<0.1%)
Areflexia	1 (<0.1%)	0	1 (<0.1%)
Ataxia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autonomic nervous system imbalance	0	1 (<0.1%)	1 (<0.1%)
Autonomic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Axonal neuropathy	0	1 (<0.1%)	1 (<0.1%)
Balance disorder	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Basal ganglia infarction	1 (<0.1%)	0	1 (<0.1%)
Basilar artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Brain stem infarction	0	2 (<0.1%)	2 (<0.1%)
Burning sensation	0	2 (<0.1%)	2 (<0.1%)
Cardiac autonomic neuropathy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Carotid arteriosclerosis	52 (2.2%)	47 (2.0%)	99 (2.1%)
Carotid artery aneurysm	0	2 (<0.1%)	2 (<0.1%)
Carotid artery disease	2 (<0.1%)	5 (0.2%)	7 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Carotid artery occlusion	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Carotid artery stenosis	28 (1.2%)	31 (1.3%)	59 (1.3%)
Carotid artery thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carpal tunnel syndrome	41 (1.8%)	29 (1.3%)	70 (1.5%)
Central nervous system lesion	1 (<0.1%)	0	1 (<0.1%)
Cerebellar stroke	1 (<0.1%)	0	1 (<0.1%)
Cerebellar syndrome	0	1 (<0.1%)	1 (<0.1%)
Cerebral arteriosclerosis	27 (1.2%)	32 (1.4%)	59 (1.3%)
Cerebral artery occlusion	0	2 (<0.1%)	2 (<0.1%)
Cerebral artery stenosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cerebral artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebral atrophy	6 (0.3%)	5 (0.2%)	11 (0.2%)
Cerebral circulatory failure	0	2 (<0.1%)	2 (<0.1%)
Cerebral disorder	1 (<0.1%)	0	1 (<0.1%)
Cerebral haematoma	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	6 (0.3%)	4 (0.2%)	10 (0.2%)
Cerebral infarction	12 (0.5%)	12 (0.5%)	24 (0.5%)
Cerebral ischaemia	26 (1.1%)	25 (1.1%)	51 (1.1%)
Cerebral microangiopathy	1 (<0.1%)	0	1 (<0.1%)
Cerebral small vessel ischaemic disease	0	2 (<0.1%)	2 (<0.1%)
Cerebral ventricle dilatation	1 (<0.1%)	0	1 (<0.1%)
Cerebrovascular accident	5 (0.2%)	9 (0.4%)	14 (0.3%)
Cerebrovascular disorder	39 (1.7%)	31 (1.3%)	70 (1.5%)
Cerebrovascular insufficiency	2 (<0.1%)	0	2 (<0.1%)
Cerebrovascular stenosis	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	6 (0.3%)	6 (0.3%)	12 (0.3%)
Cervicobrachial syndrome	5 (0.2%)	6 (0.3%)	11 (0.2%)
Cervicogenic headache	1 (<0.1%)	0	1 (<0.1%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1 (<0.1%)	1 (<0.1%)
Cluster headache	0	2 (<0.1%)	2 (<0.1%)
Cognitive disorder	5 (0.2%)	3 (0.1%)	8 (0.2%)
Coma	1 (<0.1%)	0	1 (<0.1%)
Complex regional pain syndrome	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Decreased vibratory sense	3 (0.1%)	0	3 (<0.1%)
Dementia	0	1 (<0.1%)	1 (<0.1%)
Dementia Alzheimer's type	3 (0.1%)	3 (0.1%)	6 (0.1%)
Demyelination	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic autonomic neuropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic coma	0	1 (<0.1%)	1 (<0.1%)
Diabetic encephalopathy	7 (0.3%)	10 (0.4%)	17 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Diabetic mononeuropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic neuropathy	714 (30.7%)	666 (28.9%)	1380 (29.8%)
Disturbance in attention	0	1 (<0.1%)	1 (<0.1%)
Dizziness	22 (0.9%)	17 (0.7%)	39 (0.8%)
Dizziness postural	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	0	1 (<0.1%)	1 (<0.1%)
Dysarthria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Encephalopathy	26 (1.1%)	17 (0.7%)	43 (0.9%)
Epilepsy	10 (0.4%)	8 (0.3%)	18 (0.4%)
Essential tremor	5 (0.2%)	6 (0.3%)	11 (0.2%)
Facial paralysis	15 (0.6%)	16 (0.7%)	31 (0.7%)
Facial paresis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Focal dyscognitive seizures	0	1 (<0.1%)	1 (<0.1%)
Generalised tonic-clonic seizure	1 (<0.1%)	0	1 (<0.1%)
Glossopharyngeal neuralgia	0	1 (<0.1%)	1 (<0.1%)
Guillain-Barre syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemorrhagic stroke	3 (0.1%)	3 (0.1%)	6 (0.1%)
Headache	34 (1.5%)	22 (1.0%)	56 (1.2%)
Hemianaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	0	1 (<0.1%)	1 (<0.1%)
Hemiparaesthesia	2 (<0.1%)	0	2 (<0.1%)
Hemiparesis	9 (0.4%)	12 (0.5%)	21 (0.5%)
Hemiplegia	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hippocampal sclerosis	1 (<0.1%)	0	1 (<0.1%)
Hyperaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hypersomnia	0	2 (<0.1%)	2 (<0.1%)
Hypertensive encephalopathy	0	2 (<0.1%)	2 (<0.1%)
Hypertonia	24 (1.0%)	18 (0.8%)	42 (0.9%)
Hypoaesthesia	10 (0.4%)	15 (0.7%)	25 (0.5%)
Hyporeflexia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxic-ischaemic encephalopathy	0	1 (<0.1%)	1 (<0.1%)
Intention tremor	1 (<0.1%)	0	1 (<0.1%)
Intercostal neuralgia	2 (<0.1%)	0	2 (<0.1%)
Internal capsule infarction	1 (<0.1%)	0	1 (<0.1%)
Intracranial aneurysm	0	2 (<0.1%)	2 (<0.1%)
Ischaemic stroke	212 (9.1%)	213 (9.2%)	425 (9.2%)
Lacunar infarction	13 (0.6%)	7 (0.3%)	20 (0.4%)
Lacunar stroke	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Leukoencephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Loss of consciousness	0	2 (<0.1%)	2 (<0.1%)
Lumbar radiculopathy	6 (0.3%)	4 (0.2%)	10 (0.2%)
Lumbosacral plexus lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lumbosacral radiculopathy	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Memory impairment	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Meralgia paraesthetica	0	1 (<0.1%)	1 (<0.1%)
Metabolic encephalopathy	3 (0.1%)	8 (0.3%)	11 (0.2%)
Migraine	11 (0.5%)	17 (0.7%)	28 (0.6%)
Migraine with aura	0	1 (<0.1%)	1 (<0.1%)
Mononeuropathy	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Monoplegia	0	2 (<0.1%)	2 (<0.1%)
Multiple sclerosis	0	4 (0.2%)	4 (<0.1%)
Myasthenia gravis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myelopathy	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Myotonia	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Nervous system disorder	2 (<0.1%)	0	2 (<0.1%)
Neuralgia	12 (0.5%)	8 (0.3%)	20 (0.4%)
Neuralgic amyotrophy	2 (<0.1%)	0	2 (<0.1%)
Neuritis	0	2 (<0.1%)	2 (<0.1%)
Neuritis cranial	0	1 (<0.1%)	1 (<0.1%)
Neurodegenerative disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neuropathy peripheral	98 (4.2%)	82 (3.6%)	180 (3.9%)
Normal pressure hydrocephalus	1 (<0.1%)	0	1 (<0.1%)
Nystagmus	1 (<0.1%)	0	1 (<0.1%)
Optic neuritis	0	1 (<0.1%)	1 (<0.1%)
Orthostatic intolerance	0	1 (<0.1%)	1 (<0.1%)
Paraesthesia	7 (0.3%)	15 (0.7%)	22 (0.5%)
Paralysis recurrent laryngeal nerve	0	1 (<0.1%)	1 (<0.1%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	6 (0.3%)	4 (0.2%)	10 (0.2%)
Parkinsonism	0	1 (<0.1%)	1 (<0.1%)
Parosmia	1 (<0.1%)	0	1 (<0.1%)
Partial seizures	0	2 (<0.1%)	2 (<0.1%)
Perineurial cyst	0	1 (<0.1%)	1 (<0.1%)
Periodic limb movement disorder	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve paresis	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Peripheral sensorimotor neuropathy	4 (0.2%)	6 (0.3%)	10 (0.2%)
Peripheral sensory neuropathy	8 (0.3%)	10 (0.4%)	18 (0.4%)
Peroneal nerve palsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Petit mal epilepsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phantom limb syndrome	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Pineal gland cyst	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	30 (1.3%)	38 (1.6%)	68 (1.5%)
Polyneuropathy chronic	1 (<0.1%)	0	1 (<0.1%)
Post herpetic neuralgia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Post polio syndrome	2 (<0.1%)	0	2 (<0.1%)
Posterior cortical atrophy	0	1 (<0.1%)	1 (<0.1%)
Precerebral arteriosclerosis	0	1 (<0.1%)	1 (<0.1%)
Presyncope	0	1 (<0.1%)	1 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Radicular pain	0	2 (<0.1%)	2 (<0.1%)
Radiculopathy	8 (0.3%)	6 (0.3%)	14 (0.3%)
Resting tremor	0	1 (<0.1%)	1 (<0.1%)
Restless legs syndrome	10 (0.4%)	11 (0.5%)	21 (0.5%)
Right hemisphere deficit syndrome	0	1 (<0.1%)	1 (<0.1%)
Sacral radiculopathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	20 (0.9%)	34 (1.5%)	54 (1.2%)
Seizure	4 (0.2%)	5 (0.2%)	9 (0.2%)
Sensorimotor disorder	0	1 (<0.1%)	1 (<0.1%)
Sensory disturbance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Simple partial seizures	0	1 (<0.1%)	1 (<0.1%)
Somnolence	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Spinal claudication	0	1 (<0.1%)	1 (<0.1%)
Spinal cord disorder	1 (<0.1%)	0	1 (<0.1%)
Spinal cord herniation	1 (<0.1%)	0	1 (<0.1%)
Spinal stroke	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	0	3 (0.1%)	3 (<0.1%)
Syncope	7 (0.3%)	6 (0.3%)	13 (0.3%)
Taste disorder	1 (<0.1%)	0	1 (<0.1%)
Tension headache	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Thalamic infarction	1 (<0.1%)	0	1 (<0.1%)
Thoracic outlet syndrome	1 (<0.1%)	0	1 (<0.1%)
Tongue biting	1 (<0.1%)	0	1 (<0.1%)
Toxic encephalopathy	1 (<0.1%)	0	1 (<0.1%)
Transient ischaemic attack	43 (1.8%)	25 (1.1%)	68 (1.5%)
Transverse sinus thrombosis	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Tremor	7 (0.3%)	4 (0.2%)	11 (0.2%)
Trigeminal neuralgia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
VIth nerve disorder	1 (<0.1%)	0	1 (<0.1%)
VIth nerve paralysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vascular dementia	0	1 (<0.1%)	1 (<0.1%)
Vascular encephalopathy	31 (1.3%)	27 (1.2%)	58 (1.3%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery stenosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Vertebrobasilar insufficiency	5 (0.2%)	8 (0.3%)	13 (0.3%)
Vertigo CNS origin	2 (<0.1%)	0	2 (<0.1%)
Visual field defect	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vocal cord paralysis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
White matter lesion	2 (<0.1%)	0	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	6 (0.3%)	9 (0.4%)	15 (0.3%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Gestational diabetes	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pre-eclampsia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Product issues	0	1 (<0.1%)	1 (<0.1%)
Thrombosis in device	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	307 (13.2%)	326 (14.1%)	633 (13.7%)
Adjustment disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adjustment disorder with depressed mood	0	3 (0.1%)	3 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	1 (<0.1%)	0	1 (<0.1%)
Affective disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Alcohol use disorder	0	1 (<0.1%)	1 (<0.1%)
Alcoholism	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Anxiety	61 (2.6%)	76 (3.3%)	137 (3.0%)
Anxiety disorder	18 (0.8%)	13 (0.6%)	31 (0.7%)
Attention deficit hyperactivity disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bipolar disorder	6 (0.3%)	4 (0.2%)	10 (0.2%)
Borderline personality disorder	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Breathing-related sleep disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Claustrophobia	2 (<0.1%)	0	2 (<0.1%)
Depressed mood	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Depression	133 (5.7%)	148 (6.4%)	281 (6.1%)
Disorientation	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug dependence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dyssomnia	1 (<0.1%)	0	1 (<0.1%)
Enuresis	0	1 (<0.1%)	1 (<0.1%)
Generalised anxiety disorder	8 (0.3%)	4 (0.2%)	12 (0.3%)
Hallucination	1 (<0.1%)	0	1 (<0.1%)
Insomnia	104 (4.5%)	86 (3.7%)	190 (4.1%)
Libido decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Major depression	12 (0.5%)	14 (0.6%)	26 (0.6%)
Mental disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mixed anxiety and depressive disorder	6 (0.3%)	3 (0.1%)	9 (0.2%)
Neurosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nicotine dependence	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Obsessive-compulsive disorder	0	1 (<0.1%)	1 (<0.1%)
Panic attack	1 (<0.1%)	0	1 (<0.1%)
Panic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Persistent depressive disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Personality disorder	1 (<0.1%)	0	1 (<0.1%)
Polydipsia psychogenic	1 (<0.1%)	0	1 (<0.1%)
Post-traumatic stress disorder	7 (0.3%)	9 (0.4%)	16 (0.3%)
Premature ejaculation	1 (<0.1%)	0	1 (<0.1%)
Schizophrenia	3 (0.1%)	5 (0.2%)	8 (0.2%)
Schizophreniform disorder	0	1 (<0.1%)	1 (<0.1%)
Sleep disorder	15 (0.6%)	18 (0.8%)	33 (0.7%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	1 (<0.1%)	0	1 (<0.1%)
Stress	1 (<0.1%)	0	1 (<0.1%)
Substance abuse	1 (<0.1%)	0	1 (<0.1%)
Suicide attempt	1 (<0.1%)	0	1 (<0.1%)
Tobacco abuse	8 (0.3%)	6 (0.3%)	14 (0.3%)
Renal and urinary disorders	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Acquired cystic kidney disease	4 (0.2%)	4 (0.2%)	8 (0.2%)
Acute kidney injury	9 (0.4%)	8 (0.3%)	17 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Albuminuria	129 (5.5%)	129 (5.6%)	258 (5.6%)
Azotaemia	0	2 (<0.1%)	2 (<0.1%)
Bladder discomfort	1 (<0.1%)	0	1 (<0.1%)
Bladder dysfunction	0	1 (<0.1%)	1 (<0.1%)
Bladder prolapse	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Calculus urinary	27 (1.2%)	21 (0.9%)	48 (1.0%)
Chronic kidney disease	2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Cystitis interstitial	1 (<0.1%)	0	1 (<0.1%)
Detrusor sphincter dyssynergia	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	137 (5.9%)	161 (7.0%)	298 (6.4%)
Dysuria	2 (<0.1%)	4 (0.2%)	6 (0.1%)
End stage renal disease	0	1 (<0.1%)	1 (<0.1%)
Focal segmental glomerulosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Follicular cystitis	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	6 (0.3%)	5 (0.2%)	11 (0.2%)
Glomerulonephritis membranous	1 (<0.1%)	0	1 (<0.1%)
Glomerulonephritis proliferative	0	1 (<0.1%)	1 (<0.1%)
Glycosuria	1 (<0.1%)	0	1 (<0.1%)
Haematuria	12 (0.5%)	15 (0.7%)	27 (0.6%)
Hydronephrosis	15 (0.6%)	6 (0.3%)	21 (0.5%)
Hypercalciuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypertensive nephropathy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypertonic bladder	10 (0.4%)	11 (0.5%)	21 (0.5%)
Hyperuricosuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypocitraturia	0	1 (<0.1%)	1 (<0.1%)
Intercapillary glomerulosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ketonuria	0	1 (<0.1%)	1 (<0.1%)
Kidney congestion	1 (<0.1%)	0	1 (<0.1%)
Kidney small	0	1 (<0.1%)	1 (<0.1%)
Lower urinary tract symptoms	0	2 (<0.1%)	2 (<0.1%)
Mesangioproliferative glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Microalbuminuria	70 (3.0%)	81 (3.5%)	151 (3.3%)
Micturition urgency	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nephritic syndrome	0	1 (<0.1%)	1 (<0.1%)
Nephritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephroangiosclerosis	1 (<0.1%)	0	1 (<0.1%)
Nephrolithiasis	120 (5.2%)	120 (5.2%)	240 (5.2%)
Nephropathy	11 (0.5%)	5 (0.2%)	16 (0.3%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Nephroptosis	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Nephrosclerosis	2 (<0.1%)	0	2 (<0.1%)
Nephrotic syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Neurogenic bladder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Nocturia	15 (0.6%)	10 (0.4%)	25 (0.5%)
Obstructive nephropathy	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	4 (0.2%)	5 (0.2%)	9 (0.2%)
Polyuria	0	5 (0.2%)	5 (0.1%)
Post streptococcal glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Proteinuria	86 (3.7%)	95 (4.1%)	181 (3.9%)
Pyelocaliectasis	0	1 (<0.1%)	1 (<0.1%)
Reduced bladder capacity	1 (<0.1%)	0	1 (<0.1%)
Renal artery arteriosclerosis	0	1 (<0.1%)	1 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Renal atrophy	0	2 (<0.1%)	2 (<0.1%)
Renal colic	11 (0.5%)	14 (0.6%)	25 (0.5%)
Renal cyst	81 (3.5%)	75 (3.3%)	156 (3.4%)
Renal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal failure	3 (0.1%)	4 (0.2%)	7 (0.2%)
Renal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Renal impairment	0	2 (<0.1%)	2 (<0.1%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	0	1 (<0.1%)	1 (<0.1%)
Single functional kidney	1 (<0.1%)	0	1 (<0.1%)
Stress urinary incontinence	3 (0.1%)	5 (0.2%)	8 (0.2%)
Tubulointerstitial nephritis	2 (<0.1%)	0	2 (<0.1%)
Ureteric stenosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ureterocele	0	1 (<0.1%)	1 (<0.1%)
Ureterolithiasis	15 (0.6%)	3 (0.1%)	18 (0.4%)
Urethral disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Urge incontinence	0	1 (<0.1%)	1 (<0.1%)
Urinary bladder polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary bladder varices	0	1 (<0.1%)	1 (<0.1%)
Urinary hesitation	0	1 (<0.1%)	1 (<0.1%)
Urinary incontinence	18 (0.8%)	16 (0.7%)	34 (0.7%)
Urinary retention	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Urinary tract disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Urinary tract obstruction	3 (0.1%)	1 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Urine abnormality	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Reproductive system and breast disorders	407 (17.5%)	389 (16.9%)	796 (17.2%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Adenomyosis	0	1 (<0.1%)	1 (<0.1%)
Adnexa uteri cyst	0	1 (<0.1%)	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Artificial menopause	0	1 (<0.1%)	1 (<0.1%)
Atrophic vulvovaginitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Azoospermia	1 (<0.1%)	0	1 (<0.1%)
Balanoposthitis	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Benign prostatic hyperplasia	235 (10.1%)	218 (9.5%)	453 (9.8%)
Breast calcifications	1 (<0.1%)	0	1 (<0.1%)
Breast cyst	3 (0.1%)	0	3 (<0.1%)
Breast disorder	4 (0.2%)	0	4 (<0.1%)
Breast enlargement	1 (<0.1%)	0	1 (<0.1%)
Breast fibrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast hyperplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast mass	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Breast pain	1 (<0.1%)	0	1 (<0.1%)
Calculus prostatic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	3 (0.1%)	0	3 (<0.1%)
Cystocele	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dysmenorrhoea	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Endometrial atrophy	1 (<0.1%)	0	1 (<0.1%)
Endometrial hyperplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Endometriosis	5 (0.2%)	6 (0.3%)	11 (0.2%)
Epididymal cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Erectile dysfunction	103 (4.4%)	123 (5.3%)	226 (4.9%)
Female genital tract fistula	1 (<0.1%)	0	1 (<0.1%)
Genital prolapse	0	1 (<0.1%)	1 (<0.1%)
Gynaecomastia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrosalpinx	2 (<0.1%)	0	2 (<0.1%)
Infertility	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infertility male	0	1 (<0.1%)	1 (<0.1%)
Male reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Menorrhagia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Menstruation irregular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Metrorrhagia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Organic erectile dysfunction	4 (0.2%)	3 (0.1%)	7 (0.2%)
Ovarian cyst	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Ovarian hyperfunction	0	1 (<0.1%)	1 (<0.1%)
Pelvic adhesions	2 (<0.1%)	0	2 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penile oedema	1 (<0.1%)	0	1 (<0.1%)
Perineal pain	0	1 (<0.1%)	1 (<0.1%)
Peyronie's disease	0	2 (<0.1%)	2 (<0.1%)
Polycystic ovaries	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Postmenopausal haemorrhage	2 (<0.1%)	0	2 (<0.1%)
Premature menopause	0	1 (<0.1%)	1 (<0.1%)
Prostatic calcification	8 (0.3%)	4 (0.2%)	12 (0.3%)
Prostatic cyst	2 (<0.1%)	0	2 (<0.1%)
Prostatic disorder	0	3 (0.1%)	3 (<0.1%)
Prostatic mass	1 (<0.1%)	0	1 (<0.1%)
Prostatic obstruction	0	1 (<0.1%)	1 (<0.1%)
Prostatism	4 (0.2%)	5 (0.2%)	9 (0.2%)
Prostatitis	11 (0.5%)	9 (0.4%)	20 (0.4%)
Prostatomegaly	13 (0.6%)	11 (0.5%)	24 (0.5%)
Rectocele	0	1 (<0.1%)	1 (<0.1%)
Reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal cyst	1 (<0.1%)	0	1 (<0.1%)
Scrotal swelling	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	6 (0.3%)	3 (0.1%)	9 (0.2%)
Spermatocele	0	1 (<0.1%)	1 (<0.1%)
Testicular atrophy	0	1 (<0.1%)	1 (<0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	0	2 (<0.1%)	2 (<0.1%)
Uterine disorder	1 (<0.1%)	0	1 (<0.1%)
Uterine haemorrhage	4 (0.2%)	0	4 (<0.1%)
Uterine mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine polyp	2 (<0.1%)	0	2 (<0.1%)
Uterine prolapse	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal prolapse	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Varicocele	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vulval disorder	1 (<0.1%)	0	1 (<0.1%)
Vulval polyp	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal dryness	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Vulvovaginal pruritus	1 (<0.1%)	0	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	513 (22.0%)	480 (20.8%)	993 (21.4%)
Acquired diaphragmatic eventration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acute interstitial pneumonitis	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	0	2 (<0.1%)	2 (<0.1%)
Acute respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Adenoidal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic cough	0	1 (<0.1%)	1 (<0.1%)
Allergic sinusitis	1 (<0.1%)	0	1 (<0.1%)
Apnoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aspirin-exacerbated respiratory disease	0	1 (<0.1%)	1 (<0.1%)
Asthma	95 (4.1%)	107 (4.6%)	202 (4.4%)
Atelectasis	3 (0.1%)	0	3 (<0.1%)
Atrophic pharyngitis	0	1 (<0.1%)	1 (<0.1%)
Bronchial disorder	0	1 (<0.1%)	1 (<0.1%)
Bronchial dysplasia	1 (<0.1%)	0	1 (<0.1%)
Bronchial hyperreactivity	0	1 (<0.1%)	1 (<0.1%)
Bronchiectasis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Bronchitis chronic	36 (1.5%)	27 (1.2%)	63 (1.4%)
Bronchopneumopathy	1 (<0.1%)	0	1 (<0.1%)
Bronchospasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Childhood asthma	1 (<0.1%)	0	1 (<0.1%)
Chronic obstructive pulmonary disease	128 (5.5%)	139 (6.0%)	267 (5.8%)
Chronic respiratory failure	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Cough	33 (1.4%)	14 (0.6%)	47 (1.0%)
Cough variant asthma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cystic lung disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysphonia	0	1 (<0.1%)	1 (<0.1%)
Dyspnoea	18 (0.8%)	15 (0.7%)	33 (0.7%)
Dyspnoea exertional	11 (0.5%)	7 (0.3%)	18 (0.4%)
Emphysema	10 (0.4%)	13 (0.6%)	23 (0.5%)
Epiglottic cyst	1 (<0.1%)	0	1 (<0.1%)
Epistaxis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Fibrinous bronchitis	0	1 (<0.1%)	1 (<0.1%)
Haemoptysis	0	1 (<0.1%)	1 (<0.1%)
Hiccups	1 (<0.1%)	0	1 (<0.1%)
Hypercapnia	1 (<0.1%)	0	1 (<0.1%)
Hyperventilation	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Hypoventilation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxia	0	1 (<0.1%)	1 (<0.1%)
Increased upper airway secretion	0	2 (<0.1%)	2 (<0.1%)
Interstitial lung disease	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Laryngeal disorder	0	1 (<0.1%)	1 (<0.1%)
Laryngeal oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal polyp	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Nasal congestion	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Nasal inflammation	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	0	1 (<0.1%)	1 (<0.1%)
Nasal oedema	1 (<0.1%)	0	1 (<0.1%)
Nasal polyps	3 (0.1%)	4 (0.2%)	7 (0.2%)
Nasal pruritus	1 (<0.1%)	0	1 (<0.1%)
Nasal septum deviation	8 (0.3%)	7 (0.3%)	15 (0.3%)
Nasal turbinate hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Obstructive airways disorder	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Oropharyngeal pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Orthopnoea	0	1 (<0.1%)	1 (<0.1%)
Paranasal cyst	2 (<0.1%)	0	2 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paranasal sinus inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pharyngeal fistula	1 (<0.1%)	0	1 (<0.1%)
Pharyngeal polyp	1 (<0.1%)	0	1 (<0.1%)
Pleural disorder	1 (<0.1%)	0	1 (<0.1%)
Pleural effusion	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	0	1 (<0.1%)	1 (<0.1%)
Pleurisy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pneumonitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pneumothorax	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumothorax spontaneous	2 (<0.1%)	0	2 (<0.1%)
Productive cough	0	1 (<0.1%)	1 (<0.1%)
Pulmonary arterial hypertension	0	1 (<0.1%)	1 (<0.1%)
Pulmonary calcification	0	1 (<0.1%)	1 (<0.1%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	9 (0.4%)	7 (0.3%)	16 (0.3%)
Pulmonary fibrosis	3 (0.1%)	4 (0.2%)	7 (0.2%)
Pulmonary hypertension	11 (0.5%)	5 (0.2%)	16 (0.3%)
Pulmonary mass	15 (0.6%)	12 (0.5%)	27 (0.6%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Pulmonary oedema	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Respiratory disorder	1 (<0.1%)	0	1 (<0.1%)
Respiratory failure	0	2 (<0.1%)	2 (<0.1%)
Restrictive pulmonary disease	0	1 (<0.1%)	1 (<0.1%)
Rhinitis allergic	42 (1.8%)	48 (2.1%)	90 (1.9%)
Rhinitis hypertrophic	0	1 (<0.1%)	1 (<0.1%)
Rhinitis perennial	0	2 (<0.1%)	2 (<0.1%)
Rhinorrhoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus congestion	1 (<0.1%)	0	1 (<0.1%)
Sinus disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sleep apnoea syndrome	163 (7.0%)	165 (7.2%)	328 (7.1%)
Snoring	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tonsillar hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Upper-airway cough syndrome	0	1 (<0.1%)	1 (<0.1%)
Vasomotor rhinitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vocal cord leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord thickening	0	1 (<0.1%)	1 (<0.1%)
Wheezing	3 (0.1%)	0	3 (<0.1%)
Skin and subcutaneous tissue disorders	297 (12.8%)	258 (11.2%)	555 (12.0%)
Acanthosis	0	2 (<0.1%)	2 (<0.1%)
Acanthosis nigricans	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Acne	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acquired digital fibrokeratoma	1 (<0.1%)	0	1 (<0.1%)
Actinic keratosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Alopecia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Alopecia areata	0	1 (<0.1%)	1 (<0.1%)
Androgenetic alopecia	0	1 (<0.1%)	1 (<0.1%)
Angioedema	0	2 (<0.1%)	2 (<0.1%)
Asteatosis	0	3 (0.1%)	3 (<0.1%)
Blister	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Brow ptosis	1 (<0.1%)	0	1 (<0.1%)
Chloasma	0	1 (<0.1%)	1 (<0.1%)
Chronic pigmented purpura	0	2 (<0.1%)	2 (<0.1%)
Cutaneous amyloidosis	1 (<0.1%)	0	1 (<0.1%)
Cutaneous lupus erythematosus	0	1 (<0.1%)	1 (<0.1%)
Decubitus ulcer	1 (<0.1%)	0	1 (<0.1%)
Dermal cyst	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Dermatitis	13 (0.6%)	10 (0.4%)	23 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Dermatitis allergic	5 (0.2%)	5 (0.2%)	10 (0.2%)
Dermatitis atopic	8 (0.3%)	4 (0.2%)	12 (0.3%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	7 (0.3%)	4 (0.2%)	11 (0.2%)
Dermatitis exfoliative	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Dermatosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic dermopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic foot	54 (2.3%)	53 (2.3%)	107 (2.3%)
Diabetic ulcer	0	1 (<0.1%)	1 (<0.1%)
Drug eruption	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	1 (<0.1%)	0	1 (<0.1%)
Dry skin	13 (0.6%)	23 (1.0%)	36 (0.8%)
Dyshidrotic eczema	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eczema	31 (1.3%)	21 (0.9%)	52 (1.1%)
Eczema asteatotic	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eczema nummular	0	2 (<0.1%)	2 (<0.1%)
Erythema	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Excessive skin	1 (<0.1%)	0	1 (<0.1%)
Hair disorder	1 (<0.1%)	0	1 (<0.1%)
Hidradenitis	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Hirsutism	1 (<0.1%)	0	1 (<0.1%)
Hyperhidrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperkeratosis	10 (0.4%)	7 (0.3%)	17 (0.4%)
Ingrowing nail	4 (0.2%)	3 (0.1%)	7 (0.2%)
Intertrigo	0	1 (<0.1%)	1 (<0.1%)
Ischaemic skin ulcer	2 (<0.1%)	0	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Leukoderma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lichen planus	0	1 (<0.1%)	1 (<0.1%)
Lichen sclerosus	1 (<0.1%)	0	1 (<0.1%)
Lichenoid keratosis	1 (<0.1%)	0	1 (<0.1%)
Linear IgA disease	0	1 (<0.1%)	1 (<0.1%)
Lipodystrophy acquired	0	2 (<0.1%)	2 (<0.1%)
Lipohypertrophy	1 (<0.1%)	0	1 (<0.1%)
Miliaria	2 (<0.1%)	0	2 (<0.1%)
Nail disorder	1 (<0.1%)	0	1 (<0.1%)
Nail hypertrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nail pigmentation	1 (<0.1%)	0	1 (<0.1%)
Neurodermatitis	6 (0.3%)	4 (0.2%)	10 (0.2%)
Night sweats	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Onychogryphosis	0	1 (<0.1%)	1 (<0.1%)
Palmoplantar keratoderma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Palmoplantar pustulosis	1 (<0.1%)	0	1 (<0.1%)
Papule	0	1 (<0.1%)	1 (<0.1%)
Parapsoriasis	1 (<0.1%)	0	1 (<0.1%)
Photosensitivity reaction	0	1 (<0.1%)	1 (<0.1%)
Prurigo	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pruritus	19 (0.8%)	16 (0.7%)	35 (0.8%)
Psoriasis	34 (1.5%)	37 (1.6%)	71 (1.5%)
Pyoderma gangrenosum	0	1 (<0.1%)	1 (<0.1%)
Rash	8 (0.3%)	7 (0.3%)	15 (0.3%)
Rash papular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rash pruritic	1 (<0.1%)	0	1 (<0.1%)
Rosacea	3 (0.1%)	5 (0.2%)	8 (0.2%)
Sebaceous hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	0	2 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	14 (0.6%)	8 (0.3%)	22 (0.5%)
Segmented hyalinising vasculitis	1 (<0.1%)	0	1 (<0.1%)
Senile xerosis	1 (<0.1%)	0	1 (<0.1%)
Skin atrophy	1 (<0.1%)	0	1 (<0.1%)
Skin discolouration	0	1 (<0.1%)	1 (<0.1%)
Skin exfoliation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin hyperpigmentation	2 (<0.1%)	0	2 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Skin maceration	1 (<0.1%)	0	1 (<0.1%)
Skin mass	1 (<0.1%)	0	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	25 (1.1%)	20 (0.9%)	45 (1.0%)
Skin warm	1 (<0.1%)	0	1 (<0.1%)
Solar dermatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Solar lentigo	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Telangiectasia	1 (<0.1%)	0	1 (<0.1%)
Urticaria	8 (0.3%)	6 (0.3%)	14 (0.3%)
Urticaria chronic	2 (<0.1%)	0	2 (<0.1%)
Vascular skin disorder	1 (<0.1%)	0	1 (<0.1%)
Vitiligo	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Xanthelasma	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Xeroderma	4 (0.2%)	4 (0.2%)	8 (0.2%)
Social circumstances	133 (5.7%)	115 (5.0%)	248 (5.4%)
Alcohol use	0	1 (<0.1%)	1 (<0.1%)
Corrective lens user	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug abuser	1 (<0.1%)	0	1 (<0.1%)
Edentulous	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ex-alcoholic	1 (<0.1%)	0	1 (<0.1%)
Ex-tobacco user	2 (<0.1%)	0	2 (<0.1%)
Exercise lack of	1 (<0.1%)	0	1 (<0.1%)
Familial risk factor	1 (<0.1%)	0	1 (<0.1%)
Menopause	93 (4.0%)	80 (3.5%)	173 (3.7%)
Parity	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	22 (0.9%)	23 (1.0%)	45 (1.0%)
Tobacco user	9 (0.4%)	10 (0.4%)	19 (0.4%)
Surgical and medical procedures	801 (34.4%)	770 (33.4%)	1571 (33.9%)
Abdominal hernia repair	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Abdominal wall operation	1 (<0.1%)	0	1 (<0.1%)
Abdominoplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Abscess drainage	1 (<0.1%)	4 (0.2%)	5 (0.1%)
Adenoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adenotonsillectomy	1 (<0.1%)	0	1 (<0.1%)
Adrenalectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Amputation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal fissure excision	0	1 (<0.1%)	1 (<0.1%)
Anal fistula repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Androgen replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Angioplasty	16 (0.7%)	12 (0.5%)	28 (0.6%)
Ankle arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle operation	0	1 (<0.1%)	1 (<0.1%)
Anorectal operation	1 (<0.1%)	0	1 (<0.1%)
Antibiotic therapy	0	1 (<0.1%)	1 (<0.1%)
Aorta coarctation repair	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm repair	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic bypass	3 (0.1%)	3 (0.1%)	6 (0.1%)
Aortic valve repair	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Aortic valve replacement	10 (0.4%)	7 (0.3%)	17 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Appendicectomy	75 (3.2%)	99 (4.3%)	174 (3.8%)
Arterial repair	1 (<0.1%)	0	1 (<0.1%)
Arterial stent insertion	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Arteriovenous fistula operation	0	1 (<0.1%)	1 (<0.1%)
Arthrodesis	2 (<0.1%)	0	2 (<0.1%)
Benign breast lump removal	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	0	1 (<0.1%)	1 (<0.1%)
Bladder catheter permanent	0	1 (<0.1%)	1 (<0.1%)
Bladder repair	1 (<0.1%)	0	1 (<0.1%)
Blepharoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bone graft	1 (<0.1%)	0	1 (<0.1%)
Bone marrow transplant	0	1 (<0.1%)	1 (<0.1%)
Bone operation	2 (<0.1%)	0	2 (<0.1%)
Brachytherapy	0	1 (<0.1%)	1 (<0.1%)
Breast conserving surgery	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Breast cyst excision	1 (<0.1%)	0	1 (<0.1%)
Breast reconstruction	1 (<0.1%)	0	1 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	2 (<0.1%)	0	2 (<0.1%)
Caesarean section	18 (0.8%)	11 (0.5%)	29 (0.6%)
Cancer surgery	0	1 (<0.1%)	1 (<0.1%)
Cardiac ablation	0	2 (<0.1%)	2 (<0.1%)
Cardiac pacemaker insertion	12 (0.5%)	15 (0.7%)	27 (0.6%)
Cardiac pacemaker replacement	1 (<0.1%)	0	1 (<0.1%)
Cardioversion	3 (0.1%)	0	3 (<0.1%)
Carotid angioplasty	1 (<0.1%)	0	1 (<0.1%)
Carotid endarterectomy	20 (0.9%)	22 (1.0%)	42 (0.9%)
Carpal tunnel decompression	16 (0.7%)	6 (0.3%)	22 (0.5%)
Cataract operation	65 (2.8%)	89 (3.9%)	154 (3.3%)
Catheter placement	0	1 (<0.1%)	1 (<0.1%)
Chemonucleolysis	1 (<0.1%)	0	1 (<0.1%)
Chest wall operation	0	1 (<0.1%)	1 (<0.1%)
Cholecystectomy	118 (5.1%)	114 (4.9%)	232 (5.0%)
Cholelithotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Circumcision	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Colectomy	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Colectomy total	0	2 (<0.1%)	2 (<0.1%)
Colorectostomy	1 (<0.1%)	0	1 (<0.1%)
Colostomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Colostomy closure	1 (<0.1%)	0	1 (<0.1%)
Colporrhaphy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Corneal operation	0	1 (<0.1%)	1 (<0.1%)
Coronary angioplasty	26 (1.1%)	29 (1.3%)	55 (1.2%)
Coronary arterial stent insertion	72 (3.1%)	52 (2.3%)	124 (2.7%)
Coronary artery bypass	58 (2.5%)	60 (2.6%)	118 (2.5%)
Coronary revascularisation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cranial operation	1 (<0.1%)	0	1 (<0.1%)
Cyst removal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cystostomy	1 (<0.1%)	0	1 (<0.1%)
Debridement	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dental prosthesis placement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus management	0	1 (<0.1%)	1 (<0.1%)
Dialysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Duodenal ulcer repair	1 (<0.1%)	0	1 (<0.1%)
Duodeno-jejunal bypass sleeve therapy	1 (<0.1%)	0	1 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	0	1 (<0.1%)
Ear operation	0	2 (<0.1%)	2 (<0.1%)
Elbow operation	0	1 (<0.1%)	1 (<0.1%)
Endarterectomy	1 (<0.1%)	0	1 (<0.1%)
Endarterectomy of aorta	1 (<0.1%)	0	1 (<0.1%)
Endocarditis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	0	1 (<0.1%)
Epidermoid cyst excision	1 (<0.1%)	0	1 (<0.1%)
Eventration repair	1 (<0.1%)	0	1 (<0.1%)
Explorative laparotomy	0	2 (<0.1%)	2 (<0.1%)
Eye laser surgery	10 (0.4%)	9 (0.4%)	19 (0.4%)
Eye operation	3 (0.1%)	4 (0.2%)	7 (0.2%)
Eye prosthesis insertion	3 (0.1%)	0	3 (<0.1%)
Eyelid operation	0	1 (<0.1%)	1 (<0.1%)
Facetectomy	0	1 (<0.1%)	1 (<0.1%)
Fallopian tube operation	0	1 (<0.1%)	1 (<0.1%)
Fasciotomy	0	1 (<0.1%)	1 (<0.1%)
Female sterilisation	23 (1.0%)	18 (0.8%)	41 (0.9%)
Finger amputation	5 (0.2%)	3 (0.1%)	8 (0.2%)
Finger repair operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fistula repair	0	2 (<0.1%)	2 (<0.1%)
Foot amputation	8 (0.3%)	6 (0.3%)	14 (0.3%)
Foot operation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Gallbladder operation	4 (0.2%)	5 (0.2%)	9 (0.2%)
Gastrectomy	4 (0.2%)	4 (0.2%)	8 (0.2%)
Gastric banding	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastric bypass	4 (0.2%)	7 (0.3%)	11 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Gastric electrical stimulation	1 (<0.1%)	0	1 (<0.1%)
Gastric stapling	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric ulcer surgery	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal endoscopic therapy	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal surgery	1 (<0.1%)	0	1 (<0.1%)
Gastrostomy	1 (<0.1%)	0	1 (<0.1%)
Glaucoma surgery	3 (0.1%)	5 (0.2%)	8 (0.2%)
Haemorrhoid operation	5 (0.2%)	5 (0.2%)	10 (0.2%)
Haemostasis	0	1 (<0.1%)	1 (<0.1%)
Hand amputation	1 (<0.1%)	0	1 (<0.1%)
Hand repair operation	1 (<0.1%)	0	1 (<0.1%)
Hearing aid therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	1 (<0.1%)	0	1 (<0.1%)
Hepatectomy	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B immunisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	0	1 (<0.1%)
Hernia repair	6 (0.3%)	11 (0.5%)	17 (0.4%)
High frequency ablation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hip arthroplasty	17 (0.7%)	14 (0.6%)	31 (0.7%)
Hip surgery	0	1 (<0.1%)	1 (<0.1%)
Hydrocele operation	0	2 (<0.1%)	2 (<0.1%)
Hysterectomy	61 (2.6%)	55 (2.4%)	116 (2.5%)
Hysterosalpingo-oophorectomy	6 (0.3%)	6 (0.3%)	12 (0.3%)
Ileocolostomy	1 (<0.1%)	0	1 (<0.1%)
Ileojejunal bypass	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	0	1 (<0.1%)	1 (<0.1%)
Implantable cardiac monitor insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Implantable defibrillator insertion	5 (0.2%)	3 (0.1%)	8 (0.2%)
Incisional drainage	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia repair	0	1 (<0.1%)	1 (<0.1%)
Inguinal hernia repair	22 (0.9%)	23 (1.0%)	45 (1.0%)
Internal fixation of fracture	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Internal fixation of spine	1 (<0.1%)	0	1 (<0.1%)
Internal limiting membrane peeling	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc operation	15 (0.6%)	10 (0.4%)	25 (0.5%)
Intestinal resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intra-cerebral aneurysm operation	1 (<0.1%)	0	1 (<0.1%)
Intra-ocular injection	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Intra-uterine contraceptive device insertion	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Intraocular lens implant	17 (0.7%)	11 (0.5%)	28 (0.6%)
Intravitreal implant	1 (<0.1%)	0	1 (<0.1%)
Jaw operation	0	1 (<0.1%)	1 (<0.1%)
Joint arthroplasty	2 (<0.1%)	0	2 (<0.1%)
Knee arthroplasty	26 (1.1%)	25 (1.1%)	51 (1.1%)
Knee operation	8 (0.3%)	10 (0.4%)	18 (0.4%)
Lacrimal duct procedure	0	1 (<0.1%)	1 (<0.1%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	9 (0.4%)	9 (0.4%)	18 (0.4%)
Laryngectomy	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	0	3 (0.1%)	3 (<0.1%)
Leg amputation	18 (0.8%)	18 (0.8%)	36 (0.8%)
Lens extraction	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	3 (0.1%)	3 (0.1%)	6 (0.1%)
Limb operation	1 (<0.1%)	0	1 (<0.1%)
Lipectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lipoma excision	3 (0.1%)	4 (0.2%)	7 (0.2%)
Liposuction	0	2 (<0.1%)	2 (<0.1%)
Lithotripsy	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Lung lobectomy	0	2 (<0.1%)	2 (<0.1%)
Lymphadenectomy	1 (<0.1%)	0	1 (<0.1%)
Manual lymphatic drainage	0	1 (<0.1%)	1 (<0.1%)
Mass excision	0	1 (<0.1%)	1 (<0.1%)
Mastectomy	7 (0.3%)	3 (0.1%)	10 (0.2%)
Mastoidectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Maxillary antrum operation	1 (<0.1%)	0	1 (<0.1%)
Medical device removal	1 (<0.1%)	0	1 (<0.1%)
Meningioma surgery	0	2 (<0.1%)	2 (<0.1%)
Meniscus operation	4 (0.2%)	3 (0.1%)	7 (0.2%)
Meniscus removal	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Metabolic surgery	0	1 (<0.1%)	1 (<0.1%)
Metatarsal excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mitral valve repair	0	2 (<0.1%)	2 (<0.1%)
Mole excision	1 (<0.1%)	0	1 (<0.1%)
Multiple drug therapy	2 (<0.1%)	0	2 (<0.1%)
Muscle operation	1 (<0.1%)	0	1 (<0.1%)
Myomectomy	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Nail operation	1 (<0.1%)	0	1 (<0.1%)
Nasal polypectomy	2 (<0.1%)	0	2 (<0.1%)
Nasal septal operation	4 (0.2%)	1 (<0.1%)	5 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Nephrectomy	11 (0.5%)	10 (0.4%)	21 (0.5%)
Nephrostomy	0	3 (0.1%)	3 (<0.1%)
Nerve block	0	1 (<0.1%)	1 (<0.1%)
Neurolysis	1 (<0.1%)	0	1 (<0.1%)
Oesophageal dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Oesophagogastric fundoplasty	0	1 (<0.1%)	1 (<0.1%)
Omentectomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	6 (0.3%)	2 (<0.1%)	8 (0.2%)
Oophorectomy bilateral	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Ophthalmic fluid-air exchange procedure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Orchidectomy	3 (0.1%)	0	3 (<0.1%)
Ostectomy	1 (<0.1%)	0	1 (<0.1%)
Ovarian cystectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ovarian operation	1 (<0.1%)	0	1 (<0.1%)
Palatoplasty	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pancreatic cyst drainage	1 (<0.1%)	0	1 (<0.1%)
Pancreatic stent placement	0	1 (<0.1%)	1 (<0.1%)
Papilloma excision	0	2 (<0.1%)	2 (<0.1%)
Parathyroidectomy	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Parotidectomy	0	1 (<0.1%)	1 (<0.1%)
Pelvic operation	1 (<0.1%)	0	1 (<0.1%)
Penile prosthesis insertion	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Percutaneous coronary intervention	18 (0.8%)	19 (0.8%)	37 (0.8%)
Perineoplasty	4 (0.2%)	1 (<0.1%)	5 (0.1%)
Peripheral artery angioplasty	10 (0.4%)	11 (0.5%)	21 (0.5%)
Peripheral artery bypass	10 (0.4%)	10 (0.4%)	20 (0.4%)
Peripheral artery stent insertion	10 (0.4%)	10 (0.4%)	20 (0.4%)
Peripheral endarterectomy	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Peripheral nerve decompression	2 (<0.1%)	0	2 (<0.1%)
Peripheral revascularisation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Permanent cosmetic dermapigmentation	1 (<0.1%)	0	1 (<0.1%)
Pharyngectomy	1 (<0.1%)	0	1 (<0.1%)
Phlebectomy	9 (0.4%)	7 (0.3%)	16 (0.3%)
Photorefractive keratectomy	1 (<0.1%)	0	1 (<0.1%)
Pilonidal sinus repair	2 (<0.1%)	0	2 (<0.1%)
Polypectomy	6 (0.3%)	6 (0.3%)	12 (0.3%)
Proctectomy	2 (<0.1%)	0	2 (<0.1%)
Profundaplasty	1 (<0.1%)	0	1 (<0.1%)
Prolapse repair	1 (<0.1%)	0	1 (<0.1%)
Prostatectomy	7 (0.3%)	6 (0.3%)	13 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Prostatic operation	1 (<0.1%)	0	1 (<0.1%)
Prosthesis implantation	0	1 (<0.1%)	1 (<0.1%)
Prosthetic vessel implantation	1 (<0.1%)	0	1 (<0.1%)
Pulmonary resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radical hysterectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Radiotherapy	1 (<0.1%)	0	1 (<0.1%)
Radiotherapy to pharynx	1 (<0.1%)	0	1 (<0.1%)
Rectal polypectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Renal replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	8 (0.3%)	8 (0.3%)	16 (0.3%)
Renal surgery	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal sympathetic nerve ablation	1 (<0.1%)	0	1 (<0.1%)
Renal tumour excision	0	1 (<0.1%)	1 (<0.1%)
Retinal cryoablation	1 (<0.1%)	0	1 (<0.1%)
Retinal laser coagulation	10 (0.4%)	11 (0.5%)	21 (0.5%)
Retinal operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinopexy	1 (<0.1%)	0	1 (<0.1%)
Retro-pubic prostatectomy	1 (<0.1%)	0	1 (<0.1%)
Revascularisation procedure	0	1 (<0.1%)	1 (<0.1%)
Rhinoplasty	1 (<0.1%)	0	1 (<0.1%)
Rotator cuff repair	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Roux loop conversion	1 (<0.1%)	0	1 (<0.1%)
Salivary gland resection	1 (<0.1%)	0	1 (<0.1%)
Salpingectomy	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Salpingo-oophorectomy	0	1 (<0.1%)	1 (<0.1%)
Salpingo-oophorectomy bilateral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salpingo-oophorectomy unilateral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scar excision	1 (<0.1%)	0	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)
Scrotal cystectomy	0	1 (<0.1%)	1 (<0.1%)
Sebaceous cyst excision	1 (<0.1%)	0	1 (<0.1%)
Shoulder arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Shoulder operation	4 (0.2%)	5 (0.2%)	9 (0.2%)
Sigmoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sinuplasty	0	1 (<0.1%)	1 (<0.1%)
Sinus operation	0	2 (<0.1%)	2 (<0.1%)
Skin cyst excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin graft	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin neoplasm excision	7 (0.3%)	6 (0.3%)	13 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Skin operation	1 (<0.1%)	0	1 (<0.1%)
Spinal decompression	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal fusion surgery	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal laminectomy	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Spinal operation	6 (0.3%)	3 (0.1%)	9 (0.2%)
Spinal rod insertion	0	1 (<0.1%)	1 (<0.1%)
Splenectomy	4 (0.2%)	7 (0.3%)	11 (0.2%)
Stent placement	9 (0.4%)	17 (0.7%)	26 (0.6%)
Stent removal	1 (<0.1%)	0	1 (<0.1%)
Sterilisation	2 (<0.1%)	0	2 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma evacuation	1 (<0.1%)	0	1 (<0.1%)
Surgery	0	1 (<0.1%)	1 (<0.1%)
Sympathectomy	1 (<0.1%)	0	1 (<0.1%)
Tendon sheath incision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tenoplasty	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Testicular operation	0	2 (<0.1%)	2 (<0.1%)
Testicular prosthesis insertion	0	1 (<0.1%)	1 (<0.1%)
Thoracotomy	0	1 (<0.1%)	1 (<0.1%)
Thrombectomy	1 (<0.1%)	0	1 (<0.1%)
Thromboembolectomy	2 (<0.1%)	0	2 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thrombosis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid nodule removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroidectomy	16 (0.7%)	21 (0.9%)	37 (0.8%)
Toe amputation	42 (1.8%)	23 (1.0%)	65 (1.4%)
Toe operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tonsillectomy	24 (1.0%)	24 (1.0%)	48 (1.0%)
Tooth extraction	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Trabeculectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transfusion	1 (<0.1%)	0	1 (<0.1%)
Transurethral bladder resection	0	2 (<0.1%)	2 (<0.1%)
Transurethral prostatectomy	9 (0.4%)	8 (0.3%)	17 (0.4%)
Turbinectomy	0	1 (<0.1%)	1 (<0.1%)
Turbinoplasty	1 (<0.1%)	0	1 (<0.1%)
Tympanoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia repair	10 (0.4%)	10 (0.4%)	20 (0.4%)
Ureteral stent insertion	5 (0.2%)	2 (<0.1%)	7 (0.2%)
Ureteric calculus removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Ureterocelectomy	0	1 (<0.1%)	1 (<0.1%)
Ureteroneocystostomy	1 (<0.1%)	0	1 (<0.1%)
Urethral operation	0	1 (<0.1%)	1 (<0.1%)
Urinary bladder suspension	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary cystectomy	0	1 (<0.1%)	1 (<0.1%)
Urinary tract operation	0	1 (<0.1%)	1 (<0.1%)
Urostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine cystectomy	0	1 (<0.1%)	1 (<0.1%)
Uterine dilation and curettage	1 (<0.1%)	0	1 (<0.1%)
Uterine polypectomy	1 (<0.1%)	0	1 (<0.1%)
Vaginal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Varicocele repair	0	3 (0.1%)	3 (<0.1%)
Varicose vein operation	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Vascular graft	8 (0.3%)	4 (0.2%)	12 (0.3%)
Vascular operation	0	2 (<0.1%)	2 (<0.1%)
Vascular stent insertion	0	1 (<0.1%)	1 (<0.1%)
Vasectomy	11 (0.5%)	9 (0.4%)	20 (0.4%)
Vasodilation procedure	0	1 (<0.1%)	1 (<0.1%)
Venous angioplasty	1 (<0.1%)	0	1 (<0.1%)
Ventriculo-peritoneal shunt	0	1 (<0.1%)	1 (<0.1%)
Vertebroplasty	0	1 (<0.1%)	1 (<0.1%)
Vision correction operation	1 (<0.1%)	0	1 (<0.1%)
Vitamin supplementation	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	17 (0.7%)	13 (0.6%)	30 (0.6%)
Vocal cord operation	0	2 (<0.1%)	2 (<0.1%)
Vocal cord polypectomy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Wisdom teeth removal	0	1 (<0.1%)	1 (<0.1%)
Wound treatment	0	1 (<0.1%)	1 (<0.1%)
Wrist surgery	3 (0.1%)	0	3 (<0.1%)
Vascular disorders	2241 (96.3%)	2212 (96.0%)	4453 (96.2%)
Aneurysm	1 (<0.1%)	0	1 (<0.1%)
Angiopathy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	5 (0.2%)	14 (0.6%)	19 (0.4%)
Aortic arteriosclerosis	46 (2.0%)	41 (1.8%)	87 (1.9%)
Aortic dilatation	2 (<0.1%)	5 (0.2%)	7 (0.2%)
Aortic disorder	0	1 (<0.1%)	1 (<0.1%)
Aortic dissection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic stenosis	19 (0.8%)	15 (0.7%)	34 (0.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Aortic thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arterial disorder	2 (<0.1%)	0	2 (<0.1%)
Arterial insufficiency	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	3 (0.1%)	2 (<0.1%)	5 (0.1%)
Arterial stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial wall hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriosclerosis	46 (2.0%)	37 (1.6%)	83 (1.8%)
Arteriosclerosis Moenckeberg-type	1 (<0.1%)	0	1 (<0.1%)
Arteriovenous fistula	0	2 (<0.1%)	2 (<0.1%)
Arteritis	1 (<0.1%)	0	1 (<0.1%)
Brachiocephalic arteriosclerosis	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Deep vein thrombosis	12 (0.5%)	20 (0.9%)	32 (0.7%)
Diabetic macroangiopathy	6 (0.3%)	8 (0.3%)	14 (0.3%)
Diabetic microangiopathy	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Diabetic vascular disorder	84 (3.6%)	80 (3.5%)	164 (3.5%)
Dry gangrene	1 (<0.1%)	0	1 (<0.1%)
Embolism	0	1 (<0.1%)	1 (<0.1%)
Essential hypertension	57 (2.4%)	71 (3.1%)	128 (2.8%)
Extremity necrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemorrhagic vasculitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hot flush	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperaemia	0	1 (<0.1%)	1 (<0.1%)
Hypertension	2161 (92.9%)	2118 (91.9%)	4279 (92.4%)
Hypertensive angiopathy	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hypertensive crisis	3 (0.1%)	5 (0.2%)	8 (0.2%)
Hypertensive emergency	1 (<0.1%)	0	1 (<0.1%)
Hypotension	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Intermittent claudication	21 (0.9%)	21 (0.9%)	42 (0.9%)
Lymphangiectasia	0	1 (<0.1%)	1 (<0.1%)
Lymphoedema	4 (0.2%)	3 (0.1%)	7 (0.2%)
Macroangiopathy	4 (0.2%)	5 (0.2%)	9 (0.2%)
Microangiopathy	5 (0.2%)	4 (0.2%)	9 (0.2%)
Orthostatic hypotension	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	305 (13.1%)	295 (12.8%)	600 (13.0%)
Peripheral artery aneurysm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral artery occlusion	5 (0.2%)	4 (0.2%)	9 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Peripheral artery stenosis	2 (<0.1%)	3 (0.1%)	5 (0.1%)
Peripheral artery thrombosis	0	2 (<0.1%)	2 (<0.1%)
Peripheral ischaemia	6 (0.3%)	4 (0.2%)	10 (0.2%)
Peripheral vascular disorder	25 (1.1%)	19 (0.8%)	44 (1.0%)
Peripheral venous disease	49 (2.1%)	34 (1.5%)	83 (1.8%)
Phlebitis	1 (<0.1%)	0	1 (<0.1%)
Post thrombotic syndrome	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Raynaud's phenomenon	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Subclavian artery stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subgaleal haematoma	0	1 (<0.1%)	1 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)
Systolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Takayasu's arteritis	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Thrombosis	3 (0.1%)	4 (0.2%)	7 (0.2%)
Varicophlebitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicose ulceration	1 (<0.1%)	0	1 (<0.1%)
Varicose vein	72 (3.1%)	71 (3.1%)	143 (3.1%)
Vasoconstriction	0	1 (<0.1%)	1 (<0.1%)
Vasodilatation	1 (<0.1%)	0	1 (<0.1%)
Vein disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Venous occlusion	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis limb	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
White coat hypertension	4 (0.2%)	5 (0.2%)	9 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 26JAN2023 15:16
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4.6 Concomitant medication

Table 4.6 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1693 (72.8%)	1720 (74.7%)	3413 (73.7%)
ACEI	321 (13.8%)	342 (14.8%)	663 (14.3%)
ARB	501 (21.5%)	523 (22.7%)	1024 (22.1%)
RAS-inhibitors	744 (32.0%)	765 (33.2%)	1509 (32.6%)
Beta-blocker	500 (21.5%)	513 (22.3%)	1013 (21.9%)
Diuretics	705 (30.3%)	749 (32.5%)	1454 (31.4%)
Loop diuretics	409 (17.6%)	458 (19.9%)	867 (18.7%)
Thiazide diuretics	229 (9.8%)	265 (11.5%)	494 (10.7%)
Potassium supplements	147 (6.3%)	175 (7.6%)	322 (7.0%)
Potassium lowering agents (including binders)	69 (3.0%)	45 (2.0%)	114 (2.5%)
Alpha blocking agents	532 (22.9%)	547 (23.7%)	1079 (23.3%)
Calcium channel blockers	623 (26.8%)	687 (29.8%)	1310 (28.3%)
Centrally acting antihypertensives	86 (3.7%)	105 (4.6%)	191 (4.1%)
Strong CYP3A4 inhibitors	106 (4.6%)	116 (5.0%)	222 (4.8%)
Moderate CYP3A4 inhibitors	281 (12.1%)	305 (13.2%)	586 (12.7%)
Weak CYP3A4 inhibitors	830 (35.7%)	821 (35.6%)	1651 (35.7%)
Unclassified CYP3A4 inhibitors	92 (4.0%)	106 (4.6%)	198 (4.3%)
Strong CYP3A4 inducers	29 (1.2%)	30 (1.3%)	59 (1.3%)
Moderate CYP3A4 inducers	166 (7.1%)	167 (7.2%)	333 (7.2%)
Weak CYP3A4 inducers	134 (5.8%)	126 (5.5%)	260 (5.6%)
Unclassified CYP3A4 inducers	80 (3.4%)	86 (3.7%)	166 (3.6%)
Oral anticoagulants	161 (6.9%)	161 (7.0%)	322 (7.0%)
Acetylsalycylic acid and its salts	347 (14.9%)	339 (14.7%)	686 (14.8%)
Statins	665 (28.6%)	597 (25.9%)	1262 (27.3%)
Erythropoeitin stimulating agents	28 (1.2%)	31 (1.3%)	59 (1.3%)
NSAIDS (excluding acetylsalicylic acid)	686 (29.5%)	699 (30.3%)	1385 (29.9%)
ARNIs	5 (0.2%)	5 (0.2%)	10 (0.2%)
Potassium-sparing diuretics	122 (5.2%)	144 (6.3%)	266 (5.7%)
Platelet aggregation inhibitors (excluding heparin)	513 (22.0%)	507 (22.0%)	1020 (22.0%)
Trimethoprim and derivatives	57 (2.4%)	63 (2.7%)	120 (2.6%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=2327 (100%)	Placebo N=2304 (100%)	Total N=4631 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1375 (59.1%)	1427 (61.9%)	2802 (60.5%)
Insulins and analogues	911 (39.1%)	924 (40.1%)	1835 (39.6%)
Dipeptidyl peptidase 4 inhibitors	356 (15.3%)	335 (14.5%)	691 (14.9%)
Glucagon-like peptide-1(GLP1) agonists	254 (10.9%)	242 (10.5%)	496 (10.7%)
SGLT-2 inhibitors	407 (17.5%)	424 (18.4%)	831 (17.9%)
Biguanides	657 (28.2%)	638 (27.7%)	1295 (28.0%)
Sulfonylureas	290 (12.5%)	304 (13.2%)	594 (12.8%)
Alpha glucosidase inhibitors	95 (4.1%)	87 (3.8%)	182 (3.9%)
Meglitinides	52 (2.2%)	41 (1.8%)	93 (2.0%)
Thiazolidinediones	73 (3.1%)	65 (2.8%)	138 (3.0%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:17
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1.1.1 Study duration

Table 1.1.1 / 1: Study duration (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

		BAY 94-8862 (N=2327)	Placebo (N=2304)	Total (N=4631)
Study duration (months)	n	2327	2304	4631
	Nmiss	0	0	0
	Mean	39.984	39.683	39.834
	SD	11.792	11.984	11.888
	Min	0.95	0.03	0.03
	Median	39.786	39.425	39.622
	Max	61.01	61.63	61.63

Study duration is defined as time from randomization to the EOS visit (or to last contact date if no EOS visit took place).
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl_study_duration_s.sas 06FEB2023 16:29
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1.1.2 Time-to-event analyses

Table 1.1.2 / 1: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	166 (7.1%)	211 (9.2%)
Number (%) of subjects censored	2161 (92.9%)	2093 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.63; 0.95]	
two-sided p-value from stratified logrank test	0.0134	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	166 (7.1%)	211 (9.2%)
Number (%) of subjects censored	2161 (92.9%)	2093 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.63; 0.94]	
two-sided p-value from unstratified logrank test	0.0115	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	217 (9.3%)	281 (12.2%)
Number (%) of subjects censored	2110 (90.7%)	2023 (87.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.63; 0.90]	
two-sided p-value from stratified logrank test	0.0017	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 4: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	73 (3.1%)	108 (4.7%)
Number (%) of subjects censored	2254 (96.9%)	2196 (95.3%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.49; 0.89]	
two-sided p-value from stratified logrank test	0.0063	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 5: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	73 (3.1%)	108 (4.7%)
Number (%) of subjects censored	2254 (96.9%)	2196 (95.3%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.49; 0.90]	
two-sided p-value from unstratified logrank test	0.0069	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 6: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	48 (2.1%)	78 (3.4%)
Number (%) of subjects censored	2279 (97.9%)	2226 (96.6%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.60 [0.42; 0.86]	
two-sided p-value from stratified logrank test	0.0051	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 7: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	22 (0.9%)	38 (1.6%)
Number (%) of subjects censored	2305 (99.1%)	2266 (98.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.34; 0.96]	
two-sided p-value from stratified logrank test	0.0319	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 8: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	22 (0.9%)	38 (1.6%)
Number (%) of subjects censored	2305 (99.1%)	2266 (98.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.34; 0.96]	
two-sided p-value from unstratified logrank test	0.0337	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 9: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	5 (0.2%)	19 (0.8%)
Number (%) of subjects censored	2322 (99.8%)	2285 (99.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.26 [0.10; 0.71]	
two-sided p-value from stratified logrank test	0.0043	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 10: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	17 (0.7%)	34 (1.5%)
Number (%) of subjects censored	2310 (99.3%)	2270 (98.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.49 [0.27; 0.87]	
two-sided p-value from stratified logrank test	0.0131	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 11: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	12 (0.5%)	21 (0.9%)
Number (%) of subjects censored	2315 (99.5%)	2283 (99.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.56 [0.27; 1.13]	
two-sided p-value from stratified logrank test	0.1021	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 12: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	69 (3.0%)	97 (4.2%)
Number (%) of subjects censored	2258 (97.0%)	2207 (95.8%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.51; 0.95]	
two-sided p-value from stratified logrank test	0.0210	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 13: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	0	1 (<0.1%)
Number (%) of subjects censored	2327 (100.0%)	2303 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.00 [0.00;]	
two-sided p-value from stratified logrank test	0.3653	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 14: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	56 (2.4%)	79 (3.4%)
Number (%) of subjects censored	2271 (97.6%)	2225 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.69 [0.49; 0.97]	
two-sided p-value from stratified logrank test	0.0309	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 15: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	263 (11.3%)	291 (12.6%)
Number (%) of subjects censored	2064 (88.7%)	2013 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.75; 1.05]	
two-sided p-value from stratified logrank test	0.1694	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 16: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	263 (11.3%)	291 (12.6%)
Number (%) of subjects censored	2064 (88.7%)	2013 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.75; 1.05]	
two-sided p-value from unstratified logrank test	0.1534	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 17: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	212 (9.1%)	243 (10.5%)
Number (%) of subjects censored	2115 (90.9%)	2061 (89.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.72; 1.04]	
two-sided p-value from stratified logrank test	0.1165	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 18: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	105 (4.5%)	124 (5.4%)
Number (%) of subjects censored	2222 (95.5%)	2180 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.64; 1.08]	
two-sided p-value from stratified logrank test	0.1663	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 19: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	55 (2.4%)	49 (2.1%)
Number (%) of subjects censored	2272 (97.6%)	2255 (97.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.75; 1.63]	
two-sided p-value from stratified logrank test	0.5992	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 20: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	76 (3.3%)	65 (2.8%)
Number (%) of subjects censored	2251 (96.7%)	2239 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.83; 1.61]	
two-sided p-value from stratified logrank test	0.4001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 21: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	59 (2.5%)	91 (3.9%)
Number (%) of subjects censored	2268 (97.5%)	2213 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.46; 0.89]	
two-sided p-value from stratified logrank test	0.0076	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 22: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	65 (2.8%)	53 (2.3%)
Number (%) of subjects censored	2262 (97.2%)	2251 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.21 [0.84; 1.74]	
two-sided p-value from stratified logrank test	0.3050	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 23: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	65 (2.8%)	53 (2.3%)
Number (%) of subjects censored	2262 (97.2%)	2251 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.21 [0.84; 1.74]	
two-sided p-value from unstratified logrank test	0.3078	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 24: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	55 (2.4%)	44 (1.9%)
Number (%) of subjects censored	2272 (97.6%)	2260 (98.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.21 [0.82; 1.81]	
two-sided p-value from stratified logrank test	0.3383	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 25: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	81 (3.5%)	75 (3.3%)
Number (%) of subjects censored	2246 (96.5%)	2229 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.78; 1.45]	
two-sided p-value from stratified logrank test	0.7068	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 26: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	81 (3.5%)	75 (3.3%)
Number (%) of subjects censored	2246 (96.5%)	2229 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.78; 1.45]	
two-sided p-value from unstratified logrank test	0.7089	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 27: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	64 (2.8%)	63 (2.7%)
Number (%) of subjects censored	2263 (97.2%)	2241 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.03 [0.72; 1.45]	
two-sided p-value from stratified logrank test	0.8881	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 28: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	62 (2.7%)	97 (4.2%)
Number (%) of subjects censored	2265 (97.3%)	2207 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.46; 0.87]	
two-sided p-value from stratified logrank test	0.0044	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 29: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	62 (2.7%)	97 (4.2%)
Number (%) of subjects censored	2265 (97.3%)	2207 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.46; 0.86]	
two-sided p-value from unstratified logrank test	0.0036	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 30: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	48 (2.1%)	78 (3.4%)
Number (%) of subjects censored	2279 (97.9%)	2226 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.43; 0.87]	
two-sided p-value from stratified logrank test	0.0064	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 31: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	903 (38.8%)	918 (39.8%)
Number (%) of subjects censored	1424 (61.2%)	1386 (60.2%)
Median Time to event (month) [95 % CI]	n.c.	57.100 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.88; 1.06]	
two-sided p-value from stratified logrank test	0.5056	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 32: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	903 (38.8%)	918 (39.8%)
Number (%) of subjects censored	1424 (61.2%)	1386 (60.2%)
Median Time to event (month) [95 % CI]	n.c.	57.100 [n.c.]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.88; 1.06]	
two-sided p-value from unstratified logrank test	0.4157	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 33: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2327 (100.0%)	2304 (100.0%)
Number (%) of subjects with event	833 (35.8%)	852 (37.0%)
Number (%) of subjects censored	1494 (64.2%)	1452 (63.0%)
Median Time to event (month) [95 % CI]	n.c.	59.533 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.88; 1.07]	
two-sided p-value from stratified logrank test	0.5576	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s2.sas 06FEB2023 16:30
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Table 1.1.2 / 34: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.84; 1.03]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.1517

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 06FEB2023 16:36
End of table

Figure 1.1.2 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

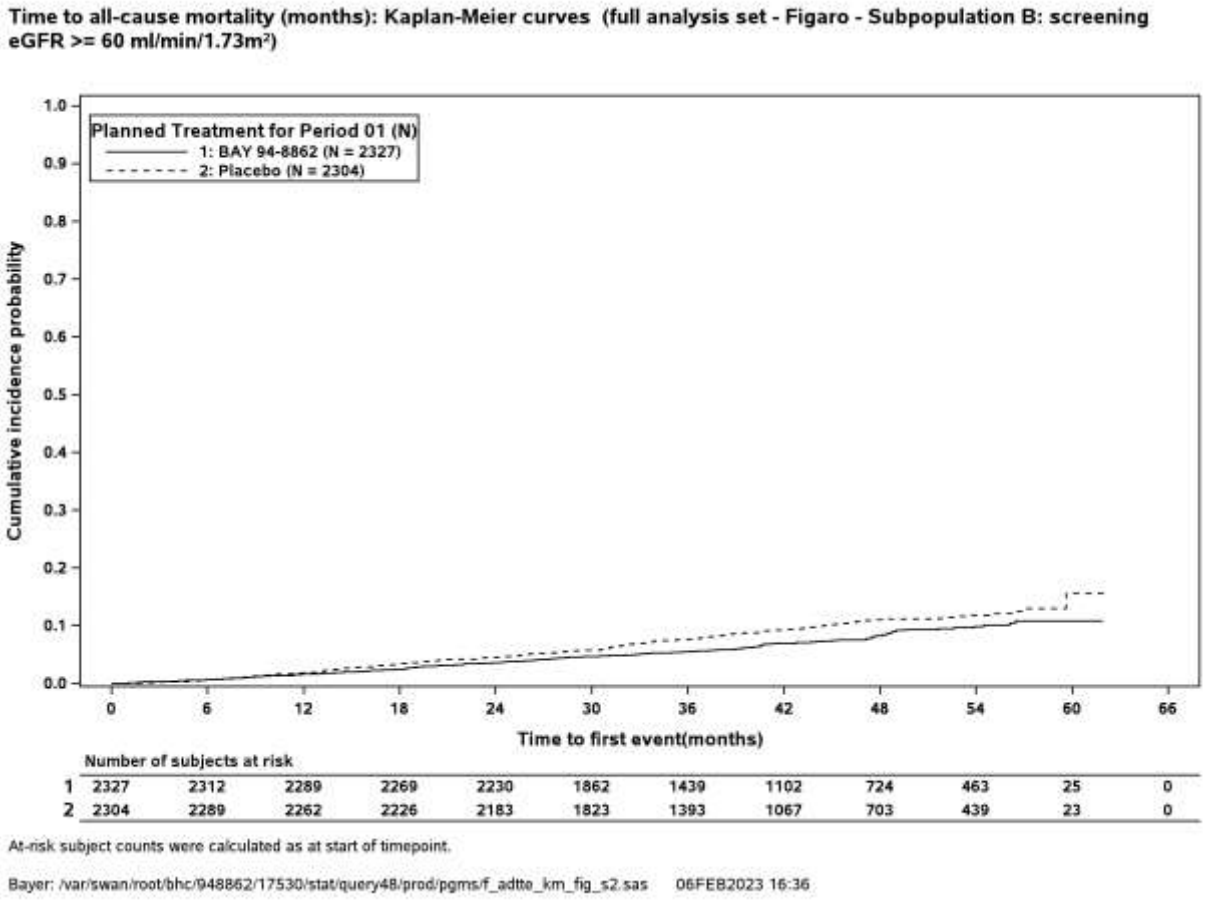


Figure 1.1.2 / 2: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

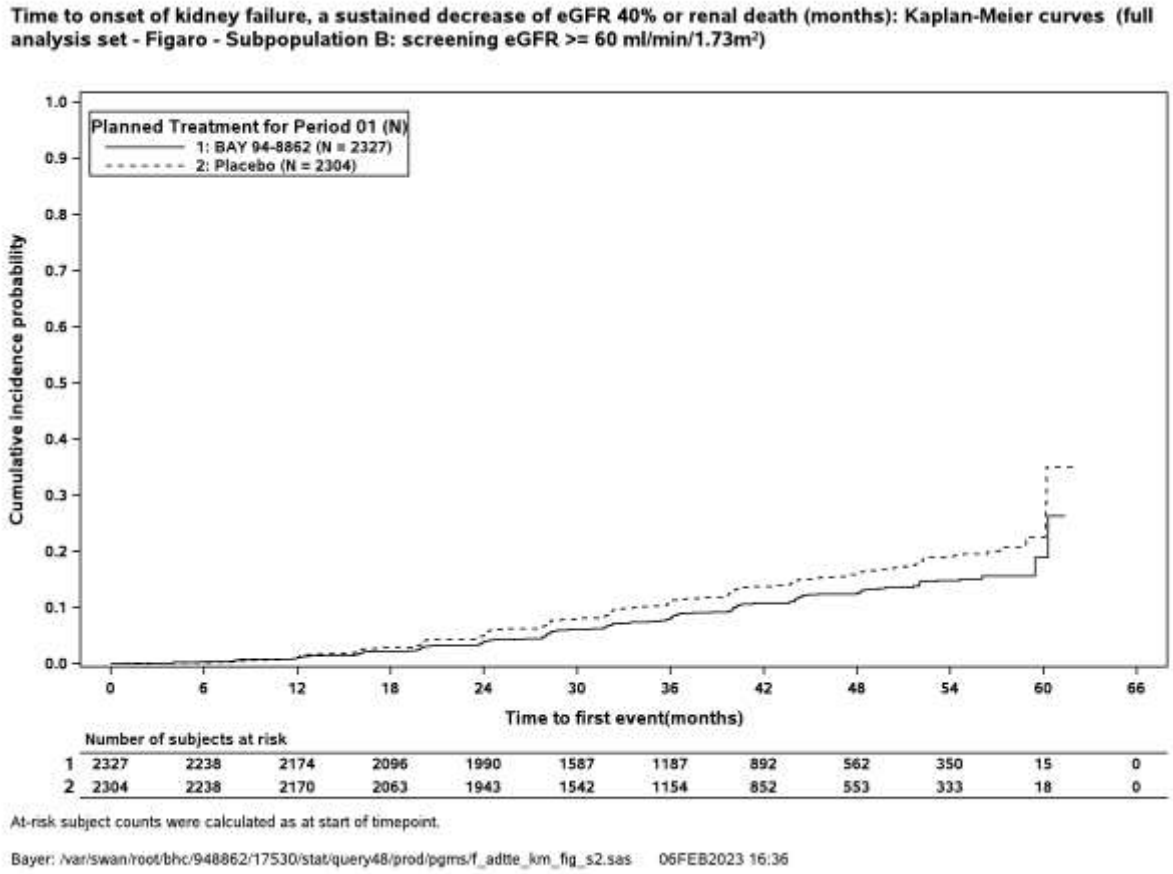


Figure 1.1.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

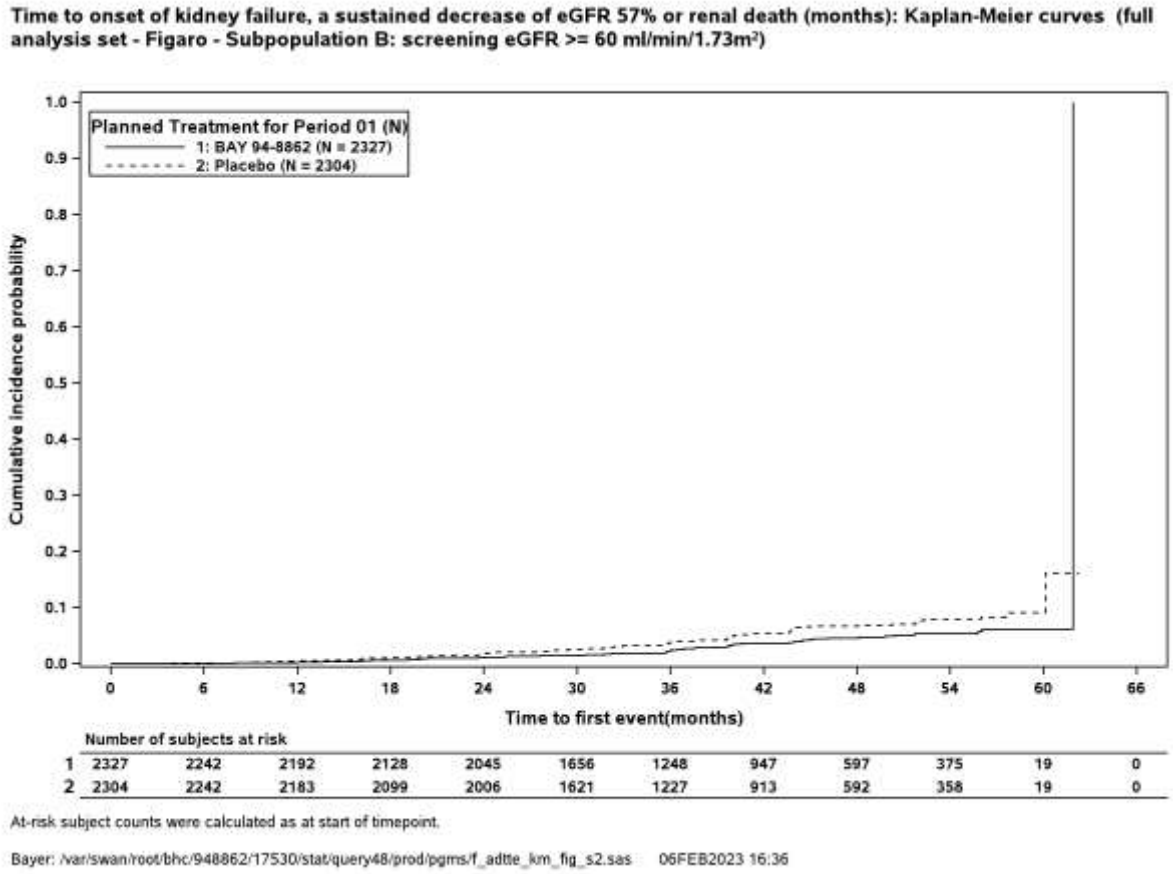


Figure 1.1.2 / 4: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

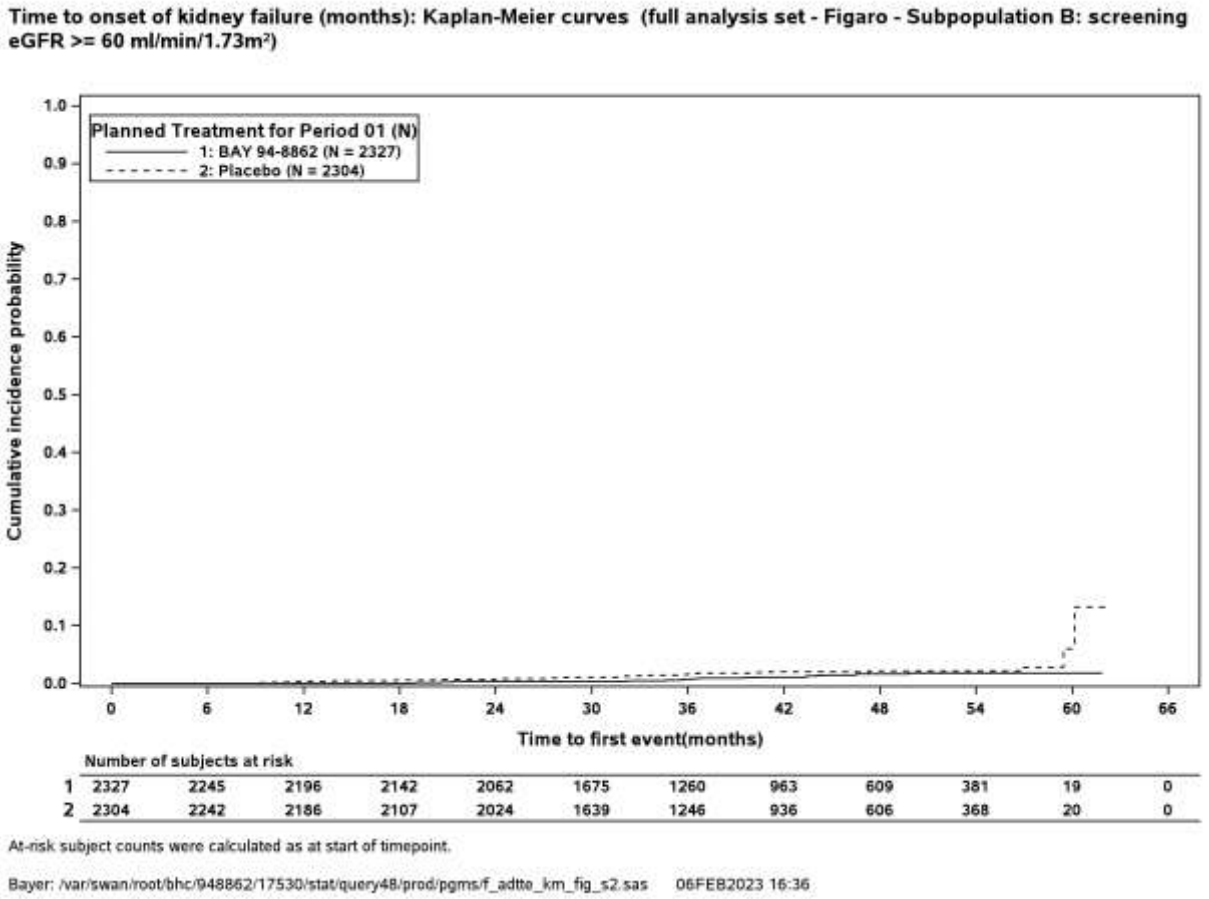


Figure 1.1.2 / 5: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

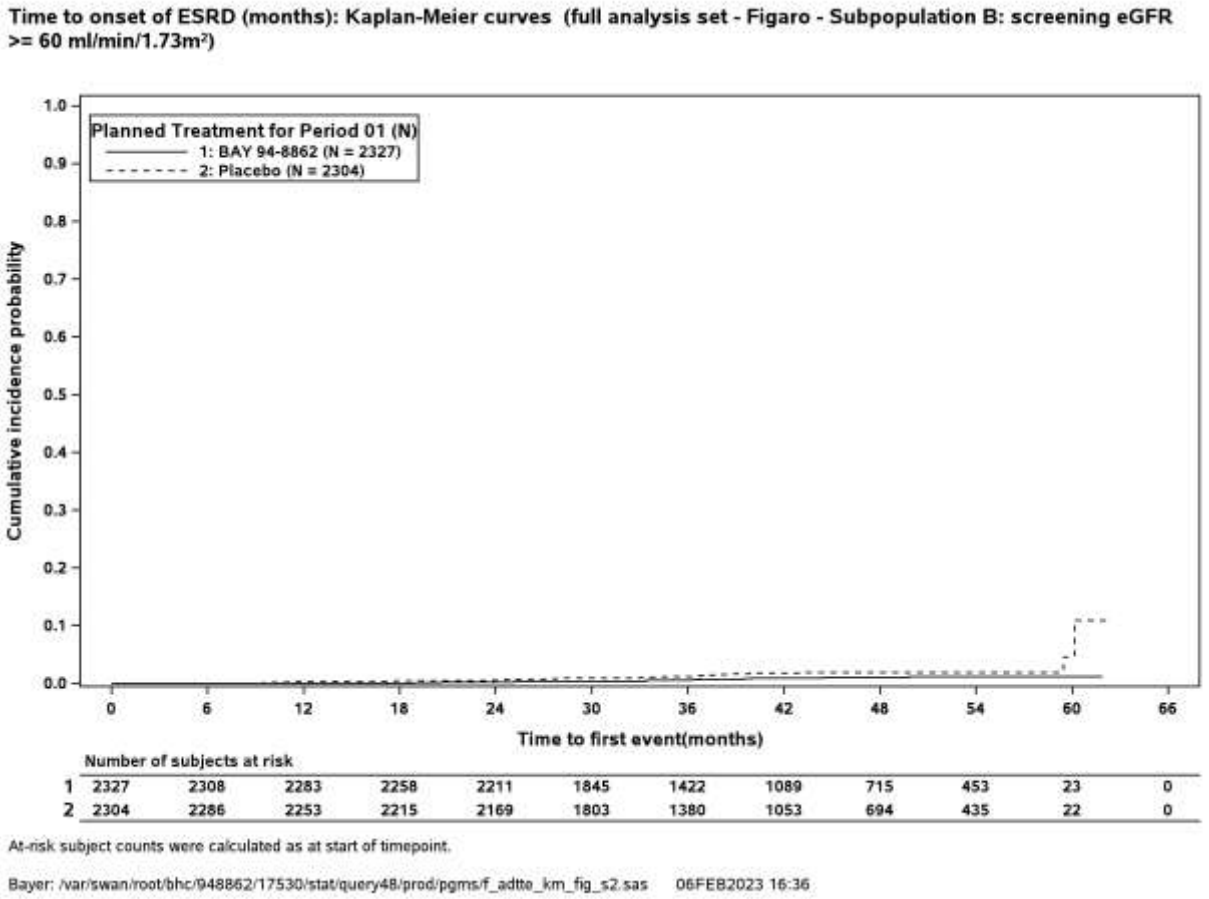


Figure 1.1.2 / 6: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

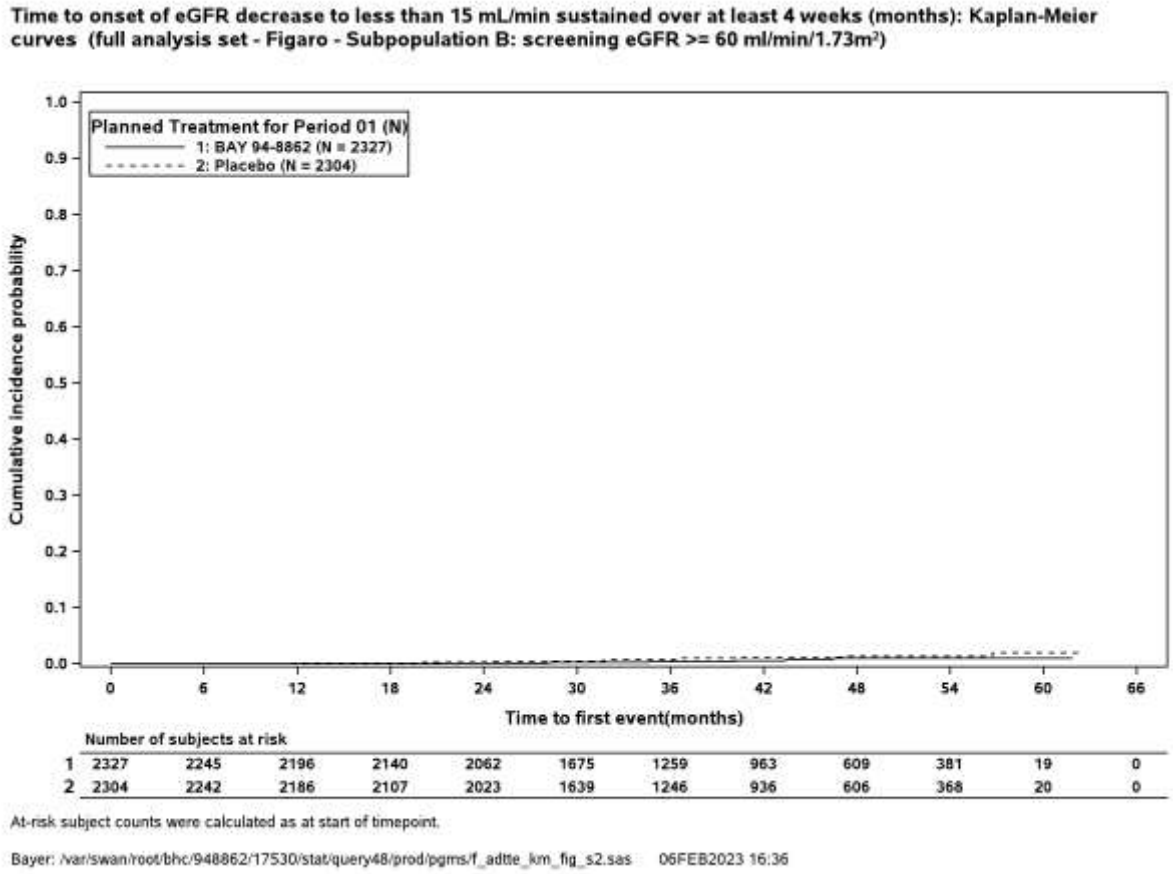


Figure 1.1.2 / 7: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

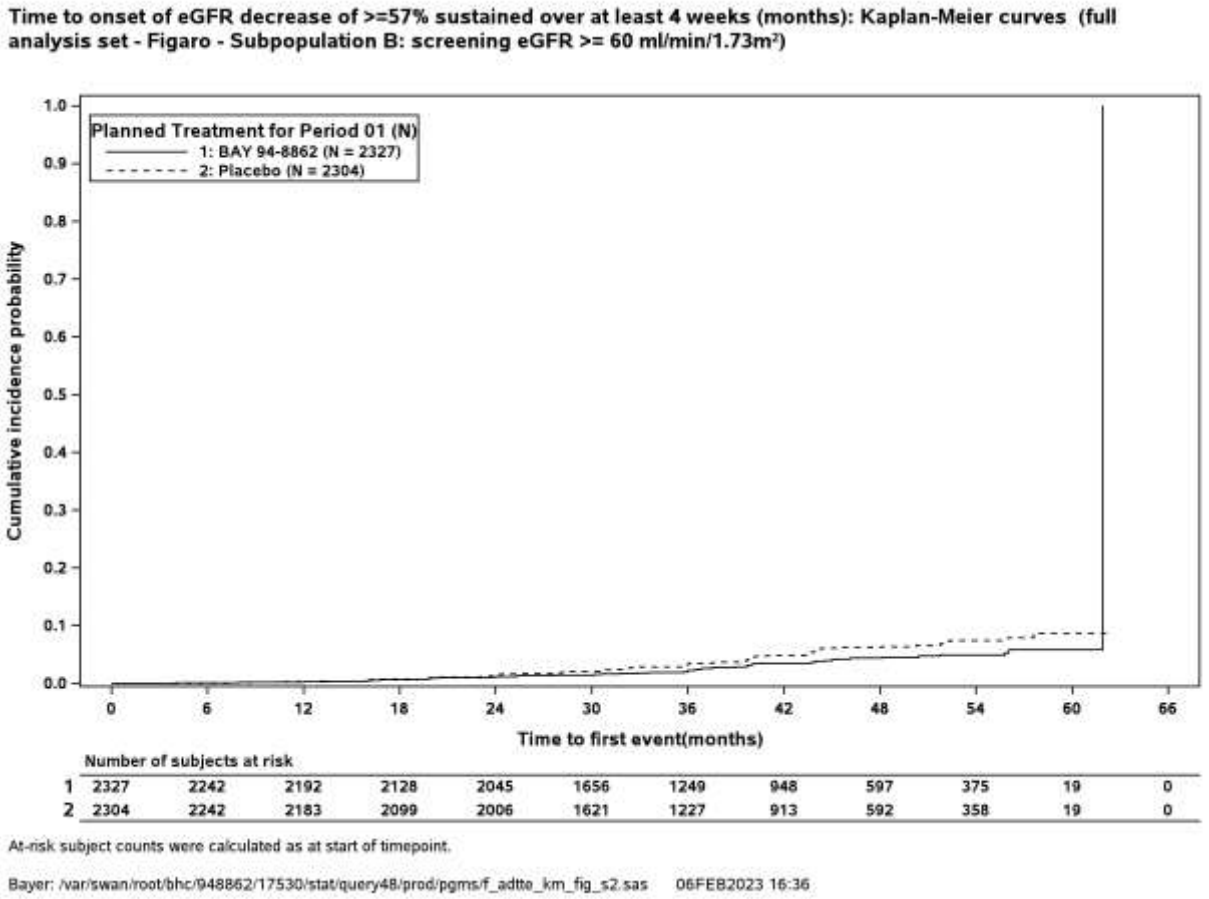


Figure 1.1.2 / 8: Time to renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

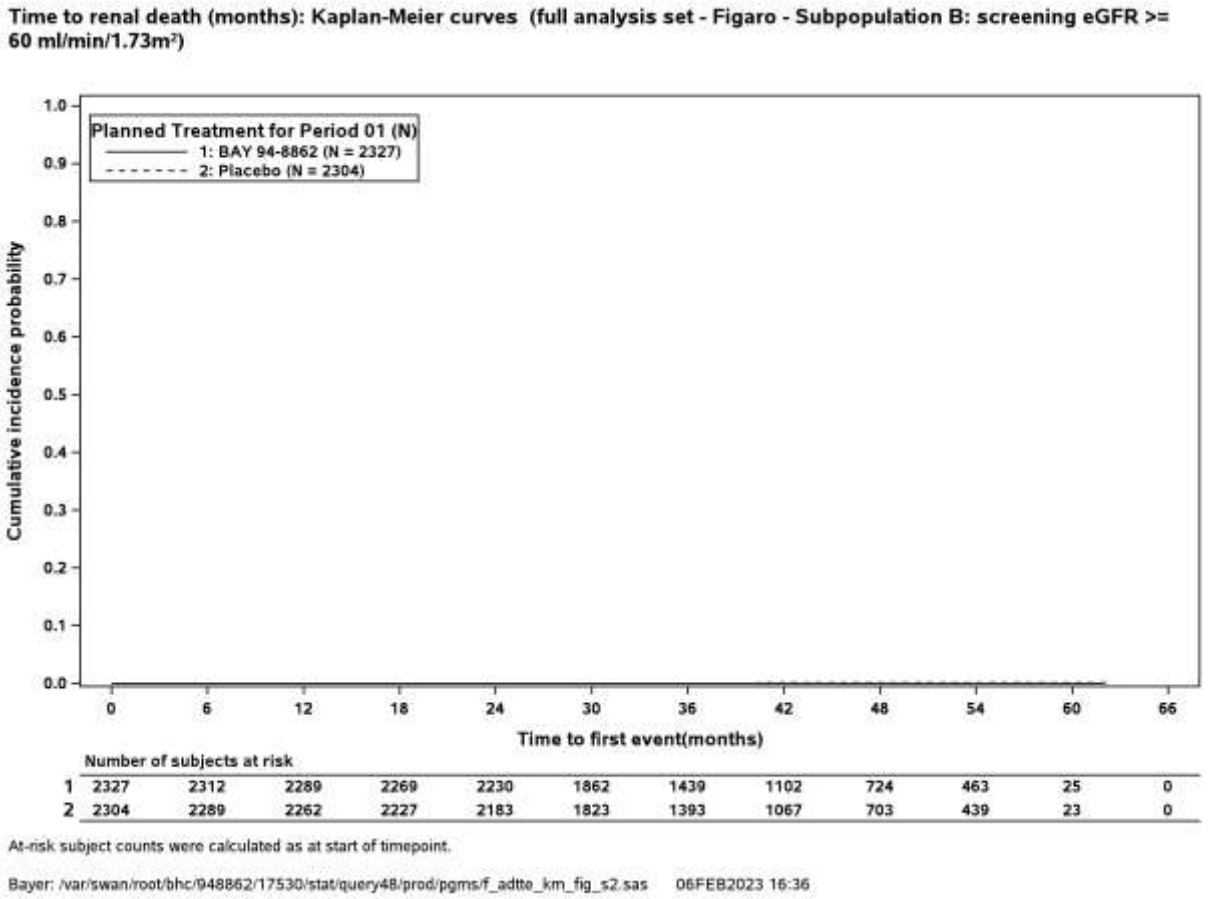


Figure 1.1.2 / 9: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

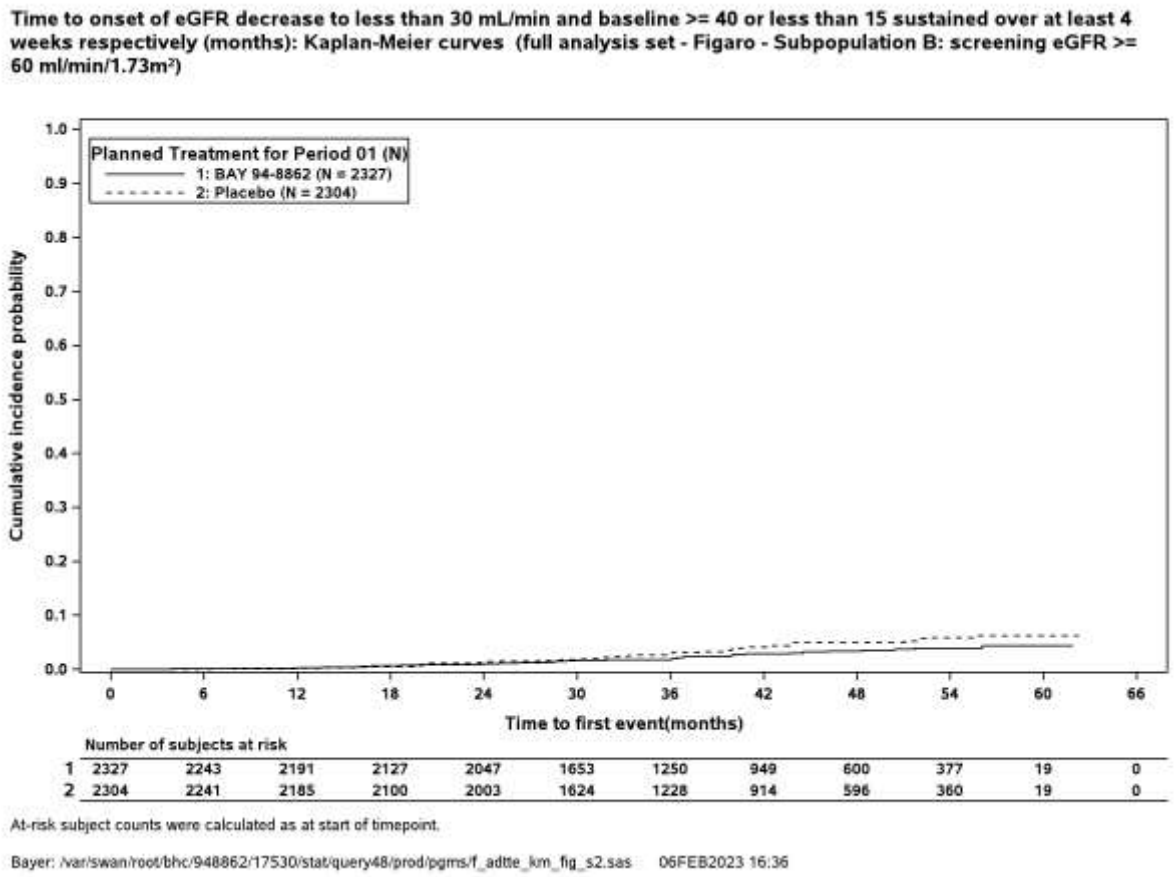


Figure 1.1.2 / 10: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

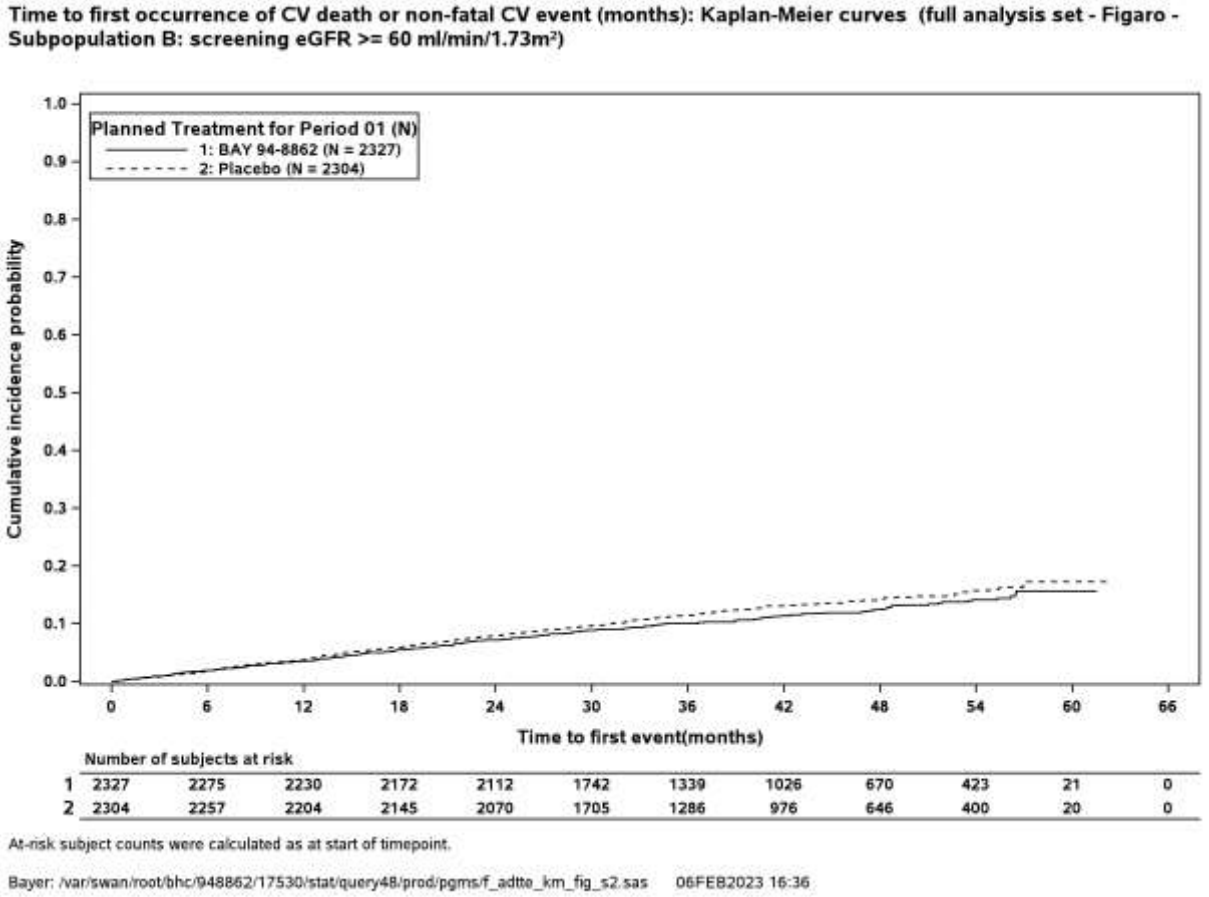


Figure 1.1.2 / 11: Time to CV death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

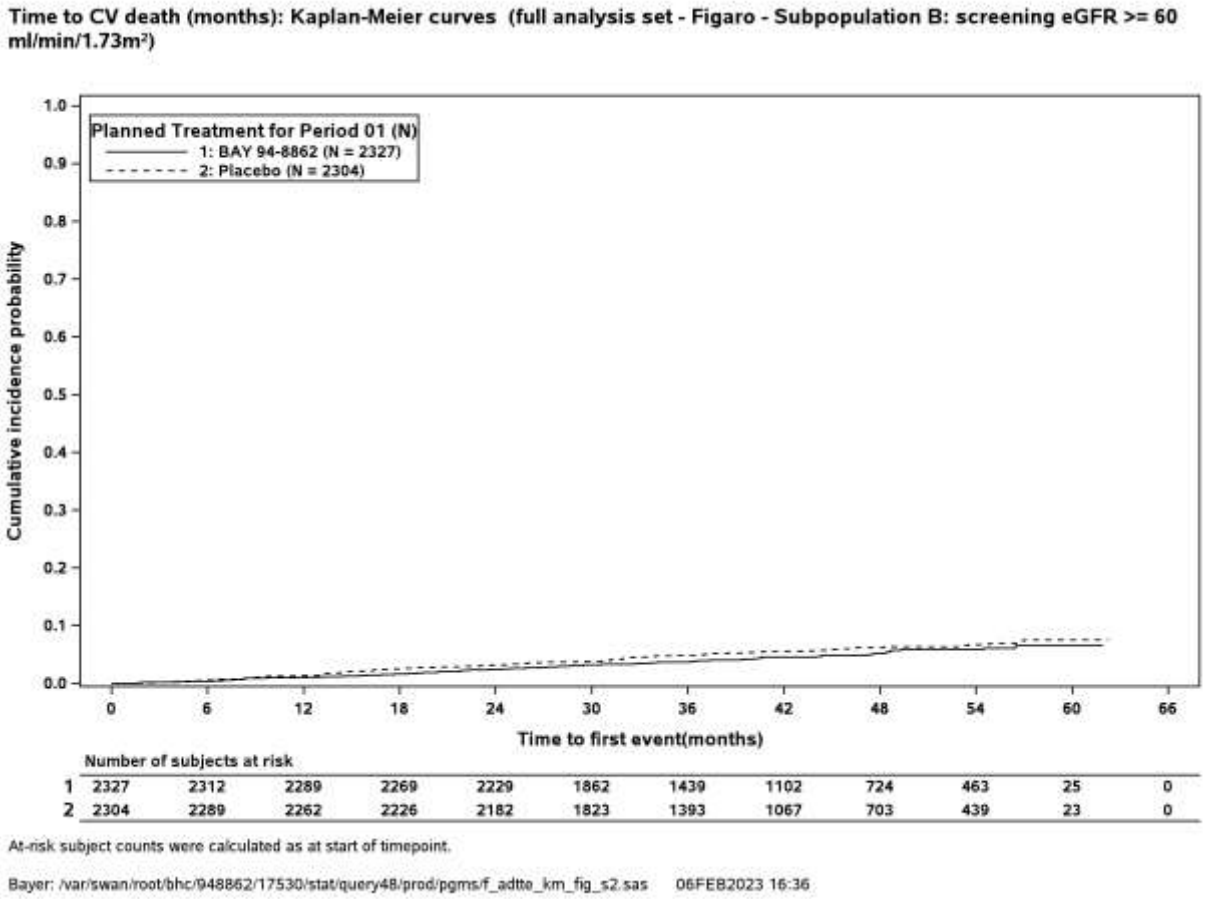


Figure 1.1.2 / 12: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

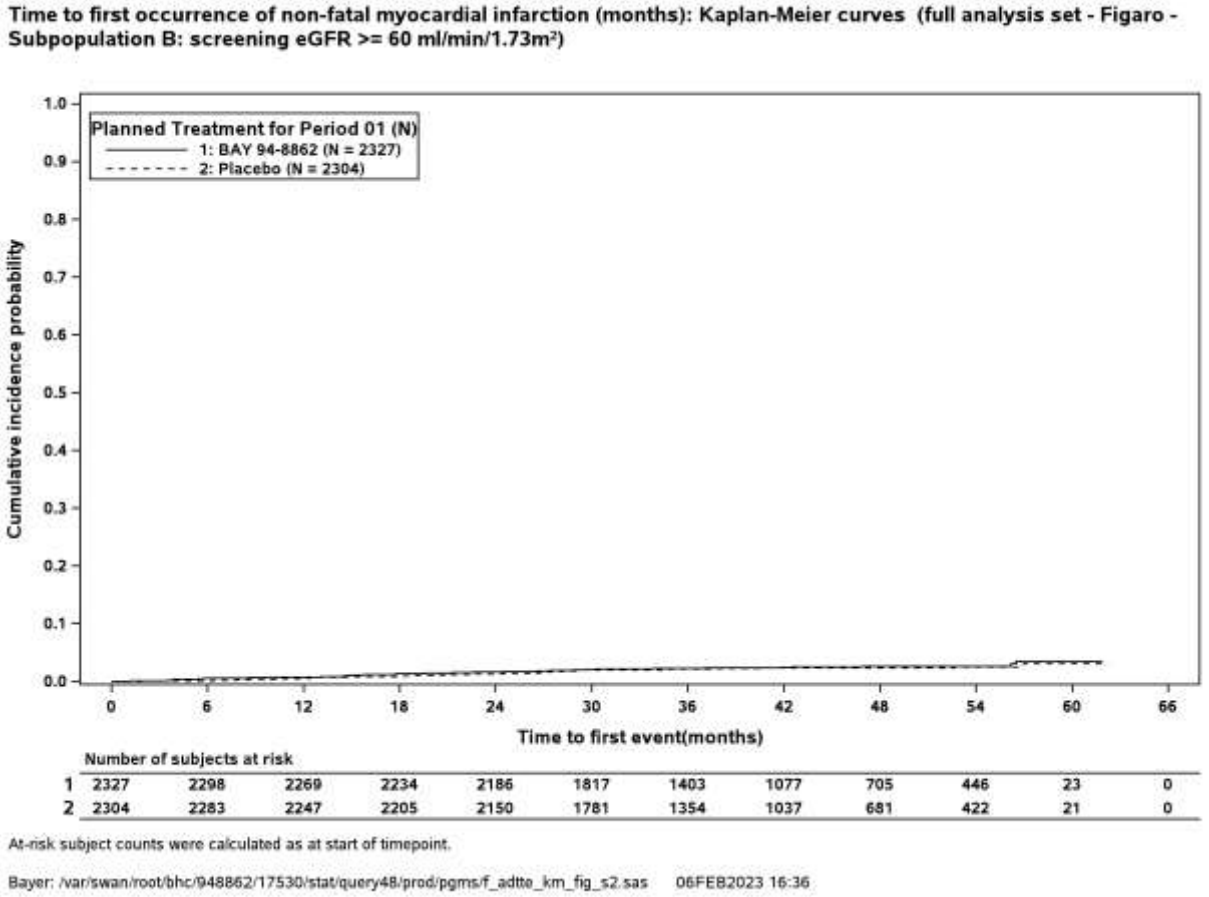


Figure 1.1.2 / 13: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

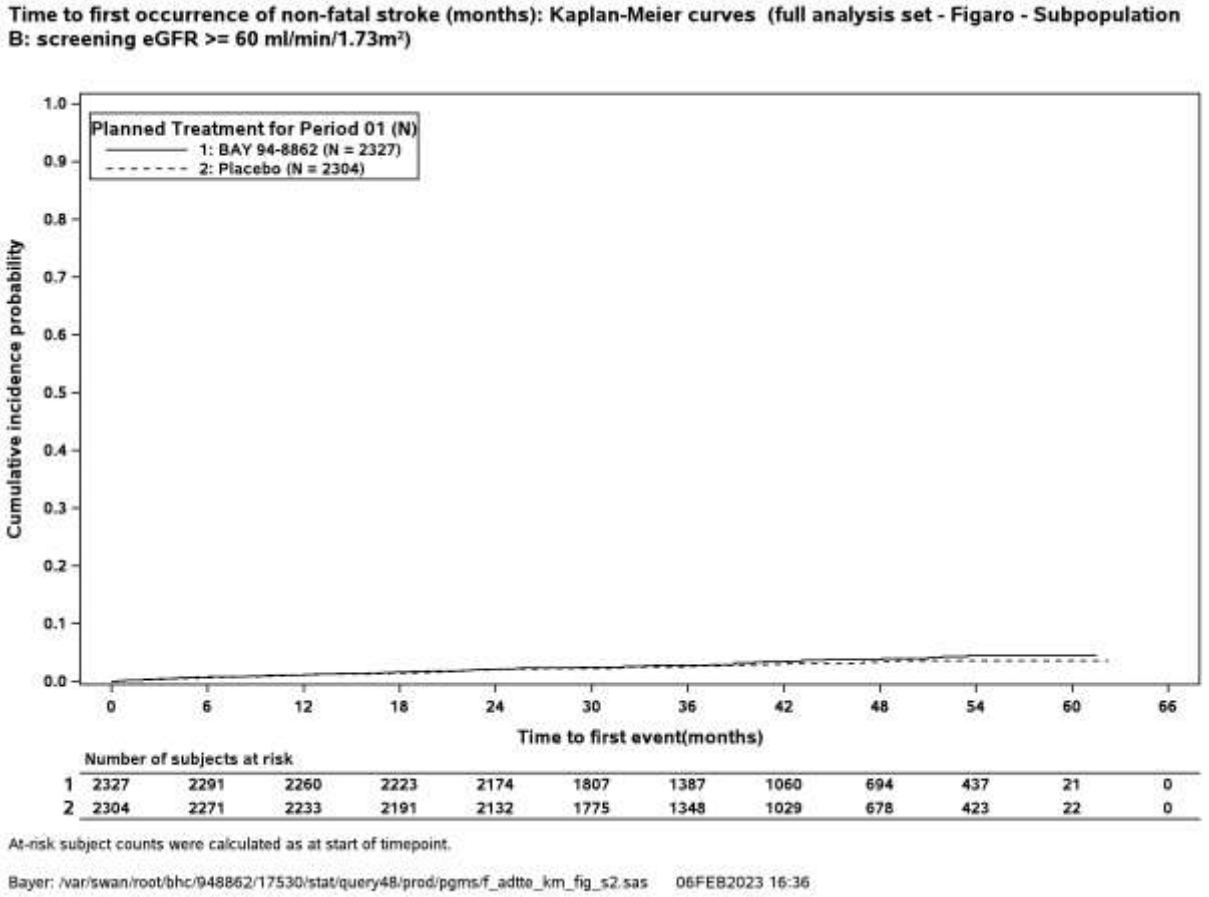


Figure 1.1.2 / 14: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

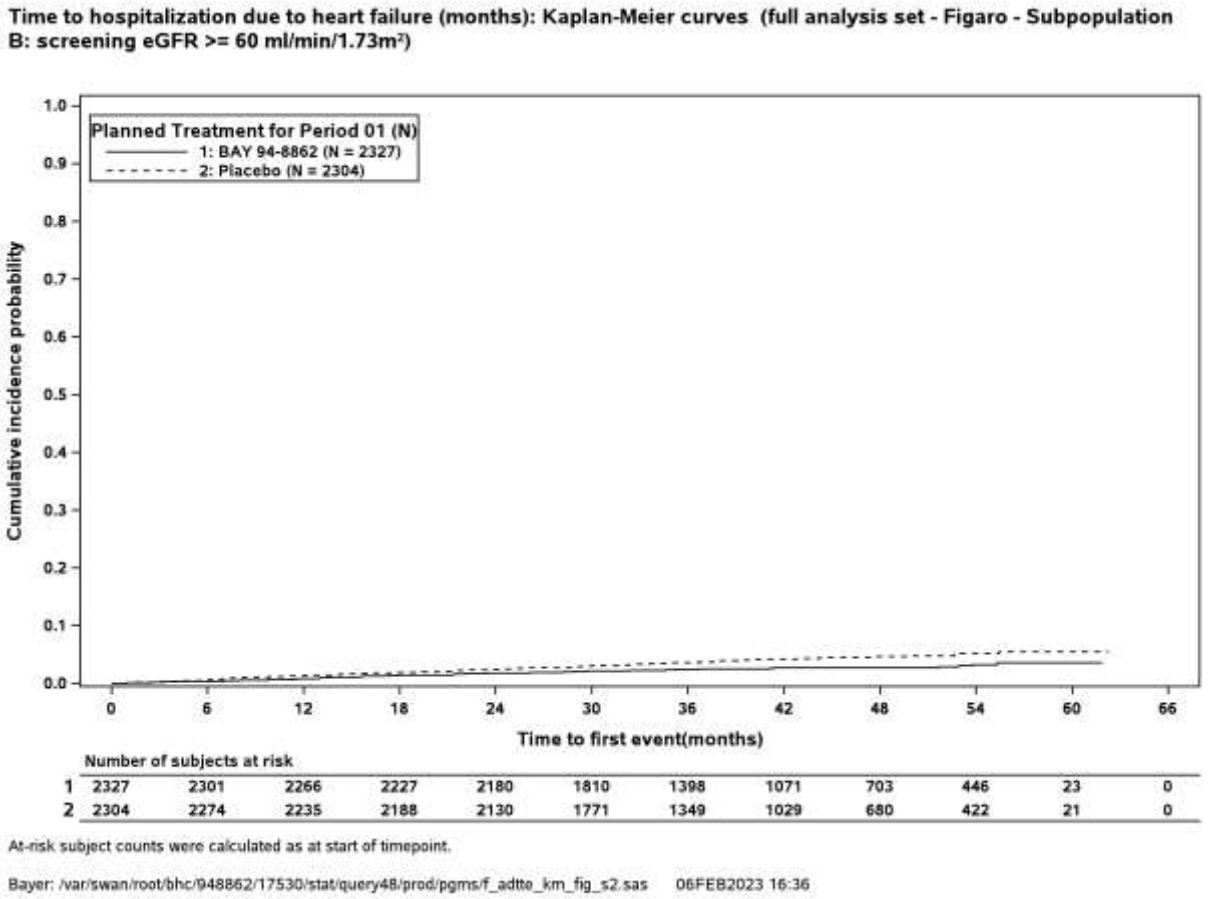


Figure 1.1.2 / 15: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

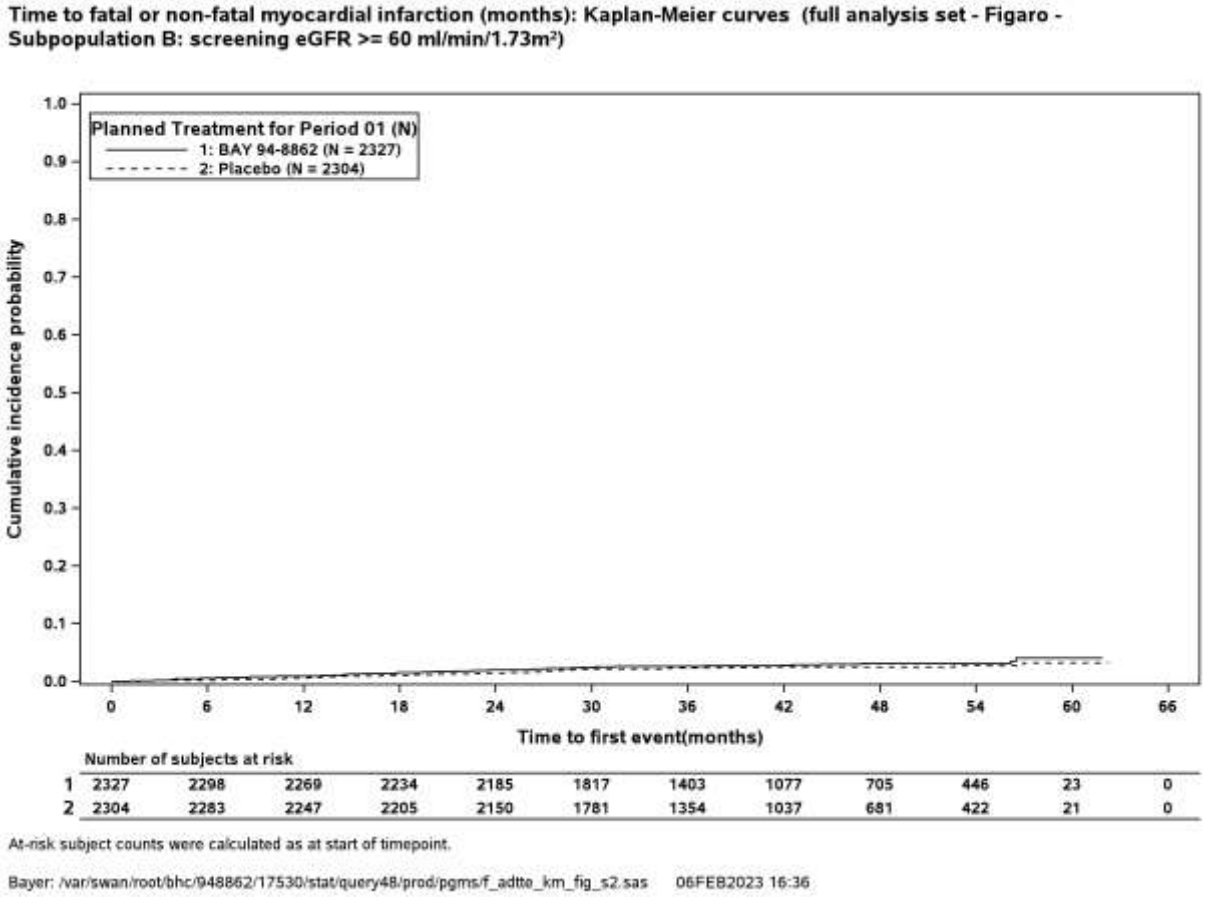


Figure 1.1.2 / 16: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

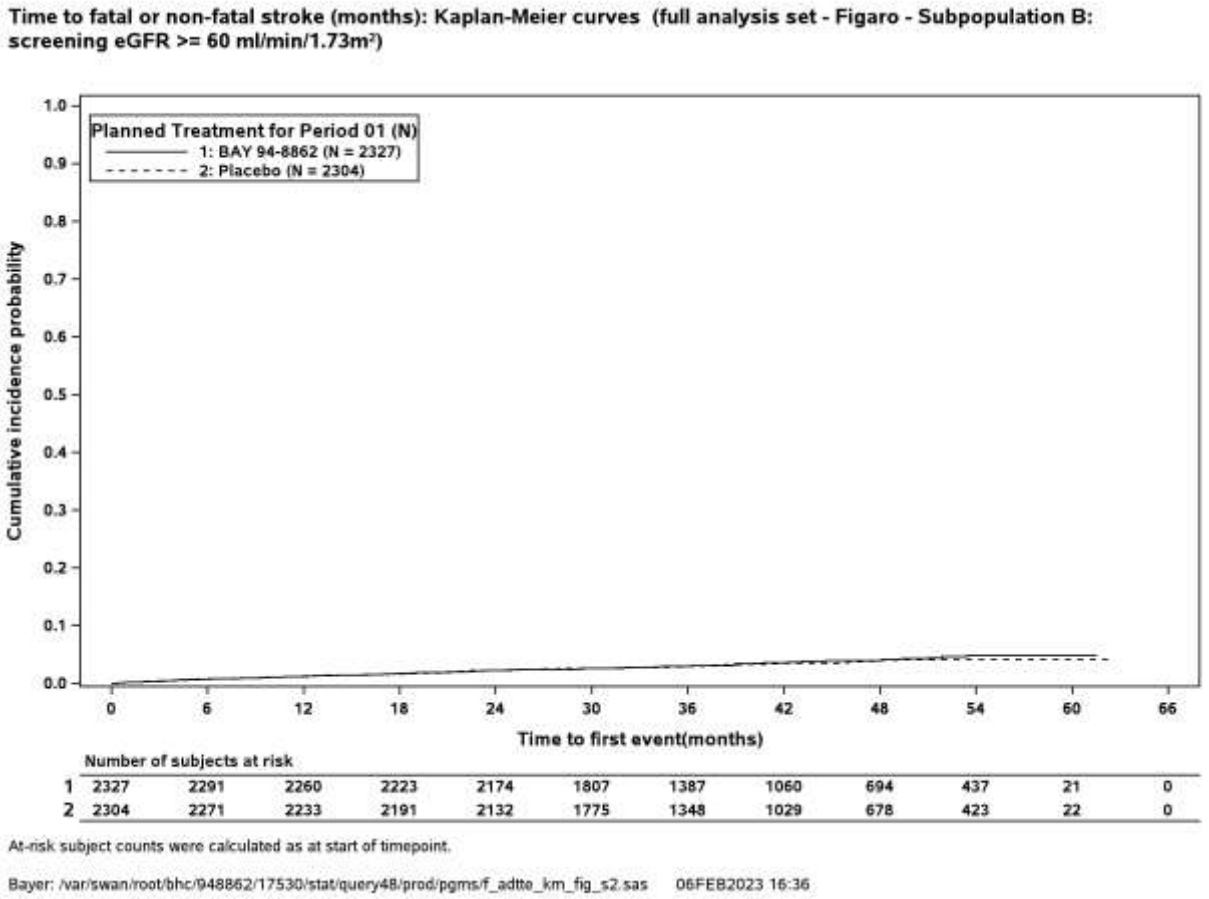


Figure 1.1.2 / 17: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

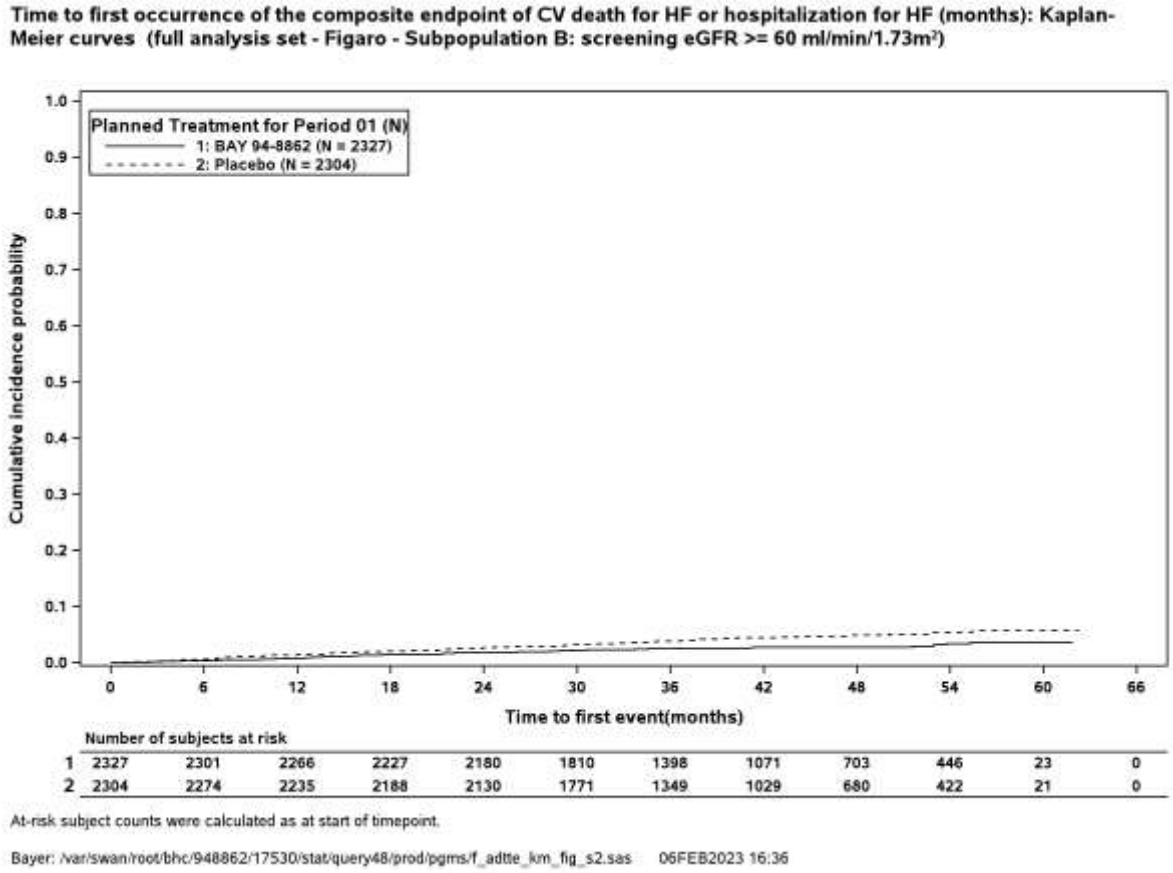


Figure 1.1.2 / 18: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

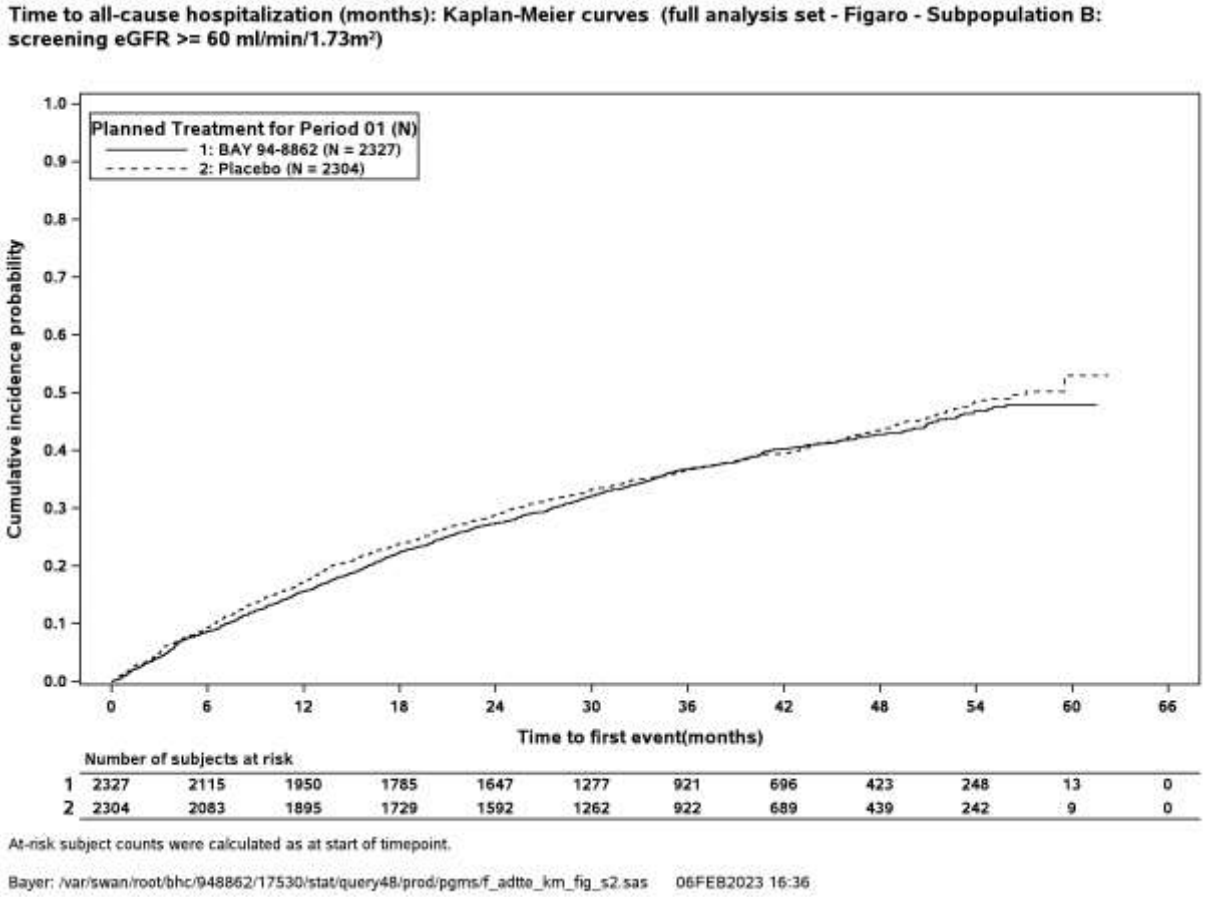


Table B3.1.1: EQ-5D VAS - Return Rate - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2302	2327	98.9%	2260	2304	98.1%	4562	4631	98.5%
Baseline	2302	2327	98.9%	2260	2304	98.1%	4562	4631	98.5%
Visit 5	2139	2327	91.9%	2132	2304	92.5%	4271	4631	92.2%
Visit 8	1934	2327	83.1%	1894	2304	82.2%	3828	4631	82.7%
Visit 11	1172	2327	50.4%	1161	2304	50.4%	2333	4631	50.4%
Visit 14	525	2327	22.6%	518	2304	22.5%	1043	4631	22.5%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2116	2327	90.9%	2107	2304	91.4%	4223	4631	91.2%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1834	2327	78.8%	1785	2304	77.5%	3619	4631	78.1%

Abbreviations: eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, VAS=Visual analog scale.

Table B3.1.2: KDQoL-36 - Return Rate of Physical Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Baseline	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Visit 5	2130	2327	91.5%	2127	2304	92.3%	4257	4631	91.9%
Visit 8	1925	2327	82.7%	1885	2304	81.8%	3810	4631	82.3%
Visit 11	1163	2327	50.0%	1154	2304	50.1%	2317	4631	50.0%
Visit 14	521	2327	22.4%	514	2304	22.3%	1035	4631	22.3%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2115	2327	90.9%	2103	2304	91.3%	4218	4631	91.1%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1830	2327	78.6%	1777	2304	77.1%	3607	4631	77.9%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.

Table B3.1.3: KDQoL-36 - Return Rate of Mental Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Baseline	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Visit 5	2130	2327	91.5%	2127	2304	92.3%	4257	4631	91.9%
Visit 8	1925	2327	82.7%	1885	2304	81.8%	3810	4631	82.3%
Visit 11	1163	2327	50.0%	1154	2304	50.1%	2317	4631	50.0%
Visit 14	521	2327	22.4%	514	2304	22.3%	1035	4631	22.3%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2115	2327	90.9%	2103	2304	91.3%	4218	4631	91.1%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1830	2327	78.6%	1777	2304	77.1%	3607	4631	77.9%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.

Table B3.1.4: KDQoL-36 - Return Rate of Burden of Kidney Disease - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2300	2327	98.8%	2255	2304	97.9%	4555	4631	98.4%
Baseline	2300	2327	98.8%	2255	2304	97.9%	4555	4631	98.4%
Visit 5	2137	2327	91.8%	2128	2304	92.4%	4265	4631	92.1%
Visit 8	1931	2327	83.0%	1892	2304	82.1%	3823	4631	82.6%
Visit 11	1172	2327	50.4%	1161	2304	50.4%	2333	4631	50.4%
Visit 14	525	2327	22.6%	517	2304	22.4%	1042	4631	22.5%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2115	2327	90.9%	2105	2304	91.4%	4220	4631	91.1%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1835	2327	78.9%	1784	2304	77.4%	3619	4631	78.1%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.

Table B3.1.5: KDQoL-36 - Return Rate of Symptoms and Problems - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2303	2327	99.0%	2261	2304	98.1%	4564	4631	98.6%
Baseline	2303	2327	99.0%	2261	2304	98.1%	4564	4631	98.6%
Visit 5	2138	2327	91.9%	2130	2304	92.4%	4268	4631	92.2%
Visit 8	1934	2327	83.1%	1895	2304	82.2%	3829	4631	82.7%
Visit 11	1174	2327	50.5%	1163	2304	50.5%	2337	4631	50.5%
Visit 14	524	2327	22.5%	518	2304	22.5%	1042	4631	22.5%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2115	2327	90.9%	2106	2304	91.4%	4221	4631	91.1%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1836	2327	78.9%	1787	2304	77.6%	3623	4631	78.2%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.

Table B3.1.6: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2294	2327	98.6%	2256	2304	97.9%	4550	4631	98.3%
Baseline	2294	2327	98.6%	2256	2304	97.9%	4550	4631	98.3%
Visit 5	2135	2327	91.7%	2132	2304	92.5%	4267	4631	92.1%
Visit 8	1933	2327	83.1%	1890	2304	82.0%	3823	4631	82.6%
Visit 11	1173	2327	50.4%	1159	2304	50.3%	2332	4631	50.4%
Visit 14	525	2327	22.6%	516	2304	22.4%	1041	4631	22.5%
Visit 17	8	2327	0.3%	6	2304	0.3%	14	4631	0.3%
Last on-treatment	2114	2327	90.8%	2105	2304	91.4%	4219	4631	91.1%
Premature discontinuation	72	2327	3.1%	83	2304	3.6%	155	4631	3.3%
End of Study Visit	1834	2327	78.8%	1781	2304	77.3%	3615	4631	78.1%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.

Table B3.1.7: EQ-5D VAS - Return Rate (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2302	2327	98.9%	2260	2304	98.1%	4562	4631	98.5%
Visit 5	2139	2242	95.4%	2132	2218	96.1%	4271	4460	95.8%
Visit 8	1934	2134	90.6%	1894	2107	89.9%	3828	4241	90.3%
Visit 11	1172	1334	87.9%	1161	1306	88.9%	2333	2640	88.4%
Visit 14	525	651	80.6%	518	637	81.3%	1043	1288	81.0%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1834	2059	89.1%	1785	2031	87.9%	3619	4090	88.5%

Abbreviations: eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, VAS=Visual analog scale.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.8: KDQoL-36 - Return Rate of Physical Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Visit 5	2130	2242	95.0%	2127	2218	95.9%	4257	4460	95.4%
Visit 8	1925	2134	90.2%	1885	2107	89.5%	3810	4241	89.8%
Visit 11	1163	1334	87.2%	1154	1306	88.4%	2317	2640	87.8%
Visit 14	521	651	80.0%	514	637	80.7%	1035	1288	80.4%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1830	2059	88.9%	1777	2031	87.5%	3607	4090	88.2%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.9: KDQoL-36 - Return Rate of Mental Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2290	2327	98.4%	2249	2304	97.6%	4539	4631	98.0%
Visit 5	2130	2242	95.0%	2127	2218	95.9%	4257	4460	95.4%
Visit 8	1925	2134	90.2%	1885	2107	89.5%	3810	4241	89.8%
Visit 11	1163	1334	87.2%	1154	1306	88.4%	2317	2640	87.8%
Visit 14	521	651	80.0%	514	637	80.7%	1035	1288	80.4%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1830	2059	88.9%	1777	2031	87.5%	3607	4090	88.2%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.10: KDQoL-36 - Return Rate of Burden of Kidney Disease (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2300	2327	98.8%	2255	2304	97.9%	4555	4631	98.4%
Visit 5	2137	2242	95.3%	2128	2218	95.9%	4265	4460	95.6%
Visit 8	1931	2134	90.5%	1892	2107	89.8%	3823	4241	90.1%
Visit 11	1172	1334	87.9%	1161	1306	88.9%	2333	2640	88.4%
Visit 14	525	651	80.6%	517	637	81.2%	1042	1288	80.9%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1835	2059	89.1%	1784	2031	87.8%	3619	4090	88.5%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.11: KDQoL-36 - Return Rate of Symptoms and Problems (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2303	2327	99.0%	2261	2304	98.1%	4564	4631	98.6%
Visit 5	2138	2242	95.4%	2130	2218	96.0%	4268	4460	95.7%
Visit 8	1934	2134	90.6%	1895	2107	89.9%	3829	4241	90.3%
Visit 11	1174	1334	88.0%	1163	1306	89.1%	2337	2640	88.5%
Visit 14	524	651	80.5%	518	637	81.3%	1042	1288	80.9%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1836	2059	89.2%	1787	2031	88.0%	3623	4090	88.6%

Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.1.12: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life (based on subject visits) - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2294	2327	98.6%	2256	2304	97.9%	4550	4631	98.3%
Visit 5	2135	2242	95.2%	2132	2218	96.1%	4267	4460	95.7%
Visit 8	1933	2134	90.6%	1890	2107	89.7%	3823	4241	90.1%
Visit 11	1173	1334	87.9%	1159	1306	88.7%	2332	2640	88.3%
Visit 14	525	651	80.6%	516	637	81.0%	1041	1288	80.8%
Visit 17	8	9	88.9%	6	6	100.0%	14	15	93.3%
Premature discontinuation	72	83	86.7%	83	98	84.7%	155	181	85.6%
End of Study Visit	1834	2059	89.1%	1781	2031	87.7%	3615	4090	88.4%

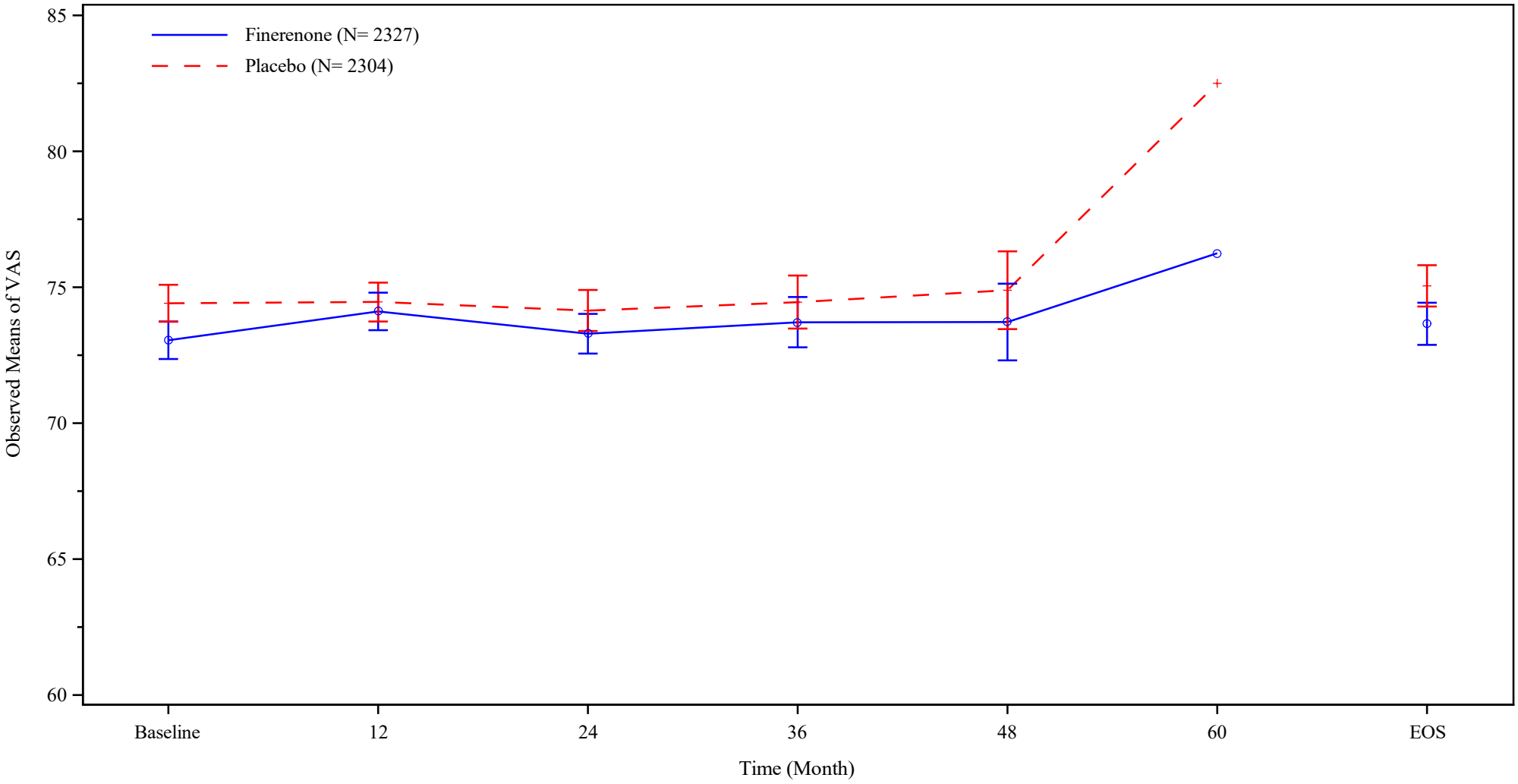
Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table B3.2.1: EQ-5D VAS - Observed Means and Change from Baseline - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2302	73.05(16.91)	(72.36, 73.74)	75.00	(0.0, 100.0)	2260	74.41(16.47)	(73.73, 75.09)	80.00	(0.0, 100.0)
Baseline	2302	73.05(16.91)	(72.36, 73.74)	75.00	(0.0, 100.0)	2260	74.41(16.47)	(73.73, 75.09)	80.00	(0.0, 100.0)
Visit 5	2139	74.11(16.26)	(73.42, 74.80)	75.00	(10.0, 100.0)	2132	74.46(16.83)	(73.74, 75.17)	80.00	(0.0, 100.0)
Visit 8	1934	73.29(16.46)	(72.56, 74.02)	75.00	(10.0, 100.0)	1894	74.14(16.65)	(73.39, 74.90)	80.00	(0.0, 100.0)
Visit 11	1172	73.71(16.15)	(72.79, 74.64)	75.00	(10.0, 100.0)	1161	74.45(16.96)	(73.48, 75.43)	80.00	(0.0, 100.0)
Visit 14	525	73.72(16.46)	(72.31, 75.13)	80.00	(5.0, 100.0)	518	74.89(16.53)	(73.46, 76.32)	80.00	(20.0, 100.0)
Visit 17	8	76.25(16.64)	(62.34, 90.16)	77.50	(50.0, 100.0)	6	82.50(10.84)	(71.12, 93.88)	80.00	(70.0, 100.0)
Last On-Treatment	2116	73.20(16.80)	(72.49, 73.92)	75.00	(4.0, 100.0)	2107	74.13(17.10)	(73.40, 74.86)	80.00	(0.0, 100.0)
Premature Discontinuation	72	70.64(19.50)	(66.06, 75.22)	77.50	(10.0, 100.0)	83	69.43(20.29)	(65.00, 73.86)	70.00	(0.0, 100.0)
End Of Study Visit	1834	73.65(16.87)	(72.88, 74.43)	75.00	(4.0, 100.0)	1785	75.05(16.38)	(74.29, 75.81)	80.00	(4.0, 100.0)
Change from Baseline										
Visit 5	2127	0.75(15.11)	(0.10, 1.39)	0.00	(-80.0, 70.0)	2108	-0.27(15.17)	(-0.92, 0.38)	0.00	(-70.0, 80.0)
Visit 8	1919	0.20(15.30)	(-0.48, 0.89)	0.00	(-70.0, 70.0)	1872	-0.80(15.87)	(-1.52, -0.08)	0.00	(-70.0, 80.0)
Visit 11	1160	-0.17(16.24)	(-1.10, 0.77)	0.00	(-62.0, 65.0)	1146	-0.78(15.47)	(-1.67, 0.12)	0.00	(-68.0, 70.0)
Visit 14	521	-0.95(16.00)	(-2.32, 0.43)	0.00	(-55.0, 60.0)	511	-2.41(16.28)	(-3.82, -0.99)	0.00	(-60.0, 65.0)
Visit 17	8	-6.88(14.13)	(-18.68, 4.93)	-5.00	(-30.0, 10.0)	6	6.67(17.80)	(-12.01, 25.34)	7.50	(-20.0, 35.0)
Last On-Treatment	2099	-0.10(16.48)	(-0.80, 0.61)	0.00	(-80.0, 70.0)	2079	-0.69(16.67)	(-1.41, 0.03)	0.00	(-68.0, 80.0)
Premature Discontinuation	71	-6.30(16.73)	(-10.25, -2.34)	-5.00	(-62.0, 30.0)	82	-8.34(19.59)	(-12.65, -4.04)	-5.00	(-70.0, 39.0)
End Of Study Visit	1821	-0.05(16.84)	(-0.82, 0.73)	0.00	(-75.0, 90.0)	1762	-0.06(16.13)	(-0.81, 0.70)	0.00	(-60.0, 75.0)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation, VAS=Visual analog scale.

Figure B3.2.1: EQ-5D VAS - Time Profile Curve
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



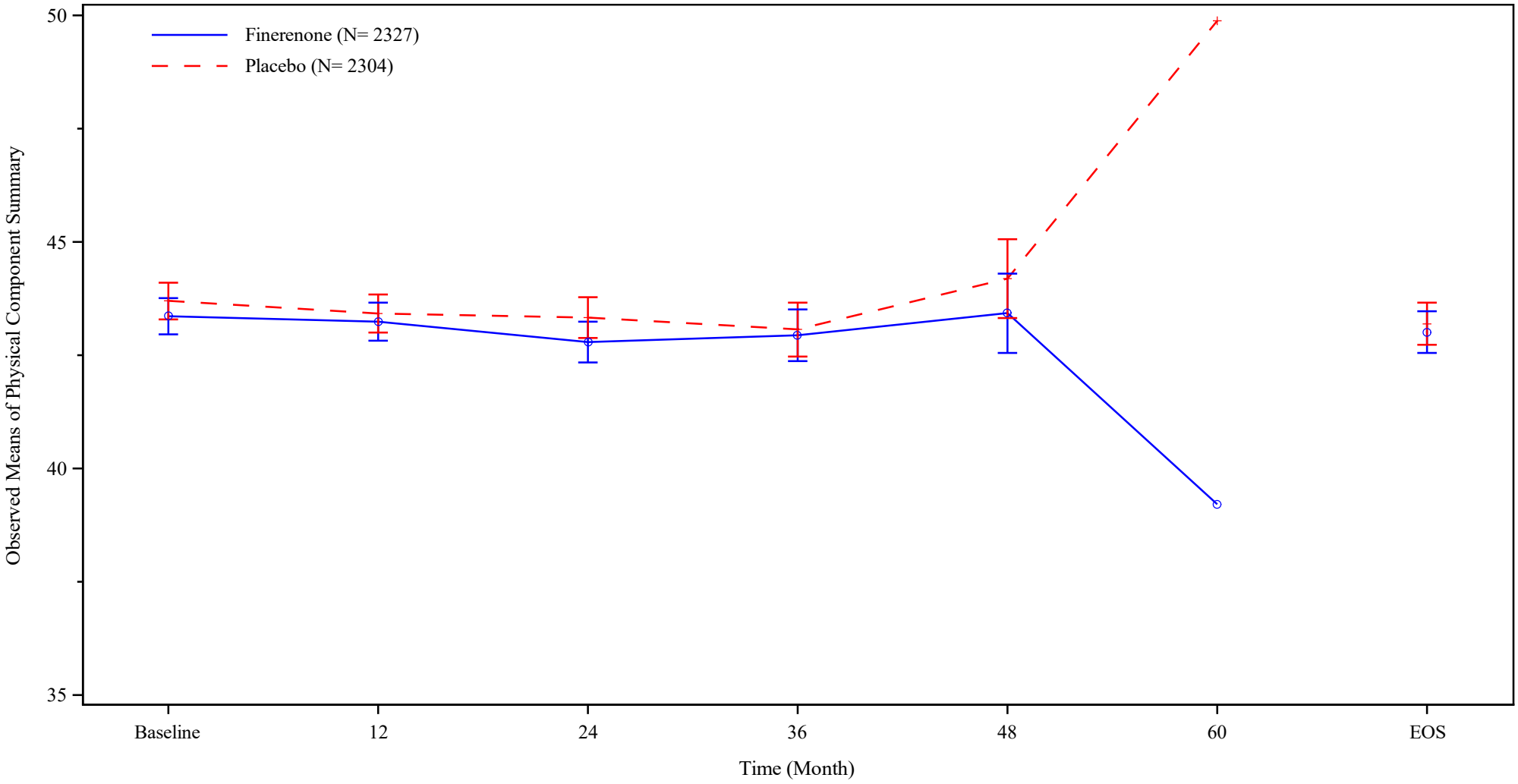
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, EQ-5D=EuroQOL group 5-dimension, N=number of patients, VAS=Visual analog scale.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.2: KDQoL-36 - Observed Means and Change from Baseline of Physical Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2290	43.36(9.80)	(42.96, 43.76)	44.84	(12.6, 65.8)	2249	43.70(9.84)	(43.29, 44.10)	45.07	(12.3, 61.3)
Baseline	2290	43.36(9.80)	(42.96, 43.76)	44.84	(12.6, 65.8)	2249	43.70(9.84)	(43.29, 44.10)	45.07	(12.3, 61.3)
Visit 5	2130	43.24(9.85)	(42.82, 43.66)	44.50	(14.3, 62.6)	2127	43.42(9.92)	(43.00, 43.84)	44.51	(14.2, 61.3)
Visit 8	1925	42.79(10.05)	(42.34, 43.24)	43.79	(12.8, 63.5)	1885	43.33(9.99)	(42.88, 43.78)	44.88	(12.0, 63.1)
Visit 11	1163	42.94(9.95)	(42.37, 43.51)	44.36	(12.6, 61.3)	1154	43.07(10.27)	(42.47, 43.66)	44.58	(13.0, 62.6)
Visit 14	521	43.43(10.19)	(42.55, 44.30)	46.03	(13.6, 59.9)	514	44.19(10.03)	(43.32, 45.06)	46.76	(16.6, 61.2)
Visit 17	8	39.21(10.77)	(30.21, 48.21)	34.65	(28.3, 56.6)	6	49.88(8.24)	(41.24, 58.53)	51.66	(38.9, 58.7)
Last On-Treatment	2115	42.54(10.00)	(42.11, 42.96)	43.50	(14.2, 64.3)	2103	42.76(10.15)	(42.32, 43.19)	44.00	(13.0, 63.1)
Premature Discontinuation	72	39.33(11.76)	(36.57, 42.09)	39.87	(15.8, 60.7)	83	40.97(10.59)	(38.65, 43.28)	40.37	(20.3, 63.0)
End Of Study Visit	1830	43.01(9.94)	(42.55, 43.47)	44.20	(13.7, 64.3)	1777	43.19(10.00)	(42.73, 43.66)	44.58	(13.9, 64.4)
Change from Baseline										
Visit 5	2107	-0.21(8.38)	(-0.57, 0.15)	0.00	(-38.8, 32.3)	2095	-0.41(8.20)	(-0.76, -0.06)	0.00	(-29.2, 31.7)
Visit 8	1903	-0.78(8.88)	(-1.18, -0.38)	-0.18	(-34.2, 29.4)	1857	-0.64(8.66)	(-1.04, -0.25)	-0.11	(-36.2, 31.7)
Visit 11	1148	-1.14(9.05)	(-1.66, -0.62)	-0.32	(-33.5, 33.6)	1137	-1.80(9.03)	(-2.33, -1.28)	-1.04	(-33.5, 31.5)
Visit 14	516	-1.51(9.01)	(-2.29, -0.73)	-0.47	(-29.5, 35.2)	509	-2.26(8.97)	(-3.05, -1.48)	-0.78	(-28.7, 29.7)
Visit 17	8	-4.80(8.70)	(-12.07, 2.48)	-1.53	(-16.7, 6.9)	6	4.42(7.57)	(-3.52, 12.36)	3.38	(-2.3, 16.0)
Last On-Treatment	2086	-0.98(9.03)	(-1.37, -0.60)	-0.27	(-33.5, 31.6)	2067	-1.20(9.06)	(-1.59, -0.81)	-0.57	(-35.1, 34.9)
Premature Discontinuation	71	-3.31(9.61)	(-5.58, -1.03)	-2.02	(-24.7, 26.8)	81	-3.88(10.53)	(-6.21, -1.55)	-1.73	(-29.8, 26.0)
End Of Study Visit	1809	-0.79(9.25)	(-1.22, -0.37)	-0.27	(-33.5, 32.1)	1746	-0.98(9.21)	(-1.41, -0.55)	-0.52	(-35.1, 34.9)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at
specified time point, SD=standard deviation.
Note: The Physical Component Summary uses items 1 to 12 of the KDQoL-36.

Figure B3.2.2: KDQoL-36 - Time Profile Curve of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



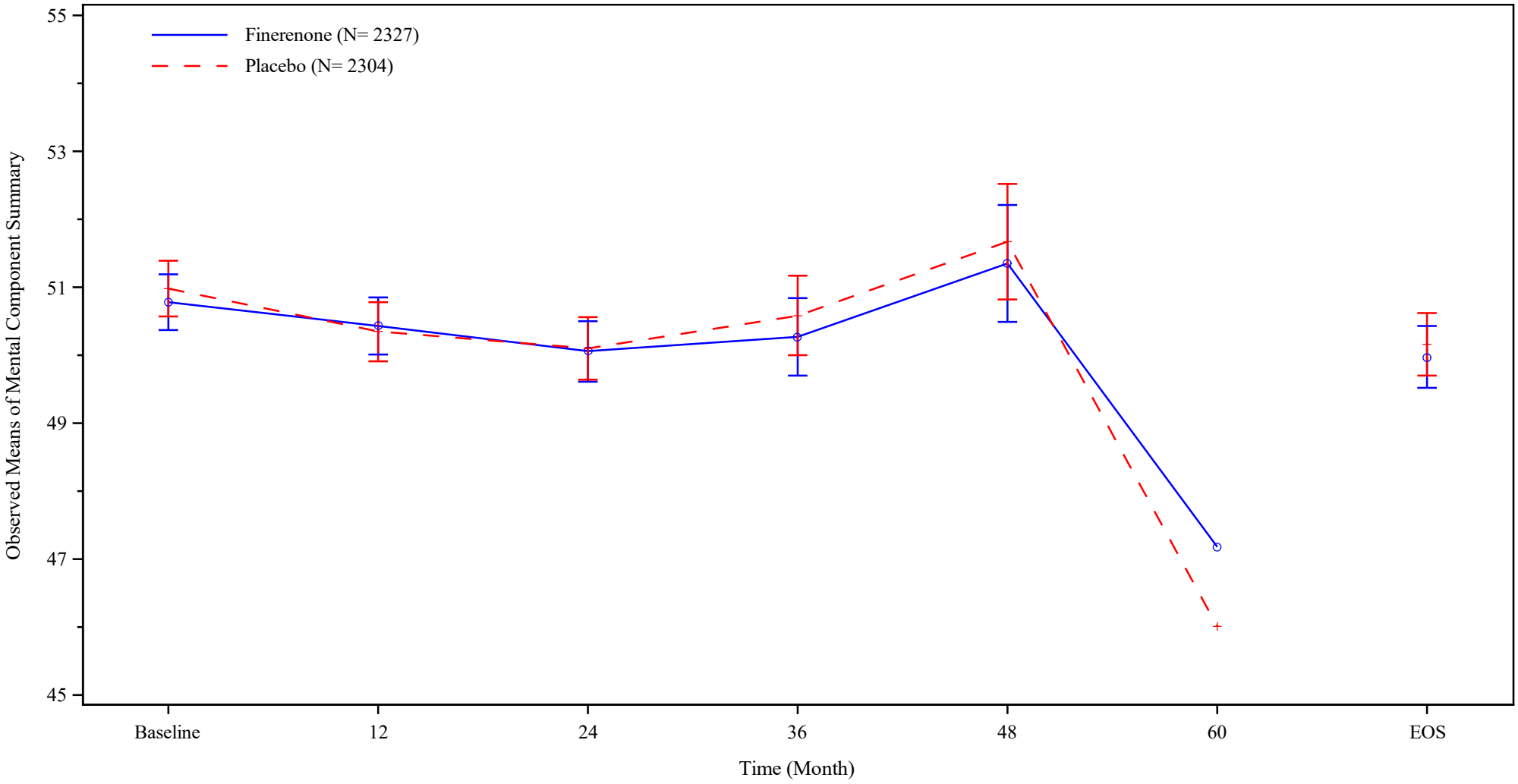
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.3: KDQoL-36 - Observed Means and Change from Baseline of Mental Component Summary - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2290	50.78(9.96)	(50.37, 51.19)	53.51	(16.1, 70.5)	2249	50.98(9.83)	(50.57, 51.39)	54.03	(12.7, 69.6)
Baseline	2290	50.78(9.96)	(50.37, 51.19)	53.51	(16.1, 70.5)	2249	50.98(9.83)	(50.57, 51.39)	54.03	(12.7, 69.6)
Visit 5	2130	50.43(9.87)	(50.01, 50.85)	52.85	(16.6, 68.9)	2127	50.35(10.20)	(49.91, 50.78)	53.13	(15.9, 69.8)
Visit 8	1925	50.06(9.99)	(49.61, 50.50)	52.51	(19.0, 69.0)	1885	50.10(10.18)	(49.64, 50.56)	53.13	(18.2, 68.7)
Visit 11	1163	50.27(9.90)	(49.70, 50.84)	52.76	(17.0, 71.1)	1154	50.58(10.08)	(50.00, 51.17)	53.38	(15.7, 67.3)
Visit 14	521	51.35(9.94)	(50.49, 52.21)	54.10	(17.8, 67.7)	514	51.67(9.79)	(50.82, 52.52)	55.04	(20.3, 70.4)
Visit 17	8	47.18(10.90)	(38.06, 56.29)	48.58	(29.2, 64.4)	6	46.01(16.43)	(28.77, 63.24)	48.35	(24.8, 62.7)
Last On-Treatment	2115	50.06(10.09)	(49.63, 50.49)	52.40	(16.6, 68.9)	2103	50.11(10.08)	(49.68, 50.54)	52.78	(15.8, 68.9)
Premature Discontinuation	72	50.01(10.68)	(47.50, 52.52)	53.15	(22.1, 66.9)	83	46.19(10.37)	(43.93, 48.46)	46.65	(19.6, 63.6)
End Of Study Visit	1830	49.97(9.94)	(49.52, 50.43)	52.10	(18.8, 68.7)	1777	50.16(9.87)	(49.70, 50.62)	52.32	(15.8, 68.9)
Change from Baseline										
Visit 5	2107	-0.41(9.41)	(-0.81, -0.01)	0.00	(-47.6, 40.7)	2095	-0.62(9.82)	(-1.04, -0.20)	0.00	(-42.7, 45.7)
Visit 8	1903	-0.81(10.04)	(-1.26, -0.35)	0.00	(-42.1, 39.1)	1857	-0.99(10.36)	(-1.46, -0.51)	-0.22	(-46.2, 39.7)
Visit 11	1148	-1.28(9.86)	(-1.85, -0.71)	-0.23	(-39.2, 32.9)	1137	-0.83(10.02)	(-1.41, -0.24)	-0.06	(-33.8, 38.2)
Visit 14	516	-0.63(9.62)	(-1.46, 0.20)	-0.41	(-34.4, 38.2)	509	-0.98(9.44)	(-1.80, -0.15)	-0.39	(-33.9, 38.5)
Visit 17	8	-6.10(12.23)	(-16.32, 4.13)	-4.02	(-30.2, 7.1)	6	-5.90(18.12)	(-24.91, 13.11)	-7.17	(-30.3, 20.6)
Last On-Treatment	2086	-0.79(10.41)	(-1.24, -0.35)	-0.08	(-47.6, 38.3)	2067	-0.94(10.52)	(-1.39, -0.48)	-0.43	(-42.7, 45.9)
Premature Discontinuation	71	-2.29(11.35)	(-4.97, 0.40)	-0.64	(-30.5, 22.3)	81	-5.29(11.96)	(-7.94, -2.65)	-2.90	(-40.2, 18.7)
End Of Study Visit	1809	-0.90(10.29)	(-1.37, -0.42)	-0.16	(-37.4, 36.2)	1746	-0.90(10.29)	(-1.38, -0.41)	-0.49	(-37.5, 45.9)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at
specified time point, SD=standard deviation.
Note: The Mental Component Summary uses items 1 to 12 of the KDQoL-36.

Figure B3.2.3: KDQoL-36 - Time Profile Curve of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

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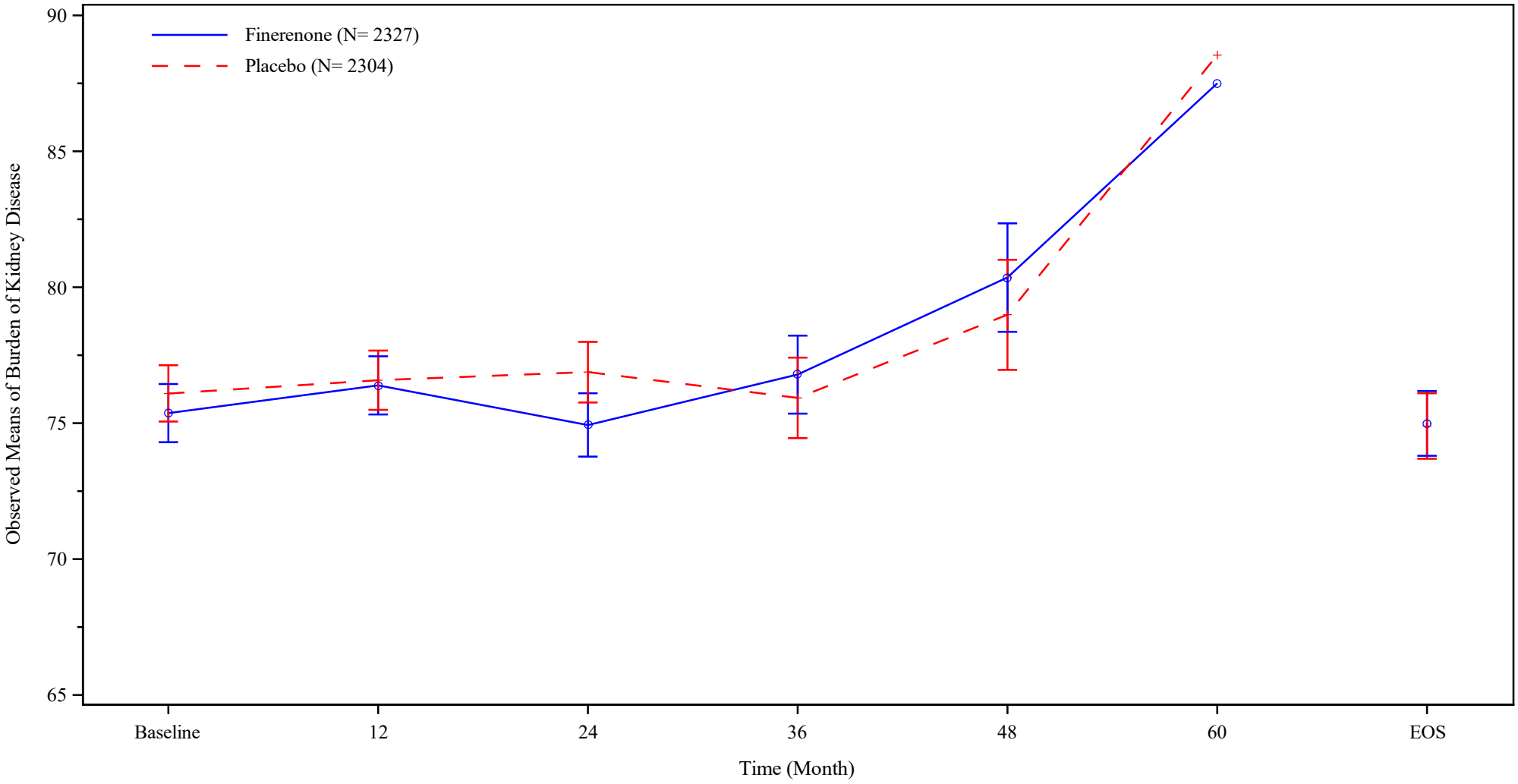
Table B3.2.4: KDQoL-36 - Observed Means and Change from Baseline of Burden of Kidney Disease - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2300	75.37(26.22)	(74.30, 76.44)	81.25	(0.0, 100.0)	2255	76.09(25.10)	(75.06, 77.13)	81.25	(0.0, 100.0)
Baseline	2300	75.37(26.22)	(74.30, 76.44)	81.25	(0.0, 100.0)	2255	76.09(25.10)	(75.06, 77.13)	81.25	(0.0, 100.0)
Visit 5	2137	76.39(25.22)	(75.32, 77.46)	81.25	(0.0, 100.0)	2128	76.58(25.67)	(75.49, 77.67)	81.25	(0.0, 100.0)
Visit 8	1931	74.93(26.07)	(73.77, 76.10)	81.25	(0.0, 100.0)	1892	76.88(24.70)	(75.76, 77.99)	81.25	(0.0, 100.0)
Visit 11	1172	76.79(25.10)	(75.35, 78.22)	81.25	(0.0, 100.0)	1161	75.93(25.70)	(74.45, 77.41)	81.25	(0.0, 100.0)
Visit 14	525	80.36(23.27)	(78.36, 82.35)	87.50	(0.0, 100.0)	517	78.99(23.46)	(76.96, 81.01)	87.50	(0.0, 100.0)
Visit 17	8	87.50(12.50)	(77.05, 97.95)	87.50	(68.8, 100.0)	6	88.54(15.01)	(72.79, 104.29)	93.75	(62.5, 100.0)
Last On-Treatment	2115	75.17(25.75)	(74.07, 76.27)	81.25	(0.0, 100.0)	2105	75.68(25.45)	(74.59, 76.77)	81.25	(0.0, 100.0)
Premature Discontinuation	72	72.57(27.49)	(66.11, 79.03)	78.13	(0.0, 100.0)	83	71.69(28.06)	(65.56, 77.81)	81.25	(0.0, 100.0)
End Of Study Visit	1835	74.99(26.01)	(73.80, 76.18)	81.25	(0.0, 100.0)	1784	74.89(26.03)	(73.69, 76.10)	81.25	(0.0, 100.0)
Change from Baseline										
Visit 5	2122	1.15(23.50)	(0.15, 2.15)	0.00	(-100.0, 100.0)	2100	0.23(23.33)	(-0.77, 1.23)	0.00	(-100.0, 100.0)
Visit 8	1915	-0.37(25.83)	(-1.53, 0.79)	0.00	(-100.0, 100.0)	1869	0.29(24.27)	(-0.81, 1.39)	0.00	(-100.0, 100.0)
Visit 11	1158	-0.83(24.86)	(-2.26, 0.61)	0.00	(-100.0, 100.0)	1147	-2.07(26.49)	(-3.60, -0.53)	0.00	(-100.0, 100.0)
Visit 14	521	-1.18(24.07)	(-3.26, 0.89)	0.00	(-100.0, 75.0)	511	-4.08(24.67)	(-6.22, -1.93)	0.00	(-93.8, 100.0)
Visit 17	8	-1.56(17.60)	(-16.28, 13.15)	-3.13	(-25.0, 31.3)	6	-4.17(19.23)	(-24.35, 16.01)	0.00	(-37.5, 18.8)
Last On-Treatment	2096	-0.16(26.44)	(-1.30, 0.97)	0.00	(-100.0, 100.0)	2074	-0.69(26.58)	(-1.83, 0.46)	0.00	(-100.0, 100.0)
Premature Discontinuation	71	-8.89(24.77)	(-14.75, -3.03)	0.00	(-75.0, 56.3)	82	-8.61(25.90)	(-14.30, -2.92)	0.00	(-75.0, 50.0)
End Of Study Visit	1819	-0.43(26.29)	(-1.64, 0.78)	0.00	(-100.0, 100.0)	1758	-1.44(27.35)	(-2.72, -0.16)	0.00	(-100.0, 100.0)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at specified time point, SD=standard deviation.
Note: Burden of Kidney Disease uses items 13 to 16 of the KDQoL-36.

Figure B3.2.4: KDQoL-36 - Time Profile Curve of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



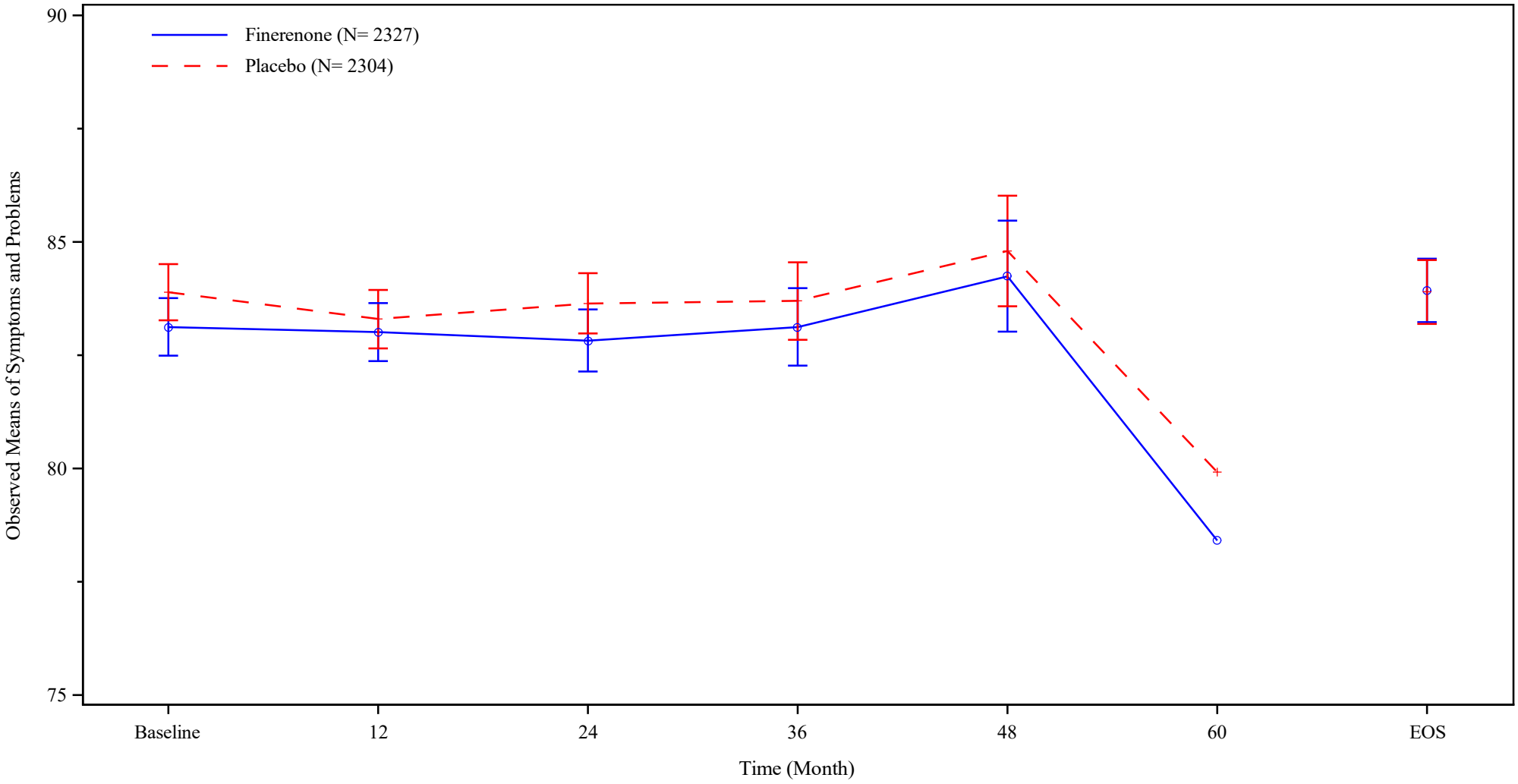
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.5: KDQoL-36 - Observed Means and Change from Baseline of Symptoms and Problems - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2303	83.12(15.55)	(82.49, 83.76)	86.36	(0.0, 100.0)	2261	83.89(15.03)	(83.27, 84.51)	88.64	(18.2, 100.0)
Baseline	2303	83.12(15.55)	(82.49, 83.76)	86.36	(0.0, 100.0)	2261	83.89(15.03)	(83.27, 84.51)	88.64	(18.2, 100.0)
Visit 5	2138	83.01(15.11)	(82.37, 83.65)	86.36	(0.0, 100.0)	2130	83.30(15.18)	(82.65, 83.94)	86.36	(6.8, 100.0)
Visit 8	1934	82.82(15.33)	(82.14, 83.51)	86.36	(9.1, 100.0)	1895	83.64(14.71)	(82.98, 84.31)	86.36	(0.0, 100.0)
Visit 11	1174	83.12(14.95)	(82.27, 83.98)	86.36	(4.5, 100.0)	1163	83.70(14.87)	(82.84, 84.55)	86.36	(0.0, 100.0)
Visit 14	524	84.24(14.27)	(83.02, 85.47)	88.64	(25.0, 100.0)	518	84.80(14.17)	(83.58, 86.02)	88.64	(27.3, 100.0)
Visit 17	8	78.41(21.63)	(60.33, 96.49)	81.82	(36.4, 100.0)	6	79.92(16.42)	(62.70, 97.15)	82.95	(54.5, 100.0)
Last On-Treatment	2115	83.38(15.25)	(82.73, 84.03)	88.64	(0.0, 100.0)	2106	83.57(15.28)	(82.92, 84.22)	86.36	(0.0, 100.0)
Premature Discontinuation	72	80.81(15.71)	(77.12, 84.51)	84.09	(31.8, 100.0)	83	79.08(16.30)	(75.52, 82.64)	81.82	(25.0, 100.0)
End Of Study Visit	1836	83.93(15.29)	(83.23, 84.63)	88.64	(0.0, 100.0)	1787	83.90(15.24)	(83.19, 84.60)	88.64	(0.0, 100.0)
Change from Baseline										
Visit 5	2126	-0.20(11.98)	(-0.71, 0.31)	0.00	(-77.3, 70.5)	2106	-0.74(11.78)	(-1.24, -0.24)	0.00	(-81.8, 72.7)
Visit 8	1920	-0.50(13.52)	(-1.10, 0.11)	0.00	(-72.7, 77.3)	1875	-0.47(12.72)	(-1.05, 0.11)	0.00	(-79.5, 61.4)
Visit 11	1162	-1.04(13.54)	(-1.82, -0.26)	0.00	(-84.1, 70.5)	1150	-1.35(13.25)	(-2.12, -0.59)	0.00	(-95.5, 72.7)
Visit 14	522	-1.26(12.74)	(-2.35, -0.16)	0.00	(-59.1, 61.4)	513	-2.19(11.77)	(-3.21, -1.17)	0.00	(-65.9, 47.7)
Visit 17	8	-7.10(12.36)	(-17.43, 3.23)	-3.41	(-34.1, 2.3)	6	-6.82(6.27)	(-13.39, -0.24)	-4.55	(-18.2, 0.0)
Last On-Treatment	2099	0.12(14.10)	(-0.48, 0.73)	0.00	(-84.1, 84.1)	2079	-0.62(13.66)	(-1.21, -0.04)	0.00	(-77.3, 72.7)
Premature Discontinuation	71	-4.06(15.16)	(-7.65, -0.47)	-4.55	(-45.5, 79.5)	82	-5.36(11.42)	(-7.87, -2.85)	-2.27	(-34.1, 20.5)
End Of Study Visit	1824	0.38(14.15)	(-0.27, 1.03)	0.00	(-84.1, 77.3)	1764	-0.26(14.02)	(-0.92, 0.39)	0.00	(-77.3, 59.1)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at
specified time point, SD=standard deviation.
Note: Symptoms and Problems uses items 17 to 28 b of the KDQoL-36.

Figure B3.2.5: KDQoL-36 - Time Profile Curve of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



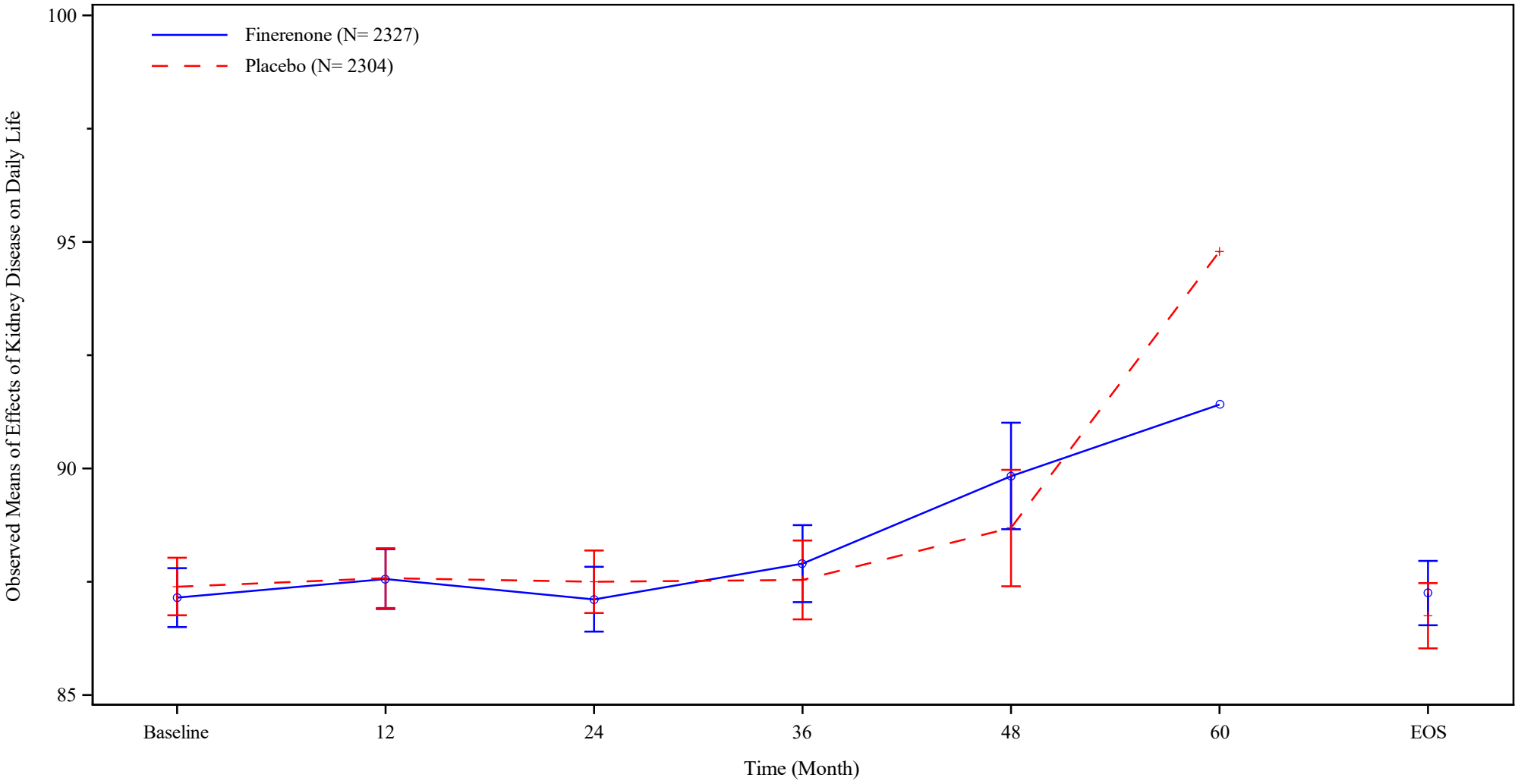
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.2.6: KDQoL-36 - Observed Means and Change from Baseline of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)					Placebo (N=2304)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2294	87.15(15.86)	(86.50, 87.80)	93.75	(0.0, 100.0)	2256	87.39(15.40)	(86.76, 88.03)	93.75	(0.0, 100.0)
Baseline	2294	87.15(15.86)	(86.50, 87.80)	93.75	(0.0, 100.0)	2256	87.39(15.40)	(86.76, 88.03)	93.75	(0.0, 100.0)
Visit 5	2135	87.56(15.60)	(86.90, 88.22)	93.75	(0.0, 100.0)	2132	87.58(15.53)	(86.92, 88.24)	93.75	(0.0, 100.0)
Visit 8	1933	87.11(16.06)	(86.40, 87.83)	93.75	(0.0, 100.0)	1890	87.50(15.24)	(86.81, 88.19)	93.75	(0.0, 100.0)
Visit 11	1173	87.90(14.84)	(87.05, 88.75)	93.75	(0.0, 100.0)	1159	87.54(15.06)	(86.67, 88.41)	93.75	(9.4, 100.0)
Visit 14	525	89.83(13.70)	(88.66, 91.01)	96.88	(3.1, 100.0)	516	88.69(14.88)	(87.40, 89.97)	93.75	(6.3, 100.0)
Visit 17	8	91.41(13.44)	(80.17, 102.64)	98.44	(65.6, 100.0)	6	94.79(7.57)	(86.85, 102.73)	98.44	(81.3, 100.0)
Last On-Treatment	2114	87.31(15.30)	(86.66, 87.96)	93.75	(0.0, 100.0)	2105	86.68(15.77)	(86.01, 87.36)	93.75	(0.0, 100.0)
Premature Discontinuation	72	83.94(18.60)	(79.57, 88.31)	93.75	(25.0, 100.0)	83	85.39(18.86)	(81.27, 89.51)	93.75	(3.1, 100.0)
End Of Study Visit	1834	87.25(15.40)	(86.54, 87.96)	93.75	(3.1, 100.0)	1781	86.75(15.47)	(86.03, 87.47)	93.75	(0.0, 100.0)
Change from Baseline										
Visit 5	2116	0.26(14.22)	(-0.34, 0.87)	0.00	(-100.0, 96.9)	2104	0.03(13.51)	(-0.55, 0.61)	0.00	(-87.5, 87.5)
Visit 8	1911	-0.12(15.22)	(-0.80, 0.57)	0.00	(-100.0, 90.6)	1866	-0.17(14.19)	(-0.81, 0.47)	0.00	(-100.0, 87.5)
Visit 11	1158	-0.20(13.90)	(-1.00, 0.60)	0.00	(-81.3, 93.8)	1145	-1.10(15.24)	(-1.99, -0.22)	0.00	(-81.3, 87.5)
Visit 14	520	-0.87(14.16)	(-2.09, 0.35)	0.00	(-93.8, 59.4)	510	-2.18(13.71)	(-3.37, -0.99)	0.00	(-68.8, 46.9)
Visit 17	8	5.08(34.80)	(-24.01, 34.17)	0.00	(-25.0, 87.5)	6	0.00(9.48)	(-9.95, 9.95)	0.00	(-15.6, 12.5)
Last On-Treatment	2091	0.00(15.01)	(-0.64, 0.65)	0.00	(-96.9, 87.5)	2074	-0.95(15.68)	(-1.62, -0.27)	0.00	(-100.0, 87.5)
Premature Discontinuation	71	-6.03(14.65)	(-9.50, -2.56)	0.00	(-53.1, 21.9)	82	-3.87(16.70)	(-7.54, -0.20)	0.00	(-78.1, 25.0)
End Of Study Visit	1814	-0.29(15.17)	(-0.99, 0.41)	0.00	(-96.9, 87.5)	1754	-0.91(15.53)	(-1.63, -0.18)	0.00	(-100.0, 78.1)

Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, Max=Maximum, Min=Minimum, N=number of patients, n=number of patients with non-missing values at
specified time point, SD=standard deviation.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.

Figure B3.2.6: KDQoL-36 - Time Profile Curve of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2



Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table B3.3.1: EQ-5D VAS - Summary and MMRM of Change from Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2127	0.71	[0.15 , 1.26]	2108	-0.29	[-0.87 , 0.28]	1.00	[0.20 , 1.80]	0.0143
Visit 8	1919	-0.02	[-0.61 , 0.57]	1872	-0.93	[-1.56 , -0.31]	0.91	[0.05 , 1.77]	0.0381
Visit 11	1160	-0.37	[-1.14 , 0.39]	1146	-1.06	[-1.82 , -0.29]	0.68	[-0.39 , 1.76]	0.2140
Visit 14	521	-1.42	[-2.53 , -0.31]	511	-2.54	[-3.63 , -1.45]	1.12	[-0.42 , 2.66]	0.1541
Overall	2151	0.43	[-0.26 , 1.12]	2133	0.41	[-0.30 , 1.12]	0.02	[-0.72 , 0.77]	0.9555
Hedges' g							0.00	[-0.06 , 0.06]	0.9665

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects, VAS=Visual Analogue Scale.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate. Separate unstructured covariance patterns are estimated for each treatment group.

Table B3.3.2: KDQoL-36 - Summary and MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2107	-0.23	[-0.55 , 0.09]	2095	-0.44	[-0.76 , -0.12]	0.21	[-0.24 , 0.67]	0.3573
Visit 8	1903	-0.85	[-1.20 , -0.49]	1857	-0.74	[-1.09 , -0.38]	-0.11	[-0.61 , 0.39]	0.6622
Visit 11	1148	-1.26	[-1.70 , -0.81]	1137	-1.84	[-2.29 , -1.39]	0.58	[-0.05 , 1.21]	0.0707
Visit 14	516	-1.81	[-2.44 , -1.17]	509	-2.47	[-3.10 , -1.83]	0.66	[-0.23 , 1.54]	0.1463
Overall	2137	-1.25	[-1.66 , -0.84]	2122	-1.24	[-1.66 , -0.82]	-0.01	[-0.45 , 0.43]	0.9636
Hedges' g							0.00	[-0.06 , 0.06]	0.9725

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
The Physical Component Summary uses items 1 to 12 of the KDQOL-36.

Table B3.3.3: KDQoL-36 - Summary and MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2107	-0.42	[-0.78 , -0.07]	2095	-0.63	[-1.00 , -0.25]	0.20	[-0.31 , 0.71]	0.4417
Visit 8	1903	-0.84	[-1.23 , -0.45]	1857	-1.03	[-1.44 , -0.62]	0.19	[-0.38 , 0.75]	0.5144
Visit 11	1148	-1.39	[-1.87 , -0.91]	1137	-0.98	[-1.47 , -0.49]	-0.41	[-1.09 , 0.27]	0.2361
Visit 14	516	-0.99	[-1.67 , -0.31]	509	-1.35	[-2.00 , -0.69]	0.36	[-0.58 , 1.29]	0.4529
Overall	2137	-0.37	[-0.81 , 0.06]	2122	-0.32	[-0.76 , 0.13]	-0.06	[-0.53 , 0.41]	0.8038
Hedges' g							-0.01	[-0.07 , 0.05]	0.8524

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
The Mental Component Summary uses items 1 to 12 of the KDQOL-36.

Table B3.3.4: KDQoL-36 - Summary and MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2122	1.13	[0.23 , 2.04]	2100	0.22	[-0.70 , 1.13]	0.92	[-0.37 , 2.21]	0.1631
Visit 8	1915	-0.39	[-1.34 , 0.55]	1869	0.20	[-0.76 , 1.16]	-0.59	[-1.94 , 0.76]	0.3900
Visit 11	1158	-0.85	[-2.02 , 0.31]	1147	-2.12	[-3.30 , -0.94]	1.27	[-0.38 , 2.92]	0.1314
Visit 14	521	-1.62	[-3.29 , 0.06]	511	-4.55	[-6.26 , -2.84]	2.94	[0.56 , 5.31]	0.0153
Overall	2148	1.47	[0.38 , 2.55]	2128	0.95	[-0.15 , 2.05]	0.51	[-0.63 , 1.66]	0.3810
Hedges' g							0.02	[-0.04 , 0.08]	0.5150

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
Separate Toeplitz covariance patterns are estimated for each treatment group.
Burden of Kidney Disease uses items 13 to 16 of the KDQOL-36.

Table B3.3.5: KDQoL-36 - Summary and MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2126	-0.22	[-0.69 , 0.24]	2106	-0.76	[-1.23 , -0.30]	0.54	[-0.12 , 1.20]	0.1090
Visit 8	1920	-0.57	[-1.11 , -0.04]	1875	-0.56	[-1.08 , -0.05]	-0.01	[-0.75 , 0.73]	0.9782
Visit 11	1162	-1.08	[-1.75 , -0.40]	1150	-1.41	[-2.06 , -0.76]	0.33	[-0.60 , 1.27]	0.4815
Visit 14	522	-1.26	[-2.16 , -0.35]	513	-2.05	[-2.87 , -1.23]	0.80	[-0.41 , 2.00]	0.1956
Overall	2151	-1.01	[-1.61 , -0.42]	2133	-1.04	[-1.63 , -0.44]	0.02	[-0.61 , 0.65]	0.9440
Hedges' g							0.00	[-0.06 , 0.06]	0.9580

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
Symptoms and Problems uses items 17 to 28 b of the KDQOL-36.

Table B3.3.6: KDQoL-36 - Summary and MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2327)			Placebo (N=2304)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2116	0.27	[-0.26 , 0.81]	2104	0.01	[-0.52 , 0.53]	0.27	[-0.48 , 1.01]	0.4837
Visit 8	1911	-0.22	[-0.82 , 0.37]	1866	-0.29	[-0.85 , 0.27]	0.07	[-0.75 , 0.89]	0.8697
Visit 11	1158	-0.40	[-1.07 , 0.26]	1145	-1.27	[-2.01 , -0.54]	0.87	[-0.11 , 1.85]	0.0828
Visit 14	520	-1.16	[-2.13 , -0.20]	510	-2.98	[-3.95 , -2.01]	1.81	[0.46 , 3.17]	0.0086
Overall	2143	0.46	[-0.18 , 1.10]	2128	-0.05	[-0.72 , 0.61]	0.52	[-0.17 , 1.20]	0.1394
Hedges' g							0.03	[-0.03 , 0.09]	0.2710

Convergence Status of MMRM:
Convergence criteria met.

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LS=least squares, MMRM=Mixed Model Repeated Measures, N=number of subjects.
Note: MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
Separate unstructured covariance patterns are estimated for each treatment group.
Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQOL-36.

Table B3.4.1: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		707 (30.4%)	704 (30.6%)	1411 (30.5%)
Number of subjects without events		1620 (69.6%)	1600 (69.4%)	3220 (69.5%)
Odds Ratio [a]				
OR, 95% CI	0.991 [0.875, 1.124]			
p-value	0.8933			
Relative Risk [b]				
RR, 95% CI	0.994 [0.911, 1.084]			
p-value	0.8903			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.028, 0.025]			
p-value	0.8996			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, VAS=Visual Analogue Scale.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.2: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		607 (26.1%)	584 (25.3%)	1191 (25.7%)
Number of subjects without events		1720 (73.9%)	1720 (74.7%)	3440 (74.3%)
Odds Ratio [a]				
OR, 95% CI	1.037 [0.909, 1.183]			
p-value	0.5878			
Relative Risk [b]				
RR, 95% CI	1.026 [0.931, 1.132]			
p-value	0.6017			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.018, 0.033]			
p-value	0.5599			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, VAS=Visual Analogue Scale.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.3: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		786 (33.8%)	753 (32.7%)	1539 (33.2%)
Number of subjects without events		1541 (66.2%)	1551 (67.3%)	3092 (66.8%)
Odds Ratio [a]				
OR, 95% CI	1.049 [0.928, 1.186]			
p-value	0.4441			
Relative Risk [b]				
RR, 95% CI	1.033 [0.952, 1.120]			
p-value	0.4381			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.017, 0.037]			
p-value	0.4778			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.4: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		758 (32.6%)	782 (33.9%)	1540 (33.3%)
Number of subjects without events		1569 (67.4%)	1522 (66.1%)	3091 (66.7%)
Odds Ratio [a]				
OR, 95% CI	0.939 [0.831, 1.062]			
p-value	0.3171			
Relative Risk [b]				
RR, 95% CI	0.958 [0.883, 1.039]			
p-value	0.3004			
Risk Difference [c]				
RD, 95% CI	-0.013 [-0.040, 0.014]			
p-value	0.3414			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.5: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		861 (37.0%)	861 (37.4%)	1722 (37.2%)
Number of subjects without events		1466 (63.0%)	1443 (62.6%)	2909 (62.8%)
Odds Ratio [a]				
OR, 95% CI	0.984 [0.873, 1.109]			
p-value	0.7885			
Relative Risk [b]				
RR, 95% CI	0.989 [0.918, 1.065]			
p-value	0.7643			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.032, 0.024]			
p-value	0.7861			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.6: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		479 (20.6%)	449 (19.5%)	928 (20.0%)
Number of subjects without events		1848 (79.4%)	1855 (80.5%)	3703 (80.0%)
Odds Ratio [a]				
OR, 95% CI	1.069 [0.925, 1.235]			
p-value	0.3677			
Relative Risk [b]				
RR, 95% CI	1.053 [0.939, 1.181]			
p-value	0.3804			
Risk Difference [c]				
RD, 95% CI	0.011 [-0.012, 0.034]			
p-value	0.3466			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.7: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		514 (22.1%)	577 (25.0%)	1091 (23.6%)
Number of subjects without events		1813 (77.9%)	1727 (75.0%)	3540 (76.4%)
Odds Ratio [a]				
OR, 95% CI	0.847 [0.739, 0.970]			
p-value	0.0168			
Relative Risk [b]				
RR, 95% CI	0.880 [0.793, 0.976]			
p-value	0.0155			
Risk Difference [c]				
RD, 95% CI	-0.029 [-0.053, -0.005]			
p-value	0.0201			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.8: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		560 (24.1%)	513 (22.3%)	1073 (23.2%)
Number of subjects without events		1767 (75.9%)	1791 (77.7%)	3558 (76.8%)
Odds Ratio [a]				
OR, 95% CI	1.106 [0.964, 1.268]			
p-value	0.1498			
Relative Risk [b]				
RR, 95% CI	1.078 [0.971, 1.197]			
p-value	0.1596			
Risk Difference [c]				
RD, 95% CI	0.019 [-0.006, 0.043]			
p-value	0.1337			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.9: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		510 (21.9%)	488 (21.2%)	998 (21.6%)
Number of subjects without events		1817 (78.1%)	1816 (78.8%)	3633 (78.4%)
Odds Ratio [a]				
OR, 95% CI	1.046 [0.909, 1.203]			
p-value	0.5323			
Relative Risk [b]				
RR, 95% CI	1.038 [0.930, 1.158]			
p-value	0.5074			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.017, 0.030]			
p-value	0.5920			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.10: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		698 (30.0%)	693 (30.1%)	1391 (30.0%)
Number of subjects without events		1629 (70.0%)	1611 (69.9%)	3240 (70.0%)
Odds Ratio [a]				
OR, 95% CI	0.998 [0.880, 1.132]			
p-value	0.9779			
Relative Risk [b]				
RR, 95% CI	0.997 [0.913, 1.088]			
p-value	0.9427			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.026, 0.027]			
p-value	0.9757			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.11: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		346 (14.9%)	285 (12.4%)	631 (13.6%)
Number of subjects without events		1981 (85.1%)	2019 (87.6%)	4000 (86.4%)
Odds Ratio [a]				
OR, 95% CI	1.239 [1.047, 1.468]			
p-value	0.0128			
Relative Risk [b]				
RR, 95% CI	1.205 [1.042, 1.393]			
p-value	0.0121			
Risk Difference [c]				
RD, 95% CI	0.024 [0.005, 0.044]			
p-value	0.0140			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B3.4.12: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2327)	Placebo (N=2304)	Total (N=4631)
Number of subjects at risk		2327 (100.0%)	2304 (100.0%)	4631 (100.0%)
Number of subjects with events		380 (16.3%)	367 (15.9%)	747 (16.1%)
Number of subjects without events		1947 (83.7%)	1937 (84.1%)	3884 (83.9%)
Odds Ratio [a]				
OR, 95% CI	1.032 [0.882, 1.208]			
p-value	0.6920			
Relative Risk [b]				
RR, 95% CI	1.028 [0.902, 1.172]			
p-value	0.6742			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.017, 0.025]			
p-value	0.7031			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk.
Note: Results shown in the second column based on GLMs with factors treatment group, region, type of albuminuria at screening, CVD history.
The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented. * = model had convergence issues.
Analysis is based on all post-baseline assessments available for this parameter.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Any TEAE	1939(83.4%)	1937(84.1%)
Infections And Infestations	973(41.8%)	1005(43.7%)
Nasopharyngitis	179(7.7%)	201(8.7%)
Urinary tract infection	143(6.1%)	131(5.7%)
Upper respiratory tract infection	133(5.7%)	132(5.7%)
Bronchitis	117(5.0%)	119(5.2%)
Influenza	89(3.8%)	103(4.5%)
Pneumonia	85(3.7%)	129(5.6%)
Cellulitis	58(2.5%)	53(2.3%)
Gastroenteritis	49(2.1%)	55(2.4%)
Respiratory tract infection	43(1.8%)	30(1.3%)
Conjunctivitis	32(1.4%)	41(1.8%)
Pharyngitis	29(1.2%)	28(1.2%)
Herpes zoster	28(1.2%)	30(1.3%)
Sinusitis	23(1.0%)	27(1.2%)
Localised infection	22(0.9%)	15(0.7%)
Periodontitis	21(0.9%)	12(0.5%)
Cystitis	20(0.9%)	18(0.8%)
Abscess limb	18(0.8%)	11(0.5%)
COVID-19	17(0.7%)	33(1.4%)
Otitis externa	17(0.7%)	9(0.4%)
Tooth abscess	16(0.7%)	7(0.3%)
Erysipelas	14(0.6%)	27(1.2%)
Viral infection	14(0.6%)	19(0.8%)
Tonsillitis	14(0.6%)	16(0.7%)
Respiratory tract infection viral	13(0.6%)	19(0.8%)
Onychomycosis	13(0.6%)	11(0.5%)
Subcutaneous abscess	13(0.6%)	6(0.3%)
Osteomyelitis	12(0.5%)	17(0.7%)
Wound infection	12(0.5%)	11(0.5%)
Sepsis	12(0.5%)	10(0.4%)
Lower respiratory tract infection	11(0.5%)	9(0.4%)
Helicobacter infection	11(0.5%)	6(0.3%)
Pulpitis dental	11(0.5%)	4(0.2%)
Ear infection	10(0.4%)	10(0.4%)
Skin infection	10(0.4%)	10(0.4%)
Tooth infection	10(0.4%)	10(0.4%)
Otitis media	10(0.4%)	8(0.3%)
Fungal skin infection	10(0.4%)	5(0.2%)
Rhinitis	9(0.4%)	14(0.6%)
Laryngitis	9(0.4%)	5(0.2%)
Postoperative wound infection	9(0.4%)	3(0.1%)
Oral herpes	8(0.3%)	4(0.2%)
Tinea pedis	7(0.3%)	14(0.6%)
Acute sinusitis	7(0.3%)	6(0.3%)
Diabetic foot infection	7(0.3%)	5(0.2%)
Urosepsis	6(0.3%)	10(0.4%)
COVID-19 pneumonia	6(0.3%)	9(0.4%)
Diverticulitis	6(0.3%)	7(0.3%)
Gastroenteritis viral	6(0.3%)	6(0.3%)
Pyelonephritis chronic	6(0.3%)	5(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Appendicitis	6(0.3%)	3(0.1%)
Infected bite	6(0.3%)	3(0.1%)
Pyelonephritis	6(0.3%)	2(0.1%)
Dermatophytosis of nail	6(0.3%)	1(0.0%)
Gingivitis	5(0.2%)	12(0.5%)
Folliculitis	5(0.2%)	5(0.2%)
Pyelonephritis acute	5(0.2%)	4(0.2%)
Chronic sinusitis	5(0.2%)	2(0.1%)
Orchitis	5(0.2%)	2(0.1%)
Infected dermal cyst	5(0.2%)	1(0.0%)
Fungal infection	4(0.2%)	5(0.2%)
Labyrinthitis	4(0.2%)	5(0.2%)
Eye infection	4(0.2%)	4(0.2%)
Abscess	4(0.2%)	3(0.1%)
Asymptomatic bacteriuria	4(0.2%)	3(0.1%)
Pharyngotonsillitis	4(0.2%)	2(0.1%)
Septic shock	4(0.2%)	2(0.1%)
Oral fungal infection	4(0.2%)	1(0.0%)
Tinea cruris	4(0.2%)	1(0.0%)
Tracheitis	4(0.2%)	1(0.0%)
Vaginal infection	4(0.2%)	1(0.0%)
Paronychia	3(0.1%)	10(0.4%)
Acarodermatitis	3(0.1%)	8(0.3%)
Furuncle	3(0.1%)	8(0.3%)
Gangrene	3(0.1%)	7(0.3%)
Pneumonia bacterial	3(0.1%)	7(0.3%)
Hordeolum	3(0.1%)	4(0.2%)
Infected skin ulcer	3(0.1%)	4(0.2%)
Suspected COVID-19	3(0.1%)	3(0.1%)
Tracheobronchitis	3(0.1%)	3(0.1%)
Gingival abscess	3(0.1%)	2(0.1%)
Osteomyelitis chronic	3(0.1%)	2(0.1%)
Viral rhinitis	3(0.1%)	2(0.1%)
Bacterial infection	3(0.1%)	1(0.0%)
Enteritis infectious	3(0.1%)	1(0.0%)
Genital candidiasis	3(0.1%)	1(0.0%)
Herpes simplex	3(0.1%)	1(0.0%)
Pustule	3(0.1%)	1(0.0%)
Vulvovaginal mycotic infection	3(0.1%)	1(0.0%)
Bronchitis bacterial	3(0.1%)	0
Dengue fever	3(0.1%)	0
Febrile infection	3(0.1%)	0
Herpes dermatitis	3(0.1%)	0
Viral upper respiratory tract infection	2(0.1%)	8(0.3%)
Vulvovaginal candidiasis	2(0.1%)	4(0.2%)
Anal abscess	2(0.1%)	3(0.1%)
Body tinea	2(0.1%)	3(0.1%)
Conjunctivitis bacterial	2(0.1%)	3(0.1%)
Pneumonia viral	2(0.1%)	3(0.1%)
Pulmonary tuberculosis	2(0.1%)	3(0.1%)
Carbuncle	2(0.1%)	2(0.1%)
Gastrointestinal viral infection	2(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Hepatitis C	2(0.1%)	2(0.1%)
Epididymitis	2(0.1%)	1(0.0%)
Genitourinary tract infection	2(0.1%)	1(0.0%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Otitis media chronic	2(0.1%)	1(0.0%)
Post procedural infection	2(0.1%)	1(0.0%)
Staphylococcal bacteraemia	2(0.1%)	1(0.0%)
Tinea infection	2(0.1%)	1(0.0%)
Enterocolitis viral	2(0.1%)	0
Gastrointestinal infection	2(0.1%)	0
Herpes virus infection	2(0.1%)	0
Infected cyst	2(0.1%)	0
Liver abscess	2(0.1%)	0
Mastoiditis	2(0.1%)	0
Scrotal abscess	2(0.1%)	0
Infection	1(0.0%)	6(0.3%)
Soft tissue infection	1(0.0%)	6(0.3%)
Genital infection fungal	1(0.0%)	5(0.2%)
Oral candidiasis	1(0.0%)	5(0.2%)
Herpes ophthalmic	1(0.0%)	4(0.2%)
Genital infection	1(0.0%)	3(0.1%)
Groin infection	1(0.0%)	3(0.1%)
Oesophageal candidiasis	1(0.0%)	3(0.1%)
Penile infection	1(0.0%)	3(0.1%)
Urethritis	1(0.0%)	3(0.1%)
Urinary tract infection bacterial	1(0.0%)	3(0.1%)
Arthritis infective	1(0.0%)	2(0.1%)
Cholecystitis infective	1(0.0%)	2(0.1%)
Dacryocystitis	1(0.0%)	2(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	2(0.1%)
Meningitis	1(0.0%)	2(0.1%)
Abscess oral	1(0.0%)	1(0.0%)
Asymptomatic COVID-19	1(0.0%)	1(0.0%)
Bacterial vaginosis	1(0.0%)	1(0.0%)
Device related infection	1(0.0%)	1(0.0%)
Diabetic gangrene	1(0.0%)	1(0.0%)
Ear infection fungal	1(0.0%)	1(0.0%)
Genital herpes	1(0.0%)	1(0.0%)
Groin abscess	1(0.0%)	1(0.0%)
Infective exacerbation of bronchiectasis	1(0.0%)	1(0.0%)
Nail infection	1(0.0%)	1(0.0%)
Necrotising fasciitis	1(0.0%)	1(0.0%)
Osteomyelitis acute	1(0.0%)	1(0.0%)
Otitis media acute	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Pharyngitis bacterial	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Pyoderma	1(0.0%)	1(0.0%)
Sialoadenitis	1(0.0%)	1(0.0%)
Staphylococcal infection	1(0.0%)	1(0.0%)
Tinea versicolour	1(0.0%)	1(0.0%)
Urogenital infection fungal	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Varicella zoster virus infection	1(0.0%)	1(0.0%)
Viral diarrhoea	1(0.0%)	1(0.0%)
Abdominal abscess	1(0.0%)	0
Abdominal infection	1(0.0%)	0
Abdominal wall abscess	1(0.0%)	0
Ascariasis	1(0.0%)	0
Bacterial disease carrier	1(0.0%)	0
Blister infected	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Burn infection	1(0.0%)	0
Cervicitis	1(0.0%)	0
Conjunctivitis viral	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Dacryocanaliculitis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Ear infection staphylococcal	1(0.0%)	0
Endocarditis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Erythema migrans	1(0.0%)	0
Escherichia bacteraemia	1(0.0%)	0
Eye infection viral	1(0.0%)	0
Eyelid infection	1(0.0%)	0
Fascioliasis	1(0.0%)	0
Fungal pharyngitis	1(0.0%)	0
Gastroenteritis rotavirus	1(0.0%)	0
Gastrointestinal candidiasis	1(0.0%)	0
HIV infection	1(0.0%)	0
Hand-foot-and-mouth disease	1(0.0%)	0
Hepatitis B	1(0.0%)	0
Hepatitis E	1(0.0%)	0
Herpangina	1(0.0%)	0
Impetigo	1(0.0%)	0
Injection site cellulitis	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Lower respiratory tract infection viral	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Mastitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Oral infection	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Otitis externa fungal	1(0.0%)	0
Otosalpingitis	1(0.0%)	0
Pharyngitis streptococcal	1(0.0%)	0
Pneumococcal infection	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia streptococcal	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Pyuria	1(0.0%)	0
Q fever	1(0.0%)	0
Respiratory tract infection bacterial	1(0.0%)	0
Sinusitis bacterial	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Staphylococcal sepsis	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Tinea blanca	1(0.0%)	0
Tongue fungal infection	1(0.0%)	0
Urinary tract infection enterococcal	1(0.0%)	0
Viral sinusitis	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Helicobacter gastritis	0	4(0.2%)
Atypical pneumonia	0	3(0.1%)
Chronic hepatitis C	0	3(0.1%)
Diarrhoea infectious	0	3(0.1%)
Tonsillitis bacterial	0	3(0.1%)
Bacteriuria	0	2(0.1%)
Balanitis candida	0	2(0.1%)
Bronchiolitis	0	2(0.1%)
Haematoma infection	0	2(0.1%)
Salmonellosis	0	2(0.1%)
Vestibular neuronitis	0	2(0.1%)
Abdominal sepsis	0	1(0.0%)
Abscess jaw	0	1(0.0%)
Abscess of eyelid	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)
Adenoviral conjunctivitis	0	1(0.0%)
Anal fistula infection	0	1(0.0%)
Anorectal cellulitis	0	1(0.0%)
Arthritis bacterial	0	1(0.0%)
Arthropod-borne disease	0	1(0.0%)
Bacteraemia	0	1(0.0%)
Bacterial vulvovaginitis	0	1(0.0%)
Balanoposthitis infective	0	1(0.0%)
Bronchitis viral	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chest wall abscess	0	1(0.0%)
Chikungunya virus infection	0	1(0.0%)
Chronic hepatitis B	0	1(0.0%)
Chronic tonsillitis	0	1(0.0%)
Clostridium colitis	0	1(0.0%)
Clostridium difficile infection	0	1(0.0%)
Dermatophytosis	0	1(0.0%)
Dysentery	0	1(0.0%)
Eczema infected	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Epstein-Barr virus infection	0	1(0.0%)
Fungal balanitis	0	1(0.0%)
Gastroenteritis norovirus	0	1(0.0%)
Gastrointestinal fungal infection	0	1(0.0%)
Herpes zoster infection neurological	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Herpes zoster oticus	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Infected varicose vein	0	1(0.0%)
Injection site infection	0	1(0.0%)
Kidney infection	0	1(0.0%)
Large intestine infection	0	1(0.0%)
Leprosy	0	1(0.0%)
Lymphangitis	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Muscle abscess	0	1(0.0%)
Ophthalmic herpes simplex	0	1(0.0%)
Parotitis	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Perineal abscess	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Pseudomonas infection	0	1(0.0%)
Pulmonary sepsis	0	1(0.0%)
Pyelitis	0	1(0.0%)
Rash pustular	0	1(0.0%)
Retroperitoneal abscess	0	1(0.0%)
Rocky mountain spotted fever	0	1(0.0%)
Root canal infection	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Skin candida	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Testicular abscess	0	1(0.0%)
Tinea manuum	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Trichomoniasis	0	1(0.0%)
Urinary tract candidiasis	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Vulvovaginitis trichomonal	0	1(0.0%)
Metabolism And Nutrition Disorders	686(29.5%)	623(27.1%)
Hyperkalaemia	149(6.4%)	77(3.3%)
Hyperuricaemia	104(4.5%)	69(3.0%)
Hypoglycaemia	100(4.3%)	91(4.0%)
Diabetes mellitus inadequate control	67(2.9%)	49(2.1%)
Diabetes mellitus	64(2.8%)	85(3.7%)
Hyperglycaemia	59(2.5%)	52(2.3%)
Type 2 diabetes mellitus	53(2.3%)	53(2.3%)
Hypertriglyceridaemia	47(2.0%)	32(1.4%)
Vitamin D deficiency	44(1.9%)	38(1.7%)
Gout	41(1.8%)	33(1.4%)
Dyslipidaemia	37(1.6%)	30(1.3%)
Diabetic metabolic decompensation	32(1.4%)	22(1.0%)
Hypokalaemia	25(1.1%)	51(2.2%)
Hyponatraemia	25(1.1%)	10(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Hyperlipidaemia	24(1.0%)	28(1.2%)
Decreased appetite	13(0.6%)	21(0.9%)
Hypomagnesaemia	13(0.6%)	11(0.5%)
Dehydration	12(0.5%)	14(0.6%)
Vitamin B12 deficiency	12(0.5%)	7(0.3%)
Iron deficiency	11(0.5%)	9(0.4%)
Hypercholesterolaemia	11(0.5%)	4(0.2%)
Hypoproteinaemia	9(0.4%)	9(0.4%)
Obesity	8(0.3%)	9(0.4%)
Metabolic acidosis	7(0.3%)	4(0.2%)
Hypocalcaemia	5(0.2%)	9(0.4%)
Folate deficiency	4(0.2%)	9(0.4%)
Hypercalcaemia	4(0.2%)	5(0.2%)
Diabetic ketoacidosis	4(0.2%)	2(0.1%)
Metabolic disorder	3(0.1%)	10(0.4%)
Hypoalbuminaemia	3(0.1%)	4(0.2%)
Hyperphosphataemia	3(0.1%)	2(0.1%)
Hypochloraemia	2(0.1%)	2(0.1%)
Lipid metabolism disorder	2(0.1%)	1(0.0%)
Malnutrition	2(0.1%)	0
Metabolic syndrome	2(0.1%)	0
Overweight	2(0.1%)	0
Electrolyte imbalance	1(0.0%)	3(0.1%)
Hyperhomocysteinaemia	1(0.0%)	2(0.1%)
Hypervolaemia	1(0.0%)	2(0.1%)
Increased appetite	1(0.0%)	2(0.1%)
Abnormal loss of weight	1(0.0%)	1(0.0%)
Fluid overload	1(0.0%)	1(0.0%)
Hypophosphataemia	1(0.0%)	1(0.0%)
Magnesium deficiency	1(0.0%)	1(0.0%)
Alkalosis	1(0.0%)	0
Diabetic ketosis	1(0.0%)	0
Hypocholesterolaemia	1(0.0%)	0
Ketoacidosis	1(0.0%)	0
Lactic acidosis	1(0.0%)	0
Cachexia	0	3(0.1%)
Hypernatraemia	0	3(0.1%)
Diabetic complication	0	2(0.1%)
Hyperchloraemia	0	2(0.1%)
Abnormal weight gain	0	1(0.0%)
Fluid retention	0	1(0.0%)
Hyperlactacidaemia	0	1(0.0%)
Hypoglycaemia unawareness	0	1(0.0%)
Hypovitaminosis	0	1(0.0%)
Hypovolaemia	0	1(0.0%)
Hypozincaemia	0	1(0.0%)
Lactose intolerance	0	1(0.0%)
Metabolic alkalosis	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Periarthritis calcarea	0	1(0.0%)
Polydipsia	0	1(0.0%)
Vitamin B complex deficiency	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Musculoskeletal And Connective Tissue Disorders	615(26.4%)	607(26.4%)
Arthralgia	176(7.6%)	154(6.7%)
Back pain	147(6.3%)	135(5.9%)
Pain in extremity	86(3.7%)	76(3.3%)
Muscle spasms	60(2.6%)	74(3.2%)
Osteoarthritis	55(2.4%)	59(2.6%)
Myalgia	41(1.8%)	47(2.0%)
Intervertebral disc protrusion	30(1.3%)	29(1.3%)
Spinal osteoarthritis	27(1.2%)	31(1.3%)
Neck pain	25(1.1%)	25(1.1%)
Arthritis	23(1.0%)	19(0.8%)
Rotator cuff syndrome	21(0.9%)	27(1.2%)
Periarthritis	18(0.8%)	16(0.7%)
Flank pain	11(0.5%)	7(0.3%)
Bursitis	10(0.4%)	14(0.6%)
Musculoskeletal chest pain	10(0.4%)	11(0.5%)
Joint swelling	10(0.4%)	9(0.4%)
Trigger finger	10(0.4%)	9(0.4%)
Tenosynovitis	9(0.4%)	6(0.3%)
Lumbar spinal stenosis	9(0.4%)	5(0.2%)
Osteoporosis	8(0.3%)	7(0.3%)
Spinal stenosis	8(0.3%)	4(0.2%)
Gouty arthritis	8(0.3%)	3(0.1%)
Plantar fasciitis	7(0.3%)	14(0.6%)
Tendon disorder	7(0.3%)	8(0.3%)
Muscular weakness	7(0.3%)	6(0.3%)
Tendonitis	6(0.3%)	7(0.3%)
Musculoskeletal stiffness	6(0.3%)	6(0.3%)
Neuropathic arthropathy	6(0.3%)	6(0.3%)
Intervertebral disc degeneration	6(0.3%)	5(0.2%)
Osteochondrosis	6(0.3%)	5(0.2%)
Synovial cyst	6(0.3%)	5(0.2%)
Spinal pain	6(0.3%)	2(0.1%)
Intervertebral disc disorder	5(0.2%)	6(0.3%)
Rheumatoid arthritis	5(0.2%)	3(0.1%)
Foot deformity	5(0.2%)	1(0.0%)
Exostosis	4(0.2%)	5(0.2%)
Synovitis	4(0.2%)	1(0.0%)
Musculoskeletal pain	3(0.1%)	8(0.3%)
Osteopenia	3(0.1%)	4(0.2%)
Tenosynovitis stenosans	3(0.1%)	1(0.0%)
Rhabdomyolysis	3(0.1%)	0
Dupuytren's contracture	2(0.1%)	5(0.2%)
Myositis	2(0.1%)	5(0.2%)
Limb discomfort	2(0.1%)	3(0.1%)
Scoliosis	2(0.1%)	3(0.1%)
Spondylolisthesis	2(0.1%)	3(0.1%)
Joint effusion	2(0.1%)	2(0.1%)
Osteitis	2(0.1%)	2(0.1%)
Muscle contracture	2(0.1%)	1(0.0%)
Muscle twitching	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Myopathy	2(0.1%)	1(0.0%)
Polymyalgia rheumatica	2(0.1%)	1(0.0%)
Chondropathy	2(0.1%)	0
Muscle atrophy	2(0.1%)	0
Sacroiliitis	2(0.1%)	0
Costochondritis	1(0.0%)	3(0.1%)
Polyarthritis	1(0.0%)	3(0.1%)
Diastasis recti abdominis	1(0.0%)	2(0.1%)
Metatarsalgia	1(0.0%)	2(0.1%)
Coccydynia	1(0.0%)	1(0.0%)
Degenerative bone disease	1(0.0%)	1(0.0%)
Fasciitis	1(0.0%)	1(0.0%)
Fibromyalgia	1(0.0%)	1(0.0%)
Haematoma muscle	1(0.0%)	1(0.0%)
Joint range of motion decreased	1(0.0%)	1(0.0%)
Musculoskeletal disorder	1(0.0%)	1(0.0%)
Spinal ligament ossification	1(0.0%)	1(0.0%)
Vertebral foraminal stenosis	1(0.0%)	1(0.0%)
Enostosis	1(0.0%)	0
Enthesopathy	1(0.0%)	0
Exostosis of jaw	1(0.0%)	0
Femoroacetabular impingement	1(0.0%)	0
Fracture nonunion	1(0.0%)	0
Groin pain	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Joint stiffness	1(0.0%)	0
Knee deformity	1(0.0%)	0
Mobility decreased	1(0.0%)	0
Muscle disorder	1(0.0%)	0
Osteonecrosis	1(0.0%)	0
Polymyositis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Soft tissue swelling	1(0.0%)	0
Spinal deformity	1(0.0%)	0
Spinal disorder	1(0.0%)	0
Spinal synovial cyst	1(0.0%)	0
Spondylitis	1(0.0%)	0
Temporomandibular joint syndrome	1(0.0%)	0
Tendon discomfort	1(0.0%)	0
Tendon pain	1(0.0%)	0
Muscle fatigue	0	4(0.2%)
Arthropathy	0	3(0.1%)
Bone pain	0	3(0.1%)
Cervical spinal stenosis	0	2(0.1%)
Chondromalacia	0	2(0.1%)
Haemarthrosis	0	2(0.1%)
Musculoskeletal discomfort	0	2(0.1%)
Pain in jaw	0	2(0.1%)
Patellofemoral pain syndrome	0	2(0.1%)
Ankylosing spondylitis	0	1(0.0%)
Arthritis reactive	0	1(0.0%)
Back disorder	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Bone formation increased	0	1(0.0%)
Chest wall haematoma	0	1(0.0%)
Chondrocalcinosis pyrophosphate	0	1(0.0%)
Joint contracture	0	1(0.0%)
Kyphoscoliosis	0	1(0.0%)
Loose body in joint	0	1(0.0%)
Muscle rigidity	0	1(0.0%)
Neck mass	0	1(0.0%)
Osteoarthropathy	0	1(0.0%)
Osteochondritis	0	1(0.0%)
Osteoporotic fracture	0	1(0.0%)
Osteosclerosis	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Plantar fascial fibromatosis	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Sjogren's syndrome	0	1(0.0%)
Soft tissue disorder	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Spondyloarthropathy	0	1(0.0%)
Tendon calcification	0	1(0.0%)
Undifferentiated connective tissue disease	0	1(0.0%)
Gastrointestinal Disorders	600(25.8%)	548(23.8%)
Diarrhoea	141(6.1%)	125(5.4%)
Constipation	98(4.2%)	93(4.0%)
Nausea	52(2.2%)	40(1.7%)
Abdominal pain	47(2.0%)	45(2.0%)
Gastrooesophageal reflux disease	39(1.7%)	49(2.1%)
Gastritis	39(1.7%)	33(1.4%)
Abdominal pain upper	39(1.7%)	31(1.3%)
Dyspepsia	39(1.7%)	25(1.1%)
Vomiting	36(1.5%)	37(1.6%)
Chronic gastritis	33(1.4%)	27(1.2%)
Haemorrhoids	27(1.2%)	23(1.0%)
Large intestine polyp	23(1.0%)	41(1.8%)
Toothache	22(0.9%)	22(1.0%)
Gastritis erosive	14(0.6%)	15(0.7%)
Abdominal discomfort	14(0.6%)	7(0.3%)
Abdominal distension	13(0.6%)	13(0.6%)
Dental caries	12(0.5%)	12(0.5%)
Diverticulum intestinal	12(0.5%)	12(0.5%)
Duodenal ulcer	11(0.5%)	4(0.2%)
Umbilical hernia	9(0.4%)	7(0.3%)
Pancreatitis acute	9(0.4%)	2(0.1%)
Flatulence	8(0.3%)	12(0.5%)
Hiatus hernia	8(0.3%)	12(0.5%)
Inguinal hernia	8(0.3%)	10(0.4%)
Gastric ulcer	7(0.3%)	10(0.4%)
Pancreatitis chronic	7(0.3%)	9(0.4%)
Gastric polyps	5(0.2%)	6(0.3%)
Colitis	5(0.2%)	5(0.2%)
Dysphagia	5(0.2%)	5(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Gastrointestinal disorder	5(0.2%)	5(0.2%)
Abdominal pain lower	5(0.2%)	4(0.2%)
Irritable bowel syndrome	5(0.2%)	3(0.1%)
Melaena	5(0.2%)	3(0.1%)
Periodontal disease	5(0.2%)	3(0.1%)
Rectal polyp	5(0.2%)	3(0.1%)
Haematochezia	4(0.2%)	8(0.3%)
Food poisoning	4(0.2%)	4(0.2%)
Duodenitis	4(0.2%)	3(0.1%)
Pancreatitis	4(0.2%)	2(0.1%)
Gastrointestinal motility disorder	4(0.2%)	0
Gastrointestinal haemorrhage	3(0.1%)	5(0.2%)
Ascites	3(0.1%)	4(0.2%)
Haemorrhoidal haemorrhage	3(0.1%)	3(0.1%)
Abdominal hernia	3(0.1%)	2(0.1%)
Enterocolitis	3(0.1%)	1(0.0%)
Gastritis haemorrhagic	3(0.1%)	1(0.0%)
Peptic ulcer	3(0.1%)	1(0.0%)
Varices oesophageal	3(0.1%)	1(0.0%)
Gastric disorder	3(0.1%)	0
Gingival bleeding	3(0.1%)	0
Oesophagitis	2(0.1%)	8(0.3%)
Diverticulum	2(0.1%)	4(0.2%)
Dry mouth	2(0.1%)	4(0.2%)
Enteritis	2(0.1%)	4(0.2%)
Stomatitis	2(0.1%)	4(0.2%)
Upper gastrointestinal haemorrhage	2(0.1%)	4(0.2%)
Gastrointestinal angiodysplasia	2(0.1%)	3(0.1%)
Rectal haemorrhage	2(0.1%)	2(0.1%)
Abnormal faeces	2(0.1%)	1(0.0%)
Faeces soft	2(0.1%)	1(0.0%)
Gastric haemorrhage	2(0.1%)	1(0.0%)
Haematemesis	2(0.1%)	1(0.0%)
Loose tooth	2(0.1%)	1(0.0%)
Mouth ulceration	2(0.1%)	1(0.0%)
Pancreatic cyst	2(0.1%)	1(0.0%)
Pancreatic steatosis	2(0.1%)	1(0.0%)
Portal hypertensive gastropathy	2(0.1%)	1(0.0%)
Angular cheilitis	2(0.1%)	0
Aphthous ulcer	2(0.1%)	0
Duodenogastric reflux	2(0.1%)	0
Intestinal haemorrhage	2(0.1%)	0
Tongue ulceration	2(0.1%)	0
Erosive duodenitis	1(0.0%)	3(0.1%)
Eructation	1(0.0%)	3(0.1%)
Small intestinal obstruction	1(0.0%)	3(0.1%)
Tooth disorder	1(0.0%)	3(0.1%)
Gastric ulcer haemorrhage	1(0.0%)	2(0.1%)
Ileus	1(0.0%)	2(0.1%)
Anal fissure	1(0.0%)	1(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Functional gastrointestinal disorder	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Gastrointestinal hypermotility	1(0.0%)	1(0.0%)
Gingival swelling	1(0.0%)	1(0.0%)
Intestinal metaplasia	1(0.0%)	1(0.0%)
Intestinal polyp	1(0.0%)	1(0.0%)
Lower gastrointestinal haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Oesophageal polyp	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Parotid gland enlargement	1(0.0%)	1(0.0%)
Proctitis	1(0.0%)	1(0.0%)
Subileus	1(0.0%)	1(0.0%)
Tooth loss	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Acid peptic disease	1(0.0%)	0
Anal polyp	1(0.0%)	0
Bile acid malabsorption	1(0.0%)	0
Change of bowel habit	1(0.0%)	0
Coeliac artery stenosis	1(0.0%)	0
Colitis ischaemic	1(0.0%)	0
Dysbiosis	1(0.0%)	0
Dyschezia	1(0.0%)	0
Epulis	1(0.0%)	0
Faeces discoloured	1(0.0%)	0
Faeces hard	1(0.0%)	0
Gastric mucosa erythema	1(0.0%)	0
Gastric mucosal lesion	1(0.0%)	0
Gastrointestinal oedema	1(0.0%)	0
Gastrointestinal polyp	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Large intestinal ulcer	1(0.0%)	0
Lip disorder	1(0.0%)	0
Lip pain	1(0.0%)	0
Lip swelling	1(0.0%)	0
Lumbar hernia	1(0.0%)	0
Mesenteric panniculitis	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Noninfective gingivitis	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Oesophageal mass	1(0.0%)	0
Oesophageal obstruction	1(0.0%)	0
Oesophageal pain	1(0.0%)	0
Oesophageal ulcer	1(0.0%)	0
Oral discomfort	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Stress ulcer	1(0.0%)	0
Submaxillary gland enlargement	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Tooth ankylosis	1(0.0%)	0
Tooth development disorder	1(0.0%)	0
Tooth impacted	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Ulcerative duodenitis	1(0.0%)	0
Volvulus	1(0.0%)	0
Intestinal obstruction	0	5(0.2%)
Frequent bowel movements	0	4(0.2%)
Impaired gastric emptying	0	4(0.2%)
Anal incontinence	0	3(0.1%)
Abdominal adhesions	0	2(0.1%)
Anal fistula	0	2(0.1%)
Barrett's oesophagus	0	2(0.1%)
Breath odour	0	2(0.1%)
Coeliac disease	0	2(0.1%)
Colitis ulcerative	0	2(0.1%)
Diaphragmatic hernia	0	2(0.1%)
Gastrointestinal inflammation	0	2(0.1%)
Glossodynia	0	2(0.1%)
Intestinal mass	0	2(0.1%)
Oral pain	0	2(0.1%)
Reflux gastritis	0	2(0.1%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal haemorrhage	0	1(0.0%)
Anal inflammation	0	1(0.0%)
Anal skin tags	0	1(0.0%)
Brunner's gland hyperplasia	0	1(0.0%)
Crohn's disease	0	1(0.0%)
Diabetic gastroparesis	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Ectopic gastric mucosa	0	1(0.0%)
Enterovesical fistula	0	1(0.0%)
Erosive oesophagitis	0	1(0.0%)
Faecaloma	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastrointestinal scarring	0	1(0.0%)
Gingival hypertrophy	0	1(0.0%)
Gingival pain	0	1(0.0%)
Glycogenic acanthosis	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Internal hernia	0	1(0.0%)
Lip oedema	0	1(0.0%)
Lymphangiectasia intestinal	0	1(0.0%)
Odynophagia	0	1(0.0%)
Oesophageal disorder	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Omental infarction	0	1(0.0%)
Oral mucosa erosion	0	1(0.0%)
Palatal disorder	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Peritoneal adhesions	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Rectal ulcer haemorrhage	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland calculus	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Salivary gland disorder	0	1(0.0%)
Small intestine ulcer	0	1(0.0%)
Steatorrhoea	0	1(0.0%)
Investigations	504(21.7%)	502(21.8%)
Glomerular filtration rate decreased	103(4.4%)	92(4.0%)
C-reactive protein increased	79(3.4%)	74(3.2%)
Blood creatine phosphokinase increased	69(3.0%)	93(4.0%)
Blood pressure increased	36(1.5%)	42(1.8%)
Glycosylated haemoglobin increased	33(1.4%)	31(1.3%)
Weight decreased	30(1.3%)	26(1.1%)
Blood creatinine increased	28(1.2%)	31(1.3%)
Blood potassium increased	27(1.2%)	14(0.6%)
Gamma-glutamyltransferase increased	26(1.1%)	31(1.3%)
Blood triglycerides increased	16(0.7%)	8(0.3%)
Alanine aminotransferase increased	14(0.6%)	17(0.7%)
Blood glucose increased	13(0.6%)	18(0.8%)
Aspartate aminotransferase increased	13(0.6%)	12(0.5%)
Blood uric acid increased	12(0.5%)	8(0.3%)
Weight increased	10(0.4%)	13(0.6%)
Hepatic enzyme increased	9(0.4%)	6(0.3%)
Liver function test increased	8(0.3%)	8(0.3%)
Haemoglobin decreased	6(0.3%)	10(0.4%)
Cardiac murmur	6(0.3%)	6(0.3%)
Blood potassium decreased	5(0.2%)	6(0.3%)
Blood lactate dehydrogenase increased	5(0.2%)	4(0.2%)
Helicobacter test positive	4(0.2%)	8(0.3%)
Blood alkaline phosphatase increased	4(0.2%)	4(0.2%)
White blood cell count increased	4(0.2%)	4(0.2%)
Blood pressure decreased	4(0.2%)	3(0.1%)
Polymerase chain reaction positive	4(0.2%)	2(0.1%)
Transaminases increased	4(0.2%)	2(0.1%)
Heart rate increased	3(0.1%)	4(0.2%)
Electrocardiogram T wave inversion	3(0.1%)	3(0.1%)
Haemoglobin increased	3(0.1%)	3(0.1%)
Ejection fraction decreased	3(0.1%)	1(0.0%)
Blood sodium decreased	3(0.1%)	0
Blood urine present	3(0.1%)	0
Electrocardiogram T wave amplitude decreased	3(0.1%)	0
Troponin T increased	3(0.1%)	0
Vitamin D decreased	3(0.1%)	0
Prostatic specific antigen increased	2(0.1%)	10(0.4%)
Occult blood positive	2(0.1%)	4(0.2%)
Blood urea increased	2(0.1%)	3(0.1%)
Liver function test abnormal	2(0.1%)	3(0.1%)
Blood magnesium decreased	2(0.1%)	2(0.1%)
Colonoscopy	2(0.1%)	2(0.1%)
High density lipoprotein decreased	2(0.1%)	2(0.1%)
N-terminal prohormone brain natriuretic peptide increased	2(0.1%)	2(0.1%)
SARS-CoV-2 test positive	2(0.1%)	2(0.1%)
Urine albumin/creatinine ratio increased	2(0.1%)	2(0.1%)
Electrocardiogram T wave abnormal	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Blood glucose decreased	2(0.1%)	0
Carcinoembryonic antigen increased	2(0.1%)	0
Electrocardiogram change	2(0.1%)	0
Escherichia test positive	2(0.1%)	0
Lipids increased	2(0.1%)	0
Electrocardiogram ST segment depression	1(0.0%)	5(0.2%)
Electrocardiogram abnormal	1(0.0%)	4(0.2%)
Intraocular pressure increased	1(0.0%)	4(0.2%)
Angiocardiogram	1(0.0%)	3(0.1%)
Blood bicarbonate decreased	1(0.0%)	3(0.1%)
Blood cholesterol increased	1(0.0%)	3(0.1%)
QRS axis abnormal	1(0.0%)	3(0.1%)
Troponin increased	1(0.0%)	3(0.1%)
Electrocardiogram QT prolonged	1(0.0%)	2(0.1%)
Haematocrit increased	1(0.0%)	2(0.1%)
Platelet count decreased	1(0.0%)	2(0.1%)
Vitamin B12 decreased	1(0.0%)	2(0.1%)
Arthroscopy	1(0.0%)	1(0.0%)
Biopsy liver	1(0.0%)	1(0.0%)
Blood calcium increased	1(0.0%)	1(0.0%)
Blood folate decreased	1(0.0%)	1(0.0%)
Blood phosphorus increased	1(0.0%)	1(0.0%)
Blood sodium increased	1(0.0%)	1(0.0%)
Blood testosterone decreased	1(0.0%)	1(0.0%)
Chest X-ray abnormal	1(0.0%)	1(0.0%)
ECG signs of myocardial ischaemia	1(0.0%)	1(0.0%)
Electrocardiogram Q wave abnormal	1(0.0%)	1(0.0%)
Electrocardiogram ST segment elevation	1(0.0%)	1(0.0%)
Fibrin D dimer increased	1(0.0%)	1(0.0%)
Inflammatory marker increased	1(0.0%)	1(0.0%)
Low density lipoprotein decreased	1(0.0%)	1(0.0%)
Protein urine present	1(0.0%)	1(0.0%)
Respiratory syncytial virus test positive	1(0.0%)	1(0.0%)
White blood cells urine positive	1(0.0%)	1(0.0%)
Amylase increased	1(0.0%)	0
Angiogram	1(0.0%)	0
Angiogram retina	1(0.0%)	0
Arteriogram carotid abnormal	1(0.0%)	0
Aspiration joint	1(0.0%)	0
Biopsy kidney	1(0.0%)	0
Blood bilirubin increased	1(0.0%)	0
Blood chloride decreased	1(0.0%)	0
Blood cholesterol decreased	1(0.0%)	0
Blood lactic acid increased	1(0.0%)	0
Blood pressure abnormal	1(0.0%)	0
Blood pressure diastolic increased	1(0.0%)	0
Blood thyroid stimulating hormone increased	1(0.0%)	0
Bone density decreased	1(0.0%)	0
Brucella test positive	1(0.0%)	0
Cardiac imaging procedure abnormal	1(0.0%)	0
Catheterisation cardiac	1(0.0%)	0
Colonoscopy abnormal	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Computerised tomogram	1(0.0%)	0
Electrocardiogram QRS complex abnormal	1(0.0%)	0
Endoscopy upper gastrointestinal tract	1(0.0%)	0
False positive investigation result	1(0.0%)	0
Haematocrit decreased	1(0.0%)	0
Hepatic enzyme abnormal	1(0.0%)	0
Hepatitis B core antibody positive	1(0.0%)	0
Hepatitis B surface antibody positive	1(0.0%)	0
Imaging procedure abnormal	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Investigation	1(0.0%)	0
Lipase increased	1(0.0%)	0
Low density lipoprotein increased	1(0.0%)	0
Neurone-specific enolase increased	1(0.0%)	0
Proteus test positive	1(0.0%)	0
Pulse absent	1(0.0%)	0
Renal function test abnormal	1(0.0%)	0
Sleep study	1(0.0%)	0
Transaminases abnormal	1(0.0%)	0
Urine alcohol test positive	1(0.0%)	0
Vascular resistance systemic increased	1(0.0%)	0
Influenza A virus test positive	0	5(0.2%)
Biopsy prostate	0	3(0.1%)
Platelet count increased	0	3(0.1%)
Body temperature increased	0	2(0.1%)
Carotid bruit	0	2(0.1%)
Electrocardiogram ST segment abnormal	0	2(0.1%)
Neutrophil count increased	0	2(0.1%)
Urinary occult blood positive	0	2(0.1%)
Angiogram cerebral	0	1(0.0%)
Aspiration pleural cavity	0	1(0.0%)
Biopsy thyroid gland	0	1(0.0%)
Blood chromium decreased	0	1(0.0%)
Blood creatine phosphokinase MB increased	0	1(0.0%)
Blood iron decreased	0	1(0.0%)
Blood magnesium increased	0	1(0.0%)
Electrocardiogram QRS complex prolonged	0	1(0.0%)
Electrocardiogram QT interval abnormal	0	1(0.0%)
Endobronchial ultrasound	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Eosinophil count increased	0	1(0.0%)
Gastric pH decreased	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Glomerular filtration rate increased	0	1(0.0%)
Heart rate decreased	0	1(0.0%)
Hepatitis C virus test positive	0	1(0.0%)
Left ventricular end-diastolic pressure increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Muscle enzyme increased	0	1(0.0%)
Mycobacterium tuberculosis complex test positive	0	1(0.0%)
Myocardial necrosis marker increased	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Oxygen consumption increased	0	1(0.0%)
Oxygen saturation decreased	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Pulmonary function test decreased	0	1(0.0%)
Pulmonary imaging procedure abnormal	0	1(0.0%)
Red blood cell count decreased	0	1(0.0%)
Red blood cell count increased	0	1(0.0%)
Red blood cell sedimentation rate increased	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
Scan myocardial perfusion abnormal	0	1(0.0%)
Staphylococcus test positive	0	1(0.0%)
Stool analysis abnormal	0	1(0.0%)
Transferrin saturation decreased	0	1(0.0%)
Troponin I increased	0	1(0.0%)
Ultrasound kidney abnormal	0	1(0.0%)
Ultrasound liver abnormal	0	1(0.0%)
White blood cell count decreased	0	1(0.0%)
Nervous System Disorders	470(20.2%)	433(18.8%)
Dizziness	100(4.3%)	79(3.4%)
Headache	85(3.7%)	73(3.2%)
Diabetic neuropathy	55(2.4%)	61(2.6%)
Hypoaesthesia	21(0.9%)	26(1.1%)
Syncope	19(0.8%)	21(0.9%)
Sciatica	18(0.8%)	28(1.2%)
Neuropathy peripheral	18(0.8%)	16(0.7%)
Paraesthesia	17(0.7%)	14(0.6%)
Carotid artery stenosis	15(0.6%)	14(0.6%)
Carpal tunnel syndrome	15(0.6%)	14(0.6%)
Carotid arteriosclerosis	13(0.6%)	20(0.9%)
Lacunar infarction	11(0.5%)	4(0.2%)
Dizziness postural	10(0.4%)	3(0.1%)
Cerebral ischaemia	8(0.3%)	5(0.2%)
Facial paralysis	8(0.3%)	3(0.1%)
Presyncope	8(0.3%)	3(0.1%)
Neuralgia	7(0.3%)	7(0.3%)
Memory impairment	7(0.3%)	1(0.0%)
Somnolence	6(0.3%)	4(0.2%)
Cognitive disorder	6(0.3%)	3(0.1%)
Hemiparesis	6(0.3%)	3(0.1%)
Parkinson's disease	5(0.2%)	9(0.4%)
Tremor	5(0.2%)	5(0.2%)
Vascular encephalopathy	5(0.2%)	1(0.0%)
Dementia	4(0.2%)	5(0.2%)
Lumbar radiculopathy	4(0.2%)	4(0.2%)
Cerebrovascular disorder	4(0.2%)	3(0.1%)
Tension headache	4(0.2%)	2(0.1%)
Transient ischaemic attack	3(0.1%)	6(0.3%)
Polyneuropathy	3(0.1%)	5(0.2%)
Cerebral arteriosclerosis	3(0.1%)	4(0.2%)
Cerebral infarction	3(0.1%)	4(0.2%)
Cervicobrachial syndrome	3(0.1%)	4(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Post herpetic neuralgia	3(0.1%)	3(0.1%)
Amnesia	3(0.1%)	2(0.1%)
Dysaesthesia	3(0.1%)	2(0.1%)
Radiculopathy	3(0.1%)	2(0.1%)
Subarachnoid haemorrhage	3(0.1%)	2(0.1%)
Carotid artery occlusion	3(0.1%)	1(0.0%)
Epilepsy	3(0.1%)	1(0.0%)
Poor quality sleep	3(0.1%)	1(0.0%)
Lumbosacral radiculopathy	3(0.1%)	0
Metabolic encephalopathy	3(0.1%)	0
Cervical radiculopathy	2(0.1%)	6(0.3%)
Balance disorder	2(0.1%)	5(0.2%)
Loss of consciousness	2(0.1%)	4(0.2%)
Burning sensation	2(0.1%)	3(0.1%)
Dementia Alzheimer's type	2(0.1%)	3(0.1%)
Dysarthria	2(0.1%)	3(0.1%)
Cerebral microangiopathy	2(0.1%)	2(0.1%)
Phantom limb syndrome	2(0.1%)	2(0.1%)
Carotid artery disease	2(0.1%)	1(0.0%)
Cerebral artery stenosis	2(0.1%)	1(0.0%)
Cerebral atrophy	2(0.1%)	1(0.0%)
Cerebrovascular accident	2(0.1%)	1(0.0%)
Demyelination	2(0.1%)	1(0.0%)
Dysgeusia	2(0.1%)	1(0.0%)
Essential tremor	2(0.1%)	1(0.0%)
Hemianaesthesia	2(0.1%)	1(0.0%)
Intercostal neuralgia	2(0.1%)	1(0.0%)
Myelopathy	2(0.1%)	1(0.0%)
Peripheral sensorimotor neuropathy	2(0.1%)	1(0.0%)
Restless legs syndrome	2(0.1%)	1(0.0%)
Cerebral circulatory failure	2(0.1%)	0
Coordination abnormal	2(0.1%)	0
Leukoencephalopathy	2(0.1%)	0
Nerve compression	2(0.1%)	0
Normal pressure hydrocephalus	2(0.1%)	0
Orthostatic intolerance	2(0.1%)	0
Seizure	2(0.1%)	0
Transient global amnesia	2(0.1%)	0
Vertebral artery occlusion	2(0.1%)	0
Vocal cord paresis	2(0.1%)	0
Encephalopathy	1(0.0%)	3(0.1%)
Sensory disturbance	1(0.0%)	3(0.1%)
Facial paresis	1(0.0%)	2(0.1%)
Hemiparaesthesia	1(0.0%)	2(0.1%)
IIIrd nerve paralysis	1(0.0%)	2(0.1%)
Monoparesis	1(0.0%)	2(0.1%)
Parkinsonism	1(0.0%)	2(0.1%)
Ataxia	1(0.0%)	1(0.0%)
Cerebral calcification	1(0.0%)	1(0.0%)
Cerebral small vessel ischaemic disease	1(0.0%)	1(0.0%)
Decreased vibratory sense	1(0.0%)	1(0.0%)
Lethargy	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Meralgia paraesthetica	1(0.0%)	1(0.0%)
Paraparesis	1(0.0%)	1(0.0%)
Vertebral artery stenosis	1(0.0%)	1(0.0%)
Altered state of consciousness	1(0.0%)	0
Amputation stump pain	1(0.0%)	0
Brachial plexopathy	1(0.0%)	0
Brain injury	1(0.0%)	0
Central nervous system lesion	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebellar stroke	1(0.0%)	0
Cerebral artery occlusion	1(0.0%)	0
Cerebrovascular insufficiency	1(0.0%)	0
Complex regional pain syndrome	1(0.0%)	0
Cubital tunnel syndrome	1(0.0%)	0
Demyelinating polyneuropathy	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Facial nerve disorder	1(0.0%)	0
Head discomfort	1(0.0%)	0
Hemianopia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0
IVth nerve paralysis	1(0.0%)	0
Intracranial aneurysm	1(0.0%)	0
Intracranial hypotension	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0
Lacunar stroke	1(0.0%)	0
Mononeuropathy	1(0.0%)	0
Motor dysfunction	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Neurodegenerative disorder	1(0.0%)	0
Peripheral sensory neuropathy	1(0.0%)	0
Sinus headache	1(0.0%)	0
Sleep deficit	1(0.0%)	0
Spinal claudication	1(0.0%)	0
Spinal cord compression	1(0.0%)	0
Trigeminal neuralgia	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
VIth nerve paralysis	1(0.0%)	0
Vascular dementia	1(0.0%)	0
Vertebrobasilar dolichoectasia	1(0.0%)	0
Migraine	0	8(0.3%)
Hypoglycaemic coma	0	2(0.1%)
Radicular pain	0	2(0.1%)
Vertigo CNS origin	0	2(0.1%)
Visual field defect	0	2(0.1%)
Ageusia	0	1(0.0%)
Anaesthesia	0	1(0.0%)
Anosmia	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Carotid artery aneurysm	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebellar atrophy	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Cerebral haemorrhage	0	1(0.0%)
Cervicogenic headache	0	1(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.0%)
Clonus	0	1(0.0%)
Coma	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hyporeflexia	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
IVth nerve paresis	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Ischaemic neuropathy	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Multiple sclerosis	0	1(0.0%)
Muscle contractions involuntary	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Myoclonus	0	1(0.0%)
Neuralgic amyotrophy	0	1(0.0%)
Neuromyopathy	0	1(0.0%)
Parosmia	0	1(0.0%)
Sacral radiculopathy	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Toxic neuropathy	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Ulnar nerve palsy	0	1(0.0%)
Ulnar tunnel syndrome	0	1(0.0%)
VIth nerve paresis	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	374(16.1%)	391(17.0%)
Cough	97(4.2%)	101(4.4%)
Dyspnoea	47(2.0%)	71(3.1%)
Chronic obstructive pulmonary disease	34(1.5%)	36(1.6%)
Oropharyngeal pain	27(1.2%)	26(1.1%)
Sleep apnoea syndrome	24(1.0%)	25(1.1%)
Dyspnoea exertional	21(0.9%)	17(0.7%)
Rhinitis allergic	17(0.7%)	12(0.5%)
Asthma	16(0.7%)	21(0.9%)
Pulmonary mass	16(0.7%)	11(0.5%)
Bronchitis chronic	15(0.6%)	5(0.2%)
Epistaxis	14(0.6%)	16(0.7%)
Respiratory disorder	12(0.5%)	6(0.3%)
Acute respiratory failure	10(0.4%)	6(0.3%)
Pleural effusion	9(0.4%)	15(0.7%)
Rhinorrhoea	9(0.4%)	10(0.4%)
Upper respiratory tract inflammation	8(0.3%)	3(0.1%)
Catarrh	6(0.3%)	4(0.2%)
Productive cough	5(0.2%)	14(0.6%)
Respiratory failure	5(0.2%)	11(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Emphysema	5(0.2%)	4(0.2%)
Atelectasis	5(0.2%)	2(0.1%)
Pulmonary embolism	4(0.2%)	8(0.3%)
Pulmonary hypertension	4(0.2%)	8(0.3%)
Hypoxia	4(0.2%)	6(0.3%)
Pulmonary fibrosis	4(0.2%)	5(0.2%)
Haemoptysis	4(0.2%)	4(0.2%)
Pulmonary oedema	3(0.1%)	6(0.3%)
Acute pulmonary oedema	3(0.1%)	5(0.2%)
Interstitial lung disease	3(0.1%)	5(0.2%)
Restrictive pulmonary disease	3(0.1%)	1(0.0%)
Upper-airway cough syndrome	3(0.1%)	1(0.0%)
Obstructive airways disorder	3(0.1%)	0
Pleurisy	3(0.1%)	0
Sinus congestion	3(0.1%)	0
Bronchospasm	2(0.1%)	3(0.1%)
Nasal congestion	2(0.1%)	3(0.1%)
Pulmonary congestion	2(0.1%)	3(0.1%)
Aphonia	2(0.1%)	2(0.1%)
Cystic lung disease	2(0.1%)	2(0.1%)
Lung disorder	2(0.1%)	2(0.1%)
Bronchiectasis	2(0.1%)	1(0.0%)
Dyspnoea paroxysmal nocturnal	2(0.1%)	1(0.0%)
Orthopnoea	2(0.1%)	1(0.0%)
Choking sensation	2(0.1%)	0
Hyperventilation	2(0.1%)	0
Lung infiltration	2(0.1%)	0
Nasal obstruction	2(0.1%)	0
Cough variant asthma	1(0.0%)	4(0.2%)
Hiccups	1(0.0%)	3(0.1%)
Wheezing	1(0.0%)	3(0.1%)
Pneumonitis	1(0.0%)	2(0.1%)
Chronic respiratory failure	1(0.0%)	1(0.0%)
Dysphonia	1(0.0%)	1(0.0%)
Nasal septum deviation	1(0.0%)	1(0.0%)
Paranasal cyst	1(0.0%)	1(0.0%)
Pneumonia aspiration	1(0.0%)	1(0.0%)
Pulmonary arterial hypertension	1(0.0%)	1(0.0%)
Respiratory acidosis	1(0.0%)	1(0.0%)
Sneezing	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Hypercapnia	1(0.0%)	0
Idiopathic pulmonary fibrosis	1(0.0%)	0
Increased bronchial secretion	1(0.0%)	0
Laryngeal cyst	1(0.0%)	0
Laryngeal polyp	1(0.0%)	0
Laryngitis allergic	1(0.0%)	0
Lung consolidation	1(0.0%)	0
Lung hyperinflation	1(0.0%)	0
Nasal dryness	1(0.0%)	0
Nasal mucosal erosion	1(0.0%)	0
Nasal polyps	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Nasal turbinate hypertrophy	1(0.0%)	0
Oropharyngeal discomfort	1(0.0%)	0
Paranasal sinus inflammation	1(0.0%)	0
Pharyngeal erythema	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pleuritic pain	1(0.0%)	0
Pneumothorax	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Respiratory tract inflammation	1(0.0%)	0
Rhinitis hypertrophic	1(0.0%)	0
Rhonchi	1(0.0%)	0
Stridor	1(0.0%)	0
Tonsillar cyst	1(0.0%)	0
Tracheal squamous cell metaplasia	1(0.0%)	0
Tracheal stenosis	1(0.0%)	0
Vocal cord inflammation	1(0.0%)	0
Dyspnoea at rest	0	2(0.1%)
Hydrothorax	0	2(0.1%)
Sinus disorder	0	2(0.1%)
Upper respiratory tract congestion	0	2(0.1%)
Acute respiratory distress syndrome	0	1(0.0%)
Allergic respiratory disease	0	1(0.0%)
Apnoea	0	1(0.0%)
Bronchial secretion retention	0	1(0.0%)
Chronic respiratory disease	0	1(0.0%)
Diaphragmatic abnormal relaxation	0	1(0.0%)
Dry throat	0	1(0.0%)
Laryngeal mass	0	1(0.0%)
Lung cyst	0	1(0.0%)
Lung hypoinflation	0	1(0.0%)
Nocturnal dyspnoea	0	1(0.0%)
Paranasal sinus hypersecretion	0	1(0.0%)
Paranasal sinus mucosal hypertrophy	0	1(0.0%)
Pharyngeal inflammation	0	1(0.0%)
Pickwickian syndrome	0	1(0.0%)
Rales	0	1(0.0%)
Reflux laryngitis	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Sinus polyp	0	1(0.0%)
Snoring	0	1(0.0%)
Sputum increased	0	1(0.0%)
Injury, Poisoning And Procedural Complications	368(15.8%)	334(14.5%)
Limb injury	50(2.1%)	58(2.5%)
Contusion	39(1.7%)	38(1.7%)
Ligament sprain	29(1.2%)	21(0.9%)
Fall	27(1.2%)	35(1.5%)
Skin abrasion	15(0.6%)	11(0.5%)
Thermal burn	13(0.6%)	13(0.6%)
Rib fracture	13(0.6%)	12(0.5%)
Foot fracture	13(0.6%)	11(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Head injury	12(0.5%)	11(0.5%)
Meniscus injury	11(0.5%)	5(0.2%)
Muscle strain	9(0.4%)	11(0.5%)
Joint injury	9(0.4%)	9(0.4%)
Procedural pain	9(0.4%)	8(0.3%)
Ankle fracture	9(0.4%)	7(0.3%)
Post-traumatic pain	9(0.4%)	6(0.3%)
Heat illness	8(0.3%)	4(0.2%)
Bone contusion	7(0.3%)	6(0.3%)
Epicondylitis	7(0.3%)	5(0.2%)
Arthropod bite	7(0.3%)	4(0.2%)
Upper limb fracture	7(0.3%)	3(0.1%)
Tibia fracture	7(0.3%)	1(0.0%)
Tendon rupture	6(0.3%)	5(0.2%)
Hand fracture	6(0.3%)	2(0.1%)
Skin laceration	5(0.2%)	10(0.4%)
Skin wound	5(0.2%)	5(0.2%)
Animal bite	5(0.2%)	4(0.2%)
Face injury	5(0.2%)	4(0.2%)
Lower limb fracture	5(0.2%)	3(0.1%)
Foreign body in eye	5(0.2%)	1(0.0%)
Accident	4(0.2%)	5(0.2%)
Femur fracture	4(0.2%)	4(0.2%)
Tooth fracture	4(0.2%)	2(0.1%)
Arthropod sting	4(0.2%)	1(0.0%)
Chest injury	4(0.2%)	1(0.0%)
Muscle injury	4(0.2%)	0
Scratch	4(0.2%)	0
Lumbar vertebral fracture	3(0.1%)	6(0.3%)
Fibula fracture	3(0.1%)	4(0.2%)
Joint dislocation	3(0.1%)	3(0.1%)
Radius fracture	3(0.1%)	3(0.1%)
Fractured coccyx	3(0.1%)	2(0.1%)
Injury	3(0.1%)	1(0.0%)
Ligament injury	3(0.1%)	1(0.0%)
Road traffic accident	3(0.1%)	1(0.0%)
Traumatic haematoma	3(0.1%)	1(0.0%)
Burns second degree	3(0.1%)	0
Hip fracture	3(0.1%)	0
Ligament rupture	3(0.1%)	0
Humerus fracture	2(0.1%)	6(0.3%)
Facial bones fracture	2(0.1%)	4(0.2%)
Subdural haematoma	2(0.1%)	4(0.2%)
Craniocerebral injury	2(0.1%)	3(0.1%)
Clavicle fracture	2(0.1%)	2(0.1%)
Eye injury	2(0.1%)	1(0.0%)
Heat stroke	2(0.1%)	1(0.0%)
Limb crushing injury	2(0.1%)	1(0.0%)
Multiple fractures	2(0.1%)	1(0.0%)
Nerve injury	2(0.1%)	1(0.0%)
Soft tissue injury	2(0.1%)	1(0.0%)
Toxicity to various agents	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Back injury	2(0.1%)	0
Foreign body	2(0.1%)	0
Nail avulsion	2(0.1%)	0
Poisoning	2(0.1%)	0
Vascular injury	2(0.1%)	0
Wound	2(0.1%)	0
Spinal compression fracture	1(0.0%)	4(0.2%)
Subcutaneous haematoma	1(0.0%)	4(0.2%)
Eye contusion	1(0.0%)	3(0.1%)
Cartilage injury	1(0.0%)	2(0.1%)
Muscle rupture	1(0.0%)	2(0.1%)
Post procedural complication	1(0.0%)	2(0.1%)
Spinal column injury	1(0.0%)	2(0.1%)
Subdural haemorrhage	1(0.0%)	2(0.1%)
Abdominal injury	1(0.0%)	1(0.0%)
Fracture	1(0.0%)	1(0.0%)
Injury corneal	1(0.0%)	1(0.0%)
Lip injury	1(0.0%)	1(0.0%)
Mallet finger	1(0.0%)	1(0.0%)
Nasal injury	1(0.0%)	1(0.0%)
Postoperative wound complication	1(0.0%)	1(0.0%)
Stomal hernia	1(0.0%)	1(0.0%)
Traumatic fracture	1(0.0%)	1(0.0%)
Wound dehiscence	1(0.0%)	1(0.0%)
Alcohol poisoning	1(0.0%)	0
Arterial bypass occlusion	1(0.0%)	0
Arterial bypass stenosis	1(0.0%)	0
Burns third degree	1(0.0%)	0
Buttock injury	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Chillblains	1(0.0%)	0
Concussion	1(0.0%)	0
Corneal abrasion	1(0.0%)	0
Device placement issue	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Foreign body in throat	1(0.0%)	0
Inflammation of wound	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Limb traumatic amputation	1(0.0%)	0
Mouth injury	1(0.0%)	0
Multiple injuries	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Patella fracture	1(0.0%)	0
Post procedural discomfort	1(0.0%)	0
Post procedural hypotension	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Scar	1(0.0%)	0
Sciatic nerve injury	1(0.0%)	0
Skin injury	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Splenic rupture	1(0.0%)	0
Tendon injury	1(0.0%)	0
Tongue injury	1(0.0%)	0
Traumatic arthritis	1(0.0%)	0
Traumatic haemorrhage	1(0.0%)	0
Ulna fracture	1(0.0%)	0
Vascular access site haematoma	1(0.0%)	0
Vascular access site thrombosis	1(0.0%)	0
Vascular pseudoaneurysm	1(0.0%)	0
Wound complication	1(0.0%)	0
Wound contamination	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Wrist fracture	0	7(0.3%)
Traumatic ulcer	0	5(0.2%)
Burns first degree	0	3(0.1%)
Hyphaema	0	3(0.1%)
Sunburn	0	3(0.1%)
Anaemia postoperative	0	2(0.1%)
Brain contusion	0	2(0.1%)
Nail injury	0	2(0.1%)
Procedural nausea	0	2(0.1%)
Thoracic vertebral fracture	0	2(0.1%)
Accidental overdose	0	1(0.0%)
Auricular haematoma	0	1(0.0%)
Bone fissure	0	1(0.0%)
Burn oral cavity	0	1(0.0%)
Cataract operation complication	0	1(0.0%)
Cervical vertebral fracture	0	1(0.0%)
Chemical burns of eye	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Ear canal injury	0	1(0.0%)
Exposure to SARS-CoV-2	0	1(0.0%)
Extra-axial haemorrhage	0	1(0.0%)
Eyelid injury	0	1(0.0%)
Incision site pain	0	1(0.0%)
Muscle contusion	0	1(0.0%)
Overdose	0	1(0.0%)
Peripheral nerve injury	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Post procedural constipation	0	1(0.0%)
Post procedural fever	0	1(0.0%)
Post procedural hypothyroidism	0	1(0.0%)
Post-traumatic neck syndrome	0	1(0.0%)
Postoperative ileus	0	1(0.0%)
Procedural vomiting	0	1(0.0%)
Radiation associated pain	0	1(0.0%)
Radiation skin injury	0	1(0.0%)
Reactive gastropathy	0	1(0.0%)
Retinal injury	0	1(0.0%)
Skull fracture	0	1(0.0%)
Superficial injury of eye	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Synovial rupture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Trunk injury	0	1(0.0%)
Ulnar nerve injury	0	1(0.0%)
Urethral injury	0	1(0.0%)
Vascular graft occlusion	0	1(0.0%)
Vascular Disorders	347(14.9%)	398(17.3%)
Hypertension	141(6.1%)	202(8.8%)
Hypotension	69(3.0%)	36(1.6%)
Peripheral arterial occlusive disease	28(1.2%)	39(1.7%)
Peripheral venous disease	12(0.5%)	11(0.5%)
Arteriosclerosis	12(0.5%)	7(0.3%)
Aortic stenosis	10(0.4%)	11(0.5%)
Hypertensive crisis	9(0.4%)	13(0.6%)
Orthostatic hypotension	9(0.4%)	10(0.4%)
Varicose vein	9(0.4%)	9(0.4%)
Deep vein thrombosis	9(0.4%)	8(0.3%)
Aortic arteriosclerosis	8(0.3%)	16(0.7%)
Intermittent claudication	8(0.3%)	8(0.3%)
Peripheral artery occlusion	7(0.3%)	3(0.1%)
Peripheral ischaemia	7(0.3%)	1(0.0%)
Peripheral artery stenosis	6(0.3%)	8(0.3%)
Blood pressure inadequately controlled	5(0.2%)	11(0.5%)
Peripheral vascular disorder	4(0.2%)	8(0.3%)
Diabetic vascular disorder	3(0.1%)	6(0.3%)
Hot flush	3(0.1%)	3(0.1%)
Hypertensive urgency	3(0.1%)	3(0.1%)
Phlebitis	3(0.1%)	3(0.1%)
Hypertensive emergency	3(0.1%)	2(0.1%)
Lymphoedema	3(0.1%)	1(0.0%)
Haematoma	2(0.1%)	6(0.3%)
Aortic aneurysm	2(0.1%)	5(0.2%)
Peripheral artery thrombosis	2(0.1%)	2(0.1%)
Peripheral coldness	2(0.1%)	2(0.1%)
Thrombophlebitis	2(0.1%)	2(0.1%)
Iliac artery stenosis	2(0.1%)	1(0.0%)
Macroangiopathy	2(0.1%)	1(0.0%)
Giant cell arteritis	2(0.1%)	0
Peripheral embolism	2(0.1%)	0
Phlebitis superficial	2(0.1%)	0
Thrombophlebitis superficial	2(0.1%)	0
Aortic dilatation	1(0.0%)	3(0.1%)
Essential hypertension	1(0.0%)	3(0.1%)
Circulatory collapse	1(0.0%)	2(0.1%)
Dry gangrene	1(0.0%)	1(0.0%)
Extremity necrosis	1(0.0%)	1(0.0%)
Poor peripheral circulation	1(0.0%)	1(0.0%)
Subclavian steal syndrome	1(0.0%)	1(0.0%)
Aortitis	1(0.0%)	0
Arterial disorder	1(0.0%)	0
Arterial occlusive disease	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Brachiocephalic arteriosclerosis	1(0.0%)	0
Diastolic hypotension	1(0.0%)	0
Embolism venous	1(0.0%)	0
Haematocoele	1(0.0%)	0
Labile hypertension	1(0.0%)	0
Lymphorrhoea	1(0.0%)	0
Neovascularisation	1(0.0%)	0
Phlebosclerosis	1(0.0%)	0
Raynaud's phenomenon	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Vasodilatation	1(0.0%)	0
Vein rupture	1(0.0%)	0
White coat hypertension	1(0.0%)	0
Flushing	0	3(0.1%)
Peripheral artery aneurysm	0	3(0.1%)
Accelerated hypertension	0	2(0.1%)
Diabetic macroangiopathy	0	2(0.1%)
Systolic hypertension	0	2(0.1%)
Venous thrombosis limb	0	2(0.1%)
Angiopathy	0	1(0.0%)
Angiosclerosis	0	1(0.0%)
Aortic aneurysm rupture	0	1(0.0%)
Aortic disorder	0	1(0.0%)
Hypovolaemic shock	0	1(0.0%)
Leriche syndrome	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Phlebolith	0	1(0.0%)
Post thrombotic syndrome	0	1(0.0%)
Shock	0	1(0.0%)
Supra-aortic trunk stenosis	0	1(0.0%)
General Disorders And Administration Site Conditions	337(14.5%)	387(16.8%)
Oedema peripheral	110(4.7%)	168(7.3%)
Chest pain	53(2.3%)	60(2.6%)
Fatigue	33(1.4%)	36(1.6%)
Pyrexia	32(1.4%)	35(1.5%)
Asthenia	30(1.3%)	28(1.2%)
Peripheral swelling	18(0.8%)	22(1.0%)
Influenza like illness	16(0.7%)	13(0.6%)
Chest discomfort	14(0.6%)	10(0.4%)
Oedema	13(0.6%)	20(0.9%)
Malaise	9(0.4%)	9(0.4%)
Pain	8(0.3%)	8(0.3%)
Death	6(0.3%)	2(0.1%)
General physical health deterioration	4(0.2%)	4(0.2%)
Generalised oedema	4(0.2%)	4(0.2%)
Chills	4(0.2%)	3(0.1%)
Cyst	4(0.2%)	3(0.1%)
Hyperthermia	4(0.2%)	0
Impaired healing	4(0.2%)	0
Inflammation	3(0.1%)	8(0.3%)
Non-cardiac chest pain	3(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Exercise tolerance decreased	3(0.1%)	0
Gait disturbance	2(0.1%)	4(0.2%)
Mass	2(0.1%)	3(0.1%)
Polyp	2(0.1%)	3(0.1%)
Multiple organ dysfunction syndrome	2(0.1%)	2(0.1%)
Nodule	2(0.1%)	1(0.0%)
Hernia	2(0.1%)	0
Oedema due to renal disease	2(0.1%)	0
Drug intolerance	1(0.0%)	3(0.1%)
Illness	1(0.0%)	3(0.1%)
Thirst	1(0.0%)	3(0.1%)
Gravitational oedema	1(0.0%)	2(0.1%)
Swelling face	1(0.0%)	2(0.1%)
Granuloma	1(0.0%)	1(0.0%)
Axillary pain	1(0.0%)	0
Catheter site pain	1(0.0%)	0
Feeling abnormal	1(0.0%)	0
Feeling cold	1(0.0%)	0
Hanging	1(0.0%)	0
Injection site atrophy	1(0.0%)	0
Physical deconditioning	1(0.0%)	0
Pseudocyst	1(0.0%)	0
Puncture site swelling	1(0.0%)	0
Soft tissue inflammation	1(0.0%)	0
Suprapubic pain	1(0.0%)	0
Vascular stent stenosis	1(0.0%)	0
Face oedema	0	2(0.1%)
Secretion discharge	0	2(0.1%)
Catheter site erythema	0	1(0.0%)
Facial pain	0	1(0.0%)
Haemorrhagic cyst	0	1(0.0%)
Hunger	0	1(0.0%)
Induration	0	1(0.0%)
Localised oedema	0	1(0.0%)
Pacemaker generated arrhythmia	0	1(0.0%)
Puncture site pain	0	1(0.0%)
Sudden death	0	1(0.0%)
Swelling	0	1(0.0%)
Temperature intolerance	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	334(14.4%)	325(14.1%)
Skin ulcer	50(2.1%)	57(2.5%)
Pruritus	41(1.8%)	40(1.7%)
Diabetic foot	36(1.5%)	30(1.3%)
Eczema	35(1.5%)	32(1.4%)
Rash	30(1.3%)	34(1.5%)
Urticaria	16(0.7%)	11(0.5%)
Dermatitis	14(0.6%)	15(0.7%)
Dermatitis allergic	14(0.6%)	4(0.2%)
Hyperkeratosis	11(0.5%)	5(0.2%)
Dry skin	10(0.4%)	14(0.6%)
Erythema	9(0.4%)	11(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Blister	8(0.3%)	9(0.4%)
Dermatitis contact	8(0.3%)	8(0.3%)
Skin lesion	8(0.3%)	7(0.3%)
Hyperhidrosis	8(0.3%)	5(0.2%)
Psoriasis	7(0.3%)	6(0.3%)
Skin disorder	6(0.3%)	0
Dermatitis atopic	5(0.2%)	4(0.2%)
Eczema asteatotic	5(0.2%)	1(0.0%)
Ingrowing nail	4(0.2%)	8(0.3%)
Alopecia	4(0.2%)	7(0.3%)
Seborrhoeic dermatitis	4(0.2%)	4(0.2%)
Stasis dermatitis	4(0.2%)	4(0.2%)
Decubitus ulcer	4(0.2%)	2(0.1%)
Hidradenitis	4(0.2%)	2(0.1%)
Angioedema	4(0.2%)	1(0.0%)
Neurodermatitis	4(0.2%)	0
Actinic keratosis	3(0.1%)	5(0.2%)
Skin discolouration	3(0.1%)	3(0.1%)
Skin exfoliation	3(0.1%)	3(0.1%)
Dyshidrotic eczema	3(0.1%)	0
Dermal cyst	2(0.1%)	7(0.3%)
Hand dermatitis	2(0.1%)	3(0.1%)
Miliaria	2(0.1%)	2(0.1%)
Palmoplantar keratoderma	2(0.1%)	2(0.1%)
Xeroderma	2(0.1%)	2(0.1%)
Asteatosis	2(0.1%)	1(0.0%)
Drug eruption	2(0.1%)	1(0.0%)
Diabetic bullosis	2(0.1%)	0
Exfoliative rash	2(0.1%)	0
Onycholysis	2(0.1%)	0
Prurigo	2(0.1%)	0
Skin reaction	2(0.1%)	0
Rash pruritic	1(0.0%)	3(0.1%)
Ecchymosis	1(0.0%)	2(0.1%)
Eczema nummular	1(0.0%)	2(0.1%)
Skin fissures	1(0.0%)	2(0.1%)
Alopecia areata	1(0.0%)	1(0.0%)
Dermatitis bullous	1(0.0%)	1(0.0%)
Dermatitis psoriasiform	1(0.0%)	1(0.0%)
Haemorrhage subcutaneous	1(0.0%)	1(0.0%)
Itching scar	1(0.0%)	1(0.0%)
Nail dystrophy	1(0.0%)	1(0.0%)
Papule	1(0.0%)	1(0.0%)
Rosacea	1(0.0%)	1(0.0%)
Scab	1(0.0%)	1(0.0%)
Skin irritation	1(0.0%)	1(0.0%)
Skin necrosis	1(0.0%)	1(0.0%)
Angiodermatitis	1(0.0%)	0
Angiokeratoma	1(0.0%)	0
Autoimmune dermatitis	1(0.0%)	0
Brow ptosis	1(0.0%)	0
Cold sweat	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Diffuse alopecia	1(0.0%)	0
Erythema ab igne	1(0.0%)	0
Fixed eruption	1(0.0%)	0
Intertrigo	1(0.0%)	0
Nail fold inflammation	1(0.0%)	0
Nail hypertrophy	1(0.0%)	0
Neuropathic ulcer	1(0.0%)	0
Pemphigoid	1(0.0%)	0
Pigmentation disorder	1(0.0%)	0
Purpura	1(0.0%)	0
Pustular psoriasis	1(0.0%)	0
Rash macular	1(0.0%)	0
Rash papular	1(0.0%)	0
Rhinophyma	1(0.0%)	0
Scar pain	1(0.0%)	0
Sebaceous adenitis	1(0.0%)	0
Seborrhoea	1(0.0%)	0
Senile xerosis	1(0.0%)	0
Skin burning sensation	1(0.0%)	0
Skin erosion	1(0.0%)	0
Solar lentigo	1(0.0%)	0
Toxic skin eruption	1(0.0%)	0
Urticaria chronic	1(0.0%)	0
Urticarial dermatitis	1(0.0%)	0
Diabetic ulcer	0	3(0.1%)
Lipohypertrophy	0	3(0.1%)
Nail discolouration	0	2(0.1%)
Rash maculo-papular	0	2(0.1%)
Skin induration	0	2(0.1%)
Skin mass	0	2(0.1%)
Vitiligo	0	2(0.1%)
Acne	0	1(0.0%)
Dandruff	0	1(0.0%)
Erythema annulare	0	1(0.0%)
Excessive skin	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Ischaemic skin ulcer	0	1(0.0%)
Lichen sclerosus	0	1(0.0%)
Nail bed bleeding	0	1(0.0%)
Nail bed inflammation	0	1(0.0%)
Nail disorder	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Night sweats	0	1(0.0%)
Onychoclasis	0	1(0.0%)
Palmoplantar pustulosis	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Pityriasis rosea	0	1(0.0%)
Pruritus allergic	0	1(0.0%)
Rash erythematous	0	1(0.0%)
Skin depigmentation	0	1(0.0%)
Skin hyperpigmentation	0	1(0.0%)
Skin hypertrophy	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Eye Disorders	285(12.3%)	287(12.5%)
Cataract	93(4.0%)	86(3.7%)
Diabetic retinopathy	69(3.0%)	72(3.1%)
Vitreous haemorrhage	32(1.4%)	18(0.8%)
Retinal haemorrhage	15(0.6%)	14(0.6%)
Macular oedema	15(0.6%)	13(0.6%)
Dry eye	15(0.6%)	12(0.5%)
Glaucoma	12(0.5%)	12(0.5%)
Vision blurred	12(0.5%)	9(0.4%)
Blepharitis	8(0.3%)	8(0.3%)
Retinal detachment	8(0.3%)	1(0.0%)
Diabetic retinal oedema	7(0.3%)	7(0.3%)
Visual impairment	5(0.2%)	12(0.5%)
Conjunctivitis allergic	5(0.2%)	7(0.3%)
Retinopathy hypertensive	4(0.2%)	6(0.3%)
Macular fibrosis	4(0.2%)	5(0.2%)
Retinopathy	4(0.2%)	4(0.2%)
Visual acuity reduced	4(0.2%)	2(0.1%)
Asthenopia	4(0.2%)	1(0.0%)
Blindness unilateral	4(0.2%)	1(0.0%)
Vitreous floaters	4(0.2%)	1(0.0%)
Eye pain	3(0.1%)	3(0.1%)
Lacrimation increased	3(0.1%)	3(0.1%)
Macular degeneration	3(0.1%)	3(0.1%)
Ocular hypertension	3(0.1%)	3(0.1%)
Conjunctival haemorrhage	3(0.1%)	2(0.1%)
Ulcerative keratitis	3(0.1%)	2(0.1%)
Eye haemorrhage	3(0.1%)	1(0.0%)
Tractional retinal detachment	3(0.1%)	1(0.0%)
Posterior capsule opacification	2(0.1%)	5(0.2%)
Retinopathy proliferative	2(0.1%)	2(0.1%)
Vitreous opacities	2(0.1%)	2(0.1%)
Chalazion	2(0.1%)	1(0.0%)
Diplopia	2(0.1%)	1(0.0%)
Maculopathy	2(0.1%)	1(0.0%)
Optic atrophy	2(0.1%)	1(0.0%)
Retinal tear	2(0.1%)	1(0.0%)
Astigmatism	2(0.1%)	0
Blindness	2(0.1%)	0
Conjunctival hyperaemia	2(0.1%)	0
Diabetic eye disease	2(0.1%)	0
Entropion	2(0.1%)	0
Ocular hyperaemia	2(0.1%)	0
Pterygium	2(0.1%)	0
Sudden visual loss	2(0.1%)	0
Eye pruritus	1(0.0%)	5(0.2%)
Age-related macular degeneration	1(0.0%)	3(0.1%)
Keratitis	1(0.0%)	3(0.1%)
Eyelid oedema	1(0.0%)	2(0.1%)
Retinal degeneration	1(0.0%)	2(0.1%)
Vitreous detachment	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Cataract diabetic	1(0.0%)	1(0.0%)
Choroidal neovascularisation	1(0.0%)	1(0.0%)
Dermatochalasis	1(0.0%)	1(0.0%)
Eczema eyelids	1(0.0%)	1(0.0%)
Eye allergy	1(0.0%)	1(0.0%)
Eye inflammation	1(0.0%)	1(0.0%)
Eye irritation	1(0.0%)	1(0.0%)
Macular cyst	1(0.0%)	1(0.0%)
Myopia	1(0.0%)	1(0.0%)
Ocular discomfort	1(0.0%)	1(0.0%)
Punctate keratitis	1(0.0%)	1(0.0%)
Refraction disorder	1(0.0%)	1(0.0%)
Retinal aneurysm	1(0.0%)	1(0.0%)
Retinal oedema	1(0.0%)	1(0.0%)
Retinal vascular disorder	1(0.0%)	1(0.0%)
Retinal vein thrombosis	1(0.0%)	1(0.0%)
Swelling of eyelid	1(0.0%)	1(0.0%)
Vitreoretinal traction syndrome	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Blepharochalasis	1(0.0%)	0
Corneal oedema	1(0.0%)	0
Deformity of orbit	1(0.0%)	0
Exposure keratitis	1(0.0%)	0
Extraocular muscle paresis	1(0.0%)	0
Eye discharge	1(0.0%)	0
Eye disorder	1(0.0%)	0
Eye ulcer	1(0.0%)	0
Hypermetropia	1(0.0%)	0
Iritis	1(0.0%)	0
Lens dislocation	1(0.0%)	0
Noninfective retinitis	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0
Ocular myasthenia	1(0.0%)	0
Orbit atrophy	1(0.0%)	0
Papilloedema	1(0.0%)	0
Pathologic myopia	1(0.0%)	0
Photophobia	1(0.0%)	0
Photopsia	1(0.0%)	0
Retinal artery spasm	1(0.0%)	0
Retinal neovascularisation	1(0.0%)	0
Rhegmatogenous retinal detachment	1(0.0%)	0
Uveitis	0	4(0.2%)
Cataract cortical	0	3(0.1%)
Corneal erosion	0	3(0.1%)
Dacryostenosis acquired	0	3(0.1%)
Eyelid ptosis	0	3(0.1%)
Retinal vein occlusion	0	3(0.1%)
Xerophthalmia	0	3(0.1%)
Arteriosclerotic retinopathy	0	2(0.1%)
Cataract nuclear	0	2(0.1%)
Eye swelling	0	2(0.1%)
Eyelid cyst	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Non-proliferative retinopathy	0	2(0.1%)
Blepharitis allergic	0	1(0.0%)
Cataract subcapsular	0	1(0.0%)
Cholesterolosis bulbi	0	1(0.0%)
Corneal infiltrates	0	1(0.0%)
Corneal leukoma	0	1(0.0%)
Cystoid macular oedema	0	1(0.0%)
Dry age-related macular degeneration	0	1(0.0%)
Ectropion	0	1(0.0%)
Episcleritis	0	1(0.0%)
Foreign body sensation in eyes	0	1(0.0%)
Hyalosis asteroid	0	1(0.0%)
Keratoconus	0	1(0.0%)
Lacrimal disorder	0	1(0.0%)
Lacrimal passage granuloma	0	1(0.0%)
Lenticular opacities	0	1(0.0%)
Open angle glaucoma	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Optic ischaemic neuropathy	0	1(0.0%)
Periorbital oedema	0	1(0.0%)
Periorbital swelling	0	1(0.0%)
Presbyopia	0	1(0.0%)
Retinal pigmentation	0	1(0.0%)
Scleritis	0	1(0.0%)
Vitreous prolapse	0	1(0.0%)
Cardiac Disorders	258(11.1%)	301(13.1%)
Cardiac failure	22(0.9%)	39(1.7%)
Angina pectoris	21(0.9%)	29(1.3%)
Myocardial ischaemia	20(0.9%)	25(1.1%)
Atrial fibrillation	20(0.9%)	14(0.6%)
Palpitations	20(0.9%)	14(0.6%)
Coronary artery disease	18(0.8%)	26(1.1%)
Cardiac failure chronic	17(0.7%)	17(0.7%)
Ventricular extrasystoles	14(0.6%)	12(0.5%)
Left ventricular hypertrophy	13(0.6%)	11(0.5%)
Mitral valve incompetence	12(0.5%)	17(0.7%)
Bundle branch block right	12(0.5%)	9(0.4%)
Bundle branch block left	10(0.4%)	14(0.6%)
Arteriosclerosis coronary artery	10(0.4%)	7(0.3%)
Sinus bradycardia	10(0.4%)	6(0.3%)
Atrioventricular block first degree	9(0.4%)	10(0.4%)
Cardiac failure congestive	8(0.3%)	14(0.6%)
Bradycardia	7(0.3%)	16(0.7%)
Tricuspid valve incompetence	7(0.3%)	10(0.4%)
Aortic valve incompetence	7(0.3%)	3(0.1%)
Tachycardia	6(0.3%)	11(0.5%)
Supraventricular extrasystoles	6(0.3%)	5(0.2%)
Atrioventricular block second degree	6(0.3%)	2(0.1%)
Coronary artery stenosis	5(0.2%)	8(0.3%)
Aortic valve stenosis	4(0.2%)	14(0.6%)
Sinus tachycardia	4(0.2%)	9(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Angina unstable	4(0.2%)	6(0.3%)
Ventricular tachycardia	4(0.2%)	4(0.2%)
Atrial flutter	4(0.2%)	2(0.1%)
Ischaemic cardiomyopathy	4(0.2%)	2(0.1%)
Left atrial enlargement	4(0.2%)	2(0.1%)
Left ventricular dysfunction	4(0.2%)	1(0.0%)
Arrhythmia	3(0.1%)	9(0.4%)
Supraventricular tachycardia	3(0.1%)	6(0.3%)
Sinus arrhythmia	3(0.1%)	4(0.2%)
Cardiomegaly	3(0.1%)	3(0.1%)
Diastolic dysfunction	3(0.1%)	3(0.1%)
Left ventricular failure	3(0.1%)	3(0.1%)
Pericardial effusion	3(0.1%)	3(0.1%)
Acute coronary syndrome	2(0.1%)	2(0.1%)
Extrasystoles	2(0.1%)	2(0.1%)
Hypertensive heart disease	2(0.1%)	2(0.1%)
Aortic valve disease mixed	2(0.1%)	1(0.0%)
Cardiac failure acute	2(0.1%)	1(0.0%)
Cardiomyopathy	2(0.1%)	1(0.0%)
Pulmonary valve incompetence	2(0.1%)	1(0.0%)
Ventricular hypokinesia	2(0.1%)	1(0.0%)
Defect conduction intraventricular	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Aortic valve sclerosis	1(0.0%)	4(0.2%)
Left atrial dilatation	1(0.0%)	4(0.2%)
Aortic valve calcification	1(0.0%)	3(0.1%)
Atrioventricular block	1(0.0%)	2(0.1%)
Conduction disorder	1(0.0%)	2(0.1%)
Mitral valve sclerosis	1(0.0%)	2(0.1%)
Cardiac valve disease	1(0.0%)	1(0.0%)
Congestive cardiomyopathy	1(0.0%)	1(0.0%)
Left ventricular dilatation	1(0.0%)	1(0.0%)
Myocardial fibrosis	1(0.0%)	1(0.0%)
Atrial thrombosis	1(0.0%)	0
Cardiac disorder	1(0.0%)	0
Cardiac hypertrophy	1(0.0%)	0
Cardiovascular insufficiency	1(0.0%)	0
Chronic left ventricular failure	1(0.0%)	0
Degenerative multivalvular disease	1(0.0%)	0
Dilatation atrial	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0
Rheumatic heart disease	1(0.0%)	0
Sigmoid-shaped ventricular septum	1(0.0%)	0
Sinus node dysfunction	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular hypertrophy	1(0.0%)	0
Atrioventricular block complete	0	3(0.1%)
Acute myocardial infarction	0	2(0.1%)
Cardiogenic shock	0	2(0.1%)
Cor pulmonale chronic	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Ventricular arrhythmia	0	2(0.1%)
Aortic valve disease	0	1(0.0%)
Bifascicular block	0	1(0.0%)
Bradyarrhythmia	0	1(0.0%)
Cardiac aneurysm	0	1(0.0%)
Cardiac arrest	0	1(0.0%)
Cardiac asthma	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cardiovascular disorder	0	1(0.0%)
Coronary artery insufficiency	0	1(0.0%)
Heart valve incompetence	0	1(0.0%)
Long QT syndrome	0	1(0.0%)
Mitral valve calcification	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Prinzmetal angina	0	1(0.0%)
Right atrial enlargement	0	1(0.0%)
Right ventricular dilatation	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Systolic dysfunction	0	1(0.0%)
Ventricular dysfunction	0	1(0.0%)
Renal And Urinary Disorders	241(10.4%)	307(13.3%)
Acute kidney injury	33(1.4%)	33(1.4%)
Renal impairment	32(1.4%)	29(1.3%)
Nephrolithiasis	31(1.3%)	34(1.5%)
Renal cyst	26(1.1%)	32(1.4%)
Haematuria	19(0.8%)	33(1.4%)
Diabetic nephropathy	11(0.5%)	29(1.3%)
Dysuria	11(0.5%)	23(1.0%)
Urinary incontinence	11(0.5%)	11(0.5%)
Pollakiuria	7(0.3%)	15(0.7%)
Urinary retention	7(0.3%)	15(0.7%)
Nocturia	7(0.3%)	14(0.6%)
Ureterolithiasis	7(0.3%)	3(0.1%)
Chronic kidney disease	6(0.3%)	17(0.7%)
Hydronephrosis	6(0.3%)	8(0.3%)
Polyuria	6(0.3%)	4(0.2%)
Renal colic	5(0.2%)	10(0.4%)
Proteinuria	5(0.2%)	8(0.3%)
Renal failure	4(0.2%)	8(0.3%)
Nephropathy	4(0.2%)	5(0.2%)
Urethral stenosis	4(0.2%)	3(0.1%)
Albuminuria	3(0.1%)	6(0.3%)
Calculus urinary	3(0.1%)	4(0.2%)
Neurogenic bladder	3(0.1%)	2(0.1%)
Nephrotic syndrome	2(0.1%)	8(0.3%)
Calculus bladder	2(0.1%)	4(0.2%)
Micturition urgency	2(0.1%)	4(0.2%)
Bladder spasm	2(0.1%)	2(0.1%)
Lower urinary tract symptoms	2(0.1%)	2(0.1%)
Renal atrophy	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Urinary hesitation	2(0.1%)	1(0.0%)
Subacute kidney injury	2(0.1%)	0
Hypertonic bladder	1(0.0%)	9(0.4%)
Nephrosclerosis	1(0.0%)	3(0.1%)
Bladder diverticulum	1(0.0%)	2(0.1%)
Renal disorder	1(0.0%)	2(0.1%)
Acquired cystic kidney disease	1(0.0%)	1(0.0%)
Haemorrhage urinary tract	1(0.0%)	1(0.0%)
Hydroureter	1(0.0%)	1(0.0%)
Oliguria	1(0.0%)	1(0.0%)
Renal artery stenosis	1(0.0%)	1(0.0%)
Strangury	1(0.0%)	1(0.0%)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Urinary tract disorder	1(0.0%)	1(0.0%)
Urinary tract obstruction	1(0.0%)	1(0.0%)
Urine odour abnormal	1(0.0%)	1(0.0%)
Bladder dysfunction	1(0.0%)	0
Bladder hyperaemia	1(0.0%)	0
Bladder irritation	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Bladder pain	1(0.0%)	0
Focal segmental glomerulosclerosis	1(0.0%)	0
Hypocitraturia	1(0.0%)	0
Hyponatriuria	1(0.0%)	0
Incontinence	1(0.0%)	0
Microalbuminuria	1(0.0%)	0
Nephrocalcinosis	1(0.0%)	0
Nephroptosis	1(0.0%)	0
Perinephritis	1(0.0%)	0
Renal cyst haemorrhage	1(0.0%)	0
Renal tubular necrosis	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0
Renal mass	0	4(0.2%)
Azotaemia	0	2(0.1%)
Bladder hypertrophy	0	2(0.1%)
Glomerulonephritis membranous	0	2(0.1%)
Renal pain	0	2(0.1%)
Stress urinary incontinence	0	2(0.1%)
Tubulointerstitial nephritis	0	2(0.1%)
Anuria	0	1(0.0%)
Chromaturia	0	1(0.0%)
End stage renal disease	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Hypertensive nephropathy	0	1(0.0%)
Hyperuricosuria	0	1(0.0%)
Intercapillary glomerulosclerosis	0	1(0.0%)
Kidney enlargement	0	1(0.0%)
Micturition disorder	0	1(0.0%)
Nephritic syndrome	0	1(0.0%)
Nephritis	0	1(0.0%)
Nephroangiosclerosis	0	1(0.0%)
Post micturition dribble	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Prerenal failure	0	1(0.0%)
Renal hypertrophy	0	1(0.0%)
Urethral meatus stenosis	0	1(0.0%)
Urine abnormality	0	1(0.0%)
Blood And Lymphatic System Disorders	189(8.1%)	182(7.9%)
Anaemia	126(5.4%)	109(4.7%)
Iron deficiency anaemia	20(0.9%)	18(0.8%)
Thrombocytopenia	14(0.6%)	10(0.4%)
Leukocytosis	6(0.3%)	8(0.3%)
Polycythaemia	6(0.3%)	2(0.1%)
Leukopenia	5(0.2%)	3(0.1%)
Splenomegaly	4(0.2%)	7(0.3%)
Blood loss anaemia	4(0.2%)	5(0.2%)
Lymphadenopathy	3(0.1%)	10(0.4%)
Nephrogenic anaemia	3(0.1%)	3(0.1%)
Normocytic anaemia	3(0.1%)	3(0.1%)
Microcytic anaemia	2(0.1%)	3(0.1%)
Normochromic normocytic anaemia	1(0.0%)	3(0.1%)
Lymphadenopathy mediastinal	1(0.0%)	1(0.0%)
Macrocytosis	1(0.0%)	1(0.0%)
Anaemia vitamin B12 deficiency	1(0.0%)	0
Bone marrow failure	1(0.0%)	0
Coagulopathy	1(0.0%)	0
Hypochromic anaemia	1(0.0%)	0
Lymph node calcification	1(0.0%)	0
Lymphocytosis	1(0.0%)	0
Neutrophilia	1(0.0%)	0
Pseudolymphoma	1(0.0%)	0
Abdominal lymphadenopathy	0	3(0.1%)
Lymphadenitis	0	2(0.1%)
Thrombocytosis	0	2(0.1%)
Antiphospholipid syndrome	0	1(0.0%)
Eosinophilia	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)
Haemorrhagic diathesis	0	1(0.0%)
Hypercoagulation	0	1(0.0%)
Neutropenia	0	1(0.0%)
Pancytopenia	0	1(0.0%)
Splenic calcification	0	1(0.0%)
Splenic lesion	0	1(0.0%)
Splenic vein thrombosis	0	1(0.0%)
White blood cell disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	155(6.7%)	171(7.4%)
Prostate cancer	11(0.5%)	17(0.7%)
Colon cancer	9(0.4%)	5(0.2%)
Basal cell carcinoma	7(0.3%)	10(0.4%)
Skin papilloma	6(0.3%)	10(0.4%)
Lipoma	6(0.3%)	6(0.3%)
Bladder cancer	6(0.3%)	1(0.0%)
Renal neoplasm	5(0.2%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Uterine leiomyoma	5(0.2%)	1(0.0%)
Seborrhoeic keratosis	3(0.1%)	7(0.3%)
Adrenal adenoma	3(0.1%)	5(0.2%)
Lung neoplasm malignant	3(0.1%)	4(0.2%)
Hepatic cancer	3(0.1%)	2(0.1%)
Hepatocellular carcinoma	3(0.1%)	2(0.1%)
Neoplasm	3(0.1%)	1(0.0%)
Transitional cell carcinoma	3(0.1%)	1(0.0%)
Colon adenoma	2(0.1%)	5(0.2%)
Pancreatic carcinoma	2(0.1%)	5(0.2%)
Adrenal neoplasm	2(0.1%)	2(0.1%)
Gastric cancer	2(0.1%)	2(0.1%)
Meningioma	2(0.1%)	2(0.1%)
Acrochordon	2(0.1%)	1(0.0%)
Large intestine benign neoplasm	2(0.1%)	1(0.0%)
Lung adenocarcinoma	2(0.1%)	1(0.0%)
Neoplasm skin	2(0.1%)	1(0.0%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)
Plasma cell myeloma	2(0.1%)	1(0.0%)
Prostate cancer recurrent	2(0.1%)	1(0.0%)
Prostatic adenoma	2(0.1%)	1(0.0%)
Squamous cell carcinoma	2(0.1%)	1(0.0%)
Squamous cell carcinoma of skin	2(0.1%)	1(0.0%)
Benign breast neoplasm	2(0.1%)	0
Bladder cancer recurrent	2(0.1%)	0
Chronic lymphocytic leukaemia	2(0.1%)	0
Endometrial cancer	2(0.1%)	0
Melanocytic naevus	1(0.0%)	5(0.2%)
Renal cancer	1(0.0%)	4(0.2%)
Breast cancer	1(0.0%)	3(0.1%)
Hypergammaglobulinaemia benign monoclonal	1(0.0%)	3(0.1%)
Adenoma benign	1(0.0%)	2(0.1%)
B-cell lymphoma	1(0.0%)	2(0.1%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Haemangioma of liver	1(0.0%)	2(0.1%)
Lung neoplasm	1(0.0%)	2(0.1%)
Oesophageal carcinoma	1(0.0%)	2(0.1%)
Papillary thyroid cancer	1(0.0%)	2(0.1%)
Squamous cell carcinoma of lung	1(0.0%)	2(0.1%)
Adenocarcinoma	1(0.0%)	1(0.0%)
Benign hepatic neoplasm	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Gastrointestinal carcinoma	1(0.0%)	1(0.0%)
Metastases to lung	1(0.0%)	1(0.0%)
Metastases to lymph nodes	1(0.0%)	1(0.0%)
Metastatic malignant melanoma	1(0.0%)	1(0.0%)
Monoclonal gammopathy	1(0.0%)	1(0.0%)
Papillary renal cell carcinoma	1(0.0%)	1(0.0%)
Pituitary tumour benign	1(0.0%)	1(0.0%)
Rectal adenoma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Anogenital warts	1(0.0%)	0
Benign bone neoplasm	1(0.0%)	0
Benign mediastinal neoplasm	1(0.0%)	0
Benign neoplasm	1(0.0%)	0
Benign neoplasm of skin	1(0.0%)	0
Benign ovarian tumour	1(0.0%)	0
Benign renal neoplasm	1(0.0%)	0
Bowen's disease	1(0.0%)	0
Cerebral haemangioma	1(0.0%)	0
Choroid neoplasm	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Fibroadenoma of breast	1(0.0%)	0
Fibroma	1(0.0%)	0
Gastric adenoma	1(0.0%)	0
Gastrointestinal submucosal tumour	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0
Intraductal papillary mucinous neoplasm	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Langerhans' cell histiocytosis	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Lymphoma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Neoplasm malignant	1(0.0%)	0
Nervous system neoplasm benign	1(0.0%)	0
Neuroendocrine tumour	1(0.0%)	0
Ocular neoplasm	1(0.0%)	0
Oral neoplasm	1(0.0%)	0
Pancreatic neuroendocrine tumour	1(0.0%)	0
Pharyngeal neoplasm	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Retroperitoneal neoplasm	1(0.0%)	0
Schwannoma	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour ulceration	1(0.0%)	0
Eye naevus	0	3(0.1%)
Adenocarcinoma of colon	0	2(0.1%)
Enchondromatosis	0	2(0.1%)
Malignant melanoma	0	2(0.1%)
Papillary cystadenoma lymphomatosum	0	2(0.1%)
Skin cancer	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Anal cancer	0	1(0.0%)
Benign lung neoplasm	0	1(0.0%)
Benign neoplasm of eyelid	0	1(0.0%)
Benign neoplasm of thyroid gland	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Cholangiocarcinoma	0	1(0.0%)
Cholesteatoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Endometrial adenocarcinoma	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Haemangioma	0	1(0.0%)
Haemangioma of bone	0	1(0.0%)
Intraductal papilloma of breast	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Laryngeal squamous cell carcinoma	0	1(0.0%)
Lip squamous cell carcinoma	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Mesenteric neoplasm	0	1(0.0%)
Metastases to bone	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oral papilloma	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Pancreatic neoplasm	0	1(0.0%)
Papilloma	0	1(0.0%)
Paraproteinaemia	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Pyogenic granuloma	0	1(0.0%)
Rectal adenocarcinoma	0	1(0.0%)
Renal hamartoma	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Seminoma	0	1(0.0%)
Testis cancer	0	1(0.0%)
Thyroid neoplasm	0	1(0.0%)
Tonsil cancer	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Reproductive System And Breast Disorders	150(6.4%)	142(6.2%)
Benign prostatic hyperplasia	66(2.8%)	65(2.8%)
Erectile dysfunction	22(0.9%)	20(0.9%)
Prostatitis	7(0.3%)	7(0.3%)
Balanoposthitis	5(0.2%)	6(0.3%)
Prostatomegaly	5(0.2%)	6(0.3%)
Pruritus genital	4(0.2%)	1(0.0%)
Breast pain	3(0.1%)	2(0.1%)
Sexual dysfunction	3(0.1%)	2(0.1%)
Vulvovaginal pruritus	3(0.1%)	1(0.0%)
Ovarian cyst	2(0.1%)	4(0.2%)
Prostatic calcification	2(0.1%)	4(0.2%)
Pelvic pain	2(0.1%)	1(0.0%)
Atrophic vulvovaginitis	2(0.1%)	0
Prostatism	1(0.0%)	2(0.1%)
Testicular pain	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Uterine polyp	1(0.0%)	2(0.1%)
Vaginal haemorrhage	1(0.0%)	2(0.1%)
Breast disorder	1(0.0%)	1(0.0%)
Breast mass	1(0.0%)	1(0.0%)
Cervical polyp	1(0.0%)	1(0.0%)
Menopausal symptoms	1(0.0%)	1(0.0%)
Metrorrhagia	1(0.0%)	1(0.0%)
Penile pain	1(0.0%)	1(0.0%)
Perineal pain	1(0.0%)	1(0.0%)
Prostatic disorder	1(0.0%)	1(0.0%)
Prostatic mass	1(0.0%)	1(0.0%)
Vaginal disorder	1(0.0%)	1(0.0%)
Breast calcifications	1(0.0%)	0
Breast dysplasia	1(0.0%)	0
Breast tenderness	1(0.0%)	0
Dysmenorrhoea	1(0.0%)	0
Endometriosis	1(0.0%)	0
Fallopian tube cyst	1(0.0%)	0
Genital lesion	1(0.0%)	0
Menstruation irregular	1(0.0%)	0
Ovarian mass	1(0.0%)	0
Pelvic adhesions	1(0.0%)	0
Penile erythema	1(0.0%)	0
Peyronie's disease	1(0.0%)	0
Scrotal disorder	1(0.0%)	0
Uterine haemorrhage	1(0.0%)	0
Vulvovaginal dryness	1(0.0%)	0
Gynaecomastia	0	3(0.1%)
Varicocele	0	3(0.1%)
Breast hyperplasia	0	2(0.1%)
Menorrhagia	0	2(0.1%)
Calculus prostatic	0	1(0.0%)
Cervical dysplasia	0	1(0.0%)
Ejaculation disorder	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Galactorrhoea	0	1(0.0%)
Genital atrophy	0	1(0.0%)
Genital discomfort	0	1(0.0%)
Haematospermia	0	1(0.0%)
Nipple pain	0	1(0.0%)
Ovarian failure	0	1(0.0%)
Prostatic cyst	0	1(0.0%)
Scrotal pain	0	1(0.0%)
Scrotal swelling	0	1(0.0%)
Testicular swelling	0	1(0.0%)
Uterine inflammation	0	1(0.0%)
Vulval eczema	0	1(0.0%)
Vulvovaginal pain	0	1(0.0%)
Surgical And Medical Procedures	145(6.2%)	113(4.9%)
Cataract operation	21(0.9%)	22(1.0%)
Tooth extraction	14(0.6%)	8(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Knee arthroplasty	5(0.2%)	5(0.2%)
Dental implantation	5(0.2%)	2(0.1%)
Leg amputation	4(0.2%)	4(0.2%)
Intraocular lens implant	4(0.2%)	2(0.1%)
Skin lesion removal	4(0.2%)	2(0.1%)
Toe amputation	3(0.1%)	5(0.2%)
Vitrectomy	3(0.1%)	3(0.1%)
Hip arthroplasty	3(0.1%)	2(0.1%)
Gastric bypass	3(0.1%)	1(0.0%)
Roux loop conversion	3(0.1%)	0
Tendon sheath incision	3(0.1%)	0
Cholecystectomy	2(0.1%)	5(0.2%)
Polypectomy	2(0.1%)	4(0.2%)
Carpal tunnel decompression	2(0.1%)	3(0.1%)
Skin neoplasm excision	2(0.1%)	2(0.1%)
Foot amputation	2(0.1%)	1(0.0%)
Hysterectomy	2(0.1%)	1(0.0%)
Intervertebral disc operation	2(0.1%)	1(0.0%)
Retinal laser coagulation	2(0.1%)	1(0.0%)
Cardioversion	2(0.1%)	0
Circumcision	2(0.1%)	0
Diabetes mellitus management	2(0.1%)	0
Eye operation	2(0.1%)	0
Removal of internal fixation	2(0.1%)	0
Shoulder operation	2(0.1%)	0
Large intestinal polypectomy	1(0.0%)	5(0.2%)
Eye laser surgery	1(0.0%)	4(0.2%)
Lens extraction	1(0.0%)	4(0.2%)
Abscess drainage	1(0.0%)	3(0.1%)
Dupuytren's contracture operation	1(0.0%)	2(0.1%)
Coronary arterial stent insertion	1(0.0%)	1(0.0%)
Drug delivery device placement	1(0.0%)	1(0.0%)
Percutaneous coronary intervention	1(0.0%)	1(0.0%)
Umbilical hernia repair	1(0.0%)	1(0.0%)
Uterine polypectomy	1(0.0%)	1(0.0%)
Abdominal hernia repair	1(0.0%)	0
Ankle operation	1(0.0%)	0
Atrial appendage closure	1(0.0%)	0
Benign tumour excision	1(0.0%)	0
Blepharoplasty	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Cardiac ablation	1(0.0%)	0
Central venous catheterisation	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Colectomy	1(0.0%)	0
Coronary revascularisation	1(0.0%)	0
Dental care	1(0.0%)	0
Drug therapy	1(0.0%)	0
Endodontic procedure	1(0.0%)	0
Eyelid operation	1(0.0%)	0
Fasciotomy	1(0.0%)	0
Finger amputation	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Gastric polypectomy	1(0.0%)	0
Glaucoma surgery	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Joint injection	1(0.0%)	0
Large intestine operation	1(0.0%)	0
Laser therapy	1(0.0%)	0
Lithotripsy	1(0.0%)	0
Meniscus operation	1(0.0%)	0
Metabolic surgery	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Nail operation	1(0.0%)	0
Neurolysis	1(0.0%)	0
Ocular stem cell transplant	1(0.0%)	0
Ostectomy	1(0.0%)	0
Peripheral artery bypass	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0
Platelet rich plasma therapy	1(0.0%)	0
Proctocolectomy	1(0.0%)	0
Ptosis repair	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Scar excision	1(0.0%)	0
Sequestrectomy	1(0.0%)	0
Small intestinal polypectomy	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Spinal operation	1(0.0%)	0
Tooth repair	1(0.0%)	0
Transurethral bladder resection	1(0.0%)	0
Tumour excision	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Vasectomy	1(0.0%)	0
Limb operation	0	3(0.1%)
Lipoma excision	0	3(0.1%)
Intra-ocular injection	0	2(0.1%)
Stent placement	0	2(0.1%)
Amputation	0	1(0.0%)
Aortic surgery	0	1(0.0%)
Aortic valve replacement	0	1(0.0%)
Bone operation	0	1(0.0%)
Bunion operation	0	1(0.0%)
Cardiac pacemaker insertion	0	1(0.0%)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Coronary angioplasty	0	1(0.0%)
Coronary artery bypass	0	1(0.0%)
Cyst removal	0	1(0.0%)
Dental operation	0	1(0.0%)
Gastrectomy	0	1(0.0%)
Haemodialysis	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Hydrocele operation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Implantable defibrillator insertion	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Intensive care	0	1(0.0%)
Intestinal polypectomy	0	1(0.0%)
Iridotomy	0	1(0.0%)
Keratomileusis	0	1(0.0%)
Knee operation	0	1(0.0%)
Ligament operation	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Mitral valve repair	0	1(0.0%)
Nasal operation	0	1(0.0%)
Parathyroidectomy	0	1(0.0%)
Peripheral nerve operation	0	1(0.0%)
Retinal operation	0	1(0.0%)
Retinopexy	0	1(0.0%)
Sinus operation	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Thyroidectomy	0	1(0.0%)
Toe operation	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Varicose vein operation	0	1(0.0%)
Hepatobiliary Disorders	143(6.1%)	130(5.6%)
Hepatic steatosis	55(2.4%)	46(2.0%)
Cholelithiasis	30(1.3%)	28(1.2%)
Hepatic function abnormal	16(0.7%)	10(0.4%)
Gallbladder polyp	12(0.5%)	6(0.3%)
Hepatic cirrhosis	7(0.3%)	8(0.3%)
Cholecystitis	6(0.3%)	4(0.2%)
Hepatomegaly	6(0.3%)	4(0.2%)
Bile duct stone	4(0.2%)	4(0.2%)
Biliary colic	3(0.1%)	3(0.1%)
Cholecystitis chronic	2(0.1%)	7(0.3%)
Cholecystitis acute	2(0.1%)	4(0.2%)
Cholestasis	2(0.1%)	4(0.2%)
Hepatic cyst	2(0.1%)	3(0.1%)
Cholangitis	2(0.1%)	2(0.1%)
Hepatosplenomegaly	2(0.1%)	2(0.1%)
Nonalcoholic fatty liver disease	2(0.1%)	2(0.1%)
Hepatic calcification	2(0.1%)	1(0.0%)
Liver disorder	2(0.1%)	1(0.0%)
Biliary dyskinesia	2(0.1%)	0
Hepatic mass	1(0.0%)	3(0.1%)
Hepatocellular injury	1(0.0%)	3(0.1%)
Jaundice cholestatic	1(0.0%)	2(0.1%)
Biliary tract disorder	1(0.0%)	1(0.0%)
Hepatic failure	1(0.0%)	1(0.0%)
Hepatic lesion	1(0.0%)	1(0.0%)
Non-alcoholic steatohepatitis	1(0.0%)	1(0.0%)
Steatohepatitis	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Biliary dilatation	1(0.0%)	0
Cholangiectasis acquired	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Drug-induced liver injury	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatitis acute	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Hepatotoxicity	1(0.0%)	0
Hyperplastic cholecystopathy	1(0.0%)	0
Hypertransaminasaemia	1(0.0%)	0
Ocular icterus	1(0.0%)	0
Cholangitis acute	0	2(0.1%)
Alcoholic liver disease	0	1(0.0%)
Biliary fistula	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Gallbladder cholesterolosis	0	1(0.0%)
Hepatitis toxic	0	1(0.0%)
Hepatobiliary disease	0	1(0.0%)
Hydrocholecystis	0	1(0.0%)
Jaundice	0	1(0.0%)
Liver injury	0	1(0.0%)
Porcelain gallbladder	0	1(0.0%)
Portal hypertension	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Psychiatric Disorders	134(5.8%)	131(5.7%)
Insomnia	49(2.1%)	42(1.8%)
Depression	36(1.5%)	41(1.8%)
Anxiety	18(0.8%)	23(1.0%)
Sleep disorder	11(0.5%)	7(0.3%)
Depressed mood	4(0.2%)	5(0.2%)
Confusional state	4(0.2%)	2(0.1%)
Mixed anxiety and depressive disorder	3(0.1%)	0
Stress	3(0.1%)	0
Nervousness	2(0.1%)	3(0.1%)
Major depression	2(0.1%)	1(0.0%)
Nicotine dependence	2(0.1%)	1(0.0%)
Mental status changes	2(0.1%)	0
Anxiety disorder	1(0.0%)	2(0.1%)
Libido decreased	1(0.0%)	2(0.1%)
Abulia	1(0.0%)	1(0.0%)
Drug use disorder	1(0.0%)	1(0.0%)
Nightmare	1(0.0%)	1(0.0%)
Affective disorder	1(0.0%)	0
Aggression	1(0.0%)	0
Attention deficit hyperactivity disorder	1(0.0%)	0
Autism spectrum disorder	1(0.0%)	0
Bipolar disorder	1(0.0%)	0
Irritability	1(0.0%)	0
Panic attack	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Schizophreniform disorder	1(0.0%)	0
Tension	1(0.0%)	0
Adjustment disorder with depressed mood	0	3(0.1%)
Restlessness	0	3(0.1%)
Abnormal dreams	0	1(0.0%)
Adjustment disorder	0	1(0.0%)
Alcohol abuse	0	1(0.0%)
Apathy	0	1(0.0%)
Behaviour disorder	0	1(0.0%)
Delirium	0	1(0.0%)
Disorientation	0	1(0.0%)
Drug abuse	0	1(0.0%)
Grief reaction	0	1(0.0%)
Hallucination	0	1(0.0%)
Impulse-control disorder	0	1(0.0%)
Mental disorder due to a general medical condition	0	1(0.0%)
Panic disorder	0	1(0.0%)
Polydipsia psychogenic	0	1(0.0%)
Psychotic disorder	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Tearfulness	0	1(0.0%)
Ear And Labyrinth Disorders	106(4.6%)	94(4.1%)
Vertigo	41(1.8%)	40(1.7%)
Tinnitus	12(0.5%)	11(0.5%)
Ear pain	9(0.4%)	7(0.3%)
Vertigo positional	9(0.4%)	5(0.2%)
Hypoacusis	7(0.3%)	3(0.1%)
Deafness	5(0.2%)	6(0.3%)
Sudden hearing loss	5(0.2%)	5(0.2%)
Deafness neurosensory	3(0.1%)	5(0.2%)
Ear discomfort	3(0.1%)	0
Cerumen impaction	2(0.1%)	6(0.3%)
Ear pruritus	2(0.1%)	2(0.1%)
Meniere's disease	2(0.1%)	0
Excessive cerumen production	1(0.0%)	3(0.1%)
Auditory disorder	1(0.0%)	1(0.0%)
Deafness unilateral	1(0.0%)	1(0.0%)
Presbyacusis	1(0.0%)	1(0.0%)
Auricular pseudocyst	1(0.0%)	0
Middle ear inflammation	1(0.0%)	0
Motion sickness	1(0.0%)	0
Otolithiasis	1(0.0%)	0
Tympanic membrane perforation	1(0.0%)	0
Deafness bilateral	0	4(0.2%)
Vestibular disorder	0	3(0.1%)
Ear disorder	0	1(0.0%)
Ear swelling	0	1(0.0%)
External ear inflammation	0	1(0.0%)
Endocrine Disorders	46(2.0%)	45(2.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Hypothyroidism	19(0.8%)	12(0.5%)
Thyroid mass	9(0.4%)	8(0.3%)
Goitre	6(0.3%)	5(0.2%)
Hyperthyroidism	3(0.1%)	4(0.2%)
Hyperparathyroidism secondary	3(0.1%)	3(0.1%)
Adrenal mass	2(0.1%)	1(0.0%)
Autoimmune thyroiditis	2(0.1%)	1(0.0%)
Thyroid cyst	1(0.0%)	1(0.0%)
Autoimmune thyroid disorder	1(0.0%)	0
Empty sella syndrome	1(0.0%)	0
Hyperparathyroidism	1(0.0%)	0
Hyperprolactinaemia	1(0.0%)	0
Primary adrenal insufficiency	1(0.0%)	0
Primary hypothyroidism	1(0.0%)	0
Adrenal cyst	0	3(0.1%)
Adrenal disorder	0	2(0.1%)
Adrenal insufficiency	0	1(0.0%)
Basedow's disease	0	1(0.0%)
Hyperparathyroidism primary	0	1(0.0%)
Hypogonadism	0	1(0.0%)
Hypoparathyroidism	0	1(0.0%)
Primary hyperaldosteronism	0	1(0.0%)
Immune System Disorders	25(1.1%)	20(0.9%)
Seasonal allergy	8(0.3%)	5(0.2%)
Hypersensitivity	6(0.3%)	7(0.3%)
Drug hypersensitivity	4(0.2%)	3(0.1%)
Anaphylactic reaction	2(0.1%)	2(0.1%)
Allergy to arthropod bite	2(0.1%)	0
Anaphylactic shock	1(0.0%)	2(0.1%)
Allergy to animal	1(0.0%)	0
Amyloidosis	1(0.0%)	0
Sarcoidosis	0	2(0.1%)
Food allergy	0	1(0.0%)
Congenital, Familial And Genetic Disorders	11(0.5%)	17(0.7%)
Phimosis	2(0.1%)	4(0.2%)
Hydrocele	2(0.1%)	2(0.1%)
Adenomatous polyposis coli	1(0.0%)	1(0.0%)
Congenital cystic kidney disease	1(0.0%)	1(0.0%)
Thalassaemia	1(0.0%)	1(0.0%)
Accessory spleen	1(0.0%)	0
Arnold-Chiari malformation	1(0.0%)	0
Arteriovenous malformation	1(0.0%)	0
Hypertrophic cardiomyopathy	1(0.0%)	0
Thalassaemia alpha	1(0.0%)	0
Anomaly of middle ear congenital	0	1(0.0%)
Atrial septal defect	0	1(0.0%)
Cone dystrophy	0	1(0.0%)
Congenital renal cyst	0	1(0.0%)
Ectrodactyly	0	1(0.0%)
Familial tremor	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Haemophilia	0	1(0.0%)
Kidney duplex	0	1(0.0%)
Rathke's cleft cyst	0	1(0.0%)
Product Issues	2(0.1%)	5(0.2%)
Device loosening	1(0.0%)	1(0.0%)
Device expulsion	1(0.0%)	0
Device breakage	0	2(0.1%)
Device dislocation	0	1(0.0%)
Device malfunction	0	1(0.0%)
Social Circumstances	0	1(0.0%)
Menopause	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Any TEAE	666(28.6%)	704(30.6%)
Infections And Infestations	202(8.7%)	236(10.3%)
Pneumonia	40(1.7%)	68(3.0%)
Cellulitis	22(0.9%)	17(0.7%)
Urinary tract infection	19(0.8%)	13(0.6%)
Sepsis	8(0.3%)	9(0.4%)
Localised infection	8(0.3%)	3(0.1%)
Osteomyelitis	7(0.3%)	10(0.4%)
Abscess limb	7(0.3%)	4(0.2%)
COVID-19	6(0.3%)	16(0.7%)
Urosepsis	6(0.3%)	9(0.4%)
Bronchitis	6(0.3%)	7(0.3%)
Gastroenteritis	6(0.3%)	7(0.3%)
Diabetic foot infection	6(0.3%)	4(0.2%)
COVID-19 pneumonia	5(0.2%)	9(0.4%)
Erysipelas	5(0.2%)	9(0.4%)
Appendicitis	5(0.2%)	2(0.1%)
Postoperative wound infection	4(0.2%)	1(0.0%)
Cystitis	3(0.1%)	2(0.1%)
Pyelonephritis acute	3(0.1%)	2(0.1%)
Pyelonephritis	3(0.1%)	1(0.0%)
Septic shock	3(0.1%)	1(0.0%)
Subcutaneous abscess	3(0.1%)	0
Gangrene	2(0.1%)	5(0.2%)
Diverticulitis	2(0.1%)	4(0.2%)
Pneumonia bacterial	2(0.1%)	3(0.1%)
Upper respiratory tract infection	2(0.1%)	3(0.1%)
Osteomyelitis chronic	2(0.1%)	2(0.1%)
Wound infection	2(0.1%)	2(0.1%)
Herpes zoster	2(0.1%)	1(0.0%)
Infected skin ulcer	2(0.1%)	1(0.0%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Respiratory tract infection	2(0.1%)	1(0.0%)
Bacterial infection	2(0.1%)	0
Bronchitis bacterial	2(0.1%)	0
Anal abscess	1(0.0%)	3(0.1%)
Cholecystitis infective	1(0.0%)	2(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	2(0.1%)
Influenza	1(0.0%)	2(0.1%)
Lower respiratory tract infection	1(0.0%)	2(0.1%)
Diabetic gangrene	1(0.0%)	1(0.0%)
Necrotising fasciitis	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Chronic sinusitis	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Dengue fever	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Endocarditis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Escherichia bacteraemia	1(0.0%)	0
Febrile infection	1(0.0%)	0
Gastroenteritis rotavirus	1(0.0%)	0
Gastroenteritis viral	1(0.0%)	0
HIV infection	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Mastoiditis	1(0.0%)	0
Meningitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0
Otitis externa	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Peritonitis	1(0.0%)	0
Pharyngitis	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia streptococcal	1(0.0%)	0
Pneumonia viral	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Pyelonephritis chronic	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0
Staphylococcal sepsis	1(0.0%)	0
Infection	0	4(0.2%)
Soft tissue infection	0	3(0.1%)
Abscess	0	2(0.1%)
Skin infection	0	2(0.1%)
Vestibular neuronitis	0	2(0.1%)
Abdominal sepsis	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)
Anorectal cellulitis	0	1(0.0%)
Arthritis bacterial	0	1(0.0%)
Atypical pneumonia	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Device related infection	0	1(0.0%)
Epididymitis	0	1(0.0%)
Furuncle	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Infected bite	0	1(0.0%)
Infective exacerbation of bronchiectasis	0	1(0.0%)
Labyrinthitis	0	1(0.0%)
Large intestine infection	0	1(0.0%)
Paronychia	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Post procedural infection	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Pulmonary sepsis	0	1(0.0%)
Pulmonary tuberculosis	0	1(0.0%)
Pyelitis	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Staphylococcal bacteraemia	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Tracheobronchitis	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Metabolism And Nutrition Disorders	106(4.6%)	92(4.0%)
Type 2 diabetes mellitus	27(1.2%)	21(0.9%)
Diabetes mellitus inadequate control	20(0.9%)	10(0.4%)
Diabetic metabolic decompensation	15(0.6%)	9(0.4%)
Diabetes mellitus	12(0.5%)	19(0.8%)
Hyperglycaemia	9(0.4%)	6(0.3%)
Hyperkalaemia	9(0.4%)	2(0.1%)
Hypoglycaemia	7(0.3%)	12(0.5%)
Hyponatraemia	4(0.2%)	2(0.1%)
Dehydration	3(0.1%)	4(0.2%)
Obesity	3(0.1%)	2(0.1%)
Diabetic ketoacidosis	2(0.1%)	2(0.1%)
Gout	1(0.0%)	1(0.0%)
Electrolyte imbalance	1(0.0%)	0
Hypercalcaemia	1(0.0%)	0
Hypomagnesaemia	1(0.0%)	0
Metabolic syndrome	1(0.0%)	0
Cachexia	0	2(0.1%)
Diabetic complication	0	2(0.1%)
Hypokalaemia	0	2(0.1%)
Metabolic acidosis	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	78(3.4%)	90(3.9%)
Colon cancer	9(0.4%)	5(0.2%)
Prostate cancer	6(0.3%)	15(0.7%)
Bladder cancer	6(0.3%)	0
Lung neoplasm malignant	3(0.1%)	4(0.2%)
Hepatic cancer	3(0.1%)	2(0.1%)
Renal neoplasm	3(0.1%)	1(0.0%)
Pancreatic carcinoma	2(0.1%)	4(0.2%)
Gastric cancer	2(0.1%)	2(0.1%)
Hepatocellular carcinoma	2(0.1%)	1(0.0%)
Lung adenocarcinoma	2(0.1%)	1(0.0%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)
Plasma cell myeloma	2(0.1%)	1(0.0%)
Transitional cell carcinoma	2(0.1%)	1(0.0%)
Bladder cancer recurrent	2(0.1%)	0
Basal cell carcinoma	1(0.0%)	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Oesophageal carcinoma	1(0.0%)	2(0.1%)
Renal cancer	1(0.0%)	2(0.1%)
Squamous cell carcinoma of lung	1(0.0%)	2(0.1%)
Adenocarcinoma	1(0.0%)	1(0.0%)
B-cell lymphoma	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Gastrointestinal carcinoma	1(0.0%)	1(0.0%)
Metastases to lung	1(0.0%)	1(0.0%)
Metastases to lymph nodes	1(0.0%)	1(0.0%)
Papillary renal cell carcinoma	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)
Choroid neoplasm	1(0.0%)	0
Chronic lymphocytic leukaemia	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Colon adenoma	1(0.0%)	0
Endometrial cancer	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Neoplasm	1(0.0%)	0
Prostatic adenoma	1(0.0%)	0
Rectal neoplasm	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Retroperitoneal neoplasm	1(0.0%)	0
Skin papilloma	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma	1(0.0%)	0
Squamous cell carcinoma of skin	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour ulceration	1(0.0%)	0
Uterine leiomyoma	1(0.0%)	0
Breast cancer	0	3(0.1%)
Adenocarcinoma of colon	0	2(0.1%)
Malignant melanoma	0	2(0.1%)
Papillary thyroid cancer	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal neoplasm	0	1(0.0%)
Anal cancer	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Glioblastoma	0	1(0.0%)
Hypergammaglobulinaemia benign monoclonal	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Laryngeal squamous cell carcinoma	0	1(0.0%)
Lung neoplasm	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastases to bone	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Pancreatic neoplasm	0	1(0.0%)
Papillary cystadenoma lymphomatosum	0	1(0.0%)
Papilloma	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Rectal adenocarcinoma	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Seminoma	0	1(0.0%)
Testis cancer	0	1(0.0%)
Tonsil cancer	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Nervous System Disorders	64(2.8%)	46(2.0%)
Diabetic neuropathy	8(0.3%)	4(0.2%)
Dizziness	5(0.2%)	4(0.2%)
Syncope	4(0.2%)	4(0.2%)
Subarachnoid haemorrhage	3(0.1%)	2(0.1%)
Facial paralysis	3(0.1%)	1(0.0%)
Cerebral ischaemia	3(0.1%)	0
Carotid artery stenosis	2(0.1%)	3(0.1%)
Epilepsy	2(0.1%)	0
Myelopathy	2(0.1%)	0
Presyncope	2(0.1%)	0
Cerebrovascular disorder	1(0.0%)	1(0.0%)
Hemiparesis	1(0.0%)	1(0.0%)
Lacunar infarction	1(0.0%)	1(0.0%)
Sensory disturbance	1(0.0%)	1(0.0%)
Transient ischaemic attack	1(0.0%)	1(0.0%)
Altered state of consciousness	1(0.0%)	0
Amputation stump pain	1(0.0%)	0
Balance disorder	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral infarction	1(0.0%)	0
Cervicobrachial syndrome	1(0.0%)	0
Dementia Alzheimer's type	1(0.0%)	0
Dizziness postural	1(0.0%)	0
Dysarthria	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0
IIIrd nerve paralysis	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Memory impairment	1(0.0%)	0
Metabolic encephalopathy	1(0.0%)	0
Mononeuropathy	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Normal pressure hydrocephalus	1(0.0%)	0
Radiculopathy	1(0.0%)	0
Sciatica	1(0.0%)	0
Seizure	1(0.0%)	0
Spinal cord compression	1(0.0%)	0
Tension headache	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
Vascular encephalopathy	1(0.0%)	0
Cervical radiculopathy	0	3(0.1%)
Encephalopathy	0	2(0.1%)
Facial paresis	0	2(0.1%)
Ataxia	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebral haemorrhage	0	1(0.0%)
Cerebrovascular accident	0	1(0.0%)
Coma	0	1(0.0%)
Dementia	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Loss of consciousness	0	1(0.0%)
Lumbar radiculopathy	0	1(0.0%)
Meralgia paraesthetica	0	1(0.0%)
Migraine	0	1(0.0%)
Neuralgia	0	1(0.0%)
Parkinson's disease	0	1(0.0%)
Somnolence	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Vertigo CNS origin	0	1(0.0%)
Injury, Poisoning And Procedural Complications	62(2.7%)	48(2.1%)
Femur fracture	4(0.2%)	4(0.2%)
Ankle fracture	4(0.2%)	3(0.1%)
Rib fracture	4(0.2%)	2(0.1%)
Meniscus injury	4(0.2%)	0
Tendon rupture	3(0.1%)	1(0.0%)
Hip fracture	3(0.1%)	0
Subdural haematoma	2(0.1%)	3(0.1%)
Limb injury	2(0.1%)	2(0.1%)
Multiple fractures	2(0.1%)	1(0.0%)
Tibia fracture	2(0.1%)	1(0.0%)
Injury	2(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Vascular injury	2(0.1%)	0
Radius fracture	1(0.0%)	3(0.1%)
Craniocerebral injury	1(0.0%)	2(0.1%)
Foot fracture	1(0.0%)	2(0.1%)
Lumbar vertebral fracture	1(0.0%)	2(0.1%)
Subdural haemorrhage	1(0.0%)	2(0.1%)
Contusion	1(0.0%)	1(0.0%)
Head injury	1(0.0%)	1(0.0%)
Lower limb fracture	1(0.0%)	1(0.0%)
Thermal burn	1(0.0%)	1(0.0%)
Toxicity to various agents	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0
Animal bite	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Cartilage injury	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Chest injury	1(0.0%)	0
Facial bones fracture	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Injury corneal	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Joint dislocation	1(0.0%)	0
Joint injury	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Poisoning	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Road traffic accident	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Skin abrasion	1(0.0%)	0
Ulna fracture	1(0.0%)	0
Upper limb fracture	1(0.0%)	0
Wound contamination	1(0.0%)	0
Fall	0	2(0.1%)
Heat illness	0	2(0.1%)
Humerus fracture	0	2(0.1%)
Anaemia postoperative	0	1(0.0%)
Brain contusion	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Eye contusion	0	1(0.0%)
Fibula fracture	0	1(0.0%)
Hand fracture	0	1(0.0%)
Overdose	0	1(0.0%)
Skin laceration	0	1(0.0%)
Skin wound	0	1(0.0%)
Skull fracture	0	1(0.0%)
Spinal compression fracture	0	1(0.0%)
Stomal hernia	0	1(0.0%)
Traumatic fracture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Traumatic ulcer	0	1(0.0%)
Gastrointestinal Disorders	57(2.5%)	65(2.8%)
Pancreatitis acute	9(0.4%)	2(0.1%)
Large intestine polyp	5(0.2%)	4(0.2%)
Abdominal pain	4(0.2%)	3(0.1%)
Vomiting	3(0.1%)	1(0.0%)
Haemorrhoids	3(0.1%)	0
Pancreatitis	3(0.1%)	0
Gastrointestinal haemorrhage	2(0.1%)	4(0.2%)
Abdominal pain upper	2(0.1%)	2(0.1%)
Chronic gastritis	2(0.1%)	2(0.1%)
Diarrhoea	2(0.1%)	2(0.1%)
Pancreatitis chronic	2(0.1%)	2(0.1%)
Duodenal ulcer	2(0.1%)	1(0.0%)
Gastritis haemorrhagic	2(0.1%)	1(0.0%)
Inguinal hernia	1(0.0%)	6(0.3%)
Small intestinal obstruction	1(0.0%)	3(0.1%)
Upper gastrointestinal haemorrhage	1(0.0%)	3(0.1%)
Gastric ulcer haemorrhage	1(0.0%)	2(0.1%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Umbilical hernia	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Colitis ischaemic	1(0.0%)	0
Food poisoning	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric haemorrhage	1(0.0%)	0
Gastric mucosal lesion	1(0.0%)	0
Gastrointestinal oedema	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Melaena	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Subileus	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Volvulus	1(0.0%)	0
Intestinal obstruction	0	4(0.2%)
Ascites	0	3(0.1%)
Gastritis erosive	0	2(0.1%)
Gastrooesophageal reflux disease	0	2(0.1%)
Abdominal adhesions	0	1(0.0%)
Abdominal hernia	0	1(0.0%)
Abdominal pain lower	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal haemorrhage	0	1(0.0%)
Barrett's oesophagus	0	1(0.0%)
Diverticular perforation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Dyspepsia	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastritis	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Haematochezia	0	1(0.0%)
Ileus	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Impaired gastric emptying	0	1(0.0%)
Internal hernia	0	1(0.0%)
Nausea	0	1(0.0%)
Oesophagitis	0	1(0.0%)
Omental infarction	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Rectal haemorrhage	0	1(0.0%)
Reflux gastritis	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Surgical And Medical Procedures	56(2.4%)	43(1.9%)
Knee arthroplasty	4(0.2%)	4(0.2%)
Leg amputation	3(0.1%)	4(0.2%)
Cataract operation	3(0.1%)	2(0.1%)
Hip arthroplasty	3(0.1%)	2(0.1%)
Toe amputation	3(0.1%)	2(0.1%)
Vitrectomy	3(0.1%)	2(0.1%)
Gastric bypass	3(0.1%)	1(0.0%)
Roux loop conversion	3(0.1%)	0
Cholecystectomy	2(0.1%)	4(0.2%)
Hysterectomy	2(0.1%)	1(0.0%)
Intervertebral disc operation	2(0.1%)	1(0.0%)
Diabetes mellitus management	2(0.1%)	0
Removal of internal fixation	2(0.1%)	0
Polypectomy	1(0.0%)	3(0.1%)
Atrial appendage closure	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Cardiac ablation	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Colectomy	1(0.0%)	0
Drug therapy	1(0.0%)	0
Eye operation	1(0.0%)	0
Eyelid operation	1(0.0%)	0
Finger amputation	1(0.0%)	0
Foot amputation	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Intraocular lens implant	1(0.0%)	0
Metabolic surgery	1(0.0%)	0
Neurolysis	1(0.0%)	0
Ocular stem cell transplant	1(0.0%)	0
Percutaneous coronary intervention	1(0.0%)	0
Peripheral artery bypass	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Proctocolectomy	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Scar excision	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Spinal operation	1(0.0%)	0
Transurethral bladder resection	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Abscess drainage	0	3(0.1%)
Aortic surgery	0	1(0.0%)
Aortic valve replacement	0	1(0.0%)
Bone operation	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Gastrectomy	0	1(0.0%)
Implantable defibrillator insertion	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Intensive care	0	1(0.0%)
Large intestinal polypectomy	0	1(0.0%)
Limb operation	0	1(0.0%)
Lipoma excision	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Parathyroidectomy	0	1(0.0%)
Thyroidectomy	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Umbilical hernia repair	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Uterine polypectomy	0	1(0.0%)
Renal And Urinary Disorders	51(2.2%)	61(2.6%)
Acute kidney injury	14(0.6%)	13(0.6%)
Nephrolithiasis	9(0.4%)	5(0.2%)
Diabetic nephropathy	7(0.3%)	22(1.0%)
Haematuria	3(0.1%)	3(0.1%)
Ureterolithiasis	3(0.1%)	2(0.1%)
Nephropathy	2(0.1%)	2(0.1%)
Urinary retention	2(0.1%)	2(0.1%)
Hydronephrosis	2(0.1%)	1(0.0%)
Renal failure	1(0.0%)	2(0.1%)
Calculus bladder	1(0.0%)	1(0.0%)
Renal colic	1(0.0%)	1(0.0%)
Renal impairment	1(0.0%)	1(0.0%)
Urinary tract obstruction	1(0.0%)	1(0.0%)
Albuminuria	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Subacute kidney injury	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Urinary hesitation	1(0.0%)	0
Urinary incontinence	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0
Calculus urinary	0	2(0.1%)
Chronic kidney disease	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Nephrotic syndrome	0	2 (0.1%)
Azotaemia	0	1 (0.0%)
End stage renal disease	0	1 (0.0%)
Glomerulonephritis chronic	0	1 (0.0%)
Glomerulonephritis membranous	0	1 (0.0%)
Proteinuria	0	1 (0.0%)
Stress urinary incontinence	0	1 (0.0%)
Musculoskeletal And Connective Tissue Disorders	44 (1.9%)	43 (1.9%)
Osteoarthritis	12 (0.5%)	4 (0.2%)
Intervertebral disc protrusion	7 (0.3%)	7 (0.3%)
Back pain	4 (0.2%)	2 (0.1%)
Spinal osteoarthritis	4 (0.2%)	2 (0.1%)
Spinal stenosis	2 (0.1%)	2 (0.1%)
Lumbar spinal stenosis	2 (0.1%)	0
Rotator cuff syndrome	1 (0.0%)	4 (0.2%)
Periarthritis	1 (0.0%)	2 (0.1%)
Vertebral foraminal stenosis	1 (0.0%)	1 (0.0%)
Arthralgia	1 (0.0%)	0
Dupuytren's contracture	1 (0.0%)	0
Fasciitis	1 (0.0%)	0
Groin pain	1 (0.0%)	0
Inclusion body myositis	1 (0.0%)	0
Muscle spasms	1 (0.0%)	0
Myositis	1 (0.0%)	0
Osteitis	1 (0.0%)	0
Osteonecrosis	1 (0.0%)	0
Osteoporosis	1 (0.0%)	0
Resorption bone increased	1 (0.0%)	0
Rhabdomyolysis	1 (0.0%)	0
Spondylolisthesis	1 (0.0%)	0
Tendon discomfort	1 (0.0%)	0
Tenosynovitis stenosans	1 (0.0%)	0
Arthritis	0	2 (0.1%)
Pain in extremity	0	2 (0.1%)
Ankylosing spondylitis	0	1 (0.0%)
Arthritis reactive	0	1 (0.0%)
Arthropathy	0	1 (0.0%)
Bursitis	0	1 (0.0%)
Cervical spinal stenosis	0	1 (0.0%)
Chondromalacia	0	1 (0.0%)
Costochondritis	0	1 (0.0%)
Diastasis recti abdominis	0	1 (0.0%)
Haemarthrosis	0	1 (0.0%)
Intervertebral disc degeneration	0	1 (0.0%)
Muscular weakness	0	1 (0.0%)
Musculoskeletal discomfort	0	1 (0.0%)
Neuropathic arthropathy	0	1 (0.0%)
Pathological fracture	0	1 (0.0%)
Plantar fascial fibromatosis	0	1 (0.0%)
Psoriatic arthropathy	0	1 (0.0%)
Soft tissue haemorrhage	0	1 (0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Spondyloarthropathy	0	1(0.0%)
Synovial cyst	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	42(1.8%)	56(2.4%)
Chronic obstructive pulmonary disease	12(0.5%)	12(0.5%)
Acute respiratory failure	8(0.3%)	4(0.2%)
Pulmonary embolism	4(0.2%)	6(0.3%)
Asthma	3(0.1%)	2(0.1%)
Respiratory failure	2(0.1%)	7(0.3%)
Epistaxis	2(0.1%)	2(0.1%)
Sleep apnoea syndrome	2(0.1%)	2(0.1%)
Dyspnoea exertional	2(0.1%)	1(0.0%)
Pulmonary mass	2(0.1%)	0
Dyspnoea	1(0.0%)	6(0.3%)
Acute pulmonary oedema	1(0.0%)	3(0.1%)
Pulmonary oedema	1(0.0%)	3(0.1%)
Hypoxia	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Lung disorder	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pneumonia aspiration	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Pleural effusion	0	6(0.3%)
Bronchospasm	0	2(0.1%)
Interstitial lung disease	0	2(0.1%)
Bronchiectasis	0	1(0.0%)
Bronchitis chronic	0	1(0.0%)
Chronic respiratory failure	0	1(0.0%)
Haemoptysis	0	1(0.0%)
Hiccups	0	1(0.0%)
Nasal septum deviation	0	1(0.0%)
Pulmonary congestion	0	1(0.0%)
Respiratory acidosis	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Eye Disorders	40(1.7%)	30(1.3%)
Vitreous haemorrhage	13(0.6%)	6(0.3%)
Cataract	9(0.4%)	7(0.3%)
Diabetic retinopathy	9(0.4%)	7(0.3%)
Glaucoma	3(0.1%)	3(0.1%)
Retinal detachment	2(0.1%)	1(0.0%)
Macular fibrosis	1(0.0%)	2(0.1%)
Macular oedema	1(0.0%)	2(0.1%)
Retinal haemorrhage	1(0.0%)	2(0.1%)
Cataract diabetic	1(0.0%)	1(0.0%)
Eye haemorrhage	1(0.0%)	1(0.0%)
Diabetic eye disease	1(0.0%)	0
Diplopia	1(0.0%)	0
Extraocular muscle paresis	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Ulcerative keratitis	1(0.0%)	0
Vision blurred	1(0.0%)	0
Cataract nuclear	0	2(0.1%)
Dermatochalasis	0	1(0.0%)
Eyelid cyst	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Retinopathy proliferative	0	1(0.0%)
Vascular Disorders	33(1.4%)	37(1.6%)
Hypertension	8(0.3%)	11(0.5%)
Deep vein thrombosis	3(0.1%)	2(0.1%)
Peripheral artery occlusion	2(0.1%)	1(0.0%)
Aortic aneurysm	2(0.1%)	0
Peripheral arterial occlusive disease	1(0.0%)	5(0.2%)
Aortic stenosis	1(0.0%)	2(0.1%)
Hypertensive emergency	1(0.0%)	2(0.1%)
Hypotension	1(0.0%)	2(0.1%)
Dry gangrene	1(0.0%)	1(0.0%)
Peripheral artery thrombosis	1(0.0%)	1(0.0%)
Peripheral ischaemia	1(0.0%)	1(0.0%)
Aortitis	1(0.0%)	0
Circulatory collapse	1(0.0%)	0
Diabetic vascular disorder	1(0.0%)	0
Extremity necrosis	1(0.0%)	0
Giant cell arteritis	1(0.0%)	0
Haematoma	1(0.0%)	0
Orthostatic hypotension	1(0.0%)	0
Peripheral artery stenosis	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Phlebitis	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Hypertensive crisis	0	3(0.1%)
Essential hypertension	0	2(0.1%)
Hypertensive urgency	0	2(0.1%)
Peripheral vascular disorder	0	2(0.1%)
Peripheral artery aneurysm	0	1(0.0%)
Shock	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
Cardiac Disorders	32(1.4%)	32(1.4%)
Coronary artery disease	4(0.2%)	6(0.3%)
Cardiac failure	3(0.1%)	4(0.2%)
Arteriosclerosis coronary artery	3(0.1%)	0
Aortic valve stenosis	2(0.1%)	2(0.1%)
Angina unstable	2(0.1%)	1(0.0%)
Myocardial ischaemia	2(0.1%)	1(0.0%)
Aortic valve disease mixed	2(0.1%)	0
Cardiac failure acute	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Bradycardia	1(0.0%)	2(0.1%)
Coronary artery stenosis	1(0.0%)	2(0.1%)
Acute coronary syndrome	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Atrial fibrillation	1(0.0%)	1(0.0%)
Cardiac failure chronic	1(0.0%)	1(0.0%)
Palpitations	1(0.0%)	1(0.0%)
Angina pectoris	1(0.0%)	0
Arrhythmia	1(0.0%)	0
Atrioventricular block second degree	1(0.0%)	0
Cardiomyopathy	1(0.0%)	0
Extrasystoles	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0
Sinus node dysfunction	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Acute myocardial infarction	0	2(0.1%)
Atrial flutter	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac failure congestive	0	1(0.0%)
Cardiac valve disease	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Tachycardia	0	1(0.0%)
General Disorders And Administration Site Conditions	28(1.2%)	34(1.5%)
Chest pain	8(0.3%)	8(0.3%)
Death	6(0.3%)	2(0.1%)
Pyrexia	4(0.2%)	5(0.2%)
Multiple organ dysfunction syndrome	2(0.1%)	1(0.0%)
Oedema	2(0.1%)	1(0.0%)
Peripheral swelling	2(0.1%)	1(0.0%)
Oedema peripheral	1(0.0%)	7(0.3%)
General physical health deterioration	1(0.0%)	3(0.1%)
Asthenia	1(0.0%)	1(0.0%)
Hanging	1(0.0%)	0
Impaired healing	1(0.0%)	0
Polyp	1(0.0%)	0
Generalised oedema	0	1(0.0%)
Haemorrhagic cyst	0	1(0.0%)
Malaise	0	1(0.0%)
Non-cardiac chest pain	0	1(0.0%)
Sudden death	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	27(1.2%)	31(1.3%)
Diabetic foot	15(0.6%)	16(0.7%)
Skin ulcer	5(0.2%)	11(0.5%)
Angioedema	2(0.1%)	1(0.0%)
Rash	1(0.0%)	1(0.0%)
Angiokeratoma	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Blister	1(0.0%)	0
Dermatitis	1(0.0%)	0
Hidradenitis	1(0.0%)	0
Neuropathic ulcer	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Decubitus ulcer	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Hepatobiliary Disorders	21(0.9%)	17(0.7%)
Cholecystitis	5(0.2%)	1(0.0%)
Bile duct stone	3(0.1%)	1(0.0%)
Cholecystitis acute	2(0.1%)	3(0.1%)
Cholelithiasis	2(0.1%)	3(0.1%)
Cholangitis	2(0.1%)	2(0.1%)
Biliary dyskinesia	2(0.1%)	0
Jaundice cholestatic	1(0.0%)	2(0.1%)
Hepatic cirrhosis	1(0.0%)	1(0.0%)
Biliary colic	1(0.0%)	0
Cholecystitis chronic	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatitis acute	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Liver disorder	1(0.0%)	0
Biliary fistula	0	1(0.0%)
Cholangitis acute	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Gallbladder polyp	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Jaundice	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Investigations	16(0.7%)	23(1.0%)
Colonoscopy	2(0.1%)	1(0.0%)
Blood glucose increased	1(0.0%)	4(0.2%)
Blood pressure increased	1(0.0%)	2(0.1%)
Blood creatinine increased	1(0.0%)	1(0.0%)
Glycosylated haemoglobin increased	1(0.0%)	1(0.0%)
Weight decreased	1(0.0%)	1(0.0%)
Angiocardiogram	1(0.0%)	0
Angiogram	1(0.0%)	0
Blood potassium decreased	1(0.0%)	0
Blood potassium increased	1(0.0%)	0
Computerised tomogram	1(0.0%)	0
Glomerular filtration rate decreased	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Investigation	1(0.0%)	0
Sleep study	1(0.0%)	0
Influenza A virus test positive	0	2(0.1%)
Angiogram cerebral	0	1(0.0%)
Arthroscopy	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Biopsy liver	0	1(0.0%)
Biopsy prostate	0	1(0.0%)
Electrocardiogram abnormal	0	1(0.0%)
Endobronchial ultrasound	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Liver function test increased	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
SARS-CoV-2 test positive	0	1(0.0%)
Reproductive System And Breast Disorders	13(0.6%)	15(0.7%)
Benign prostatic hyperplasia	7(0.3%)	8(0.3%)
Prostatitis	1(0.0%)	2(0.1%)
Prostatomegaly	1(0.0%)	2(0.1%)
Ovarian cyst	1(0.0%)	1(0.0%)
Breast mass	1(0.0%)	0
Prostatic disorder	1(0.0%)	0
Prostatism	1(0.0%)	0
Erectile dysfunction	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Blood And Lymphatic System Disorders	11(0.5%)	5(0.2%)
Anaemia	7(0.3%)	2(0.1%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Coagulopathy	1(0.0%)	0
Iron deficiency anaemia	1(0.0%)	0
Febrile neutropenia	0	1(0.0%)
Neutropenia	0	1(0.0%)
Ear And Labyrinth Disorders	7(0.3%)	4(0.2%)
Vertigo	3(0.1%)	0
Sudden hearing loss	2(0.1%)	2(0.1%)
Tympanic membrane perforation	1(0.0%)	0
Vertigo positional	1(0.0%)	0
Deafness	0	1(0.0%)
Vestibular disorder	0	1(0.0%)
Psychiatric Disorders	5(0.2%)	3(0.1%)
Depression	2(0.1%)	1(0.0%)
Mental status changes	2(0.1%)	0
Confusional state	1(0.0%)	0
Major depression	1(0.0%)	0
Drug abuse	0	1(0.0%)
Suicide threat	0	1(0.0%)
Congenital, Familial And Genetic Disorders	2(0.1%)	1(0.0%)
Adenomatous polyposis coli	1(0.0%)	0
Arnold-Chiari malformation	1(0.0%)	0
Anomaly of middle ear congenital	0	1(0.0%)
Endocrine Disorders	2(0.1%)	0
Goitre	2(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Immune System Disorders	1(0.0%)	1(0.0%)
Anaphylactic shock	1(0.0%)	1(0.0%)
Anaphylactic reaction	0	1(0.0%)
Product Issues	0	2(0.1%)
Device loosening	0	1(0.0%)
Device malfunction	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Any TEAE	349(15.0%)	410(17.8%)
Infections And Infestations	96(4.1%)	117(5.1%)
Pneumonia	14(0.6%)	27(1.2%)
Cellulitis	7(0.3%)	8(0.3%)
Localised infection	7(0.3%)	3(0.1%)
Sepsis	6(0.3%)	10(0.4%)
COVID-19	4(0.2%)	11(0.5%)
Osteomyelitis	4(0.2%)	6(0.3%)
Urosepsis	4(0.2%)	6(0.3%)
Influenza	3(0.1%)	3(0.1%)
Urinary tract infection	3(0.1%)	3(0.1%)
Septic shock	3(0.1%)	2(0.1%)
Abscess limb	3(0.1%)	1(0.0%)
Postoperative wound infection	3(0.1%)	0
COVID-19 pneumonia	2(0.1%)	6(0.3%)
Erysipelas	2(0.1%)	2(0.1%)
Herpes zoster	2(0.1%)	2(0.1%)
Pyelonephritis acute	2(0.1%)	2(0.1%)
Bronchitis	2(0.1%)	1(0.0%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Infected skin ulcer	2(0.1%)	0
Gastroenteritis	1(0.0%)	3(0.1%)
Diabetic foot infection	1(0.0%)	2(0.1%)
Lower respiratory tract infection	1(0.0%)	2(0.1%)
Wound infection	1(0.0%)	2(0.1%)
Appendicitis	1(0.0%)	1(0.0%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	1(0.0%)
Meningitis	1(0.0%)	1(0.0%)
Osteomyelitis chronic	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Pneumonia viral	1(0.0%)	1(0.0%)
Pyelonephritis	1(0.0%)	1(0.0%)
Staphylococcal bacteraemia	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Bacterial infection	1(0.0%)	0
Cholecystitis infective	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Cystitis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Endocarditis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Genital candidiasis	1(0.0%)	0
HIV infection	1(0.0%)	0
Liver abscess	1(0.0%)	0
Necrotising fasciitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Pharyngitis	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Pneumonia bacterial	1(0.0%)	0
Pneumonia influenzal	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Respiratory tract infection	1(0.0%)	0
Subcutaneous abscess	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Gangrene	0	4(0.2%)
Infection	0	3(0.1%)
Skin infection	0	3(0.1%)
Anal abscess	0	2(0.1%)
Soft tissue infection	0	2(0.1%)
Arthritis bacterial	0	1(0.0%)
Atypical pneumonia	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Conjunctivitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Diverticulitis	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Gastroenteritis norovirus	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Paronychia	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Pulmonary sepsis	0	1(0.0%)
Pulmonary tuberculosis	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Urinary tract infection bacterial	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	48(2.1%)	47(2.0%)
Colon cancer	5(0.2%)	2(0.1%)
Renal neoplasm	5(0.2%)	1(0.0%)
Hepatic cancer	3(0.1%)	2(0.1%)
Transitional cell carcinoma	3(0.1%)	0
Prostate cancer	2(0.1%)	6(0.3%)
Pancreatic carcinoma	2(0.1%)	4(0.2%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)
Bladder cancer	2(0.1%)	0
Endometrial cancer	2(0.1%)	0
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Lung neoplasm malignant	1(0.0%)	2(0.1%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Oesophageal carcinoma	1(0.0%)	1(0.0%)
Plasma cell myeloma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)
Adenocarcinoma	1(0.0%)	0
Bladder cancer recurrent	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Chronic lymphocytic leukaemia	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Colon adenoma	1(0.0%)	0
Hepatocellular carcinoma	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Metastases to lymph nodes	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Neoplasm malignant	1(0.0%)	0
Prostate cancer recurrent	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
B-cell lymphoma	0	2(0.1%)
Breast cancer	0	2(0.1%)
Adenocarcinoma of colon	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)
Gastrointestinal carcinoma	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Lung neoplasm	0	1(0.0%)
Malignant melanoma	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastases to bone	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Pancreatic neoplasm	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Papilloma	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Renal cancer	0	1(0.0%)
Seminoma	0	1(0.0%)
Metabolism And Nutrition Disorders	46(2.0%)	44(1.9%)
Hypoglycaemia	11(0.5%)	10(0.4%)
Hyperkalaemia	7(0.3%)	3(0.1%)
Diabetes mellitus	4(0.2%)	6(0.3%)
Hyponatraemia	4(0.2%)	1(0.0%)
Hyperglycaemia	3(0.1%)	4(0.2%)
Type 2 diabetes mellitus	3(0.1%)	4(0.2%)
Dehydration	3(0.1%)	1(0.0%)
Hypertriglyceridaemia	2(0.1%)	1(0.0%)
Vitamin D deficiency	2(0.1%)	1(0.0%)
Diabetes mellitus inadequate control	1(0.0%)	7(0.3%)
Gout	1(0.0%)	3(0.1%)
Diabetic ketoacidosis	1(0.0%)	1(0.0%)
Hypoproteinaemia	1(0.0%)	1(0.0%)
Metabolic acidosis	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Obesity	1(0.0%)	1(0.0%)
Diabetic metabolic decompensation	1(0.0%)	0
Lactic acidosis	1(0.0%)	0
Cachexia	0	2(0.1%)
Decreased appetite	0	1(0.0%)
Diabetic complication	0	1(0.0%)
Electrolyte imbalance	0	1(0.0%)
Hypokalaemia	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	36(1.5%)	38(1.7%)
Acute respiratory failure	7(0.3%)	6(0.3%)
Chronic obstructive pulmonary disease	6(0.3%)	6(0.3%)
Dyspnoea	5(0.2%)	4(0.2%)
Acute pulmonary oedema	3(0.1%)	3(0.1%)
Pulmonary embolism	3(0.1%)	3(0.1%)
Respiratory failure	2(0.1%)	5(0.2%)
Sleep apnoea syndrome	2(0.1%)	3(0.1%)
Asthma	2(0.1%)	1(0.0%)
Hypoxia	2(0.1%)	1(0.0%)
Pulmonary hypertension	2(0.1%)	0
Pulmonary oedema	1(0.0%)	3(0.1%)
Pneumonia aspiration	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Hypercapnia	1(0.0%)	0
Obstructive airways disorder	1(0.0%)	0
Pneumothorax	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Pulmonary mass	1(0.0%)	0
Respiratory acidosis	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Restrictive pulmonary disease	1(0.0%)	0
Pleural effusion	0	3(0.1%)
Apnoea	0	1(0.0%)
Bronchiectasis	0	1(0.0%)
Bronchospasm	0	1(0.0%)
Cough	0	1(0.0%)
Interstitial lung disease	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Vascular Disorders	33(1.4%)	32(1.4%)
Hypertension	7(0.3%)	10(0.4%)
Hypotension	4(0.2%)	0
Peripheral arterial occlusive disease	2(0.1%)	5(0.2%)
Hypertensive emergency	2(0.1%)	2(0.1%)
Peripheral artery stenosis	2(0.1%)	2(0.1%)
Aortic stenosis	2(0.1%)	1(0.0%)
Peripheral artery occlusion	2(0.1%)	1(0.0%)
Peripheral ischaemia	2(0.1%)	1(0.0%)
Deep vein thrombosis	2(0.1%)	0
Hypertensive urgency	1(0.0%)	1(0.0%)
Aortitis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Diabetic vascular disorder	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Extremity necrosis	1(0.0%)	0
Giant cell arteritis	1(0.0%)	0
Haematoma	1(0.0%)	0
Intermittent claudication	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Hypertensive crisis	0	2(0.1%)
Aortic aneurysm	0	1(0.0%)
Aortic aneurysm rupture	0	1(0.0%)
Hypovolaemic shock	0	1(0.0%)
Peripheral artery aneurysm	0	1(0.0%)
Peripheral vascular disorder	0	1(0.0%)
Peripheral venous disease	0	1(0.0%)
Shock	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
Nervous System Disorders	26(1.1%)	38(1.7%)
Syncope	2(0.1%)	3(0.1%)
Dizziness	2(0.1%)	1(0.0%)
Hemiparesis	2(0.1%)	1(0.0%)
Subarachnoid haemorrhage	2(0.1%)	1(0.0%)
Carotid artery stenosis	1(0.0%)	4(0.2%)
Diabetic neuropathy	1(0.0%)	2(0.1%)
Cerebrovascular accident	1(0.0%)	1(0.0%)
Cerebrovascular disorder	1(0.0%)	1(0.0%)
Epilepsy	1(0.0%)	1(0.0%)
Loss of consciousness	1(0.0%)	1(0.0%)
Paraparesis	1(0.0%)	1(0.0%)
Altered state of consciousness	1(0.0%)	0
Brain injury	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral ischaemia	1(0.0%)	0
Dizziness postural	1(0.0%)	0
Facial paralysis	1(0.0%)	0
Headache	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0
IVth nerve paralysis	1(0.0%)	0
Myelopathy	1(0.0%)	0
Presyncope	1(0.0%)	0
Sciatica	1(0.0%)	0
Seizure	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Cervical radiculopathy	0	2(0.1%)
Encephalopathy	0	2(0.1%)
Brain stem haemorrhage	0	1(0.0%)
Carpal tunnel syndrome	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cognitive disorder	0	1(0.0%)
Coma	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Dementia	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Facial paresis	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Parkinson's disease	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Transient ischaemic attack	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Vertebral artery stenosis	0	1(0.0%)
Vertigo CNS origin	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	26(1.1%)	26(1.1%)
Osteoarthritis	5(0.2%)	4(0.2%)
Back pain	5(0.2%)	2(0.1%)
Arthralgia	2(0.1%)	3(0.1%)
Pain in extremity	2(0.1%)	1(0.0%)
Spinal osteoarthritis	2(0.1%)	1(0.0%)
Intervertebral disc protrusion	1(0.0%)	3(0.1%)
Intervertebral disc degeneration	1(0.0%)	1(0.0%)
Muscle spasms	1(0.0%)	1(0.0%)
Groin pain	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Lumbar spinal stenosis	1(0.0%)	0
Musculoskeletal pain	1(0.0%)	0
Myositis	1(0.0%)	0
Osteitis	1(0.0%)	0
Osteochondrosis	1(0.0%)	0
Osteoporosis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Rotator cuff syndrome	1(0.0%)	0
Spinal synovial cyst	1(0.0%)	0
Neuropathic arthropathy	0	3(0.1%)
Bursitis	0	2(0.1%)
Cervical spinal stenosis	0	2(0.1%)
Myalgia	0	2(0.1%)
Arthritis	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Cardiac Disorders	24(1.0%)	36(1.6%)
Coronary artery disease	4(0.2%)	7(0.3%)
Cardiac failure	3(0.1%)	6(0.3%)
Cardiac failure congestive	2(0.1%)	2(0.1%)
Angina unstable	2(0.1%)	1(0.0%)
Cardiac failure acute	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Acute coronary syndrome	2(0.1%)	0
Angina pectoris	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Aortic valve stenosis	1(0.0%)	4(0.2%)
Ischaemic cardiomyopathy	1(0.0%)	2(0.1%)
Aortic valve disease mixed	1(0.0%)	1(0.0%)
Aortic valve incompetence	1(0.0%)	0
Atrioventricular block	1(0.0%)	0
Cardiac disorder	1(0.0%)	0
Cardiovascular insufficiency	1(0.0%)	0
Mitral valve incompetence	1(0.0%)	0
Myocardial ischaemia	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Bradycardia	0	2(0.1%)
Cardiogenic shock	0	2(0.1%)
Atrial fibrillation	0	1(0.0%)
Atrial flutter	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Atrioventricular block second degree	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac arrest	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac failure chronic	0	1(0.0%)
Cardiomegaly	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Renal And Urinary Disorders	22(0.9%)	34(1.5%)
Acute kidney injury	9(0.4%)	10(0.4%)
Nephrolithiasis	4(0.2%)	2(0.1%)
Renal failure	2(0.1%)	3(0.1%)
Renal impairment	2(0.1%)	0
Hydronephrosis	1(0.0%)	2(0.1%)
Urinary tract obstruction	1(0.0%)	1(0.0%)
Oliguria	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Urinary incontinence	1(0.0%)	0
Urinary retention	1(0.0%)	0
Diabetic nephropathy	0	4(0.2%)
Chronic kidney disease	0	3(0.1%)
Haematuria	0	3(0.1%)
Nephropathy	0	2(0.1%)
Calculus urinary	0	1(0.0%)
End stage renal disease	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Nephrotic syndrome	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Proteinuria	0	1(0.0%)
Ureterolithiasis	0	1(0.0%)
Injury, Poisoning And Procedural Complications	21(0.9%)	16(0.7%)
Rib fracture	3(0.1%)	1(0.0%)
Hip fracture	2(0.1%)	0
Procedural pain	2(0.1%)	0
Foot fracture	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0
Ankle fracture	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Chest injury	1(0.0%)	0
Contusion	1(0.0%)	0
Fall	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Femur fracture	1(0.0%)	0
Lower limb fracture	1(0.0%)	0
Poisoning	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Road traffic accident	1(0.0%)	0
Thermal burn	1(0.0%)	0
Toxicity to various agents	1(0.0%)	0
Traumatic haematoma	1(0.0%)	0
Upper limb fracture	1(0.0%)	0
Lumbar vertebral fracture	0	2(0.1%)
Subdural haematoma	0	2(0.1%)
Brain contusion	0	1(0.0%)
Craniocerebral injury	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Eye contusion	0	1(0.0%)
Heat illness	0	1(0.0%)
Hyphaema	0	1(0.0%)
Limb injury	0	1(0.0%)
Multiple fractures	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Radius fracture	0	1(0.0%)
Skull fracture	0	1(0.0%)
Subdural haemorrhage	0	1(0.0%)
Thoracic vertebral fracture	0	1(0.0%)
Traumatic fracture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Gastrointestinal Disorders	19(0.8%)	31(1.3%)
Pancreatitis acute	2(0.1%)	1(0.0%)
Gastrointestinal haemorrhage	1(0.0%)	2(0.1%)
Abdominal pain	1(0.0%)	1(0.0%)
Abdominal pain upper	1(0.0%)	1(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Chronic gastritis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Functional gastrointestinal disorder	1(0.0%)	0
Gastric ulcer haemorrhage	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Pancreatitis	1(0.0%)	0
Pancreatitis chronic	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Toothache	1(0.0%)	0
Volvulus	1(0.0%)	0
Vomiting	1(0.0%)	0
Intestinal obstruction	0	4(0.2%)
Upper gastrointestinal haemorrhage	0	3(0.1%)
Ascites	0	2(0.1%)
Inguinal hernia	0	2(0.1%)
Nausea	0	2(0.1%)
Small intestinal obstruction	0	2(0.1%)
Abdominal adhesions	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Constipation	0	1(0.0%)
Diarrhoea	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Dyspepsia	0	1(0.0%)
Enteritis	0	1(0.0%)
Gastritis	0	1(0.0%)
Haematochezia	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Large intestine polyp	0	1(0.0%)
Omental infarction	0	1(0.0%)
Rectal haemorrhage	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
General Disorders And Administration Site Conditions	19(0.8%)	19(0.8%)
Death	6(0.3%)	2(0.1%)
Chest pain	2(0.1%)	5(0.2%)
Multiple organ dysfunction syndrome	2(0.1%)	2(0.1%)
General physical health deterioration	2(0.1%)	1(0.0%)
Peripheral swelling	2(0.1%)	1(0.0%)
Oedema peripheral	2(0.1%)	0
Oedema	1(0.0%)	1(0.0%)
Hanging	1(0.0%)	0
Malaise	1(0.0%)	0
Pyrexia	0	2(0.1%)
Asthenia	0	1(0.0%)
Fatigue	0	1(0.0%)
Generalised oedema	0	1(0.0%)
Non-cardiac chest pain	0	1(0.0%)
Sudden death	0	1(0.0%)
Investigations	19(0.8%)	19(0.8%)
Glomerular filtration rate decreased	5(0.2%)	6(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Blood creatinine increased	2(0.1%)	2(0.1%)
Weight decreased	2(0.1%)	2(0.1%)
Blood creatine phosphokinase increased	1(0.0%)	3(0.1%)
Blood pressure increased	1(0.0%)	2(0.1%)
Blood potassium increased	1(0.0%)	0
Blood sodium decreased	1(0.0%)	0
C-reactive protein increased	1(0.0%)	0
Glycosylated haemoglobin increased	1(0.0%)	0
Haemoglobin decreased	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Sleep study	1(0.0%)	0
Biopsy prostate	0	1(0.0%)
Influenza A virus test positive	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
White blood cell count increased	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	18(0.8%)	21(0.9%)
Diabetic foot	9(0.4%)	7(0.3%)
Skin ulcer	2(0.1%)	7(0.3%)
Angioedema	2(0.1%)	0
Hidradenitis	1(0.0%)	1(0.0%)
Blister	1(0.0%)	0
Dermatitis allergic	1(0.0%)	0
Diabetic bullosis	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Ingrowing nail	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Pruritus	0	1(0.0%)
Psoriasis	0	1(0.0%)
Rash	0	1(0.0%)
Rash pruritic	0	1(0.0%)
Eye Disorders	15(0.6%)	19(0.8%)
Diabetic retinopathy	7(0.3%)	6(0.3%)
Cataract	3(0.1%)	1(0.0%)
Vitreous haemorrhage	2(0.1%)	5(0.2%)
Sudden visual loss	2(0.1%)	0
Visual impairment	1(0.0%)	2(0.1%)
Glaucoma	1(0.0%)	1(0.0%)
Retinal detachment	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Blindness	1(0.0%)	0
Diabetic eye disease	1(0.0%)	0
Eye haemorrhage	1(0.0%)	0
Blindness unilateral	0	1(0.0%)
Dermatochalasis	0	1(0.0%)
Diabetic retinal oedema	0	1(0.0%)
Diplopia	0	1(0.0%)
Retinal vein occlusion	0	1(0.0%)
Retinopathy proliferative	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Surgical And Medical Procedures	14(0.6%)	21(0.9%)
Leg amputation	2(0.1%)	3(0.1%)
Gastric bypass	2(0.1%)	1(0.0%)
Toe amputation	1(0.0%)	5(0.2%)
Intervertebral disc operation	1(0.0%)	1(0.0%)
Finger amputation	1(0.0%)	0
Foot amputation	1(0.0%)	0
Hip arthroplasty	1(0.0%)	0
Hysterectomy	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Neurolysis	1(0.0%)	0
Roux loop conversion	1(0.0%)	0
Vitrectomy	1(0.0%)	0
Cataract operation	0	2(0.1%)
Knee arthroplasty	0	2(0.1%)
Abscess drainage	0	1(0.0%)
Cardiac pacemaker insertion	0	1(0.0%)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cholecystectomy	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Intensive care	0	1(0.0%)
Lens extraction	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Blood And Lymphatic System Disorders	8(0.3%)	6(0.3%)
Anaemia	5(0.2%)	4(0.2%)
Blood loss anaemia	2(0.1%)	0
Coagulopathy	1(0.0%)	0
Febrile neutropenia	0	1(0.0%)
Iron deficiency anaemia	0	1(0.0%)
Hepatobiliary Disorders	7(0.3%)	10(0.4%)
Cholecystitis acute	1(0.0%)	2(0.1%)
Cholangitis	1(0.0%)	1(0.0%)
Cholecystitis	1(0.0%)	1(0.0%)
Cholelithiasis	1(0.0%)	1(0.0%)
Biliary colic	1(0.0%)	0
Biliary dyskinesia	1(0.0%)	0
Cholecystitis chronic	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Liver disorder	1(0.0%)	0
Jaundice cholestatic	0	2(0.1%)
Cirrhosis alcoholic	0	1(0.0%)
Hepatic cirrhosis	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Hepatic mass	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Portal vein thrombosis	0	1(0.0%)
Psychiatric Disorders	4(0.2%)	6(0.3%)
Depression	1(0.0%)	2(0.1%)
Anxiety	1(0.0%)	0
Major depression	1(0.0%)	0
Mental status changes	1(0.0%)	0
Depressed mood	0	1(0.0%)
Drug abuse	0	1(0.0%)
Hallucination	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Reproductive System And Breast Disorders	2(0.1%)	5(0.2%)
Benign prostatic hyperplasia	1(0.0%)	2(0.1%)
Uterine haemorrhage	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Female genital tract fistula	0	1(0.0%)
Ovarian cyst	0	1(0.0%)
Prostatitis	0	1(0.0%)
Ear And Labyrinth Disorders	2(0.1%)	1(0.0%)
Tympanic membrane perforation	1(0.0%)	0
Vertigo	1(0.0%)	0
Vestibular disorder	0	1(0.0%)
Immune System Disorders	1(0.0%)	2(0.1%)
Anaphylactic shock	1(0.0%)	2(0.1%)
Product Issues	0	2(0.1%)
Device loosening	0	1(0.0%)
Device malfunction	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Any TEAE	85(3.7%)	94(4.1%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	13(0.6%)	20(0.9%)
Colon cancer	2(0.1%)	2(0.1%)
Transitional cell carcinoma	2(0.1%)	0
Plasma cell myeloma	1(0.0%)	1(0.0%)
Clear cell renal cell carcinoma	1(0.0%)	0
Diffuse large B-cell lymphoma	1(0.0%)	0
Gastric cancer	1(0.0%)	0
Lymphoma	1(0.0%)	0
Meningioma	1(0.0%)	0
Pancreatic carcinoma metastatic	1(0.0%)	0
Prostate cancer	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Breast cancer	0	2(0.1%)
Pancreatic carcinoma	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Endometrial adenocarcinoma	0	1(0.0%)
Hepatic cancer	0	1(0.0%)
Hepatocellular carcinoma	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Lung neoplasm malignant	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Pancreatic neoplasm	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Tonsil cancer	0	1(0.0%)
Metabolism And Nutrition Disorders	12(0.5%)	6(0.3%)
Hyperkalaemia	9(0.4%)	4(0.2%)
Hyponatraemia	3(0.1%)	0
Cachexia	0	1(0.0%)
Hypokalaemia	0	1(0.0%)
Investigations	11(0.5%)	6(0.3%)
Glomerular filtration rate decreased	6(0.3%)	2(0.1%)
Blood potassium increased	3(0.1%)	1(0.0%)
Blood creatinine increased	1(0.0%)	1(0.0%)
Liver function test increased	1(0.0%)	0
Blood pressure increased	0	1(0.0%)
Hepatic enzyme increased	0	1(0.0%)
Nervous System Disorders	9(0.4%)	15(0.7%)
Dementia	2(0.1%)	3(0.1%)
Dizziness	1(0.0%)	2(0.1%)
Subarachnoid haemorrhage	1(0.0%)	2(0.1%)
Syncope	1(0.0%)	2(0.1%)
Cognitive disorder	1(0.0%)	1(0.0%)
Somnolence	1(0.0%)	1(0.0%)
Hemiparesis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Presyncope	1(0.0%)	0
Cerebral atrophy	0	1(0.0%)
Dementia Alzheimer's type	0	1(0.0%)
Dizziness postural	0	1(0.0%)
Loss of consciousness	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Gastrointestinal Disorders	9(0.4%)	13(0.6%)
Diarrhoea	4(0.2%)	3(0.1%)
Constipation	1(0.0%)	3(0.1%)
Vomiting	1(0.0%)	1(0.0%)
Abdominal pain	1(0.0%)	0
Chronic gastritis	1(0.0%)	0
Dyspepsia	1(0.0%)	0
Gastrointestinal motility disorder	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Ascites	0	2(0.1%)
Nausea	0	2(0.1%)
Gastrooesophageal reflux disease	0	1(0.0%)
Oesophageal varices haemorrhage	0	1(0.0%)
Oesophagitis	0	1(0.0%)
Cardiac Disorders	4(0.2%)	7(0.3%)
Palpitations	1(0.0%)	1(0.0%)
Atrioventricular block	1(0.0%)	0
Cardiac failure acute	1(0.0%)	0
Cardiac failure congestive	1(0.0%)	0
Cardiac failure	0	2(0.1%)
Aortic valve stenosis	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Myocardial ischaemia	0	1(0.0%)
Tachycardia	0	1(0.0%)
General Disorders And Administration Site Conditions	4(0.2%)	6(0.3%)
Chest pain	1(0.0%)	0
General physical health deterioration	1(0.0%)	0
Malaise	1(0.0%)	0
Peripheral swelling	1(0.0%)	0
Asthenia	0	1(0.0%)
Fatigue	0	1(0.0%)
Multiple organ dysfunction syndrome	0	1(0.0%)
Oedema peripheral	0	1(0.0%)
Pain	0	1(0.0%)
Pyrexia	0	1(0.0%)
Renal And Urinary Disorders	4(0.2%)	5(0.2%)
Acute kidney injury	3(0.1%)	2(0.1%)
Subacute kidney injury	1(0.0%)	0
Glomerulonephritis membranous	0	1(0.0%)
Proteinuria	0	1(0.0%)
Renal failure	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Renal pain	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Infections And Infestations	4(0.2%)	4(0.2%)
Dengue fever	1(0.0%)	0
HIV infection	1(0.0%)	0
Helicobacter infection	1(0.0%)	0
Necrotising fasciitis	1(0.0%)	0
COVID-19	0	1(0.0%)
Diabetic foot infection	0	1(0.0%)
Pneumonia	0	1(0.0%)
Upper respiratory tract infection	0	1(0.0%)
Psychiatric Disorders	4(0.2%)	3(0.1%)
Anxiety	1(0.0%)	0
Bipolar disorder	1(0.0%)	0
Depression	1(0.0%)	0
Mental status changes	1(0.0%)	0
Behaviour disorder	0	1(0.0%)
Depressed mood	0	1(0.0%)
Nervousness	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	4(0.2%)	0
Dyspnoea	1(0.0%)	0
Dyspnoea exertional	1(0.0%)	0
Lung disorder	1(0.0%)	0
Productive cough	1(0.0%)	0
Vascular Disorders	3(0.1%)	1(0.0%)
Deep vein thrombosis	1(0.0%)	0
Hypertension	1(0.0%)	0
Hypotension	1(0.0%)	0
Flushing	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	2(0.1%)	7(0.3%)
Rash	1(0.0%)	3(0.1%)
Dermatitis allergic	1(0.0%)	0
Dermatitis psoriasiform	0	1(0.0%)
Hyperhidrosis	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Pruritus	0	1(0.0%)
Injury, Poisoning And Procedural Complications	2(0.1%)	3(0.1%)
Craniocerebral injury	1(0.0%)	1(0.0%)
Subdural haemorrhage	1(0.0%)	0
Brain contusion	0	1(0.0%)
Lumbar vertebral fracture	0	1(0.0%)
Skull fracture	0	1(0.0%)
Subdural haematoma	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	2(0.1%)	2(0.1%)
Muscle spasms	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2326)	Placebo (N=2302)
Myalgia	1(0.0%)	0
Intervertebral disc protrusion	0	1(0.0%)
Joint swelling	0	1(0.0%)
Hepatobiliary Disorders	1(0.0%)	5(0.2%)
Hepatic cirrhosis	1(0.0%)	1(0.0%)
Chronic hepatitis	1(0.0%)	0
Hepatic function abnormal	0	1(0.0%)
Hepatic mass	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver injury	0	1(0.0%)
Reproductive System And Breast Disorders	1(0.0%)	1(0.0%)
Erectile dysfunction	1(0.0%)	1(0.0%)
Immune System Disorders	1(0.0%)	0
Hypersensitivity	1(0.0%)	0
Eye Disorders	0	2(0.1%)
Optic ischaemic neuropathy	0	1(0.0%)
Periorbital swelling	0	1(0.0%)
Blood And Lymphatic System Disorders	0	1(0.0%)
Blood loss anaemia	0	1(0.0%)
Ear And Labyrinth Disorders	0	1(0.0%)
Vertigo	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA=Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Treatment duration (months)			
n	2326	2302	4628
Mean	35.7	35.4	35.6
SD	14.48	14.40	14.44
Median	35.8	35.6	35.7
Q1-Q3	27.2 - 46.9	26.8 - 47.0	27.0 - 46.9
Range	0.03 - 61.01	0.20 - 61.37	0.03 - 61.37

Abbreviations: eGFR=estimated glomerular filtration rate, N=number of subjects, n=number of subjects with non-missing values in category, Q1=first quartile, Q3=third quartile, SD=standard deviation.
Note: Treatment duration is defined as the time from start of study drug to permanent stop of study drug (in months).

Table B2.1.1: Effect Measures of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		1939 (83.4%)	1937 (84.1%)	3876 (83.8%)
Number of subjects without events		387 (16.6%)	365 (15.9%)	752 (16.2%)
Odds Ratio [a]				
OR, 95% CI	0.944 [0.808, 1.104]			
p-value	0.4708			
Relative Risk [b]				
RR, 95% CI	0.991 [0.966, 1.016]			
p-value	0.4707			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.029, 0.013]			
p-value	0.4707			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.2: Effect Measures of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		1926 (82.8%)	1924 (83.6%)	3850 (83.2%)
Number of subjects without events		400 (17.2%)	378 (16.4%)	778 (16.8%)
Odds Ratio [a]				
OR, 95% CI	0.946 [0.811, 1.104]			
p-value	0.4801			
Relative Risk [b]				
RR, 95% CI	0.991 [0.965, 1.017]			
p-value	0.4800			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.029, 0.014]			
p-value	0.4800			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.3: Effect Measures of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		666 (28.6%)	704 (30.6%)	1370 (29.6%)
Number of subjects without events		1660 (71.4%)	1598 (69.4%)	3258 (70.4%)
Odds Ratio [a]				
OR, 95% CI	0.911 [0.803, 1.033]			
p-value	0.1464			
Relative Risk [b]				
RR, 95% CI	0.936 [0.857, 1.023]			
p-value	0.1465			
Risk Difference [c]				
RD, 95% CI	-0.019 [-0.046, 0.007]			
p-value	0.1463			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.4: Effect Measures of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		661 (28.4%)	696 (30.2%)	1357 (29.3%)
Number of subjects without events		1665 (71.6%)	1606 (69.8%)	3271 (70.7%)
Odds Ratio [a]				
OR, 95% CI	0.916 [0.807, 1.040]			
p-value	0.1747			
Relative Risk [b]				
RR, 95% CI	0.940 [0.859, 1.028]			
p-value	0.1748			
Risk Difference [c]				
RD, 95% CI	-0.018 [-0.044, 0.008]			
p-value	0.1746			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.5: Effect Measures of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		349 (15.0%)	410 (17.8%)	759 (16.4%)
Number of subjects without events		1977 (85.0%)	1892 (82.2%)	3869 (83.6%)
Odds Ratio [a]				
OR, 95% CI	0.815 [0.697, 0.952]			
p-value	0.0100			
Relative Risk [b]				
RR, 95% CI	0.842 [0.739, 0.960]			
p-value	0.0101			
Risk Difference [c]				
RD, 95% CI	-0.028 [-0.049, -0.007]			
p-value	0.0099			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.6: Effect Measures of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		339 (14.6%)	404 (17.5%)	743 (16.1%)
Number of subjects without events		1987 (85.4%)	1898 (82.5%)	3885 (83.9%)
Odds Ratio [a]				
OR, 95% CI	0.802 [0.685, 0.938]			
p-value	0.0059			
Relative Risk [b]				
RR, 95% CI	0.830 [0.727, 0.948]			
p-value	0.0059			
Risk Difference [c]				
RD, 95% CI	-0.030 [-0.051, -0.009]			
p-value	0.0058			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.7: Effect Measures of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		85 (3.7%)	94 (4.1%)	179 (3.9%)
Number of subjects without events		2241 (96.3%)	2208 (95.9%)	4449 (96.1%)
Odds Ratio [a]				
OR, 95% CI	0.891 [0.661, 1.202]			
p-value	0.4494			
Relative Risk [b]				
RR, 95% CI	0.895 [0.671, 1.193]			
p-value	0.4494			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.015, 0.007]			
p-value	0.4492			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, RD=risk difference, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.8: Effect Measures of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		189 (8.1%)	182 (7.9%)	371 (8.0%)
Number of subjects without events		2137 (91.9%)	2120 (92.1%)	4257 (92.0%)
Odds Ratio [a]				
OR, 95% CI	1.030 [0.833, 1.274]			
p-value	0.7835			
Relative Risk [b]				
RR, 95% CI	1.028 [0.845, 1.249]			
p-value	0.7835			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.013, 0.018]			
p-value	0.7835			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.9: Effect Measures of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		126 (5.4%)	109 (4.7%)	235 (5.1%)
Number of subjects without events		2200 (94.6%)	2193 (95.3%)	4393 (94.9%)
Odds Ratio [a]				
OR, 95% CI	1.152 [0.886, 1.499]			
p-value	0.2910			
Relative Risk [b]				
RR, 95% CI	1.144 [0.891, 1.469]			
p-value	0.2911			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.006, 0.019]			
p-value	0.2905			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.10: Effect Measures of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		258 (11.1%)	301 (13.1%)	559 (12.1%)
Number of subjects without events		2068 (88.9%)	2001 (86.9%)	4069 (87.9%)
Odds Ratio [a]				
OR, 95% CI	0.829 [0.695, 0.990]			
p-value	0.0386			
Relative Risk [b]				
RR, 95% CI	0.848 [0.726, 0.991]			
p-value	0.0387			
Risk Difference [c]				
RD, 95% CI	-0.020 [-0.039, -0.001]			
p-value	0.0384			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.11: Effect Measures of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		21 (0.9%)	29 (1.3%)	50 (1.1%)
Number of subjects without events		2305 (99.1%)	2273 (98.7%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.714 [0.406, 1.256]			
p-value	0.2424			
Relative Risk [b]				
RR, 95% CI	0.717 [0.410, 1.253]			
p-value	0.2425			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.010, 0.002]			
p-value	0.2406			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.12: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		22 (0.9%)	39 (1.7%)	61 (1.3%)
Number of subjects without events		2304 (99.1%)	2263 (98.3%)	4567 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.554 [0.327, 0.937]			
p-value	0.0277			
Relative Risk [b]				
RR, 95% CI	0.558 [0.332, 0.938]			
p-value	0.0278			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.014, -0.001]			
p-value	0.0258			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.13: Effect Measures of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		18 (0.8%)	26 (1.1%)	44 (1.0%)
Number of subjects without events		2308 (99.2%)	2276 (98.9%)	4584 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.683 [0.373, 1.249]			
p-value	0.2153			
Relative Risk [b]				
RR, 95% CI	0.685 [0.377, 1.246]			
p-value	0.2154			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.009, 0.002]			
p-value	0.2130			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.14: Effect Measures of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		20 (0.9%)	25 (1.1%)	45 (1.0%)
Number of subjects without events		2306 (99.1%)	2277 (98.9%)	4583 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.790 [0.438, 1.426]			
p-value	0.4341			
Relative Risk [b]				
RR, 95% CI	0.792 [0.441, 1.421]			
p-value	0.4341			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.003]			
p-value	0.4333			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.15: Effect Measures of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		106 (4.6%)	94 (4.1%)	200 (4.3%)
Number of subjects without events		2220 (95.4%)	2208 (95.9%)	4428 (95.7%)
Odds Ratio [a]				
OR, 95% CI	1.122 [0.844, 1.490]			
p-value	0.4283			
Relative Risk [b]				
RR, 95% CI	1.116 [0.851, 1.464]			
p-value	0.4283			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.007, 0.016]			
p-value	0.4279			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.16: Effect Measures of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		41 (1.8%)	40 (1.7%)	81 (1.8%)
Number of subjects without events		2285 (98.2%)	2262 (98.3%)	4547 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.015 [0.654, 1.575]			
p-value	0.9482			
Relative Risk [b]				
RR, 95% CI	1.014 [0.659, 1.562]			
p-value	0.9482			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.008]			
p-value	0.9482			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.17: Effect Measures of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		46 (2.0%)	45 (2.0%)	91 (2.0%)
Number of subjects without events		2280 (98.0%)	2257 (98.0%)	4537 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.012 [0.668, 1.532]			
p-value	0.9554			
Relative Risk [b]				
RR, 95% CI	1.012 [0.673, 1.520]			
p-value	0.9554			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9554			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.18: Effect Measures of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		285 (12.3%)	287 (12.5%)	572 (12.4%)
Number of subjects without events		2041 (87.7%)	2015 (87.5%)	4056 (87.6%)
Odds Ratio [a]				
OR, 95% CI	0.980 [0.823, 1.168]			
p-value	0.8245			
Relative Risk [b]				
RR, 95% CI	0.983 [0.843, 1.146]			
p-value	0.8245			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.021, 0.017]			
p-value	0.8245			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.19: Effect Measures of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		93 (4.0%)	86 (3.7%)	179 (3.9%)
Number of subjects without events		2233 (96.0%)	2216 (96.3%)	4449 (96.1%)
Odds Ratio [a]				
OR, 95% CI	1.073 [0.796, 1.447]			
p-value	0.6435			
Relative Risk [b]				
RR, 95% CI	1.070 [0.803, 1.427]			
p-value	0.6435			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.008, 0.014]			
p-value	0.6434			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.20: Effect Measures of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		69 (3.0%)	72 (3.1%)	141 (3.0%)
Number of subjects without events		2257 (97.0%)	2230 (96.9%)	4487 (97.0%)
Odds Ratio [a]				
OR, 95% CI	0.947 [0.677, 1.324]			
p-value	0.7497			
Relative Risk [b]				
RR, 95% CI	0.948 [0.685, 1.313]			
p-value	0.7497			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.012, 0.008]			
p-value	0.7497			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.21: Effect Measures of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	18 (0.8%)	50 (1.1%)
Number of subjects without events		2294 (98.6%)	2284 (99.2%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.770 [0.991, 3.162]			
p-value	0.0538			
Relative Risk [b]				
RR, 95% CI	1.759 [0.990, 3.125]			
p-value	0.0539			
Risk Difference [c]				
RD, 95% CI	0.006 [0.000, 0.012]			
p-value	0.0503			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.22: Effect Measures of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		600 (25.8%)	548 (23.8%)	1148 (24.8%)
Number of subjects without events		1726 (74.2%)	1754 (76.2%)	3480 (75.2%)
Odds Ratio [a]				
OR, 95% CI	1.113 [0.974, 1.272]			
p-value	0.1171			
Relative Risk [b]				
RR, 95% CI	1.084 [0.980, 1.198]			
p-value	0.1173			
Risk Difference [c]				
RD, 95% CI	0.020 [-0.005, 0.045]			
p-value	0.1169			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.23: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		47 (2.0%)	45 (2.0%)	92 (2.0%)
Number of subjects without events		2279 (98.0%)	2257 (98.0%)	4536 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.034 [0.684, 1.563]			
p-value	0.8726			
Relative Risk [b]				
RR, 95% CI	1.034 [0.690, 1.549]			
p-value	0.8726			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.007, 0.009]			
p-value	0.8726			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.24: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		39 (1.7%)	31 (1.3%)	70 (1.5%)
Number of subjects without events		2287 (98.3%)	2271 (98.7%)	4558 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.249 [0.777, 2.009]			
p-value	0.3586			
Relative Risk [b]				
RR, 95% CI	1.245 [0.780, 1.988]			
p-value	0.3587			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.004, 0.010]			
p-value	0.3574			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.25: Effect Measures of Proportion of Subjects with TEAEs - Chronic gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	27 (1.2%)	60 (1.3%)
Number of subjects without events		2293 (98.6%)	2275 (98.8%)	4568 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.213 [0.727, 2.023]			
p-value	0.4604			
Relative Risk [b]				
RR, 95% CI	1.210 [0.730, 2.005]			
p-value	0.4605			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.009]			
p-value	0.4595			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.26: Effect Measures of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		98 (4.2%)	93 (4.0%)	191 (4.1%)
Number of subjects without events		2228 (95.8%)	2209 (96.0%)	4437 (95.9%)
Odds Ratio [a]				
OR, 95% CI	1.045 [0.782, 1.396]			
p-value	0.7670			
Relative Risk [b]				
RR, 95% CI	1.043 [0.790, 1.377]			
p-value	0.7670			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.010, 0.013]			
p-value	0.7670			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.27: Effect Measures of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		141 (6.1%)	125 (5.4%)	266 (5.7%)
Number of subjects without events		2185 (93.9%)	2177 (94.6%)	4362 (94.3%)
Odds Ratio [a]				
OR, 95% CI	1.124 [0.877, 1.440]			
p-value	0.3560			
Relative Risk [b]				
RR, 95% CI	1.116 [0.884, 1.410]			
p-value	0.3561			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.007, 0.020]			
p-value	0.3556			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.28: Effect Measures of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		39 (1.7%)	25 (1.1%)	64 (1.4%)
Number of subjects without events		2287 (98.3%)	2277 (98.9%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.553 [0.937, 2.575]			
p-value	0.0878			
Relative Risk [b]				
RR, 95% CI	1.544 [0.938, 2.543]			
p-value	0.0879			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.001, 0.013]			
p-value	0.0849			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.29: Effect Measures of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		39 (1.7%)	33 (1.4%)	72 (1.6%)
Number of subjects without events		2287 (98.3%)	2269 (98.6%)	4556 (98.4%)
Odds Ratio [a]				
OR, 95% CI	1.173 [0.735, 1.871]			
p-value	0.5044			
Relative Risk [b]				
RR, 95% CI	1.170 [0.738, 1.853]			
p-value	0.5044			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.005, 0.010]			
p-value	0.5037			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.30: Effect Measures of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		39 (1.7%)	49 (2.1%)	88 (1.9%)
Number of subjects without events		2287 (98.3%)	2253 (97.9%)	4540 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.784 [0.513, 1.199]			
p-value	0.2615			
Relative Risk [b]				
RR, 95% CI	0.788 [0.519, 1.195]			
p-value	0.2616			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.003]			
p-value	0.2606			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.31: Effect Measures of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	23 (1.0%)	50 (1.1%)
Number of subjects without events		2299 (98.8%)	2279 (99.0%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.164 [0.665, 2.036]			
p-value	0.5951			
Relative Risk [b]				
RR, 95% CI	1.162 [0.668, 2.020]			
p-value	0.5952			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.008]			
p-value	0.5946			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.32: Effect Measures of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		23 (1.0%)	41 (1.8%)	64 (1.4%)
Number of subjects without events		2303 (99.0%)	2261 (98.2%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.551 [0.329, 0.921]			
p-value	0.0229			
Relative Risk [b]				
RR, 95% CI	0.555 [0.334, 0.922]			
p-value	0.0230			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.015, -0.001]			
p-value	0.0211			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.33: Effect Measures of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		52 (2.2%)	40 (1.7%)	92 (2.0%)
Number of subjects without events		2274 (97.8%)	2262 (98.3%)	4536 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.293 [0.853, 1.961]			
p-value	0.2261			
Relative Risk [b]				
RR, 95% CI	1.287 [0.855, 1.935]			
p-value	0.2263			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.003, 0.013]			
p-value	0.2246			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.34: Effect Measures of Proportion of Subjects with TEAEs - Toothache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		22 (0.9%)	22 (1.0%)	44 (1.0%)
Number of subjects without events		2304 (99.1%)	2280 (99.0%)	4584 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.990 [0.546, 1.792]			
p-value	0.9724			
Relative Risk [b]				
RR, 95% CI	0.990 [0.550, 1.782]			
p-value	0.9724			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.005]			
p-value	0.9724			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.35: Effect Measures of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		36 (1.5%)	37 (1.6%)	73 (1.6%)
Number of subjects without events		2290 (98.5%)	2265 (98.4%)	4555 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.962 [0.606, 1.528]			
p-value	0.8708			
Relative Risk [b]				
RR, 95% CI	0.963 [0.611, 1.518]			
p-value	0.8708			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.007]			
p-value	0.8708			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.36: Effect Measures of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		337 (14.5%)	387 (16.8%)	724 (15.6%)
Number of subjects without events		1989 (85.5%)	1915 (83.2%)	3904 (84.4%)
Odds Ratio [a]				
OR, 95% CI	0.838 [0.715, 0.983]			
p-value	0.0297			
Relative Risk [b]				
RR, 95% CI	0.862 [0.754, 0.986]			
p-value	0.0298			
Risk Difference [c]				
RD, 95% CI	-0.023 [-0.044, -0.002]			
p-value	0.0296			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.37: Effect Measures of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		30 (1.3%)	28 (1.2%)	58 (1.3%)
Number of subjects without events		2296 (98.7%)	2274 (98.8%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.061 [0.632, 1.782]			
p-value	0.8224			
Relative Risk [b]				
RR, 95% CI	1.060 [0.636, 1.769]			
p-value	0.8224			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.007]			
p-value	0.8223			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.38: Effect Measures of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		53 (2.3%)	60 (2.6%)	113 (2.4%)
Number of subjects without events		2273 (97.7%)	2242 (97.4%)	4515 (97.6%)
Odds Ratio [a]				
OR, 95% CI	0.871 [0.599, 1.267]			
p-value	0.4703			
Relative Risk [b]				
RR, 95% CI	0.874 [0.607, 1.259]			
p-value	0.4703			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.006]			
p-value	0.4701			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.39: Effect Measures of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	36 (1.6%)	69 (1.5%)
Number of subjects without events		2293 (98.6%)	2266 (98.4%)	4559 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.906 [0.563, 1.458]			
p-value	0.6839			
Relative Risk [b]				
RR, 95% CI	0.907 [0.568, 1.450]			
p-value	0.6839			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.6839			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.40: Effect Measures of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		110 (4.7%)	168 (7.3%)	278 (6.0%)
Number of subjects without events		2216 (95.3%)	2134 (92.7%)	4350 (94.0%)
Odds Ratio [a]				
OR, 95% CI	0.631 [0.492, 0.808]			
p-value	0.0003			
Relative Risk [b]				
RR, 95% CI	0.648 [0.513, 0.818]			
p-value	0.0003			
Risk Difference [c]				
RD, 95% CI	-0.026 [-0.039, -0.012]			
p-value	0.0002			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.41: Effect Measures of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		18 (0.8%)	22 (1.0%)	40 (0.9%)
Number of subjects without events		2308 (99.2%)	2280 (99.0%)	4588 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.808 [0.432, 1.511]			
p-value	0.5048			
Relative Risk [b]				
RR, 95% CI	0.810 [0.435, 1.506]			
p-value	0.5048			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.004]			
p-value	0.5042			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.42: Effect Measures of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	35 (1.5%)	67 (1.4%)
Number of subjects without events		2294 (98.6%)	2267 (98.5%)	4561 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.904 [0.557, 1.464]			
p-value	0.6805			
Relative Risk [b]				
RR, 95% CI	0.905 [0.562, 1.456]			
p-value	0.6805			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.005]			
p-value	0.6804			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.43: Effect Measures of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		143 (6.1%)	130 (5.6%)	273 (5.9%)
Number of subjects without events		2183 (93.9%)	2172 (94.4%)	4355 (94.1%)
Odds Ratio [a]				
OR, 95% CI	1.094 [0.857, 1.398]			
p-value	0.4700			
Relative Risk [b]				
RR, 95% CI	1.089 [0.865, 1.371]			
p-value	0.4700			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.009, 0.019]			
p-value	0.4697			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.44: Effect Measures of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		30 (1.3%)	28 (1.2%)	58 (1.3%)
Number of subjects without events		2296 (98.7%)	2274 (98.8%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.061 [0.632, 1.782]			
p-value	0.8224			
Relative Risk [b]				
RR, 95% CI	1.060 [0.636, 1.769]			
p-value	0.8224			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.007]			
p-value	0.8223			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.45: Effect Measures of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		55 (2.4%)	46 (2.0%)	101 (2.2%)
Number of subjects without events		2271 (97.6%)	2256 (98.0%)	4527 (97.8%)
Odds Ratio [a]				
OR, 95% CI	1.188 [0.799, 1.765]			
p-value	0.3943			
Relative Risk [b]				
RR, 95% CI	1.183 [0.803, 1.743]			
p-value	0.3944			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.005, 0.012]			
p-value	0.3935			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.46: Effect Measures of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		25 (1.1%)	20 (0.9%)	45 (1.0%)
Number of subjects without events		2301 (98.9%)	2282 (99.1%)	4583 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.240 [0.687, 2.238]			
p-value	0.4760			
Relative Risk [b]				
RR, 95% CI	1.237 [0.689, 2.221]			
p-value	0.4761			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.008]			
p-value	0.4749			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.47: Effect Measures of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		973 (41.8%)	1005 (43.7%)	1978 (42.7%)
Number of subjects without events		1353 (58.2%)	1297 (56.3%)	2650 (57.3%)
Odds Ratio [a]				
OR, 95% CI	0.928 [0.826, 1.043]			
p-value	0.2093			
Relative Risk [b]				
RR, 95% CI	0.958 [0.896, 1.024]			
p-value	0.2093			
Risk Difference [c]				
RD, 95% CI	-0.018 [-0.047, 0.010]			
p-value	0.2092			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.48: Effect Measures of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		117 (5.0%)	119 (5.2%)	236 (5.1%)
Number of subjects without events		2209 (95.0%)	2183 (94.8%)	4392 (94.9%)
Odds Ratio [a]				
OR, 95% CI	0.972 [0.748, 1.263]			
p-value	0.8294			
Relative Risk [b]				
RR, 95% CI	0.973 [0.759, 1.248]			
p-value	0.8294			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.014, 0.011]			
p-value	0.8294			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.49: Effect Measures of Proportion of Subjects with TEAEs - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		17 (0.7%)	33 (1.4%)	50 (1.1%)
Number of subjects without events		2309 (99.3%)	2269 (98.6%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.506 [0.281, 0.911]			
p-value	0.0233			
Relative Risk [b]				
RR, 95% CI	0.510 [0.285, 0.913]			
p-value	0.0234			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.013, -0.001]			
p-value	0.0209			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.50: Effect Measures of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		58 (2.5%)	53 (2.3%)	111 (2.4%)
Number of subjects without events		2268 (97.5%)	2249 (97.7%)	4517 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.085 [0.744, 1.582]			
p-value	0.6709			
Relative Risk [b]				
RR, 95% CI	1.083 [0.750, 1.565]			
p-value	0.6709			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.007, 0.011]			
p-value	0.6707			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.51: Effect Measures of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	41 (1.8%)	73 (1.6%)
Number of subjects without events		2294 (98.6%)	2261 (98.2%)	4555 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.769 [0.483, 1.226]			
p-value	0.2698			
Relative Risk [b]				
RR, 95% CI	0.772 [0.488, 1.222]			
p-value	0.2699			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.011, 0.003]			
p-value	0.2688			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.52: Effect Measures of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		14 (0.6%)	27 (1.2%)	41 (0.9%)
Number of subjects without events		2312 (99.4%)	2275 (98.8%)	4587 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.510 [0.267, 0.975]			
p-value	0.0418			
Relative Risk [b]				
RR, 95% CI	0.513 [0.270, 0.976]			
p-value	0.0420			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.011, 0.000]			
p-value	0.0384			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.53: Effect Measures of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		49 (2.1%)	55 (2.4%)	104 (2.2%)
Number of subjects without events		2277 (97.9%)	2247 (97.6%)	4524 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.879 [0.596, 1.298]			
p-value	0.5169			
Relative Risk [b]				
RR, 95% CI	0.882 [0.603, 1.290]			
p-value	0.5169			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.006]			
p-value	0.5167			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.54: Effect Measures of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		28 (1.2%)	30 (1.3%)	58 (1.3%)
Number of subjects without events		2298 (98.8%)	2272 (98.7%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.923 [0.550, 1.549]			
p-value	0.7612			
Relative Risk [b]				
RR, 95% CI	0.924 [0.554, 1.541]			
p-value	0.7612			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.007, 0.005]			
p-value	0.7612			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.55: Effect Measures of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		89 (3.8%)	103 (4.5%)	192 (4.1%)
Number of subjects without events		2237 (96.2%)	2199 (95.5%)	4436 (95.9%)
Odds Ratio [a]				
OR, 95% CI	0.849 [0.636, 1.135]			
p-value	0.2695			
Relative Risk [b]				
RR, 95% CI	0.855 [0.648, 1.129]			
p-value	0.2695			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.018, 0.005]			
p-value	0.2691			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.56: Effect Measures of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		179 (7.7%)	201 (8.7%)	380 (8.2%)
Number of subjects without events		2147 (92.3%)	2101 (91.3%)	4248 (91.8%)
Odds Ratio [a]				
OR, 95% CI	0.871 [0.706, 1.075]			
p-value	0.1996			
Relative Risk [b]				
RR, 95% CI	0.881 [0.727, 1.069]			
p-value	0.1997			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.026, 0.005]			
p-value	0.1994			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.57: Effect Measures of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		29 (1.2%)	28 (1.2%)	57 (1.2%)
Number of subjects without events		2297 (98.8%)	2274 (98.8%)	4571 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.025 [0.608, 1.729]			
p-value	0.9252			
Relative Risk [b]				
RR, 95% CI	1.025 [0.612, 1.717]			
p-value	0.9252			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.007]			
p-value	0.9252			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.58: Effect Measures of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		85 (3.7%)	129 (5.6%)	214 (4.6%)
Number of subjects without events		2241 (96.3%)	2173 (94.4%)	4414 (95.4%)
Odds Ratio [a]				
OR, 95% CI	0.639 [0.483, 0.845]			
p-value	0.0017			
Relative Risk [b]				
RR, 95% CI	0.652 [0.499, 0.852]			
p-value	0.0017			
Risk Difference [c]				
RD, 95% CI	-0.019 [-0.032, -0.007]			
p-value	0.0016			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.59: Effect Measures of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		43 (1.8%)	30 (1.3%)	73 (1.6%)
Number of subjects without events		2283 (98.2%)	2272 (98.7%)	4555 (98.4%)
Odds Ratio [a]				
OR, 95% CI	1.426 [0.892, 2.282]			
p-value	0.1384			
Relative Risk [b]				
RR, 95% CI	1.419 [0.893, 2.253]			
p-value	0.1386			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.002, 0.013]			
p-value	0.1360			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.60: Effect Measures of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		23 (1.0%)	27 (1.2%)	50 (1.1%)
Number of subjects without events		2303 (99.0%)	2275 (98.8%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.841 [0.481, 1.472]			
p-value	0.5452			
Relative Risk [b]				
RR, 95% CI	0.843 [0.485, 1.466]			
p-value	0.5453			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.5449			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.61: Effect Measures of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		133 (5.7%)	132 (5.7%)	265 (5.7%)
Number of subjects without events		2193 (94.3%)	2170 (94.3%)	4363 (94.3%)
Odds Ratio [a]				
OR, 95% CI	0.997 [0.778, 1.278]			
p-value	0.9811			
Relative Risk [b]				
RR, 95% CI	0.997 [0.789, 1.260]			
p-value	0.9811			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.014, 0.013]			
p-value	0.9811			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.62: Effect Measures of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		143 (6.1%)	131 (5.7%)	274 (5.9%)
Number of subjects without events		2183 (93.9%)	2171 (94.3%)	4354 (94.1%)
Odds Ratio [a]				
OR, 95% CI	1.086 [0.850, 1.386]			
p-value	0.5100			
Relative Risk [b]				
RR, 95% CI	1.080 [0.858, 1.360]			
p-value	0.5101			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.009, 0.018]			
p-value	0.5098			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.63: Effect Measures of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		368 (15.8%)	334 (14.5%)	702 (15.2%)
Number of subjects without events		1958 (84.2%)	1968 (85.5%)	3926 (84.8%)
Odds Ratio [a]				
OR, 95% CI	1.107 [0.943, 1.301]			
p-value	0.2136			
Relative Risk [b]				
RR, 95% CI	1.090 [0.951, 1.250]			
p-value	0.2137			
Risk Difference [c]				
RD, 95% CI	0.013 [-0.008, 0.034]			
p-value	0.2133			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.64: Effect Measures of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		39 (1.7%)	38 (1.7%)	77 (1.7%)
Number of subjects without events		2287 (98.3%)	2264 (98.3%)	4551 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.016 [0.647, 1.594]			
p-value	0.9450			
Relative Risk [b]				
RR, 95% CI	1.016 [0.652, 1.582]			
p-value	0.9450			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.008]			
p-value	0.9450			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.65: Effect Measures of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	35 (1.5%)	62 (1.3%)
Number of subjects without events		2299 (98.8%)	2267 (98.5%)	4566 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.761 [0.459, 1.261]			
p-value	0.2888			
Relative Risk [b]				
RR, 95% CI	0.763 [0.464, 1.257]			
p-value	0.2888			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.010, 0.003]			
p-value	0.2876			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.66: Effect Measures of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		29 (1.2%)	21 (0.9%)	50 (1.1%)
Number of subjects without events		2297 (98.8%)	2281 (99.1%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.371 [0.780, 2.412]			
p-value	0.2730			
Relative Risk [b]				
RR, 95% CI	1.367 [0.782, 2.389]			
p-value	0.2731			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.003, 0.009]			
p-value	0.2706			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.67: Effect Measures of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		50 (2.1%)	58 (2.5%)	108 (2.3%)
Number of subjects without events		2276 (97.9%)	2244 (97.5%)	4520 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.850 [0.580, 1.246]			
p-value	0.4051			
Relative Risk [b]				
RR, 95% CI	0.853 [0.587, 1.240]			
p-value	0.4051			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.012, 0.005]			
p-value	0.4047			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.68: Effect Measures of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		504 (21.7%)	502 (21.8%)	1006 (21.7%)
Number of subjects without events		1822 (78.3%)	1800 (78.2%)	3622 (78.3%)
Odds Ratio [a]				
OR, 95% CI	0.992 [0.863, 1.141]			
p-value	0.9087			
Relative Risk [b]				
RR, 95% CI	0.994 [0.891, 1.108]			
p-value	0.9087			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.025, 0.022]			
p-value	0.9087			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.69: Effect Measures of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		69 (3.0%)	93 (4.0%)	162 (3.5%)
Number of subjects without events		2257 (97.0%)	2209 (96.0%)	4466 (96.5%)
Odds Ratio [a]				
OR, 95% CI	0.726 [0.529, 0.997]			
p-value	0.0478			
Relative Risk [b]				
RR, 95% CI	0.734 [0.541, 0.997]			
p-value	0.0479			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.021, 0.000]			
p-value	0.0470			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.70: Effect Measures of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		28 (1.2%)	31 (1.3%)	59 (1.3%)
Number of subjects without events		2298 (98.8%)	2271 (98.7%)	4569 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.893 [0.534, 1.493]			
p-value	0.6650			
Relative Risk [b]				
RR, 95% CI	0.894 [0.538, 1.485]			
p-value	0.6651			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.005]			
p-value	0.6650			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.71: Effect Measures of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	14 (0.6%)	41 (0.9%)
Number of subjects without events		2299 (98.8%)	2288 (99.4%)	4587 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.919 [1.004, 3.670]			
p-value	0.0486			
Relative Risk [b]				
RR, 95% CI	1.909 [1.003, 3.630]			
p-value	0.0488			
Risk Difference [c]				
RD, 95% CI	0.006 [0.000, 0.011]			
p-value	0.0444			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.72: Effect Measures of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		36 (1.5%)	42 (1.8%)	78 (1.7%)
Number of subjects without events		2290 (98.5%)	2260 (98.2%)	4550 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.846 [0.540, 1.325]			
p-value	0.4651			
Relative Risk [b]				
RR, 95% CI	0.848 [0.546, 1.319]			
p-value	0.4651			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.005]			
p-value	0.4647			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.73: Effect Measures of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		79 (3.4%)	74 (3.2%)	153 (3.3%)
Number of subjects without events		2247 (96.6%)	2228 (96.8%)	4475 (96.7%)
Odds Ratio [a]				
OR, 95% CI	1.059 [0.767, 1.461]			
p-value	0.7295			
Relative Risk [b]				
RR, 95% CI	1.057 [0.774, 1.443]			
p-value	0.7295			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.008, 0.012]			
p-value	0.7294			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.74: Effect Measures of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		26 (1.1%)	31 (1.3%)	57 (1.2%)
Number of subjects without events		2300 (98.9%)	2271 (98.7%)	4571 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.828 [0.490, 1.399]			
p-value	0.4809			
Relative Risk [b]				
RR, 95% CI	0.830 [0.494, 1.393]			
p-value	0.4810			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.004]			
p-value	0.4805			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.75: Effect Measures of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		103 (4.4%)	92 (4.0%)	195 (4.2%)
Number of subjects without events		2223 (95.6%)	2210 (96.0%)	4433 (95.8%)
Odds Ratio [a]				
OR, 95% CI	1.113 [0.835, 1.483]			
p-value	0.4650			
Relative Risk [b]				
RR, 95% CI	1.108 [0.841, 1.459]			
p-value	0.4651			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.007, 0.016]			
p-value	0.4647			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.76: Effect Measures of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	31 (1.3%)	64 (1.4%)
Number of subjects without events		2293 (98.6%)	2271 (98.7%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.054 [0.644, 1.727]			
p-value	0.8337			
Relative Risk [b]				
RR, 95% CI	1.054 [0.647, 1.714]			
p-value	0.8337			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.007]			
p-value	0.8337			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.77: Effect Measures of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		30 (1.3%)	26 (1.1%)	56 (1.2%)
Number of subjects without events		2296 (98.7%)	2276 (98.9%)	4572 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.144 [0.674, 1.940]			
p-value	0.6182			
Relative Risk [b]				
RR, 95% CI	1.142 [0.678, 1.925]			
p-value	0.6182			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.005, 0.008]			
p-value	0.6178			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.78: Effect Measures of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		686 (29.5%)	623 (27.1%)	1309 (28.3%)
Number of subjects without events		1640 (70.5%)	1679 (72.9%)	3319 (71.7%)
Odds Ratio [a]				
OR, 95% CI	1.127 [0.992, 1.281]			
p-value	0.0666			
Relative Risk [b]				
RR, 95% CI	1.090 [0.994, 1.195]			
p-value	0.0668			
Risk Difference [c]				
RD, 95% CI	0.024 [-0.002, 0.050]			
p-value	0.0664			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.79: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		64 (2.8%)	85 (3.7%)	149 (3.2%)
Number of subjects without events		2262 (97.2%)	2217 (96.3%)	4479 (96.8%)
Odds Ratio [a]				
OR, 95% CI	0.738 [0.531, 1.026]			
p-value	0.0708			
Relative Risk [b]				
RR, 95% CI	0.745 [0.542, 1.025]			
p-value	0.0709			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.020, 0.001]			
p-value	0.0699			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.80: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		67 (2.9%)	49 (2.1%)	116 (2.5%)
Number of subjects without events		2259 (97.1%)	2253 (97.9%)	4512 (97.5%)
Odds Ratio [a]				
OR, 95% CI	1.364 [0.939, 1.980]			
p-value	0.1031			
Relative Risk [b]				
RR, 95% CI	1.353 [0.940, 1.947]			
p-value	0.1032			
Risk Difference [c]				
RD, 95% CI	0.008 [-0.001, 0.017]			
p-value	0.1015			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.81: Effect Measures of Proportion of Subjects with TEAEs - Diabetic metabolic decompensation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	22 (1.0%)	54 (1.2%)
Number of subjects without events		2294 (98.6%)	2280 (99.0%)	4574 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.446 [0.837, 2.495]			
p-value	0.1857			
Relative Risk [b]				
RR, 95% CI	1.440 [0.839, 2.470]			
p-value	0.1859			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.002, 0.010]			
p-value	0.1829			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.82: Effect Measures of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		37 (1.6%)	30 (1.3%)	67 (1.4%)
Number of subjects without events		2289 (98.4%)	2272 (98.7%)	4561 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.224 [0.754, 1.988]			
p-value	0.4137			
Relative Risk [b]				
RR, 95% CI	1.221 [0.757, 1.969]			
p-value	0.4138			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.004, 0.010]			
p-value	0.4127			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.83: Effect Measures of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		41 (1.8%)	33 (1.4%)	74 (1.6%)
Number of subjects without events		2285 (98.2%)	2269 (98.6%)	4554 (98.4%)
Odds Ratio [a]				
OR, 95% CI	1.234 [0.777, 1.958]			
p-value	0.3729			
Relative Risk [b]				
RR, 95% CI	1.230 [0.780, 1.938]			
p-value	0.3730			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.004, 0.011]			
p-value	0.3718			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.84: Effect Measures of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		59 (2.5%)	52 (2.3%)	111 (2.4%)
Number of subjects without events		2267 (97.5%)	2250 (97.7%)	4517 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.126 [0.772, 1.642]			
p-value	0.5373			
Relative Risk [b]				
RR, 95% CI	1.123 [0.777, 1.623]			
p-value	0.5373			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.006, 0.012]			
p-value	0.5369			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.85: Effect Measures of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		149 (6.4%)	77 (3.3%)	226 (4.9%)
Number of subjects without events		2177 (93.6%)	2225 (96.7%)	4402 (95.1%)
Odds Ratio [a]				
OR, 95% CI	1.978 [1.493, 2.620]			
p-value	0.0000			
Relative Risk [b]				
RR, 95% CI	1.915 [1.463, 2.506]			
p-value	0.0000			
Risk Difference [c]				
RD, 95% CI	0.031 [0.018, 0.043]			
p-value	0.0000			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.86: Effect Measures of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		24 (1.0%)	28 (1.2%)	52 (1.1%)
Number of subjects without events		2302 (99.0%)	2274 (98.8%)	4576 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.847 [0.489, 1.465]			
p-value	0.5520			
Relative Risk [b]				
RR, 95% CI	0.848 [0.493, 1.459]			
p-value	0.5520			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.5517			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.87: Effect Measures of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		47 (2.0%)	32 (1.4%)	79 (1.7%)
Number of subjects without events		2279 (98.0%)	2270 (98.6%)	4549 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.463 [0.930, 2.301]			
p-value	0.0997			
Relative Risk [b]				
RR, 95% CI	1.454 [0.931, 2.269]			
p-value	0.0998			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.001, 0.014]			
p-value	0.0974			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.88: Effect Measures of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		104 (4.5%)	69 (3.0%)	173 (3.7%)
Number of subjects without events		2222 (95.5%)	2233 (97.0%)	4455 (96.3%)
Odds Ratio [a]				
OR, 95% CI	1.515 [1.111, 2.065]			
p-value	0.0086			
Relative Risk [b]				
RR, 95% CI	1.492 [1.106, 2.011]			
p-value	0.0087			
Risk Difference [c]				
RD, 95% CI	0.015 [0.004, 0.026]			
p-value	0.0081			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.89: Effect Measures of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		100 (4.3%)	91 (4.0%)	191 (4.1%)
Number of subjects without events		2226 (95.7%)	2211 (96.0%)	4437 (95.9%)
Odds Ratio [a]				
OR, 95% CI	1.091 [0.817, 1.459]			
p-value	0.5540			
Relative Risk [b]				
RR, 95% CI	1.088 [0.824, 1.436]			
p-value	0.5541			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.008, 0.015]			
p-value	0.5538			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.90: Effect Measures of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		25 (1.1%)	51 (2.2%)	76 (1.6%)
Number of subjects without events		2301 (98.9%)	2251 (97.8%)	4552 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.480 [0.296, 0.777]			
p-value	0.0028			
Relative Risk [b]				
RR, 95% CI	0.485 [0.302, 0.780]			
p-value	0.0028			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.019, -0.004]			
p-value	0.0023			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.91: Effect Measures of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		25 (1.1%)	10 (0.4%)	35 (0.8%)
Number of subjects without events		2301 (98.9%)	2292 (99.6%)	4593 (99.2%)
Odds Ratio [a]				
OR, 95% CI	2.490 [1.193, 5.197]			
p-value	0.0151			
Relative Risk [b]				
RR, 95% CI	2.474 [1.191, 5.140]			
p-value	0.0152			
Risk Difference [c]				
RD, 95% CI	0.006 [0.001, 0.011]			
p-value	0.0117			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.92: Effect Measures of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		53 (2.3%)	53 (2.3%)	106 (2.3%)
Number of subjects without events		2273 (97.7%)	2249 (97.7%)	4522 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.989 [0.673, 1.454]			
p-value	0.9569			
Relative Risk [b]				
RR, 95% CI	0.990 [0.679, 1.442]			
p-value	0.9569			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.009, 0.008]			
p-value	0.9569			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.93: Effect Measures of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		44 (1.9%)	38 (1.7%)	82 (1.8%)
Number of subjects without events		2282 (98.1%)	2264 (98.3%)	4546 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.149 [0.741, 1.780]			
p-value	0.5348			
Relative Risk [b]				
RR, 95% CI	1.146 [0.745, 1.762]			
p-value	0.5348			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.005, 0.010]			
p-value	0.5343			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.94: Effect Measures of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		615 (26.4%)	607 (26.4%)	1222 (26.4%)
Number of subjects without events		1711 (73.6%)	1695 (73.6%)	3406 (73.6%)
Odds Ratio [a]				
OR, 95% CI	1.004 [0.881, 1.144]			
p-value	0.9558			
Relative Risk [b]				
RR, 95% CI	1.003 [0.911, 1.104]			
p-value	0.9558			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.025, 0.026]			
p-value	0.9558			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.95: Effect Measures of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		176 (7.6%)	154 (6.7%)	330 (7.1%)
Number of subjects without events		2150 (92.4%)	2148 (93.3%)	4298 (92.9%)
Odds Ratio [a]				
OR, 95% CI	1.142 [0.912, 1.429]			
p-value	0.2468			
Relative Risk [b]				
RR, 95% CI	1.131 [0.918, 1.393]			
p-value	0.2469			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.006, 0.024]			
p-value	0.2463			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.96: Effect Measures of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		23 (1.0%)	19 (0.8%)	42 (0.9%)
Number of subjects without events		2303 (99.0%)	2283 (99.2%)	4586 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.200 [0.652, 2.209]			
p-value	0.5582			
Relative Risk [b]				
RR, 95% CI	1.198 [0.654, 2.194]			
p-value	0.5582			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.007]			
p-value	0.5575			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.97: Effect Measures of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		147 (6.3%)	135 (5.9%)	282 (6.1%)
Number of subjects without events		2179 (93.7%)	2167 (94.1%)	4346 (93.9%)
Odds Ratio [a]				
OR, 95% CI	1.083 [0.851, 1.378]			
p-value	0.5174			
Relative Risk [b]				
RR, 95% CI	1.078 [0.859, 1.351]			
p-value	0.5174			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.009, 0.018]			
p-value	0.5172			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.98: Effect Measures of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		30 (1.3%)	29 (1.3%)	59 (1.3%)
Number of subjects without events		2296 (98.7%)	2273 (98.7%)	4569 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.024 [0.613, 1.712]			
p-value	0.9275			
Relative Risk [b]				
RR, 95% CI	1.024 [0.617, 1.700]			
p-value	0.9275			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.007]			
p-value	0.9275			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.99: Effect Measures of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		60 (2.6%)	74 (3.2%)	134 (2.9%)
Number of subjects without events		2266 (97.4%)	2228 (96.8%)	4494 (97.1%)
Odds Ratio [a]				
OR, 95% CI	0.797 [0.564, 1.126]			
p-value	0.1985			
Relative Risk [b]				
RR, 95% CI	0.802 [0.574, 1.122]			
p-value	0.1986			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.016, 0.003]			
p-value	0.1978			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.100: Effect Measures of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		41 (1.8%)	47 (2.0%)	88 (1.9%)
Number of subjects without events		2285 (98.2%)	2255 (98.0%)	4540 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.861 [0.564, 1.314]			
p-value	0.4875			
Relative Risk [b]				
RR, 95% CI	0.863 [0.570, 1.307]			
p-value	0.4875			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.005]			
p-value	0.4873			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.101: Effect Measures of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		25 (1.1%)	25 (1.1%)	50 (1.1%)
Number of subjects without events		2301 (98.9%)	2277 (98.9%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.990 [0.567, 1.728]			
p-value	0.9706			
Relative Risk [b]				
RR, 95% CI	0.990 [0.570, 1.718]			
p-value	0.9706			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9706			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.102: Effect Measures of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		55 (2.4%)	59 (2.6%)	114 (2.5%)
Number of subjects without events		2271 (97.6%)	2243 (97.4%)	4514 (97.5%)
Odds Ratio [a]				
OR, 95% CI	0.921 [0.635, 1.336]			
p-value	0.6634			
Relative Risk [b]				
RR, 95% CI	0.923 [0.642, 1.326]			
p-value	0.6634			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.007]			
p-value	0.6633			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.103: Effect Measures of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		86 (3.7%)	76 (3.3%)	162 (3.5%)
Number of subjects without events		2240 (96.3%)	2226 (96.7%)	4466 (96.5%)
Odds Ratio [a]				
OR, 95% CI	1.125 [0.821, 1.539]			
p-value	0.4640			
Relative Risk [b]				
RR, 95% CI	1.120 [0.827, 1.516]			
p-value	0.4641			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.007, 0.015]			
p-value	0.4636			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.104: Effect Measures of Proportion of Subjects with TEAEs - Rotator cuff syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		21 (0.9%)	27 (1.2%)	48 (1.0%)
Number of subjects without events		2305 (99.1%)	2275 (98.8%)	4580 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.768 [0.433, 1.362]			
p-value	0.3659			
Relative Risk [b]				
RR, 95% CI	0.770 [0.436, 1.358]			
p-value	0.3660			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.003]			
p-value	0.3649			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.105: Effect Measures of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	31 (1.3%)	58 (1.3%)
Number of subjects without events		2299 (98.8%)	2271 (98.7%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.860 [0.512, 1.446]			
p-value	0.5702			
Relative Risk [b]				
RR, 95% CI	0.862 [0.516, 1.439]			
p-value	0.5702			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.005]			
p-value	0.5700			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.106: Effect Measures of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		155 (6.7%)	171 (7.4%)	326 (7.0%)
Number of subjects without events		2171 (93.3%)	2131 (92.6%)	4302 (93.0%)
Odds Ratio [a]				
OR, 95% CI	0.890 [0.710, 1.115]			
p-value	0.3097			
Relative Risk [b]				
RR, 95% CI	0.897 [0.727, 1.106]			
p-value	0.3098			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.022, 0.007]			
p-value	0.3096			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.107: Effect Measures of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		470 (20.2%)	433 (18.8%)	903 (19.5%)
Number of subjects without events		1856 (79.8%)	1869 (81.2%)	3725 (80.5%)
Odds Ratio [a]				
OR, 95% CI	1.093 [0.945, 1.264]			
p-value	0.2307			
Relative Risk [b]				
RR, 95% CI	1.074 [0.955, 1.208]			
p-value	0.2308			
Risk Difference [c]				
RD, 95% CI	0.014 [-0.009, 0.037]			
p-value	0.2305			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.108: Effect Measures of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		55 (2.4%)	61 (2.6%)	116 (2.5%)
Number of subjects without events		2271 (97.6%)	2241 (97.4%)	4512 (97.5%)
Odds Ratio [a]				
OR, 95% CI	0.890 [0.615, 1.287]			
p-value	0.5350			
Relative Risk [b]				
RR, 95% CI	0.892 [0.623, 1.279]			
p-value	0.5350			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.006]			
p-value	0.5348			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.109: Effect Measures of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		100 (4.3%)	79 (3.4%)	179 (3.9%)
Number of subjects without events		2226 (95.7%)	2223 (96.6%)	4449 (96.1%)
Odds Ratio [a]				
OR, 95% CI	1.264 [0.936, 1.708]			
p-value	0.1268			
Relative Risk [b]				
RR, 95% CI	1.253 [0.938, 1.673]			
p-value	0.1269			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.002, 0.020]			
p-value	0.1257			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.110: Effect Measures of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		85 (3.7%)	73 (3.2%)	158 (3.4%)
Number of subjects without events		2241 (96.3%)	2229 (96.8%)	4470 (96.6%)
Odds Ratio [a]				
OR, 95% CI	1.158 [0.843, 1.592]			
p-value	0.3658			
Relative Risk [b]				
RR, 95% CI	1.152 [0.847, 1.567]			
p-value	0.3659			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.006, 0.015]			
p-value	0.3652			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.111: Effect Measures of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		21 (0.9%)	26 (1.1%)	47 (1.0%)
Number of subjects without events		2305 (99.1%)	2276 (98.9%)	4581 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.798 [0.447, 1.422]			
p-value	0.4430			
Relative Risk [b]				
RR, 95% CI	0.799 [0.451, 1.417]			
p-value	0.4430			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.4422			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.112: Effect Measures of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		18 (0.8%)	28 (1.2%)	46 (1.0%)
Number of subjects without events		2308 (99.2%)	2274 (98.8%)	4582 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.633 [0.349, 1.148]			
p-value	0.1325			
Relative Risk [b]				
RR, 95% CI	0.636 [0.353, 1.147]			
p-value	0.1326			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.010, 0.001]			
p-value	0.1296			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.113: Effect Measures of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		134 (5.8%)	131 (5.7%)	265 (5.7%)
Number of subjects without events		2192 (94.2%)	2171 (94.3%)	4363 (94.3%)
Odds Ratio [a]				
OR, 95% CI	1.013 [0.791, 1.298]			
p-value	0.9181			
Relative Risk [b]				
RR, 95% CI	1.012 [0.801, 1.279]			
p-value	0.9181			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.013, 0.014]			
p-value	0.9181			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.114: Effect Measures of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		18 (0.8%)	23 (1.0%)	41 (0.9%)
Number of subjects without events		2308 (99.2%)	2279 (99.0%)	4587 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.773 [0.416, 1.436]			
p-value	0.4148			
Relative Risk [b]				
RR, 95% CI	0.775 [0.419, 1.431]			
p-value	0.4148			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.003]			
p-value	0.4138			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.115: Effect Measures of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		36 (1.5%)	41 (1.8%)	77 (1.7%)
Number of subjects without events		2290 (98.5%)	2261 (98.2%)	4551 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.867 [0.552, 1.362]			
p-value	0.5353			
Relative Risk [b]				
RR, 95% CI	0.869 [0.557, 1.355]			
p-value	0.5353			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.010, 0.005]			
p-value	0.5351			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.116: Effect Measures of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		49 (2.1%)	42 (1.8%)	91 (2.0%)
Number of subjects without events		2277 (97.9%)	2260 (98.2%)	4537 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.158 [0.764, 1.756]			
p-value	0.4898			
Relative Risk [b]				
RR, 95% CI	1.155 [0.768, 1.737]			
p-value	0.4899			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.005, 0.011]			
p-value	0.4893			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.117: Effect Measures of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		241 (10.4%)	307 (13.3%)	548 (11.8%)
Number of subjects without events		2085 (89.6%)	1995 (86.7%)	4080 (88.2%)
Odds Ratio [a]				
OR, 95% CI	0.751 [0.628, 0.899]			
p-value	0.0018			
Relative Risk [b]				
RR, 95% CI	0.777 [0.663, 0.910]			
p-value	0.0018			
Risk Difference [c]				
RD, 95% CI	-0.030 [-0.048, -0.011]			
p-value	0.0017			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.118: Effect Measures of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	33 (1.4%)	66 (1.4%)
Number of subjects without events		2293 (98.6%)	2269 (98.6%)	4562 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.990 [0.609, 1.609]			
p-value	0.9662			
Relative Risk [b]				
RR, 95% CI	0.990 [0.613, 1.598]			
p-value	0.9662			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.007]			
p-value	0.9662			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.119: Effect Measures of Proportion of Subjects with TEAEs - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		11 (0.5%)	29 (1.3%)	40 (0.9%)
Number of subjects without events		2315 (99.5%)	2273 (98.7%)	4588 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.372 [0.186, 0.747]			
p-value	0.0054			
Relative Risk [b]				
RR, 95% CI	0.375 [0.188, 0.750]			
p-value	0.0055			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.013, -0.003]			
p-value	0.0039			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.120: Effect Measures of Proportion of Subjects with TEAEs - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		11 (0.5%)	23 (1.0%)	34 (0.7%)
Number of subjects without events		2315 (99.5%)	2279 (99.0%)	4594 (99.3%)
Odds Ratio [a]				
OR, 95% CI	0.471 [0.229, 0.968]			
p-value	0.0405			
Relative Risk [b]				
RR, 95% CI	0.473 [0.231, 0.969]			
p-value	0.0407			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.000]			
p-value	0.0363			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.121: Effect Measures of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		19 (0.8%)	33 (1.4%)	52 (1.1%)
Number of subjects without events		2307 (99.2%)	2269 (98.6%)	4576 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.566 [0.321, 0.999]			
p-value	0.0495			
Relative Risk [b]				
RR, 95% CI	0.570 [0.325, 0.999]			
p-value	0.0496			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.012, 0.000]			
p-value	0.0468			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.122: Effect Measures of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		31 (1.3%)	34 (1.5%)	65 (1.4%)
Number of subjects without events		2295 (98.7%)	2268 (98.5%)	4563 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.901 [0.552, 1.471]			
p-value	0.6769			
Relative Risk [b]				
RR, 95% CI	0.902 [0.557, 1.463]			
p-value	0.6769			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.005]			
p-value	0.6769			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.123: Effect Measures of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		26 (1.1%)	32 (1.4%)	58 (1.3%)
Number of subjects without events		2300 (98.9%)	2270 (98.6%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.802 [0.476, 1.350]			
p-value	0.4060			
Relative Risk [b]				
RR, 95% CI	0.804 [0.481, 1.345]			
p-value	0.4060			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.004]			
p-value	0.4053			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.124: Effect Measures of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	29 (1.3%)	61 (1.3%)
Number of subjects without events		2294 (98.6%)	2273 (98.7%)	4567 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.093 [0.659, 1.813]			
p-value	0.7295			
Relative Risk [b]				
RR, 95% CI	1.092 [0.663, 1.799]			
p-value	0.7295			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.005, 0.008]			
p-value	0.7294			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.125: Effect Measures of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		150 (6.4%)	142 (6.2%)	292 (6.3%)
Number of subjects without events		2176 (93.6%)	2160 (93.8%)	4336 (93.7%)
Odds Ratio [a]				
OR, 95% CI	1.049 [0.827, 1.329]			
p-value	0.6950			
Relative Risk [b]				
RR, 95% CI	1.045 [0.837, 1.305]			
p-value	0.6950			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.011, 0.017]			
p-value	0.6949			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.126: Effect Measures of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		66 (2.8%)	65 (2.8%)	131 (2.8%)
Number of subjects without events		2260 (97.2%)	2237 (97.2%)	4497 (97.2%)
Odds Ratio [a]				
OR, 95% CI	1.005 [0.710, 1.423]			
p-value	0.9773			
Relative Risk [b]				
RR, 95% CI	1.005 [0.717, 1.408]			
p-value	0.9773			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.009, 0.010]			
p-value	0.9773			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.127: Effect Measures of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		374 (16.1%)	391 (17.0%)	765 (16.5%)
Number of subjects without events		1952 (83.9%)	1911 (83.0%)	3863 (83.5%)
Odds Ratio [a]				
OR, 95% CI	0.936 [0.802, 1.094]			
p-value	0.4067			
Relative Risk [b]				
RR, 95% CI	0.947 [0.832, 1.078]			
p-value	0.4068			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.030, 0.012]			
p-value	0.4067			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.128: Effect Measures of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		34 (1.5%)	36 (1.6%)	70 (1.5%)
Number of subjects without events		2292 (98.5%)	2266 (98.4%)	4558 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.934 [0.582, 1.497]			
p-value	0.7760			
Relative Risk [b]				
RR, 95% CI	0.935 [0.587, 1.488]			
p-value	0.7760			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.7760			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.129: Effect Measures of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		97 (4.2%)	101 (4.4%)	198 (4.3%)
Number of subjects without events		2229 (95.8%)	2201 (95.6%)	4430 (95.7%)
Odds Ratio [a]				
OR, 95% CI	0.948 [0.713, 1.261]			
p-value	0.7150			
Relative Risk [b]				
RR, 95% CI	0.950 [0.724, 1.248]			
p-value	0.7150			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.014, 0.009]			
p-value	0.7150			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.130: Effect Measures of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		47 (2.0%)	71 (3.1%)	118 (2.5%)
Number of subjects without events		2279 (98.0%)	2231 (96.9%)	4510 (97.5%)
Odds Ratio [a]				
OR, 95% CI	0.648 [0.446, 0.941]			
p-value	0.0227			
Relative Risk [b]				
RR, 95% CI	0.655 [0.455, 0.943]			
p-value	0.0228			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.020, -0.002]			
p-value	0.0218			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.131: Effect Measures of Proportion of Subjects with TEAEs - Oropharyngeal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	26 (1.1%)	53 (1.1%)
Number of subjects without events		2299 (98.8%)	2276 (98.9%)	4575 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.028 [0.598, 1.767]			
p-value	0.9202			
Relative Risk [b]				
RR, 95% CI	1.028 [0.602, 1.756]			
p-value	0.9202			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9202			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.132: Effect Measures of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		24 (1.0%)	25 (1.1%)	49 (1.1%)
Number of subjects without events		2302 (99.0%)	2277 (98.9%)	4579 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.950 [0.541, 1.668]			
p-value	0.8571			
Relative Risk [b]				
RR, 95% CI	0.950 [0.544, 1.659]			
p-value	0.8571			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.005]			
p-value	0.8571			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.133: Effect Measures of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		334 (14.4%)	325 (14.1%)	659 (14.2%)
Number of subjects without events		1992 (85.6%)	1977 (85.9%)	3969 (85.8%)
Odds Ratio [a]				
OR, 95% CI	1.020 [0.865, 1.203]			
p-value	0.8143			
Relative Risk [b]				
RR, 95% CI	1.017 [0.883, 1.172]			
p-value	0.8143			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.018, 0.023]			
p-value	0.8143			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.134: Effect Measures of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		36 (1.5%)	30 (1.3%)	66 (1.4%)
Number of subjects without events		2290 (98.5%)	2272 (98.7%)	4562 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.191 [0.731, 1.939]			
p-value	0.4836			
Relative Risk [b]				
RR, 95% CI	1.188 [0.734, 1.921]			
p-value	0.4836			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.009]			
p-value	0.4828			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.135: Effect Measures of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		35 (1.5%)	32 (1.4%)	67 (1.4%)
Number of subjects without events		2291 (98.5%)	2270 (98.6%)	4561 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.084 [0.669, 1.756]			
p-value	0.7442			
Relative Risk [b]				
RR, 95% CI	1.082 [0.673, 1.742]			
p-value	0.7442			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.008]			
p-value	0.7440			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.136: Effect Measures of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		41 (1.8%)	40 (1.7%)	81 (1.8%)
Number of subjects without events		2285 (98.2%)	2262 (98.3%)	4547 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.015 [0.654, 1.575]			
p-value	0.9482			
Relative Risk [b]				
RR, 95% CI	1.014 [0.659, 1.562]			
p-value	0.9482			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.008]			
p-value	0.9482			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.137: Effect Measures of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		30 (1.3%)	34 (1.5%)	64 (1.4%)
Number of subjects without events		2296 (98.7%)	2268 (98.5%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.872 [0.532, 1.429]			
p-value	0.5858			
Relative Risk [b]				
RR, 95% CI	0.873 [0.536, 1.422]			
p-value	0.5859			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.005]			
p-value	0.5857			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.138: Effect Measures of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		50 (2.1%)	57 (2.5%)	107 (2.3%)
Number of subjects without events		2276 (97.9%)	2245 (97.5%)	4521 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.865 [0.589, 1.271]			
p-value	0.4603			
Relative Risk [b]				
RR, 95% CI	0.868 [0.596, 1.264]			
p-value	0.4603			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.005]			
p-value	0.4601			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.139: Effect Measures of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		145 (6.2%)	113 (4.9%)	258 (5.6%)
Number of subjects without events		2181 (93.8%)	2189 (95.1%)	4370 (94.4%)
Odds Ratio [a]				
OR, 95% CI	1.288 [1.000, 1.659]			
p-value	0.0500			
Relative Risk [b]				
RR, 95% CI	1.270 [1.000, 1.613]			
p-value	0.0501			
Risk Difference [c]				
RD, 95% CI	0.013 [0.000, 0.026]			
p-value	0.0492			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.140: Effect Measures of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		21 (0.9%)	22 (1.0%)	43 (0.9%)
Number of subjects without events		2305 (99.1%)	2280 (99.0%)	4585 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.944 [0.518, 1.722]			
p-value	0.8514			
Relative Risk [b]				
RR, 95% CI	0.945 [0.521, 1.713]			
p-value	0.8514			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.005]			
p-value	0.8514			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.141: Effect Measures of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		347 (14.9%)	398 (17.3%)	745 (16.1%)
Number of subjects without events		1979 (85.1%)	1904 (82.7%)	3883 (83.9%)
Odds Ratio [a]				
OR, 95% CI	0.839 [0.717, 0.982]			
p-value	0.0283			
Relative Risk [b]				
RR, 95% CI	0.863 [0.756, 0.985]			
p-value	0.0284			
Risk Difference [c]				
RD, 95% CI	-0.024 [-0.045, -0.003]			
p-value	0.0282			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.142: Effect Measures of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		141 (6.1%)	202 (8.8%)	343 (7.4%)
Number of subjects without events		2185 (93.9%)	2100 (91.2%)	4285 (92.6%)
Odds Ratio [a]				
OR, 95% CI	0.671 [0.537, 0.839]			
p-value	0.0005			
Relative Risk [b]				
RR, 95% CI	0.691 [0.562, 0.850]			
p-value	0.0005			
Risk Difference [c]				
RD, 95% CI	-0.027 [-0.042, -0.012]			
p-value	0.0004			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.143: Effect Measures of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		69 (3.0%)	36 (1.6%)	105 (2.3%)
Number of subjects without events		2257 (97.0%)	2266 (98.4%)	4523 (97.7%)
Odds Ratio [a]				
OR, 95% CI	1.924 [1.281, 2.891]			
p-value	0.0016			
Relative Risk [b]				
RR, 95% CI	1.897 [1.273, 2.827]			
p-value	0.0017			
Risk Difference [c]				
RD, 95% CI	0.014 [0.005, 0.023]			
p-value	0.0013			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.144: Effect Measures of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		28 (1.2%)	39 (1.7%)	67 (1.4%)
Number of subjects without events		2298 (98.8%)	2263 (98.3%)	4561 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.707 [0.434, 1.153]			
p-value	0.1646			
Relative Risk [b]				
RR, 95% CI	0.711 [0.439, 1.151]			
p-value	0.1647			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.002]			
p-value	0.1628			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.145: Effect Measures of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		32 (1.4%)	32 (1.4%)	64 (1.4%)
Number of subjects without events		2294 (98.6%)	2270 (98.6%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.990 [0.604, 1.621]			
p-value	0.9667			
Relative Risk [b]				
RR, 95% CI	0.990 [0.608, 1.610]			
p-value	0.9667			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.007]			
p-value	0.9667			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.146: Effect Measures of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		40 (1.7%)	30 (1.3%)	70 (1.5%)
Number of subjects without events		2286 (98.3%)	2272 (98.7%)	4558 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.325 [0.823, 2.135]			
p-value	0.2473			
Relative Risk [b]				
RR, 95% CI	1.320 [0.825, 2.111]			
p-value	0.2474			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.003, 0.011]			
p-value	0.2454			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.147: Effect Measures of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		57 (2.5%)	65 (2.8%)	122 (2.6%)
Number of subjects without events		2269 (97.5%)	2237 (97.2%)	4506 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.865 [0.603, 1.240]			
p-value	0.4287			
Relative Risk [b]				
RR, 95% CI	0.868 [0.611, 1.233]			
p-value	0.4287			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.013, 0.006]			
p-value	0.4284			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.148: Effect Measures of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		28 (1.2%)	34 (1.5%)	62 (1.3%)
Number of subjects without events		2298 (98.8%)	2268 (98.5%)	4566 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.813 [0.491, 1.345]			
p-value	0.4197			
Relative Risk [b]				
RR, 95% CI	0.815 [0.496, 1.340]			
p-value	0.4198			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.004]			
p-value	0.4191			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.149: Effect Measures of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		202 (8.7%)	236 (10.3%)	438 (9.5%)
Number of subjects without events		2124 (91.3%)	2066 (89.7%)	4190 (90.5%)
Odds Ratio [a]				
OR, 95% CI	0.833 [0.683, 1.014]			
p-value	0.0688			
Relative Risk [b]				
RR, 95% CI	0.847 [0.708, 1.013]			
p-value	0.0689			
Risk Difference [c]				
RD, 95% CI	-0.016 [-0.033, 0.001]			
p-value	0.0685			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.150: Effect Measures of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		40 (1.7%)	68 (3.0%)	108 (2.3%)
Number of subjects without events		2286 (98.3%)	2234 (97.0%)	4520 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.575 [0.387, 0.853]			
p-value	0.0060			
Relative Risk [b]				
RR, 95% CI	0.582 [0.396, 0.857]			
p-value	0.0061			
Risk Difference [c]				
RD, 95% CI	-0.012 [-0.021, -0.004]			
p-value	0.0054			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.151: Effect Measures of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		62 (2.7%)	48 (2.1%)	110 (2.4%)
Number of subjects without events		2264 (97.3%)	2254 (97.9%)	4518 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.286 [0.878, 1.883]			
p-value	0.1961			
Relative Risk [b]				
RR, 95% CI	1.278 [0.881, 1.855]			
p-value	0.1962			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.003, 0.015]			
p-value	0.1946			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.152: Effect Measures of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		16 (0.7%)	23 (1.0%)	39 (0.8%)
Number of subjects without events		2310 (99.3%)	2279 (99.0%)	4589 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.686 [0.362, 1.302]			
p-value	0.2495			
Relative Risk [b]				
RR, 95% CI	0.688 [0.365, 1.300]			
p-value	0.2496			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.008, 0.002]			
p-value	0.2472			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.153: Effect Measures of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		106 (4.6%)	92 (4.0%)	198 (4.3%)
Number of subjects without events		2220 (95.4%)	2210 (96.0%)	4430 (95.7%)
Odds Ratio [a]				
OR, 95% CI	1.147 [0.862, 1.526]			
p-value	0.3463			
Relative Risk [b]				
RR, 95% CI	1.140 [0.868, 1.499]			
p-value	0.3464			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.006, 0.017]			
p-value	0.3458			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.154: Effect Measures of Proportion of Subjects with TESAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	21 (0.9%)	48 (1.0%)
Number of subjects without events		2299 (98.8%)	2281 (99.1%)	4580 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.276 [0.719, 2.263]			
p-value	0.4052			
Relative Risk [b]				
RR, 95% CI	1.272 [0.722, 2.244]			
p-value	0.4052			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.003, 0.008]			
p-value	0.4037			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.155: Effect Measures of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		44 (1.9%)	43 (1.9%)	87 (1.9%)
Number of subjects without events		2282 (98.1%)	2259 (98.1%)	4541 (98.1%)
Odds Ratio [a]				
OR, 95% CI	1.013 [0.663, 1.548]			
p-value	0.9526			
Relative Risk [b]				
RR, 95% CI	1.013 [0.668, 1.536]			
p-value	0.9526			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9526			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.156: Effect Measures of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		78 (3.4%)	90 (3.9%)	168 (3.6%)
Number of subjects without events		2248 (96.6%)	2212 (96.1%)	4460 (96.4%)
Odds Ratio [a]				
OR, 95% CI	0.853 [0.626, 1.161]			
p-value	0.3122			
Relative Risk [b]				
RR, 95% CI	0.858 [0.637, 1.155]			
p-value	0.3123			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.016, 0.005]			
p-value	0.3119			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.157: Effect Measures of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		64 (2.8%)	46 (2.0%)	110 (2.4%)
Number of subjects without events		2262 (97.2%)	2256 (98.0%)	4518 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.388 [0.946, 2.036]			
p-value	0.0939			
Relative Risk [b]				
RR, 95% CI	1.377 [0.947, 2.002]			
p-value	0.0941			
Risk Difference [c]				
RD, 95% CI	0.008 [-0.001, 0.016]			
p-value	0.0922			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.158: Effect Measures of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		51 (2.2%)	61 (2.6%)	112 (2.4%)
Number of subjects without events		2275 (97.8%)	2241 (97.4%)	4516 (97.6%)
Odds Ratio [a]				
OR, 95% CI	0.824 [0.565, 1.200]			
p-value	0.3122			
Relative Risk [b]				
RR, 95% CI	0.827 [0.573, 1.195]			
p-value	0.3122			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.013, 0.004]			
p-value	0.3117			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.159: Effect Measures of Proportion of Subjects with TESAEs - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		7 (0.3%)	22 (1.0%)	29 (0.6%)
Number of subjects without events		2319 (99.7%)	2280 (99.0%)	4599 (99.4%)
Odds Ratio [a]				
OR, 95% CI	0.313 [0.133, 0.734]			
p-value	0.0075			
Relative Risk [b]				
RR, 95% CI	0.315 [0.135, 0.736]			
p-value	0.0076			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.011, -0.002]			
p-value	0.0048			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.160: Effect Measures of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		42 (1.8%)	56 (2.4%)	98 (2.1%)
Number of subjects without events		2284 (98.2%)	2246 (97.6%)	4530 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.738 [0.492, 1.105]			
p-value	0.1399			
Relative Risk [b]				
RR, 95% CI	0.742 [0.500, 1.103]			
p-value	0.1401			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.015, 0.002]			
p-value	0.1387			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.161: Effect Measures of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		27 (1.2%)	31 (1.3%)	58 (1.3%)
Number of subjects without events		2299 (98.8%)	2271 (98.7%)	4570 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.860 [0.512, 1.446]			
p-value	0.5702			
Relative Risk [b]				
RR, 95% CI	0.862 [0.516, 1.439]			
p-value	0.5702			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.005]			
p-value	0.5700			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.162: Effect Measures of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		56 (2.4%)	43 (1.9%)	99 (2.1%)
Number of subjects without events		2270 (97.6%)	2259 (98.1%)	4529 (97.9%)
Odds Ratio [a]				
OR, 95% CI	1.296 [0.867, 1.937]			
p-value	0.2058			
Relative Risk [b]				
RR, 95% CI	1.289 [0.870, 1.910]			
p-value	0.2059			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.003, 0.014]			
p-value	0.2042			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.163: Effect Measures of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	37 (1.6%)	70 (1.5%)
Number of subjects without events		2293 (98.6%)	2265 (98.4%)	4558 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.881 [0.549, 1.414]			
p-value	0.5995			
Relative Risk [b]				
RR, 95% CI	0.883 [0.554, 1.406]			
p-value	0.5995			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.005]			
p-value	0.5994			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.164: Effect Measures of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		24 (1.0%)	36 (1.6%)	60 (1.3%)
Number of subjects without events		2302 (99.0%)	2266 (98.4%)	4568 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.656 [0.390, 1.104]			
p-value	0.1122			
Relative Risk [b]				
RR, 95% CI	0.660 [0.395, 1.102]			
p-value	0.1123			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.001]			
p-value	0.1099			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.165: Effect Measures of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		19 (0.8%)	31 (1.3%)	50 (1.1%)
Number of subjects without events		2307 (99.2%)	2271 (98.7%)	4578 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.603 [0.340, 1.071]			
p-value	0.0845			
Relative Risk [b]				
RR, 95% CI	0.607 [0.344, 1.071]			
p-value	0.0846			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.011, 0.001]			
p-value	0.0816			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.166: Effect Measures of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		96 (4.1%)	117 (5.1%)	213 (4.6%)
Number of subjects without events		2230 (95.9%)	2185 (94.9%)	4415 (95.4%)
Odds Ratio [a]				
OR, 95% CI	0.804 [0.610, 1.060]			
p-value	0.1216			
Relative Risk [b]				
RR, 95% CI	0.812 [0.624, 1.057]			
p-value	0.1217			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.022, 0.003]			
p-value	0.1211			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.167: Effect Measures of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		14 (0.6%)	27 (1.2%)	41 (0.9%)
Number of subjects without events		2312 (99.4%)	2275 (98.8%)	4587 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.510 [0.267, 0.975]			
p-value	0.0418			
Relative Risk [b]				
RR, 95% CI	0.513 [0.270, 0.976]			
p-value	0.0420			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.011, 0.000]			
p-value	0.0384			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.168: Effect Measures of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		46 (2.0%)	44 (1.9%)	90 (1.9%)
Number of subjects without events		2280 (98.0%)	2258 (98.1%)	4538 (98.1%)
Odds Ratio [a]				
OR, 95% CI	1.035 [0.682, 1.572]			
p-value	0.8704			
Relative Risk [b]				
RR, 95% CI	1.035 [0.687, 1.558]			
p-value	0.8704			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.007, 0.009]			
p-value	0.8703			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.169: Effect Measures of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		26 (1.1%)	26 (1.1%)	52 (1.1%)
Number of subjects without events		2300 (98.9%)	2276 (98.9%)	4576 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.990 [0.573, 1.709]			
p-value	0.9700			
Relative Risk [b]				
RR, 95% CI	0.990 [0.576, 1.699]			
p-value	0.9700			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9700			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.170: Effect Measures of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		48 (2.1%)	47 (2.0%)	95 (2.1%)
Number of subjects without events		2278 (97.9%)	2255 (98.0%)	4533 (97.9%)
Odds Ratio [a]				
OR, 95% CI	1.011 [0.673, 1.518]			
p-value	0.9581			
Relative Risk [b]				
RR, 95% CI	1.011 [0.679, 1.505]			
p-value	0.9581			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9581			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.171: Effect Measures of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		26 (1.1%)	38 (1.7%)	64 (1.4%)
Number of subjects without events		2300 (98.9%)	2264 (98.3%)	4564 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.674 [0.408, 1.113]			
p-value	0.1229			
Relative Risk [b]				
RR, 95% CI	0.677 [0.413, 1.111]			
p-value	0.1230			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.001]			
p-value	0.1209			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.172: Effect Measures of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		22 (0.9%)	34 (1.5%)	56 (1.2%)
Number of subjects without events		2304 (99.1%)	2268 (98.5%)	4572 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.637 [0.371, 1.092]			
p-value	0.1012			
Relative Risk [b]				
RR, 95% CI	0.640 [0.376, 1.091]			
p-value	0.1013			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.001]			
p-value	0.0987			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.173: Effect Measures of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		36 (1.5%)	38 (1.7%)	74 (1.6%)
Number of subjects without events		2290 (98.5%)	2264 (98.3%)	4554 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.937 [0.592, 1.483]			
p-value	0.7800			
Relative Risk [b]				
RR, 95% CI	0.938 [0.597, 1.474]			
p-value	0.7800			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.7800			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table B2.1.174: Effect Measures of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2326)	Placebo (N=2302)	Total (N=4628)
Number of subjects at risk		2326 (100.0%)	2302 (100.0%)	4628 (100.0%)
Number of subjects with events		33 (1.4%)	32 (1.4%)	65 (1.4%)
Number of subjects without events		2293 (98.6%)	2270 (98.6%)	4563 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.021 [0.626, 1.666]			
p-value	0.9340			
Relative Risk [b]				
RR, 95% CI	1.021 [0.630, 1.654]			
p-value	0.9340			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.007]			
p-value	0.9340			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

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4.2 Disposition

Table 4.2 / 1: Subject disposition (all enrolled - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			33292
Screening failures			20121
Randomized	2563	2556	5119
GCP VIOLATIONS	25	31	56
Full analysis set	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)
Study drug never administered	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Treated	2536 (>99.9%)	2523 (>99.9%)	5059 (>99.9%)
Did not complete treatment due COVID-19	17 (0.7%)	23 (0.9%)	40 (0.8%)
Subject decision: COVID-19 pandemic related	13 (0.5%)	14 (0.6%)	27 (0.5%)
Physician decision: COVID-19 pandemic related	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Logistical reason: COVID-19 pandemic related	3 (0.1%)	7 (0.3%)	10 (0.2%)
Did not complete study	3 (0.1%)	7 (0.3%)	10 (0.2%)
WITHDRAWN CONSENT	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
LOST TO FOLLOW-UP	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Completed study	2535 (99.9%)	2518 (99.7%)	5053 (99.8%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
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Table 4.2 / 2: Disposition: End of treatment (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Completed epoch	1937 (76.3%)	1883 (74.6%)	3820 (75.4%)
Not completed	601 (23.7%)	642 (25.4%)	1243 (24.6%)
Primary reason			
ADVERSE EVENT	145 (5.7%)	162 (6.4%)	307 (6.1%)
DEATH	123 (4.8%)	164 (6.5%)	287 (5.7%)
WITHDRAWAL BY SUBJECT	169 (6.7%)	140 (5.5%)	309 (6.1%)
LOST TO FOLLOW-UP	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	6 (0.2%)	7 (0.3%)	13 (0.3%)
PHYSICIAN DECISION	78 (3.1%)	82 (3.2%)	160 (3.2%)
TECHNICAL PROBLEMS	37 (1.5%)	40 (1.6%)	77 (1.5%)
DETERIORATION OF GENERAL CONDITIONS	0	1 (<0.1%)	1 (<0.1%)
PROTOCOL DEVIATION	10 (0.4%)	12 (0.5%)	22 (0.4%)
SITE TERMINATED BY SPONSOR	3 (0.1%)	3 (0.1%)	6 (0.1%)
SUBJECT DECISION	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	13 (0.5%)	14 (0.6%)	27 (0.5%)
PHYSICIAN DECISION: COVID-19 PANDEMIC RELATED	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
LOGISTICAL REASON: COVID-19 PANDEMIC RELATED	3 (0.1%)	7 (0.3%)	10 (0.2%)
OTHER	9 (0.4%)	5 (0.2%)	14 (0.3%)

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4.3 Demographic characteristics

Table 4.3 / 1: Demographics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Race (N)			
WHITE	1799 (70.9%)	1765 (69.9%)	3564 (70.4%)
BLACK OR AFRICAN AMERICAN	80 (3.2%)	83 (3.3%)	163 (3.2%)
ASIAN	503 (19.8%)	530 (21.0%)	1033 (20.4%)
AMERICAN INDIAN OR ALASKA NATIVE	69 (2.7%)	70 (2.8%)	139 (2.7%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	16 (0.6%)	8 (0.3%)	24 (0.5%)
NOT REPORTED	6 (0.2%)	4 (0.2%)	10 (0.2%)
MULTIPLE	65 (2.6%)	65 (2.6%)	130 (2.6%)
Sex (N)			
Male	1764 (69.5%)	1794 (71.0%)	3558 (70.3%)
Female	774 (30.5%)	731 (29.0%)	1505 (29.7%)
Age (YEARS)			
n	2538	2525	5063
Mean	61.41	61.20	61.30
SD	9.36	9.78	9.57
Min	27.0	23.0	23.0
Q1	55.00	55.00	55.00
Median	62.00	62.00	62.00
Q3	68.00	68.00	68.00
Max	88.0	86.0	88.0
Run-in age group (years) category (N)			
18 - 44 years	126 (5.0%)	126 (5.0%)	252 (5.0%)
45 - 64 years	1389 (54.7%)	1391 (55.1%)	2780 (54.9%)
65 - 74 years	856 (33.7%)	820 (32.5%)	1676 (33.1%)
>= 75 years	167 (6.6%)	188 (7.4%)	355 (7.0%)
Age group (years) category 3 (N)			
< 65 years	1515 (59.7%)	1517 (60.1%)	3032 (59.9%)
>= 65 years	1023 (40.3%)	1008 (39.9%)	2031 (40.1%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	2039 (80.3%)	2038 (80.7%)	4077 (80.5%)
HISPANIC OR LATINO	489 (19.3%)	486 (19.2%)	975 (19.3%)
NOT REPORTED	10 (0.4%)	1 (<0.1%)	11 (0.2%)

Table 4.3 / 1: Demographics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Region (N)			
Europe	1218 (48.0%)	1223 (48.4%)	2441 (48.2%)
North America	334 (13.2%)	317 (12.6%)	651 (12.9%)
Asia	561 (22.1%)	564 (22.3%)	1125 (22.2%)
Latin America	343 (13.5%)	340 (13.5%)	683 (13.5%)
Others	82 (3.2%)	81 (3.2%)	163 (3.2%)
Baseline Weight (kg)			
n	2533	2521	5054
Mean	89.37	89.39	89.38
SD	20.56	20.17	20.37
Min	35.5	37.3	35.5
Q1	74.50	75.50	75.00
Median	87.00	87.50	87.20
Q3	101.90	101.00	101.30
Max	190.4	172.7	190.4
Baseline weight (kg) category (N)			
missing	5 (0.2%)	4 (0.2%)	9 (0.2%)
< 60 kg	118 (4.6%)	122 (4.8%)	240 (4.7%)
60 - < 90 kg	1296 (51.1%)	1261 (49.9%)	2557 (50.5%)
>= 90 kg	1119 (44.1%)	1138 (45.1%)	2257 (44.6%)
Baseline Height (cm)			
n	2536	2522	5058
Mean	167.95	168.26	168.10
SD	9.95	9.67	9.81
Min	118.0	121.0	118.0
Q1	161.00	162.00	162.00
Median	168.00	169.00	169.00
Q3	175.00	175.00	175.00
Max	198.0	206.0	206.0

Table 4.3 / 1: Demographics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline Body Mass Index (kg/m2)			
n	2531	2520	5051
Mean	31.55	31.44	31.50
SD	6.18	6.02	6.10
Min	16.7	15.9	15.9
Q1	27.20	27.20	27.20
Median	30.70	30.70	30.70
Q3	34.90	34.70	34.80
Max	83.9	56.3	83.9
Baseline BMI (kg/m2) category 2 (N)			
missing	7 (0.3%)	5 (0.2%)	12 (0.2%)
< 30 kg/m2	1107 (43.6%)	1124 (44.5%)	2231 (44.1%)
>= 30 kg/m2	1424 (56.1%)	1396 (55.3%)	2820 (55.7%)
Baseline BMI (kg/m2) category 3 (N)			
missing	7 (0.3%)	5 (0.2%)	12 (0.2%)
< 20 kg/m2	14 (0.6%)	23 (0.9%)	37 (0.7%)
20 - < 25 kg/m2	277 (10.9%)	273 (10.8%)	550 (10.9%)
25 - < 30 kg/m2	816 (32.2%)	828 (32.8%)	1644 (32.5%)
30 - < 35 kg/m2	799 (31.5%)	797 (31.6%)	1596 (31.5%)
>= 35 kg/m2	625 (24.6%)	599 (23.7%)	1224 (24.2%)
Baseline Hip Circumference (cm)			
n	2529	2520	5049
Mean	107.50	107.35	107.43
SD	14.13	13.78	13.95
Min	48.4	40.6	40.6
Q1	99.00	99.00	99.00
Median	106.00	106.00	106.00
Q3	115.00	115.00	115.00
Max	199.0	161.0	199.0

Table 4.3 / 1: Demographics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline waist circumference (cm)			
n	2530	2520	5050
Mean	107.09	106.96	107.03
SD	15.31	14.90	15.11
Min	51.0	51.0	51.0
Q1	97.00	97.00	97.00
Median	106.00	106.00	106.00
Q3	117.00	116.00	116.20
Max	240.0	166.0	240.0
Baseline waist circumf. (cm) cat. (N)			
missing	8 (0.3%)	5 (0.2%)	13 (0.3%)
normal	307 (12.1%)	289 (11.4%)	596 (11.8%)
increased	455 (17.9%)	466 (18.5%)	921 (18.2%)
substantially increased	1768 (69.7%)	1765 (69.9%)	3533 (69.8%)
Baseline waist-hip ratio (N)			
n	2529	2518	5047
Mean	1.00	1.00	1.00
SD	0.11	0.12	0.11
Min	0.6	0.4	0.4
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.05	1.05
Max	2.7	2.3	2.7
Smoking History (N)			
NEVER	1209 (47.6%)	1125 (44.6%)	2334 (46.1%)
FORMER	788 (31.0%)	847 (33.5%)	1635 (32.3%)
CURRENT	541 (21.3%)	553 (21.9%)	1094 (21.6%)

Table 4.3 / 1: Demographics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Alcohol Use (N)			
missing	2 (<0.1%)	0	2 (<0.1%)
ABSTINENT	1498 (59.0%)	1457 (57.7%)	2955 (58.4%)
LIGHT	868 (34.2%)	881 (34.9%)	1749 (34.5%)
MODERATE	158 (6.2%)	173 (6.9%)	331 (6.5%)
HEAVY	12 (0.5%)	14 (0.6%)	26 (0.5%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
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4.4 Baseline characteristics

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline potassium (mmol/L)			
n	2538	2524	5062
Arithm. Mean	4.31	4.31	4.31
Arithm. SD	0.42	0.43	0.43
Min	2.8	2.6	2.6
Q1	4.10	4.00	4.00
Median	4.30	4.30	4.30
Q3	4.60	4.60	4.60
Max	6.0	5.9	6.0
Baseline ser. potassium (mmol/L) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.5 mmol/L	1863 (73.4%)	1838 (72.8%)	3701 (73.1%)
> 4.5 mmol/L	675 (26.6%)	686 (27.2%)	1361 (26.9%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.8 mmol/L	2307 (90.9%)	2292 (90.8%)	4599 (90.8%)
>4.8 to <=5.0 mmol/L	132 (5.2%)	126 (5.0%)	258 (5.1%)
>5.0 mmol/L	99 (3.9%)	106 (4.2%)	205 (4.0%)
Basel. potass (mmol/L) median FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1384 (54.5%)	1369 (54.2%)	2753 (54.4%)
> 4.30 mmol/L (median in FAS)	1154 (45.5%)	1155 (45.7%)	2309 (45.6%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	871 (34.3%)	878 (34.8%)	1749 (34.5%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	513 (20.2%)	491 (19.4%)	1004 (19.8%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	653 (25.7%)	655 (25.9%)	1308 (25.8%)
>4.6 mmol/L (>Q3 in FAS)	501 (19.7%)	500 (19.8%)	1001 (19.8%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	2538	2525	5063
Arithm. Mean	136.67	136.67	136.67
Arithm. SD	13.54	13.71	13.63
Min	82.7	93.3	82.7
Q1	127.67	127.67	127.67
Median	136.67	136.67	136.67
Q3	145.67	146.33	146.00
Max	208.0	200.0	208.0
Baseline SBP (mmHg) category (N)			
< 130 mmHg	757 (29.8%)	754 (29.9%)	1511 (29.8%)
130 - < 160 mmHg	1699 (66.9%)	1681 (66.6%)	3380 (66.8%)
>= 160 mmHg	82 (3.2%)	90 (3.6%)	172 (3.4%)
Baseline SBP (mmHg) median for FAS (N)			
<= 137.00 mmHg (median in FAS)	1308 (51.5%)	1297 (51.4%)	2605 (51.5%)
> 137.00 mmHg (median in FAS)	1230 (48.5%)	1228 (48.6%)	2458 (48.5%)
Baseline Diastolic Blood Pressure (mmHg)			
n	2538	2525	5063
Arithm. Mean	78.29	78.60	78.45
Arithm. SD	9.01	9.00	9.00
Min	39.7	47.7	39.7
Q1	72.00	72.67	72.33
Median	79.00	79.33	79.33
Q3	84.33	84.33	84.33
Max	112.3	108.0	112.3
Baseline Heart Rate (BEATS/MIN)			
n	2538	2525	5063
Arithm. Mean	75.09	74.91	75.00
Arithm. SD	10.87	11.22	11.04
Min	37.0	41.7	37.0
Q1	67.67	66.67	67.33
Median	74.67	74.67	74.67
Q3	82.00	82.00	82.00
Max	115.7	144.0	144.0

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	2538	2525	5063
Arithm. Mean	78.89	79.34	79.11
Arithm. SD	15.69	15.72	15.70
Min	24.7	29.3	24.7
Q1	66.90	67.60	67.30
Median	77.50	77.90	77.70
Q3	90.40	90.60	90.40
Max	137.1	131.5	137.1
Baseline eGFR (mL/min/1.73m2) cat.(N)			
< 25 mL/min/1.73m2	1 (<0.1%)	0	1 (<0.1%)
25 - < 45 mL/min/1.73m2	27 (1.1%)	15 (0.6%)	42 (0.8%)
45 - < 60 mL/min/1.73m2	227 (8.9%)	232 (9.2%)	459 (9.1%)
>= 60 mL/min/1.73m2	2283 (90.0%)	2278 (90.2%)	4561 (90.1%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
< 30 mL/min/1.73m2	4 (0.2%)	2 (<0.1%)	6 (0.1%)
30 - < 60 mL/min/1.73m2	251 (9.9%)	245 (9.7%)	496 (9.8%)
60 - < 90 mL/min/1.73m2	1630 (64.2%)	1624 (64.3%)	3254 (64.3%)
>= 90 mL/min/1.73m2	653 (25.7%)	654 (25.9%)	1307 (25.8%)
Screening eGFR (mL/min/1.73m2)			
n	2535	2522	5057
Arithm. Mean	80.32	80.37	80.34
Arithm. SD	14.18	14.40	14.29
Min	40.3	45.4	40.3
Q1	68.80	68.30	68.60
Median	77.90	78.00	77.90
Q3	90.00	90.40	90.20
Max	147.0	135.0	147.0
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	3 (0.1%)	3 (0.1%)	6 (0.1%)
25 - < 45 mL/min/1.73m2	2 (<0.1%)	0	2 (<0.1%)
45 - < 60 mL/min/1.73m2	8 (0.3%)	9 (0.4%)	17 (0.3%)
>= 60 mL/min/1.73m2	2525 (99.5%)	2513 (99.5%)	5038 (99.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	3 (0.1%)	3 (0.1%)	6 (0.1%)
30 - < 60 mL/min/1.73m2	10 (0.4%)	9 (0.4%)	19 (0.4%)
60 - < 90 mL/min/1.73m2	1888 (74.4%)	1869 (74.0%)	3757 (74.2%)
>= 90 mL/min/1.73m2	637 (25.1%)	644 (25.5%)	1281 (25.3%)
Baseline UACR (mg/g)			
n	2538	2523	5061
Geom. Mean	543.89	546.17	545.03
Geom. SD	2.89	2.93	2.91
Min	6.2	1.8	1.8
Q1	317.47	335.42	327.76
Median	585.29	580.29	583.05
Q3	1135.46	1141.59	1136.74
Max	7630.5	5924.9	7630.5
Baseline albuminuria (mg/g) cat. (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	22 (0.9%)	26 (1.0%)	48 (0.9%)
High albuminuria (30 mg/g - < 300 mg/g)	567 (22.3%)	516 (20.4%)	1083 (21.4%)
Very high albuminuria (>= 300 mg/g)	1949 (76.8%)	1981 (78.5%)	3930 (77.6%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<= 514.7 mg/g (median in FAS)	1131 (44.6%)	1142 (45.2%)	2273 (44.9%)
> 514.7 mg/g (median in FAS)	1407 (55.4%)	1381 (54.7%)	2788 (55.1%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
NO	2526 (99.5%)	2516 (99.6%)	5042 (99.6%)
YES	12 (0.5%)	8 (0.3%)	20 (0.4%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Baseline Creatinine (mg/dL)			
n	2538	2525	5063
Arithm. Mean	0.96	0.96	0.96
Arithm. SD	0.22	0.21	0.22
Min	0.4	0.4	0.4
Q1	0.80	0.80	0.80
Median	0.95	0.95	0.95
Q3	1.09	1.09	1.09
Max	2.5	2.2	2.5
Baseline Albumin (g/dL) in Serum			
n	2537	2524	5061
Arithm. Mean	4.24	4.22	4.23
Arithm. SD	0.32	0.34	0.33
Min	2.4	2.0	2.0
Q1	4.10	4.00	4.00
Median	4.30	4.20	4.20
Q3	4.40	4.40	4.40
Max	5.3	5.4	5.4
Baseline Hemoglobin (g/dL) in Blood			
n	2532	2523	5055
Arithm. Mean	13.85	13.85	13.85
Arithm. SD	1.63	1.62	1.62
Min	6.6	5.8	5.8
Q1	12.80	12.90	12.80
Median	13.90	13.80	13.90
Q3	15.00	14.90	14.90
Max	19.4	19.6	19.6
Baseline Hemoglobin A1C (%)			
n	2536	2522	5058
Arithm. Mean	7.83	7.82	7.83
Arithm. SD	1.43	1.41	1.42
Min	4.7	4.5	4.5
Q1	6.80	6.70	6.80
Median	7.60	7.60	7.60
Q3	8.70	8.70	8.70
Max	14.5	12.6	14.5

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
<= 7.5%	1227 (48.3%)	1225 (48.5%)	2452 (48.4%)
> 7.5%	1309 (51.6%)	1297 (51.4%)	2606 (51.5%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
<=6.7 % (<= Q1 in FAS)	608 (24.0%)	636 (25.2%)	1244 (24.6%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	619 (24.4%)	589 (23.3%)	1208 (23.9%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	598 (23.6%)	581 (23.0%)	1179 (23.3%)
>8.5 % (>Q3 in FAS)	711 (28.0%)	716 (28.4%)	1427 (28.2%)
Baseline C Reactive Protein (mg/L)			
n	2537	2521	5058
Arithm. Mean	4.95	4.66	4.80
Arithm. SD	11.92	9.83	10.93
Min	0.1	0.1	0.1
Q1	0.95	0.96	0.95
Median	2.14	2.20	2.16
Q3	4.99	5.03	5.00
Max	311.0	212.0	311.0
Basel. C Reactive Protein Quartiles (N)			
missing	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
<=0.95 % (<= Q1 in FAS)	638 (25.1%)	627 (24.8%)	1265 (25.0%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	666 (26.2%)	638 (25.3%)	1304 (25.8%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	621 (24.5%)	644 (25.5%)	1265 (25.0%)
>5.13 % (>Q3 in FAS)	612 (24.1%)	612 (24.2%)	1224 (24.2%)
Stratification factor 3 (N)			
CVD present	899 (35.4%)	892 (35.3%)	1791 (35.4%)
CVD absent	1639 (64.6%)	1633 (64.7%)	3272 (64.6%)
Hyperkalemia (based on MLG) in MH (N)			
NO	2524 (99.4%)	2512 (99.5%)	5036 (99.5%)
YES	14 (0.6%)	13 (0.5%)	27 (0.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Hepatic impairment in medical history(N)			
NO	2091 (82.4%)	2051 (81.2%)	4142 (81.8%)
YES	447 (17.6%)	474 (18.8%)	921 (18.2%)
Child Pugh (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
likely Child Pugh A	2467 (97.2%)	2442 (96.7%)	4909 (97.0%)
likely Child Pugh B	69 (2.7%)	79 (3.1%)	148 (2.9%)
certain Child Pugh B	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Duration of diabetes (in years) (N)			
n	2536	2521	5057
Arithm. Mean	13.79	13.66	13.72
Arithm. SD	7.94	7.88	7.91
Min	0.2	0.2	0.2
Q1	8.12	8.09	8.11
Median	12.36	13.11	13.01
Q3	18.94	18.17	18.24
Max	52.1	47.7	52.1
ACEI use (N)			
NO	1432 (56.4%)	1419 (56.2%)	2851 (56.3%)
YES	1106 (43.6%)	1106 (43.8%)	2212 (43.7%)
ARB use (N)			
NO	1107 (43.6%)	1108 (43.9%)	2215 (43.7%)
YES	1431 (56.4%)	1417 (56.1%)	2848 (56.3%)
Beta blocker use at baseline (N)			
NO	1457 (57.4%)	1421 (56.3%)	2878 (56.8%)
YES	1081 (42.6%)	1104 (43.7%)	2185 (43.2%)
Diuretic use at baseline (N)			
NO	1465 (57.7%)	1440 (57.0%)	2905 (57.4%)
YES	1073 (42.3%)	1085 (43.0%)	2158 (42.6%)
Statins use at baseline (N)			
NO	894 (35.2%)	810 (32.1%)	1704 (33.7%)
YES	1644 (64.8%)	1715 (67.9%)	3359 (66.3%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Anti-diabetic use at baseline (N)			
NO	32 (1.3%)	29 (1.1%)	61 (1.2%)
YES	2506 (98.7%)	2496 (98.9%)	5002 (98.8%)
Insul. and analo. use at baseline (N)			
NO	1120 (44.1%)	1140 (45.1%)	2260 (44.6%)
YES	1418 (55.9%)	1385 (54.9%)	2803 (55.4%)
Dip pep 4 inhibitors use at baseline (N)			
NO	1973 (77.7%)	1999 (79.2%)	3972 (78.5%)
YES	565 (22.3%)	526 (20.8%)	1091 (21.5%)
GLP1 agonists use at baseline (N)			
NO	2328 (91.7%)	2352 (93.1%)	4680 (92.4%)
YES	210 (8.3%)	173 (6.9%)	383 (7.6%)
SGLT-2 inhib. use at baseline (N)			
NO	2286 (90.1%)	2283 (90.4%)	4569 (90.2%)
YES	252 (9.9%)	242 (9.6%)	494 (9.8%)
Biguanides use at baseline (N)			
NO	549 (21.6%)	584 (23.1%)	1133 (22.4%)
YES	1989 (78.4%)	1941 (76.9%)	3930 (77.6%)
Sulfonamides use at baseline (N)			
NO	1843 (72.6%)	1803 (71.4%)	3646 (72.0%)
YES	695 (27.4%)	722 (28.6%)	1417 (28.0%)
Alpha gluc. inhib. use at baseline (N)			
NO	2415 (95.2%)	2399 (95.0%)	4814 (95.1%)
YES	123 (4.8%)	126 (5.0%)	249 (4.9%)
Meglitinides use at baseline (N)			
NO	2471 (97.4%)	2470 (97.8%)	4941 (97.6%)
YES	67 (2.6%)	55 (2.2%)	122 (2.4%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Thiazolidinediones use at baseline (N)			
NO	2443 (96.3%)	2438 (96.6%)	4881 (96.4%)
YES	95 (3.7%)	87 (3.4%)	182 (3.6%)
Potassium supplement use at baseline (N)			
NO	2482 (97.8%)	2468 (97.7%)	4950 (97.8%)
YES	56 (2.2%)	57 (2.3%)	113 (2.2%)
Potassium lowering use at baseline (N)			
NO	2525 (99.5%)	2514 (99.6%)	5039 (99.5%)
YES	13 (0.5%)	11 (0.4%)	24 (0.5%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	18 (0.7%)	23 (0.9%)	41 (0.8%)
unclassified	28 (1.1%)	43 (1.7%)	71 (1.4%)
moderate	51 (2.0%)	46 (1.8%)	97 (1.9%)
weak	1366 (53.8%)	1376 (54.5%)	2742 (54.2%)
none	1075 (42.4%)	1037 (41.1%)	2112 (41.7%)
Potency CYP3A4 inducer at baseline (N)			
strong	3 (0.1%)	7 (0.3%)	10 (0.2%)
unclassified	6 (0.2%)	6 (0.2%)	12 (0.2%)
moderate	2 (<0.1%)	6 (0.2%)	8 (0.2%)
weak	86 (3.4%)	81 (3.2%)	167 (3.3%)
none	2441 (96.2%)	2425 (96.0%)	4866 (96.1%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:35
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4.5 Medical History

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Number (%) of subjects with at least one medical history finding	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)
Blood and lymphatic system disorders	214 (8.4%)	212 (8.4%)	426 (8.4%)
Anaemia	118 (4.6%)	130 (5.1%)	248 (4.9%)
Anaemia macrocytic	0	1 (<0.1%)	1 (<0.1%)
Anaemia megaloblastic	0	1 (<0.1%)	1 (<0.1%)
Anaemia of chronic disease	0	2 (<0.1%)	2 (<0.1%)
Anaemia vitamin B12 deficiency	1 (<0.1%)	0	1 (<0.1%)
Aplasia pure red cell	1 (<0.1%)	0	1 (<0.1%)
Blood loss anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coagulopathy	1 (<0.1%)	0	1 (<0.1%)
Deficiency anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eosinophilia	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic diathesis	1 (<0.1%)	0	1 (<0.1%)
Hypercoagulation	2 (<0.1%)	0	2 (<0.1%)
Hyperfibrinogenaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	0	2 (<0.1%)
Immune thrombocytopenia	0	1 (<0.1%)	1 (<0.1%)
Increased tendency to bruise	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	27 (1.1%)	28 (1.1%)	55 (1.1%)
Leukocytosis	11 (0.4%)	8 (0.3%)	19 (0.4%)
Leukopenia	0	4 (0.2%)	4 (<0.1%)
Lymphadenitis	1 (<0.1%)	0	1 (<0.1%)
Lymphadenopathy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Lymphadenopathy mediastinal	0	1 (<0.1%)	1 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Macrocytosis	0	2 (<0.1%)	2 (<0.1%)
Microcytic anaemia	2 (<0.1%)	0	2 (<0.1%)
Microcytosis	0	1 (<0.1%)	1 (<0.1%)
Nephrogenic anaemia	8 (0.3%)	5 (0.2%)	13 (0.3%)
Normochromic normocytic anaemia	0	3 (0.1%)	3 (<0.1%)
Normocytic anaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pancytopenia	0	1 (<0.1%)	1 (<0.1%)
Pernicious anaemia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Polycythaemia	8 (0.3%)	8 (0.3%)	16 (0.3%)
Spleen disorder	0	1 (<0.1%)	1 (<0.1%)
Splenic infarction	1 (<0.1%)	0	1 (<0.1%)
Splenic lesion	1 (<0.1%)	0	1 (<0.1%)
Splenitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Splenomegaly	12 (0.5%)	6 (0.2%)	18 (0.4%)
Thrombocytopenia	12 (0.5%)	13 (0.5%)	25 (0.5%)
Thrombocytosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Cardiac disorders	1101 (43.4%)	1079 (42.7%)	2180 (43.1%)
Acute coronary syndrome	0	2 (<0.1%)	2 (<0.1%)
Acute myocardial infarction	7 (0.3%)	6 (0.2%)	13 (0.3%)
Angina pectoris	124 (4.9%)	121 (4.8%)	245 (4.8%)
Angina unstable	21 (0.8%)	23 (0.9%)	44 (0.9%)
Aortic valve calcification	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Aortic valve disease	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Aortic valve incompetence	16 (0.6%)	11 (0.4%)	27 (0.5%)
Aortic valve sclerosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Aortic valve stenosis	6 (0.2%)	5 (0.2%)	11 (0.2%)
Aortic valve thickening	0	1 (<0.1%)	1 (<0.1%)
Arrhythmia	18 (0.7%)	23 (0.9%)	41 (0.8%)
Arrhythmia supraventricular	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Arteriosclerosis coronary artery	43 (1.7%)	40 (1.6%)	83 (1.6%)
Atrial conduction time prolongation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrial enlargement	2 (<0.1%)	0	2 (<0.1%)
Atrial fibrillation	156 (6.1%)	163 (6.5%)	319 (6.3%)
Atrial flutter	19 (0.7%)	13 (0.5%)	32 (0.6%)
Atrial tachycardia	1 (<0.1%)	0	1 (<0.1%)
Atrial thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrioventricular block	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Atrioventricular block complete	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Atrioventricular block first degree	21 (0.8%)	37 (1.5%)	58 (1.1%)
Atrioventricular block second degree	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Bradyarrhythmia	1 (<0.1%)	0	1 (<0.1%)
Bradycardia	6 (0.2%)	6 (0.2%)	12 (0.2%)
Bundle branch block bilateral	0	2 (<0.1%)	2 (<0.1%)
Bundle branch block left	25 (1.0%)	45 (1.8%)	70 (1.4%)
Bundle branch block right	51 (2.0%)	46 (1.8%)	97 (1.9%)
Cardiac aneurysm	3 (0.1%)	0	3 (<0.1%)
Cardiac arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiac asthma	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	2 (<0.1%)	0	2 (<0.1%)
Cardiac dysfunction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac failure	37 (1.5%)	38 (1.5%)	75 (1.5%)
Cardiac failure acute	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Cardiac failure chronic	104 (4.1%)	85 (3.4%)	189 (3.7%)
Cardiac failure congestive	19 (0.7%)	16 (0.6%)	35 (0.7%)
Cardiac hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac septal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Cardiac valve disease	3 (0.1%)	5 (0.2%)	8 (0.2%)
Cardiac valve sclerosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiomegaly	8 (0.3%)	9 (0.4%)	17 (0.3%)
Cardiomyopathy	15 (0.6%)	8 (0.3%)	23 (0.5%)
Cardiovascular disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiovascular insufficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic left ventricular failure	5 (0.2%)	5 (0.2%)	10 (0.2%)
Congestive cardiomyopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Cor pulmonale	1 (<0.1%)	0	1 (<0.1%)
Cor pulmonale chronic	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Coronary artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Coronary artery disease	625 (24.6%)	592 (23.4%)	1217 (24.0%)
Coronary artery insufficiency	1 (<0.1%)	0	1 (<0.1%)
Coronary artery occlusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Coronary artery stenosis	2 (<0.1%)	7 (0.3%)	9 (0.2%)
Coronary artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Defect conduction intraventricular	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Degenerative aortic valve disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Diastolic dysfunction	8 (0.3%)	11 (0.4%)	19 (0.4%)
Dilatation atrial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dressler's syndrome	0	1 (<0.1%)	1 (<0.1%)
Extrasystoles	4 (0.2%)	7 (0.3%)	11 (0.2%)
Heart valve calcification	0	1 (<0.1%)	1 (<0.1%)
Heart valve incompetence	0	1 (<0.1%)	1 (<0.1%)
Hypertensive cardiomyopathy	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Hypertensive heart disease	24 (0.9%)	31 (1.2%)	55 (1.1%)
Ischaemic cardiomyopathy	7 (0.3%)	7 (0.3%)	14 (0.3%)
Left atrial dilatation	4 (0.2%)	4 (0.2%)	8 (0.2%)
Left atrial enlargement	4 (0.2%)	7 (0.3%)	11 (0.2%)
Left atrial hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Left ventricular dysfunction	6 (0.2%)	7 (0.3%)	13 (0.3%)
Left ventricular enlargement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular failure	5 (0.2%)	4 (0.2%)	9 (0.2%)
Left ventricular hypertrophy	56 (2.2%)	68 (2.7%)	124 (2.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Low cardiac output syndrome	0	1 (<0.1%)	1 (<0.1%)
Malignant hypertensive heart disease	0	1 (<0.1%)	1 (<0.1%)
Metabolic cardiomyopathy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Mitral valve calcification	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mitral valve disease	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Mitral valve incompetence	32 (1.3%)	23 (0.9%)	55 (1.1%)
Mitral valve prolapse	0	1 (<0.1%)	1 (<0.1%)
Mitral valve sclerosis	1 (<0.1%)	0	1 (<0.1%)
Mitral valve stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Myocardial fibrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Myocardial infarction	341 (13.4%)	324 (12.8%)	665 (13.1%)
Myocardial ischaemia	113 (4.5%)	102 (4.0%)	215 (4.2%)
Myocardial necrosis	0	1 (<0.1%)	1 (<0.1%)
Myocarditis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodal rhythm	1 (<0.1%)	0	1 (<0.1%)
Palpitations	7 (0.3%)	8 (0.3%)	15 (0.3%)
Pericardial cyst	1 (<0.1%)	0	1 (<0.1%)
Pericardial effusion	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pericarditis	3 (0.1%)	0	3 (<0.1%)
Pericarditis constrictive	0	1 (<0.1%)	1 (<0.1%)
Prinzmetal angina	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pulmonary valve incompetence	1 (<0.1%)	0	1 (<0.1%)
Rheumatic heart disease	1 (<0.1%)	0	1 (<0.1%)
Right atrial enlargement	0	1 (<0.1%)	1 (<0.1%)
Right ventricular dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular dysfunction	0	1 (<0.1%)	1 (<0.1%)
Right ventricular hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Silent myocardial infarction	0	1 (<0.1%)	1 (<0.1%)
Sinus arrhythmia	6 (0.2%)	4 (0.2%)	10 (0.2%)
Sinus bradycardia	12 (0.5%)	21 (0.8%)	33 (0.7%)
Sinus node dysfunction	4 (0.2%)	4 (0.2%)	8 (0.2%)
Sinus tachycardia	6 (0.2%)	9 (0.4%)	15 (0.3%)
Supraventricular extrasystoles	17 (0.7%)	12 (0.5%)	29 (0.6%)
Supraventricular tachycardia	9 (0.4%)	4 (0.2%)	13 (0.3%)
Systolic dysfunction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tachyarrhythmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tachycardia	7 (0.3%)	5 (0.2%)	12 (0.2%)
Tachycardia induced cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Tachycardia paroxysmal	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Tricuspid valve disease	0	3 (0.1%)	3 (<0.1%)
Tricuspid valve incompetence	22 (0.9%)	17 (0.7%)	39 (0.8%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Tricuspid valve sclerosis	1 (<0.1%)	0	1 (<0.1%)
Trifascicular block	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Ventricular extrasystoles	18 (0.7%)	17 (0.7%)	35 (0.7%)
Ventricular fibrillation	0	2 (<0.1%)	2 (<0.1%)
Ventricular hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Ventricular hypokinesia	1 (<0.1%)	0	1 (<0.1%)
Ventricular remodelling	1 (<0.1%)	0	1 (<0.1%)
Ventricular tachycardia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Wolff-Parkinson-White syndrome	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Congenital, familial and genetic disorders	118 (4.6%)	100 (4.0%)	218 (4.3%)
Accessory spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adenomatous polyposis coli	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Albinism	1 (<0.1%)	0	1 (<0.1%)
Arnold-Chiari malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cone dystrophy	0	1 (<0.1%)	1 (<0.1%)
Congenital cystic kidney disease	0	1 (<0.1%)	1 (<0.1%)
Congenital ectopic pancreas	0	1 (<0.1%)	1 (<0.1%)
Congenital hearing disorder	1 (<0.1%)	0	1 (<0.1%)
Congenital hydronephrosis	0	1 (<0.1%)	1 (<0.1%)
Congenital hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Congenital musculoskeletal anomaly	1 (<0.1%)	0	1 (<0.1%)
Congenital myopia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Congenital nose malformation	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	8 (0.3%)	5 (0.2%)	13 (0.3%)
Congenital spinal fusion	0	1 (<0.1%)	1 (<0.1%)
Congenital ureteric anomaly	1 (<0.1%)	0	1 (<0.1%)
Corneal dystrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Craniofacial deformity	1 (<0.1%)	0	1 (<0.1%)
Cryptorchism	0	1 (<0.1%)	1 (<0.1%)
Dermoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Developmental hip dysplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dolichocolon	0	2 (<0.1%)	2 (<0.1%)
Ectopic kidney	5 (0.2%)	0	5 (<0.1%)
Exomphalos	1 (<0.1%)	0	1 (<0.1%)
Familial hypertriglyceridaemia	1 (<0.1%)	0	1 (<0.1%)
Familial mediterranean fever	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	2 (<0.1%)	0	2 (<0.1%)
Gitelman's syndrome	1 (<0.1%)	0	1 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	0	1 (<0.1%)	1 (<0.1%)
Haemoglobinopathy	1 (<0.1%)	0	1 (<0.1%)
Heart disease congenital	1 (<0.1%)	0	1 (<0.1%)
Hepatic hamartoma	0	1 (<0.1%)	1 (<0.1%)
Hereditary motor and sensory neuropathy	1 (<0.1%)	0	1 (<0.1%)
Homocystinaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Homocystinuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrocele	3 (0.1%)	4 (0.2%)	7 (0.1%)
Hypertrophic cardiomyopathy	4 (0.2%)	8 (0.3%)	12 (0.2%)
Kidney duplex	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Kimmerle's anomaly	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	2 (<0.1%)	2 (<0.1%)
Klippel-Feil syndrome	1 (<0.1%)	0	1 (<0.1%)
Multiple endocrine neoplasia Type 1	1 (<0.1%)	0	1 (<0.1%)
Muscular dystrophy	1 (<0.1%)	0	1 (<0.1%)
Myocardial bridging	0	1 (<0.1%)	1 (<0.1%)
Myotonic dystrophy	1 (<0.1%)	0	1 (<0.1%)
Patent ductus arteriosus	0	1 (<0.1%)	1 (<0.1%)
Phimosis	8 (0.3%)	4 (0.2%)	12 (0.2%)
Protein C deficiency	0	1 (<0.1%)	1 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Renal fusion anomaly	1 (<0.1%)	0	1 (<0.1%)
Retinopathy congenital	1 (<0.1%)	0	1 (<0.1%)
Sickle cell trait	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Spinal muscular atrophy	1 (<0.1%)	0	1 (<0.1%)
Strabismus congenital	1 (<0.1%)	0	1 (<0.1%)
Synostosis	1 (<0.1%)	0	1 (<0.1%)
Thalassaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thalassaemia alpha	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Thalassaemia beta	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Thalassaemia minor	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Thyroglossal cyst	1 (<0.1%)	0	1 (<0.1%)
Type IIa hyperlipidaemia	4 (0.2%)	7 (0.3%)	11 (0.2%)
Type IIb hyperlipidaemia	3 (0.1%)	4 (0.2%)	7 (0.1%)
Type V hyperlipidaemia	34 (1.3%)	26 (1.0%)	60 (1.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Ventricular septal defect	0	1 (<0.1%)	1 (<0.1%)
Ear and labyrinth disorders	131 (5.2%)	114 (4.5%)	245 (4.8%)
Allergic otitis media	0	1 (<0.1%)	1 (<0.1%)
Auditory disorder	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Aural polyp	1 (<0.1%)	0	1 (<0.1%)
Cerumen impaction	0	1 (<0.1%)	1 (<0.1%)
Conductive deafness	1 (<0.1%)	0	1 (<0.1%)
Deafness	23 (0.9%)	17 (0.7%)	40 (0.8%)
Deafness bilateral	7 (0.3%)	9 (0.4%)	16 (0.3%)
Deafness neurosensory	14 (0.6%)	6 (0.2%)	20 (0.4%)
Deafness unilateral	4 (0.2%)	8 (0.3%)	12 (0.2%)
Ear discomfort	1 (<0.1%)	0	1 (<0.1%)
Ear pain	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Eustachian tube disorder	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	1 (<0.1%)	0	1 (<0.1%)
Eustachian tube stenosis	0	1 (<0.1%)	1 (<0.1%)
Excessive cerumen production	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exostosis of external ear canal	0	1 (<0.1%)	1 (<0.1%)
Hypoacusis	15 (0.6%)	12 (0.5%)	27 (0.5%)
Labyrinthine fistula	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Middle ear disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Middle ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	1 (<0.1%)	0	1 (<0.1%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	0	2 (<0.1%)	2 (<0.1%)
Otosclerosis	3 (0.1%)	0	3 (<0.1%)
Presbyacusis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sudden hearing loss	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tinnitus	25 (1.0%)	13 (0.5%)	38 (0.8%)
Tympanic membrane perforation	0	4 (0.2%)	4 (<0.1%)
Vertigo	26 (1.0%)	32 (1.3%)	58 (1.1%)
Vertigo positional	7 (0.3%)	6 (0.2%)	13 (0.3%)
Vestibular ataxia	5 (0.2%)	4 (0.2%)	9 (0.2%)
Vestibular disorder	5 (0.2%)	3 (0.1%)	8 (0.2%)
Endocrine disorders	352 (13.9%)	334 (13.2%)	686 (13.5%)
Acromegaly	0	1 (<0.1%)	1 (<0.1%)
Adrenal cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Adrenal mass	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Androgen deficiency	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Autoimmune hypothyroidism	3 (0.1%)	0	3 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	0	1 (<0.1%)
Autoimmune thyroiditis	24 (0.9%)	21 (0.8%)	45 (0.9%)
Basedow's disease	8 (0.3%)	3 (0.1%)	11 (0.2%)
Cushing's syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Endocrine disorder	0	1 (<0.1%)	1 (<0.1%)
Goitre	90 (3.5%)	75 (3.0%)	165 (3.3%)
Hyperaldosteronism	0	4 (0.2%)	4 (<0.1%)
Hyperparathyroidism	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Hyperparathyroidism primary	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hyperparathyroidism secondary	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyperplasia adrenal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperprolactinaemia	2 (<0.1%)	0	2 (<0.1%)
Hyperthyroidism	14 (0.6%)	17 (0.7%)	31 (0.6%)
Hypogonadism	7 (0.3%)	6 (0.2%)	13 (0.3%)
Hypogonadism male	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypopituitarism	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Hypothalamo-pituitary disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypothyroidism	173 (6.8%)	165 (6.5%)	338 (6.7%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	0	1 (<0.1%)	1 (<0.1%)
Oestrogen deficiency	1 (<0.1%)	0	1 (<0.1%)
Primary hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary hypothyroidism	3 (0.1%)	5 (0.2%)	8 (0.2%)
Secondary hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Testicular failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Thyroid calcification	2 (<0.1%)	0	2 (<0.1%)
Thyroid cyst	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Thyroid disorder	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Thyroid mass	36 (1.4%)	30 (1.2%)	66 (1.3%)
Thyroiditis	0	1 (<0.1%)	1 (<0.1%)
Thyroiditis chronic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Toxic nodular goitre	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Eye disorders	1192 (47.0%)	1177 (46.6%)	2369 (46.8%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Age-related macular degeneration	3 (0.1%)	3 (0.1%)	6 (0.1%)
Amaurosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Amaurosis fugax	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amblyopia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amblyopia strabismic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angle closure glaucoma	0	1 (<0.1%)	1 (<0.1%)
Arcus lipoides	1 (<0.1%)	0	1 (<0.1%)
Arteriosclerotic retinopathy	8 (0.3%)	9 (0.4%)	17 (0.3%)
Asthenopia	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Astigmatism	13 (0.5%)	13 (0.5%)	26 (0.5%)
Atrophy of globe	1 (<0.1%)	0	1 (<0.1%)
Blepharitis	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Blepharitis allergic	0	1 (<0.1%)	1 (<0.1%)
Blepharochalasis	1 (<0.1%)	0	1 (<0.1%)
Blindness	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Blindness unilateral	11 (0.4%)	6 (0.2%)	17 (0.3%)
Borderline glaucoma	4 (0.2%)	6 (0.2%)	10 (0.2%)
Cataract	315 (12.4%)	313 (12.4%)	628 (12.4%)
Cataract cortical	2 (<0.1%)	0	2 (<0.1%)
Cataract diabetic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cataract nuclear	10 (0.4%)	7 (0.3%)	17 (0.3%)
Cataract subcapsular	2 (<0.1%)	0	2 (<0.1%)
Chorioretinal atrophy	2 (<0.1%)	0	2 (<0.1%)
Choroidal neovascularisation	1 (<0.1%)	0	1 (<0.1%)
Conjunctival haemorrhage	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Conjunctival hyperaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conjunctivitis allergic	13 (0.5%)	7 (0.3%)	20 (0.4%)
Corneal degeneration	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	1 (<0.1%)	0	1 (<0.1%)
Corneal erosion	0	2 (<0.1%)	2 (<0.1%)
Corneal leukoma	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	0	1 (<0.1%)	1 (<0.1%)
Dacryolith	1 (<0.1%)	0	1 (<0.1%)
Dacryostenosis acquired	1 (<0.1%)	0	1 (<0.1%)
Dermatochalasis	0	1 (<0.1%)	1 (<0.1%)
Diabetic eye disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinal oedema	15 (0.6%)	7 (0.3%)	22 (0.4%)
Diabetic retinopathy	885 (34.9%)	830 (32.9%)	1715 (33.9%)
Diplopia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dry age-related macular degeneration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dry eye	20 (0.8%)	28 (1.1%)	48 (0.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Eales' disease	0	1 (<0.1%)	1 (<0.1%)
Ectropion	1 (<0.1%)	0	1 (<0.1%)
Eczema eyelids	1 (<0.1%)	0	1 (<0.1%)
Endocrine ophthalmopathy	0	1 (<0.1%)	1 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye allergy	0	1 (<0.1%)	1 (<0.1%)
Eye disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye oedema	1 (<0.1%)	0	1 (<0.1%)
Eye opacity	0	1 (<0.1%)	1 (<0.1%)
Eye pruritus	1 (<0.1%)	0	1 (<0.1%)
Eyelid oedema	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eyelid pain	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	5 (0.2%)	4 (0.2%)	9 (0.2%)
Eyelid skin dryness	1 (<0.1%)	0	1 (<0.1%)
Flat anterior chamber of eye	1 (<0.1%)	0	1 (<0.1%)
Glaucoma	108 (4.3%)	120 (4.8%)	228 (4.5%)
Heerfordt's syndrome	0	1 (<0.1%)	1 (<0.1%)
Hypermetropia	15 (0.6%)	21 (0.8%)	36 (0.7%)
Idiopathic orbital inflammation	1 (<0.1%)	0	1 (<0.1%)
Iridocyclitis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Iris adhesions	0	1 (<0.1%)	1 (<0.1%)
Keratitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Keratoconus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	1 (<0.1%)	0	1 (<0.1%)
Lacrimal disorder	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lacrimation increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lenticular opacities	0	1 (<0.1%)	1 (<0.1%)
Macular cyst	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	14 (0.6%)	13 (0.5%)	27 (0.5%)
Macular fibrosis	7 (0.3%)	4 (0.2%)	11 (0.2%)
Macular hole	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	17 (0.7%)	16 (0.6%)	33 (0.7%)
Macular scar	0	1 (<0.1%)	1 (<0.1%)
Maculopathy	9 (0.4%)	8 (0.3%)	17 (0.3%)
Meibomianitis	1 (<0.1%)	0	1 (<0.1%)
Metamorphopsia	0	1 (<0.1%)	1 (<0.1%)
Myopia	36 (1.4%)	34 (1.3%)	70 (1.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Myopic chorioretinal degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neovascular age-related macular degeneration	0	1 (<0.1%)	1 (<0.1%)
Non-proliferative retinopathy	0	3 (0.1%)	3 (<0.1%)
Normal tension glaucoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ocular discomfort	2 (<0.1%)	0	2 (<0.1%)
Ocular hyperaemia	0	1 (<0.1%)	1 (<0.1%)
Ocular hypertension	4 (0.2%)	9 (0.4%)	13 (0.3%)
Open angle glaucoma	7 (0.3%)	5 (0.2%)	12 (0.2%)
Ophthalmoplegia	2 (<0.1%)	0	2 (<0.1%)
Optic atrophy	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Optic disc haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Optic ischaemic neuropathy	0	5 (0.2%)	5 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Pathologic myopia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Periorbital fat herniation	1 (<0.1%)	0	1 (<0.1%)
Posterior capsule opacification	0	3 (0.1%)	3 (<0.1%)
Presbyopia	31 (1.2%)	40 (1.6%)	71 (1.4%)
Pseudopapilloedema	0	1 (<0.1%)	1 (<0.1%)
Pterygium	6 (0.2%)	13 (0.5%)	19 (0.4%)
Punctate keratitis	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	6 (0.2%)	8 (0.3%)	14 (0.3%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery embolism	1 (<0.1%)	0	1 (<0.1%)
Retinal artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Retinal artery spasm	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Retinal cyst	1 (<0.1%)	0	1 (<0.1%)
Retinal degeneration	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Retinal detachment	13 (0.5%)	13 (0.5%)	26 (0.5%)
Retinal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal drusen	0	2 (<0.1%)	2 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	7 (0.3%)	12 (0.5%)	19 (0.4%)
Retinal oedema	1 (<0.1%)	0	1 (<0.1%)
Retinal pigment epitheliopathy	2 (<0.1%)	0	2 (<0.1%)
Retinal scar	0	1 (<0.1%)	1 (<0.1%)
Retinal tear	0	1 (<0.1%)	1 (<0.1%)
Retinal vascular disorder	11 (0.4%)	13 (0.5%)	24 (0.5%)
Retinal vascular thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal vein occlusion	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Retinal vein thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Retinopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Retinopathy hypertensive	27 (1.1%)	36 (1.4%)	63 (1.2%)
Retinopathy proliferative	2 (<0.1%)	0	2 (<0.1%)
Retinoschisis	1 (<0.1%)	0	1 (<0.1%)
Scintillating scotoma	0	1 (<0.1%)	1 (<0.1%)
Scleritis	0	2 (<0.1%)	2 (<0.1%)
Strabismus	3 (0.1%)	3 (0.1%)	6 (0.1%)
Swelling of eyelid	0	1 (<0.1%)	1 (<0.1%)
Trichiasis	0	1 (<0.1%)	1 (<0.1%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	0	1 (<0.1%)	1 (<0.1%)
Vision blurred	4 (0.2%)	4 (0.2%)	8 (0.2%)
Visual acuity reduced	5 (0.2%)	5 (0.2%)	10 (0.2%)
Visual impairment	5 (0.2%)	8 (0.3%)	13 (0.3%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	5 (0.2%)	0	5 (<0.1%)
Vitreous detachment	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Vitreous fibrin	0	1 (<0.1%)	1 (<0.1%)
Vitreous floaters	0	2 (<0.1%)	2 (<0.1%)
Vitreous haemorrhage	22 (0.9%)	12 (0.5%)	34 (0.7%)
Vitreous opacities	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vogt-Koyanagi-Harada disease	0	1 (<0.1%)	1 (<0.1%)
Xanthopsia	0	1 (<0.1%)	1 (<0.1%)
Xerophthalmia	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	788 (31.0%)	812 (32.2%)	1600 (31.6%)
Abdominal discomfort	0	1 (<0.1%)	1 (<0.1%)
Abdominal distension	3 (0.1%)	3 (0.1%)	6 (0.1%)
Abdominal hernia	8 (0.3%)	9 (0.4%)	17 (0.3%)
Abdominal pain	4 (0.2%)	4 (0.2%)	8 (0.2%)
Abdominal pain lower	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Abdominal pain upper	6 (0.2%)	12 (0.5%)	18 (0.4%)
Abnormal faeces	0	1 (<0.1%)	1 (<0.1%)
Acid peptic disease	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Acquired oesophageal web	2 (<0.1%)	0	2 (<0.1%)
Aerophagia	1 (<0.1%)	0	1 (<0.1%)
Alcoholic pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Anal fistula	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Anal haemorrhage	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Anal incontinence	3 (0.1%)	0	3 (<0.1%)
Anal polyp	0	1 (<0.1%)	1 (<0.1%)
Anal pruritus	0	1 (<0.1%)	1 (<0.1%)
Anal skin tags	0	1 (<0.1%)	1 (<0.1%)
Aphthous ulcer	0	1 (<0.1%)	1 (<0.1%)
Appendicitis noninfective	0	1 (<0.1%)	1 (<0.1%)
Aptyalism	1 (<0.1%)	0	1 (<0.1%)
Ascites	1 (<0.1%)	0	1 (<0.1%)
Barrett's oesophagus	6 (0.2%)	5 (0.2%)	11 (0.2%)
Cardiospasm	0	1 (<0.1%)	1 (<0.1%)
Change of bowel habit	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	74 (2.9%)	96 (3.8%)	170 (3.4%)
Coeliac disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colitis	10 (0.4%)	9 (0.4%)	19 (0.4%)
Colitis ulcerative	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Colon dysplasia	1 (<0.1%)	0	1 (<0.1%)
Constipation	83 (3.3%)	64 (2.5%)	147 (2.9%)
Crohn's disease	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dental caries	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Dental cyst	0	1 (<0.1%)	1 (<0.1%)
Diabetic enteropathy	1 (<0.1%)	0	1 (<0.1%)
Diabetic gastroparesis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Diabetic gastropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic hernia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Diarrhoea	29 (1.1%)	38 (1.5%)	67 (1.3%)
Diverticulum	13 (0.5%)	26 (1.0%)	39 (0.8%)
Diverticulum intestinal	26 (1.0%)	12 (0.5%)	38 (0.8%)
Dry mouth	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Duodenal polyp	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Duodenal ulcer	16 (0.6%)	18 (0.7%)	34 (0.7%)
Duodenal ulcer haemorrhage	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Duodenitis	6 (0.2%)	6 (0.2%)	12 (0.2%)
Duodenogastric reflux	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dyspepsia	35 (1.4%)	41 (1.6%)	76 (1.5%)
Dysphagia	6 (0.2%)	5 (0.2%)	11 (0.2%)
Ectopic gastric mucosa	0	1 (<0.1%)	1 (<0.1%)
Enteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterocolitis	1 (<0.1%)	0	1 (<0.1%)
Enterovesical fistula	1 (<0.1%)	0	1 (<0.1%)
Epigastric discomfort	0	2 (<0.1%)	2 (<0.1%)
Erosive duodenitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Erosive oesophagitis	2 (<0.1%)	0	2 (<0.1%)
Fistula of small intestine	0	1 (<0.1%)	1 (<0.1%)
Flatulence	4 (0.2%)	3 (0.1%)	7 (0.1%)
Food poisoning	0	1 (<0.1%)	1 (<0.1%)
Functional gastrointestinal disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallstone ileus	1 (<0.1%)	0	1 (<0.1%)
Gastric disorder	4 (0.2%)	0	4 (<0.1%)
Gastric haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	0	2 (<0.1%)	2 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	9 (0.4%)	9 (0.4%)	18 (0.4%)
Gastric ulcer	27 (1.1%)	27 (1.1%)	54 (1.1%)
Gastric ulcer haemorrhage	2 (<0.1%)	0	2 (<0.1%)
Gastric ulcer perforation	1 (<0.1%)	0	1 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastritis	83 (3.3%)	74 (2.9%)	157 (3.1%)
Gastritis erosive	12 (0.5%)	11 (0.4%)	23 (0.5%)
Gastritis haemorrhagic	0	1 (<0.1%)	1 (<0.1%)
Gastroduodenal ulcer	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Gastrointestinal angiectasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal angiodysplasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorder	4 (0.2%)	5 (0.2%)	9 (0.2%)
Gastrointestinal dysplasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal haemorrhage	5 (0.2%)	4 (0.2%)	9 (0.2%)
Gastrointestinal hypomotility	0	2 (<0.1%)	2 (<0.1%)
Gastrointestinal inflammation	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal motility disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal polyp haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal scarring	0	3 (0.1%)	3 (<0.1%)
Gastrooesophageal reflux disease	193 (7.6%)	200 (7.9%)	393 (7.8%)
Gingival bleeding	1 (<0.1%)	0	1 (<0.1%)
Gingival hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gingival pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematochezia	0	3 (0.1%)	3 (<0.1%)
Haemorrhagic erosive gastritis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoidal haemorrhage	3 (0.1%)	0	3 (<0.1%)
Haemorrhoids	47 (1.9%)	52 (2.1%)	99 (2.0%)
Hernial eventration	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Hiatus hernia	27 (1.1%)	31 (1.2%)	58 (1.1%)
Ileus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Impaired gastric emptying	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Incarcerated umbilical hernia	1 (<0.1%)	0	1 (<0.1%)
Inflammatory bowel disease	0	2 (<0.1%)	2 (<0.1%)
Inguinal hernia	12 (0.5%)	30 (1.2%)	42 (0.8%)
Internal hernia	0	1 (<0.1%)	1 (<0.1%)
Intestinal ischaemia	2 (<0.1%)	0	2 (<0.1%)
Intestinal metaplasia	0	1 (<0.1%)	1 (<0.1%)
Intestinal obstruction	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Intestinal perforation	3 (0.1%)	0	3 (<0.1%)
Intestinal polyp	3 (0.1%)	5 (0.2%)	8 (0.2%)
Irritable bowel syndrome	17 (0.7%)	26 (1.0%)	43 (0.8%)
Large intestinal haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	0	1 (<0.1%)	1 (<0.1%)
Large intestinal stenosis	0	1 (<0.1%)	1 (<0.1%)
Large intestine polyp	27 (1.1%)	40 (1.6%)	67 (1.3%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lip disorder	1 (<0.1%)	0	1 (<0.1%)
Lip swelling	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Lumbar hernia	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Melaena	0	3 (0.1%)	3 (<0.1%)
Mouth cyst	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nausea	10 (0.4%)	15 (0.6%)	25 (0.5%)
Odynophagia	0	1 (<0.1%)	1 (<0.1%)
Oesophageal dilatation	0	1 (<0.1%)	1 (<0.1%)
Oesophageal disorder	1 (<0.1%)	0	1 (<0.1%)
Oesophageal obstruction	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophagitis	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Oesophagitis ulcerative	0	1 (<0.1%)	1 (<0.1%)
Oral disorder	0	1 (<0.1%)	1 (<0.1%)
Pancreatic atrophy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic cyst	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Pancreatic failure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pancreatic necrosis	0	1 (<0.1%)	1 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	2 (<0.1%)	0	2 (<0.1%)
Pancreatitis	12 (0.5%)	10 (0.4%)	22 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Pancreatitis acute	14 (0.6%)	9 (0.4%)	23 (0.5%)
Pancreatitis chronic	35 (1.4%)	38 (1.5%)	73 (1.4%)
Pancreatitis necrotising	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatitis relapsing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatolithiasis	0	1 (<0.1%)	1 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer	15 (0.6%)	15 (0.6%)	30 (0.6%)
Periodontal disease	126 (5.0%)	122 (4.8%)	248 (4.9%)
Peristalsis visible	1 (<0.1%)	0	1 (<0.1%)
Poor dental condition	1 (<0.1%)	0	1 (<0.1%)
Presbyoesophagus	1 (<0.1%)	0	1 (<0.1%)
Proctitis	0	1 (<0.1%)	1 (<0.1%)
Rectal fissure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal haemorrhage	3 (0.1%)	5 (0.2%)	8 (0.2%)
Rectal polyp	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Rectal prolapse	1 (<0.1%)	0	1 (<0.1%)
Salivary gland disorder	0	1 (<0.1%)	1 (<0.1%)
Short-bowel syndrome	1 (<0.1%)	0	1 (<0.1%)
Spigelian hernia	1 (<0.1%)	0	1 (<0.1%)
Splenic artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Stomatitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tongue dysplasia	0	1 (<0.1%)	1 (<0.1%)
Tongue oedema	0	1 (<0.1%)	1 (<0.1%)
Tooth disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth loss	2 (<0.1%)	0	2 (<0.1%)
Toothache	3 (0.1%)	4 (0.2%)	7 (0.1%)
Ulcerative gastritis	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	25 (1.0%)	36 (1.4%)	61 (1.2%)
Upper gastrointestinal haemorrhage	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varices oesophageal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vomiting	4 (0.2%)	7 (0.3%)	11 (0.2%)
General disorders and administration site conditions	210 (8.3%)	192 (7.6%)	402 (7.9%)
Asthenia	4 (0.2%)	8 (0.3%)	12 (0.2%)
Axillary pain	1 (<0.1%)	0	1 (<0.1%)
Calcinosis	1 (<0.1%)	0	1 (<0.1%)
Chest discomfort	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Chest pain	18 (0.7%)	14 (0.6%)	32 (0.6%)
Chills	0	1 (<0.1%)	1 (<0.1%)
Chronic fatigue syndrome	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Cyst	6 (0.2%)	6 (0.2%)	12 (0.2%)
Disease susceptibility	0	1 (<0.1%)	1 (<0.1%)
Drug ineffective	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	8 (0.3%)	9 (0.4%)	17 (0.3%)
Face oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial discomfort	0	1 (<0.1%)	1 (<0.1%)
Facial pain	1 (<0.1%)	0	1 (<0.1%)
Fatigue	14 (0.6%)	15 (0.6%)	29 (0.6%)
Feeling cold	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	3 (0.1%)	4 (0.2%)	7 (0.1%)
Generalised oedema	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gravitational oedema	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Hernia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Illness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Impaired healing	2 (<0.1%)	0	2 (<0.1%)
Inflammation	4 (0.2%)	3 (0.1%)	7 (0.1%)
Influenza like illness	2 (<0.1%)	0	2 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Malaise	2 (<0.1%)	0	2 (<0.1%)
Nodule	0	1 (<0.1%)	1 (<0.1%)
Non-cardiac chest pain	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oedema	24 (0.9%)	18 (0.7%)	42 (0.8%)
Oedema peripheral	94 (3.7%)	97 (3.8%)	191 (3.8%)
Pain	13 (0.5%)	12 (0.5%)	25 (0.5%)
Peripheral swelling	6 (0.2%)	5 (0.2%)	11 (0.2%)
Polyp	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Pyrexia	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Secretion discharge	1 (<0.1%)	0	1 (<0.1%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Temperature intolerance	2 (<0.1%)	0	2 (<0.1%)
Tissue infiltration	0	1 (<0.1%)	1 (<0.1%)
Treatment noncompliance	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Xerosis	0	2 (<0.1%)	2 (<0.1%)
Hepatobiliary disorders	515 (20.3%)	525 (20.8%)	1040 (20.5%)
Acute hepatic failure	1 (<0.1%)	0	1 (<0.1%)
Alcoholic liver disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Autoimmune hepatitis	0	2 (<0.1%)	2 (<0.1%)
Bile duct stone	3 (0.1%)	3 (0.1%)	6 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Biliary colic	2 (<0.1%)	0	2 (<0.1%)
Biliary dilatation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biliary dyskinesia	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Cholangitis	1 (<0.1%)	0	1 (<0.1%)
Cholangitis acute	1 (<0.1%)	0	1 (<0.1%)
Cholangitis chronic	1 (<0.1%)	0	1 (<0.1%)
Cholangitis sclerosing	2 (<0.1%)	0	2 (<0.1%)
Cholecystitis	18 (0.7%)	18 (0.7%)	36 (0.7%)
Cholecystitis acute	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Cholecystitis chronic	23 (0.9%)	29 (1.1%)	52 (1.0%)
Cholelithiasis	119 (4.7%)	105 (4.2%)	224 (4.4%)
Cholestasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Chronic hepatitis	9 (0.4%)	7 (0.3%)	16 (0.3%)
Cirrhosis alcoholic	0	1 (<0.1%)	1 (<0.1%)
Diabetic hepatopathy	11 (0.4%)	5 (0.2%)	16 (0.3%)
Drug-induced liver injury	0	1 (<0.1%)	1 (<0.1%)
Fatty liver alcoholic	0	1 (<0.1%)	1 (<0.1%)
Gallbladder cholesterolosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gallbladder disorder	4 (0.2%)	0	4 (<0.1%)
Gallbladder enlargement	2 (<0.1%)	0	2 (<0.1%)
Gallbladder hypofunction	1 (<0.1%)	0	1 (<0.1%)
Gallbladder polyp	10 (0.4%)	21 (0.8%)	31 (0.6%)
Granulomatous liver disease	0	1 (<0.1%)	1 (<0.1%)
Hepatic calcification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic cirrhosis	7 (0.3%)	4 (0.2%)	11 (0.2%)
Hepatic cyst	7 (0.3%)	13 (0.5%)	20 (0.4%)
Hepatic fibrosis	1 (<0.1%)	0	1 (<0.1%)
Hepatic function abnormal	6 (0.2%)	10 (0.4%)	16 (0.3%)
Hepatic lesion	0	2 (<0.1%)	2 (<0.1%)
Hepatic mass	0	1 (<0.1%)	1 (<0.1%)
Hepatic steatosis	320 (12.6%)	354 (14.0%)	674 (13.3%)
Hepatitis	3 (0.1%)	11 (0.4%)	14 (0.3%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Hepatocellular injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatomegaly	11 (0.4%)	8 (0.3%)	19 (0.4%)
Hepatotoxicity	1 (<0.1%)	0	1 (<0.1%)
Hydrocholecystis	0	1 (<0.1%)	1 (<0.1%)
Hyperbilirubinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperplastic cholecystopathy	0	2 (<0.1%)	2 (<0.1%)
Hypertransaminasaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Jaundice	0	2 (<0.1%)	2 (<0.1%)
Liver disorder	13 (0.5%)	17 (0.7%)	30 (0.6%)
Liver injury	3 (0.1%)	0	3 (<0.1%)
Non-alcoholic steatohepatitis	8 (0.3%)	7 (0.3%)	15 (0.3%)
Nonalcoholic fatty liver disease	28 (1.1%)	19 (0.8%)	47 (0.9%)
Post cholecystectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Primary biliary cholangitis	1 (<0.1%)	0	1 (<0.1%)
Sphincter of Oddi dysfunction	0	1 (<0.1%)	1 (<0.1%)
Steatohepatitis	6 (0.2%)	9 (0.4%)	15 (0.3%)
Immune system disorders	106 (4.2%)	121 (4.8%)	227 (4.5%)
Allergy to animal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Allergy to arthropod sting	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Allergy to chemicals	3 (0.1%)	0	3 (<0.1%)
Allergy to metals	0	2 (<0.1%)	2 (<0.1%)
Allergy to vaccine	0	1 (<0.1%)	1 (<0.1%)
Alloimmunisation	0	1 (<0.1%)	1 (<0.1%)
Anaphylactic reaction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaphylactic shock	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Autoimmune disorder	0	1 (<0.1%)	1 (<0.1%)
Contrast media allergy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Contrast media reaction	0	1 (<0.1%)	1 (<0.1%)
Cryofibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Drug hypersensitivity	36 (1.4%)	51 (2.0%)	87 (1.7%)
Dust allergy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Food allergy	6 (0.2%)	3 (0.1%)	9 (0.2%)
Graft versus host disease	0	1 (<0.1%)	1 (<0.1%)
Hypersensitivity	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immune system disorder	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	3 (0.1%)	5 (0.2%)	8 (0.2%)
Mite allergy	3 (0.1%)	0	3 (<0.1%)
Multiple allergies	6 (0.2%)	5 (0.2%)	11 (0.2%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	2 (<0.1%)	2 (<0.1%)
Rubber sensitivity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sarcoidosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Seasonal allergy	44 (1.7%)	52 (2.1%)	96 (1.9%)
Selective IgA immunodeficiency	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Infections and infestations	565 (22.3%)	549 (21.7%)	1114 (22.0%)
Abdominal abscess	1 (<0.1%)	0	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	0	1 (<0.1%)
Abscess	0	1 (<0.1%)	1 (<0.1%)
Abscess limb	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Abscess neck	0	1 (<0.1%)	1 (<0.1%)
Abscess oral	1 (<0.1%)	0	1 (<0.1%)
Acarodermatitis	0	1 (<0.1%)	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	0	2 (<0.1%)
American trypanosomiasis	0	2 (<0.1%)	2 (<0.1%)
Anal abscess	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Antibiotic associated colitis	0	1 (<0.1%)	1 (<0.1%)
Appendicitis	11 (0.4%)	13 (0.5%)	24 (0.5%)
Appendicitis perforated	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	0	2 (<0.1%)	2 (<0.1%)
Arthritis infective	0	1 (<0.1%)	1 (<0.1%)
Aspergilloma	1 (<0.1%)	0	1 (<0.1%)
Aspergillus infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	0	1 (<0.1%)	1 (<0.1%)
Atypical mycobacterial pneumonia	1 (<0.1%)	0	1 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)
Bacteraemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bacterial disease carrier	0	1 (<0.1%)	1 (<0.1%)
Bacterial infection	1 (<0.1%)	0	1 (<0.1%)
Bacterial sepsis	1 (<0.1%)	0	1 (<0.1%)
Balanitis candida	2 (<0.1%)	0	2 (<0.1%)
Balanoposthitis infective	1 (<0.1%)	0	1 (<0.1%)
Body tinea	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bone tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Borrelia infection	1 (<0.1%)	0	1 (<0.1%)
Bronchiolitis	1 (<0.1%)	0	1 (<0.1%)
Bronchitis	22 (0.9%)	33 (1.3%)	55 (1.1%)
Bronchitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Brucellosis	0	2 (<0.1%)	2 (<0.1%)
Campylobacter colitis	0	1 (<0.1%)	1 (<0.1%)
Candida infection	2 (<0.1%)	0	2 (<0.1%)
Carbuncle	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cellulitis	26 (1.0%)	18 (0.7%)	44 (0.9%)
Cellulitis of male external genital organ	1 (<0.1%)	0	1 (<0.1%)
Chancroid	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Cholecystitis infective	2 (<0.1%)	0	2 (<0.1%)
Chorioretinitis	1 (<0.1%)	0	1 (<0.1%)
Chronic hepatitis B	6 (0.2%)	7 (0.3%)	13 (0.3%)
Chronic hepatitis C	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Chronic sinusitis	19 (0.7%)	13 (0.5%)	32 (0.6%)
Chronic tonsillitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Conjunctivitis	21 (0.8%)	12 (0.5%)	33 (0.7%)
Conjunctivitis viral	1 (<0.1%)	0	1 (<0.1%)
Cystitis	6 (0.2%)	5 (0.2%)	11 (0.2%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dengue fever	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Dermatophytosis of nail	6 (0.2%)	12 (0.5%)	18 (0.4%)
Diabetic foot infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Diabetic gangrene	4 (0.2%)	4 (0.2%)	8 (0.2%)
Diarrhoea infectious	1 (<0.1%)	0	1 (<0.1%)
Disseminated tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Disseminated varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Diverticulitis	11 (0.4%)	13 (0.5%)	24 (0.5%)
Ear infection	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Echinococciasis	1 (<0.1%)	0	1 (<0.1%)
Eczema impetiginous	0	1 (<0.1%)	1 (<0.1%)
Eczema infected	0	2 (<0.1%)	2 (<0.1%)
Emphysematous cystitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	0	2 (<0.1%)	2 (<0.1%)
Endocarditis bacterial	0	1 (<0.1%)	1 (<0.1%)
Epididymitis	3 (0.1%)	0	3 (<0.1%)
Epiglottitis	0	1 (<0.1%)	1 (<0.1%)
Epstein-Barr virus infection	0	1 (<0.1%)	1 (<0.1%)
Erysipelas	11 (0.4%)	8 (0.3%)	19 (0.4%)
Eye infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye infection toxoplasmal	1 (<0.1%)	0	1 (<0.1%)
Folliculitis	4 (0.2%)	3 (0.1%)	7 (0.1%)
Fournier's gangrene	1 (<0.1%)	0	1 (<0.1%)
Fungal infection	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Fungal skin infection	11 (0.4%)	3 (0.1%)	14 (0.3%)
Furuncle	5 (0.2%)	3 (0.1%)	8 (0.2%)
Gallbladder abscess	1 (<0.1%)	0	1 (<0.1%)
Gangrene	2 (<0.1%)	9 (0.4%)	11 (0.2%)
Gastroenteritis	4 (0.2%)	7 (0.3%)	11 (0.2%)
Gastroenteritis viral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Genital herpes	0	2 (<0.1%)	2 (<0.1%)
Genital infection fungal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gingivitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Groin abscess	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
HIV infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Helicobacter gastritis	0	1 (<0.1%)	1 (<0.1%)
Helicobacter infection	4 (0.2%)	7 (0.3%)	11 (0.2%)
Hepatic echinococciasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis A	10 (0.4%)	3 (0.1%)	13 (0.3%)
Hepatitis B	18 (0.7%)	11 (0.4%)	29 (0.6%)
Hepatitis C	11 (0.4%)	15 (0.6%)	26 (0.5%)
Herpes dermatitis	0	1 (<0.1%)	1 (<0.1%)
Herpes ophthalmic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Herpes simplex	0	2 (<0.1%)	2 (<0.1%)
Herpes virus infection	0	1 (<0.1%)	1 (<0.1%)
Herpes zoster	14 (0.6%)	7 (0.3%)	21 (0.4%)
Human T-cell lymphocytic virus type II infection	0	1 (<0.1%)	1 (<0.1%)
Human T-cell lymphotropic virus type I infection	0	1 (<0.1%)	1 (<0.1%)
Infected bite	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	0	1 (<0.1%)	1 (<0.1%)
Infection	1 (<0.1%)	0	1 (<0.1%)
Infectious pleural effusion	1 (<0.1%)	0	1 (<0.1%)
Infective spondylitis	0	1 (<0.1%)	1 (<0.1%)
Influenza	14 (0.6%)	13 (0.5%)	27 (0.5%)
Intervertebral discitis	0	2 (<0.1%)	2 (<0.1%)
Klebsiella bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Labyrinthitis	5 (0.2%)	0	5 (<0.1%)
Laryngitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Legionella infection	1 (<0.1%)	0	1 (<0.1%)
Leprosy	3 (0.1%)	0	3 (<0.1%)
Liver abscess	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Localised infection	6 (0.2%)	7 (0.3%)	13 (0.3%)
Lower respiratory tract infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lower respiratory tract infection viral	0	1 (<0.1%)	1 (<0.1%)
Lung abscess	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Lyme disease	0	1 (<0.1%)	1 (<0.1%)
Lymphangitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Malaria	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	1 (<0.1%)	0	1 (<0.1%)
Mediastinal abscess	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Mediastinitis	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	1 (<0.1%)	0	1 (<0.1%)
Meningitis	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Meningitis tuberculous	1 (<0.1%)	0	1 (<0.1%)
Muscle abscess	0	1 (<0.1%)	1 (<0.1%)
Myringitis	1 (<0.1%)	0	1 (<0.1%)
Nail candida	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	15 (0.6%)	18 (0.7%)	33 (0.7%)
Necrotising fasciitis	0	2 (<0.1%)	2 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Onychomycosis	40 (1.6%)	29 (1.1%)	69 (1.4%)
Oophoritis	0	1 (<0.1%)	1 (<0.1%)
Opisthorchiasis	0	1 (<0.1%)	1 (<0.1%)
Oral candidiasis	0	2 (<0.1%)	2 (<0.1%)
Oral fungal infection	0	1 (<0.1%)	1 (<0.1%)
Oral herpes	0	3 (0.1%)	3 (<0.1%)
Orchitis	0	1 (<0.1%)	1 (<0.1%)
Osteomyelitis	14 (0.6%)	15 (0.6%)	29 (0.6%)
Osteomyelitis chronic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Otitis externa	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Otitis media	3 (0.1%)	4 (0.2%)	7 (0.1%)
Otitis media chronic	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Otosalpingitis	0	1 (<0.1%)	1 (<0.1%)
Pancreas infection	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	0	1 (<0.1%)	1 (<0.1%)
Paronychia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Parotitis	4 (0.2%)	0	4 (<0.1%)
Penile infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Periodontitis	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Peritonsillar abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	4 (0.2%)	9 (0.4%)	13 (0.3%)
Pharyngotonsillitis	1 (<0.1%)	0	1 (<0.1%)
Pilonidal cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonia	30 (1.2%)	26 (1.0%)	56 (1.1%)
Pneumonia bacterial	0	1 (<0.1%)	1 (<0.1%)
Pneumonia legionella	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonia pseudomonal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia viral	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Poliomyelitis	5 (0.2%)	3 (0.1%)	8 (0.2%)
Post procedural infection	1 (<0.1%)	0	1 (<0.1%)
Postoperative wound infection	2 (<0.1%)	0	2 (<0.1%)
Pulmonary tuberculoma	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	8 (0.3%)	10 (0.4%)	18 (0.4%)
Pulpitis dental	0	1 (<0.1%)	1 (<0.1%)
Pustule	0	1 (<0.1%)	1 (<0.1%)
Pyelonephritis	6 (0.2%)	12 (0.5%)	18 (0.4%)
Pyelonephritis acute	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pyelonephritis chronic	42 (1.7%)	40 (1.6%)	82 (1.6%)
Pyoderma	1 (<0.1%)	0	1 (<0.1%)
Pyuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal abscess	0	1 (<0.1%)	1 (<0.1%)
Respiratory tract infection	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Respiratory tract infection viral	1 (<0.1%)	0	1 (<0.1%)
Retroperitoneal abscess	0	1 (<0.1%)	1 (<0.1%)
Rhinitis	9 (0.4%)	11 (0.4%)	20 (0.4%)
Salpingo-oophoritis	0	1 (<0.1%)	1 (<0.1%)
Scrotal infection	0	1 (<0.1%)	1 (<0.1%)
Sepsis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Septic arthritis staphylococcal	1 (<0.1%)	0	1 (<0.1%)
Septic shock	1 (<0.1%)	0	1 (<0.1%)
Sialoadenitis	0	1 (<0.1%)	1 (<0.1%)
Sinusitis	13 (0.5%)	19 (0.8%)	32 (0.6%)
Skin candida	0	2 (<0.1%)	2 (<0.1%)
Skin infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Staphylococcal infection	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal sepsis	0	1 (<0.1%)	1 (<0.1%)
Streptococcal endocarditis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	3 (0.1%)	3 (0.1%)	6 (0.1%)
Syphilis	2 (<0.1%)	0	2 (<0.1%)
Systemic candida	1 (<0.1%)	0	1 (<0.1%)
Tinea capitis	0	2 (<0.1%)	2 (<0.1%)
Tinea cruris	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Tinea infection	3 (0.1%)	6 (0.2%)	9 (0.2%)
Tinea pedis	19 (0.7%)	30 (1.2%)	49 (1.0%)
Tinea versicolour	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tonsillitis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Tonsillitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Tooth abscess	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tooth infection	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Tracheitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tuberculosis	9 (0.4%)	8 (0.3%)	17 (0.3%)
Tuberculous pleurisy	2 (<0.1%)	0	2 (<0.1%)
Tubo-ovarian abscess	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	28 (1.1%)	27 (1.1%)	55 (1.1%)
Urethritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary tract infection	32 (1.3%)	46 (1.8%)	78 (1.5%)
Urinary tract infection bacterial	0	1 (<0.1%)	1 (<0.1%)
Urosepsis	0	2 (<0.1%)	2 (<0.1%)
Vaginal infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicella	1 (<0.1%)	0	1 (<0.1%)
Vascular device infection	1 (<0.1%)	0	1 (<0.1%)
Vestibular neuronitis	0	1 (<0.1%)	1 (<0.1%)
Viral hepatitis carrier	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Viral infection	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vulvitis	0	1 (<0.1%)	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal mycotic infection	0	1 (<0.1%)	1 (<0.1%)
Vulvovaginitis	0	1 (<0.1%)	1 (<0.1%)
Wound infection	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Zika virus infection	1 (<0.1%)	0	1 (<0.1%)
Injury, poisoning and procedural complications	213 (8.4%)	194 (7.7%)	407 (8.0%)
Abdominal injury	0	1 (<0.1%)	1 (<0.1%)
Accident	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Airway burns	0	1 (<0.1%)	1 (<0.1%)
Anastomotic ulcer	0	1 (<0.1%)	1 (<0.1%)
Animal bite	1 (<0.1%)	0	1 (<0.1%)
Ankle fracture	13 (0.5%)	9 (0.4%)	22 (0.4%)
Aortic injury	1 (<0.1%)	0	1 (<0.1%)
Arthropod sting	1 (<0.1%)	0	1 (<0.1%)
Asbestosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blindness traumatic	2 (<0.1%)	0	2 (<0.1%)
Bone contusion	0	1 (<0.1%)	1 (<0.1%)
Breast injury	1 (<0.1%)	0	1 (<0.1%)
Burns second degree	1 (<0.1%)	0	1 (<0.1%)
Burns third degree	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cartilage injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cervical vertebral fracture	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Chest injury	0	4 (0.2%)	4 (<0.1%)
Chillblains	0	1 (<0.1%)	1 (<0.1%)
Clavicle fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Concussion	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Contusion	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Corneal abrasion	0	2 (<0.1%)	2 (<0.1%)
Coronary bypass stenosis	0	1 (<0.1%)	1 (<0.1%)
Craniocerebral injury	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Electric injury	1 (<0.1%)	0	1 (<0.1%)
Endotracheal intubation complication	1 (<0.1%)	0	1 (<0.1%)
Epicondylitis	12 (0.5%)	5 (0.2%)	17 (0.3%)
Exposure to communicable disease	0	1 (<0.1%)	1 (<0.1%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye contusion	1 (<0.1%)	0	1 (<0.1%)
Eye injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye laser scar	1 (<0.1%)	0	1 (<0.1%)
Eyeball avulsion	0	1 (<0.1%)	1 (<0.1%)
Face injury	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Facial bones fracture	1 (<0.1%)	0	1 (<0.1%)
Fall	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Femoral neck fracture	1 (<0.1%)	0	1 (<0.1%)
Femur fracture	5 (0.2%)	6 (0.2%)	11 (0.2%)
Fibula fracture	4 (0.2%)	4 (0.2%)	8 (0.2%)
Foot fracture	8 (0.3%)	1 (<0.1%)	9 (0.2%)
Forearm fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body	0	1 (<0.1%)	1 (<0.1%)
Foreign body in eye	2 (<0.1%)	0	2 (<0.1%)
Fracture	0	1 (<0.1%)	1 (<0.1%)
Fracture of penis	1 (<0.1%)	0	1 (<0.1%)
Fractured coccyx	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastrointestinal anastomotic leak	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	1 (<0.1%)	0	1 (<0.1%)
Hand fracture	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Head injury	4 (0.2%)	3 (0.1%)	7 (0.1%)
Hip fracture	0	1 (<0.1%)	1 (<0.1%)
Humerus fracture	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Iliotibial band syndrome	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia	6 (0.2%)	7 (0.3%)	13 (0.3%)
Injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injury corneal	0	2 (<0.1%)	2 (<0.1%)
Intentional overdose	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Intervertebral disc injury	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Iris injury	1 (<0.1%)	0	1 (<0.1%)
Jaw fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Joint dislocation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint injury	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Ligament injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament rupture	5 (0.2%)	6 (0.2%)	11 (0.2%)
Ligament sprain	6 (0.2%)	6 (0.2%)	12 (0.2%)
Limb injury	11 (0.4%)	12 (0.5%)	23 (0.5%)
Limb traumatic amputation	3 (0.1%)	5 (0.2%)	8 (0.2%)
Lower limb fracture	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Lumbar vertebral fracture	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Median nerve injury	0	1 (<0.1%)	1 (<0.1%)
Meniscus injury	17 (0.7%)	9 (0.4%)	26 (0.5%)
Multiple fractures	1 (<0.1%)	0	1 (<0.1%)
Multiple injuries	1 (<0.1%)	0	1 (<0.1%)
Muscle injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Muscle rupture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Muscle strain	4 (0.2%)	0	4 (<0.1%)
Patella fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic bone injury	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Persistent corneal epithelial defect	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	2 (<0.1%)	0	2 (<0.1%)
Post concussion syndrome	1 (<0.1%)	0	1 (<0.1%)
Post laminectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypothyroidism	7 (0.3%)	8 (0.3%)	15 (0.3%)
Post procedural swelling	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic neck syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post-traumatic pain	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Postoperative adhesion	1 (<0.1%)	0	1 (<0.1%)
Procedural intestinal perforation	1 (<0.1%)	0	1 (<0.1%)
Procedural pain	0	3 (0.1%)	3 (<0.1%)
Radiation skin injury	1 (<0.1%)	0	1 (<0.1%)
Radius fracture	6 (0.2%)	3 (0.1%)	9 (0.2%)
Rib fracture	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Road traffic accident	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Scar	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Silicosis	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Skin abrasion	1 (<0.1%)	0	1 (<0.1%)
Skin laceration	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Skin wound	1 (<0.1%)	0	1 (<0.1%)
Skull fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Snake bite	0	1 (<0.1%)	1 (<0.1%)
Soft tissue injury	2 (<0.1%)	0	2 (<0.1%)
Spinal column injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal compression fracture	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Spinal cord injury	0	1 (<0.1%)	1 (<0.1%)
Spinal cord injury thoracic	0	1 (<0.1%)	1 (<0.1%)
Spinal fracture	0	2 (<0.1%)	2 (<0.1%)
Spleen contusion	1 (<0.1%)	0	1 (<0.1%)
Splenic rupture	0	2 (<0.1%)	2 (<0.1%)
Stab wound	0	1 (<0.1%)	1 (<0.1%)
Stoma site irritation	0	1 (<0.1%)	1 (<0.1%)
Stomal hernia	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	0	1 (<0.1%)
Subdural haematoma	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Synovial rupture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tendon injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tendon rupture	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Testicular injury	0	1 (<0.1%)	1 (<0.1%)
Thermal burn	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Thermal burns of eye	0	1 (<0.1%)	1 (<0.1%)
Thoracic vertebral fracture	1 (<0.1%)	0	1 (<0.1%)
Tibia fracture	3 (0.1%)	4 (0.2%)	7 (0.1%)
Tobacco poisoning	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth fracture	0	2 (<0.1%)	2 (<0.1%)
Toxicity to various agents	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthritis	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthrosis	2 (<0.1%)	0	2 (<0.1%)
Traumatic fracture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Traumatic haemothorax	0	2 (<0.1%)	2 (<0.1%)
Traumatic renal injury	1 (<0.1%)	0	1 (<0.1%)
Traumatic ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ulna fracture	0	1 (<0.1%)	1 (<0.1%)
Upper limb fracture	7 (0.3%)	5 (0.2%)	12 (0.2%)
Wound dehiscence	0	1 (<0.1%)	1 (<0.1%)
Wound necrosis	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Wrist fracture	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Investigations	263 (10.4%)	274 (10.9%)	537 (10.6%)
Alanine aminotransferase increased	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Albumin urine present	0	1 (<0.1%)	1 (<0.1%)
Angiocardiogram	21 (0.8%)	16 (0.6%)	37 (0.7%)
Angiogram	4 (0.2%)	4 (0.2%)	8 (0.2%)
Angiogram cerebral	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Antinuclear antibody positive	2 (<0.1%)	0	2 (<0.1%)
Aortic bruit	0	2 (<0.1%)	2 (<0.1%)
Arthroscopy	5 (0.2%)	11 (0.4%)	16 (0.3%)
Aspartate aminotransferase increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Aspiration pleural cavity	1 (<0.1%)	0	1 (<0.1%)
Autoantibody positive	0	1 (<0.1%)	1 (<0.1%)
Biopsy breast	0	1 (<0.1%)	1 (<0.1%)
Biopsy kidney	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Biopsy prostate	0	1 (<0.1%)	1 (<0.1%)
Biopsy thyroid gland	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	0	1 (<0.1%)	1 (<0.1%)
Blood bicarbonate decreased	1 (<0.1%)	0	1 (<0.1%)
Blood calcium increased	0	1 (<0.1%)	1 (<0.1%)
Blood cholesterol increased	34 (1.3%)	51 (2.0%)	85 (1.7%)
Blood creatine phosphokinase abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood creatine phosphokinase increased	35 (1.4%)	42 (1.7%)	77 (1.5%)
Blood creatinine increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood lactate dehydrogenase increased	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Blood magnesium decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Blood potassium decreased	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	1 (<0.1%)	0	1 (<0.1%)
Blood pressure increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Blood sodium decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Blood testosterone decreased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Blood thyroid stimulating hormone normal	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	6 (0.2%)	8 (0.3%)	14 (0.3%)
Blood uric acid abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood uric acid increased	5 (0.2%)	8 (0.3%)	13 (0.3%)
Body mass index increased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Bone density decreased	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Borrelia test positive	0	1 (<0.1%)	1 (<0.1%)
Breath sounds abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	14 (0.6%)	7 (0.3%)	21 (0.4%)
Carcinoembryonic antigen increased	1 (<0.1%)	0	1 (<0.1%)
Cardiac function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Cardiac murmur	14 (0.6%)	9 (0.4%)	23 (0.5%)
Cardiac stress test normal	0	1 (<0.1%)	1 (<0.1%)
Carotid bruit	1 (<0.1%)	0	1 (<0.1%)
Carotid intima-media thickness increased	0	1 (<0.1%)	1 (<0.1%)
Catheterisation cardiac	9 (0.4%)	7 (0.3%)	16 (0.3%)
Catheterisation cardiac normal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cystoscopy	2 (<0.1%)	0	2 (<0.1%)
ECG electrically inactive area	2 (<0.1%)	0	2 (<0.1%)
ECG signs of myocardial infarction	1 (<0.1%)	0	1 (<0.1%)
Ejection fraction decreased	0	1 (<0.1%)	1 (<0.1%)
Ejection fraction normal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram PR shortened	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QRS complex abnormal	2 (<0.1%)	0	2 (<0.1%)
Electrocardiogram QT interval abnormal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Electrocardiogram QT prolonged	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram ST segment abnormal	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Electrocardiogram ST segment depression	0	3 (0.1%)	3 (<0.1%)
Electrocardiogram ST segment elevation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram ST-T change	2 (<0.1%)	0	2 (<0.1%)
Electrocardiogram ST-T segment abnormal	0	3 (0.1%)	3 (<0.1%)
Electrocardiogram T wave abnormal	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Electrocardiogram T wave amplitude decreased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Electrocardiogram T wave inversion	4 (0.2%)	5 (0.2%)	9 (0.2%)
Electrocardiogram abnormal	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Electrocardiogram repolarisation abnormality	3 (0.1%)	5 (0.2%)	8 (0.2%)
False positive investigation result	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Forced expiratory volume decreased	0	1 (<0.1%)	1 (<0.1%)
Gamma-glutamyltransferase increased	15 (0.6%)	16 (0.6%)	31 (0.6%)
Gastric pH decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glycosylated haemoglobin increased	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin decreased	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Haemoglobin increased	0	2 (<0.1%)	2 (<0.1%)
Heart rate decreased	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Helicobacter test positive	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Hepatic enzyme abnormal	0	2 (<0.1%)	2 (<0.1%)
Hepatic enzyme increased	7 (0.3%)	5 (0.2%)	12 (0.2%)
Hepatitis B antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B core antibody positive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis B surface antibody positive	1 (<0.1%)	0	1 (<0.1%)
Hepatitis B surface antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	0	2 (<0.1%)
Hepatitis C antibody positive	0	1 (<0.1%)	1 (<0.1%)
Human papilloma virus test negative	1 (<0.1%)	0	1 (<0.1%)
Hysteroscopy	0	1 (<0.1%)	1 (<0.1%)
Intraocular pressure increased	4 (0.2%)	3 (0.1%)	7 (0.1%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)
Left ventricular end-diastolic pressure increased	0	1 (<0.1%)	1 (<0.1%)
Lipids abnormal	0	2 (<0.1%)	2 (<0.1%)
Lipoprotein (a) increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipoprotein abnormal	0	1 (<0.1%)	1 (<0.1%)
Liver function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Liver function test increased	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Liver scan abnormal	1 (<0.1%)	0	1 (<0.1%)
Low density lipoprotein increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mean cell volume increased	0	1 (<0.1%)	1 (<0.1%)
Muscle enzyme increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myocardial strain	0	1 (<0.1%)	1 (<0.1%)
Occult blood positive	2 (<0.1%)	0	2 (<0.1%)
Oxygen consumption increased	1 (<0.1%)	0	1 (<0.1%)
Peripheral arteriogram	2 (<0.1%)	0	2 (<0.1%)
Peripheral pulse decreased	0	1 (<0.1%)	1 (<0.1%)
Physical examination	0	1 (<0.1%)	1 (<0.1%)
Platelet count decreased	0	1 (<0.1%)	1 (<0.1%)
Prostatic specific antigen increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Protein urine present	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary imaging procedure abnormal	2 (<0.1%)	0	2 (<0.1%)
Pulse absent	1 (<0.1%)	0	1 (<0.1%)
QRS axis abnormal	14 (0.6%)	15 (0.6%)	29 (0.6%)
Red blood cell sedimentation rate increased	0	1 (<0.1%)	1 (<0.1%)
Scan myocardial perfusion	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Thyroid function test normal	1 (<0.1%)	0	1 (<0.1%)
Transaminases increased	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Treponema test positive	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Troponin increased	2 (<0.1%)	0	2 (<0.1%)
Ultrasound Doppler abnormal	0	1 (<0.1%)	1 (<0.1%)
Ultrasound kidney abnormal	0	1 (<0.1%)	1 (<0.1%)
Ureteroscopy	1 (<0.1%)	0	1 (<0.1%)
Urinary occult blood positive	0	1 (<0.1%)	1 (<0.1%)
Urine albumin/creatinine ratio increased	0	2 (<0.1%)	2 (<0.1%)
Urogram	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	0	2 (<0.1%)	2 (<0.1%)
Vitamin D decreased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Vitamin E decreased	0	1 (<0.1%)	1 (<0.1%)
Weight decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Weight increased	0	2 (<0.1%)	2 (<0.1%)
White blood cell count increased	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Metabolism and nutrition disorders	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)
Abnormal loss of weight	1 (<0.1%)	0	1 (<0.1%)
Acidosis	1 (<0.1%)	0	1 (<0.1%)
Acquired mixed hyperlipidaemia	0	2 (<0.1%)	2 (<0.1%)
Calcium deficiency	1 (<0.1%)	0	1 (<0.1%)
Central obesity	14 (0.6%)	20 (0.8%)	34 (0.7%)
Decreased appetite	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Dehydration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus	2 (<0.1%)	0	2 (<0.1%)
Diabetes mellitus inadequate control	5 (0.2%)	8 (0.3%)	13 (0.3%)
Diabetic dyslipidaemia	0	3 (0.1%)	3 (<0.1%)
Diabetic ketoacidosis	0	5 (0.2%)	5 (<0.1%)
Diabetic ketosis	0	3 (0.1%)	3 (<0.1%)
Dyslipidaemia	831 (32.7%)	861 (34.1%)	1692 (33.4%)
Fluid retention	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Folate deficiency	3 (0.1%)	5 (0.2%)	8 (0.2%)
Fructose intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	0	1 (<0.1%)	1 (<0.1%)
Gout	119 (4.7%)	137 (5.4%)	256 (5.1%)
Haemochromatosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyper HDL cholesterolaemia	1 (<0.1%)	0	1 (<0.1%)
Hypercalcaemia	8 (0.3%)	6 (0.2%)	14 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Hypercholesterolaemia	288 (11.3%)	293 (11.6%)	581 (11.5%)
Hyperferritinaemia	0	2 (<0.1%)	2 (<0.1%)
Hyperglycaemia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Hyperhomocysteinaemia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Hyperinsulinaemic hypoglycaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperkalaemia	13 (0.5%)	13 (0.5%)	26 (0.5%)
Hyperlipidaemia	599 (23.6%)	607 (24.0%)	1206 (23.8%)
Hyperphosphataemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypertriglyceridaemia	68 (2.7%)	60 (2.4%)	128 (2.5%)
Hyperuricaemia	229 (9.0%)	212 (8.4%)	441 (8.7%)
Hypervolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypo HDL cholesterolaemia	1 (<0.1%)	0	1 (<0.1%)
Hypoalbuminaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypocalcaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hypocholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypoglycaemia	12 (0.5%)	12 (0.5%)	24 (0.5%)
Hypokalaemia	25 (1.0%)	19 (0.8%)	44 (0.9%)
Hypomagnesaemia	9 (0.4%)	7 (0.3%)	16 (0.3%)
Hyponatraemia	11 (0.4%)	6 (0.2%)	17 (0.3%)
Hypoproteinaemia	4 (0.2%)	6 (0.2%)	10 (0.2%)
Hypovitaminosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Impaired fasting glucose	0	2 (<0.1%)	2 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iodine deficiency	0	1 (<0.1%)	1 (<0.1%)
Iron deficiency	15 (0.6%)	15 (0.6%)	30 (0.6%)
Iron overload	0	1 (<0.1%)	1 (<0.1%)
Ketosis	0	1 (<0.1%)	1 (<0.1%)
Lactose intolerance	0	2 (<0.1%)	2 (<0.1%)
Lipid metabolism disorder	7 (0.3%)	7 (0.3%)	14 (0.3%)
Lipomatosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipoprotein deficiency	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Metabolic acidosis	0	3 (0.1%)	3 (<0.1%)
Metabolic alkalosis	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metabolic syndrome	22 (0.9%)	22 (0.9%)	44 (0.9%)
Obesity	1083 (42.7%)	1106 (43.8%)	2189 (43.2%)
Overweight	22 (0.9%)	25 (1.0%)	47 (0.9%)
Purine metabolism disorder	0	1 (<0.1%)	1 (<0.1%)
Type 2 diabetes mellitus	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Vitamin B complex deficiency	4 (0.2%)	6 (0.2%)	10 (0.2%)
Vitamin B12 deficiency	29 (1.1%)	25 (1.0%)	54 (1.1%)
Vitamin C deficiency	1 (<0.1%)	0	1 (<0.1%)
Vitamin D deficiency	134 (5.3%)	114 (4.5%)	248 (4.9%)
Musculoskeletal and connective tissue disorders	832 (32.8%)	832 (33.0%)	1664 (32.9%)
Acquired claw toe	1 (<0.1%)	0	1 (<0.1%)
Ankylosing spondylitis	3 (0.1%)	7 (0.3%)	10 (0.2%)
Arthralgia	88 (3.5%)	102 (4.0%)	190 (3.8%)
Arthritis	32 (1.3%)	26 (1.0%)	58 (1.1%)
Arthritis reactive	0	1 (<0.1%)	1 (<0.1%)
Arthropathy	4 (0.2%)	3 (0.1%)	7 (0.1%)
Autoimmune arthritis	1 (<0.1%)	0	1 (<0.1%)
Back disorder	6 (0.2%)	10 (0.4%)	16 (0.3%)
Back pain	138 (5.4%)	159 (6.3%)	297 (5.9%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	0	1 (<0.1%)	1 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone infarction	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	1 (<0.1%)	0	1 (<0.1%)
Bone loss	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bone pain	1 (<0.1%)	0	1 (<0.1%)
Bone swelling	1 (<0.1%)	0	1 (<0.1%)
Bursitis	13 (0.5%)	10 (0.4%)	23 (0.5%)
Cervical spinal stenosis	6 (0.2%)	7 (0.3%)	13 (0.3%)
Chondrocalcinosis	0	1 (<0.1%)	1 (<0.1%)
Chondrocalcinosis pyrophosphate	2 (<0.1%)	0	2 (<0.1%)
Chondromalacia	0	2 (<0.1%)	2 (<0.1%)
Chondropathy	0	1 (<0.1%)	1 (<0.1%)
Chronic kidney disease-mineral and bone disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Clubbing	0	1 (<0.1%)	1 (<0.1%)
Coccydynia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Collagen disorder	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	1 (<0.1%)	0	1 (<0.1%)
Connective tissue inflammation	0	1 (<0.1%)	1 (<0.1%)
Costochondritis	1 (<0.1%)	0	1 (<0.1%)
Crowned dens syndrome	1 (<0.1%)	0	1 (<0.1%)
Crystal arthropathy	1 (<0.1%)	0	1 (<0.1%)
Dactylitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Diastasis recti abdominis	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Diffuse idiopathic skeletal hyperostosis	0	1 (<0.1%)	1 (<0.1%)
Dupuytren's contracture	10 (0.4%)	4 (0.2%)	14 (0.3%)
Enthesopathy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Exostosis	7 (0.3%)	9 (0.4%)	16 (0.3%)
Facet joint syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fasciitis	0	2 (<0.1%)	2 (<0.1%)
Fibromyalgia	6 (0.2%)	5 (0.2%)	11 (0.2%)
Finger deformity	0	1 (<0.1%)	1 (<0.1%)
Fistula	1 (<0.1%)	0	1 (<0.1%)
Flank pain	4 (0.2%)	0	4 (<0.1%)
Foot deformity	14 (0.6%)	16 (0.6%)	30 (0.6%)
Gouty arthritis	14 (0.6%)	7 (0.3%)	21 (0.4%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)
Haemarthrosis	0	1 (<0.1%)	1 (<0.1%)
Inclusion body myositis	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc compression	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc degeneration	23 (0.9%)	22 (0.9%)	45 (0.9%)
Intervertebral disc disorder	28 (1.1%)	20 (0.8%)	48 (0.9%)
Intervertebral disc displacement	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc protrusion	62 (2.4%)	75 (3.0%)	137 (2.7%)
Jaw cyst	1 (<0.1%)	0	1 (<0.1%)
Joint deposit	1 (<0.1%)	0	1 (<0.1%)
Joint effusion	0	2 (<0.1%)	2 (<0.1%)
Joint range of motion decreased	1 (<0.1%)	0	1 (<0.1%)
Joint stiffness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint swelling	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Knee deformity	1 (<0.1%)	0	1 (<0.1%)
Kyphosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Limb asymmetry	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Limb deformity	0	1 (<0.1%)	1 (<0.1%)
Limb discomfort	2 (<0.1%)	0	2 (<0.1%)
Lumbar spinal stenosis	18 (0.7%)	12 (0.5%)	30 (0.6%)
Metatarsalgia	1 (<0.1%)	0	1 (<0.1%)
Muscle atrophy	0	1 (<0.1%)	1 (<0.1%)
Muscle contracture	2 (<0.1%)	0	2 (<0.1%)
Muscle fatigue	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	50 (2.0%)	48 (1.9%)	98 (1.9%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscle twitching	0	1 (<0.1%)	1 (<0.1%)
Muscular weakness	2 (<0.1%)	3 (0.1%)	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Musculoskeletal chest pain	1 (<0.1%)	0	1 (<0.1%)
Musculoskeletal discomfort	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Musculoskeletal pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Musculoskeletal stiffness	3 (0.1%)	5 (0.2%)	8 (0.2%)
Myalgia	32 (1.3%)	28 (1.1%)	60 (1.2%)
Myofascial pain syndrome	0	2 (<0.1%)	2 (<0.1%)
Myopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Myositis	2 (<0.1%)	0	2 (<0.1%)
Neck mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neck pain	22 (0.9%)	21 (0.8%)	43 (0.8%)
Neuropathic arthropathy	12 (0.5%)	11 (0.4%)	23 (0.5%)
Oligoarthritis	1 (<0.1%)	0	1 (<0.1%)
Osteitis	3 (0.1%)	0	3 (<0.1%)
Osteoarthritis	263 (10.4%)	276 (10.9%)	539 (10.6%)
Osteoarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteochondritis	1 (<0.1%)	0	1 (<0.1%)
Osteochondrosis	35 (1.4%)	38 (1.5%)	73 (1.4%)
Osteomalacia	1 (<0.1%)	0	1 (<0.1%)
Osteonecrosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Osteopenia	20 (0.8%)	15 (0.6%)	35 (0.7%)
Osteoporosis	52 (2.0%)	50 (2.0%)	102 (2.0%)
Osteoporosis postmenopausal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Osteosclerosis	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	33 (1.3%)	30 (1.2%)	63 (1.2%)
Patellofemoral pain syndrome	0	3 (0.1%)	3 (<0.1%)
Pathological fracture	1 (<0.1%)	0	1 (<0.1%)
Periarthritis	26 (1.0%)	12 (0.5%)	38 (0.8%)
Perthes disease	1 (<0.1%)	0	1 (<0.1%)
Plantar fascial fibromatosis	0	2 (<0.1%)	2 (<0.1%)
Plantar fasciitis	7 (0.3%)	4 (0.2%)	11 (0.2%)
Polyarthritis	4 (0.2%)	5 (0.2%)	9 (0.2%)
Polymyalgia rheumatica	0	2 (<0.1%)	2 (<0.1%)
Psoriatic arthropathy	5 (0.2%)	7 (0.3%)	12 (0.2%)
Rhabdomyolysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rheumatic disorder	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Rheumatic fever	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Rheumatoid arthritis	20 (0.8%)	16 (0.6%)	36 (0.7%)
Rotator cuff syndrome	25 (1.0%)	30 (1.2%)	55 (1.1%)
Sacroiliitis	2 (<0.1%)	0	2 (<0.1%)
Scleroderma	0	1 (<0.1%)	1 (<0.1%)
Scoliosis	4 (0.2%)	3 (0.1%)	7 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Sjogren's syndrome	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Soft tissue disorder	1 (<0.1%)	0	1 (<0.1%)
Spinal deformity	3 (0.1%)	0	3 (<0.1%)
Spinal disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Spinal fusion acquired	1 (<0.1%)	0	1 (<0.1%)
Spinal instability	1 (<0.1%)	0	1 (<0.1%)
Spinal ligament ossification	0	2 (<0.1%)	2 (<0.1%)
Spinal osteoarthritis	97 (3.8%)	95 (3.8%)	192 (3.8%)
Spinal pain	15 (0.6%)	13 (0.5%)	28 (0.6%)
Spinal retrolisthesis	2 (<0.1%)	0	2 (<0.1%)
Spinal stenosis	13 (0.5%)	11 (0.4%)	24 (0.5%)
Spondylitis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Spondyloarthropathy	4 (0.2%)	4 (0.2%)	8 (0.2%)
Spondylolisthesis	8 (0.3%)	6 (0.2%)	14 (0.3%)
Sympathetic posterior cervical syndrome	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	10 (0.4%)	4 (0.2%)	14 (0.3%)
Synovitis	0	2 (<0.1%)	2 (<0.1%)
Systemic lupus erythematosus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Temporomandibular joint syndrome	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Tendon calcification	1 (<0.1%)	0	1 (<0.1%)
Tendon disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tendonitis	12 (0.5%)	6 (0.2%)	18 (0.4%)
Tenosynovitis	5 (0.2%)	8 (0.3%)	13 (0.3%)
Tenosynovitis stenosans	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Torticollis	0	1 (<0.1%)	1 (<0.1%)
Trigger finger	7 (0.3%)	9 (0.4%)	16 (0.3%)
Vertebral foraminal stenosis	0	4 (0.2%)	4 (<0.1%)
Vertebral lesion	1 (<0.1%)	0	1 (<0.1%)
Vertebral osteophyte	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	248 (9.8%)	237 (9.4%)	485 (9.6%)
Acoustic neuroma	0	1 (<0.1%)	1 (<0.1%)
Acrochordon	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Acute myeloid leukaemia	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma	2 (<0.1%)	0	2 (<0.1%)
Adenocarcinoma of colon	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenoma benign	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Adrenal adenoma	6 (0.2%)	9 (0.4%)	15 (0.3%)
Adrenal neoplasm	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Angiomyolipoma	0	1 (<0.1%)	1 (<0.1%)
B-cell lymphoma	1 (<0.1%)	0	1 (<0.1%)
Basal cell carcinoma	14 (0.6%)	9 (0.4%)	23 (0.5%)
Basosquamous carcinoma	1 (<0.1%)	0	1 (<0.1%)
Benign abdominal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign breast neoplasm	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Benign duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Benign hepatobiliary neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign lung neoplasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Benign neoplasm of adrenal gland	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of cornea	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of eyelid	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of skin	0	3 (0.1%)	3 (<0.1%)
Benign neoplasm of thyroid gland	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Benign ovarian tumour	0	1 (<0.1%)	1 (<0.1%)
Benign pancreatic neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Bladder cancer	5 (0.2%)	6 (0.2%)	11 (0.2%)
Bladder neoplasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bladder papilloma	4 (0.2%)	0	4 (<0.1%)
Bladder transitional cell carcinoma	0	2 (<0.1%)	2 (<0.1%)
Bone neoplasm	1 (<0.1%)	0	1 (<0.1%)
Bowen's disease	0	2 (<0.1%)	2 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Breast adenoma	1 (<0.1%)	0	1 (<0.1%)
Breast cancer	10 (0.4%)	10 (0.4%)	20 (0.4%)
Breast cancer metastatic	0	1 (<0.1%)	1 (<0.1%)
Breast fibroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast neoplasm	0	1 (<0.1%)	1 (<0.1%)
Carcinoid tumour of the stomach	1 (<0.1%)	0	1 (<0.1%)
Cerebellopontine angle tumour	1 (<0.1%)	0	1 (<0.1%)
Cerebral haemangioma	0	1 (<0.1%)	1 (<0.1%)
Cervix carcinoma	0	3 (0.1%)	3 (<0.1%)
Chronic lymphocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)
Clear cell renal cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Colon adenoma	7 (0.3%)	7 (0.3%)	14 (0.3%)
Colon cancer	7 (0.3%)	6 (0.2%)	13 (0.3%)
Colon cancer stage 0	1 (<0.1%)	0	1 (<0.1%)
Colon cancer stage I	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Colon neoplasm	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cutaneous lymphoma	1 (<0.1%)	0	1 (<0.1%)
Duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Enchondromatosis	1 (<0.1%)	0	1 (<0.1%)
Endometrial cancer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Epiglottic cancer	1 (<0.1%)	0	1 (<0.1%)
Erythroplasia	1 (<0.1%)	0	1 (<0.1%)
Essential thrombocythaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Extragonadal primary non-seminoma	0	1 (<0.1%)	1 (<0.1%)
Eye naevus	0	2 (<0.1%)	2 (<0.1%)
Fibroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibrous histiocytoma	0	2 (<0.1%)	2 (<0.1%)
Focal nodular hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Gallbladder adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallbladder cancer	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Gastrointestinal carcinoma	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal submucosal tumour	2 (<0.1%)	0	2 (<0.1%)
Gastrointestinal tract adenoma	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	2 (<0.1%)	0	2 (<0.1%)
Haemangioma of bone	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemangioma of liver	5 (0.2%)	9 (0.4%)	14 (0.3%)
Haemangioma of spleen	1 (<0.1%)	0	1 (<0.1%)
Hepatic adenoma	0	1 (<0.1%)	1 (<0.1%)
Hepatic cancer	0	1 (<0.1%)	1 (<0.1%)
Hepatocellular carcinoma	0	2 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	1 (<0.1%)	0	1 (<0.1%)
Intraductal papillary mucinous neoplasm	1 (<0.1%)	0	1 (<0.1%)
Iris neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Langerhans' cell histiocytosis	0	1 (<0.1%)	1 (<0.1%)
Large intestine benign neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal cancer	0	2 (<0.1%)	2 (<0.1%)
Laryngeal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Laryngeal papilloma	1 (<0.1%)	0	1 (<0.1%)
Leiomyosarcoma	0	1 (<0.1%)	1 (<0.1%)
Lipoma	12 (0.5%)	8 (0.3%)	20 (0.4%)
Lipoma of breast	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malignant melanoma	6 (0.2%)	2 (<0.1%)	8 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Malignant neoplasm of conjunctiva	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eye	1 (<0.1%)	0	1 (<0.1%)
Malignant palate neoplasm	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	4 (0.2%)	6 (0.2%)	10 (0.2%)
Meningioma	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Meningioma benign	1 (<0.1%)	0	1 (<0.1%)
Metastases to lymph nodes	1 (<0.1%)	0	1 (<0.1%)
Monoclonal gammopathy	0	2 (<0.1%)	2 (<0.1%)
Myelodysplastic syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nasopharyngeal neoplasm benign	1 (<0.1%)	0	1 (<0.1%)
Neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neoplasm prostate	0	2 (<0.1%)	2 (<0.1%)
Neoplasm skin	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-secretory adenoma of pituitary	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ocular lymphoma	1 (<0.1%)	0	1 (<0.1%)
Osteochondroma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian adenoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	0	2 (<0.1%)	2 (<0.1%)
Paget's disease of nipple	1 (<0.1%)	0	1 (<0.1%)
Pancreatic neuroendocrine tumour	0	1 (<0.1%)	1 (<0.1%)
Papillary cystadenoma lymphomatosum	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Papillary thyroid cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Parathyroid tumour benign	1 (<0.1%)	0	1 (<0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	5 (0.2%)	6 (0.2%)	11 (0.2%)
Pleomorphic adenoma	0	1 (<0.1%)	1 (<0.1%)
Polycythaemia vera	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary myelofibrosis	1 (<0.1%)	0	1 (<0.1%)
Prolactin-producing pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Prostate cancer	16 (0.6%)	16 (0.6%)	32 (0.6%)
Prostatic adenoma	8 (0.3%)	10 (0.4%)	18 (0.4%)
Rectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Rectal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Renal cancer	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal cell carcinoma	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Renal hamartoma	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Renal neoplasm	3 (0.1%)	1 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Renal oncocytoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland adenoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland neoplasm	1 (<0.1%)	0	1 (<0.1%)
Schwannoma	0	1 (<0.1%)	1 (<0.1%)
Seborrhoeic keratosis	7 (0.3%)	9 (0.4%)	16 (0.3%)
Seminoma	1 (<0.1%)	0	1 (<0.1%)
Skin cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin papilloma	5 (0.2%)	3 (0.1%)	8 (0.2%)
Small cell lung cancer	0	1 (<0.1%)	1 (<0.1%)
Spinal meningioma benign	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Squamous cell carcinoma of skin	2 (<0.1%)	0	2 (<0.1%)
Squamous cell carcinoma of the tongue	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testis cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thyroid adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thyroid cancer	5 (0.2%)	6 (0.2%)	11 (0.2%)
Tongue neoplasm malignant stage unspecified	0	1 (<0.1%)	1 (<0.1%)
Tonsil cancer	1 (<0.1%)	0	1 (<0.1%)
Transitional cell cancer of the renal pelvis and ureter	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	0	2 (<0.1%)	2 (<0.1%)
Urinary bladder adenoma	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Uterine leiomyoma	29 (1.1%)	27 (1.1%)	56 (1.1%)
Vulvovaginal warts	1 (<0.1%)	0	1 (<0.1%)
Waldenstrom's macroglobulinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nervous system disorders	1294 (51.0%)	1259 (49.9%)	2553 (50.4%)
Acoustic neuritis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Akinesia	1 (<0.1%)	0	1 (<0.1%)
Amnesia	7 (0.3%)	3 (0.1%)	10 (0.2%)
Anaesthesia	1 (<0.1%)	0	1 (<0.1%)
Anosmia	1 (<0.1%)	0	1 (<0.1%)
Arachnoid cyst	2 (<0.1%)	0	2 (<0.1%)
Areflexia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ataxia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autonomic nervous system imbalance	0	1 (<0.1%)	1 (<0.1%)
Autonomic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Axonal neuropathy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Balance disorder	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Basal ganglia infarction	1 (<0.1%)	0	1 (<0.1%)
Basilar artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Brain stem infarction	0	2 (<0.1%)	2 (<0.1%)
Burning sensation	0	2 (<0.1%)	2 (<0.1%)
Cardiac autonomic neuropathy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Carotid arteriosclerosis	53 (2.1%)	48 (1.9%)	101 (2.0%)
Carotid artery aneurysm	0	2 (<0.1%)	2 (<0.1%)
Carotid artery disease	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Carotid artery occlusion	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Carotid artery stenosis	31 (1.2%)	35 (1.4%)	66 (1.3%)
Carotid artery thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carpal tunnel syndrome	44 (1.7%)	32 (1.3%)	76 (1.5%)
Central nervous system lesion	1 (<0.1%)	0	1 (<0.1%)
Central nervous system vasculitis	0	1 (<0.1%)	1 (<0.1%)
Cerebellar stroke	1 (<0.1%)	0	1 (<0.1%)
Cerebellar syndrome	0	1 (<0.1%)	1 (<0.1%)
Cerebral arteriosclerosis	28 (1.1%)	34 (1.3%)	62 (1.2%)
Cerebral artery occlusion	0	2 (<0.1%)	2 (<0.1%)
Cerebral artery stenosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cerebral artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebral atrophy	6 (0.2%)	7 (0.3%)	13 (0.3%)
Cerebral circulatory failure	0	2 (<0.1%)	2 (<0.1%)
Cerebral disorder	1 (<0.1%)	0	1 (<0.1%)
Cerebral haematoma	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	6 (0.2%)	4 (0.2%)	10 (0.2%)
Cerebral infarction	14 (0.6%)	12 (0.5%)	26 (0.5%)
Cerebral ischaemia	28 (1.1%)	26 (1.0%)	54 (1.1%)
Cerebral microangiopathy	1 (<0.1%)	0	1 (<0.1%)
Cerebral small vessel ischaemic disease	0	2 (<0.1%)	2 (<0.1%)
Cerebral ventricle dilatation	1 (<0.1%)	0	1 (<0.1%)
Cerebrospinal fluid circulation disorder	0	1 (<0.1%)	1 (<0.1%)
Cerebrovascular accident	6 (0.2%)	13 (0.5%)	19 (0.4%)
Cerebrovascular disorder	44 (1.7%)	34 (1.3%)	78 (1.5%)
Cerebrovascular insufficiency	2 (<0.1%)	0	2 (<0.1%)
Cerebrovascular stenosis	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	6 (0.2%)	6 (0.2%)	12 (0.2%)
Cervicobrachial syndrome	5 (0.2%)	7 (0.3%)	12 (0.2%)
Cervicogenic headache	1 (<0.1%)	0	1 (<0.1%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1 (<0.1%)	1 (<0.1%)
Cluster headache	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Cognitive disorder	5 (0.2%)	4 (0.2%)	9 (0.2%)
Coma	1 (<0.1%)	0	1 (<0.1%)
Complex regional pain syndrome	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Decreased vibratory sense	3 (0.1%)	0	3 (<0.1%)
Dementia	0	2 (<0.1%)	2 (<0.1%)
Dementia Alzheimer's type	3 (0.1%)	3 (0.1%)	6 (0.1%)
Demyelination	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic autonomic neuropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic coma	0	1 (<0.1%)	1 (<0.1%)
Diabetic encephalopathy	8 (0.3%)	11 (0.4%)	19 (0.4%)
Diabetic mononeuropathy	0	2 (<0.1%)	2 (<0.1%)
Diabetic neuropathy	774 (30.5%)	733 (29.0%)	1507 (29.8%)
Disturbance in attention	0	1 (<0.1%)	1 (<0.1%)
Dizziness	24 (0.9%)	20 (0.8%)	44 (0.9%)
Dizziness postural	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	0	1 (<0.1%)	1 (<0.1%)
Dysarthria	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Encephalopathy	26 (1.0%)	17 (0.7%)	43 (0.8%)
Epilepsy	10 (0.4%)	9 (0.4%)	19 (0.4%)
Essential tremor	5 (0.2%)	6 (0.2%)	11 (0.2%)
Facial paralysis	18 (0.7%)	17 (0.7%)	35 (0.7%)
Facial paresis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Focal dyscognitive seizures	0	1 (<0.1%)	1 (<0.1%)
Generalised tonic-clonic seizure	1 (<0.1%)	0	1 (<0.1%)
Glossopharyngeal neuralgia	0	1 (<0.1%)	1 (<0.1%)
Guillain-Barre syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemorrhagic stroke	3 (0.1%)	4 (0.2%)	7 (0.1%)
Headache	37 (1.5%)	22 (0.9%)	59 (1.2%)
Hemianaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	0	1 (<0.1%)	1 (<0.1%)
Hemiparaesthesia	2 (<0.1%)	0	2 (<0.1%)
Hemiparesis	9 (0.4%)	12 (0.5%)	21 (0.4%)
Hemiplegia	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hippocampal sclerosis	1 (<0.1%)	0	1 (<0.1%)
Hydrocephalus	1 (<0.1%)	0	1 (<0.1%)
Hyperaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hypersomnia	0	2 (<0.1%)	2 (<0.1%)
Hypertensive encephalopathy	0	4 (0.2%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Hypertonia	24 (0.9%)	18 (0.7%)	42 (0.8%)
Hypoaesthesia	11 (0.4%)	17 (0.7%)	28 (0.6%)
Hyporeflexia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxic-ischaemic encephalopathy	0	1 (<0.1%)	1 (<0.1%)
IIIrd nerve paralysis	1 (<0.1%)	0	1 (<0.1%)
Intention tremor	1 (<0.1%)	0	1 (<0.1%)
Intercostal neuralgia	2 (<0.1%)	0	2 (<0.1%)
Internal capsule infarction	1 (<0.1%)	0	1 (<0.1%)
Intracranial aneurysm	0	2 (<0.1%)	2 (<0.1%)
Ischaemic stroke	231 (9.1%)	236 (9.3%)	467 (9.2%)
Lacunar infarction	14 (0.6%)	8 (0.3%)	22 (0.4%)
Lacunar stroke	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)
Leukoencephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Loss of consciousness	0	2 (<0.1%)	2 (<0.1%)
Lumbar radiculopathy	6 (0.2%)	5 (0.2%)	11 (0.2%)
Lumbosacral plexus lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lumbosacral radiculopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Memory impairment	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Meralgia paraesthetica	0	1 (<0.1%)	1 (<0.1%)
Metabolic encephalopathy	3 (0.1%)	8 (0.3%)	11 (0.2%)
Migraine	12 (0.5%)	19 (0.8%)	31 (0.6%)
Migraine with aura	0	1 (<0.1%)	1 (<0.1%)
Mononeuropathy	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Monoplegia	0	2 (<0.1%)	2 (<0.1%)
Multiple sclerosis	0	4 (0.2%)	4 (<0.1%)
Myasthenia gravis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myelopathy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Myotonia	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Nervous system disorder	2 (<0.1%)	0	2 (<0.1%)
Neuralgia	13 (0.5%)	8 (0.3%)	21 (0.4%)
Neuralgic amyotrophy	2 (<0.1%)	0	2 (<0.1%)
Neuritis	0	2 (<0.1%)	2 (<0.1%)
Neuritis cranial	0	1 (<0.1%)	1 (<0.1%)
Neurodegenerative disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neuromuscular pain	1 (<0.1%)	0	1 (<0.1%)
Neuropathy peripheral	108 (4.3%)	94 (3.7%)	202 (4.0%)
Normal pressure hydrocephalus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Nystagmus	1 (<0.1%)	0	1 (<0.1%)
Optic neuritis	0	1 (<0.1%)	1 (<0.1%)
Orthostatic intolerance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paraesthesia	9 (0.4%)	16 (0.6%)	25 (0.5%)
Paralysis recurrent laryngeal nerve	0	1 (<0.1%)	1 (<0.1%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	7 (0.3%)	4 (0.2%)	11 (0.2%)
Parkinsonism	0	1 (<0.1%)	1 (<0.1%)
Parosmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Partial seizures	0	2 (<0.1%)	2 (<0.1%)
Perineurial cyst	0	1 (<0.1%)	1 (<0.1%)
Periodic limb movement disorder	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve paresis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral sensorimotor neuropathy	4 (0.2%)	6 (0.2%)	10 (0.2%)
Peripheral sensory neuropathy	8 (0.3%)	10 (0.4%)	18 (0.4%)
Peroneal nerve palsy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Petit mal epilepsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phantom limb syndrome	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Pineal gland cyst	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	35 (1.4%)	42 (1.7%)	77 (1.5%)
Polyneuropathy chronic	1 (<0.1%)	0	1 (<0.1%)
Post herpetic neuralgia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Post polio syndrome	2 (<0.1%)	0	2 (<0.1%)
Posterior cortical atrophy	0	1 (<0.1%)	1 (<0.1%)
Precerebral arteriosclerosis	0	1 (<0.1%)	1 (<0.1%)
Presyncope	0	1 (<0.1%)	1 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Radicular pain	0	2 (<0.1%)	2 (<0.1%)
Radiculopathy	9 (0.4%)	7 (0.3%)	16 (0.3%)
Resting tremor	0	1 (<0.1%)	1 (<0.1%)
Restless legs syndrome	12 (0.5%)	11 (0.4%)	23 (0.5%)
Right hemisphere deficit syndrome	0	1 (<0.1%)	1 (<0.1%)
Sacral radiculopathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	23 (0.9%)	37 (1.5%)	60 (1.2%)
Seizure	5 (0.2%)	5 (0.2%)	10 (0.2%)
Sensorimotor disorder	0	1 (<0.1%)	1 (<0.1%)
Sensory disturbance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Simple partial seizures	0	1 (<0.1%)	1 (<0.1%)
Sleep deficit	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Somnolence	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Spinal claudication	0	1 (<0.1%)	1 (<0.1%)
Spinal cord disorder	1 (<0.1%)	0	1 (<0.1%)
Spinal cord herniation	1 (<0.1%)	0	1 (<0.1%)
Spinal stroke	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	0	3 (0.1%)	3 (<0.1%)
Syncope	9 (0.4%)	6 (0.2%)	15 (0.3%)
Taste disorder	1 (<0.1%)	0	1 (<0.1%)
Tension headache	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Thalamic infarction	1 (<0.1%)	0	1 (<0.1%)
Thoracic outlet syndrome	1 (<0.1%)	0	1 (<0.1%)
Tongue biting	1 (<0.1%)	0	1 (<0.1%)
Toxic encephalopathy	1 (<0.1%)	0	1 (<0.1%)
Transient ischaemic attack	44 (1.7%)	30 (1.2%)	74 (1.5%)
Transverse sinus thrombosis	1 (<0.1%)	0	1 (<0.1%)
Tremor	7 (0.3%)	4 (0.2%)	11 (0.2%)
Trigeminal neuralgia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
VIth nerve disorder	1 (<0.1%)	0	1 (<0.1%)
VIth nerve paralysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vascular dementia	0	1 (<0.1%)	1 (<0.1%)
Vascular encephalopathy	33 (1.3%)	29 (1.1%)	62 (1.2%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery stenosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Vertebrobasilar insufficiency	5 (0.2%)	8 (0.3%)	13 (0.3%)
Vertigo CNS origin	2 (<0.1%)	0	2 (<0.1%)
Visual field defect	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vocal cord paralysis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
White matter lesion	2 (<0.1%)	0	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	6 (0.2%)	9 (0.4%)	15 (0.3%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Gestational diabetes	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pre-eclampsia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Product issues	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Thrombosis in device	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	335 (13.2%)	362 (14.3%)	697 (13.8%)
Adjustment disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adjustment disorder with depressed mood	0	3 (0.1%)	3 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	1 (<0.1%)	0	1 (<0.1%)
Affective disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Alcohol use disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Alcoholism	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Anxiety	65 (2.6%)	80 (3.2%)	145 (2.9%)
Anxiety disorder	18 (0.7%)	14 (0.6%)	32 (0.6%)
Attention deficit hyperactivity disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bipolar disorder	6 (0.2%)	5 (0.2%)	11 (0.2%)
Borderline personality disorder	0	1 (<0.1%)	1 (<0.1%)
Breathing-related sleep disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Claustrophobia	2 (<0.1%)	0	2 (<0.1%)
Depressed mood	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Depression	145 (5.7%)	161 (6.4%)	306 (6.0%)
Disorientation	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Drug dependence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dyssomnia	1 (<0.1%)	0	1 (<0.1%)
Enuresis	0	1 (<0.1%)	1 (<0.1%)
Generalised anxiety disorder	8 (0.3%)	4 (0.2%)	12 (0.2%)
Hallucination	1 (<0.1%)	0	1 (<0.1%)
Insomnia	114 (4.5%)	103 (4.1%)	217 (4.3%)
Libido decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Major depression	13 (0.5%)	14 (0.6%)	27 (0.5%)
Mental disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mixed anxiety and depressive disorder	6 (0.2%)	5 (0.2%)	11 (0.2%)
Neurosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nicotine dependence	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Obsessive-compulsive disorder	0	1 (<0.1%)	1 (<0.1%)
Panic attack	1 (<0.1%)	0	1 (<0.1%)
Panic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Persistent depressive disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Personality disorder	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Polydipsia psychogenic	1 (<0.1%)	0	1 (<0.1%)
Post-traumatic stress disorder	7 (0.3%)	9 (0.4%)	16 (0.3%)
Premature ejaculation	1 (<0.1%)	0	1 (<0.1%)
Schizophrenia	3 (0.1%)	5 (0.2%)	8 (0.2%)
Schizophreniform disorder	0	1 (<0.1%)	1 (<0.1%)
Sleep disorder	17 (0.7%)	18 (0.7%)	35 (0.7%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	1 (<0.1%)	0	1 (<0.1%)
Stress	1 (<0.1%)	0	1 (<0.1%)
Substance abuse	1 (<0.1%)	0	1 (<0.1%)
Suicide attempt	1 (<0.1%)	0	1 (<0.1%)
Tobacco abuse	10 (0.4%)	7 (0.3%)	17 (0.3%)
Renal and urinary disorders	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)
Acquired cystic kidney disease	4 (0.2%)	4 (0.2%)	8 (0.2%)
Acute kidney injury	9 (0.4%)	8 (0.3%)	17 (0.3%)
Albuminuria	136 (5.4%)	146 (5.8%)	282 (5.6%)
Azotaemia	0	2 (<0.1%)	2 (<0.1%)
Bladder discomfort	1 (<0.1%)	0	1 (<0.1%)
Bladder dysfunction	0	1 (<0.1%)	1 (<0.1%)
Bladder prolapse	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Bladder spasm	0	1 (<0.1%)	1 (<0.1%)
Bladder ulcer	0	1 (<0.1%)	1 (<0.1%)
Calculus urinary	29 (1.1%)	22 (0.9%)	51 (1.0%)
Chronic kidney disease	2538 (100.0%)	2525 (100.0%)	5063 (100.0%)
Cystitis interstitial	1 (<0.1%)	0	1 (<0.1%)
Detrusor sphincter dyssynergia	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	156 (6.1%)	185 (7.3%)	341 (6.7%)
Dysuria	2 (<0.1%)	5 (0.2%)	7 (0.1%)
End stage renal disease	0	1 (<0.1%)	1 (<0.1%)
Focal segmental glomerulosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Follicular cystitis	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	6 (0.2%)	6 (0.2%)	12 (0.2%)
Glomerulonephritis membranous	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glomerulonephritis proliferative	0	1 (<0.1%)	1 (<0.1%)
Glycosuria	1 (<0.1%)	0	1 (<0.1%)
Haematuria	13 (0.5%)	16 (0.6%)	29 (0.6%)
Hydronephrosis	16 (0.6%)	6 (0.2%)	22 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Hypercalciuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypertensive nephropathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hypertonic bladder	11 (0.4%)	14 (0.6%)	25 (0.5%)
Hyperuricosuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypocitraturia	0	1 (<0.1%)	1 (<0.1%)
IgA nephropathy	0	1 (<0.1%)	1 (<0.1%)
Intercapillary glomerulosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ketonuria	0	1 (<0.1%)	1 (<0.1%)
Kidney congestion	1 (<0.1%)	0	1 (<0.1%)
Kidney enlargement	1 (<0.1%)	0	1 (<0.1%)
Kidney small	0	1 (<0.1%)	1 (<0.1%)
Lower urinary tract symptoms	0	2 (<0.1%)	2 (<0.1%)
Mesangioproliferative glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Microalbuminuria	71 (2.8%)	87 (3.4%)	158 (3.1%)
Micturition urgency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nephritic syndrome	0	2 (<0.1%)	2 (<0.1%)
Nephritis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nephroangiosclerosis	2 (<0.1%)	0	2 (<0.1%)
Nephrolithiasis	132 (5.2%)	130 (5.1%)	262 (5.2%)
Nephropathy	11 (0.4%)	5 (0.2%)	16 (0.3%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)
Nephroptosis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Nephrosclerosis	2 (<0.1%)	0	2 (<0.1%)
Nephrotic syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Neurogenic bladder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Nocturia	15 (0.6%)	10 (0.4%)	25 (0.5%)
Obstructive nephropathy	1 (<0.1%)	0	1 (<0.1%)
Oedematous kidney	1 (<0.1%)	0	1 (<0.1%)
Oliguria	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	6 (0.2%)	5 (0.2%)	11 (0.2%)
Polyuria	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Post streptococcal glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Proteinuria	102 (4.0%)	116 (4.6%)	218 (4.3%)
Pyelocaliectasis	0	1 (<0.1%)	1 (<0.1%)
Reduced bladder capacity	1 (<0.1%)	0	1 (<0.1%)
Renal artery arteriosclerosis	0	1 (<0.1%)	1 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Renal atrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Renal colic	15 (0.6%)	14 (0.6%)	29 (0.6%)
Renal cyst	90 (3.5%)	82 (3.2%)	172 (3.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Renal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal failure	3 (0.1%)	4 (0.2%)	7 (0.1%)
Renal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Renal impairment	0	2 (<0.1%)	2 (<0.1%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	0	1 (<0.1%)	1 (<0.1%)
Single functional kidney	1 (<0.1%)	0	1 (<0.1%)
Stress urinary incontinence	3 (0.1%)	6 (0.2%)	9 (0.2%)
Tubulointerstitial nephritis	2 (<0.1%)	0	2 (<0.1%)
Ureteric stenosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ureterocele	0	1 (<0.1%)	1 (<0.1%)
Ureterolithiasis	16 (0.6%)	3 (0.1%)	19 (0.4%)
Urethral disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral stenosis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Urge incontinence	0	1 (<0.1%)	1 (<0.1%)
Urinary bladder polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary bladder varices	0	1 (<0.1%)	1 (<0.1%)
Urinary hesitation	0	2 (<0.1%)	2 (<0.1%)
Urinary incontinence	22 (0.9%)	19 (0.8%)	41 (0.8%)
Urinary retention	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Urinary tract disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Urinary tract obstruction	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Urine abnormality	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Reproductive system and breast disorders	448 (17.7%)	432 (17.1%)	880 (17.4%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Adenomyosis	0	1 (<0.1%)	1 (<0.1%)
Adnexa uteri cyst	0	1 (<0.1%)	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Artificial menopause	0	1 (<0.1%)	1 (<0.1%)
Atrophic vulvovaginitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Azoospermia	1 (<0.1%)	0	1 (<0.1%)
Balanoposthitis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Benign prostatic hyperplasia	260 (10.2%)	239 (9.5%)	499 (9.9%)
Breast calcifications	1 (<0.1%)	0	1 (<0.1%)
Breast cyst	3 (0.1%)	0	3 (<0.1%)
Breast disorder	4 (0.2%)	0	4 (<0.1%)
Breast enlargement	1 (<0.1%)	0	1 (<0.1%)
Breast fibrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast hyperplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Breast mass	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Breast pain	1 (<0.1%)	0	1 (<0.1%)
Calculus prostatic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	3 (0.1%)	0	3 (<0.1%)
Colpocele	1 (<0.1%)	0	1 (<0.1%)
Cystocele	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Dysmenorrhoea	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Endometrial atrophy	1 (<0.1%)	0	1 (<0.1%)
Endometrial hyperplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Endometriosis	5 (0.2%)	6 (0.2%)	11 (0.2%)
Epididymal cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Erectile dysfunction	114 (4.5%)	140 (5.5%)	254 (5.0%)
Female genital tract fistula	1 (<0.1%)	0	1 (<0.1%)
Genital prolapse	0	1 (<0.1%)	1 (<0.1%)
Gynaecomastia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrosalpinx	2 (<0.1%)	0	2 (<0.1%)
Infertility	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infertility male	0	1 (<0.1%)	1 (<0.1%)
Male reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Menorrhagia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Menstruation irregular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metrorrhagia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Organic erectile dysfunction	4 (0.2%)	4 (0.2%)	8 (0.2%)
Ovarian cyst	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Ovarian cyst ruptured	1 (<0.1%)	0	1 (<0.1%)
Ovarian hyperfunction	0	1 (<0.1%)	1 (<0.1%)
Pelvic adhesions	2 (<0.1%)	0	2 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penile oedema	1 (<0.1%)	0	1 (<0.1%)
Perineal pain	0	1 (<0.1%)	1 (<0.1%)
Peyronie's disease	0	2 (<0.1%)	2 (<0.1%)
Polycystic ovaries	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Postmenopausal haemorrhage	2 (<0.1%)	0	2 (<0.1%)
Premature menopause	0	1 (<0.1%)	1 (<0.1%)
Prostatic calcification	8 (0.3%)	5 (0.2%)	13 (0.3%)
Prostatic cyst	2 (<0.1%)	0	2 (<0.1%)
Prostatic disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Prostatic mass	1 (<0.1%)	0	1 (<0.1%)
Prostatic obstruction	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Prostatism	4 (0.2%)	6 (0.2%)	10 (0.2%)
Prostatitis	14 (0.6%)	10 (0.4%)	24 (0.5%)
Prostatomegaly	13 (0.5%)	13 (0.5%)	26 (0.5%)
Rectocele	0	1 (<0.1%)	1 (<0.1%)
Reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal cyst	1 (<0.1%)	0	1 (<0.1%)
Scrotal swelling	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	6 (0.2%)	3 (0.1%)	9 (0.2%)
Spermatocele	0	1 (<0.1%)	1 (<0.1%)
Testicular atrophy	0	1 (<0.1%)	1 (<0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	0	2 (<0.1%)	2 (<0.1%)
Uterine disorder	1 (<0.1%)	0	1 (<0.1%)
Uterine haemorrhage	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Uterine mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine polyp	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Uterine prolapse	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal prolapse	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Varicocele	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vulval disorder	1 (<0.1%)	0	1 (<0.1%)
Vulval polyp	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal dryness	2 (<0.1%)	0	2 (<0.1%)
Vulvovaginal pruritus	1 (<0.1%)	0	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	545 (21.5%)	526 (20.8%)	1071 (21.2%)
Acquired diaphragmatic eventration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acute interstitial pneumonitis	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	0	2 (<0.1%)	2 (<0.1%)
Acute respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Adenoidal hypertrophy	0	2 (<0.1%)	2 (<0.1%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic cough	0	1 (<0.1%)	1 (<0.1%)
Allergic sinusitis	1 (<0.1%)	0	1 (<0.1%)
Apnoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aspirin-exacerbated respiratory disease	0	1 (<0.1%)	1 (<0.1%)
Asthma	100 (3.9%)	115 (4.6%)	215 (4.2%)
Atelectasis	4 (0.2%)	0	4 (<0.1%)
Atrophic pharyngitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Bronchial disorder	0	1 (<0.1%)	1 (<0.1%)
Bronchial dysplasia	1 (<0.1%)	0	1 (<0.1%)
Bronchial hyperreactivity	0	1 (<0.1%)	1 (<0.1%)
Bronchiectasis	4 (0.2%)	3 (0.1%)	7 (0.1%)
Bronchitis chronic	38 (1.5%)	30 (1.2%)	68 (1.3%)
Bronchopneumopathy	1 (<0.1%)	0	1 (<0.1%)
Bronchospasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Catarrh	0	1 (<0.1%)	1 (<0.1%)
Childhood asthma	1 (<0.1%)	0	1 (<0.1%)
Chronic obstructive pulmonary disease	134 (5.3%)	150 (5.9%)	284 (5.6%)
Chronic respiratory disease	0	1 (<0.1%)	1 (<0.1%)
Chronic respiratory failure	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Cough	35 (1.4%)	17 (0.7%)	52 (1.0%)
Cough variant asthma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cystic lung disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysphonia	0	1 (<0.1%)	1 (<0.1%)
Dyspnoea	22 (0.9%)	16 (0.6%)	38 (0.8%)
Dyspnoea exertional	12 (0.5%)	7 (0.3%)	19 (0.4%)
Emphysema	11 (0.4%)	14 (0.6%)	25 (0.5%)
Epiglottic cyst	1 (<0.1%)	0	1 (<0.1%)
Epistaxis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Fibrinous bronchitis	0	1 (<0.1%)	1 (<0.1%)
Haemoptysis	0	1 (<0.1%)	1 (<0.1%)
Hiccups	1 (<0.1%)	0	1 (<0.1%)
Hypercapnia	1 (<0.1%)	0	1 (<0.1%)
Hyperventilation	1 (<0.1%)	0	1 (<0.1%)
Hypoventilation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxia	0	2 (<0.1%)	2 (<0.1%)
Increased upper airway secretion	0	2 (<0.1%)	2 (<0.1%)
Interstitial lung disease	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Laryngeal disorder	0	1 (<0.1%)	1 (<0.1%)
Laryngeal oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal polyp	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Nasal congestion	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Nasal inflammation	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	0	1 (<0.1%)	1 (<0.1%)
Nasal oedema	1 (<0.1%)	0	1 (<0.1%)
Nasal polyps	3 (0.1%)	4 (0.2%)	7 (0.1%)
Nasal pruritus	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Nasal septum deviation	8 (0.3%)	7 (0.3%)	15 (0.3%)
Nasal turbinate hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Obstructive airways disorder	3 (0.1%)	4 (0.2%)	7 (0.1%)
Oropharyngeal pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Orthopnoea	0	1 (<0.1%)	1 (<0.1%)
Paranasal cyst	2 (<0.1%)	0	2 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paranasal sinus inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pharyngeal fistula	1 (<0.1%)	0	1 (<0.1%)
Pharyngeal polyp	1 (<0.1%)	0	1 (<0.1%)
Pleural disorder	1 (<0.1%)	0	1 (<0.1%)
Pleural effusion	6 (0.2%)	3 (0.1%)	9 (0.2%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	0	1 (<0.1%)	1 (<0.1%)
Pleurisy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pneumonitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pneumothorax	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumothorax spontaneous	2 (<0.1%)	0	2 (<0.1%)
Productive cough	0	1 (<0.1%)	1 (<0.1%)
Pulmonary arterial hypertension	0	1 (<0.1%)	1 (<0.1%)
Pulmonary calcification	0	1 (<0.1%)	1 (<0.1%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	9 (0.4%)	8 (0.3%)	17 (0.3%)
Pulmonary fibrosis	3 (0.1%)	5 (0.2%)	8 (0.2%)
Pulmonary hypertension	11 (0.4%)	5 (0.2%)	16 (0.3%)
Pulmonary mass	16 (0.6%)	14 (0.6%)	30 (0.6%)
Pulmonary oedema	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Respiratory alkalosis	1 (<0.1%)	0	1 (<0.1%)
Respiratory disorder	1 (<0.1%)	0	1 (<0.1%)
Respiratory failure	0	2 (<0.1%)	2 (<0.1%)
Restrictive pulmonary disease	0	1 (<0.1%)	1 (<0.1%)
Rhinitis allergic	43 (1.7%)	56 (2.2%)	99 (2.0%)
Rhinitis hypertrophic	0	1 (<0.1%)	1 (<0.1%)
Rhinitis perennial	0	2 (<0.1%)	2 (<0.1%)
Rhinorrhoea	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sinus congestion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sleep apnoea syndrome	174 (6.9%)	175 (6.9%)	349 (6.9%)
Snoring	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tonsillar hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Upper-airway cough syndrome	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Vasomotor rhinitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vocal cord leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polyp	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vocal cord thickening	0	1 (<0.1%)	1 (<0.1%)
Wheezing	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Skin and subcutaneous tissue disorders	319 (12.6%)	285 (11.3%)	604 (11.9%)
Acanthosis	0	2 (<0.1%)	2 (<0.1%)
Acanthosis nigricans	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Acne	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Acquired digital fibrokeratoma	1 (<0.1%)	0	1 (<0.1%)
Actinic keratosis	6 (0.2%)	5 (0.2%)	11 (0.2%)
Alopecia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Alopecia areata	0	1 (<0.1%)	1 (<0.1%)
Androgenetic alopecia	0	1 (<0.1%)	1 (<0.1%)
Angioedema	0	2 (<0.1%)	2 (<0.1%)
Asteatosis	0	3 (0.1%)	3 (<0.1%)
Blister	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Brow ptosis	1 (<0.1%)	0	1 (<0.1%)
Chloasma	0	1 (<0.1%)	1 (<0.1%)
Chronic pigmented purpura	0	2 (<0.1%)	2 (<0.1%)
Cutaneous amyloidosis	1 (<0.1%)	0	1 (<0.1%)
Cutaneous lupus erythematosus	0	1 (<0.1%)	1 (<0.1%)
Decubitus ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dermal cyst	5 (0.2%)	3 (0.1%)	8 (0.2%)
Dermatitis	16 (0.6%)	10 (0.4%)	26 (0.5%)
Dermatitis allergic	5 (0.2%)	7 (0.3%)	12 (0.2%)
Dermatitis atopic	8 (0.3%)	6 (0.2%)	14 (0.3%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	7 (0.3%)	5 (0.2%)	12 (0.2%)
Dermatitis exfoliative	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Dermatosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic dermopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic foot	58 (2.3%)	57 (2.3%)	115 (2.3%)
Diabetic ulcer	0	1 (<0.1%)	1 (<0.1%)
Drug eruption	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	1 (<0.1%)	0	1 (<0.1%)
Dry skin	14 (0.6%)	24 (1.0%)	38 (0.8%)
Dyshidrotic eczema	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Eczema	35 (1.4%)	25 (1.0%)	60 (1.2%)
Eczema asteatotic	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eczema nummular	0	2 (<0.1%)	2 (<0.1%)
Erythema	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Excessive skin	1 (<0.1%)	0	1 (<0.1%)
Hair disorder	1 (<0.1%)	0	1 (<0.1%)
Hidradenitis	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Hirsutism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperhidrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperkeratosis	10 (0.4%)	10 (0.4%)	20 (0.4%)
Ingrowing nail	4 (0.2%)	3 (0.1%)	7 (0.1%)
Intertrigo	0	1 (<0.1%)	1 (<0.1%)
Ischaemic skin ulcer	2 (<0.1%)	0	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Leukoderma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lichen planus	0	1 (<0.1%)	1 (<0.1%)
Lichen sclerosus	1 (<0.1%)	0	1 (<0.1%)
Lichenoid keratosis	1 (<0.1%)	0	1 (<0.1%)
Linear IgA disease	0	1 (<0.1%)	1 (<0.1%)
Lipodystrophy acquired	0	2 (<0.1%)	2 (<0.1%)
Lipohypertrophy	1 (<0.1%)	0	1 (<0.1%)
Miliaria	2 (<0.1%)	0	2 (<0.1%)
Nail disorder	1 (<0.1%)	0	1 (<0.1%)
Nail hypertrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nail pigmentation	1 (<0.1%)	0	1 (<0.1%)
Neurodermatitis	6 (0.2%)	4 (0.2%)	10 (0.2%)
Night sweats	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Onychalgia	1 (<0.1%)	0	1 (<0.1%)
Onychogryphosis	0	1 (<0.1%)	1 (<0.1%)
Palmoplantar keratoderma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Palmoplantar pustulosis	1 (<0.1%)	0	1 (<0.1%)
Papule	0	1 (<0.1%)	1 (<0.1%)
Parapsoriasis	1 (<0.1%)	0	1 (<0.1%)
Photosensitivity reaction	0	1 (<0.1%)	1 (<0.1%)
Pityriasis rosea	0	1 (<0.1%)	1 (<0.1%)
Prurigo	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pruritus	21 (0.8%)	17 (0.7%)	38 (0.8%)
Psoriasis	36 (1.4%)	41 (1.6%)	77 (1.5%)
Pyoderma gangrenosum	0	1 (<0.1%)	1 (<0.1%)
Rash	8 (0.3%)	7 (0.3%)	15 (0.3%)
Rash papular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Rash pruritic	1 (<0.1%)	0	1 (<0.1%)
Rosacea	5 (0.2%)	5 (0.2%)	10 (0.2%)
Sebaceous hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	0	2 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	14 (0.6%)	8 (0.3%)	22 (0.4%)
Segmented hyalinising vasculitis	1 (<0.1%)	0	1 (<0.1%)
Senile xerosis	1 (<0.1%)	0	1 (<0.1%)
Skin atrophy	1 (<0.1%)	0	1 (<0.1%)
Skin discolouration	0	1 (<0.1%)	1 (<0.1%)
Skin dystrophy	0	1 (<0.1%)	1 (<0.1%)
Skin exfoliation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin hyperpigmentation	2 (<0.1%)	0	2 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Skin maceration	1 (<0.1%)	0	1 (<0.1%)
Skin mass	1 (<0.1%)	0	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	29 (1.1%)	22 (0.9%)	51 (1.0%)
Skin warm	1 (<0.1%)	0	1 (<0.1%)
Solar dermatitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Solar lentigo	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	5 (0.2%)	6 (0.2%)	11 (0.2%)
Telangiectasia	1 (<0.1%)	0	1 (<0.1%)
Urticaria	9 (0.4%)	6 (0.2%)	15 (0.3%)
Urticaria chronic	2 (<0.1%)	0	2 (<0.1%)
Vascular skin disorder	1 (<0.1%)	0	1 (<0.1%)
Vitiligo	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Xanthelasma	1 (<0.1%)	0	1 (<0.1%)
Xeroderma	4 (0.2%)	4 (0.2%)	8 (0.2%)
Social circumstances	144 (5.7%)	133 (5.3%)	277 (5.5%)
Alcohol use	0	1 (<0.1%)	1 (<0.1%)
Caffeine consumption	1 (<0.1%)	0	1 (<0.1%)
Corrective lens user	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug abuser	1 (<0.1%)	0	1 (<0.1%)
Edentulous	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ex-alcoholic	1 (<0.1%)	0	1 (<0.1%)
Ex-tobacco user	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Exercise lack of	1 (<0.1%)	0	1 (<0.1%)
Familial risk factor	1 (<0.1%)	0	1 (<0.1%)
Menopause	100 (3.9%)	90 (3.6%)	190 (3.8%)
Parity	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	25 (1.0%)	30 (1.2%)	55 (1.1%)
Tobacco user	10 (0.4%)	11 (0.4%)	21 (0.4%)
Surgical and medical procedures	875 (34.5%)	857 (33.9%)	1732 (34.2%)
Abdominal hernia repair	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Abdominal wall operation	1 (<0.1%)	0	1 (<0.1%)
Abdominoplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Abscess drainage	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Adenoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adenotonsillectomy	1 (<0.1%)	0	1 (<0.1%)
Adrenalectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Amputation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal fissure excision	0	1 (<0.1%)	1 (<0.1%)
Anal fistula repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Androgen replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Angioplasty	17 (0.7%)	12 (0.5%)	29 (0.6%)
Ankle arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anorectal operation	1 (<0.1%)	0	1 (<0.1%)
Antibiotic therapy	0	1 (<0.1%)	1 (<0.1%)
Aorta coarctation repair	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm repair	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Aortic bypass	3 (0.1%)	4 (0.2%)	7 (0.1%)
Aortic valve repair	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Aortic valve replacement	11 (0.4%)	8 (0.3%)	19 (0.4%)
Appendicectomy	82 (3.2%)	110 (4.4%)	192 (3.8%)
Arterial repair	1 (<0.1%)	0	1 (<0.1%)
Arterial stent insertion	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Arteriovenous fistula operation	0	1 (<0.1%)	1 (<0.1%)
Arthrodesis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Benign breast lump removal	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	0	1 (<0.1%)	1 (<0.1%)
Bladder catheter permanent	0	1 (<0.1%)	1 (<0.1%)
Bladder catheter temporary	1 (<0.1%)	0	1 (<0.1%)
Bladder repair	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Blepharoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bone graft	1 (<0.1%)	0	1 (<0.1%)
Bone marrow transplant	0	1 (<0.1%)	1 (<0.1%)
Bone operation	2 (<0.1%)	0	2 (<0.1%)
Brachytherapy	0	1 (<0.1%)	1 (<0.1%)
Breast conserving surgery	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Breast cyst excision	1 (<0.1%)	0	1 (<0.1%)
Breast reconstruction	1 (<0.1%)	0	1 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	2 (<0.1%)	0	2 (<0.1%)
Caesarean section	18 (0.7%)	13 (0.5%)	31 (0.6%)
Cancer surgery	0	1 (<0.1%)	1 (<0.1%)
Cardiac ablation	0	2 (<0.1%)	2 (<0.1%)
Cardiac pacemaker insertion	14 (0.6%)	19 (0.8%)	33 (0.7%)
Cardiac pacemaker replacement	1 (<0.1%)	0	1 (<0.1%)
Cardiopulmonary bypass	1 (<0.1%)	0	1 (<0.1%)
Cardioversion	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Carotid angioplasty	1 (<0.1%)	0	1 (<0.1%)
Carotid endarterectomy	21 (0.8%)	24 (1.0%)	45 (0.9%)
Carpal tunnel decompression	16 (0.6%)	8 (0.3%)	24 (0.5%)
Cataract operation	68 (2.7%)	102 (4.0%)	170 (3.4%)
Catheter placement	0	1 (<0.1%)	1 (<0.1%)
Chemonucleolysis	1 (<0.1%)	0	1 (<0.1%)
Chest wall operation	0	1 (<0.1%)	1 (<0.1%)
Cholecystectomy	131 (5.2%)	126 (5.0%)	257 (5.1%)
Cholelithotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholesteatoma removal	0	1 (<0.1%)	1 (<0.1%)
Circumcision	5 (0.2%)	3 (0.1%)	8 (0.2%)
Colectomy	7 (0.3%)	3 (0.1%)	10 (0.2%)
Colectomy total	0	2 (<0.1%)	2 (<0.1%)
Colorectostomy	1 (<0.1%)	0	1 (<0.1%)
Colostomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Colostomy closure	1 (<0.1%)	0	1 (<0.1%)
Colporrhaphy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Corneal operation	0	1 (<0.1%)	1 (<0.1%)
Coronary angioplasty	26 (1.0%)	32 (1.3%)	58 (1.1%)
Coronary arterial stent insertion	81 (3.2%)	56 (2.2%)	137 (2.7%)
Coronary artery bypass	63 (2.5%)	71 (2.8%)	134 (2.6%)
Coronary revascularisation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cox-Maze procedure	0	1 (<0.1%)	1 (<0.1%)
Cranial operation	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Cyst removal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cystostomy	1 (<0.1%)	0	1 (<0.1%)
Debridement	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dental prosthesis placement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus management	0	1 (<0.1%)	1 (<0.1%)
Dialysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Duodenal ulcer repair	1 (<0.1%)	0	1 (<0.1%)
Duodeno-jejunal bypass sleeve therapy	1 (<0.1%)	0	1 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	0	1 (<0.1%)
Ear operation	0	2 (<0.1%)	2 (<0.1%)
Elbow operation	0	1 (<0.1%)	1 (<0.1%)
Endarterectomy	1 (<0.1%)	0	1 (<0.1%)
Endarterectomy of aorta	1 (<0.1%)	0	1 (<0.1%)
Endocarditis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	0	1 (<0.1%)
Epidermoid cyst excision	1 (<0.1%)	0	1 (<0.1%)
Eventration repair	1 (<0.1%)	0	1 (<0.1%)
Explorative laparotomy	0	2 (<0.1%)	2 (<0.1%)
Eye laser surgery	10 (0.4%)	9 (0.4%)	19 (0.4%)
Eye operation	3 (0.1%)	4 (0.2%)	7 (0.1%)
Eye prosthesis insertion	3 (0.1%)	0	3 (<0.1%)
Eyelid operation	0	1 (<0.1%)	1 (<0.1%)
Facetectomy	0	1 (<0.1%)	1 (<0.1%)
Fallopian tube operation	0	1 (<0.1%)	1 (<0.1%)
Fasciotomy	0	1 (<0.1%)	1 (<0.1%)
Female sterilisation	23 (0.9%)	19 (0.8%)	42 (0.8%)
Finger amputation	5 (0.2%)	3 (0.1%)	8 (0.2%)
Finger repair operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fistula repair	0	2 (<0.1%)	2 (<0.1%)
Foot amputation	9 (0.4%)	7 (0.3%)	16 (0.3%)
Foot operation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Gallbladder operation	4 (0.2%)	5 (0.2%)	9 (0.2%)
Gastrectomy	4 (0.2%)	5 (0.2%)	9 (0.2%)
Gastric banding	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Gastric bypass	4 (0.2%)	7 (0.3%)	11 (0.2%)
Gastric electrical stimulation	1 (<0.1%)	0	1 (<0.1%)
Gastric stapling	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric ulcer surgery	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal endoscopic therapy	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal surgery	1 (<0.1%)	0	1 (<0.1%)
Gastrostomy	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Glaucoma surgery	4 (0.2%)	5 (0.2%)	9 (0.2%)
Haemorrhoid operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Haemostasis	0	1 (<0.1%)	1 (<0.1%)
Hand amputation	1 (<0.1%)	0	1 (<0.1%)
Hand repair operation	1 (<0.1%)	0	1 (<0.1%)
Hearing aid therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	2 (<0.1%)	0	2 (<0.1%)
Hepatectomy	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B immunisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	0	1 (<0.1%)
Hernia repair	7 (0.3%)	13 (0.5%)	20 (0.4%)
High frequency ablation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hip arthroplasty	18 (0.7%)	17 (0.7%)	35 (0.7%)
Hip surgery	0	1 (<0.1%)	1 (<0.1%)
Hydrocele operation	0	2 (<0.1%)	2 (<0.1%)
Hysterectomy	67 (2.6%)	61 (2.4%)	128 (2.5%)
Hysterosalpingo-oophorectomy	7 (0.3%)	6 (0.2%)	13 (0.3%)
Ileocolostomy	1 (<0.1%)	0	1 (<0.1%)
Ileojejunal bypass	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	0	1 (<0.1%)	1 (<0.1%)
Implantable cardiac monitor insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Implantable defibrillator insertion	5 (0.2%)	4 (0.2%)	9 (0.2%)
Incisional drainage	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia repair	0	1 (<0.1%)	1 (<0.1%)
Inguinal hernia repair	25 (1.0%)	24 (1.0%)	49 (1.0%)
Internal fixation of fracture	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Internal fixation of spine	1 (<0.1%)	0	1 (<0.1%)
Internal limiting membrane peeling	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc operation	16 (0.6%)	10 (0.4%)	26 (0.5%)
Intestinal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Intestinal resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intra-cerebral aneurysm operation	1 (<0.1%)	0	1 (<0.1%)
Intra-ocular injection	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Intra-uterine contraceptive device insertion	1 (<0.1%)	0	1 (<0.1%)
Intraocular lens implant	17 (0.7%)	16 (0.6%)	33 (0.7%)
Intravitreal implant	1 (<0.1%)	0	1 (<0.1%)
Jaw operation	0	1 (<0.1%)	1 (<0.1%)
Joint arthroplasty	2 (<0.1%)	0	2 (<0.1%)
Knee arthroplasty	28 (1.1%)	27 (1.1%)	55 (1.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Knee operation	10 (0.4%)	11 (0.4%)	21 (0.4%)
Lacrimal duct procedure	0	1 (<0.1%)	1 (<0.1%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	10 (0.4%)	10 (0.4%)	20 (0.4%)
Large intestine anastomosis	0	1 (<0.1%)	1 (<0.1%)
Laryngectomy	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	0	3 (0.1%)	3 (<0.1%)
Leg amputation	19 (0.7%)	20 (0.8%)	39 (0.8%)
Lens extraction	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	3 (0.1%)	3 (0.1%)	6 (0.1%)
Limb operation	1 (<0.1%)	0	1 (<0.1%)
Lipectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lipoma excision	3 (0.1%)	4 (0.2%)	7 (0.1%)
Liposuction	0	2 (<0.1%)	2 (<0.1%)
Lithotripsy	8 (0.3%)	3 (0.1%)	11 (0.2%)
Lung lobectomy	0	3 (0.1%)	3 (<0.1%)
Lymphadenectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Manual lymphatic drainage	0	1 (<0.1%)	1 (<0.1%)
Mass excision	0	2 (<0.1%)	2 (<0.1%)
Mastectomy	7 (0.3%)	3 (0.1%)	10 (0.2%)
Mastoidectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Maxillary antrum operation	1 (<0.1%)	0	1 (<0.1%)
Medical device removal	1 (<0.1%)	0	1 (<0.1%)
Meningioma surgery	0	2 (<0.1%)	2 (<0.1%)
Meniscus operation	4 (0.2%)	3 (0.1%)	7 (0.1%)
Meniscus removal	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Metabolic surgery	0	1 (<0.1%)	1 (<0.1%)
Metatarsal excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mitral valve repair	0	3 (0.1%)	3 (<0.1%)
Mole excision	1 (<0.1%)	0	1 (<0.1%)
Multiple drug therapy	2 (<0.1%)	0	2 (<0.1%)
Muscle operation	2 (<0.1%)	0	2 (<0.1%)
Myomectomy	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Nail operation	1 (<0.1%)	0	1 (<0.1%)
Nasal polypectomy	2 (<0.1%)	0	2 (<0.1%)
Nasal septal operation	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Nephrectomy	12 (0.5%)	13 (0.5%)	25 (0.5%)
Nephrostomy	0	3 (0.1%)	3 (<0.1%)
Nerve block	0	1 (<0.1%)	1 (<0.1%)
Neurolysis	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Oesophageal dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Oesophagogastric fundoplasty	0	1 (<0.1%)	1 (<0.1%)
Omentectomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Oophorectomy bilateral	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Ophthalmic fluid-air exchange procedure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Orchidectomy	3 (0.1%)	0	3 (<0.1%)
Ostectomy	1 (<0.1%)	0	1 (<0.1%)
Ovarian cystectomy	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Ovarian operation	1 (<0.1%)	0	1 (<0.1%)
Palatoplasty	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pancreatic cyst drainage	1 (<0.1%)	0	1 (<0.1%)
Pancreatic stent placement	0	1 (<0.1%)	1 (<0.1%)
Papilloma excision	0	2 (<0.1%)	2 (<0.1%)
Parathyroidectomy	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Parotidectomy	0	1 (<0.1%)	1 (<0.1%)
Pelvic operation	1 (<0.1%)	0	1 (<0.1%)
Penile prosthesis insertion	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Percutaneous coronary intervention	18 (0.7%)	21 (0.8%)	39 (0.8%)
Perineoplasty	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Peripheral artery angioplasty	12 (0.5%)	12 (0.5%)	24 (0.5%)
Peripheral artery bypass	13 (0.5%)	12 (0.5%)	25 (0.5%)
Peripheral artery stent insertion	10 (0.4%)	11 (0.4%)	21 (0.4%)
Peripheral endarterectomy	8 (0.3%)	1 (<0.1%)	9 (0.2%)
Peripheral nerve decompression	2 (<0.1%)	0	2 (<0.1%)
Peripheral revascularisation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Permanent cosmetic dermapigmentation	1 (<0.1%)	0	1 (<0.1%)
Pharyngectomy	1 (<0.1%)	0	1 (<0.1%)
Phlebectomy	11 (0.4%)	8 (0.3%)	19 (0.4%)
Photocoagulation	0	1 (<0.1%)	1 (<0.1%)
Photorefractive keratectomy	1 (<0.1%)	0	1 (<0.1%)
Pilonidal sinus repair	2 (<0.1%)	0	2 (<0.1%)
Pituitary tumour removal	0	1 (<0.1%)	1 (<0.1%)
Polypectomy	6 (0.2%)	6 (0.2%)	12 (0.2%)
Proctectomy	2 (<0.1%)	0	2 (<0.1%)
Profundaplasty	1 (<0.1%)	0	1 (<0.1%)
Prolapse repair	1 (<0.1%)	0	1 (<0.1%)
Prostatectomy	8 (0.3%)	6 (0.2%)	14 (0.3%)
Prostatic operation	1 (<0.1%)	0	1 (<0.1%)
Prosthesis implantation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Prosthetic vessel implantation	1 (<0.1%)	0	1 (<0.1%)
Pterygium operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radical hysterectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Radiotherapy	1 (<0.1%)	0	1 (<0.1%)
Radiotherapy to pharynx	1 (<0.1%)	0	1 (<0.1%)
Rectal polypectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal artery stent placement	0	1 (<0.1%)	1 (<0.1%)
Renal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Renal replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	10 (0.4%)	9 (0.4%)	19 (0.4%)
Renal surgery	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal sympathetic nerve ablation	1 (<0.1%)	0	1 (<0.1%)
Renal tumour excision	0	1 (<0.1%)	1 (<0.1%)
Retinal cryoablation	1 (<0.1%)	0	1 (<0.1%)
Retinal laser coagulation	10 (0.4%)	15 (0.6%)	25 (0.5%)
Retinal operation	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Retinopexy	1 (<0.1%)	0	1 (<0.1%)
Retro-pubic prostatectomy	1 (<0.1%)	0	1 (<0.1%)
Revascularisation procedure	0	1 (<0.1%)	1 (<0.1%)
Rhinoplasty	1 (<0.1%)	0	1 (<0.1%)
Rotator cuff repair	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Roux loop conversion	1 (<0.1%)	0	1 (<0.1%)
Salivary gland resection	1 (<0.1%)	0	1 (<0.1%)
Salpingectomy	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Salpingo-oophorectomy	0	1 (<0.1%)	1 (<0.1%)
Salpingo-oophorectomy bilateral	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Salpingo-oophorectomy unilateral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scar excision	1 (<0.1%)	0	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)
Scrotal cystectomy	0	1 (<0.1%)	1 (<0.1%)
Sebaceous cyst excision	1 (<0.1%)	0	1 (<0.1%)
Shoulder arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Shoulder operation	4 (0.2%)	5 (0.2%)	9 (0.2%)
Sigmoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sinuplasty	0	1 (<0.1%)	1 (<0.1%)
Sinus operation	0	3 (0.1%)	3 (<0.1%)
Skin cyst excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin graft	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin neoplasm excision	7 (0.3%)	6 (0.2%)	13 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Skin operation	1 (<0.1%)	0	1 (<0.1%)
Small intestinal anastomosis	0	1 (<0.1%)	1 (<0.1%)
Spinal decompression	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Spinal fusion surgery	3 (0.1%)	3 (0.1%)	6 (0.1%)
Spinal laminectomy	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Spinal operation	7 (0.3%)	5 (0.2%)	12 (0.2%)
Spinal rod insertion	0	1 (<0.1%)	1 (<0.1%)
Splenectomy	4 (0.2%)	7 (0.3%)	11 (0.2%)
Stent placement	11 (0.4%)	18 (0.7%)	29 (0.6%)
Stent removal	1 (<0.1%)	0	1 (<0.1%)
Sterilisation	2 (<0.1%)	0	2 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma evacuation	1 (<0.1%)	0	1 (<0.1%)
Surgery	0	1 (<0.1%)	1 (<0.1%)
Sympathectomy	1 (<0.1%)	0	1 (<0.1%)
Synovial cyst removal	0	1 (<0.1%)	1 (<0.1%)
Tendon sheath incision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tenoplasty	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Testicular operation	0	2 (<0.1%)	2 (<0.1%)
Testicular prosthesis insertion	0	1 (<0.1%)	1 (<0.1%)
Thoracotomy	0	1 (<0.1%)	1 (<0.1%)
Thrombectomy	1 (<0.1%)	0	1 (<0.1%)
Thromboembolectomy	2 (<0.1%)	0	2 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thrombosis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid adenoma removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid nodule removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroidectomy	19 (0.7%)	22 (0.9%)	41 (0.8%)
Toe amputation	44 (1.7%)	27 (1.1%)	71 (1.4%)
Toe operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tonsillectomy	28 (1.1%)	30 (1.2%)	58 (1.1%)
Tooth extraction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Trabeculectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transfusion	1 (<0.1%)	0	1 (<0.1%)
Transurethral bladder resection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Transurethral prostatectomy	10 (0.4%)	9 (0.4%)	19 (0.4%)
Tricuspid valve repair	0	1 (<0.1%)	1 (<0.1%)
Turbinectomy	0	1 (<0.1%)	1 (<0.1%)
Turbinoplasty	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Tympanoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia repair	11 (0.4%)	11 (0.4%)	22 (0.4%)
Ureteral stent insertion	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Ureteric calculus removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ureterocelectomy	0	1 (<0.1%)	1 (<0.1%)
Ureterolithotomy	0	1 (<0.1%)	1 (<0.1%)
Ureteroneocystostomy	1 (<0.1%)	0	1 (<0.1%)
Urethral operation	0	1 (<0.1%)	1 (<0.1%)
Urinary bladder suspension	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary cystectomy	0	1 (<0.1%)	1 (<0.1%)
Urinary tract operation	0	1 (<0.1%)	1 (<0.1%)
Urostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine cystectomy	0	1 (<0.1%)	1 (<0.1%)
Uterine dilation and curettage	1 (<0.1%)	0	1 (<0.1%)
Uterine polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vaginal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Varicocele repair	0	3 (0.1%)	3 (<0.1%)
Varicose vein operation	4 (0.2%)	4 (0.2%)	8 (0.2%)
Vascular graft	8 (0.3%)	4 (0.2%)	12 (0.2%)
Vascular operation	0	2 (<0.1%)	2 (<0.1%)
Vascular stent insertion	0	1 (<0.1%)	1 (<0.1%)
Vasectomy	11 (0.4%)	12 (0.5%)	23 (0.5%)
Vasodilation procedure	0	1 (<0.1%)	1 (<0.1%)
Venous angioplasty	1 (<0.1%)	0	1 (<0.1%)
Ventriculo-peritoneal shunt	0	2 (<0.1%)	2 (<0.1%)
Vertebroplasty	0	1 (<0.1%)	1 (<0.1%)
Vision correction operation	1 (<0.1%)	0	1 (<0.1%)
Vitamin supplementation	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	18 (0.7%)	17 (0.7%)	35 (0.7%)
Vocal cord operation	0	2 (<0.1%)	2 (<0.1%)
Vocal cord polypectomy	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Wisdom teeth removal	0	2 (<0.1%)	2 (<0.1%)
Wound treatment	0	1 (<0.1%)	1 (<0.1%)
Wrist surgery	3 (0.1%)	0	3 (<0.1%)
Vascular disorders	2444 (96.3%)	2429 (96.2%)	4873 (96.2%)
Aneurysm	1 (<0.1%)	0	1 (<0.1%)
Angiopathy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	7 (0.3%)	14 (0.6%)	21 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Aortic arteriosclerosis	49 (1.9%)	42 (1.7%)	91 (1.8%)
Aortic dilatation	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Aortic disorder	0	1 (<0.1%)	1 (<0.1%)
Aortic dissection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic stenosis	22 (0.9%)	16 (0.6%)	38 (0.8%)
Aortic thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arterial disorder	2 (<0.1%)	0	2 (<0.1%)
Arterial insufficiency	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Arterial stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial wall hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriosclerosis	47 (1.9%)	43 (1.7%)	90 (1.8%)
Arteriosclerosis Moenckeberg-type	1 (<0.1%)	0	1 (<0.1%)
Arteriovenous fistula	0	2 (<0.1%)	2 (<0.1%)
Arteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brachiocephalic arteriosclerosis	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Deep vein thrombosis	12 (0.5%)	23 (0.9%)	35 (0.7%)
Diabetic macroangiopathy	6 (0.2%)	8 (0.3%)	14 (0.3%)
Diabetic microangiopathy	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Diabetic vascular disorder	90 (3.5%)	81 (3.2%)	171 (3.4%)
Dry gangrene	1 (<0.1%)	0	1 (<0.1%)
Embolism	0	1 (<0.1%)	1 (<0.1%)
Essential hypertension	65 (2.6%)	78 (3.1%)	143 (2.8%)
Extremity necrosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haematoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemorrhagic vasculitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hot flush	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperaemia	0	1 (<0.1%)	1 (<0.1%)
Hypertension	2352 (92.7%)	2326 (92.1%)	4678 (92.4%)
Hypertensive angiopathy	6 (0.2%)	3 (0.1%)	9 (0.2%)
Hypertensive crisis	3 (0.1%)	5 (0.2%)	8 (0.2%)
Hypertensive emergency	1 (<0.1%)	0	1 (<0.1%)
Hypotension	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Intermittent claudication	23 (0.9%)	25 (1.0%)	48 (0.9%)
Lymphangiectasia	0	1 (<0.1%)	1 (<0.1%)
Lymphoedema	4 (0.2%)	4 (0.2%)	8 (0.2%)
Macroangiopathy	4 (0.2%)	5 (0.2%)	9 (0.2%)
Microangiopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Orthostatic hypotension	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	339 (13.4%)	324 (12.8%)	663 (13.1%)
Peripheral artery aneurysm	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Peripheral artery occlusion	5 (0.2%)	4 (0.2%)	9 (0.2%)
Peripheral artery stenosis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Peripheral artery thrombosis	0	2 (<0.1%)	2 (<0.1%)
Peripheral ischaemia	6 (0.2%)	5 (0.2%)	11 (0.2%)
Peripheral vascular disorder	29 (1.1%)	19 (0.8%)	48 (0.9%)
Peripheral venous disease	53 (2.1%)	39 (1.5%)	92 (1.8%)
Phlebitis	1 (<0.1%)	0	1 (<0.1%)
Post thrombotic syndrome	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Raynaud's phenomenon	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Subclavian artery stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subgaleal haematoma	0	1 (<0.1%)	1 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)
Systolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Takayasu's arteritis	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis	3 (0.1%)	5 (0.2%)	8 (0.2%)
Thrombosis	4 (0.2%)	4 (0.2%)	8 (0.2%)
Varicophlebitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicose ulceration	1 (<0.1%)	0	1 (<0.1%)
Varicose vein	77 (3.0%)	82 (3.2%)	159 (3.1%)
Vasoconstriction	0	1 (<0.1%)	1 (<0.1%)
Vasodilatation	1 (<0.1%)	0	1 (<0.1%)
Vein disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Venous occlusion	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis limb	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
White coat hypertension	4 (0.2%)	6 (0.2%)	10 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 26JAN2023 15:35
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4.6 Concomitant medication

Table 4.6 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1850 (72.9%)	1887 (74.7%)	3737 (73.8%)
ACEI	353 (13.9%)	368 (14.6%)	721 (14.2%)
ARB	549 (21.6%)	574 (22.7%)	1123 (22.2%)
RAS-inhibitors	816 (32.2%)	836 (33.1%)	1652 (32.6%)
Beta-blocker	552 (21.7%)	568 (22.5%)	1120 (22.1%)
Diuretics	773 (30.5%)	828 (32.8%)	1601 (31.6%)
Loop diuretics	447 (17.6%)	513 (20.3%)	960 (19.0%)
Thiazide diuretics	256 (10.1%)	293 (11.6%)	549 (10.8%)
Potassium supplements	157 (6.2%)	188 (7.4%)	345 (6.8%)
Potassium lowering agents (including binders)	83 (3.3%)	48 (1.9%)	131 (2.6%)
Alpha blocking agents	588 (23.2%)	607 (24.0%)	1195 (23.6%)
Calcium channel blockers	683 (26.9%)	755 (29.9%)	1438 (28.4%)
Centrally acting antihypertensives	97 (3.8%)	119 (4.7%)	216 (4.3%)
Strong CYP3A4 inhibitors	118 (4.6%)	128 (5.1%)	246 (4.9%)
Moderate CYP3A4 inhibitors	306 (12.1%)	332 (13.1%)	638 (12.6%)
Weak CYP3A4 inhibitors	905 (35.7%)	902 (35.7%)	1807 (35.7%)
Unclassified CYP3A4 inhibitors	104 (4.1%)	112 (4.4%)	216 (4.3%)
Strong CYP3A4 inducers	30 (1.2%)	33 (1.3%)	63 (1.2%)
Moderate CYP3A4 inducers	181 (7.1%)	180 (7.1%)	361 (7.1%)
Weak CYP3A4 inducers	143 (5.6%)	134 (5.3%)	277 (5.5%)
Unclassified CYP3A4 inducers	86 (3.4%)	93 (3.7%)	179 (3.5%)
Oral anticoagulants	178 (7.0%)	175 (6.9%)	353 (7.0%)
Acetylsalycylic acid and its salts	382 (15.1%)	378 (15.0%)	760 (15.0%)
Statins	723 (28.5%)	662 (26.2%)	1385 (27.4%)
Erythropoeitin stimulating agents	30 (1.2%)	38 (1.5%)	68 (1.3%)
NSAIDS (excluding acetylsalicylic acid)	729 (28.7%)	757 (30.0%)	1486 (29.4%)
ARNIs	7 (0.3%)	7 (0.3%)	14 (0.3%)
Potassium-sparing diuretics	138 (5.4%)	161 (6.4%)	299 (5.9%)
Platelet aggregation inhibitors (excluding heparin)	560 (22.1%)	563 (22.3%)	1123 (22.2%)
Trimethoprim and derivatives	63 (2.5%)	70 (2.8%)	133 (2.6%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:37
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=2538 (100%)	Placebo N=2525 (100%)	Total N=5063 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1498 (59.0%)	1560 (61.8%)	3058 (60.4%)
Insulins and analogues	999 (39.4%)	1018 (40.3%)	2017 (39.8%)
Dipeptidyl peptidase 4 inhibitors	386 (15.2%)	359 (14.2%)	745 (14.7%)
Glucagon-like peptide-1(GLP1) agonists	275 (10.8%)	265 (10.5%)	540 (10.7%)
SGLT-2 inhibitors	432 (17.0%)	451 (17.9%)	883 (17.4%)
Biguanides	713 (28.1%)	690 (27.3%)	1403 (27.7%)
Sulfonylureas	319 (12.6%)	327 (13.0%)	646 (12.8%)
Alpha glucosidase inhibitors	103 (4.1%)	97 (3.8%)	200 (4.0%)
Meglitinides	61 (2.4%)	46 (1.8%)	107 (2.1%)
Thiazolidinediones	77 (3.0%)	70 (2.8%)	147 (2.9%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:37
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1.2.1 Time-to-event analyses

Table 1.2.1 / 1: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	183 (7.2%)	225 (8.9%)
Number (%) of subjects censored	2355 (92.8%)	2300 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.66; 0.98]	
two-sided p-value from stratified logrank test	0.0278	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	104 (8.5%)	119 (9.7%)
Number (%) of subjects censored	1114 (91.5%)	1104 (90.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.67; 1.13]	
two-sided p-value from stratified logrank test	0.2912	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	31 (9.3%)	24 (7.6%)
Number (%) of subjects censored	303 (90.7%)	293 (92.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.29 [0.76; 2.21]	
two-sided p-value from stratified logrank test	0.3421	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	21 (3.7%)	27 (4.8%)
Number (%) of subjects censored	540 (96.3%)	537 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.44; 1.39]	
two-sided p-value from stratified logrank test	0.3983	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	24 (7.0%)	45 (13.2%)
Number (%) of subjects censored	319 (93.0%)	295 (86.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.52 [0.32; 0.85]	
two-sided p-value from stratified logrank test	0.0081	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	3 (3.7%)	10 (12.3%)
Number (%) of subjects censored	79 (96.3%)	71 (87.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.26 [0.07; 0.95]	
two-sided p-value from stratified logrank test	0.0284	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 3: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0535

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	31 (8.3%)	38 (11.0%)
Number (%) of subjects censored	342 (91.7%)	306 (89.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.46; 1.19]	
two-sided p-value from stratified logrank test	0.2096	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	152 (7.0%)	185 (8.5%)
Number (%) of subjects censored	2009 (93.0%)	1990 (91.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.66; 1.02]	
two-sided p-value from stratified logrank test	0.0773	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 5: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.6847

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	98 (10.9%)	112 (12.6%)
Number (%) of subjects censored	801 (89.1%)	780 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.66; 1.14]	
two-sided p-value from stratified logrank test	0.3216	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	85 (5.2%)	113 (6.9%)
Number (%) of subjects censored	1554 (94.8%)	1520 (93.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.56; 0.98]	
two-sided p-value from stratified logrank test	0.0325	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 7: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3972

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	127 (6.8%)	160 (8.7%)
Number (%) of subjects censored	1736 (93.2%)	1678 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.62; 0.98]	
two-sided p-value from stratified logrank test	0.0347	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	56 (8.3%)	65 (9.5%)
Number (%) of subjects censored	619 (91.7%)	621 (90.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.63; 1.30]	
two-sided p-value from stratified logrank test	0.5845	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 9: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5772

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	49 (6.5%)	55 (7.3%)
Number (%) of subjects censored	708 (93.5%)	699 (92.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.61; 1.32]	
two-sided p-value from stratified logrank test	0.5799	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	125 (7.4%)	163 (9.7%)
Number (%) of subjects censored	1574 (92.6%)	1518 (90.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.59; 0.94]	
two-sided p-value from stratified logrank test	0.0145	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	9 (11.0%)	7 (7.8%)
Number (%) of subjects censored	73 (89.0%)	83 (92.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.41 [0.49; 4.09]	
two-sided p-value from stratified logrank test	0.5249	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 11: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.4038

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	145 (8.1%)	176 (10.0%)
Number (%) of subjects censored	1654 (91.9%)	1589 (90.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.65; 1.01]	
two-sided p-value from stratified logrank test	0.0554	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	9 (11.3%)	12 (14.5%)
Number (%) of subjects censored	71 (88.8%)	71 (85.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.37; 2.49]	
two-sided p-value from stratified logrank test	0.9318	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	19 (3.8%)	20 (3.8%)
Number (%) of subjects censored	484 (96.2%)	510 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.54; 1.90]	
two-sided p-value from stratified logrank test	0.9735	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	10 (6.4%)	17 (11.6%)
Number (%) of subjects censored	146 (93.6%)	130 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.29; 1.40]	
two-sided p-value from stratified logrank test	0.2531	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 13: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.7751

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	130 (7.4%)	158 (8.8%)
Number (%) of subjects censored	1634 (92.6%)	1636 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.67; 1.06]	
two-sided p-value from stratified logrank test	0.1388	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	53 (6.8%)	67 (9.2%)
Number (%) of subjects censored	721 (93.2%)	664 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.51; 1.06]	
two-sided p-value from stratified logrank test	0.1019	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 15: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.5215

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	88 (5.8%)	107 (7.1%)
Number (%) of subjects censored	1427 (94.2%)	1410 (92.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.61; 1.08]	
two-sided p-value from stratified logrank test	0.1506	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	95 (9.3%)	118 (11.7%)
Number (%) of subjects censored	928 (90.7%)	890 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.62; 1.06]	
two-sided p-value from stratified logrank test	0.1234	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 17: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9953

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 18: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	183 (7.2%)	225 (8.9%)
Number (%) of subjects censored	2355 (92.8%)	2300 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.66; 0.97]	
two-sided p-value from unstratified logrank test	0.0246	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	251 (9.9%)	317 (12.6%)
Number (%) of subjects censored	2287 (90.1%)	2208 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.66; 0.92]	
two-sided p-value from stratified logrank test	0.0032	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 20: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	80 (3.2%)	124 (4.9%)
Number (%) of subjects censored	2458 (96.8%)	2401 (95.1%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.48; 0.84]	
two-sided p-value from stratified logrank test	0.0013	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	29 (2.4%)	40 (3.3%)
Number (%) of subjects censored	1189 (97.6%)	1183 (96.7%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.45; 1.17]	
two-sided p-value from stratified logrank test	0.1828	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	7 (2.1%)	12 (3.8%)
Number (%) of subjects censored	327 (97.9%)	305 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.22; 1.46]	
two-sided p-value from stratified logrank test	0.2333	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	23 (4.1%)	52 (9.2%)
Number (%) of subjects censored	538 (95.9%)	512 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.43 [0.26; 0.71]	
two-sided p-value from stratified logrank test	0.0006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	17 (5.0%)	17 (5.0%)
Number (%) of subjects censored	326 (95.0%)	323 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.51; 1.97]	
two-sided p-value from stratified logrank test	0.9946	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	4 (4.9%)	3 (3.7%)
Number (%) of subjects censored	78 (95.1%)	78 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.22; 4.51]	
two-sided p-value from stratified logrank test	0.9884	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 22: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.3125

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	4 (1.1%)	5 (1.5%)
Number (%) of subjects censored	369 (98.9%)	339 (98.5%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.20; 2.84]	
two-sided p-value from stratified logrank test	0.6841	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	76 (3.5%)	119 (5.5%)
Number (%) of subjects censored	2085 (96.5%)	2056 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.48; 0.85]	
two-sided p-value from stratified logrank test	0.0022	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 24: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.8195

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	27 (3.0%)	42 (4.7%)
Number (%) of subjects censored	872 (97.0%)	850 (95.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.39; 1.03]	
two-sided p-value from stratified logrank test	0.0646	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	53 (3.2%)	82 (5.0%)
Number (%) of subjects censored	1586 (96.8%)	1551 (95.0%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.45; 0.89]	
two-sided p-value from stratified logrank test	0.0083	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 26: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.9843

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	57 (3.1%)	93 (5.1%)
Number (%) of subjects censored	1806 (96.9%)	1745 (94.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.60 [0.43; 0.84]	
two-sided p-value from stratified logrank test	0.0024	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	23 (3.4%)	31 (4.5%)
Number (%) of subjects censored	652 (96.6%)	655 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.46; 1.39]	
two-sided p-value from stratified logrank test	0.4286	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 28: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5508

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	13 (1.7%)	22 (2.9%)
Number (%) of subjects censored	744 (98.3%)	732 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.59 [0.29; 1.19]	
two-sided p-value from stratified logrank test	0.1354	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	60 (3.5%)	92 (5.5%)
Number (%) of subjects censored	1639 (96.5%)	1589 (94.5%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.45; 0.87]	
two-sided p-value from stratified logrank test	0.0052	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	7 (8.5%)	10 (11.1%)
Number (%) of subjects censored	75 (91.5%)	80 (88.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.31; 2.97]	
two-sided p-value from stratified logrank test	0.9507	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 30: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.8331

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	43 (2.4%)	55 (3.1%)
Number (%) of subjects censored	1756 (97.6%)	1710 (96.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.50; 1.12]	
two-sided p-value from stratified logrank test	0.1622	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	4 (5.0%)	5 (6.0%)
Number (%) of subjects censored	76 (95.0%)	78 (94.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.22; 4.07]	
two-sided p-value from stratified logrank test	0.9438	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	23 (4.6%)	52 (9.8%)
Number (%) of subjects censored	480 (95.4%)	478 (90.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.48 [0.29; 0.78]	
two-sided p-value from stratified logrank test	0.0027	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	10 (6.4%)	12 (8.2%)
Number (%) of subjects censored	146 (93.6%)	135 (91.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.34; 2.06]	
two-sided p-value from stratified logrank test	0.6894	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 32: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.4022

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	67 (3.8%)	93 (5.2%)
Number (%) of subjects censored	1697 (96.2%)	1701 (94.8%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.52; 0.97]	
two-sided p-value from stratified logrank test	0.0323	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	13 (1.7%)	31 (4.2%)
Number (%) of subjects censored	761 (98.3%)	700 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.41 [0.21; 0.79]	
two-sided p-value from stratified logrank test	0.0062	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 34: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1266

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	60 (4.0%)	95 (6.3%)
Number (%) of subjects censored	1455 (96.0%)	1422 (93.7%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.47; 0.90]	
two-sided p-value from stratified logrank test	0.0085	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	20 (2.0%)	29 (2.9%)
Number (%) of subjects censored	1003 (98.0%)	979 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.69 [0.39; 1.23]	
two-sided p-value from stratified logrank test	0.2076	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 36: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9905

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 37: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	80 (3.2%)	124 (4.9%)
Number (%) of subjects censored	2458 (96.8%)	2401 (95.1%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.48; 0.84]	
two-sided p-value from unstratified logrank test	0.0015	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 38: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	55 (2.2%)	89 (3.5%)
Number (%) of subjects censored	2483 (97.8%)	2436 (96.5%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.60 [0.43; 0.84]	
two-sided p-value from stratified logrank test	0.0026	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 39: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	24 (0.9%)	46 (1.8%)
Number (%) of subjects censored	2514 (99.1%)	2479 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.52 [0.32; 0.85]	
two-sided p-value from stratified logrank test	0.0079	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 40: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	5 (0.4%)	12 (1.0%)
Number (%) of subjects censored	1213 (99.6%)	1211 (99.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.43 [0.15; 1.21]	
two-sided p-value from stratified logrank test	0.0996	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 40: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	2 (0.6%)	4 (1.3%)
Number (%) of subjects censored	332 (99.4%)	313 (98.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.56 [0.10; 3.07]	
two-sided p-value from stratified logrank test	0.4976	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 40: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	6 (1.1%)	24 (4.3%)
Number (%) of subjects censored	555 (98.9%)	540 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.25 [0.10; 0.60]	
two-sided p-value from stratified logrank test	0.0009	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 40: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	9 (2.6%)	6 (1.8%)
Number (%) of subjects censored	334 (97.4%)	334 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.41 [0.50; 3.97]	
two-sided p-value from stratified logrank test	0.5132	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 40: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	2 (2.4%)	0
Number (%) of subjects censored	80 (97.6%)	81 (100.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	76835032.41 [0.00;]	
two-sided p-value from stratified logrank test	0.1710	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 41: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.1735

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 42: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	0	1 (0.3%)
Number (%) of subjects censored	373 (100.0%)	343 (99.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.00 [0.00;]	
two-sided p-value from stratified logrank test	0.2953	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 42: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	24 (1.1%)	45 (2.1%)
Number (%) of subjects censored	2137 (98.9%)	2130 (97.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.53 [0.32; 0.87]	
two-sided p-value from stratified logrank test	0.0109	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 43: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9880

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	7 (0.8%)	18 (2.0%)
Number (%) of subjects censored	892 (99.2%)	874 (98.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.39 [0.16; 0.93]	
two-sided p-value from stratified logrank test	0.0270	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	17 (1.0%)	28 (1.7%)
Number (%) of subjects censored	1622 (99.0%)	1605 (98.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.60 [0.33; 1.10]	
two-sided p-value from stratified logrank test	0.0963	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 45: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.4127

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	13 (0.7%)	31 (1.7%)
Number (%) of subjects censored	1850 (99.3%)	1807 (98.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.43 [0.23; 0.83]	
two-sided p-value from stratified logrank test	0.0091	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	11 (1.6%)	15 (2.2%)
Number (%) of subjects censored	664 (98.4%)	671 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.34; 1.66]	
two-sided p-value from stratified logrank test	0.4726	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 47: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.3205

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	6 (0.8%)	6 (0.8%)
Number (%) of subjects censored	751 (99.2%)	748 (99.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.32; 3.09]	
two-sided p-value from stratified logrank test	0.9886	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	15 (0.9%)	37 (2.2%)
Number (%) of subjects censored	1684 (99.1%)	1644 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.39 [0.21; 0.70]	
two-sided p-value from stratified logrank test	0.0013	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	3 (3.7%)	3 (3.3%)
Number (%) of subjects censored	79 (96.3%)	87 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.17; 4.41]	
two-sided p-value from stratified logrank test	0.8627	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 49: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.2182

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	12 (0.7%)	16 (0.9%)
Number (%) of subjects censored	1787 (99.3%)	1749 (99.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.33; 1.51]	
two-sided p-value from stratified logrank test	0.3701	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	3 (3.8%)	2 (2.4%)
Number (%) of subjects censored	77 (96.3%)	81 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.59 [0.26; 9.82]	
two-sided p-value from stratified logrank test	0.6138	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	6 (1.2%)	26 (4.9%)
Number (%) of subjects censored	497 (98.8%)	504 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.27 [0.11; 0.66]	
two-sided p-value from stratified logrank test	0.0020	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	3 (1.9%)	2 (1.4%)
Number (%) of subjects censored	153 (98.1%)	145 (98.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.40 [0.23; 8.42]	
two-sided p-value from stratified logrank test	0.7112	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 51: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.1217

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	18 (1.0%)	41 (2.3%)
Number (%) of subjects censored	1746 (99.0%)	1753 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.45 [0.26; 0.78]	
two-sided p-value from stratified logrank test	0.0037	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	6 (0.8%)	5 (0.7%)
Number (%) of subjects censored	768 (99.2%)	726 (99.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.33; 3.60]	
two-sided p-value from stratified logrank test	0.8779	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 53: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1647

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	19 (1.3%)	36 (2.4%)
Number (%) of subjects censored	1496 (98.7%)	1481 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.32; <1.00]	
two-sided p-value from stratified logrank test	0.0470	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	5 (0.5%)	10 (1.0%)
Number (%) of subjects censored	1018 (99.5%)	998 (99.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.45 [0.15; 1.33]	
two-sided p-value from stratified logrank test	0.1394	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 55: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.6485

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	24 (0.9%)	46 (1.8%)
Number (%) of subjects censored	2514 (99.1%)	2479 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.51 [0.31; 0.84]	
two-sided p-value from unstratified logrank test	0.0073	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 57: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	7 (0.3%)	21 (0.8%)
Number (%) of subjects censored	2531 (99.7%)	2504 (99.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.34 [0.14; 0.80]	
two-sided p-value from stratified logrank test	0.0092	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 58: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	18 (0.7%)	39 (1.5%)
Number (%) of subjects censored	2520 (99.3%)	2486 (98.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.46 [0.26; 0.80]	
two-sided p-value from stratified logrank test	0.0049	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 59: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	13 (0.5%)	27 (1.1%)
Number (%) of subjects censored	2525 (99.5%)	2498 (98.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.48 [0.25; 0.93]	
two-sided p-value from stratified logrank test	0.0260	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 60: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	75 (3.0%)	113 (4.5%)
Number (%) of subjects censored	2463 (97.0%)	2412 (95.5%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.48; 0.87]	
two-sided p-value from stratified logrank test	0.0035	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 61: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	0	1 (<0.1%)
Number (%) of subjects censored	2538 (100.0%)	2524 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.00 [0.00;]	
two-sided p-value from stratified logrank test	0.3653	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 62: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	67 (2.6%)	97 (3.8%)
Number (%) of subjects censored	2471 (97.4%)	2428 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.49; 0.91]	
two-sided p-value from stratified logrank test	0.0110	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 63: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	297 (11.7%)	324 (12.8%)
Number (%) of subjects censored	2241 (88.3%)	2201 (87.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.78; 1.06]	
two-sided p-value from stratified logrank test	0.2381	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 64: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	154 (12.6%)	160 (13.1%)
Number (%) of subjects censored	1064 (87.4%)	1063 (86.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.76; 1.19]	
two-sided p-value from stratified logrank test	0.6727	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 64: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	50 (15.0%)	44 (13.9%)
Number (%) of subjects censored	284 (85.0%)	273 (86.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.12 [0.75; 1.69]	
two-sided p-value from stratified logrank test	0.5726	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 64: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	51 (9.1%)	65 (11.5%)
Number (%) of subjects censored	510 (90.9%)	499 (88.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.56; 1.16]	
two-sided p-value from stratified logrank test	0.2419	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 64: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	31 (9.0%)	42 (12.4%)
Number (%) of subjects censored	312 (91.0%)	298 (87.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.45; 1.14]	
two-sided p-value from stratified logrank test	0.1629	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 64: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	11 (13.4%)	13 (16.0%)
Number (%) of subjects censored	71 (86.6%)	68 (84.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.35; 1.76]	
two-sided p-value from stratified logrank test	0.5541	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 65: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.5977

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 66: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	45 (12.1%)	43 (12.5%)
Number (%) of subjects censored	328 (87.9%)	301 (87.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.64; 1.51]	
two-sided p-value from stratified logrank test	0.9406	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 66: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	252 (11.7%)	280 (12.9%)
Number (%) of subjects censored	1909 (88.3%)	1895 (87.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.76; 1.08]	
two-sided p-value from stratified logrank test	0.2608	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 67: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.7299

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 68: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	167 (18.6%)	189 (21.2%)
Number (%) of subjects censored	732 (81.4%)	703 (78.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.71; 1.08]	
two-sided p-value from stratified logrank test	0.2224	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 68: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	130 (7.9%)	135 (8.3%)
Number (%) of subjects censored	1509 (92.1%)	1498 (91.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.75; 1.21]	
two-sided p-value from stratified logrank test	0.6946	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 69: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.6166

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	210 (11.3%)	231 (12.6%)
Number (%) of subjects censored	1653 (88.7%)	1607 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.74; 1.07]	
two-sided p-value from stratified logrank test	0.2203	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	87 (12.9%)	93 (13.6%)
Number (%) of subjects censored	588 (87.1%)	593 (86.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.68; 1.23]	
two-sided p-value from stratified logrank test	0.5488	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 71: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.8072

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	74 (9.8%)	63 (8.4%)
Number (%) of subjects censored	683 (90.2%)	691 (91.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.17 [0.83; 1.64]	
two-sided p-value from stratified logrank test	0.3623	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	208 (12.2%)	242 (14.4%)
Number (%) of subjects censored	1491 (87.8%)	1439 (85.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.70; 1.01]	
two-sided p-value from stratified logrank test	0.0640	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	15 (18.3%)	19 (21.1%)
Number (%) of subjects censored	67 (81.7%)	71 (78.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.62 [0.29; 1.32]	
two-sided p-value from stratified logrank test	0.2097	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 73: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.2280

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	225 (12.5%)	238 (13.5%)
Number (%) of subjects censored	1574 (87.5%)	1527 (86.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.76; 1.09]	
two-sided p-value from stratified logrank test	0.3215	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	11 (13.8%)	13 (15.7%)
Number (%) of subjects censored	69 (86.3%)	70 (84.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.37 [0.55; 3.45]	
two-sided p-value from stratified logrank test	0.4994	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	44 (8.7%)	51 (9.6%)
Number (%) of subjects censored	459 (91.3%)	479 (90.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.65; 1.49]	
two-sided p-value from stratified logrank test	0.9581	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	17 (10.9%)	22 (15.0%)
Number (%) of subjects censored	139 (89.1%)	125 (85.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.33; 1.25]	
two-sided p-value from stratified logrank test	0.1890	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 75: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.9160

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	214 (12.1%)	241 (13.4%)
Number (%) of subjects censored	1550 (87.9%)	1553 (86.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.75; 1.08]	
two-sided p-value from stratified logrank test	0.2674	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	83 (10.7%)	83 (11.4%)
Number (%) of subjects censored	691 (89.3%)	648 (88.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.70; 1.30]	
two-sided p-value from stratified logrank test	0.7791	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 77: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.8173

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	162 (10.7%)	175 (11.5%)
Number (%) of subjects censored	1353 (89.3%)	1342 (88.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.73; 1.13]	
two-sided p-value from stratified logrank test	0.3830	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	135 (13.2%)	149 (14.8%)
Number (%) of subjects censored	888 (86.8%)	859 (85.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.72; 1.16]	
two-sided p-value from stratified logrank test	0.4598	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 79: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9089

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	297 (11.7%)	324 (12.8%)
Number (%) of subjects censored	2241 (88.3%)	2201 (87.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.77; 1.06]	
two-sided p-value from unstratified logrank test	0.2128	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 81: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	244 (9.6%)	269 (10.7%)
Number (%) of subjects censored	2294 (90.4%)	2256 (89.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.75; 1.06]	
two-sided p-value from stratified logrank test	0.2021	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 82: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	118 (4.6%)	136 (5.4%)
Number (%) of subjects censored	2420 (95.4%)	2389 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.67; 1.10]	
two-sided p-value from stratified logrank test	0.2246	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 83: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	63 (2.5%)	58 (2.3%)
Number (%) of subjects censored	2475 (97.5%)	2467 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.77; 1.57]	
two-sided p-value from stratified logrank test	0.6077	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 84: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	84 (3.3%)	76 (3.0%)
Number (%) of subjects censored	2454 (96.7%)	2449 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.81; 1.51]	
two-sided p-value from stratified logrank test	0.5136	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 85: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	68 (2.7%)	104 (4.1%)
Number (%) of subjects censored	2470 (97.3%)	2421 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.48; 0.88]	
two-sided p-value from stratified logrank test	0.0053	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 86: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	74 (2.9%)	63 (2.5%)
Number (%) of subjects censored	2464 (97.1%)	2462 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.18 [0.84; 1.66]	
two-sided p-value from stratified logrank test	0.3291	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 87: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	36 (3.0%)	32 (2.6%)
Number (%) of subjects censored	1182 (97.0%)	1191 (97.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.69; 1.79]	
two-sided p-value from stratified logrank test	0.6640	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 87: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	9 (2.7%)	10 (3.2%)
Number (%) of subjects censored	325 (97.3%)	307 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.36; 2.17]	
two-sided p-value from stratified logrank test	0.7838	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 87: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	16 (2.9%)	13 (2.3%)
Number (%) of subjects censored	545 (97.1%)	551 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.42 [0.66; 3.02]	
two-sided p-value from stratified logrank test	0.3661	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 87: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	7 (2.0%)	4 (1.2%)
Number (%) of subjects censored	336 (98.0%)	336 (98.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.72 [0.50; 5.87]	
two-sided p-value from stratified logrank test	0.3829	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 87: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	6 (7.3%)	4 (4.9%)
Number (%) of subjects censored	76 (92.7%)	77 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.32 [0.37; 4.68]	
two-sided p-value from stratified logrank test	0.6709	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 88: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.8988

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 89: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	9 (2.4%)	9 (2.6%)
Number (%) of subjects censored	364 (97.6%)	335 (97.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.35; 2.24]	
two-sided p-value from stratified logrank test	0.8015	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 89: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	65 (3.0%)	54 (2.5%)
Number (%) of subjects censored	2096 (97.0%)	2121 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.23 [0.86; 1.78]	
two-sided p-value from stratified logrank test	0.2556	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 90: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.6328

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 91: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	49 (5.5%)	40 (4.5%)
Number (%) of subjects censored	850 (94.5%)	852 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.25 [0.82; 1.91]	
two-sided p-value from stratified logrank test	0.2920	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 91: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	25 (1.5%)	23 (1.4%)
Number (%) of subjects censored	1614 (98.5%)	1610 (98.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.60; 1.88]	
two-sided p-value from stratified logrank test	0.8281	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 92: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.6495

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 93: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	55 (3.0%)	44 (2.4%)
Number (%) of subjects censored	1808 (97.0%)	1794 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.19 [0.79; 1.78]	
two-sided p-value from stratified logrank test	0.3998	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 93: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	19 (2.8%)	19 (2.8%)
Number (%) of subjects censored	656 (97.2%)	667 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.54; 1.99]	
two-sided p-value from stratified logrank test	0.9056	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 94: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.7483

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	16 (2.1%)	13 (1.7%)
Number (%) of subjects censored	741 (97.9%)	741 (98.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.25 [0.59; 2.62]	
two-sided p-value from stratified logrank test	0.5587	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	57 (3.4%)	46 (2.7%)
Number (%) of subjects censored	1642 (96.6%)	1635 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.28 [0.86; 1.90]	
two-sided p-value from stratified logrank test	0.2204	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	1 (1.2%)	4 (4.4%)
Number (%) of subjects censored	81 (98.8%)	86 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.27 [0.03; 2.48]	
two-sided p-value from stratified logrank test	0.2176	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 96: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.4458

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	59 (3.3%)	50 (2.8%)
Number (%) of subjects censored	1740 (96.7%)	1715 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.13 [0.77; 1.64]	
two-sided p-value from stratified logrank test	0.5363	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	0	2 (2.4%)
Number (%) of subjects censored	80 (100.0%)	81 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.00 [0.00;]	
two-sided p-value from stratified logrank test	0.4142	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	11 (2.2%)	8 (1.5%)
Number (%) of subjects censored	492 (97.8%)	522 (98.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	2.78 [0.89; 8.74]	
two-sided p-value from stratified logrank test	0.0672	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	4 (2.6%)	3 (2.0%)
Number (%) of subjects censored	152 (97.4%)	144 (98.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.24; 5.03]	
two-sided p-value from stratified logrank test	0.8994	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 98: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8817

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	59 (3.3%)	53 (3.0%)
Number (%) of subjects censored	1705 (96.7%)	1741 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.13 [0.78; 1.64]	
two-sided p-value from stratified logrank test	0.5147	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	15 (1.9%)	10 (1.4%)
Number (%) of subjects censored	759 (98.1%)	721 (98.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.81 [0.76; 4.33]	
two-sided p-value from stratified logrank test	0.1779	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 100: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.5383

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	40 (2.6%)	33 (2.2%)
Number (%) of subjects censored	1475 (97.4%)	1484 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.22 [0.76; 1.94]	
two-sided p-value from stratified logrank test	0.4102	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	34 (3.3%)	30 (3.0%)
Number (%) of subjects censored	989 (96.7%)	978 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.20 [0.73; 1.99]	
two-sided p-value from stratified logrank test	0.4750	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 102: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9577

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 103: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	74 (2.9%)	63 (2.5%)
Number (%) of subjects censored	2464 (97.1%)	2462 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.17 [0.83; 1.63]	
two-sided p-value from unstratified logrank test	0.3647	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 104: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	62 (2.4%)	53 (2.1%)
Number (%) of subjects censored	2476 (97.6%)	2472 (97.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.13 [0.78; 1.63]	
two-sided p-value from stratified logrank test	0.5228	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 105: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	93 (3.7%)	87 (3.4%)
Number (%) of subjects censored	2445 (96.3%)	2438 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.80; 1.43]	
two-sided p-value from stratified logrank test	0.6471	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 106: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	47 (3.9%)	42 (3.4%)
Number (%) of subjects censored	1171 (96.1%)	1181 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.12 [0.74; 1.70]	
two-sided p-value from stratified logrank test	0.5865	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 106: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	11 (3.3%)	8 (2.5%)
Number (%) of subjects censored	323 (96.7%)	309 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.40 [0.56; 3.48]	
two-sided p-value from stratified logrank test	0.4687	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 106: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	23 (4.1%)	25 (4.4%)
Number (%) of subjects censored	538 (95.9%)	539 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.53; 1.66]	
two-sided p-value from stratified logrank test	0.8391	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 106: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	10 (2.9%)	8 (2.4%)
Number (%) of subjects censored	333 (97.1%)	332 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.17 [0.46; 2.98]	
two-sided p-value from stratified logrank test	0.7353	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 106: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	2 (2.4%)	4 (4.9%)
Number (%) of subjects censored	80 (97.6%)	77 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.47 [0.09; 2.57]	
two-sided p-value from stratified logrank test	0.3726	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 107: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.8247

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 108: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	18 (4.8%)	12 (3.5%)
Number (%) of subjects censored	355 (95.2%)	332 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.64 [0.76; 3.56]	
two-sided p-value from stratified logrank test	0.2052	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 108: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	75 (3.5%)	75 (3.4%)
Number (%) of subjects censored	2086 (96.5%)	2100 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.74; 1.40]	
two-sided p-value from stratified logrank test	0.9268	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 109: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.4301

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 110: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	48 (5.3%)	54 (6.1%)
Number (%) of subjects censored	851 (94.7%)	838 (93.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.61; 1.33]	
two-sided p-value from stratified logrank test	0.5894	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 110: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	45 (2.7%)	33 (2.0%)
Number (%) of subjects censored	1594 (97.3%)	1600 (98.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.35 [0.86; 2.12]	
two-sided p-value from stratified logrank test	0.1898	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 111: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.1801

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 112: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	66 (3.5%)	62 (3.4%)
Number (%) of subjects censored	1797 (96.5%)	1776 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.75; 1.51]	
two-sided p-value from stratified logrank test	0.7096	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 112: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	27 (4.0%)	25 (3.6%)
Number (%) of subjects censored	648 (96.0%)	661 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.14 [0.66; 1.97]	
two-sided p-value from stratified logrank test	0.6404	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 113: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.9353

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 114: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	24 (3.2%)	13 (1.7%)
Number (%) of subjects censored	733 (96.8%)	741 (98.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.85 [0.94; 3.66]	
two-sided p-value from stratified logrank test	0.0727	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 114: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	64 (3.8%)	67 (4.0%)
Number (%) of subjects censored	1635 (96.2%)	1614 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.67; 1.33]	
two-sided p-value from stratified logrank test	0.7224	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 114: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	5 (6.1%)	7 (7.8%)
Number (%) of subjects censored	77 (93.9%)	83 (92.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.58 [0.16; 2.15]	
two-sided p-value from stratified logrank test	0.4096	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 115: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.1911

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	65 (3.6%)	60 (3.4%)
Number (%) of subjects censored	1734 (96.4%)	1705 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.75; 1.51]	
two-sided p-value from stratified logrank test	0.7319	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	2 (2.5%)	3 (3.6%)
Number (%) of subjects censored	78 (97.5%)	80 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.05 [0.15; 7.48]	
two-sided p-value from stratified logrank test	0.9631	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	21 (4.2%)	18 (3.4%)
Number (%) of subjects censored	482 (95.8%)	512 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.22 [0.65; 2.29]	
two-sided p-value from stratified logrank test	0.5342	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	5 (3.2%)	6 (4.1%)
Number (%) of subjects censored	151 (96.8%)	141 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.22; 2.46]	
two-sided p-value from stratified logrank test	0.6210	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 117: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8401

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	64 (3.6%)	58 (3.2%)
Number (%) of subjects censored	1700 (96.4%)	1736 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.81; 1.64]	
two-sided p-value from stratified logrank test	0.4385	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	29 (3.7%)	29 (4.0%)
Number (%) of subjects censored	745 (96.3%)	702 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.54; 1.54]	
two-sided p-value from stratified logrank test	0.7295	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 119: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.5029

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	45 (3.0%)	48 (3.2%)
Number (%) of subjects censored	1470 (97.0%)	1469 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.61; 1.38]	
two-sided p-value from stratified logrank test	0.6667	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	48 (4.7%)	39 (3.9%)
Number (%) of subjects censored	975 (95.3%)	969 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.22 [0.80; 1.88]	
two-sided p-value from stratified logrank test	0.3518	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 121: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.3069

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 122: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	93 (3.7%)	87 (3.4%)
Number (%) of subjects censored	2445 (96.3%)	2438 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.79; 1.42]	
two-sided p-value from unstratified logrank test	0.7032	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 123: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	75 (3.0%)	73 (2.9%)
Number (%) of subjects censored	2463 (97.0%)	2452 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.76; 1.44]	
two-sided p-value from stratified logrank test	0.7902	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 124: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	71 (2.8%)	110 (4.4%)
Number (%) of subjects censored	2467 (97.2%)	2415 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.47; 0.86]	
two-sided p-value from stratified logrank test	0.0032	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 125: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	34 (2.8%)	54 (4.4%)
Number (%) of subjects censored	1184 (97.2%)	1169 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.41; 0.96]	
two-sided p-value from stratified logrank test	0.0305	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 125: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	18 (5.4%)	20 (6.3%)
Number (%) of subjects censored	316 (94.6%)	297 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.48; 1.72]	
two-sided p-value from stratified logrank test	0.7679	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 125: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	8 (1.4%)	20 (3.5%)
Number (%) of subjects censored	553 (98.6%)	544 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.40 [0.18; 0.91]	
two-sided p-value from stratified logrank test	0.0232	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 125: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	9 (2.6%)	11 (3.2%)
Number (%) of subjects censored	334 (97.4%)	329 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.34; 1.96]	
two-sided p-value from stratified logrank test	0.6384	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 125: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	2 (2.4%)	5 (6.2%)
Number (%) of subjects censored	80 (97.6%)	76 (93.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.35 [0.07; 1.80]	
two-sided p-value from stratified logrank test	0.1877	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 126: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.5201

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 127: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	6 (1.6%)	11 (3.2%)
Number (%) of subjects censored	367 (98.4%)	333 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.50 [0.18; 1.34]	
two-sided p-value from stratified logrank test	0.1587	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 127: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	65 (3.0%)	99 (4.6%)
Number (%) of subjects censored	2096 (97.0%)	2076 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.49; 0.91]	
two-sided p-value from stratified logrank test	0.0104	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 128: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.5909

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 129: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	42 (4.7%)	67 (7.5%)
Number (%) of subjects censored	857 (95.3%)	825 (92.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.43; 0.92]	
two-sided p-value from stratified logrank test	0.0169	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 129: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	29 (1.8%)	43 (2.6%)
Number (%) of subjects censored	1610 (98.2%)	1590 (97.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.41; 1.06]	
two-sided p-value from stratified logrank test	0.0816	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 130: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.8699

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 131: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	48 (2.6%)	80 (4.4%)
Number (%) of subjects censored	1815 (97.4%)	1758 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.40; 0.82]	
two-sided p-value from stratified logrank test	0.0020	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 131: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	23 (3.4%)	30 (4.4%)
Number (%) of subjects censored	652 (96.6%)	656 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.40; 1.22]	
two-sided p-value from stratified logrank test	0.2102	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 132: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.3493

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 133: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	16 (2.1%)	19 (2.5%)
Number (%) of subjects censored	741 (97.9%)	735 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.41; 1.59]	
two-sided p-value from stratified logrank test	0.5363	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 133: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	50 (2.9%)	85 (5.1%)
Number (%) of subjects censored	1649 (97.1%)	1596 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.58 [0.41; 0.82]	
two-sided p-value from stratified logrank test	0.0020	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 133: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	5 (6.1%)	6 (6.7%)
Number (%) of subjects censored	77 (93.9%)	84 (93.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.15; 2.48]	
two-sided p-value from stratified logrank test	0.4819	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 134: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.5023

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 135: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	55 (3.1%)	80 (4.5%)
Number (%) of subjects censored	1744 (96.9%)	1685 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.48; 0.95]	
two-sided p-value from stratified logrank test	0.0236	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 135: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	3 (3.8%)	4 (4.8%)
Number (%) of subjects censored	77 (96.3%)	79 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.24 [0.20; 7.63]	
two-sided p-value from stratified logrank test	0.8143	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 135: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	7 (1.4%)	18 (3.4%)
Number (%) of subjects censored	496 (98.6%)	512 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.42 [0.17; 1.01]	
two-sided p-value from stratified logrank test	0.0451	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 135: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	6 (3.8%)	8 (5.4%)
Number (%) of subjects censored	150 (96.2%)	139 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.46 [0.14; 1.54]	
two-sided p-value from stratified logrank test	0.1958	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 136: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.7575

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	50 (2.8%)	89 (5.0%)
Number (%) of subjects censored	1714 (97.2%)	1705 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.56 [0.40; 0.80]	
two-sided p-value from stratified logrank test	0.0010	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	21 (2.7%)	21 (2.9%)
Number (%) of subjects censored	753 (97.3%)	710 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.52; 1.76]	
two-sided p-value from stratified logrank test	0.8907	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 138: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1409

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	41 (2.7%)	59 (3.9%)
Number (%) of subjects censored	1474 (97.3%)	1458 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.47; 1.04]	
two-sided p-value from stratified logrank test	0.0744	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	30 (2.9%)	51 (5.1%)
Number (%) of subjects censored	993 (97.1%)	957 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.62 [0.39; 0.97]	
two-sided p-value from stratified logrank test	0.0351	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 140: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.6756

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 141: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	71 (2.8%)	110 (4.4%)
Number (%) of subjects censored	2467 (97.2%)	2415 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.47; 0.86]	
two-sided p-value from unstratified logrank test	0.0027	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 142: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	56 (2.2%)	86 (3.4%)
Number (%) of subjects censored	2482 (97.8%)	2439 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.46; 0.90]	
two-sided p-value from stratified logrank test	0.0096	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 143: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	990 (39.0%)	1012 (40.1%)
Number (%) of subjects censored	1548 (61.0%)	1513 (59.9%)
Median Time to event (month) [95 % CI]	n.c.	56.133 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.89; 1.06]	
two-sided p-value from stratified logrank test	0.4526	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 144: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1223 (100.0%)
Number (%) of subjects with event	482 (39.6%)	477 (39.0%)
Number (%) of subjects censored	736 (60.4%)	746 (61.0%)
Median Time to event (month) [95 % CI]	n.c.	59.533 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.89; 1.14]	
two-sided p-value from stratified logrank test	0.9202	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 144: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	334 (100.0%)	317 (100.0%)
Number (%) of subjects with event	116 (34.7%)	101 (31.9%)
Number (%) of subjects censored	218 (65.3%)	216 (68.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.13 [0.87; 1.48]	
two-sided p-value from stratified logrank test	0.3636	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 144: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	561 (100.0%)	564 (100.0%)
Number (%) of subjects with event	277 (49.4%)	284 (50.4%)
Number (%) of subjects censored	284 (50.6%)	280 (49.6%)
Median Time to event (month) [95 % CI]	43.300 [34.567;50.900]	44.933 [35.567;50.833]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.83; 1.16]	
two-sided p-value from stratified logrank test	0.8633	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 144: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	343 (100.0%)	340 (100.0%)
Number (%) of subjects with event	77 (22.4%)	107 (31.5%)
Number (%) of subjects censored	266 (77.6%)	233 (68.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.50; 0.91]	
two-sided p-value from stratified logrank test	0.0082	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 144: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	81 (100.0%)
Number (%) of subjects with event	38 (46.3%)	43 (53.1%)
Number (%) of subjects censored	44 (53.7%)	38 (46.9%)
Median Time to event (month) [95 % CI]	53.233 [n.c.]	31.733 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.50; 1.21]	
two-sided p-value from stratified logrank test	0.2567	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 145: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0751

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 146: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	373 (100.0%)	344 (100.0%)
Number (%) of subjects with event	175 (46.9%)	162 (47.1%)
Number (%) of subjects censored	198 (53.1%)	182 (52.9%)
Median Time to event (month) [95 % CI]	55.067 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.78; 1.20]	
two-sided p-value from stratified logrank test	0.7581	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 146: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2161 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	814 (37.7%)	848 (39.0%)
Number (%) of subjects censored	1347 (62.3%)	1327 (61.0%)
Median Time to event (month) [95 % CI]	n.c.	56.100 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.88; 1.07]	
two-sided p-value from stratified logrank test	0.5129	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 147: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9388

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 148: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	899 (100.0%)	892 (100.0%)
Number (%) of subjects with event	431 (47.9%)	431 (48.3%)
Number (%) of subjects censored	468 (52.1%)	461 (51.7%)
Median Time to event (month) [95 % CI]	41.367 [35.933;49.333]	43.900 [36.300;48.067]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.86; 1.13]	
two-sided p-value from stratified logrank test	0.8203	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 148: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1639 (100.0%)	1633 (100.0%)
Number (%) of subjects with event	559 (34.1%)	581 (35.6%)
Number (%) of subjects censored	1080 (65.9%)	1052 (64.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.85; 1.07]	
two-sided p-value from stratified logrank test	0.4256	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 149: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.7261

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 150: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1863 (100.0%)	1838 (100.0%)
Number (%) of subjects with event	733 (39.3%)	741 (40.3%)
Number (%) of subjects censored	1130 (60.7%)	1097 (59.7%)
Median Time to event (month) [95 % CI]	n.c.	56.133 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.89; 1.09]	
two-sided p-value from stratified logrank test	0.7468	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 150: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	675 (100.0%)	686 (100.0%)
Number (%) of subjects with event	257 (38.1%)	271 (39.5%)
Number (%) of subjects censored	418 (61.9%)	415 (60.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.77; 1.09]	
two-sided p-value from stratified logrank test	0.3459	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 151: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.4951

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 152: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	757 (100.0%)	754 (100.0%)
Number (%) of subjects with event	261 (34.5%)	257 (34.1%)
Number (%) of subjects censored	496 (65.5%)	497 (65.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.87; 1.24]	
two-sided p-value from stratified logrank test	0.6524	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 152: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	1699 (100.0%)	1681 (100.0%)
Number (%) of subjects with event	690 (40.6%)	710 (42.2%)
Number (%) of subjects censored	1009 (59.4%)	971 (57.8%)
Median Time to event (month) [95 % CI]	55.867 [n.c.]	52.633 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.85; 1.05]	
two-sided p-value from stratified logrank test	0.2611	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 152: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	82 (100.0%)	90 (100.0%)
Number (%) of subjects with event	39 (47.6%)	45 (50.0%)
Number (%) of subjects censored	43 (52.4%)	45 (50.0%)
Median Time to event (month) [95 % CI]	50.833 [n.c.]	41.000 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.21 [0.75; 1.96]	
two-sided p-value from stratified logrank test	0.4330	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 153: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.6814

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 154: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	1799 (100.0%)	1765 (100.0%)
Number (%) of subjects with event	687 (38.2%)	673 (38.1%)
Number (%) of subjects censored	1112 (61.8%)	1092 (61.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.89; 1.10]	
two-sided p-value from stratified logrank test	0.7997	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 154: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	80 (100.0%)	83 (100.0%)
Number (%) of subjects with event	23 (28.8%)	26 (31.3%)
Number (%) of subjects censored	57 (71.3%)	57 (68.7%)
Median Time to event (month) [95 % CI]	n.c.	53.933 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.03 [0.55; 1.92]	
two-sided p-value from stratified logrank test	0.9344	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 154: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	503 (100.0%)	530 (100.0%)
Number (%) of subjects with event	231 (45.9%)	259 (48.9%)
Number (%) of subjects censored	272 (54.1%)	271 (51.1%)
Median Time to event (month) [95 % CI]	49.333 [n.c.]	46.733 [40.400;53.733]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.80; 1.15]	
two-sided p-value from stratified logrank test	0.6580	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 154: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	147 (100.0%)
Number (%) of subjects with event	49 (31.4%)	54 (36.7%)
Number (%) of subjects censored	107 (68.6%)	93 (63.3%)
Median Time to event (month) [95 % CI]	n.c.	50.700 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.54; 1.22]	
two-sided p-value from stratified logrank test	0.3130	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 155: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.7094

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 156: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	1764 (100.0%)	1794 (100.0%)
Number (%) of subjects with event	729 (41.3%)	760 (42.4%)
Number (%) of subjects censored	1035 (58.7%)	1034 (57.6%)
Median Time to event (month) [95 % CI]	55.067 [n.c.]	52.900 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.87; 1.07]	
two-sided p-value from stratified logrank test	0.4656	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 156: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	774 (100.0%)	731 (100.0%)
Number (%) of subjects with event	261 (33.7%)	252 (34.5%)
Number (%) of subjects censored	513 (66.3%)	479 (65.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.85; 1.20]	
two-sided p-value from stratified logrank test	0.9203	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 157: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.7592

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1515 (100.0%)	1517 (100.0%)
Number (%) of subjects with event	541 (35.7%)	568 (37.4%)
Number (%) of subjects censored	974 (64.3%)	949 (62.6%)
Median Time to event (month) [95 % CI]	n.c.	59.533 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.84; 1.06]	
two-sided p-value from stratified logrank test	0.3583	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24

Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	1023 (100.0%)	1008 (100.0%)
Number (%) of subjects with event	449 (43.9%)	444 (44.0%)
Number (%) of subjects censored	574 (56.1%)	564 (56.0%)
Median Time to event (month) [95 % CI]	51.300 [46.467;55.067]	49.533 [46.400;54.100]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.88; 1.15]	
two-sided p-value from stratified logrank test	0.9517	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 159: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.5390

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	990 (39.0%)	1012 (40.1%)
Number (%) of subjects censored	1548 (61.0%)	1513 (59.9%)
Median Time to event (month) [95 % CI]	n.c.	56.133 [n.c.]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.88; 1.05]	
two-sided p-value from unstratified logrank test	0.3839	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 161: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2525 (100.0%)
Number (%) of subjects with event	915 (36.1%)	941 (37.3%)
Number (%) of subjects censored	1623 (63.9%)	1584 (62.7%)
Median Time to event (month) [95 % CI]	n.c.	56.100 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.88; 1.06]	
two-sided p-value from stratified logrank test	0.4579	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s2.sas 07FEB2023 9:24
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Table 1.2.1 / 162: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.84; 1.03]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.1517

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 07FEB2023 9:36
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Figure 1.2.1 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

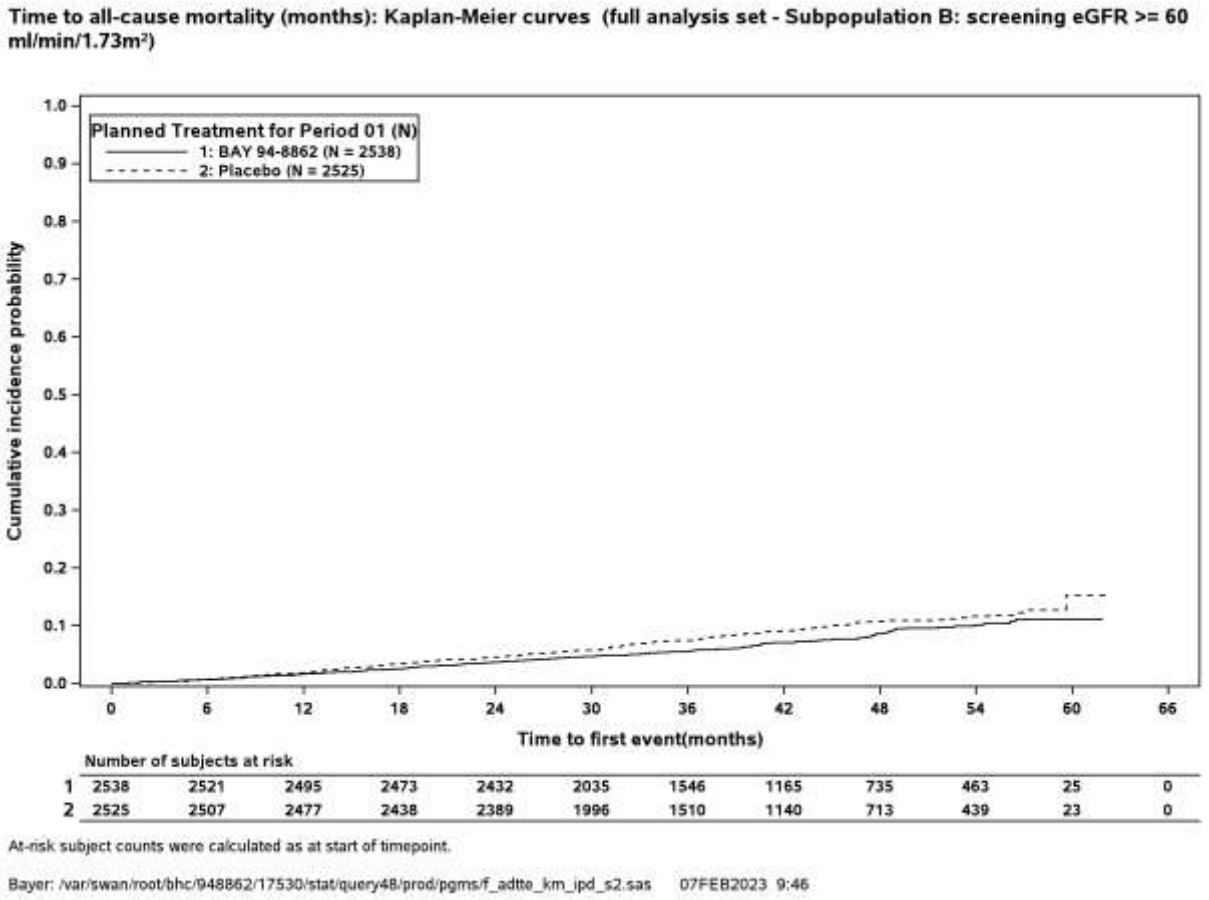


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

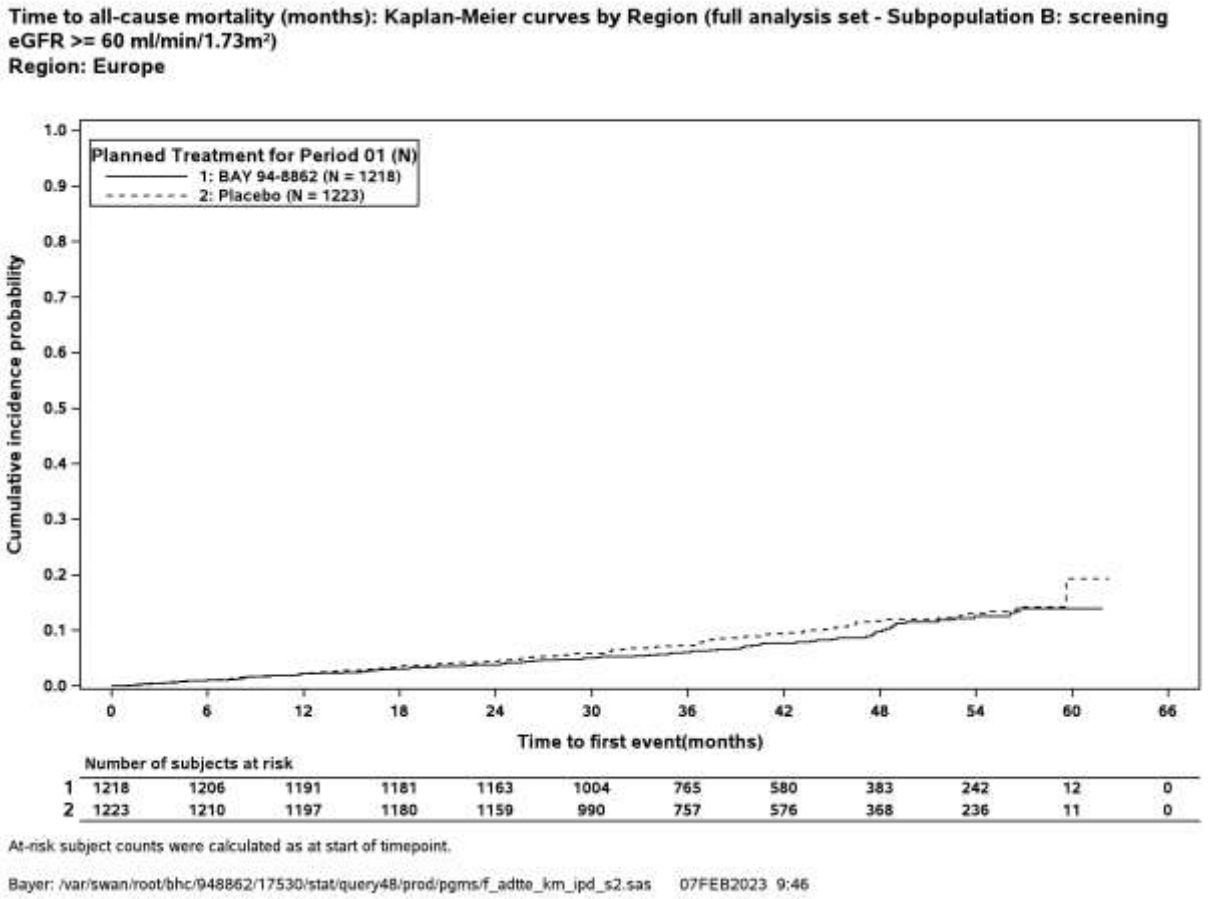


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

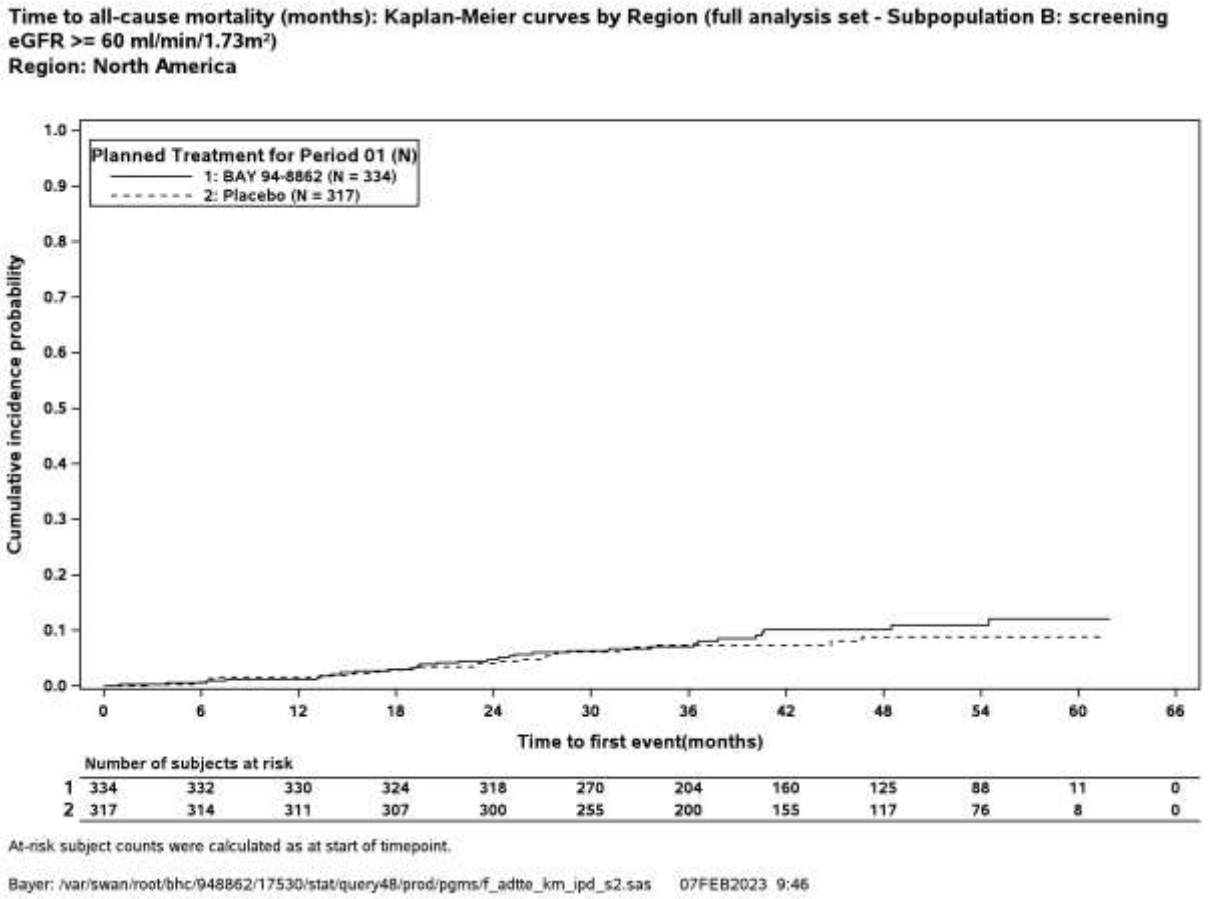


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

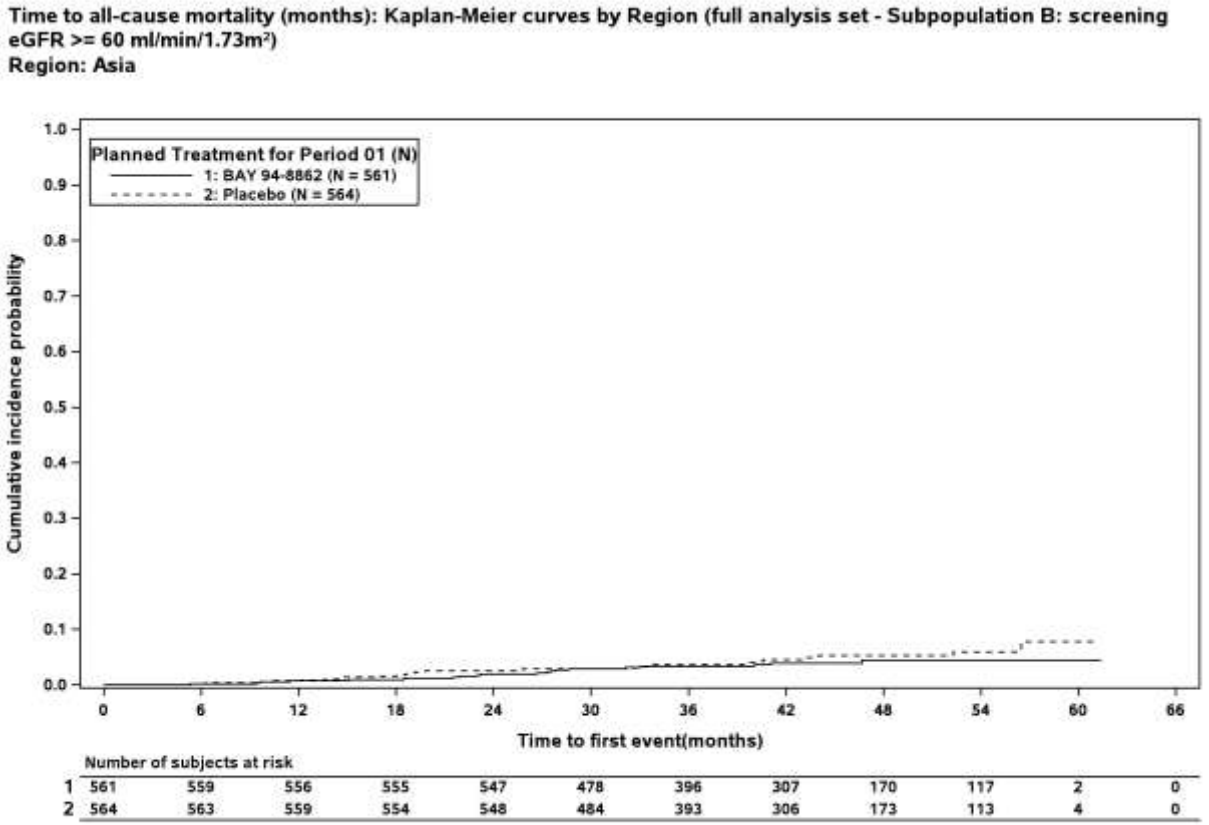


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

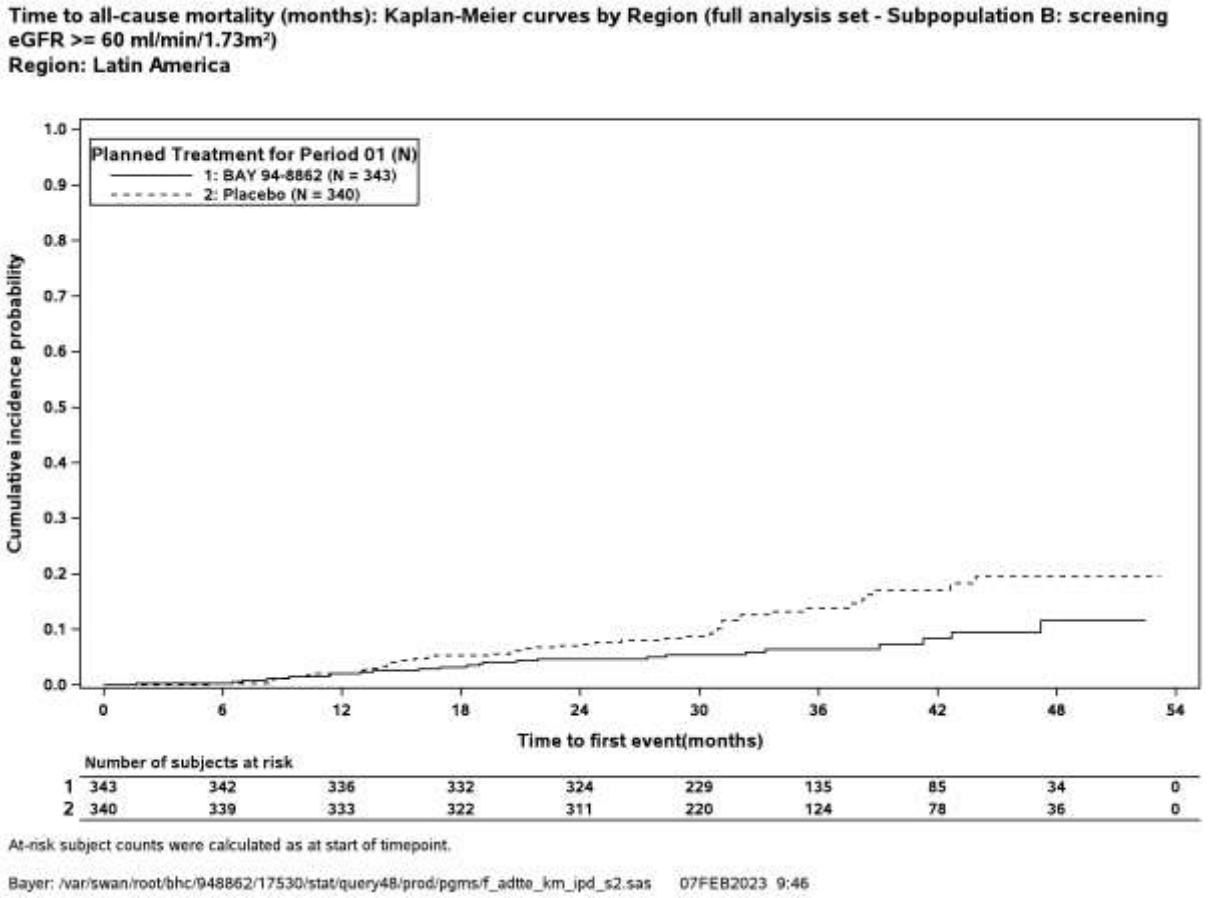


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

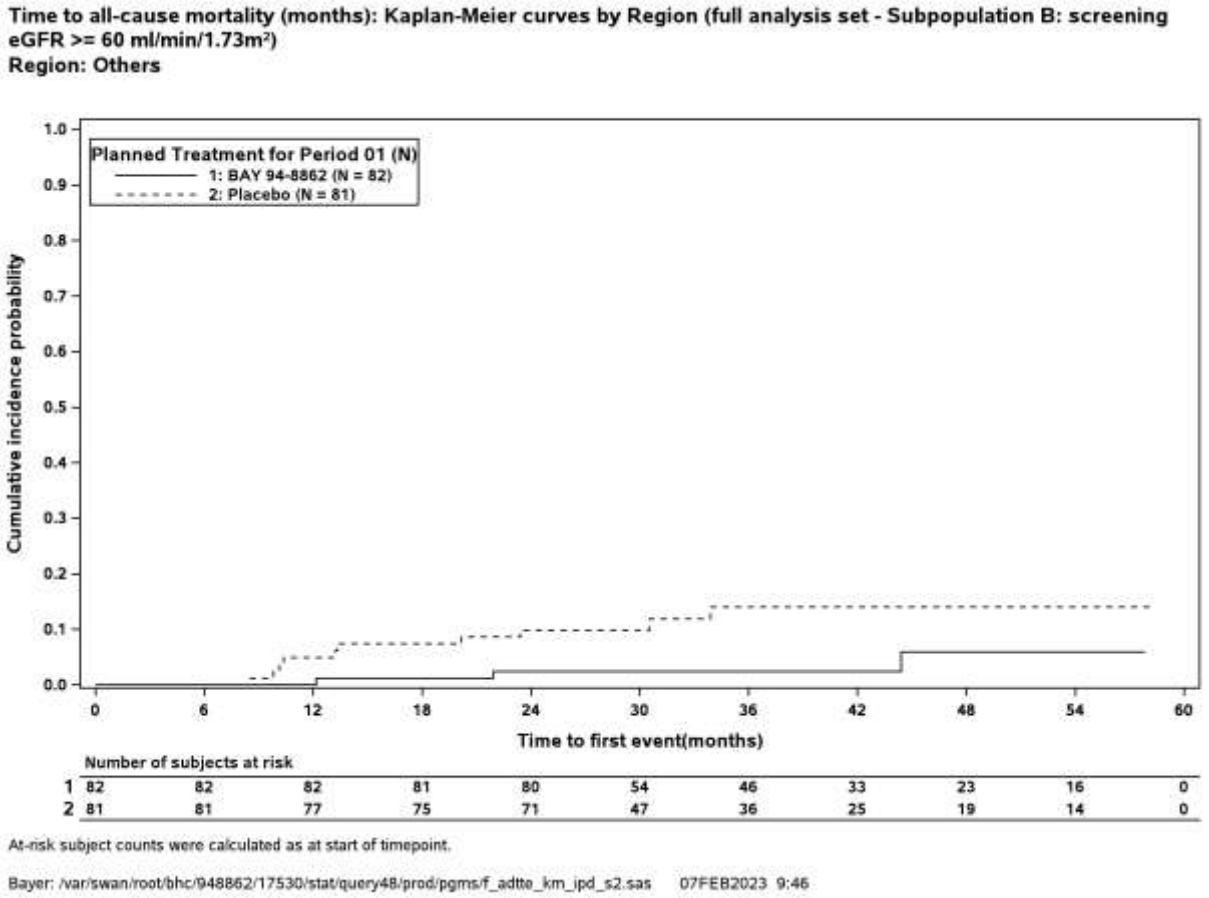


Figure 1.2.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

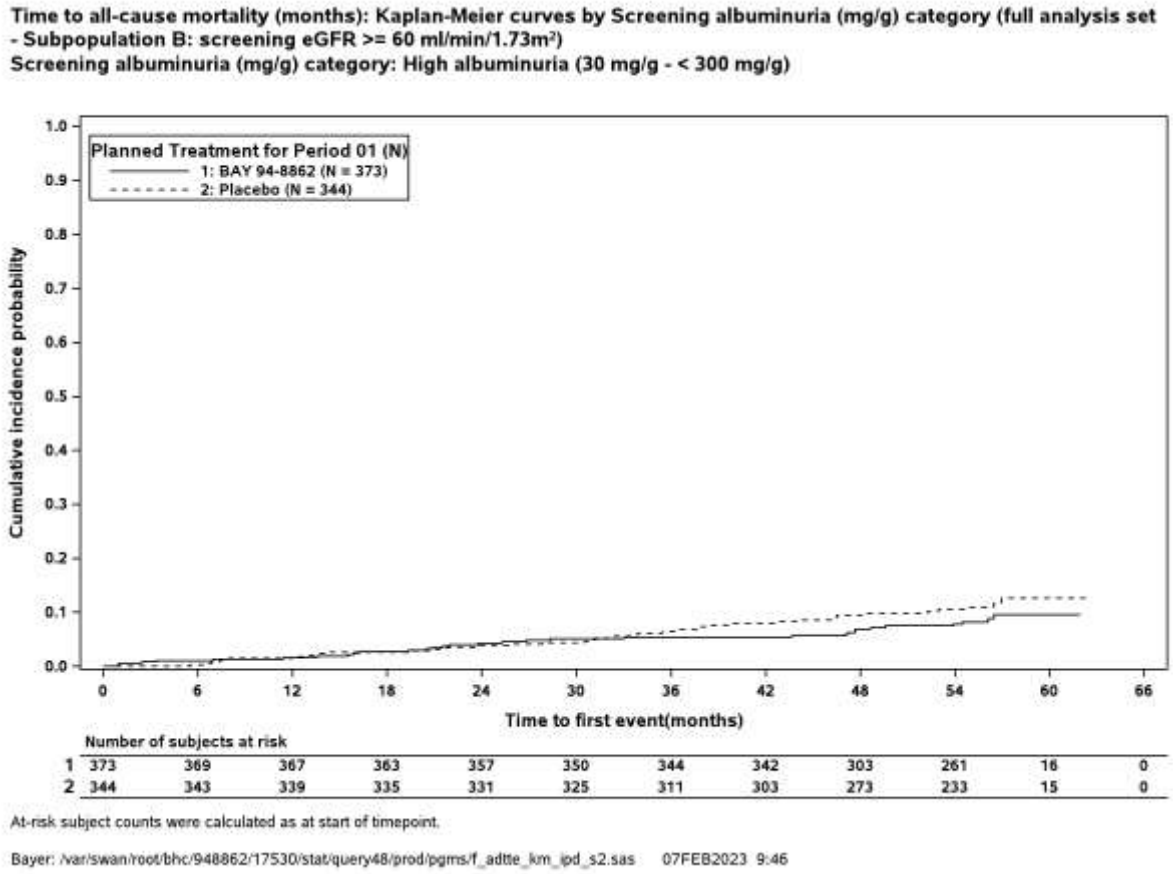


Figure 1.2.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

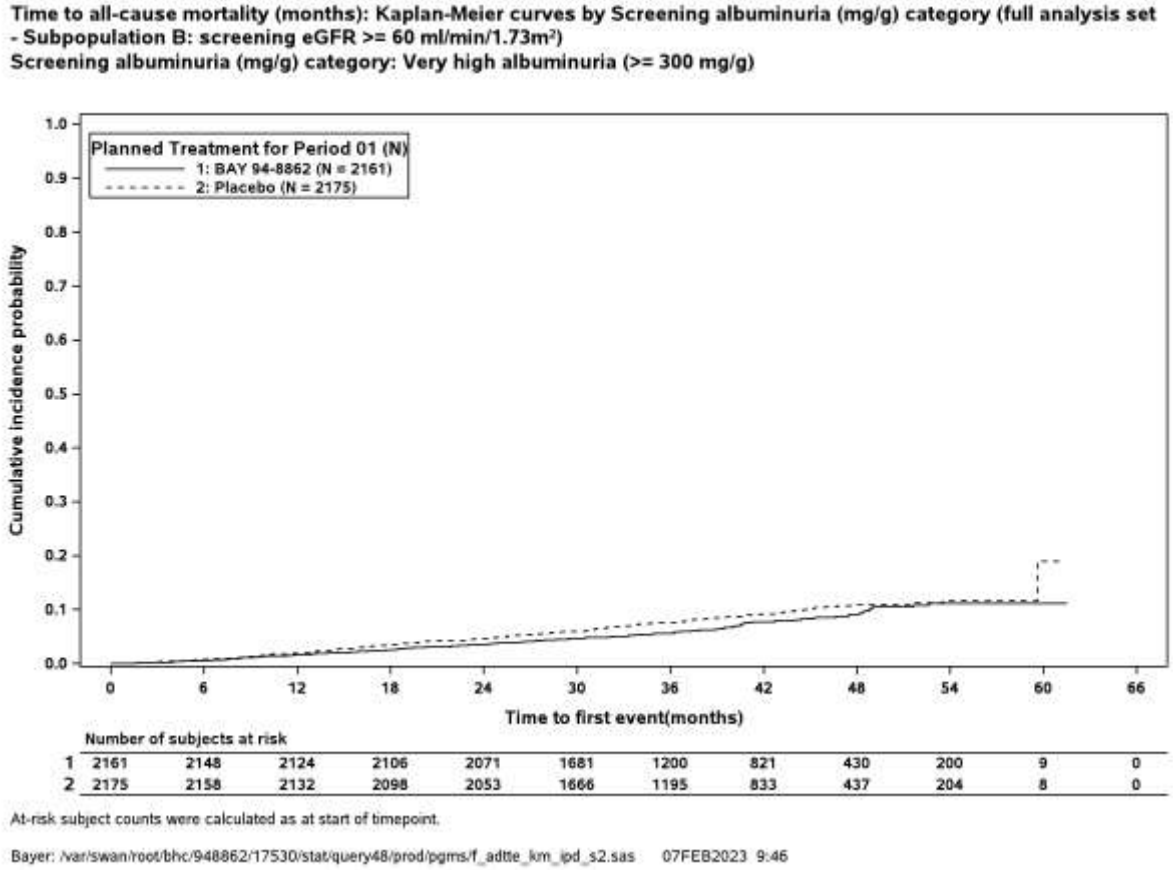


Figure 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

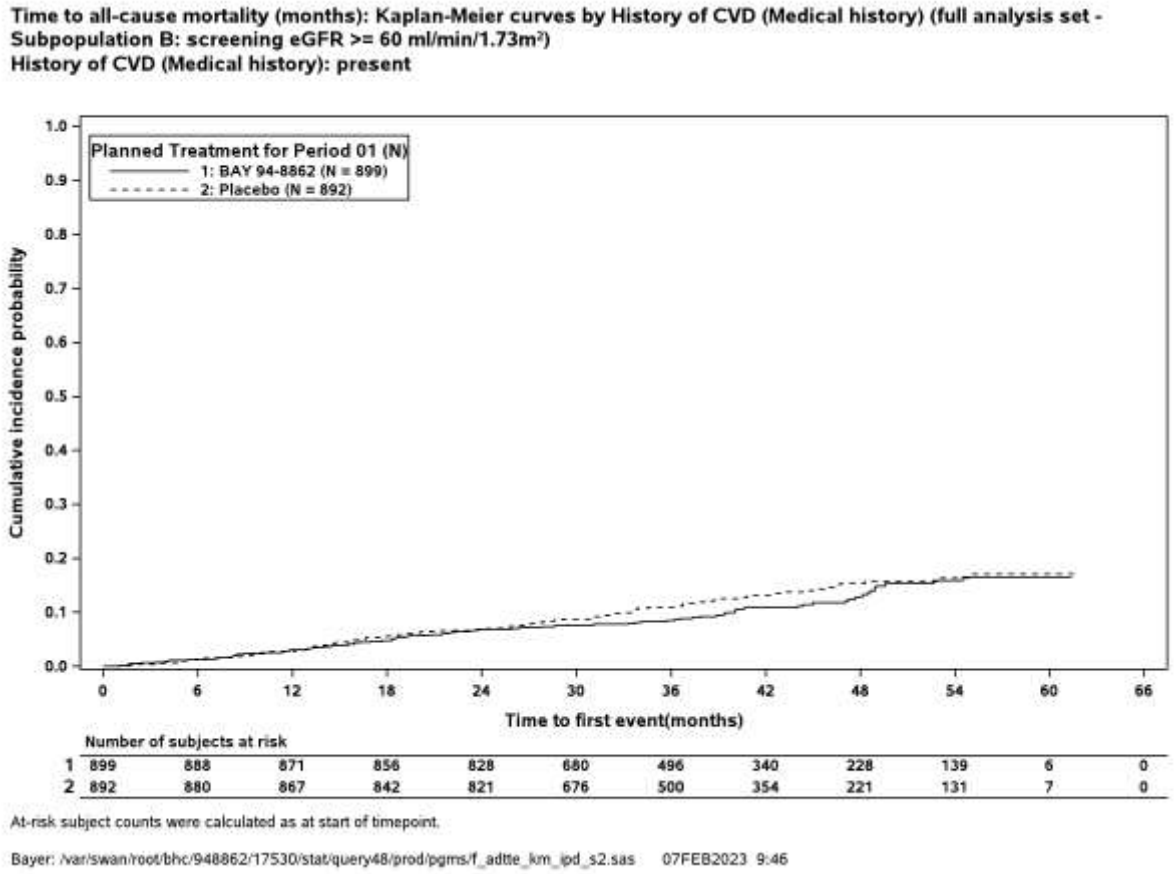


Figure 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

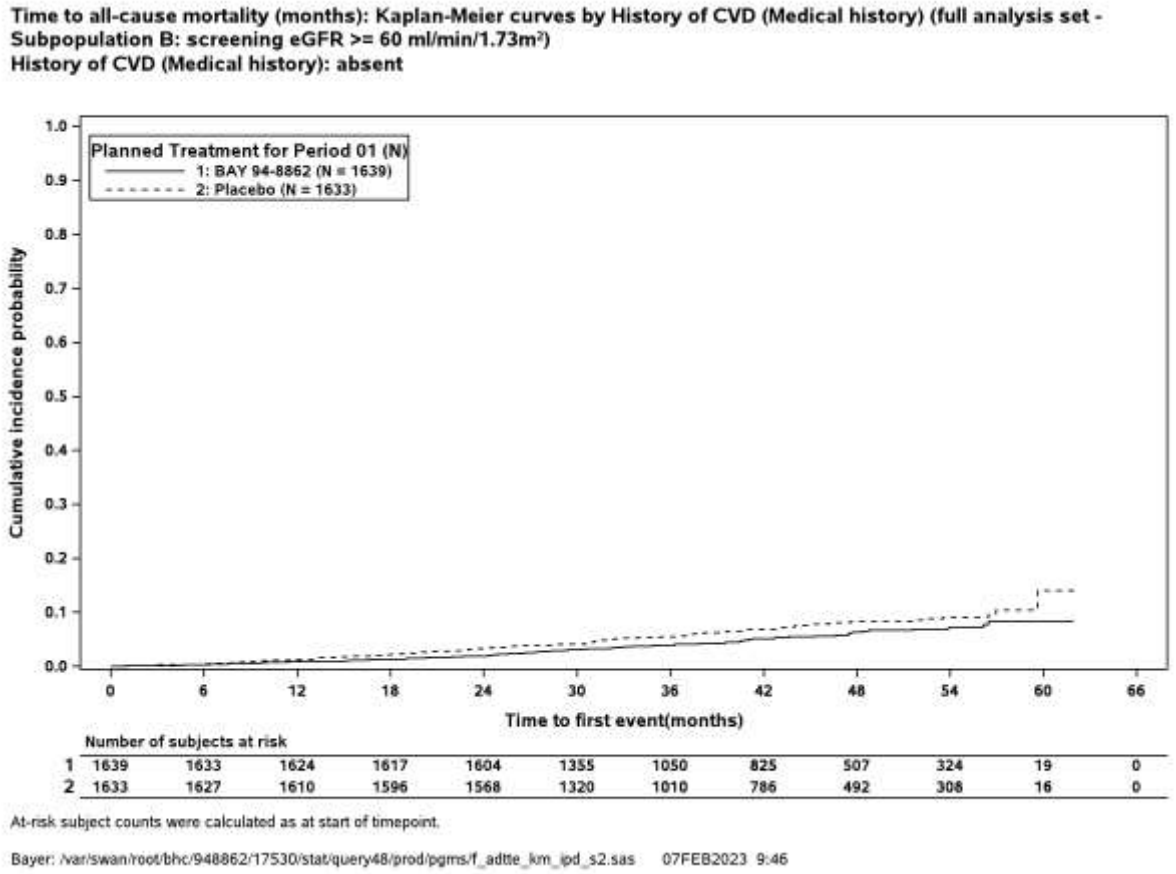


Figure 1.2.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

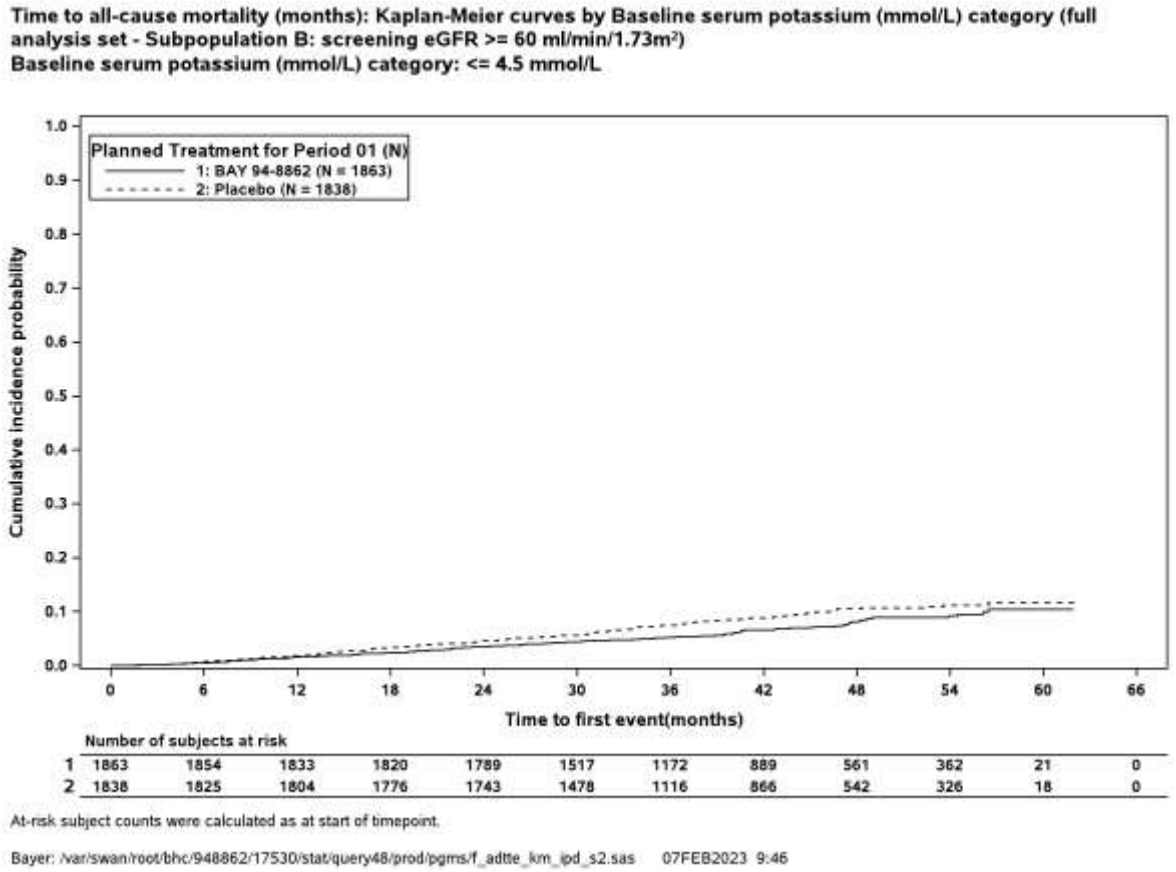


Figure 1.2.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

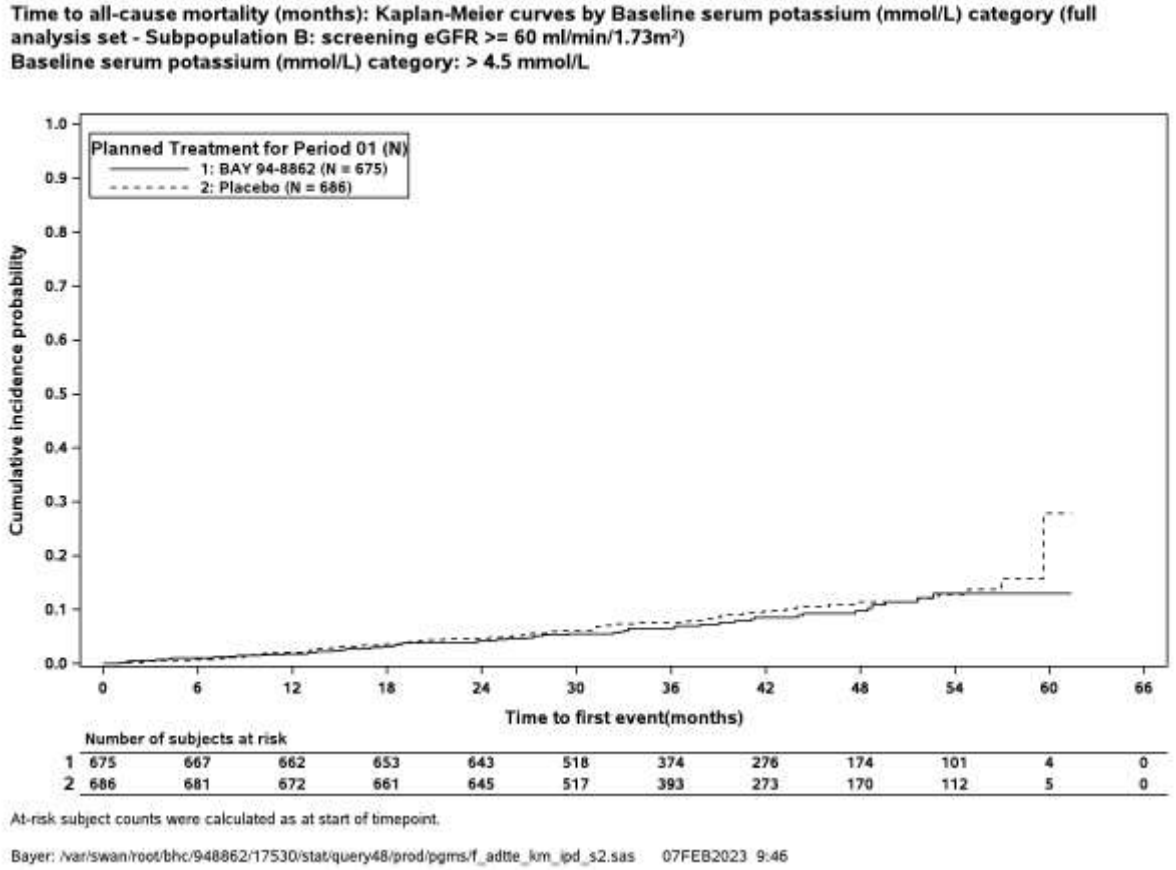


Figure 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

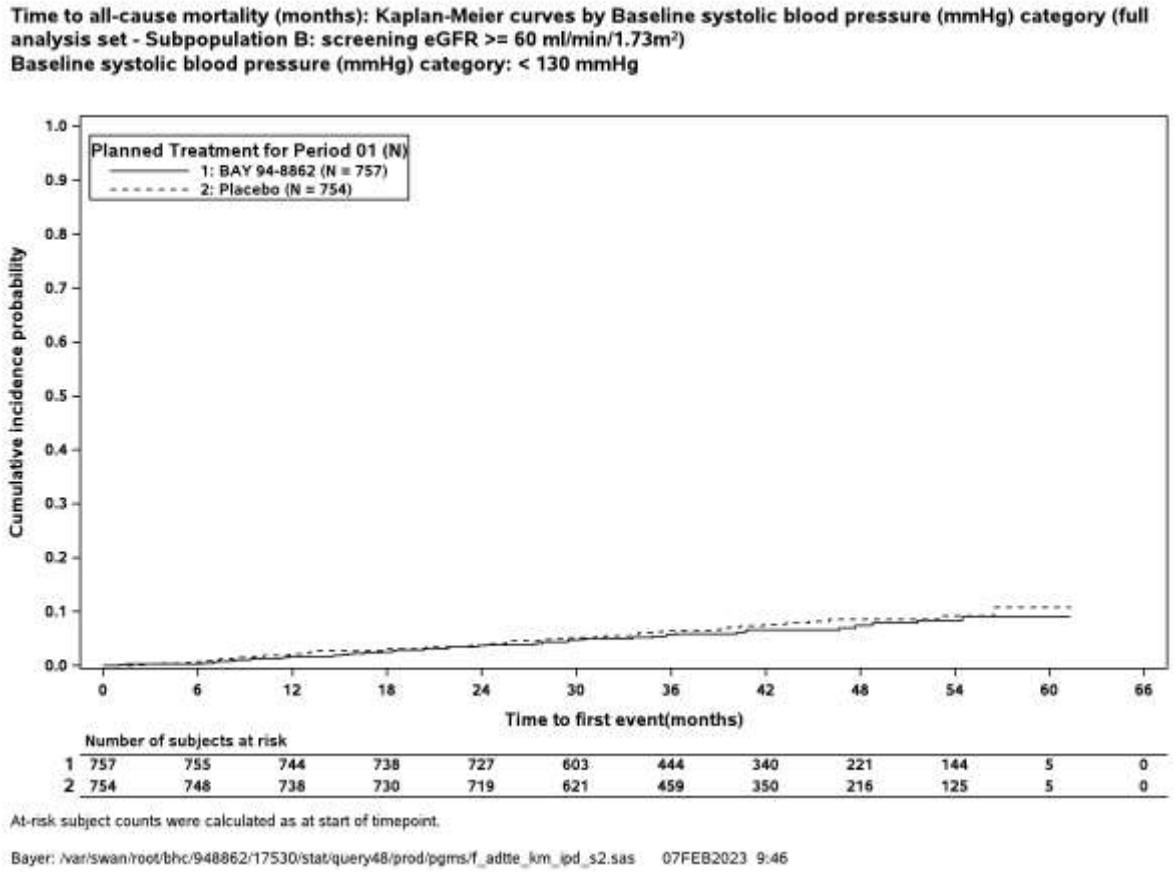


Figure 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

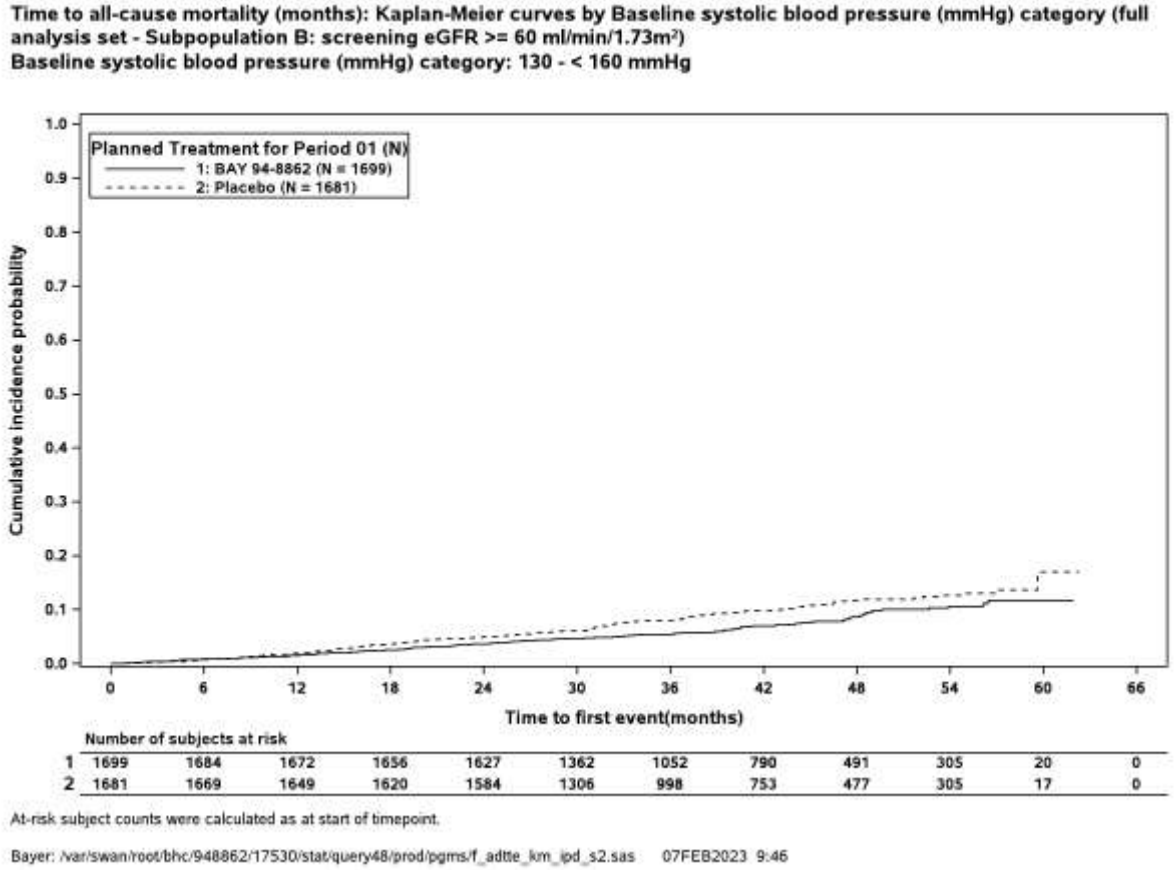
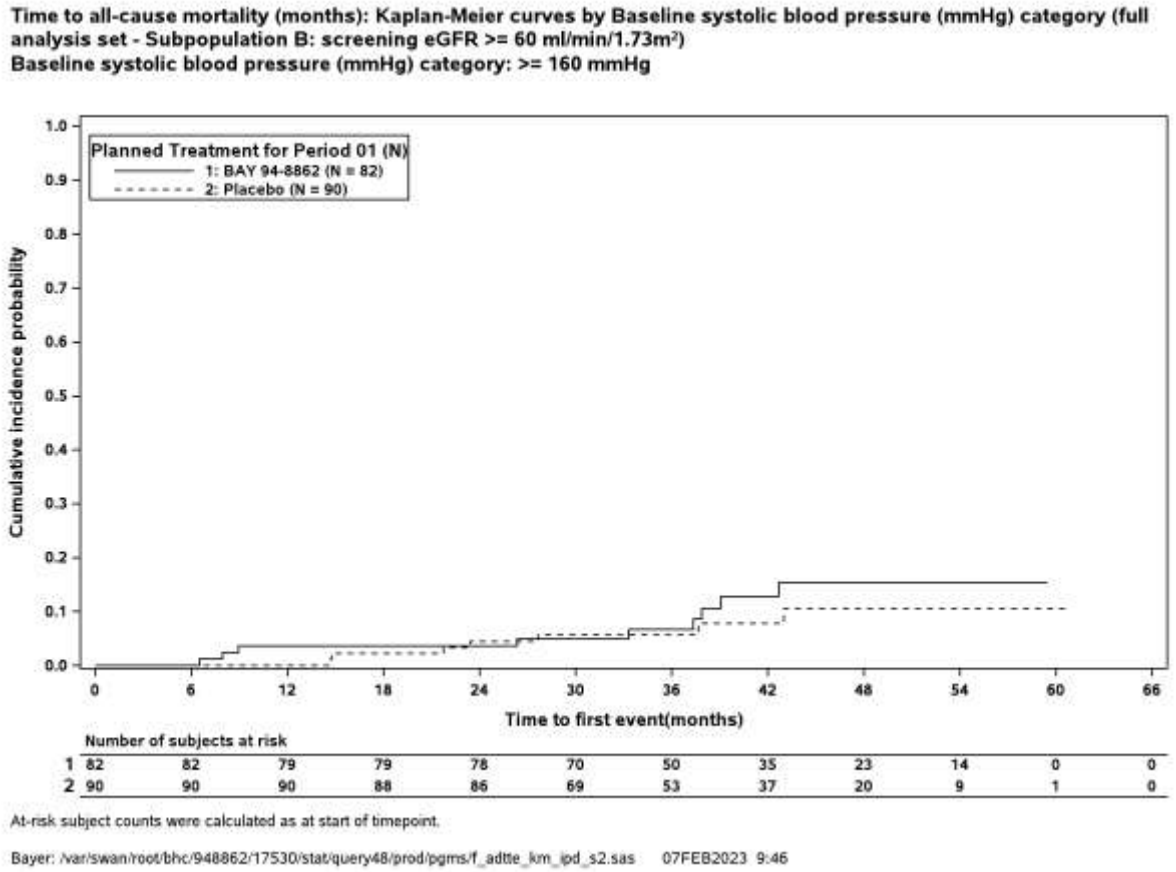


Figure 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

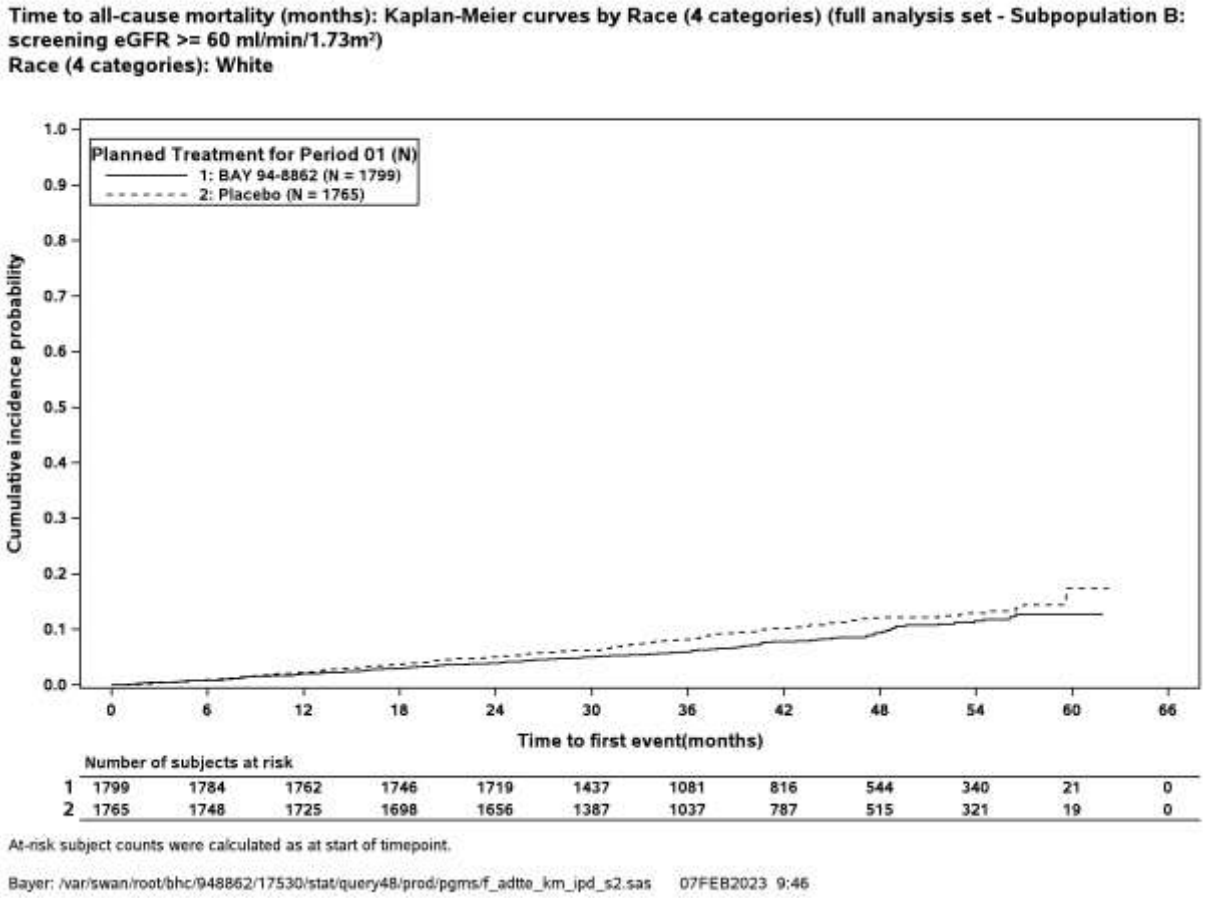


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

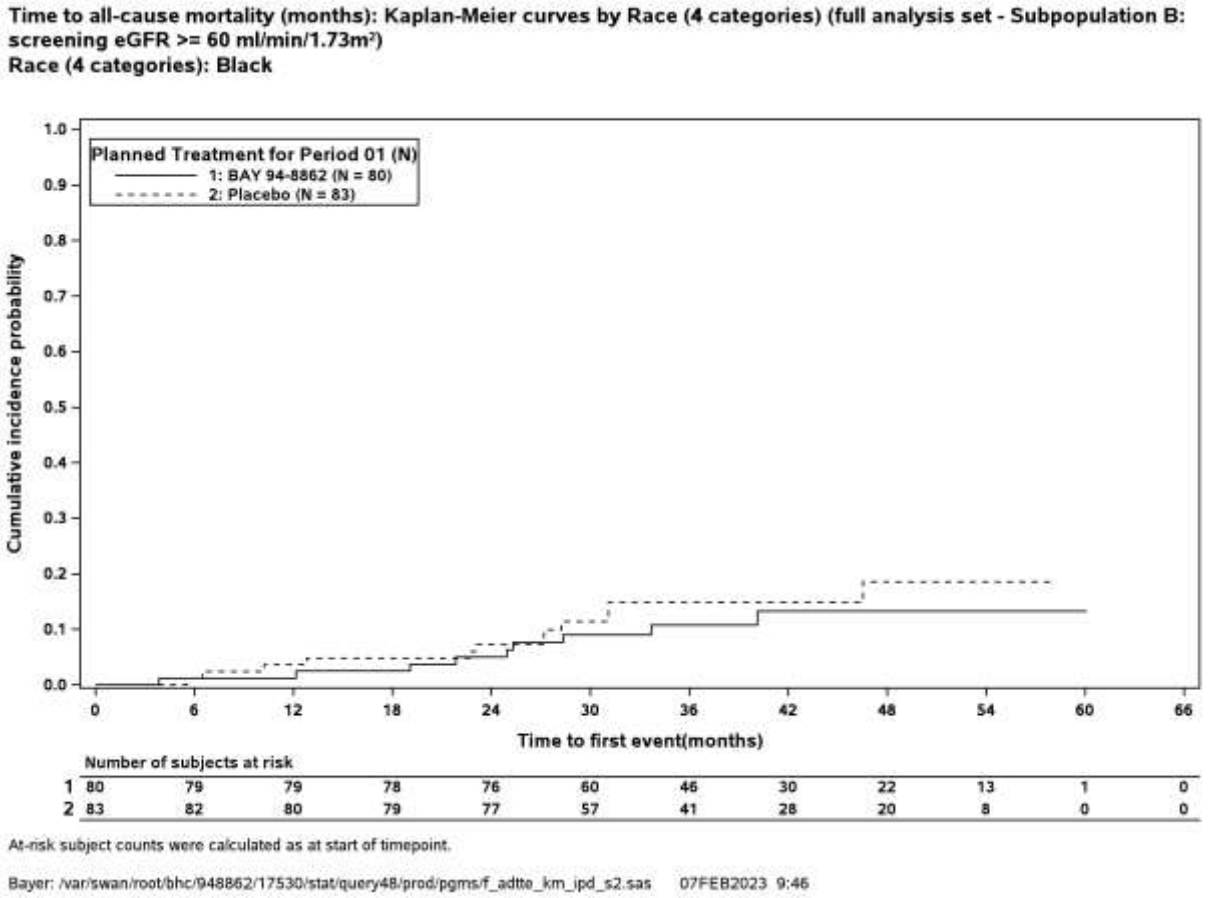


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

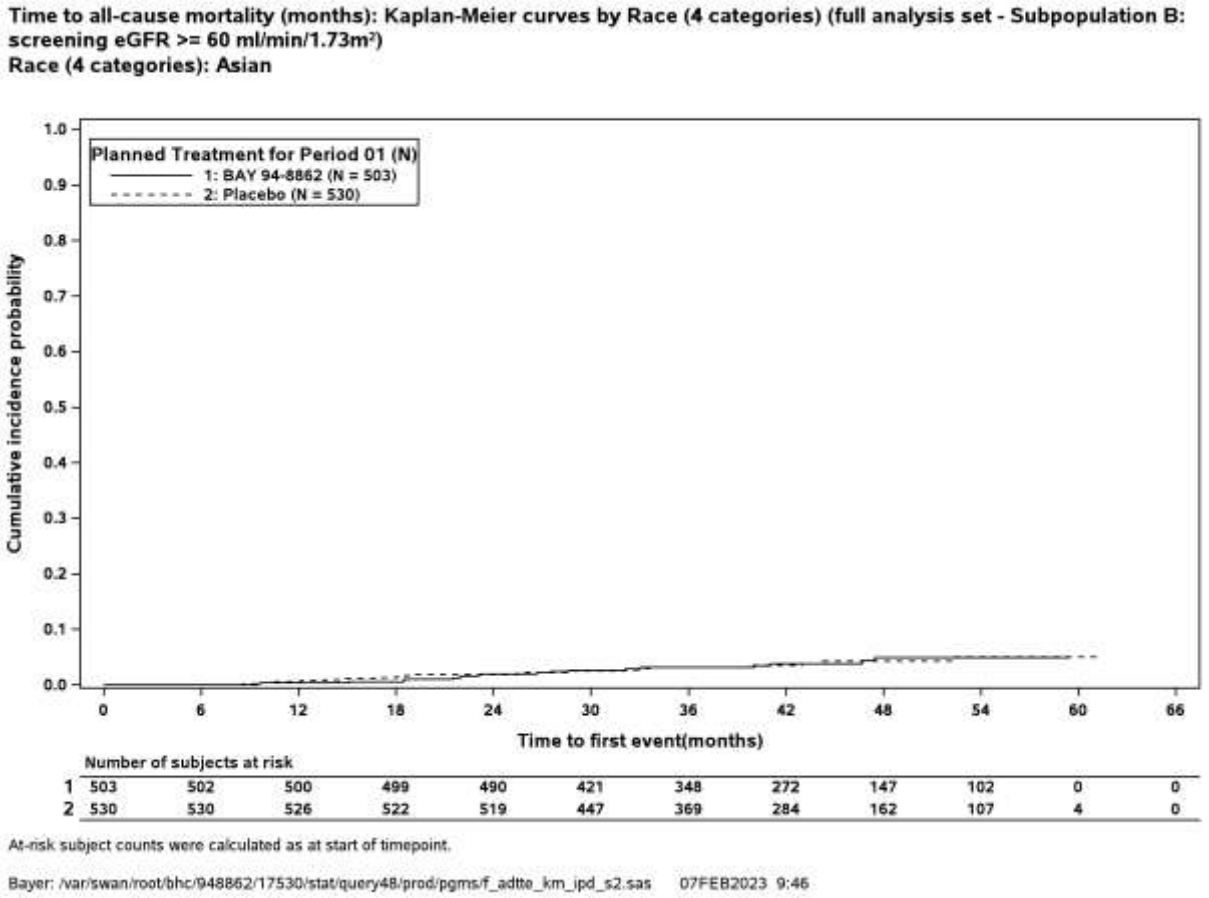


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

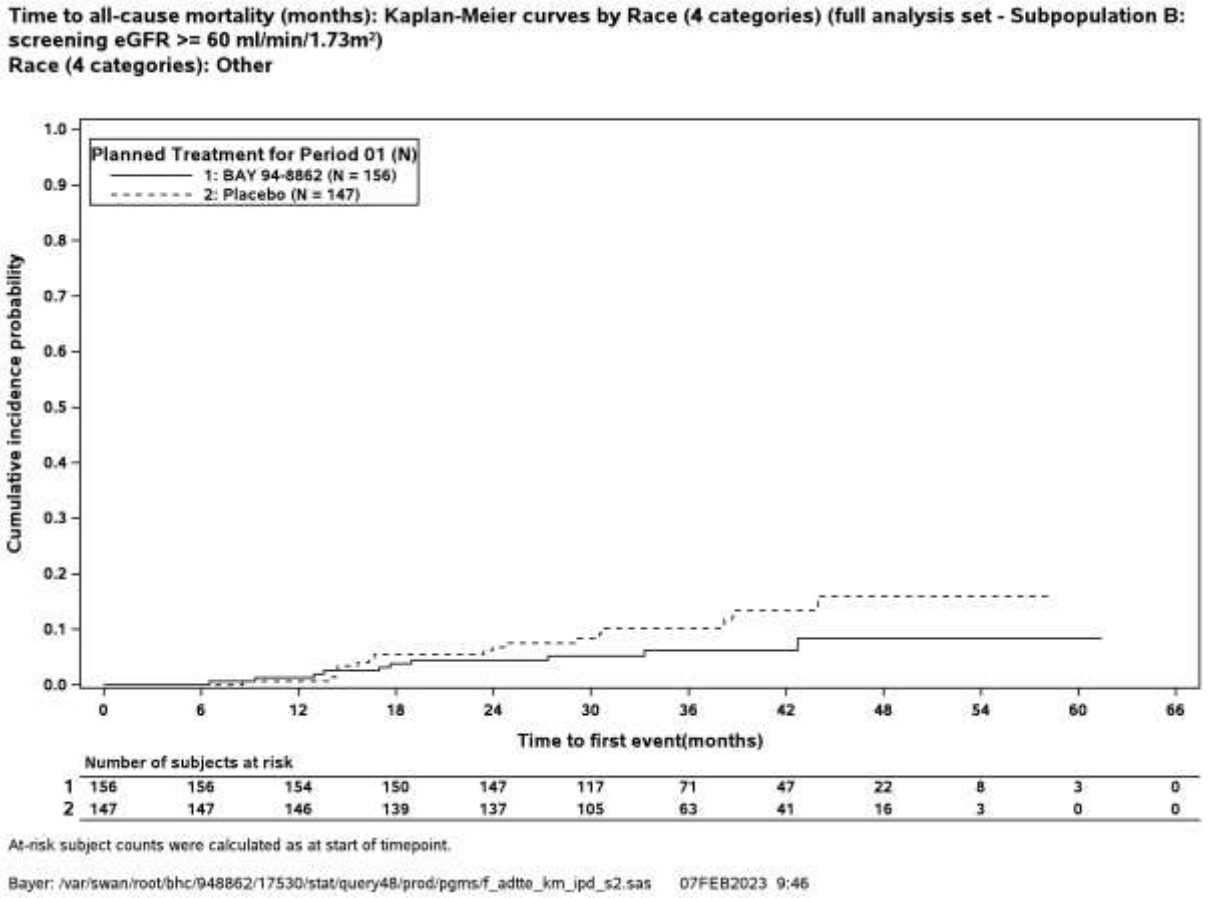


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

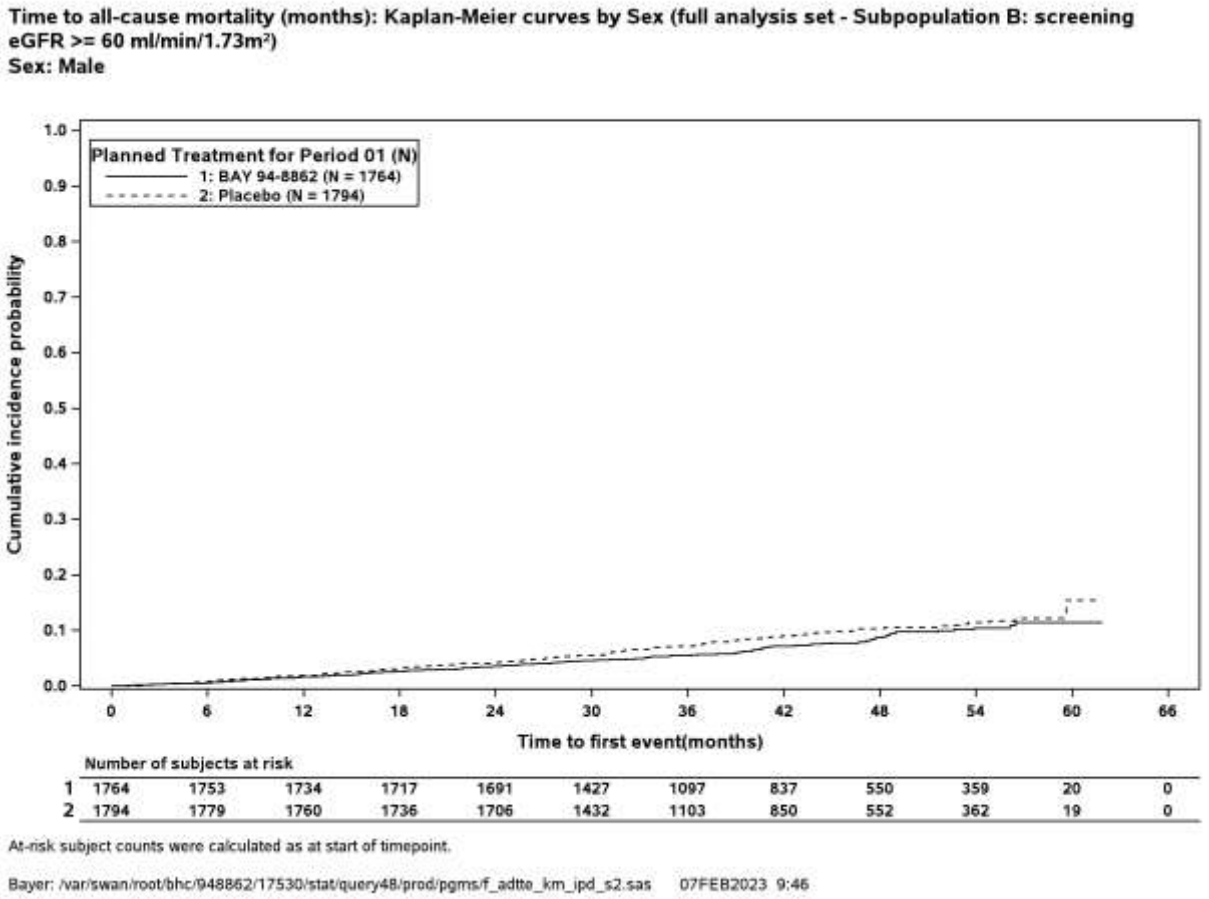


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

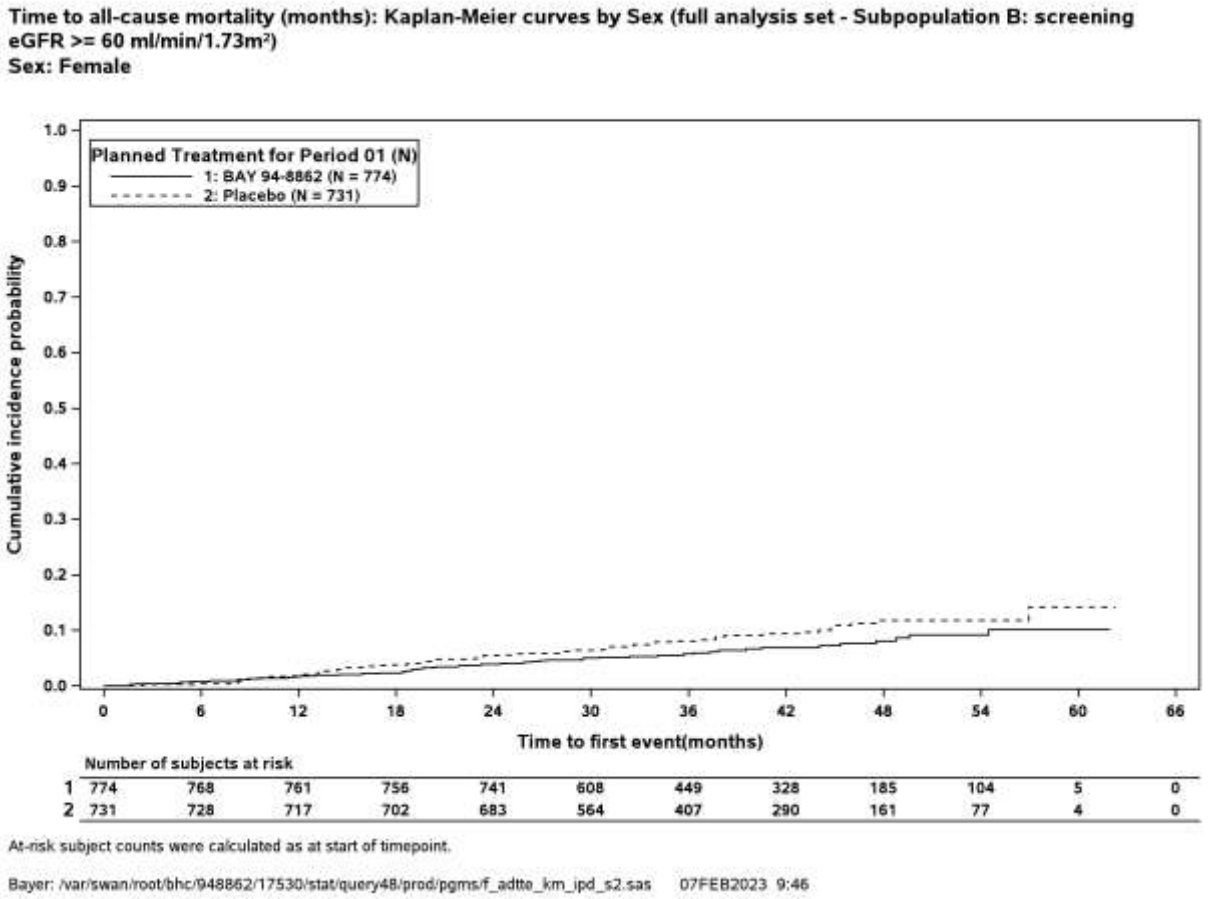


Figure 1.2.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

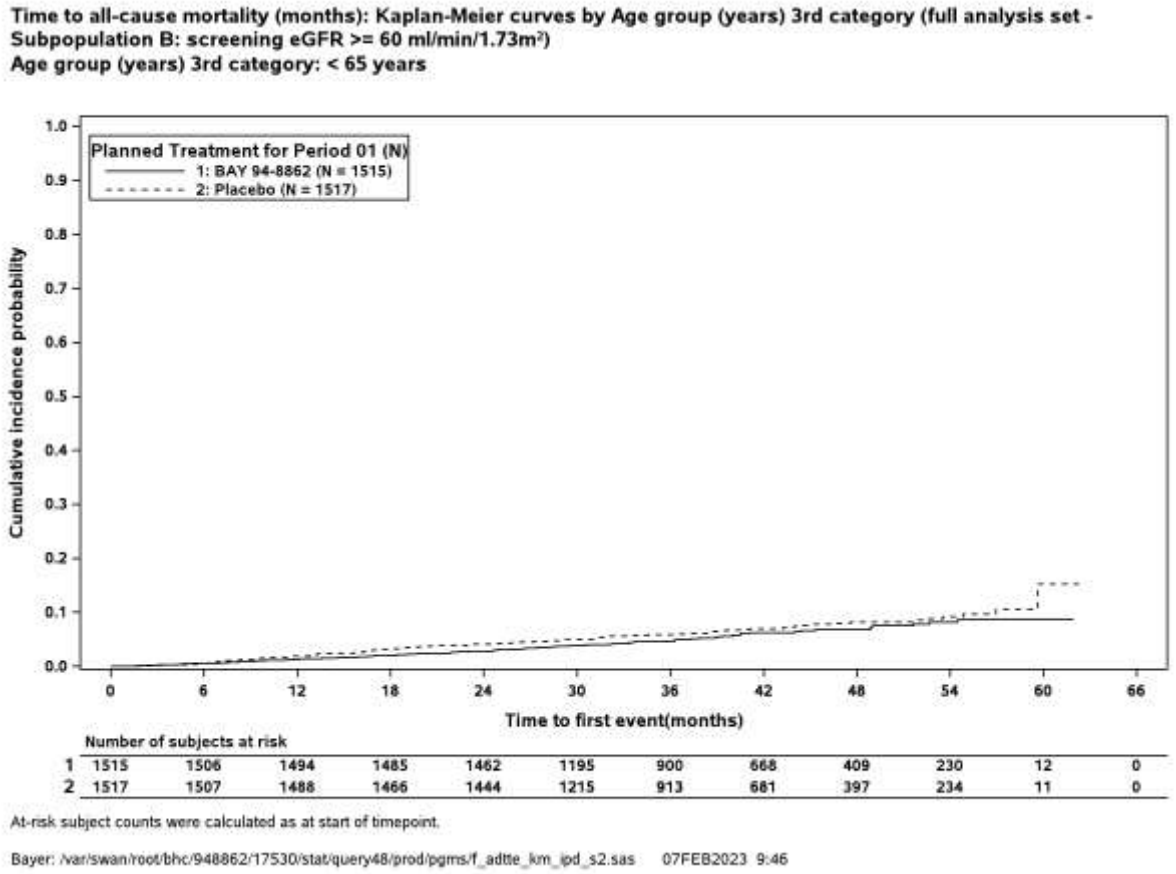


Figure 1.2.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

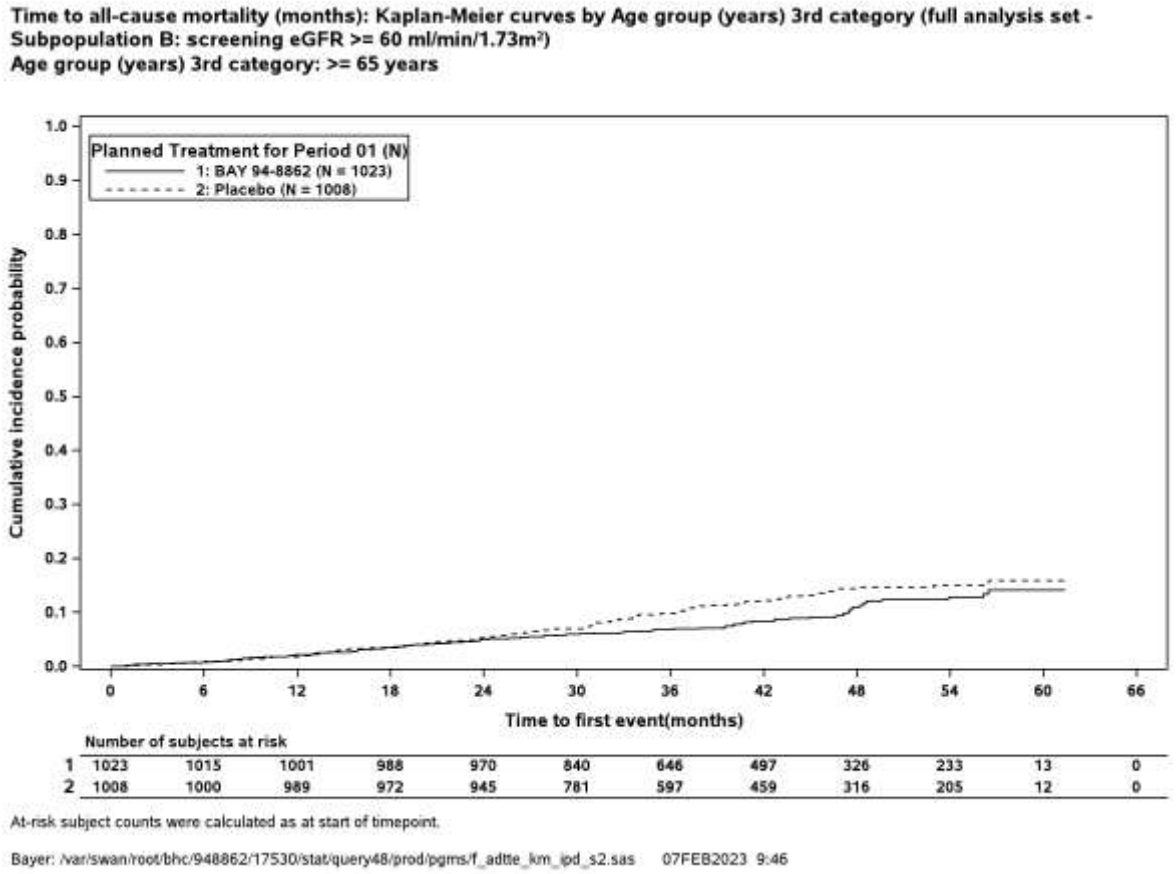


Figure 1.2.1 / 10: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

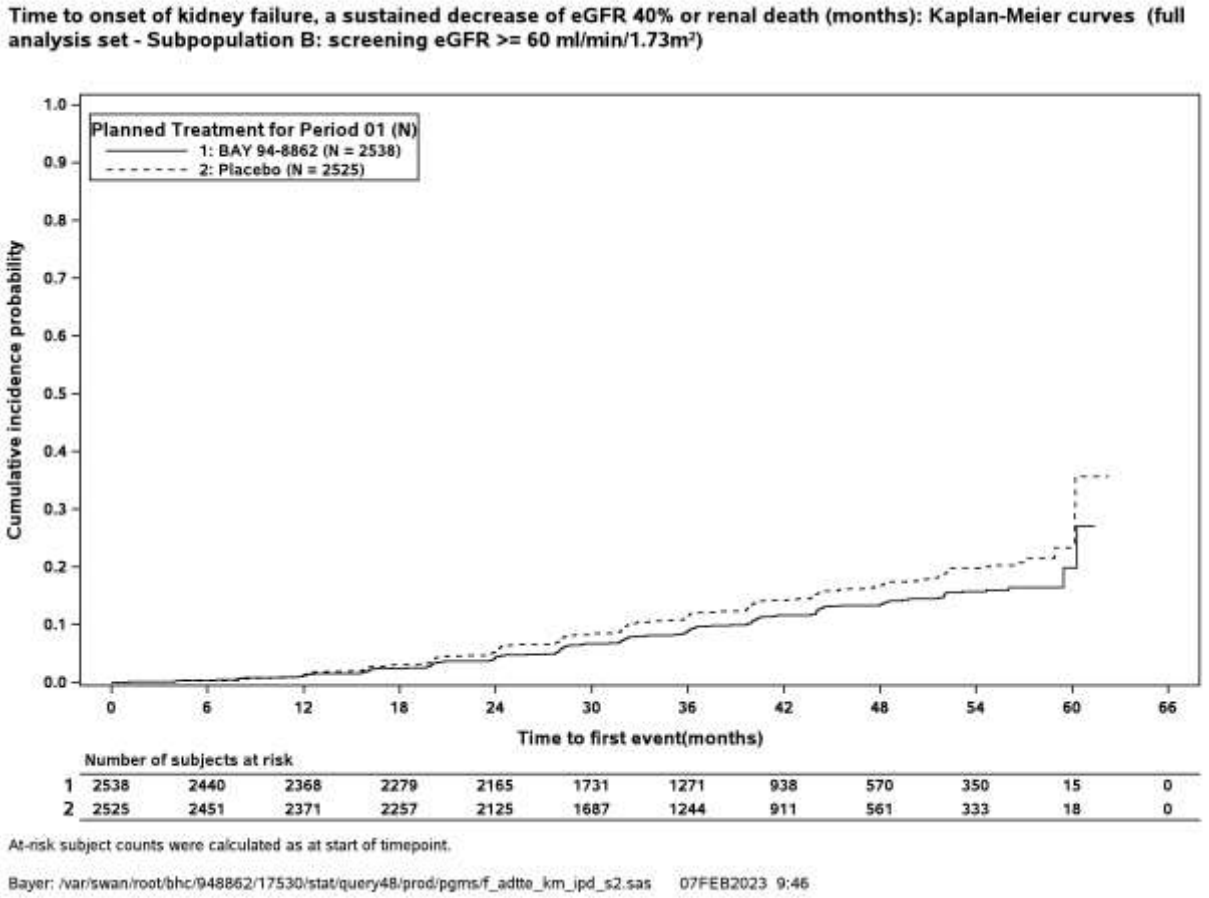


Figure 1.2.1 / 11: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

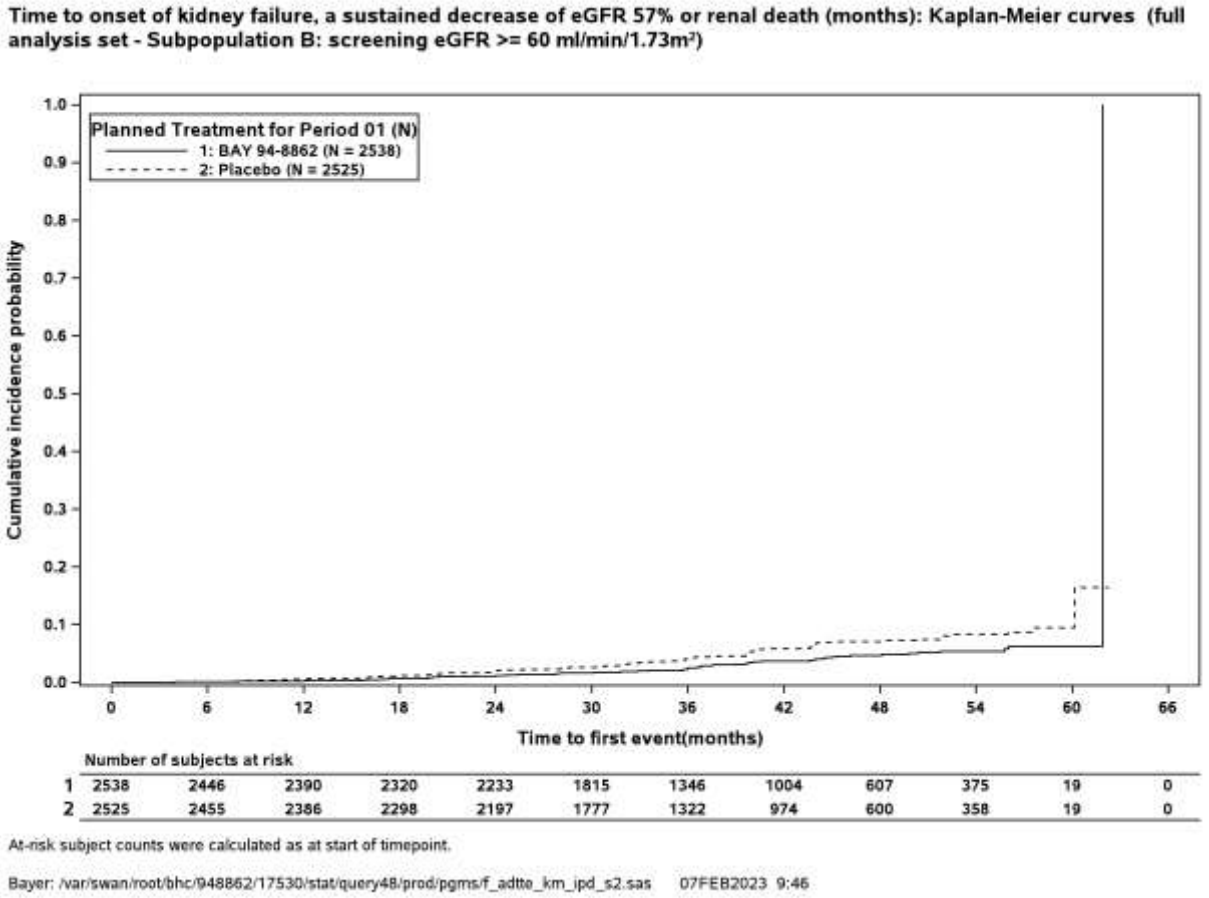


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

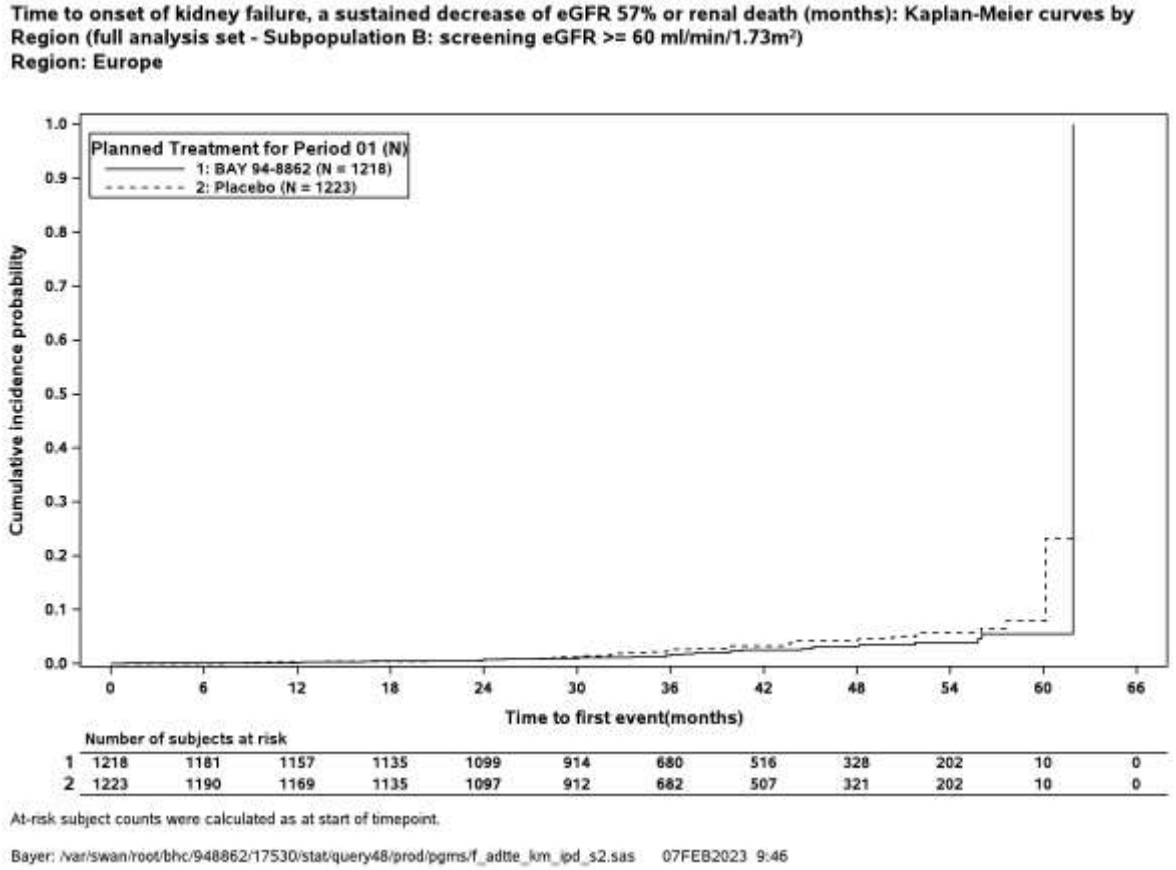


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

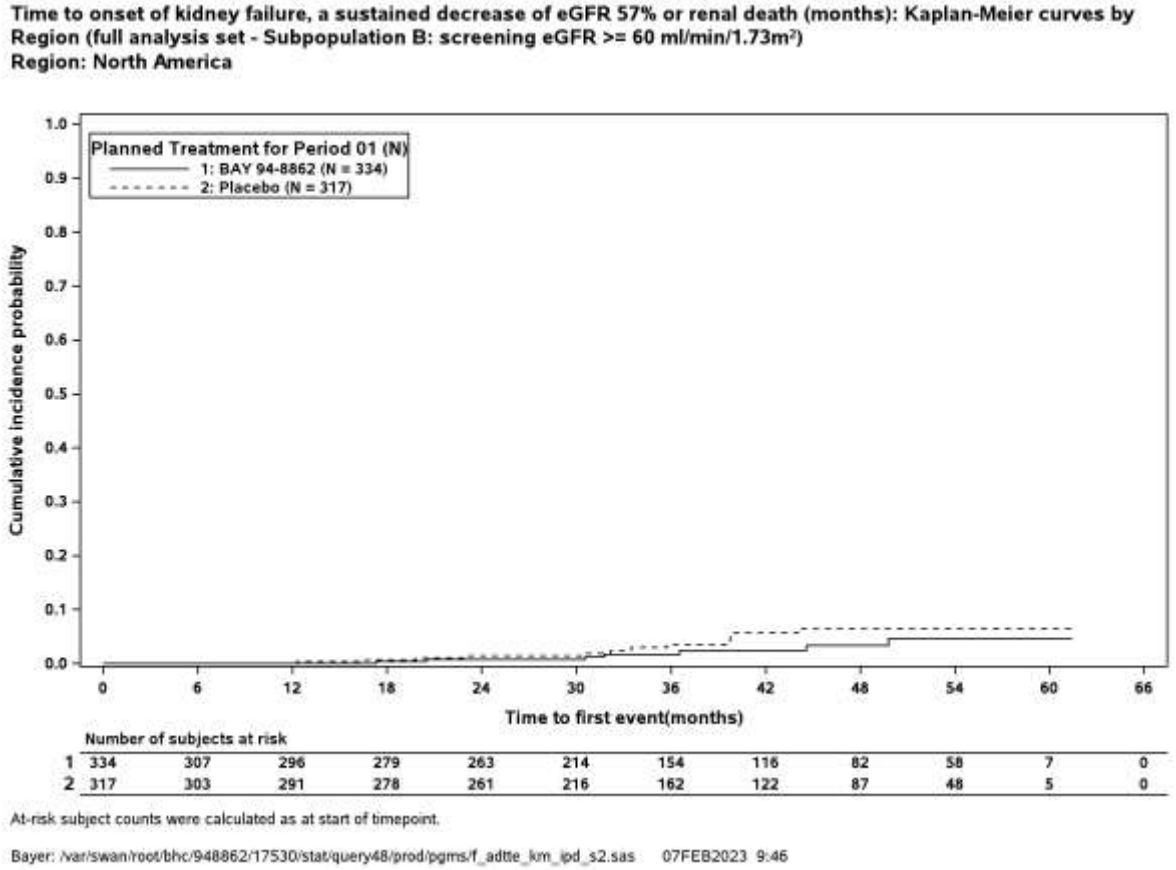


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

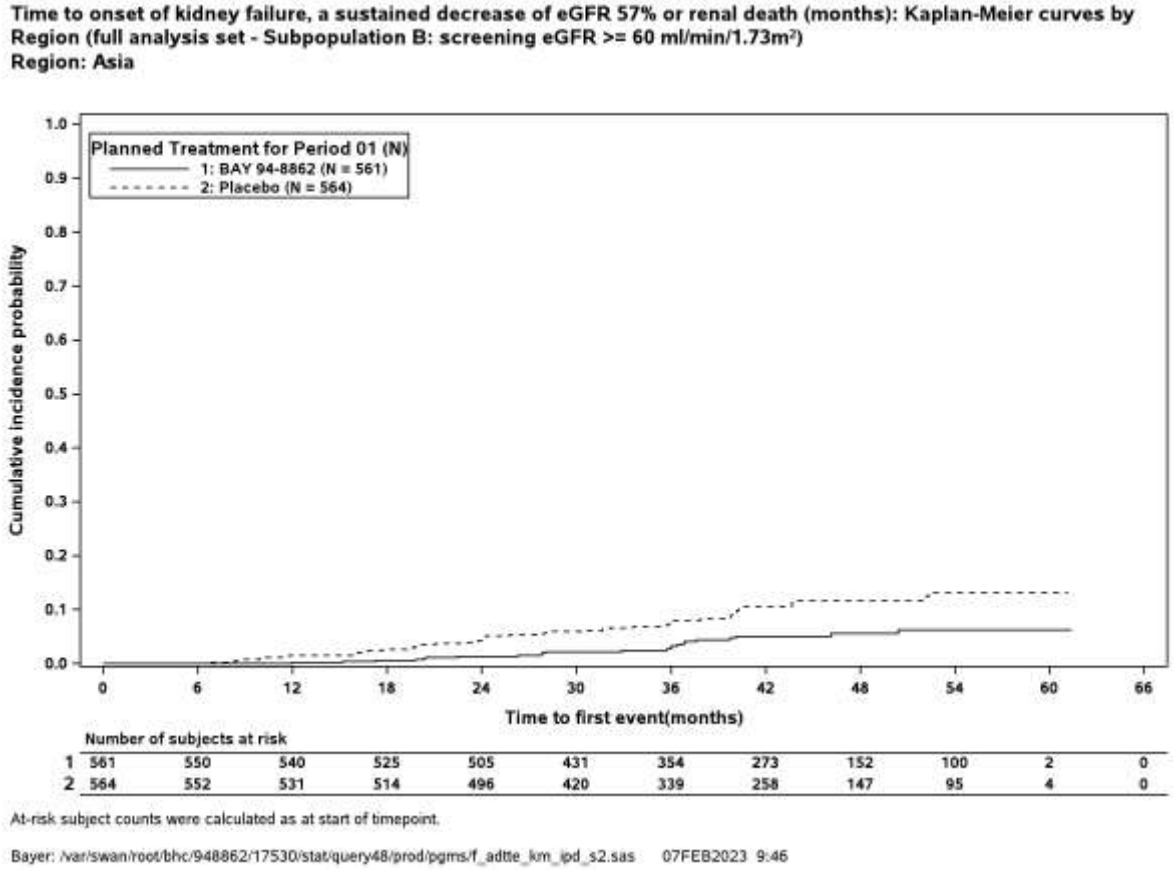


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

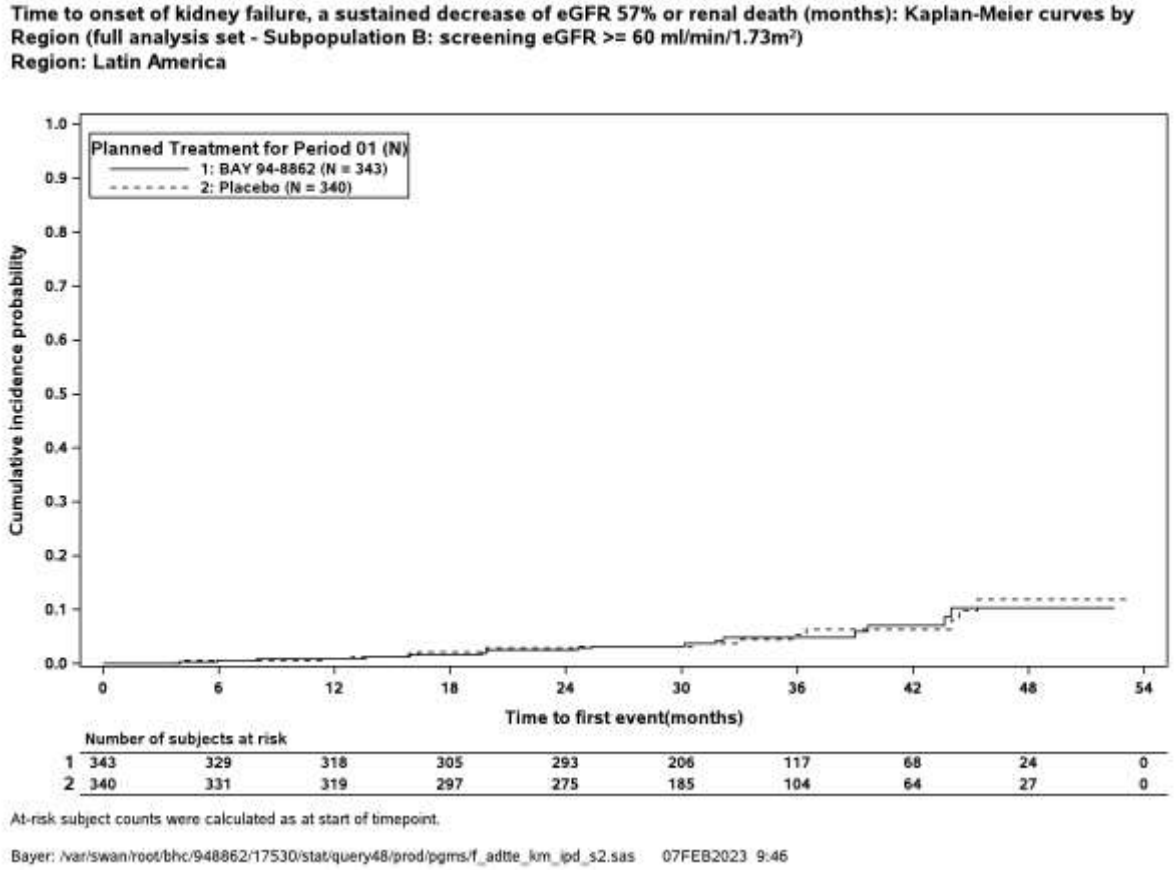


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

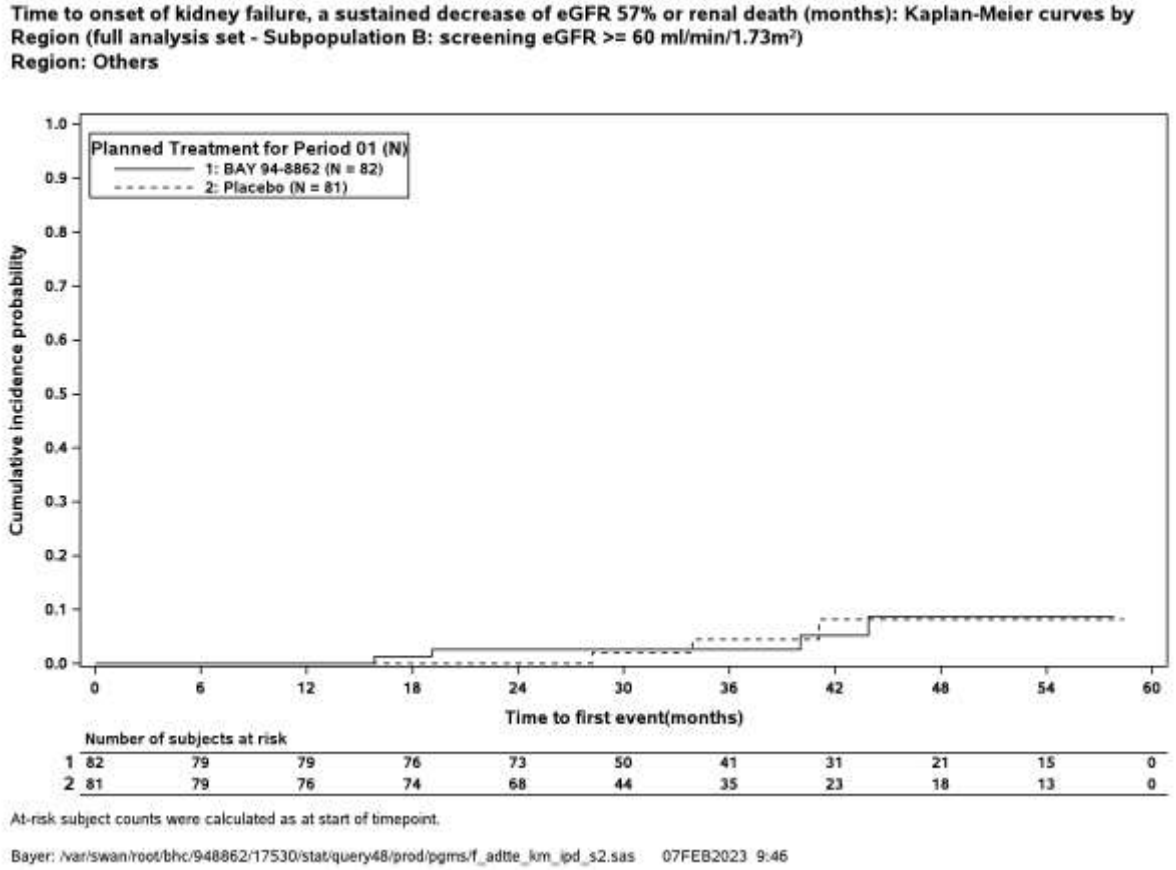


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

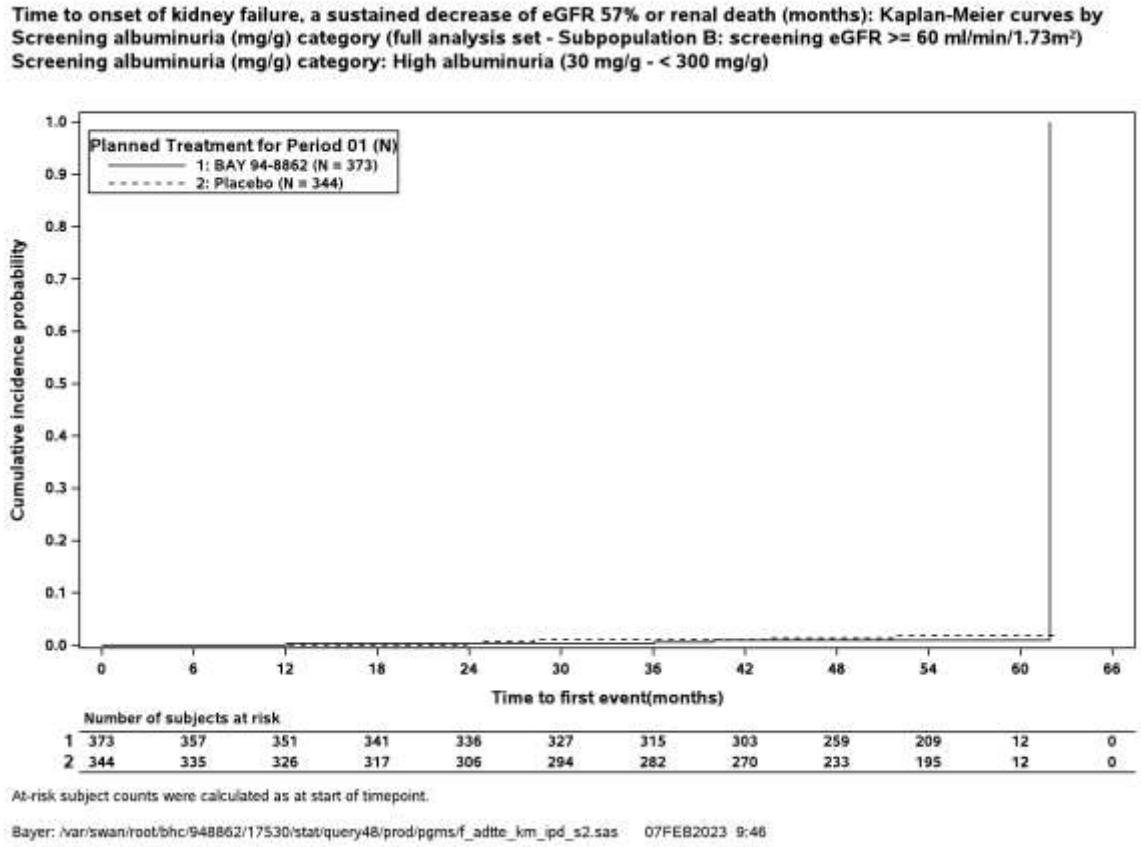


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

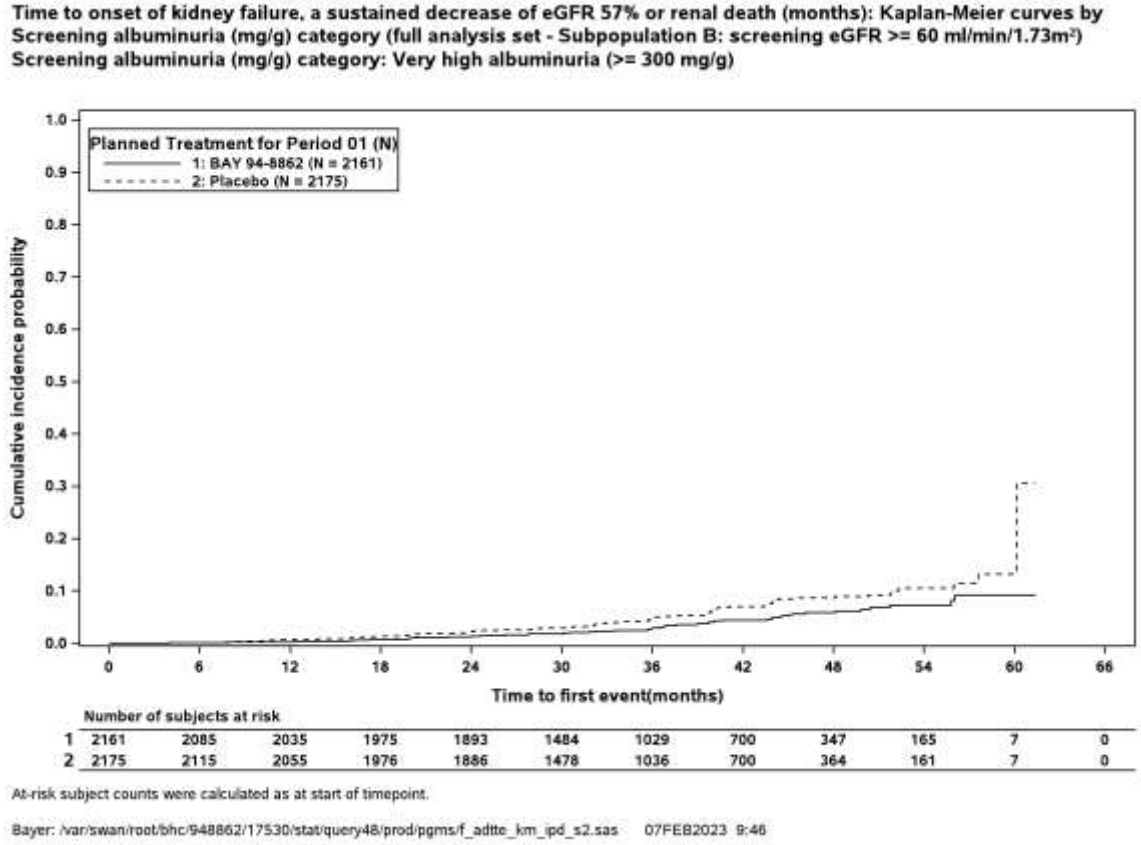


Figure 1.2.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

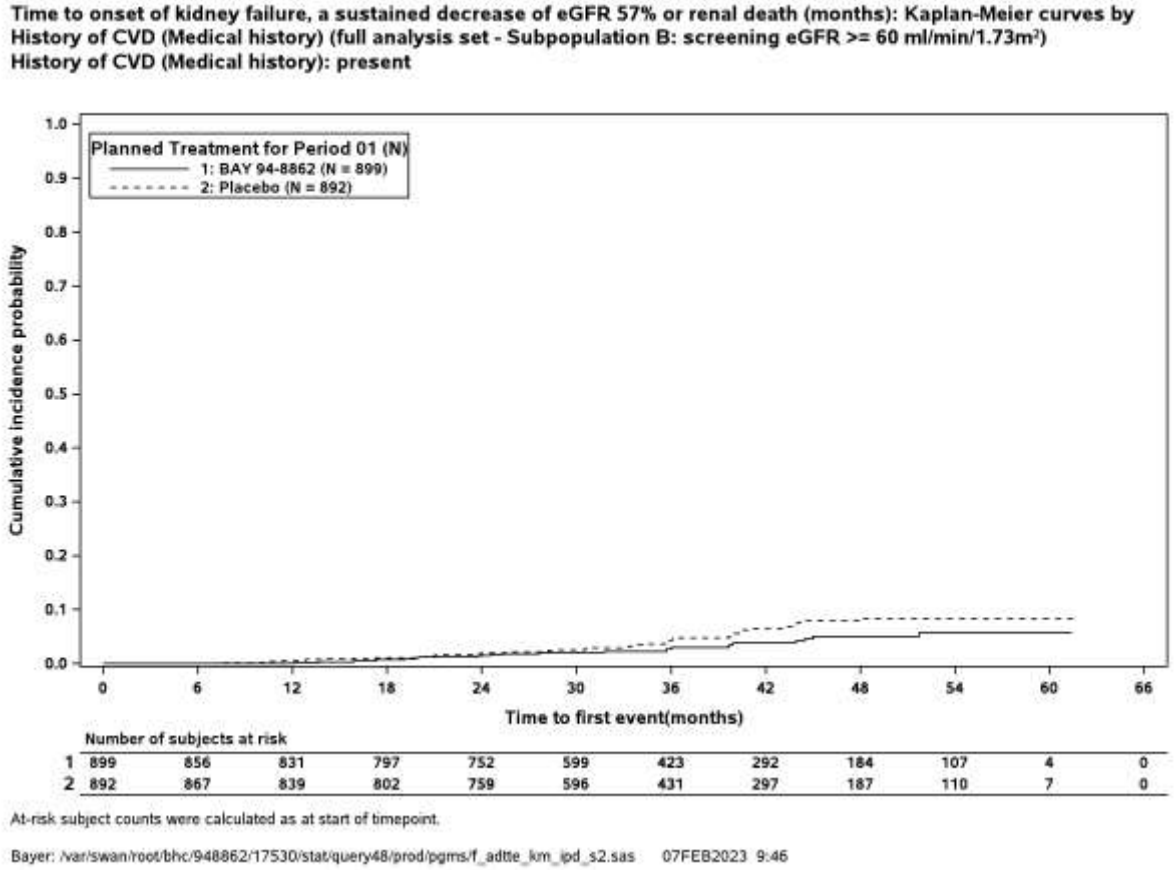


Figure 1.2.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

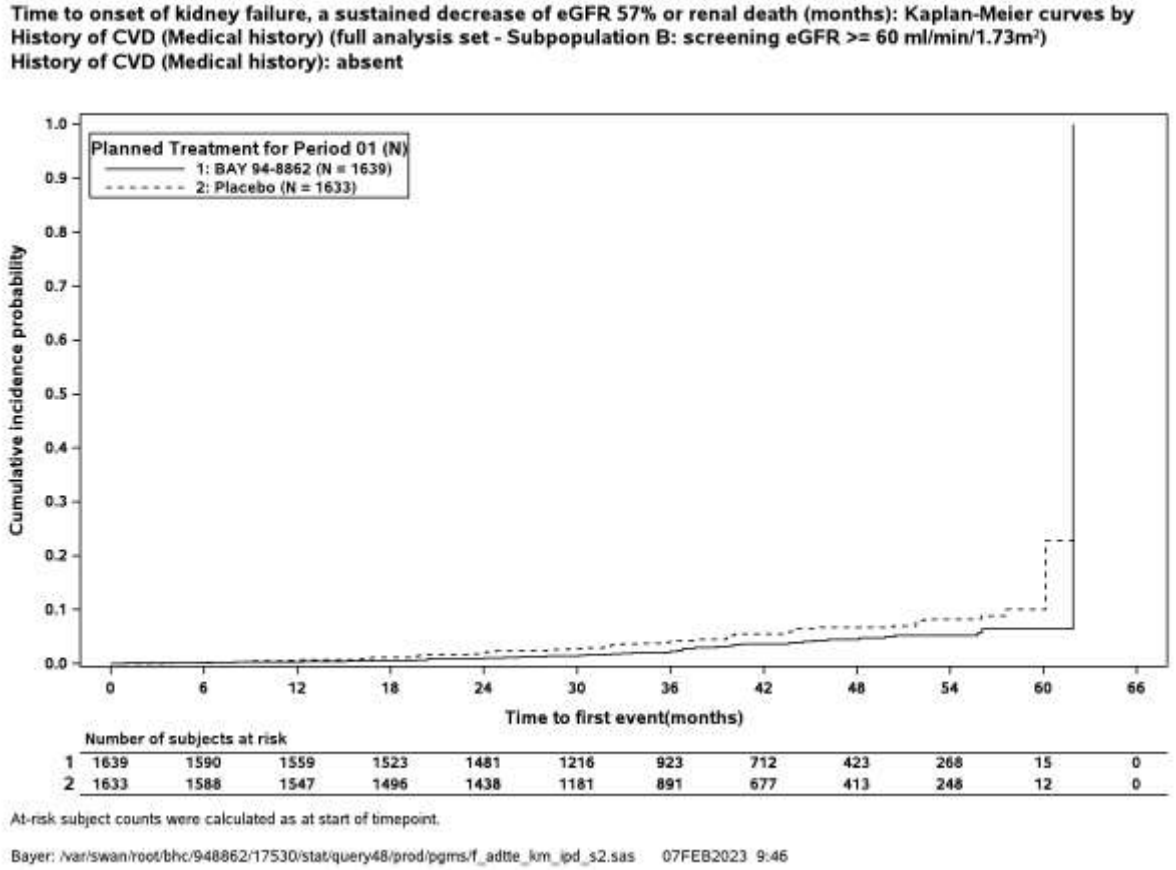


Figure 1.2.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

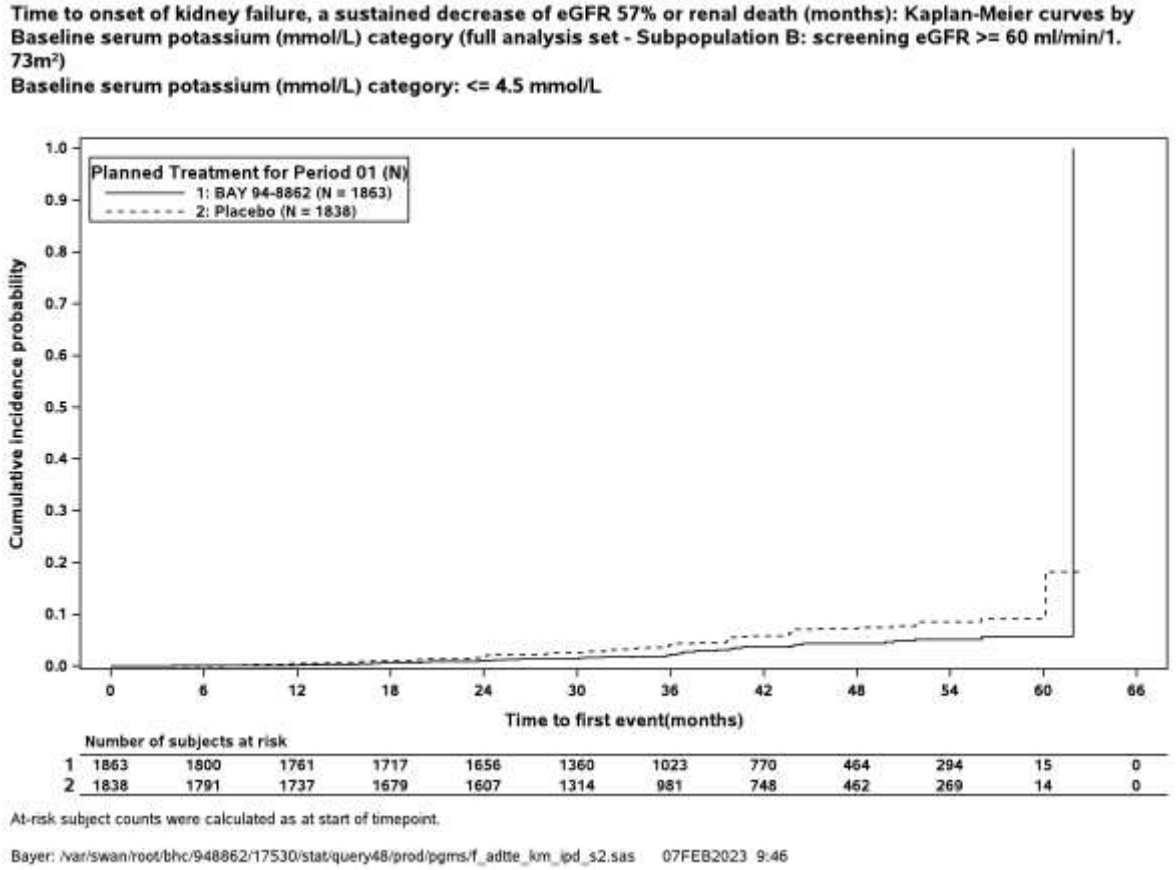


Figure 1.2.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

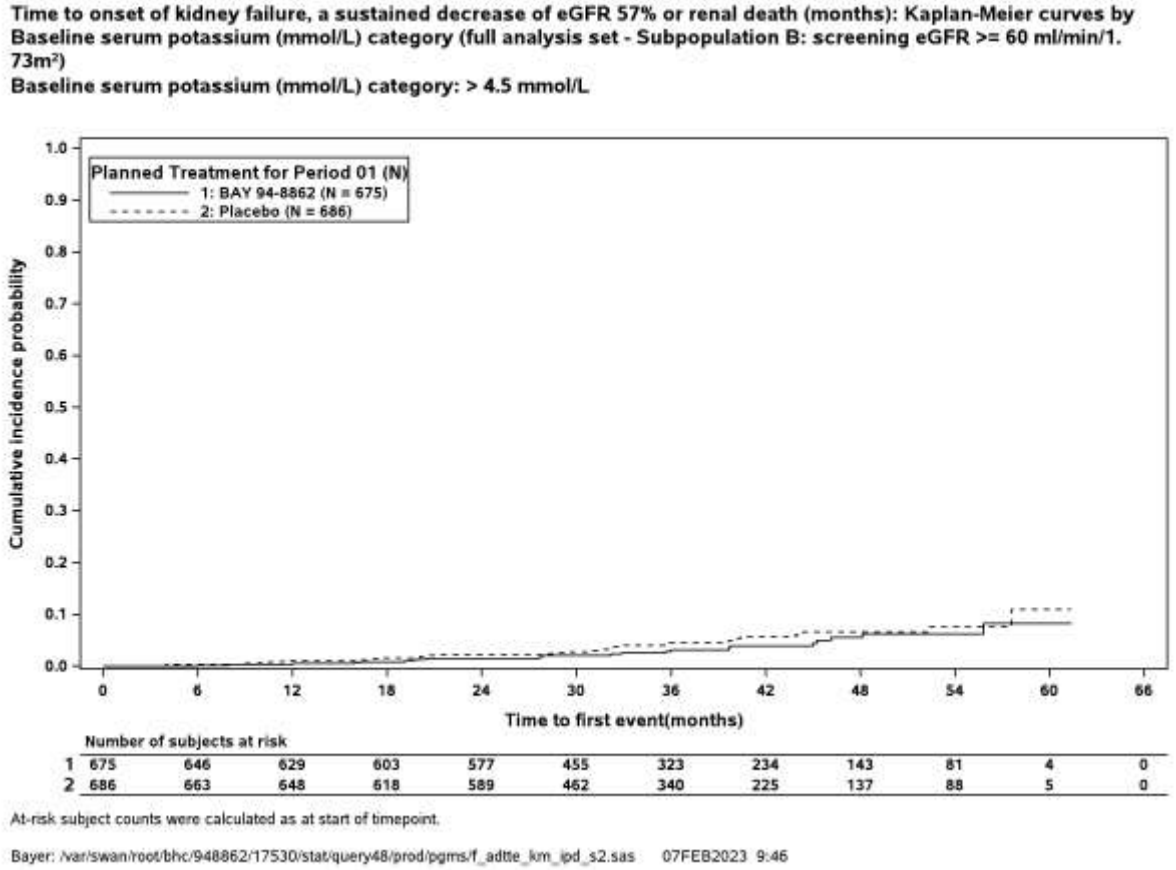


Figure 1.2.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

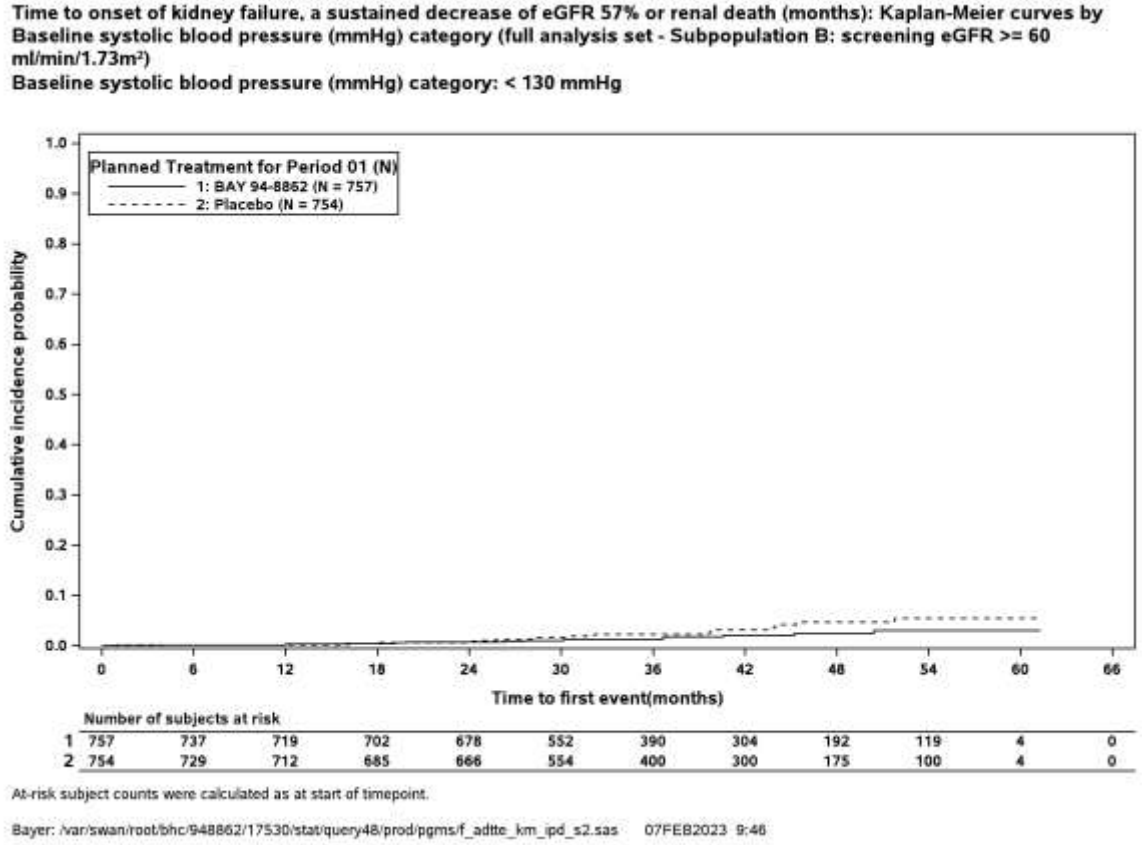


Figure 1.2.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

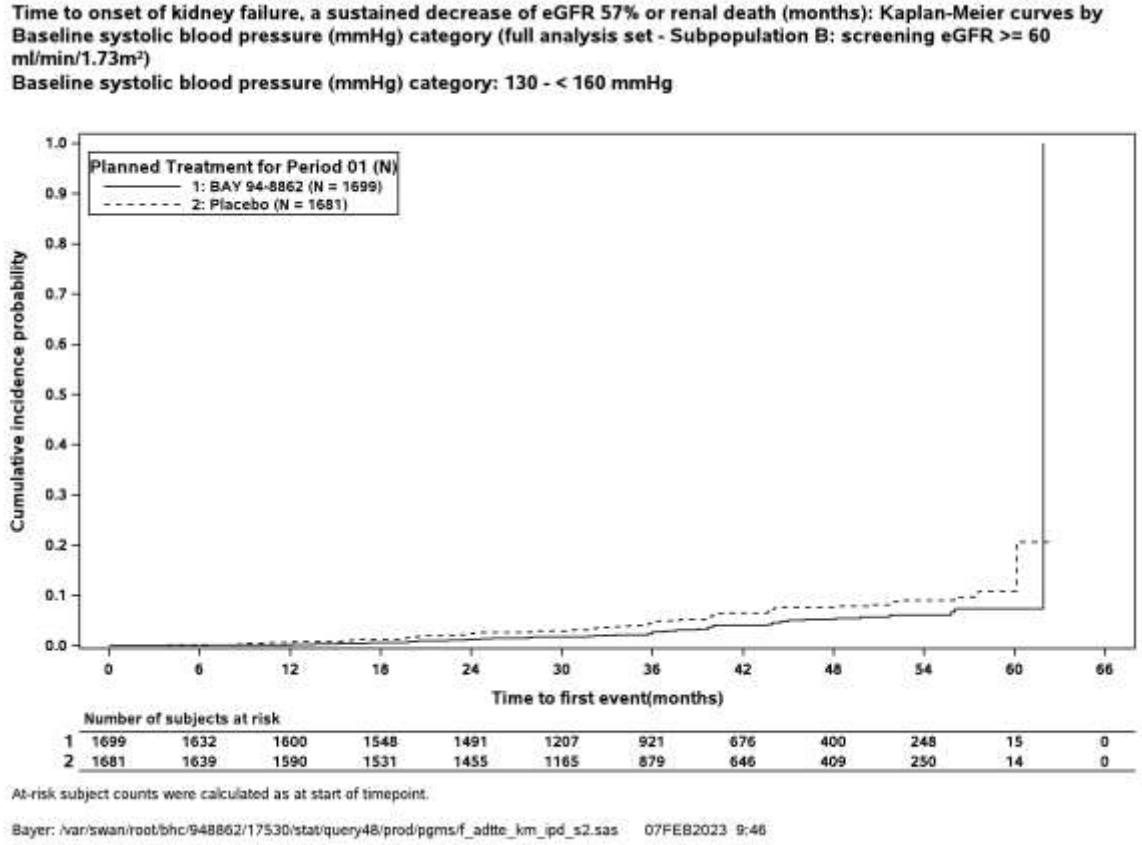
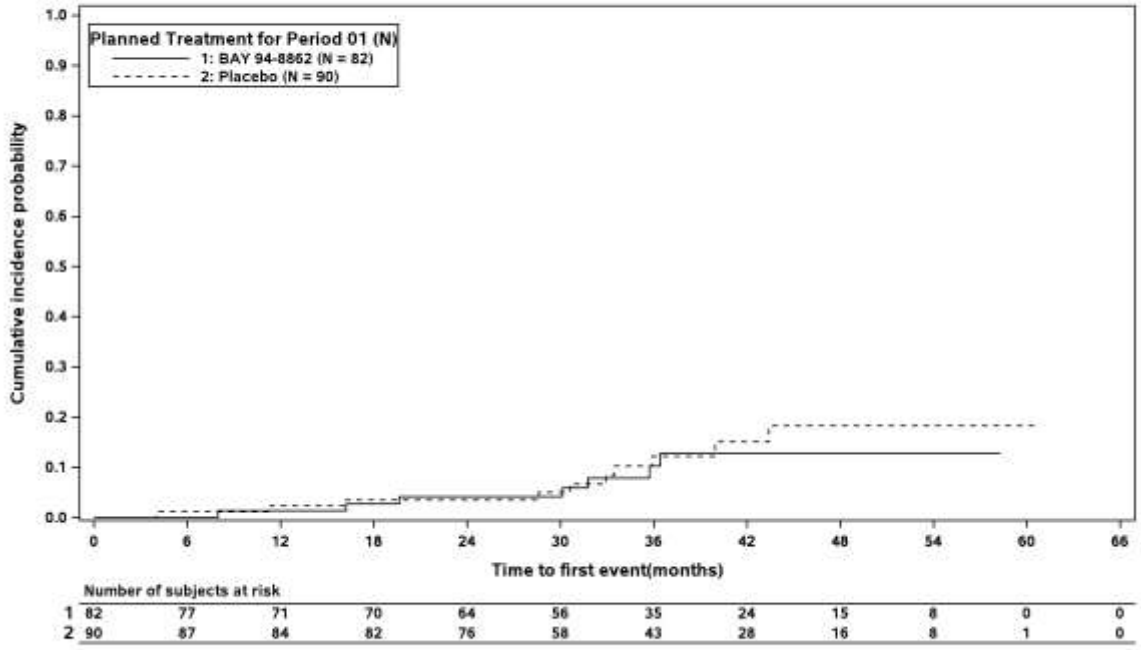


Figure 1.2.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)
Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

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Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

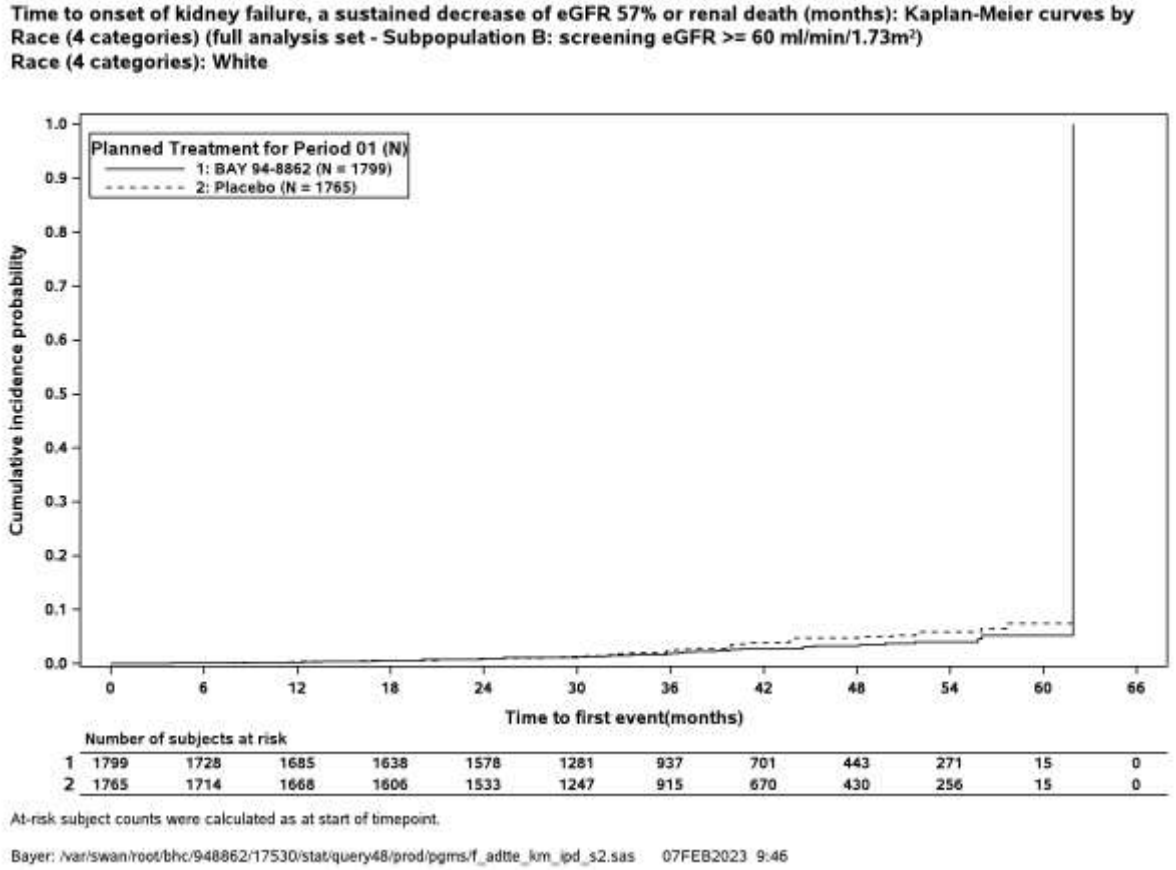


Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

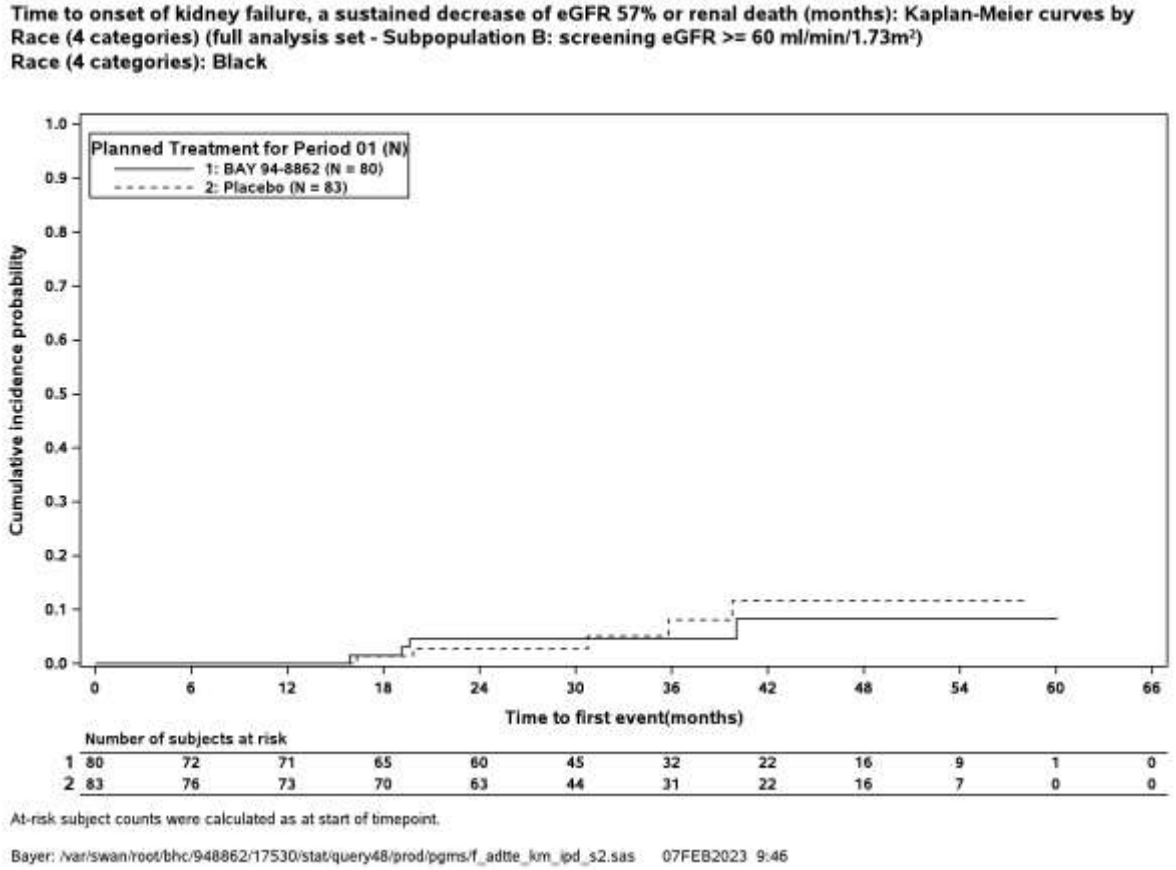


Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

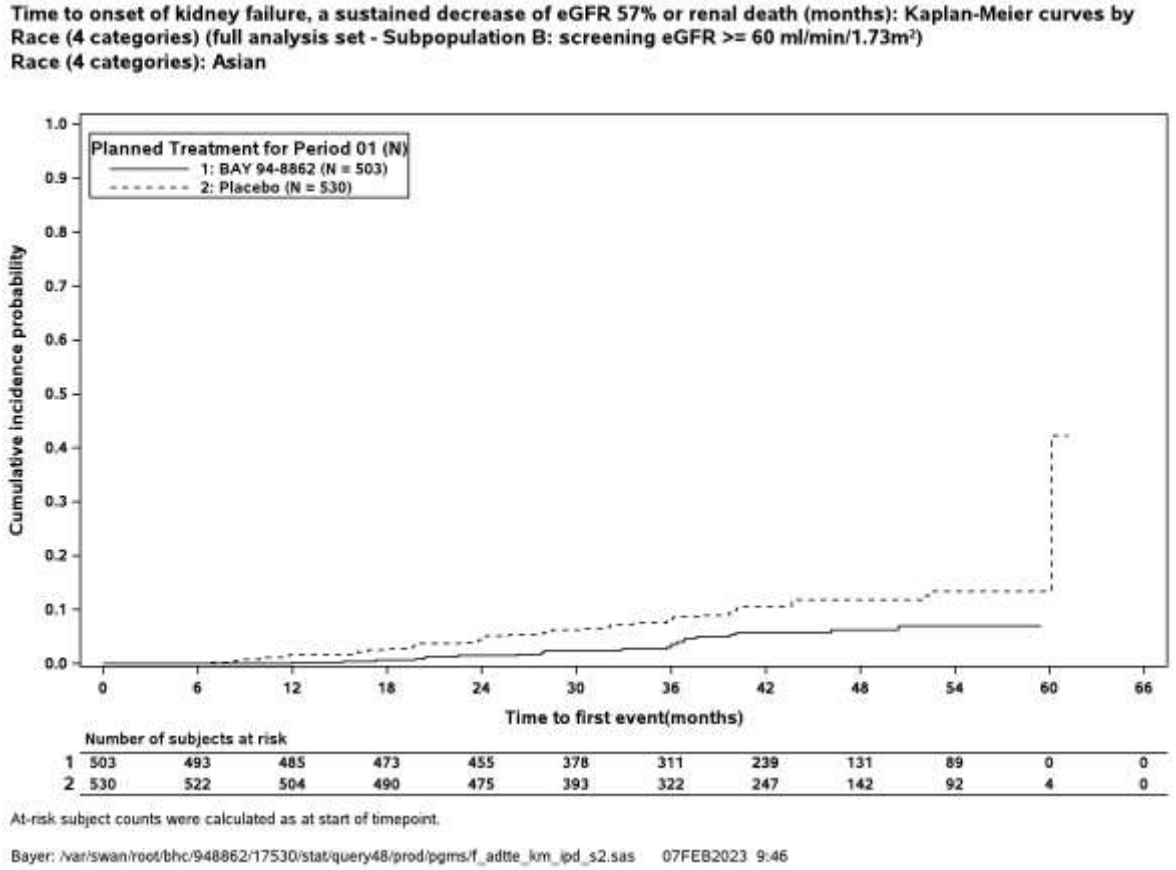


Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

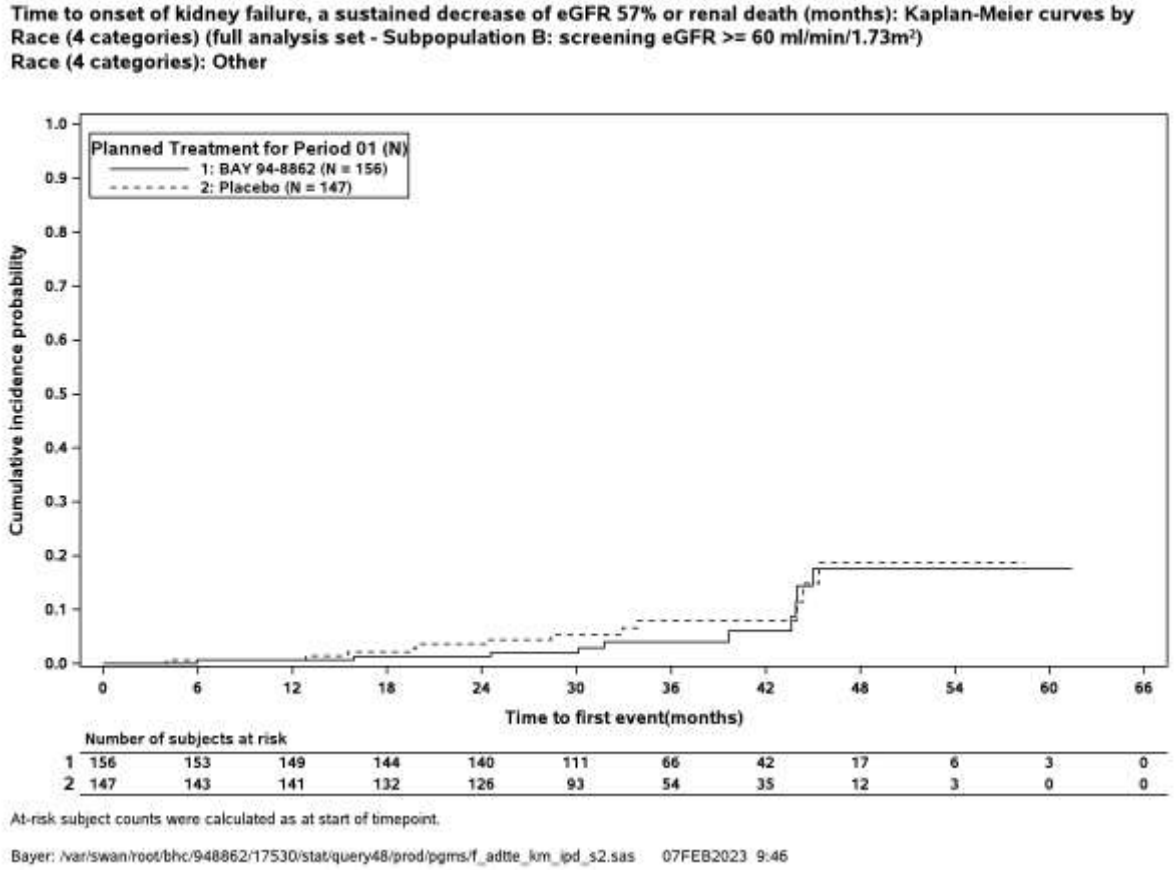


Figure 1.2.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

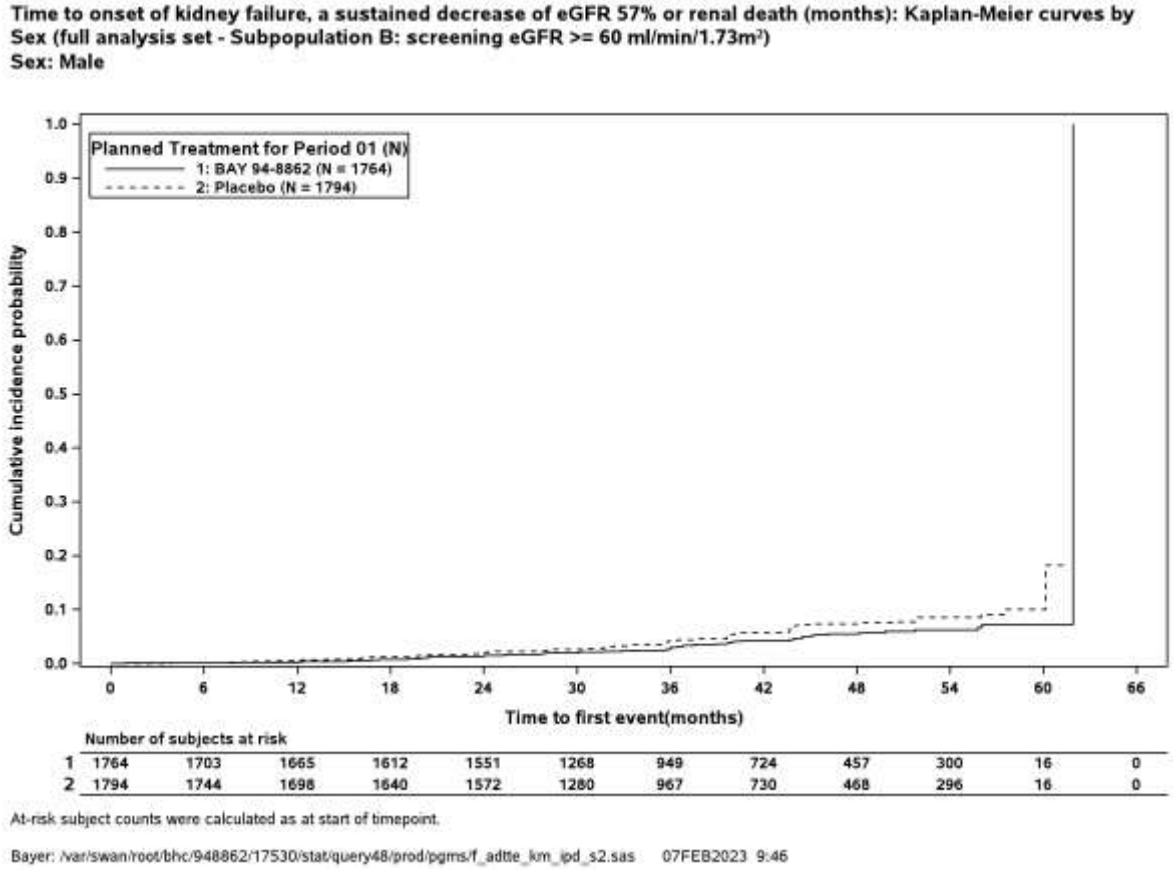


Figure 1.2.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

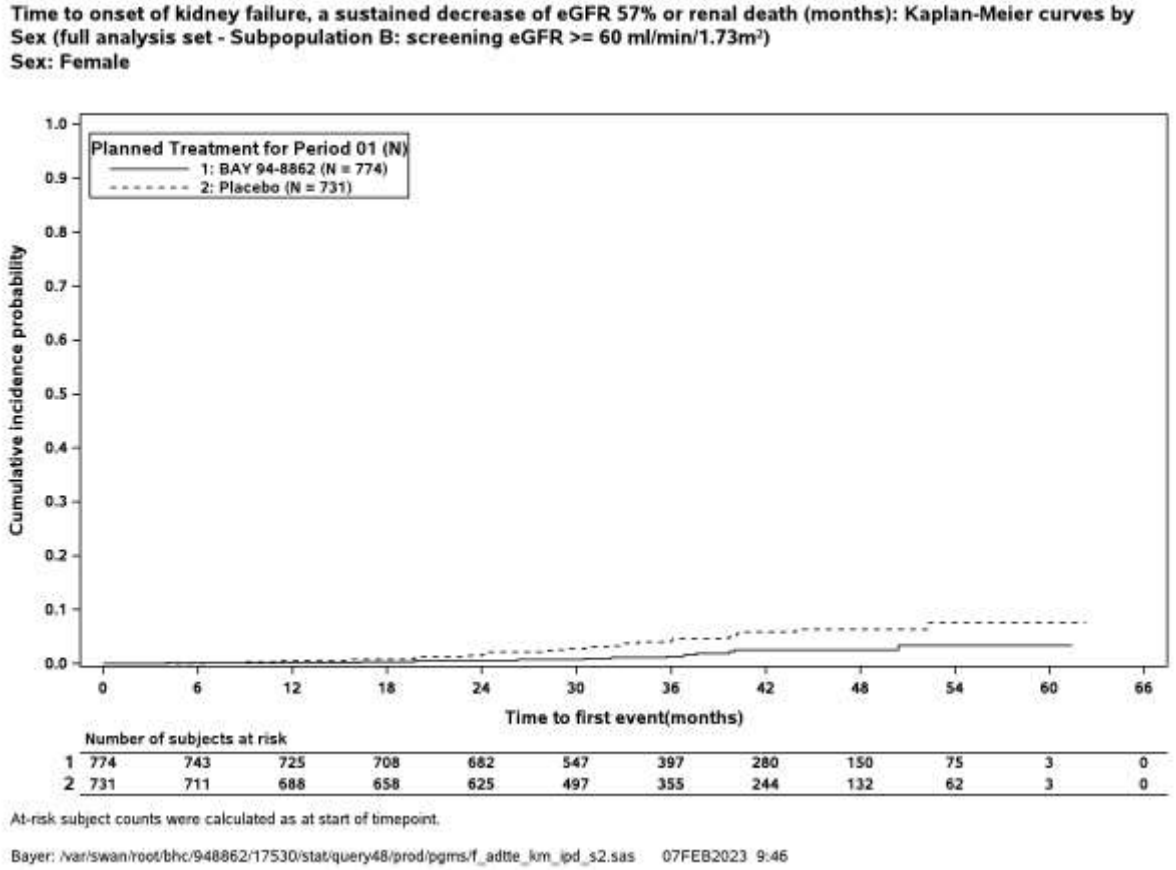


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

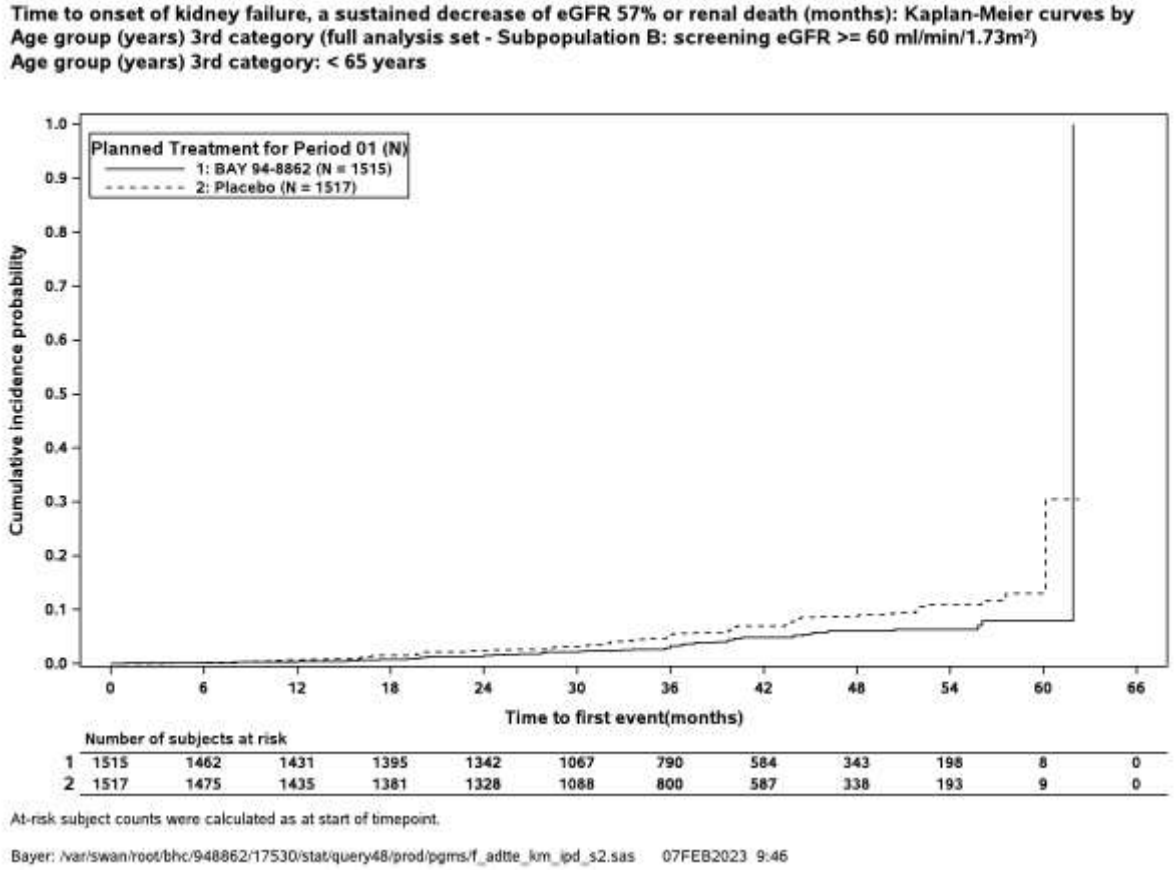
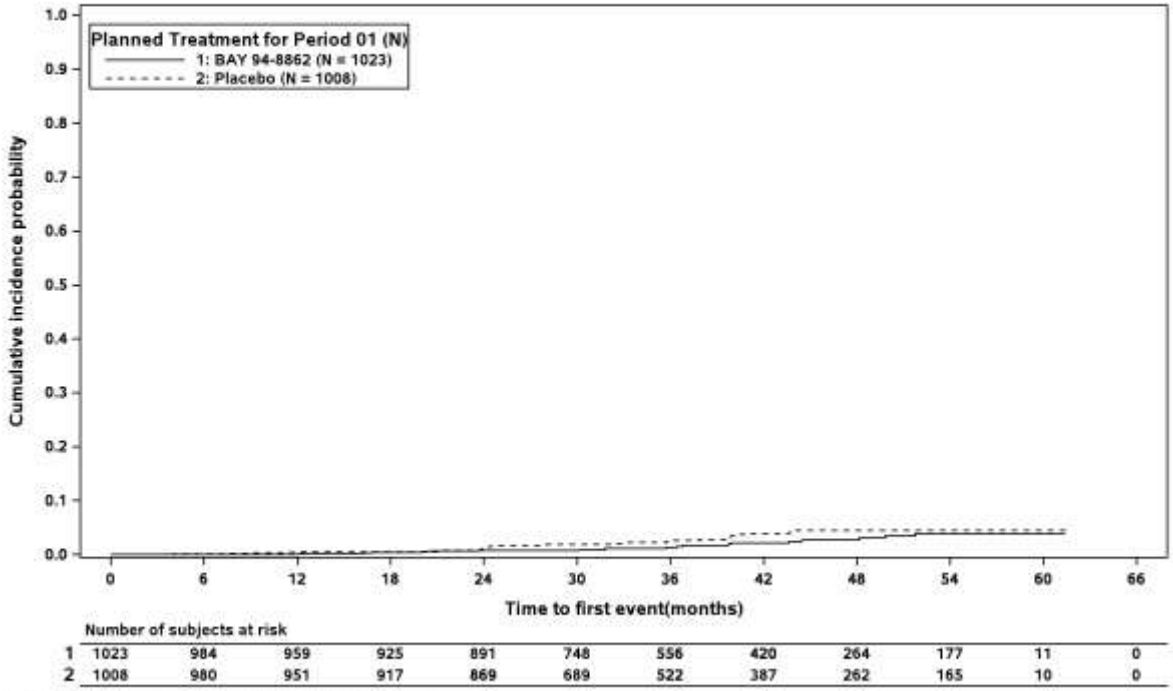


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) Age group (years) 3rd category: >= 65 years



Number of subjects at risk

1	1023	984	959	925	891	748	556	420	264	177	11	0
2	1008	980	951	917	869	689	522	387	262	165	10	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 20: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

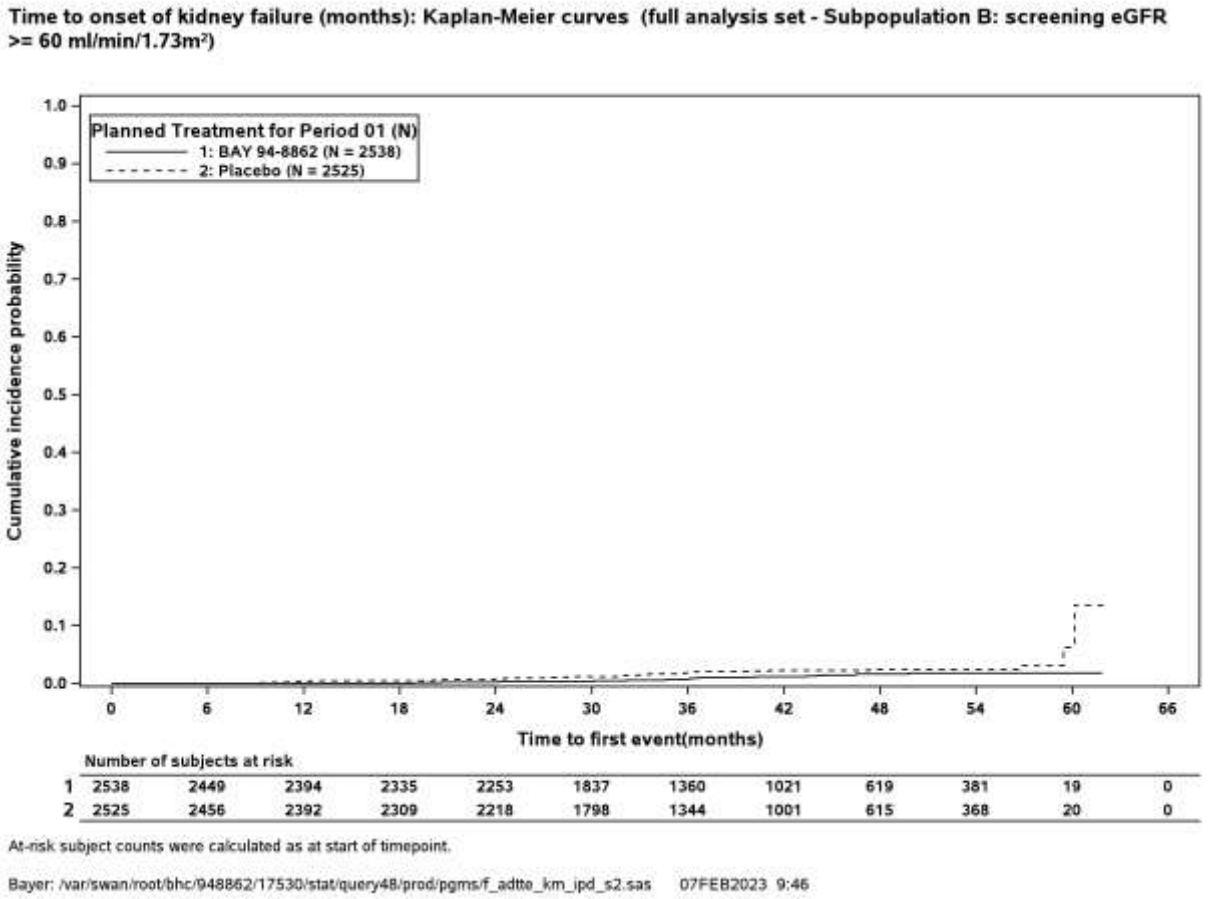


Figure 1.2.1 / 21: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

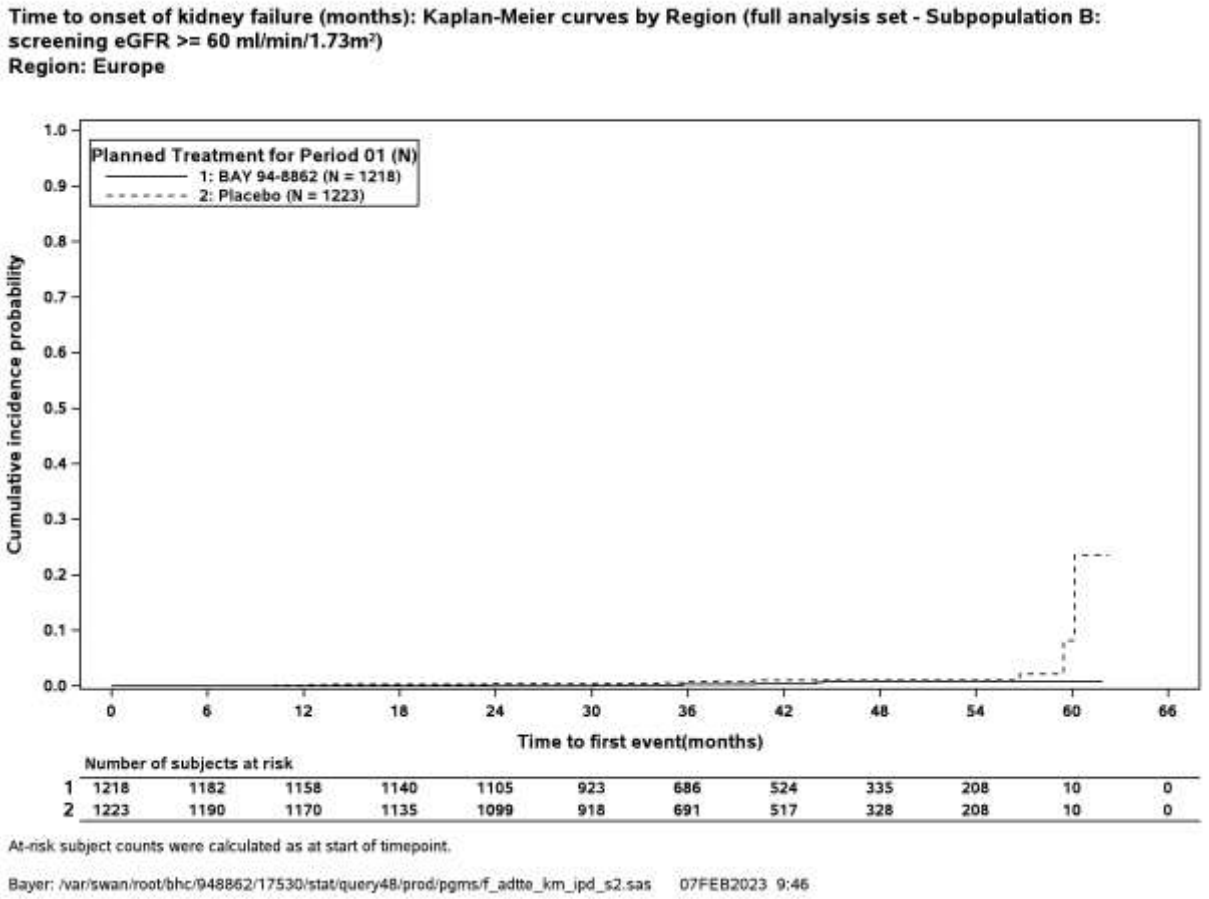


Figure 1.2.1 / 21: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

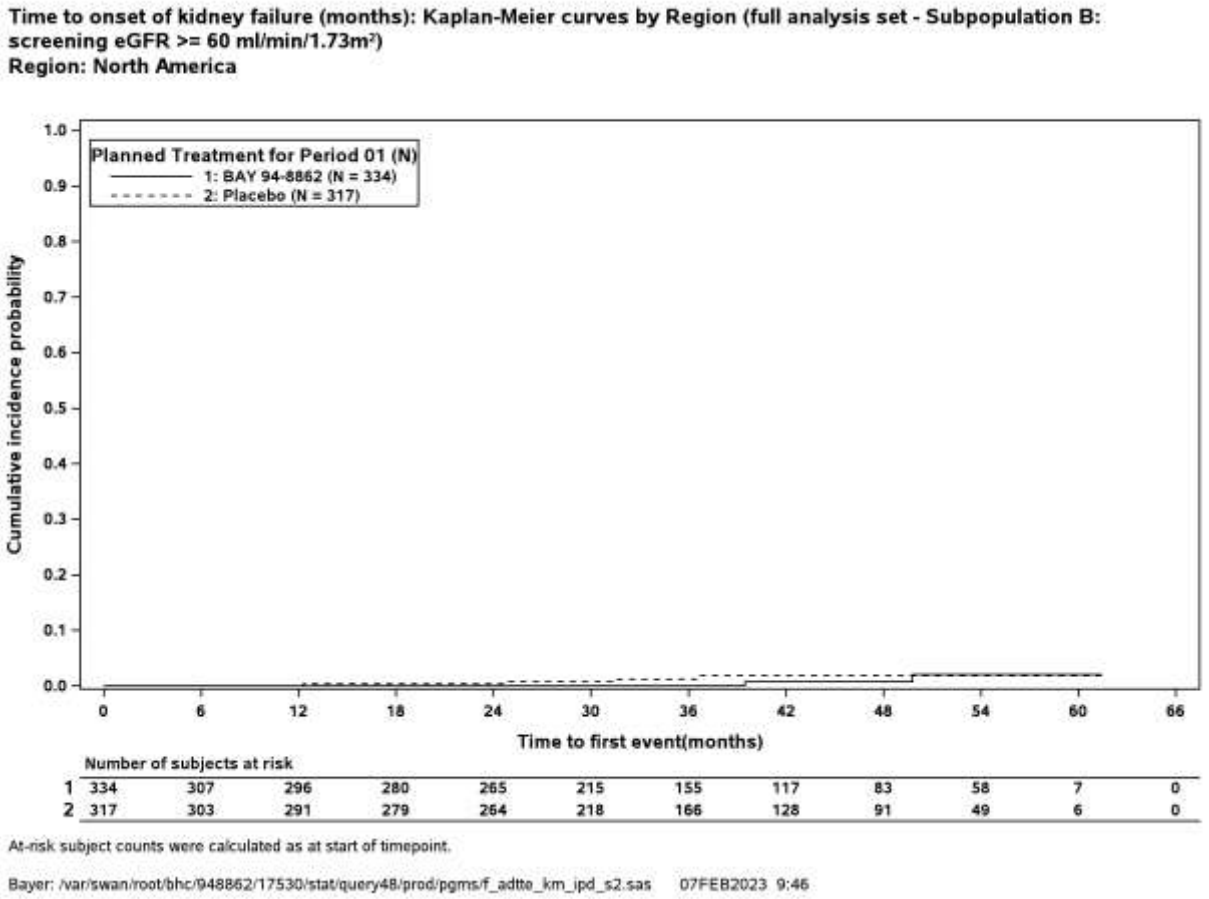


Figure 1.2.1 / 21: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

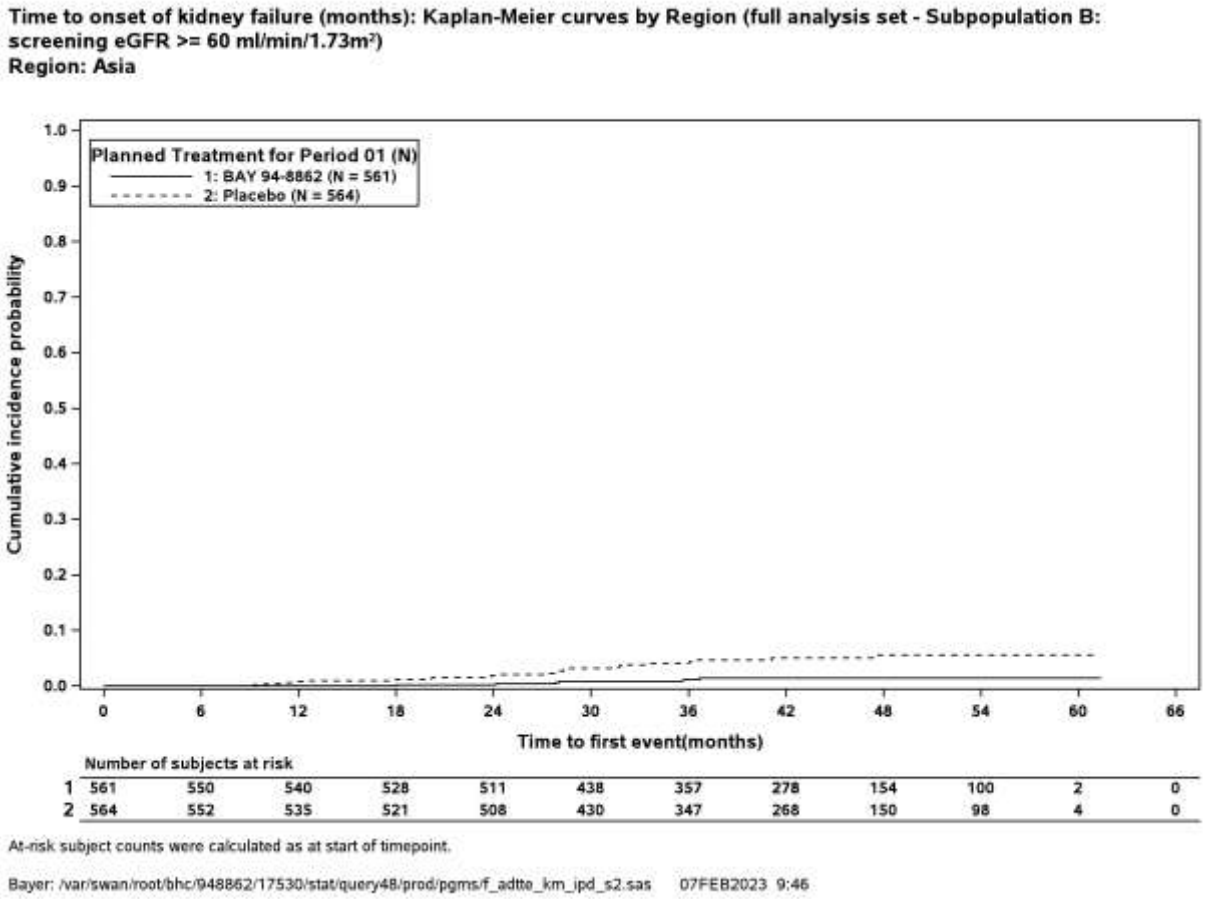


Figure 1.2.1 / 21: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

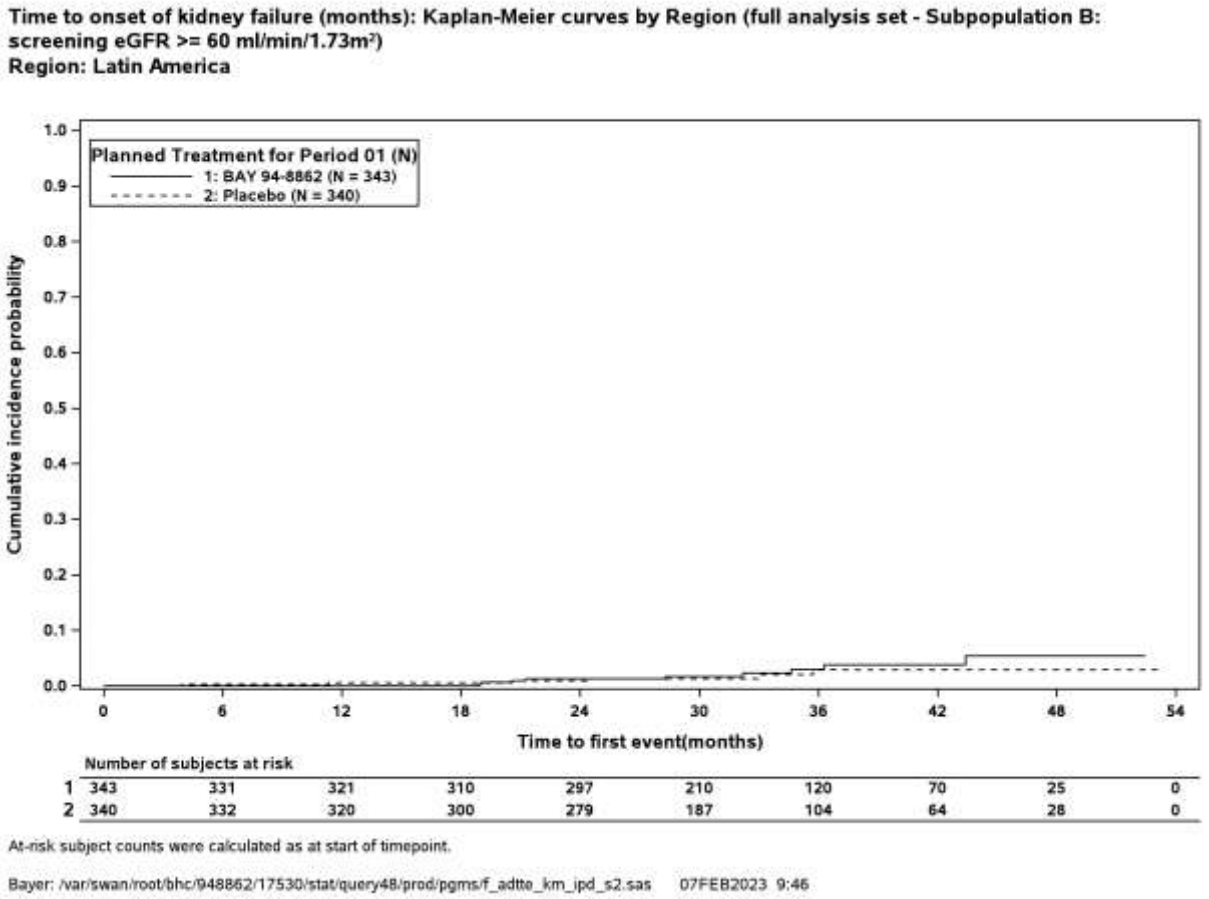


Figure 1.2.1 / 21: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

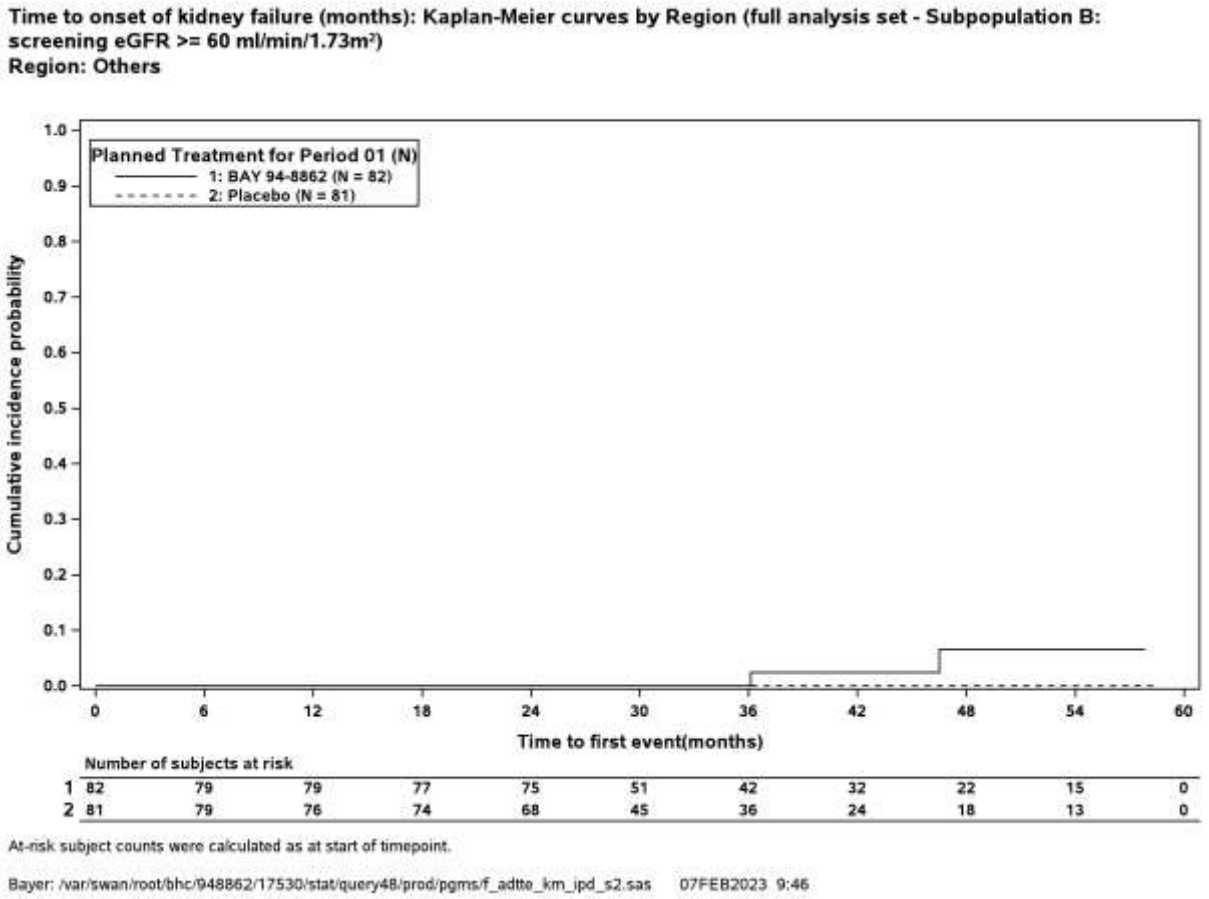


Figure 1.2.1 / 22: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

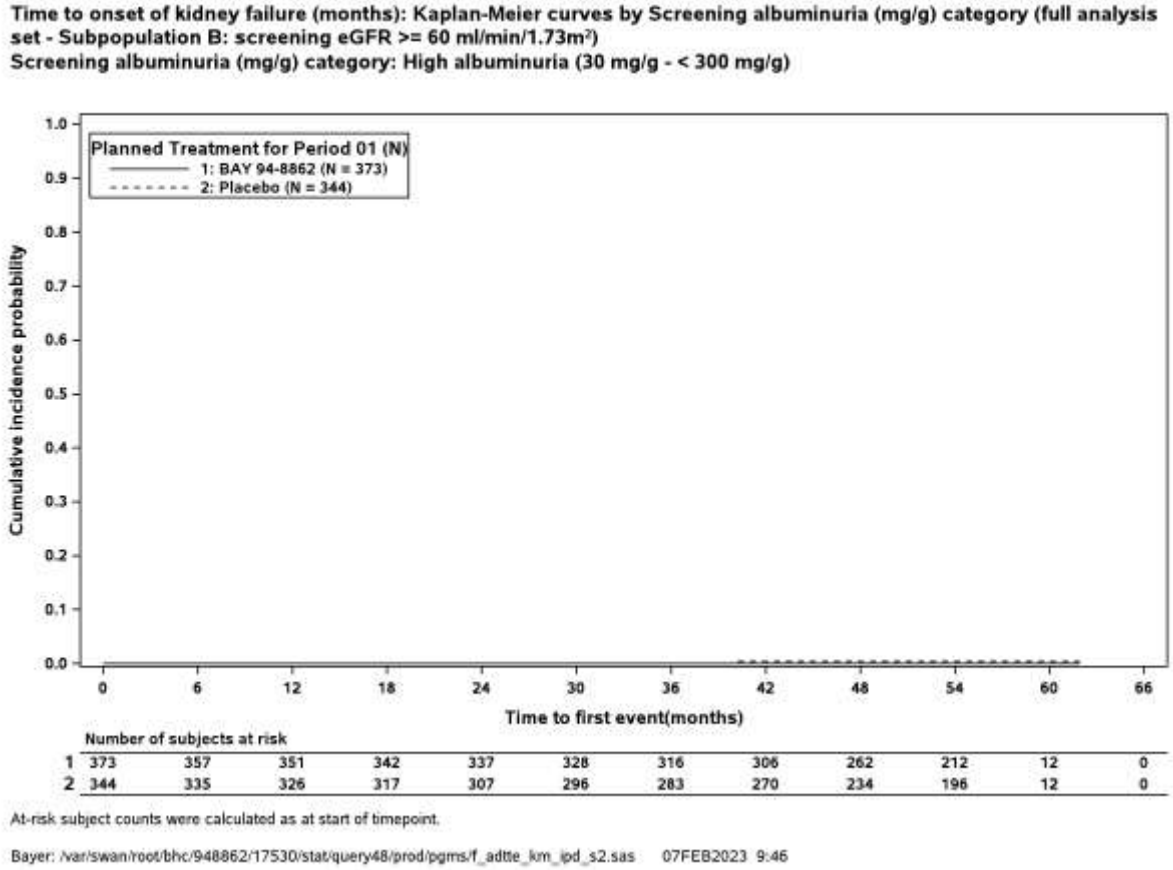


Figure 1.2.1 / 22: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

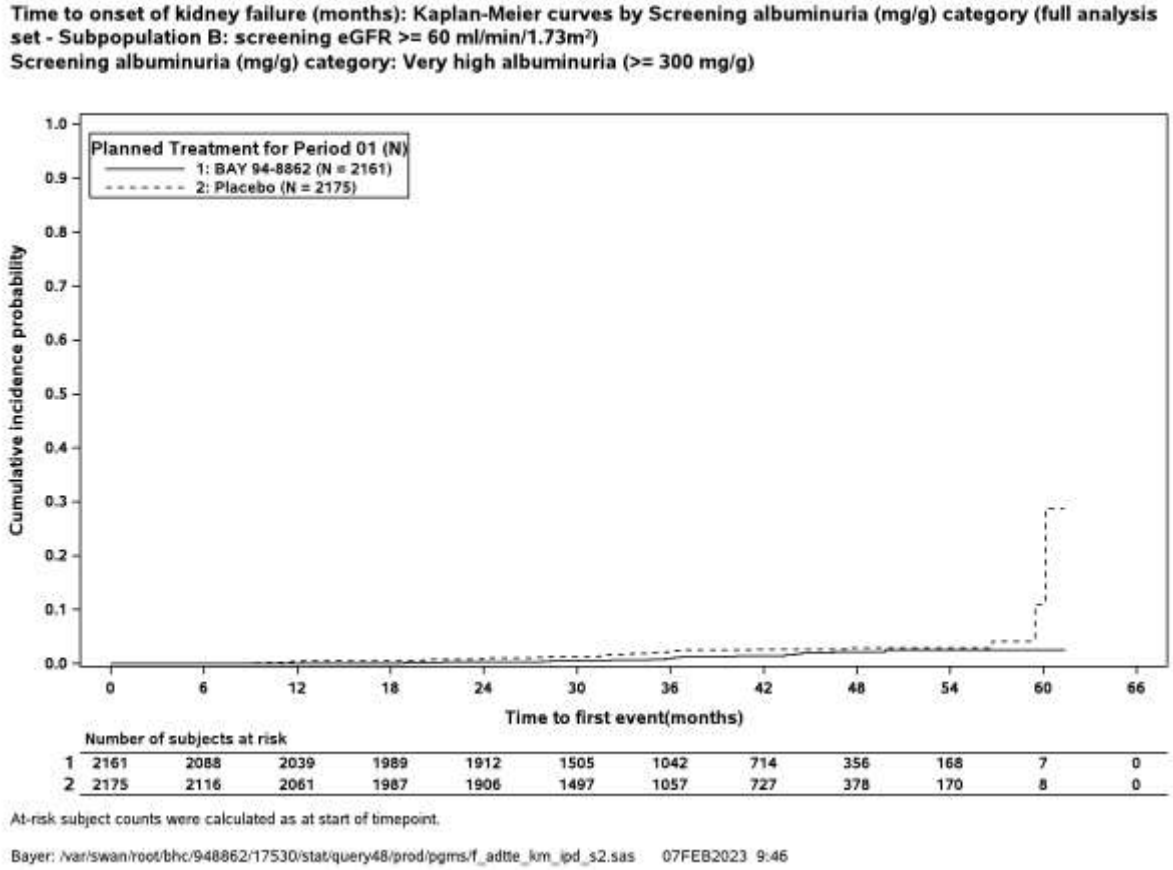


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

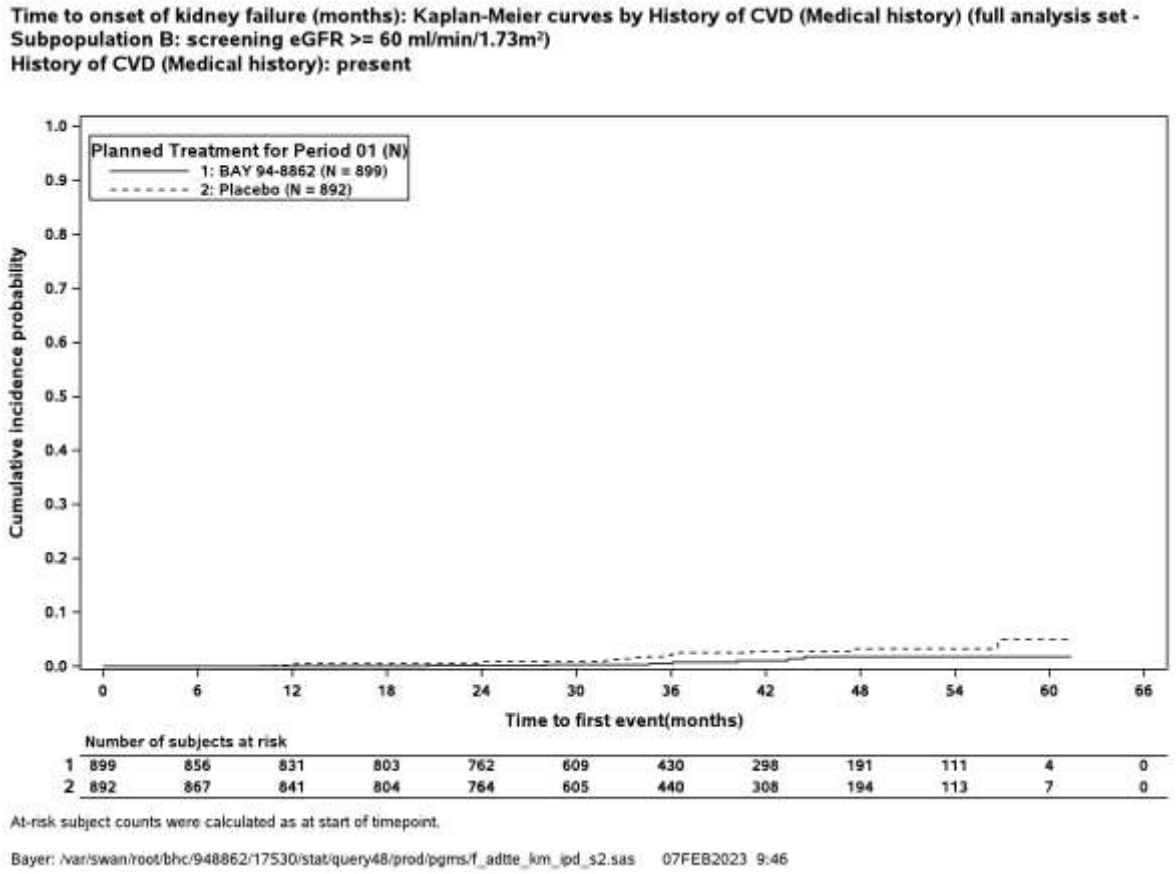


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

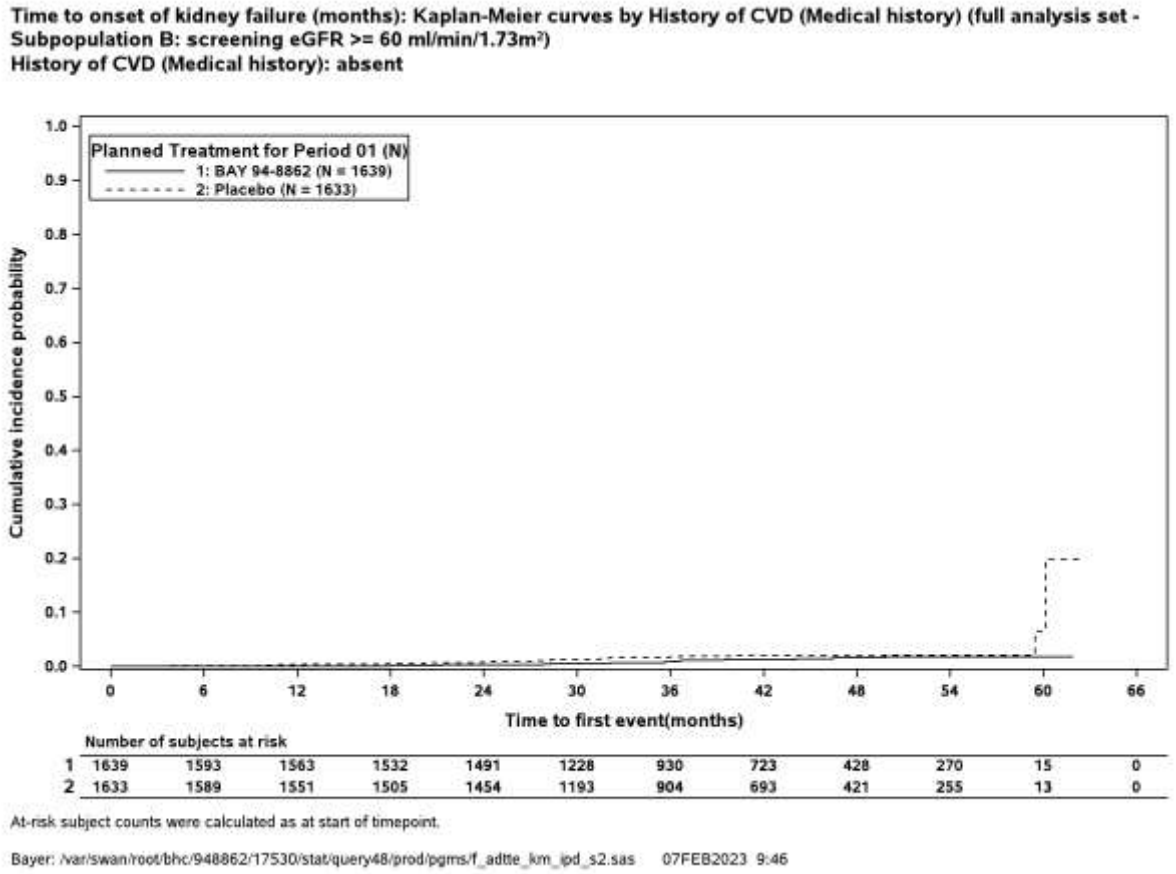


Figure 1.2.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

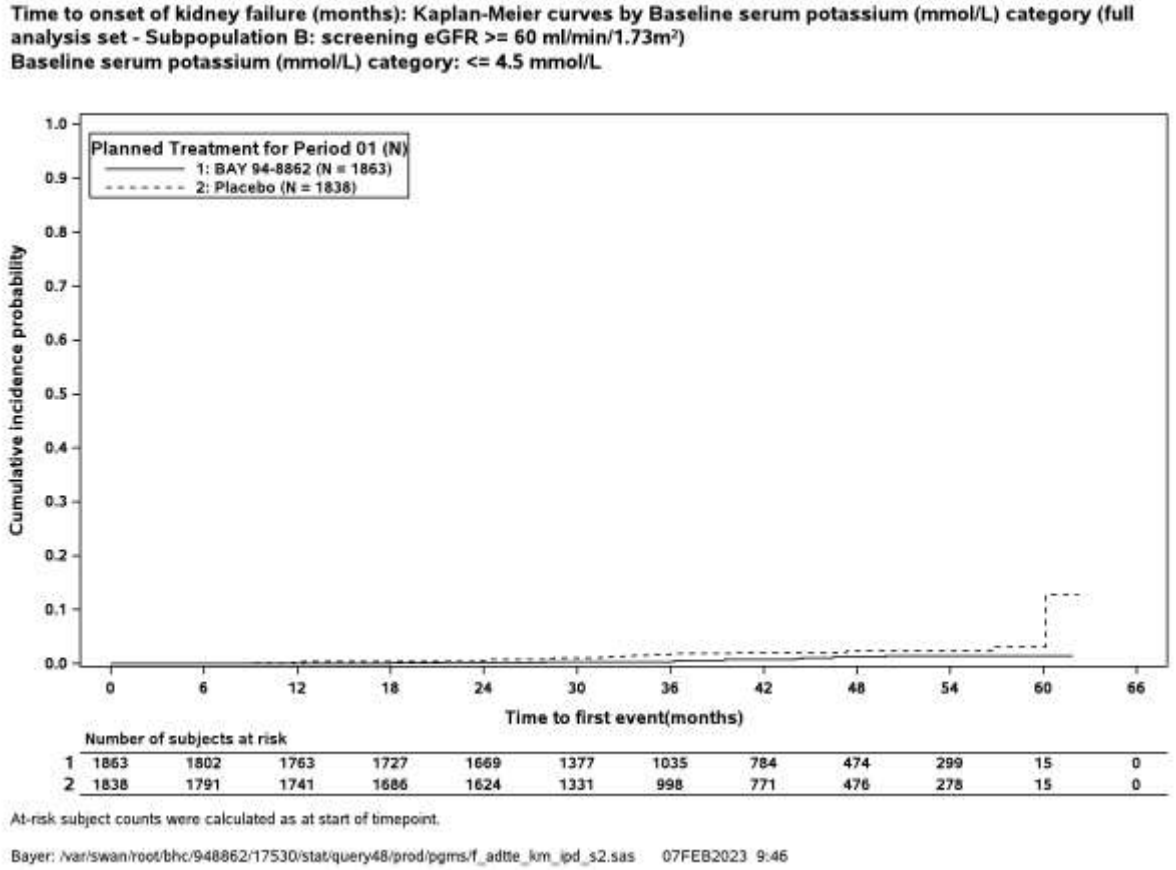


Figure 1.2.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

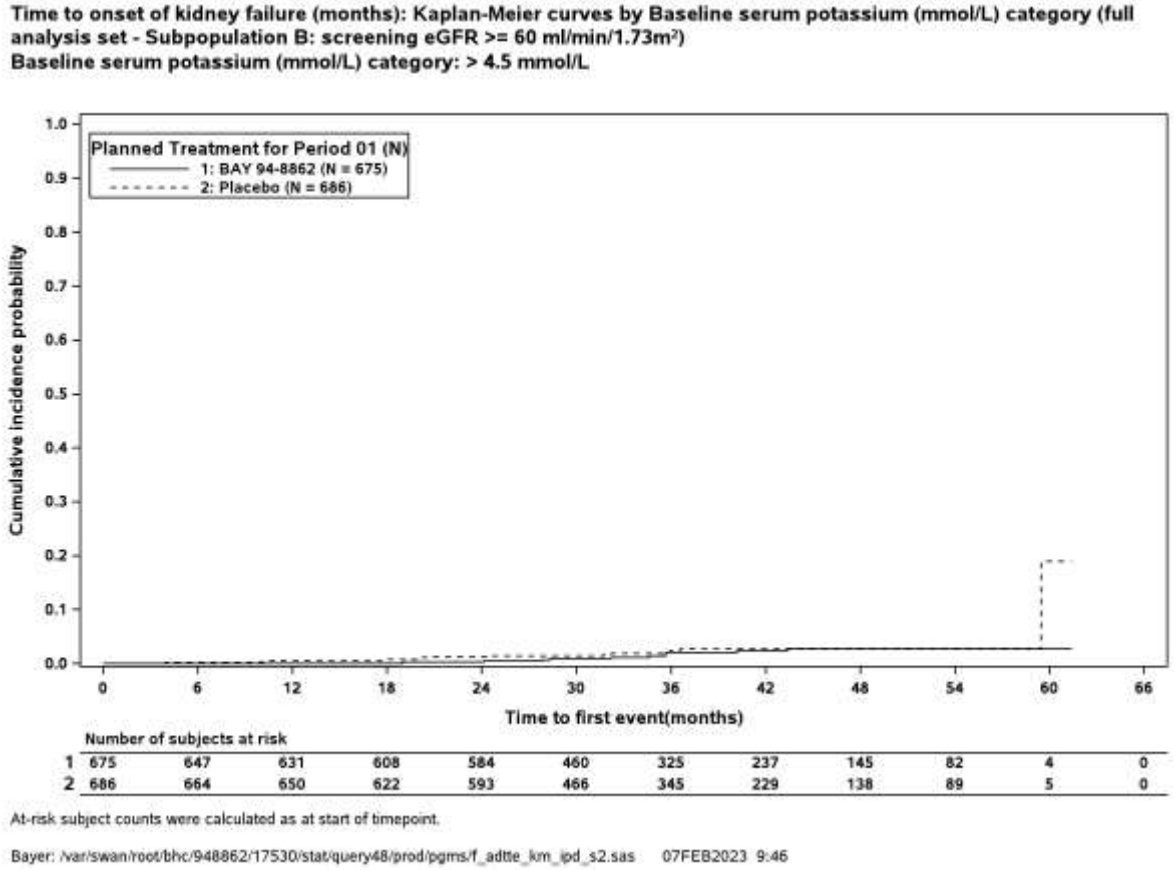


Figure 1.2.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

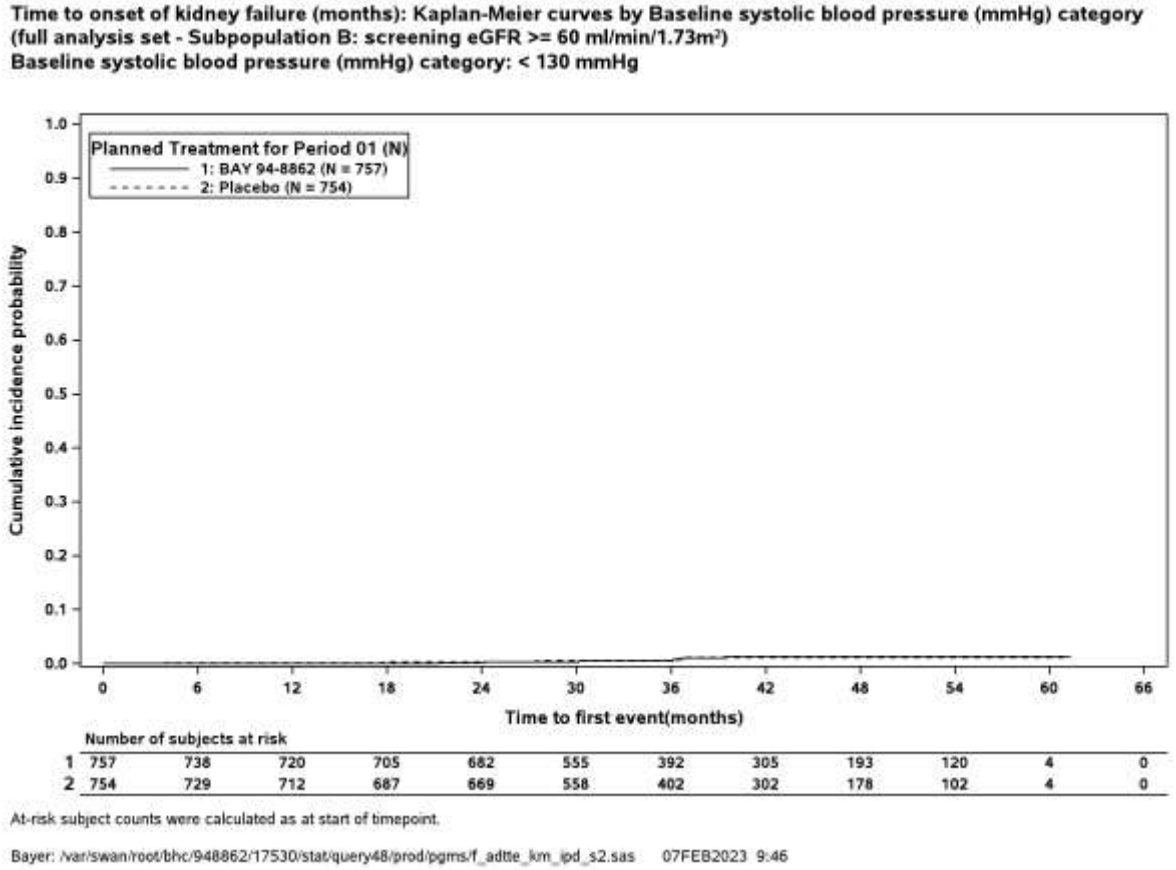


Figure 1.2.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

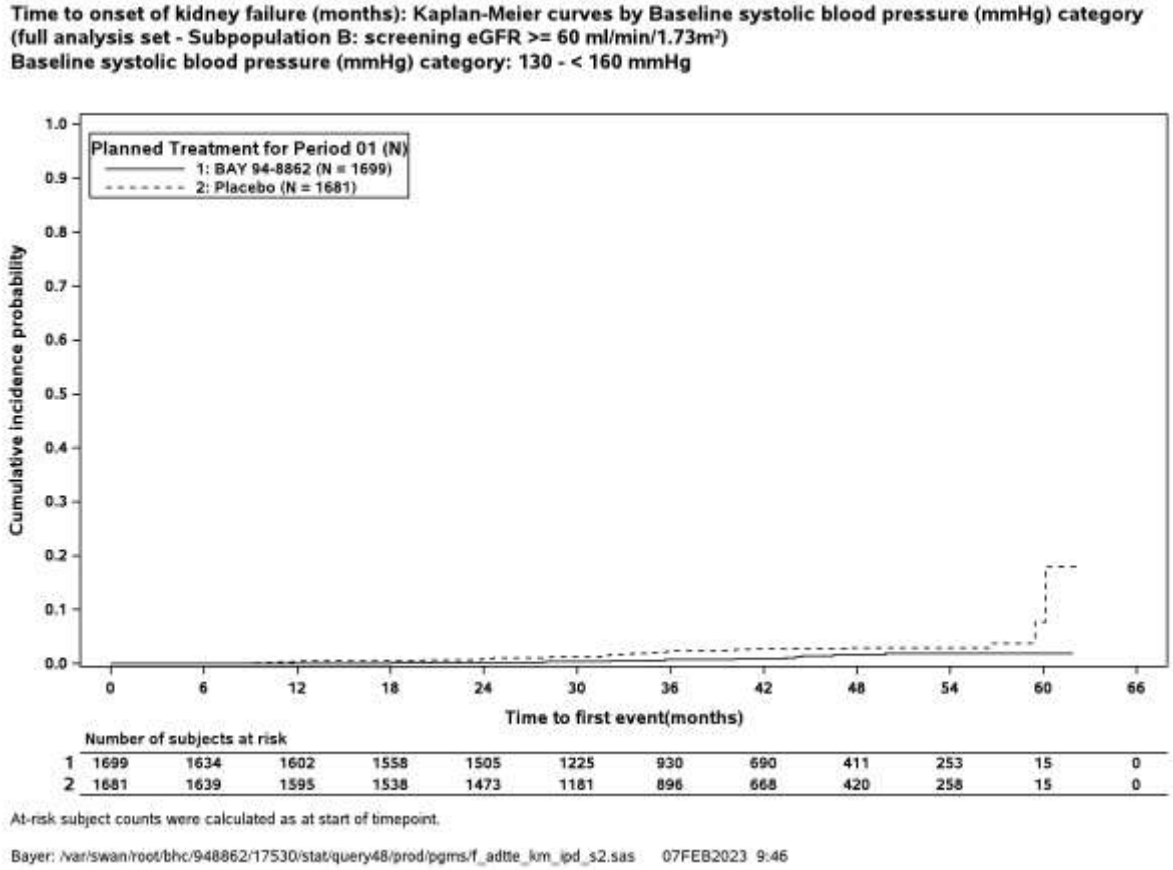


Figure 1.2.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

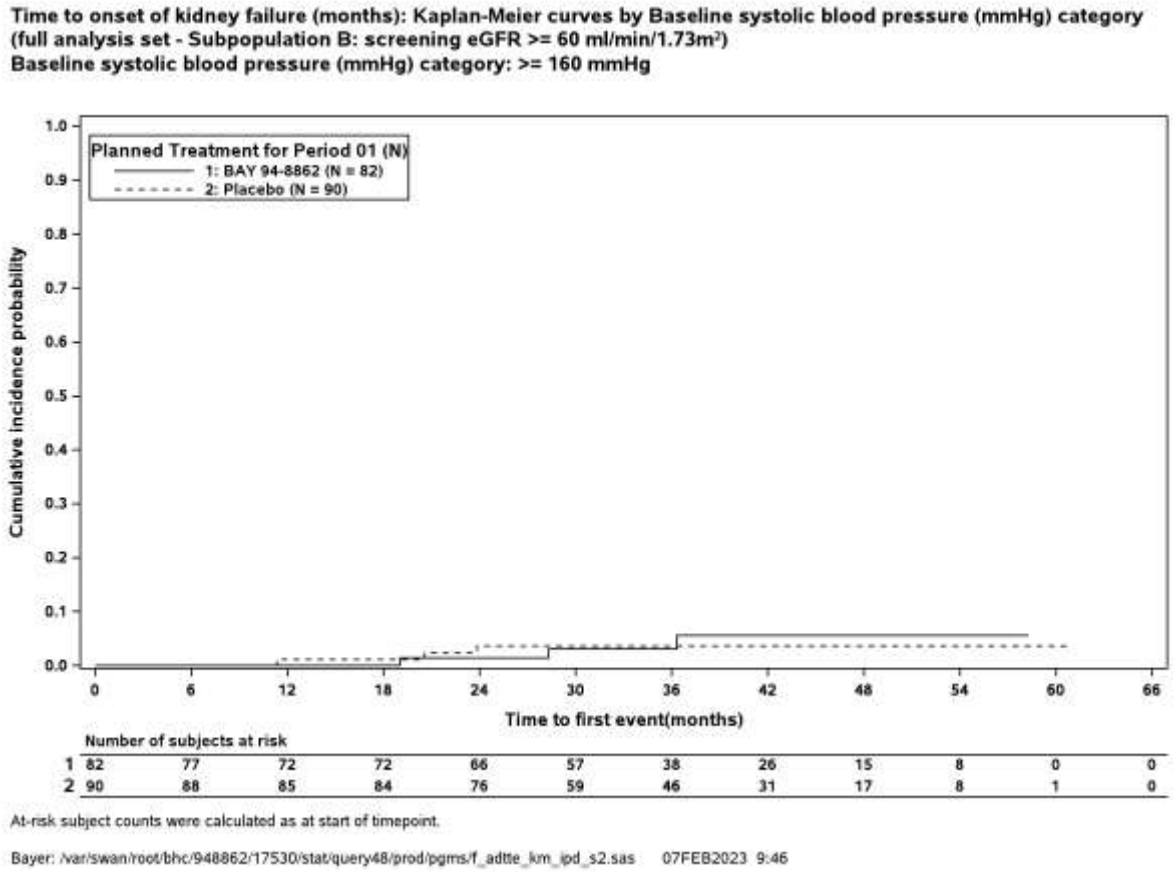


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

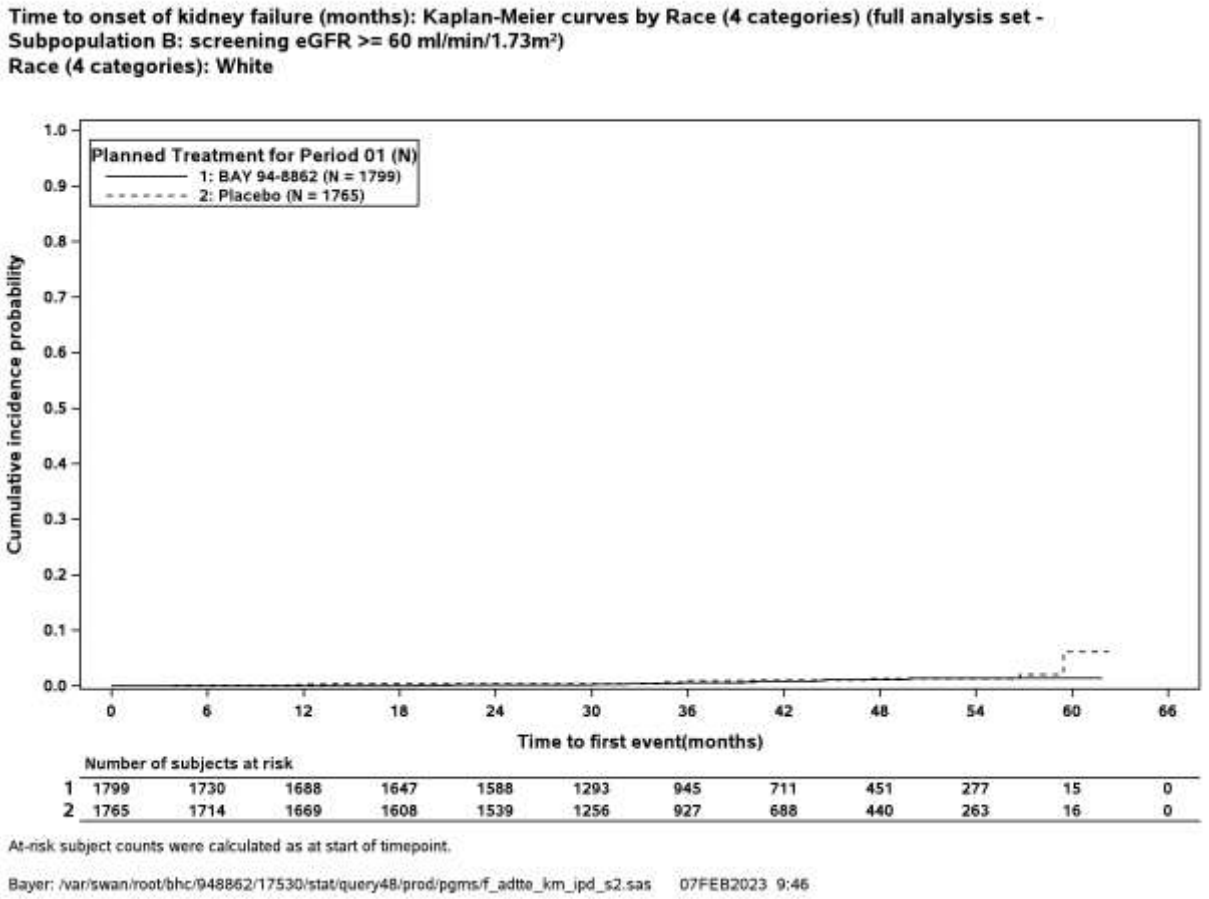


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

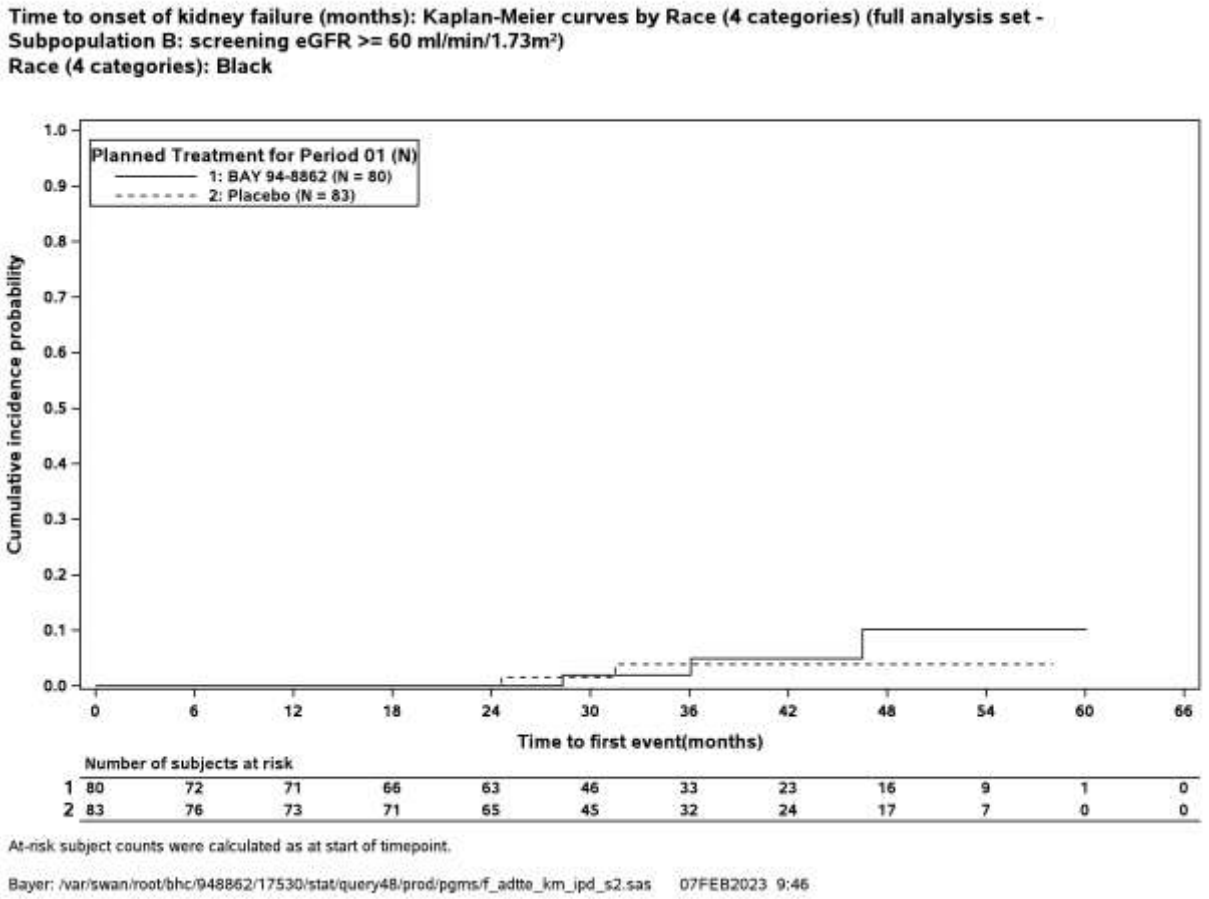


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

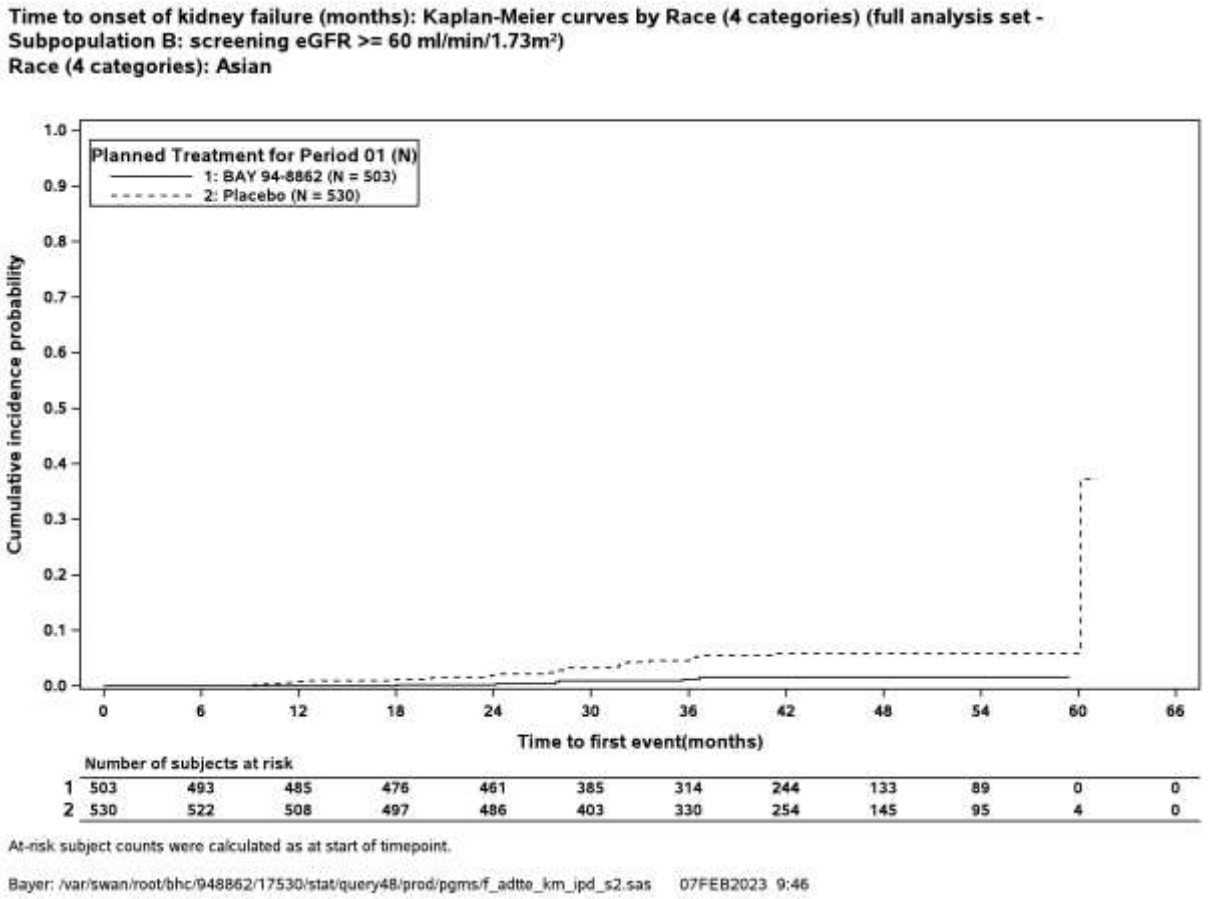


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

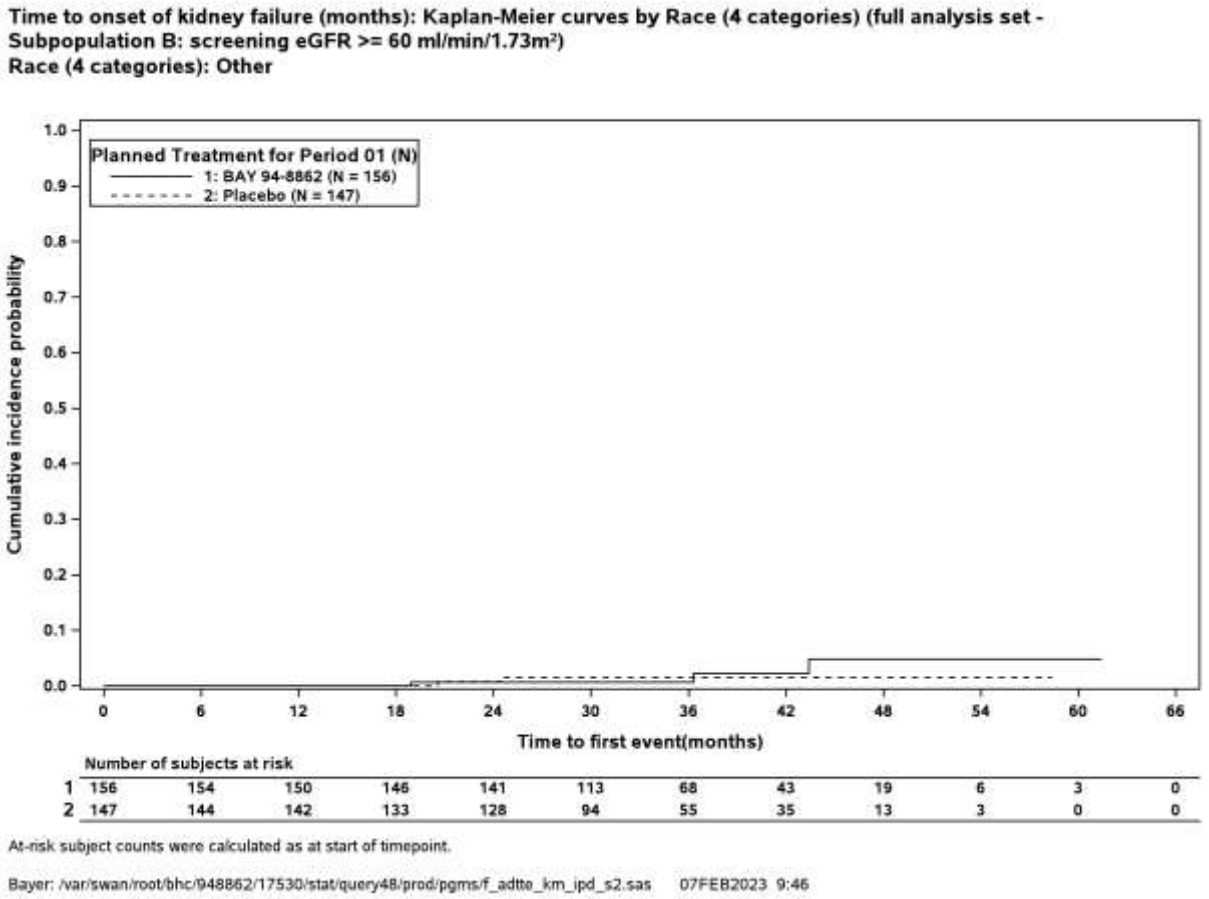


Figure 1.2.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

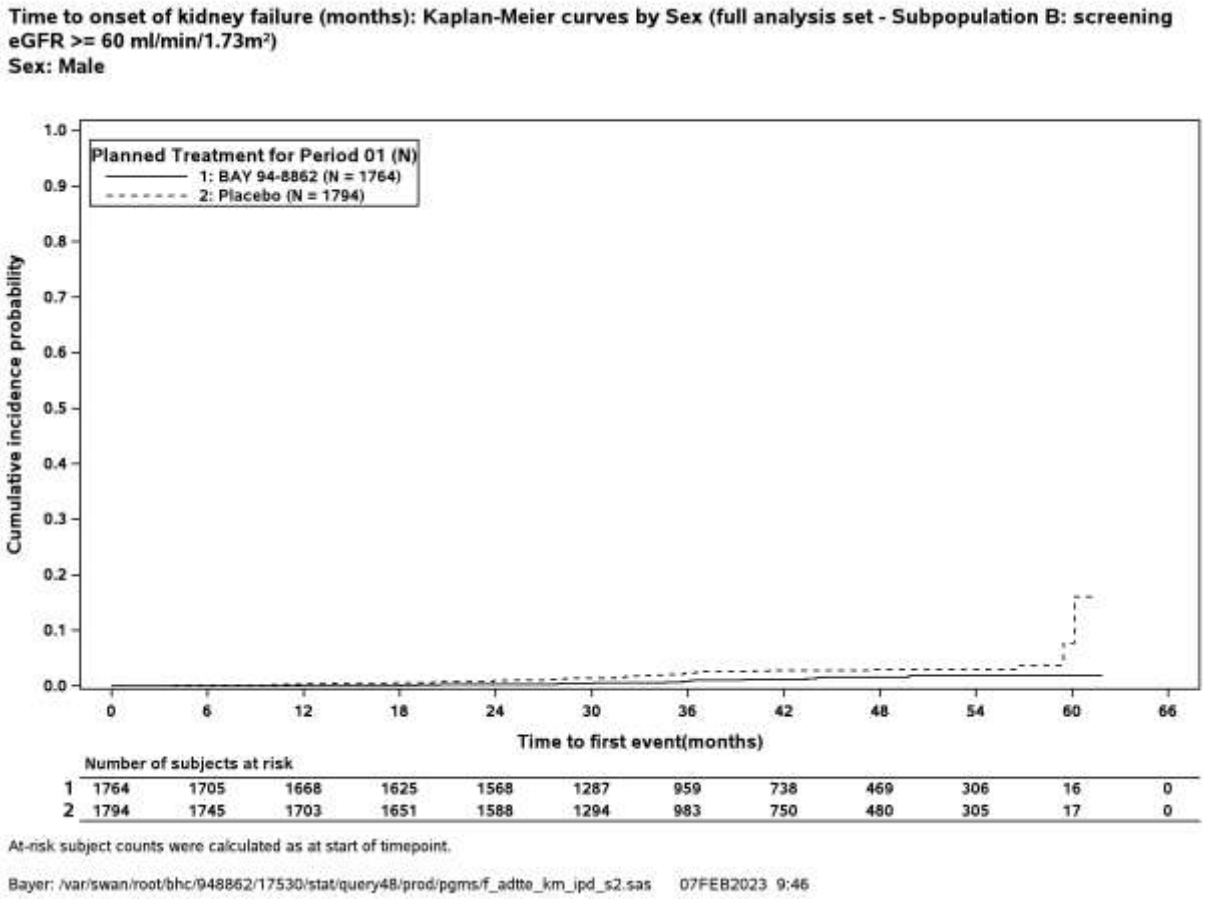


Figure 1.2.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

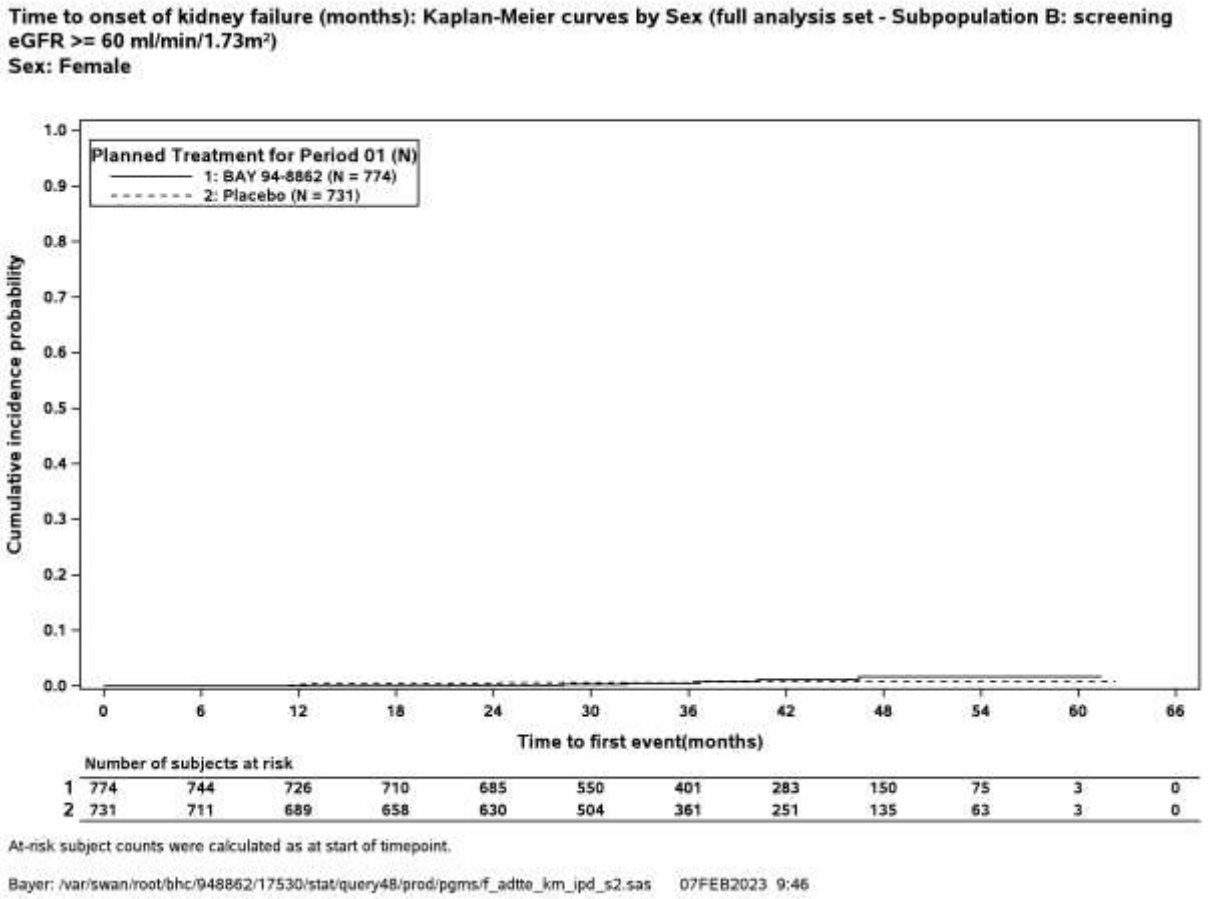


Figure 1.2.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

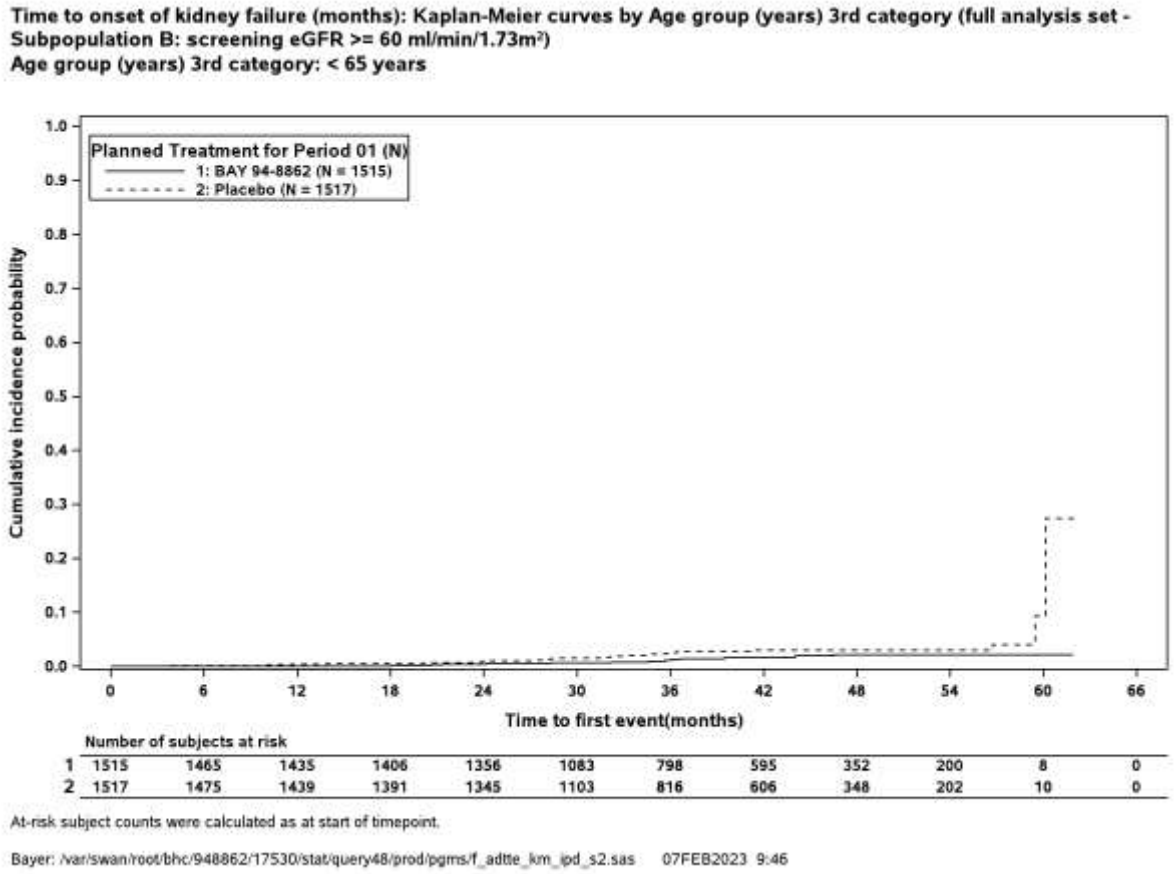


Figure 1.2.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

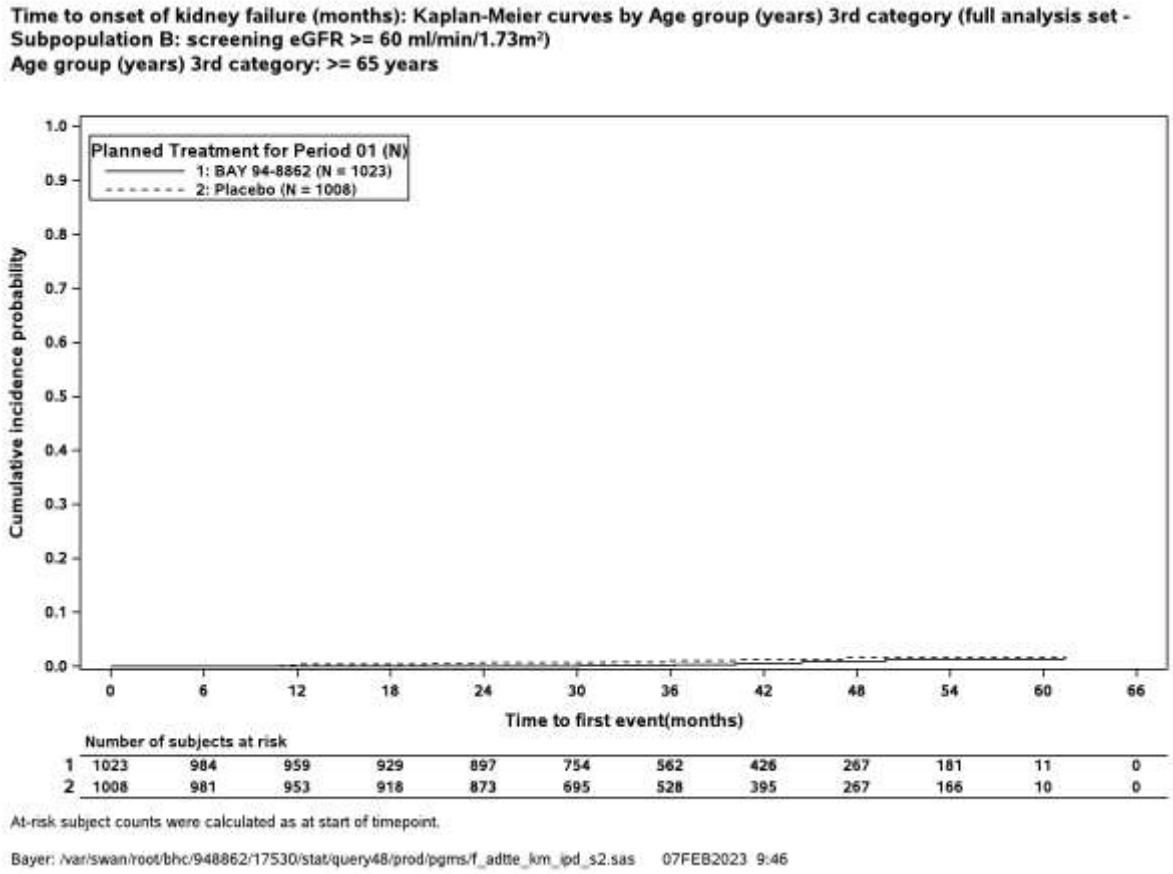


Figure 1.2.1 / 29: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

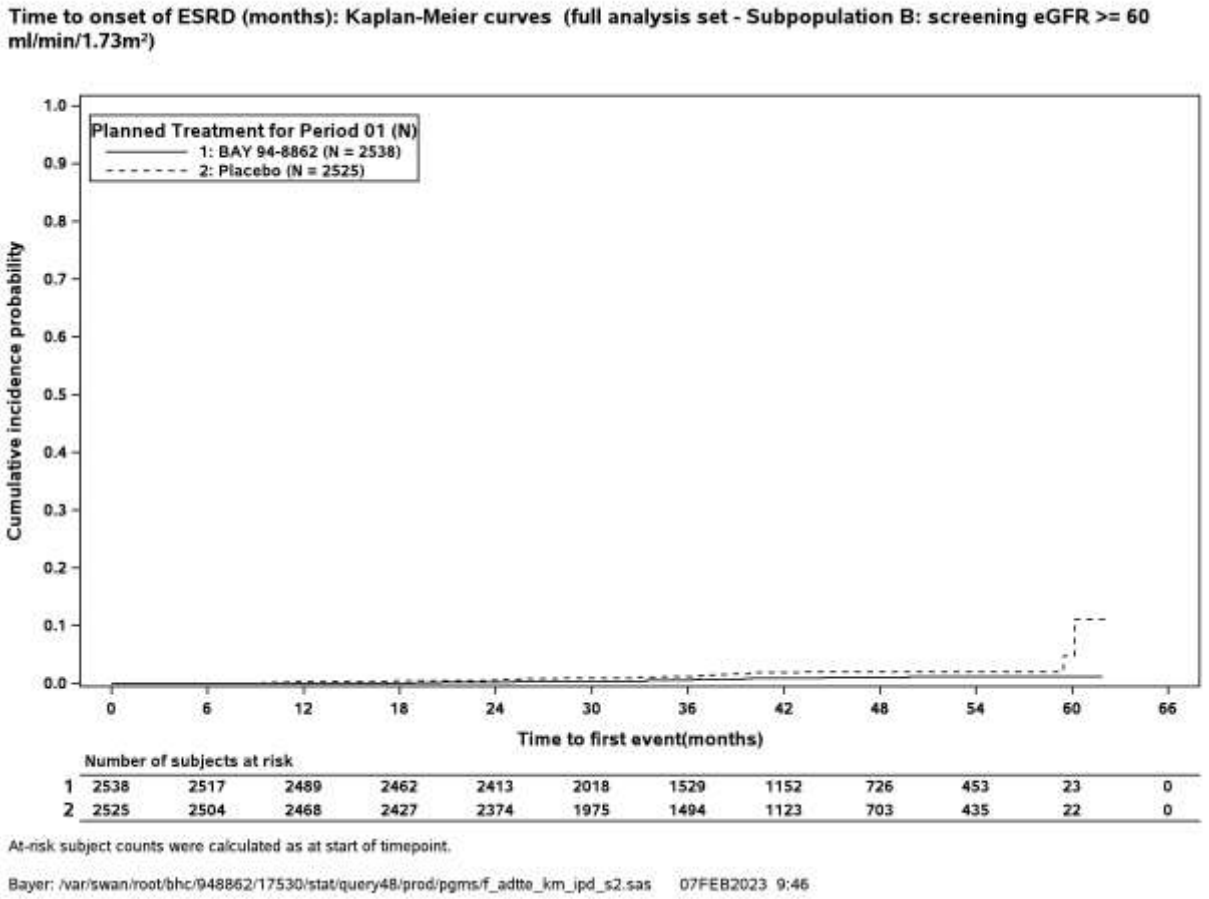


Figure 1.2.1 / 30: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

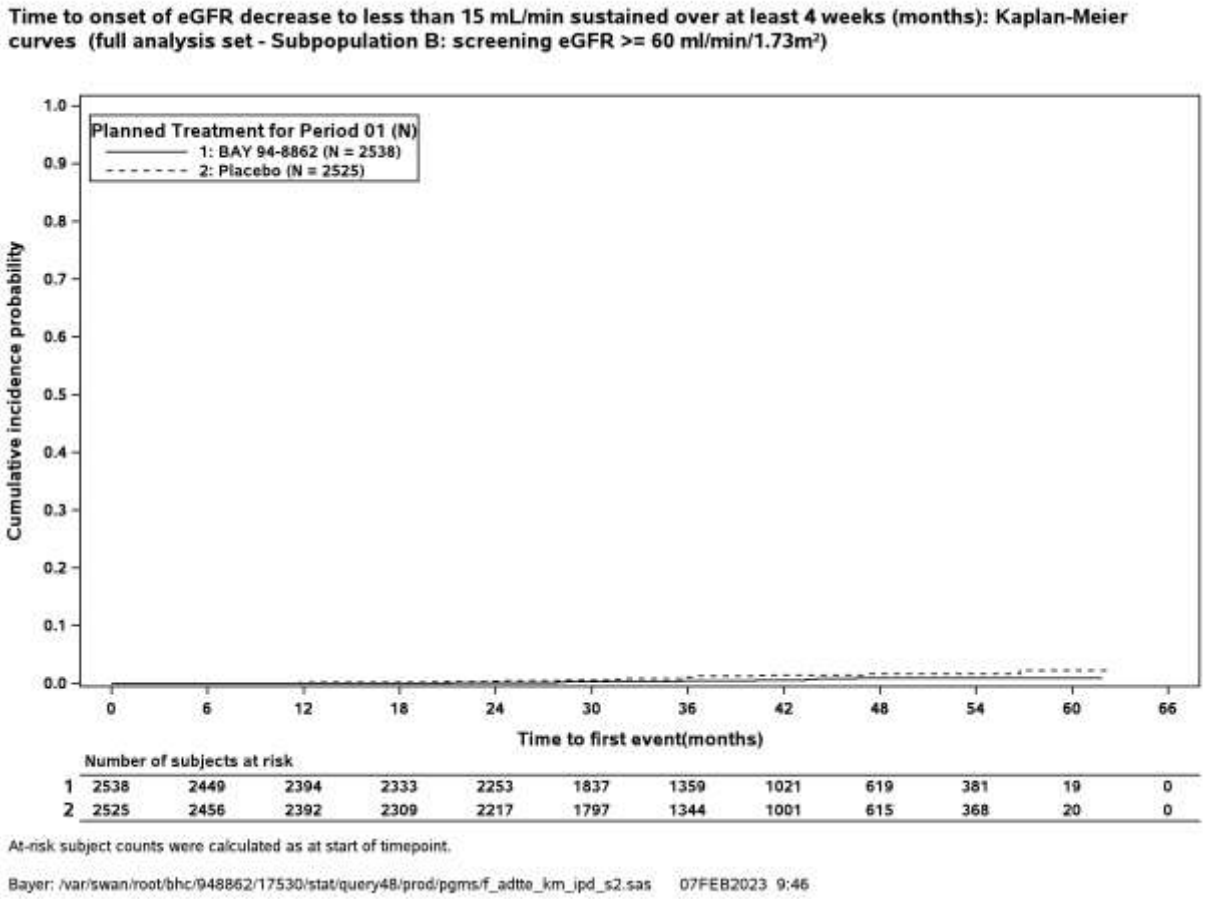


Figure 1.2.1 / 31: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

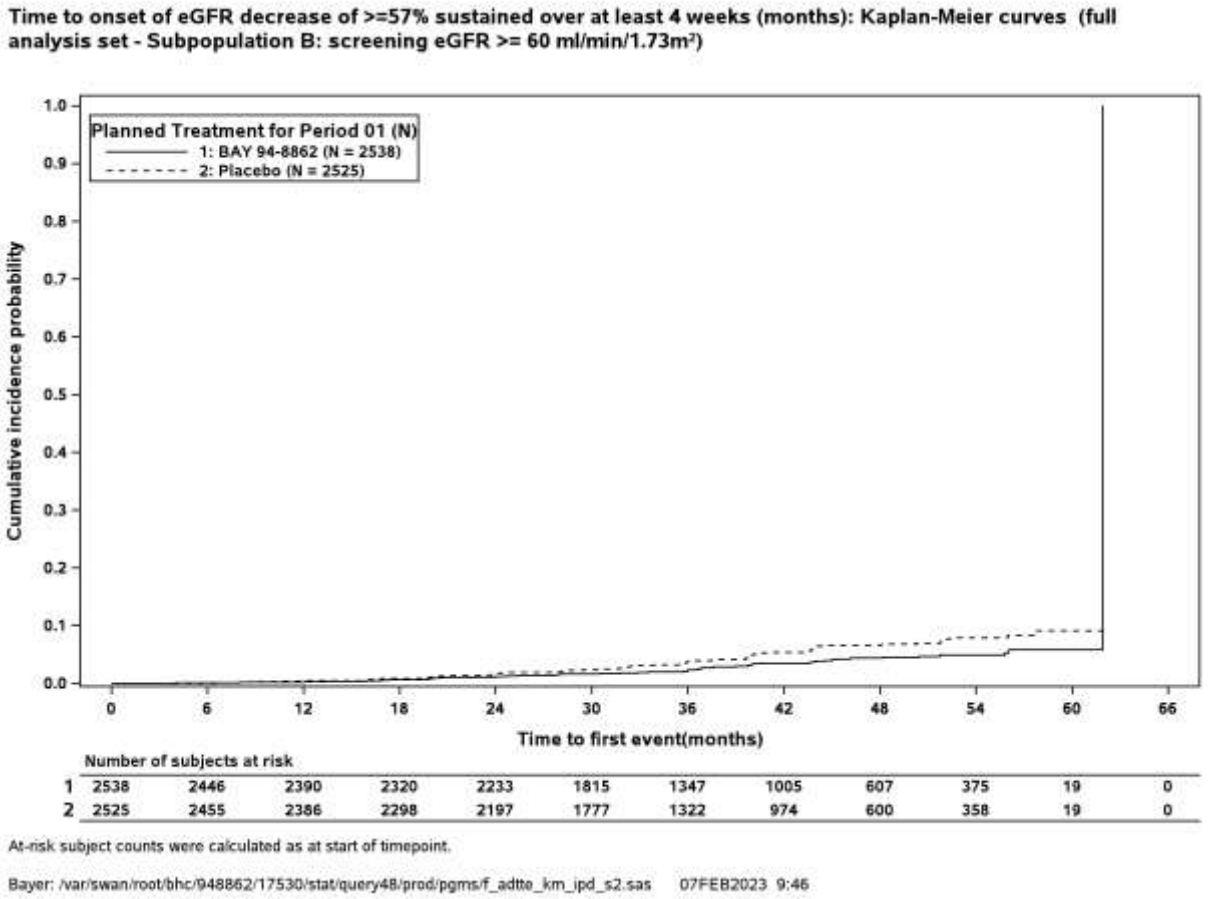


Figure 1.2.1 / 32: Time to renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

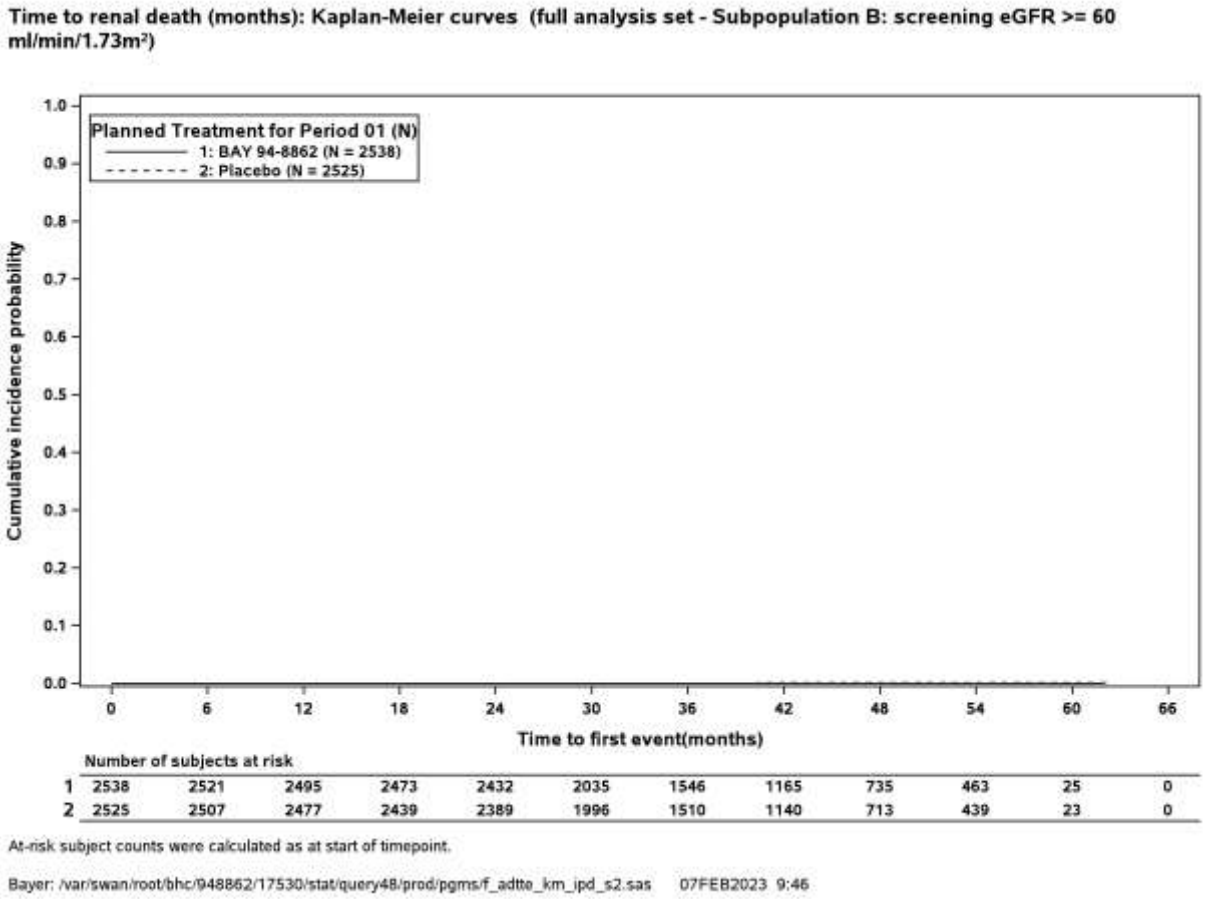


Figure 1.2.1 / 33: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

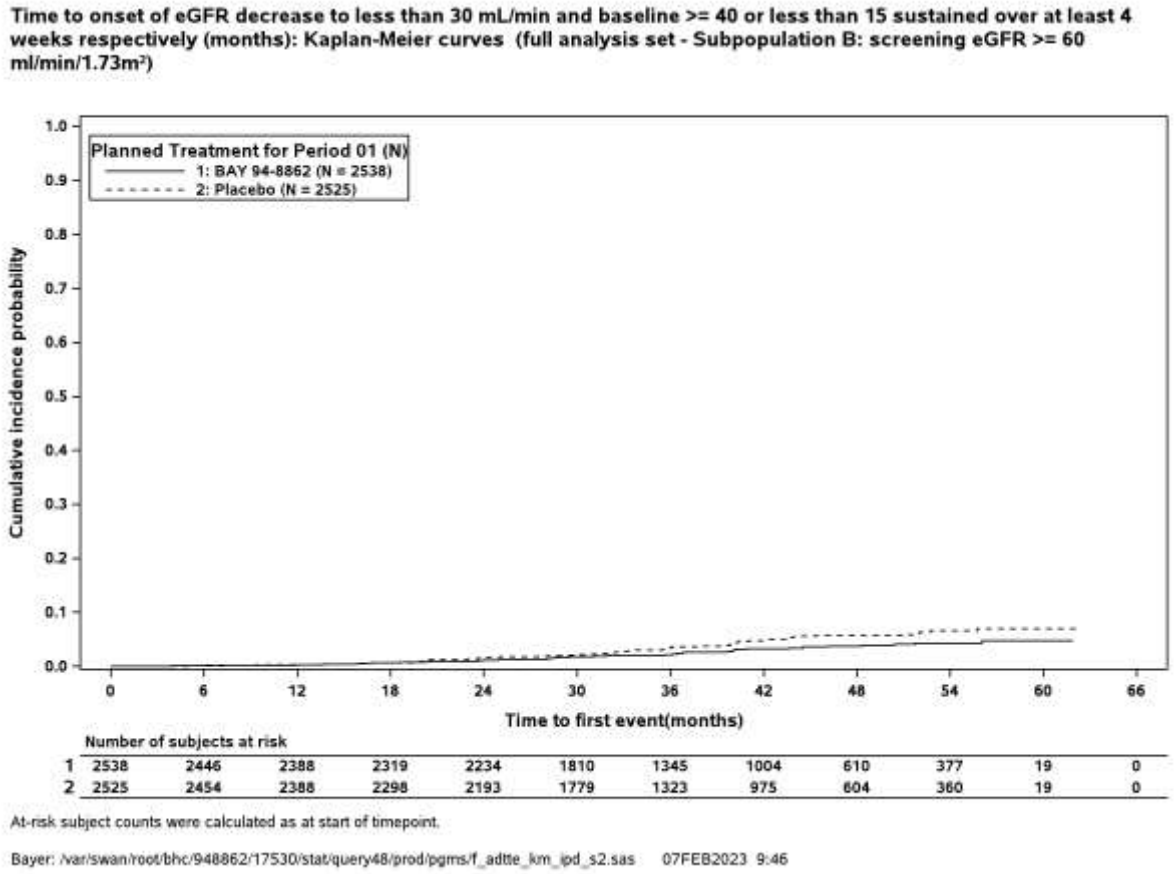


Figure 1.2.1 / 34: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

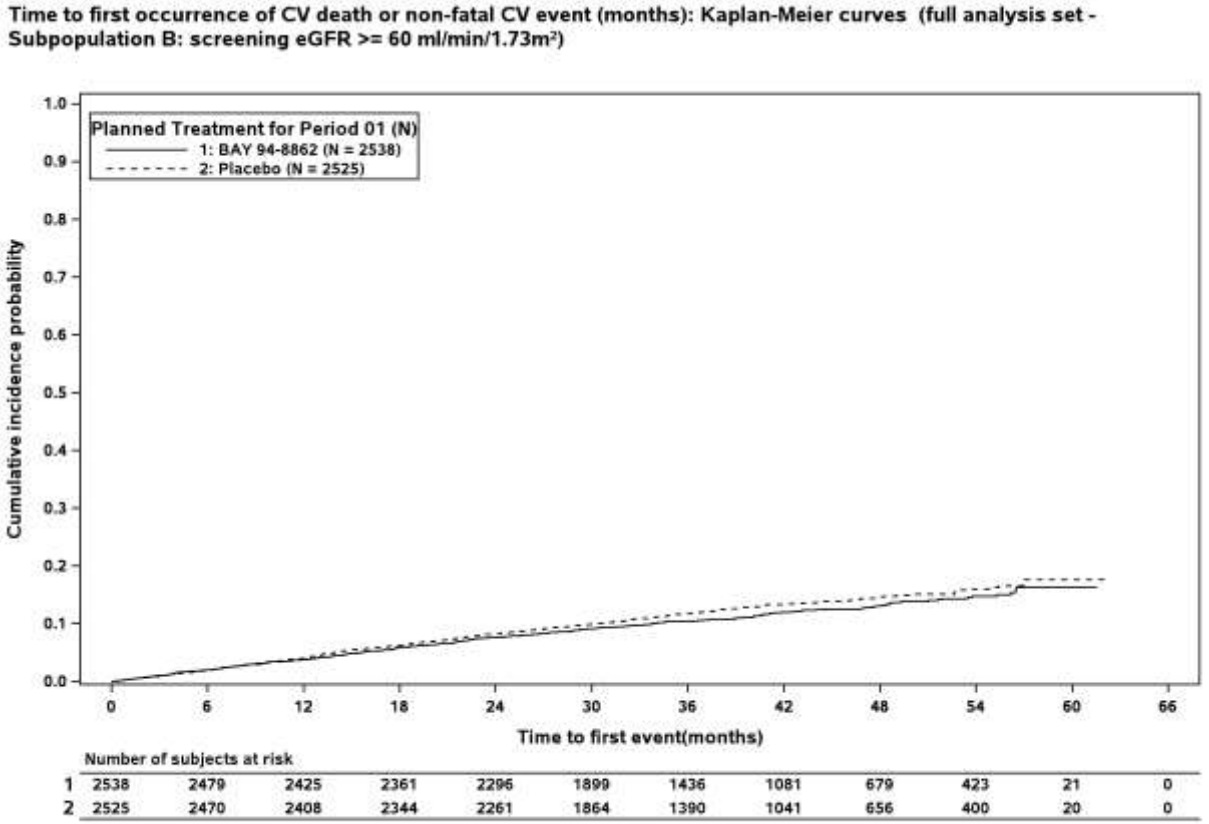


Figure 1.2.1 / 35: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

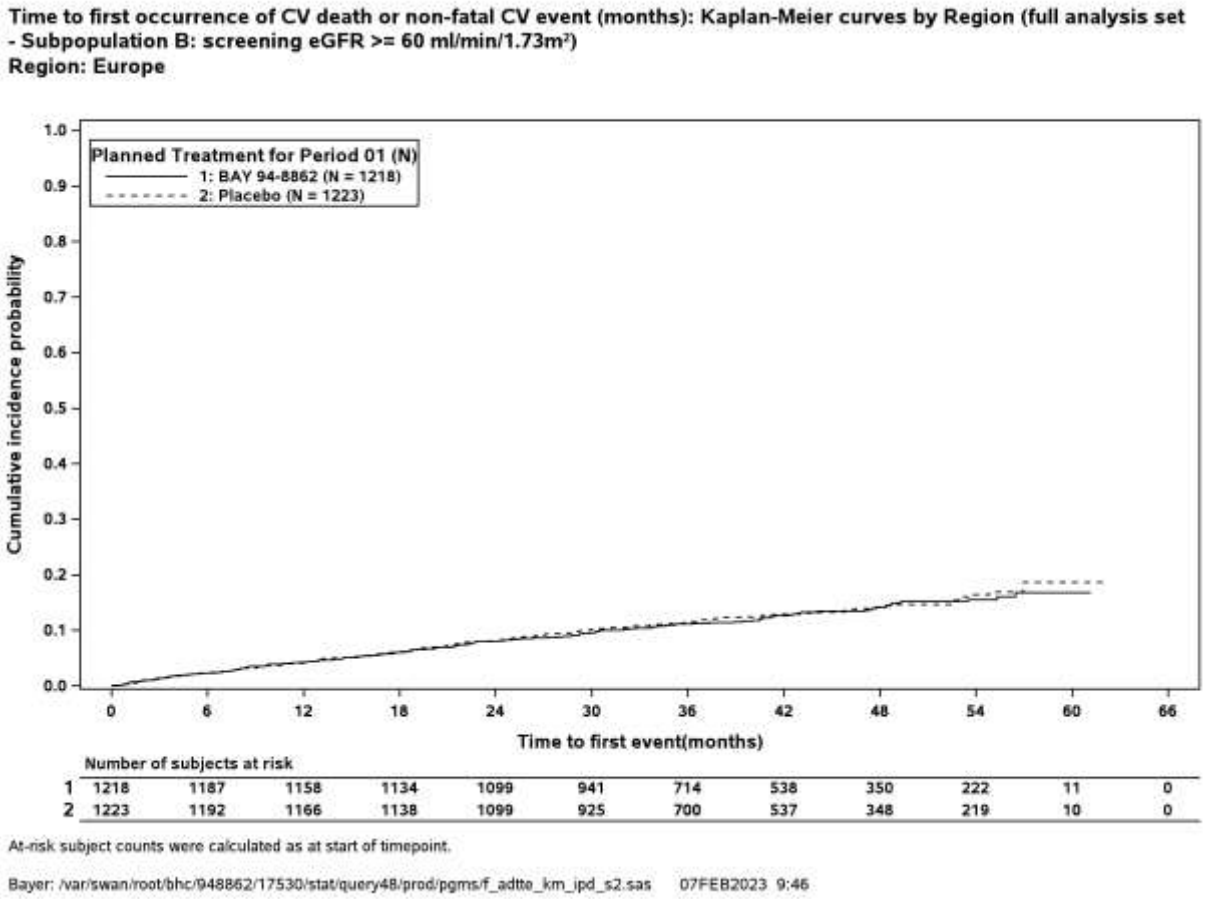


Figure 1.2.1 / 35: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

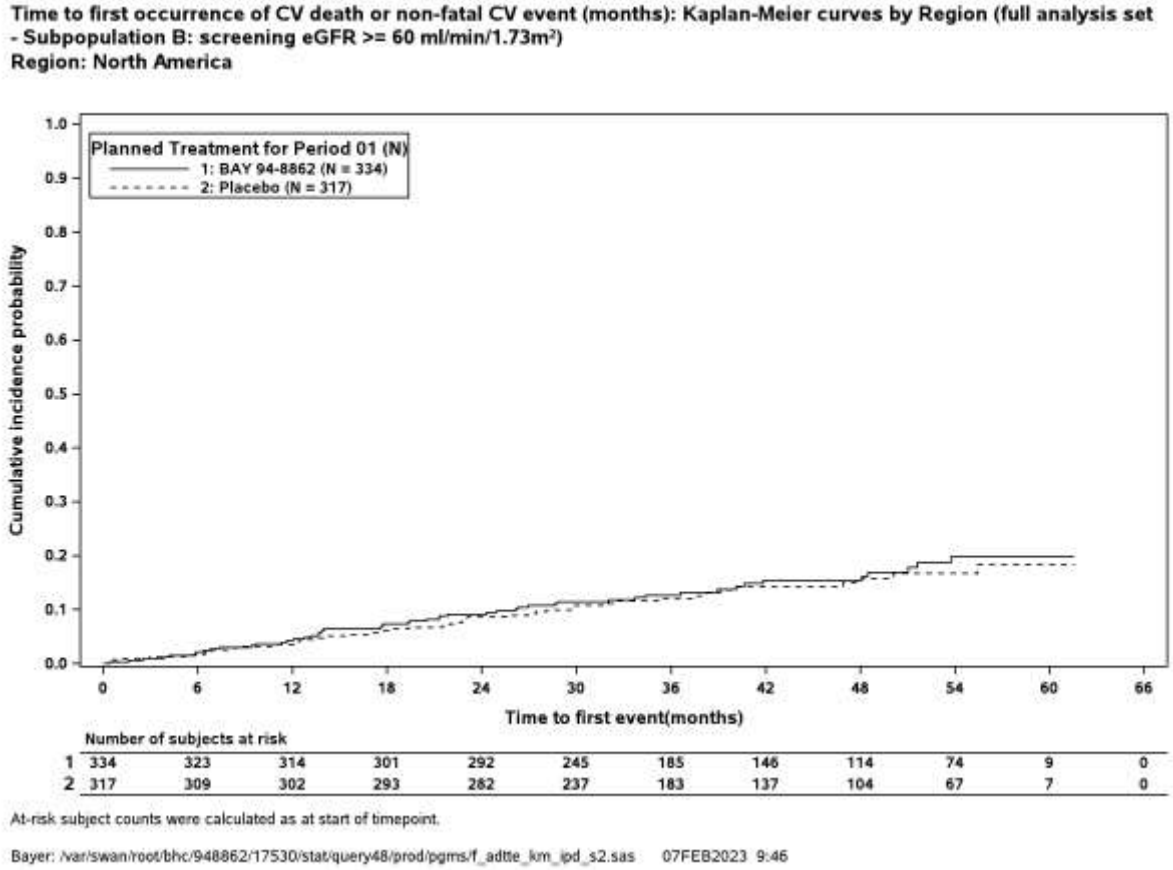


Figure 1.2.1 / 35: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

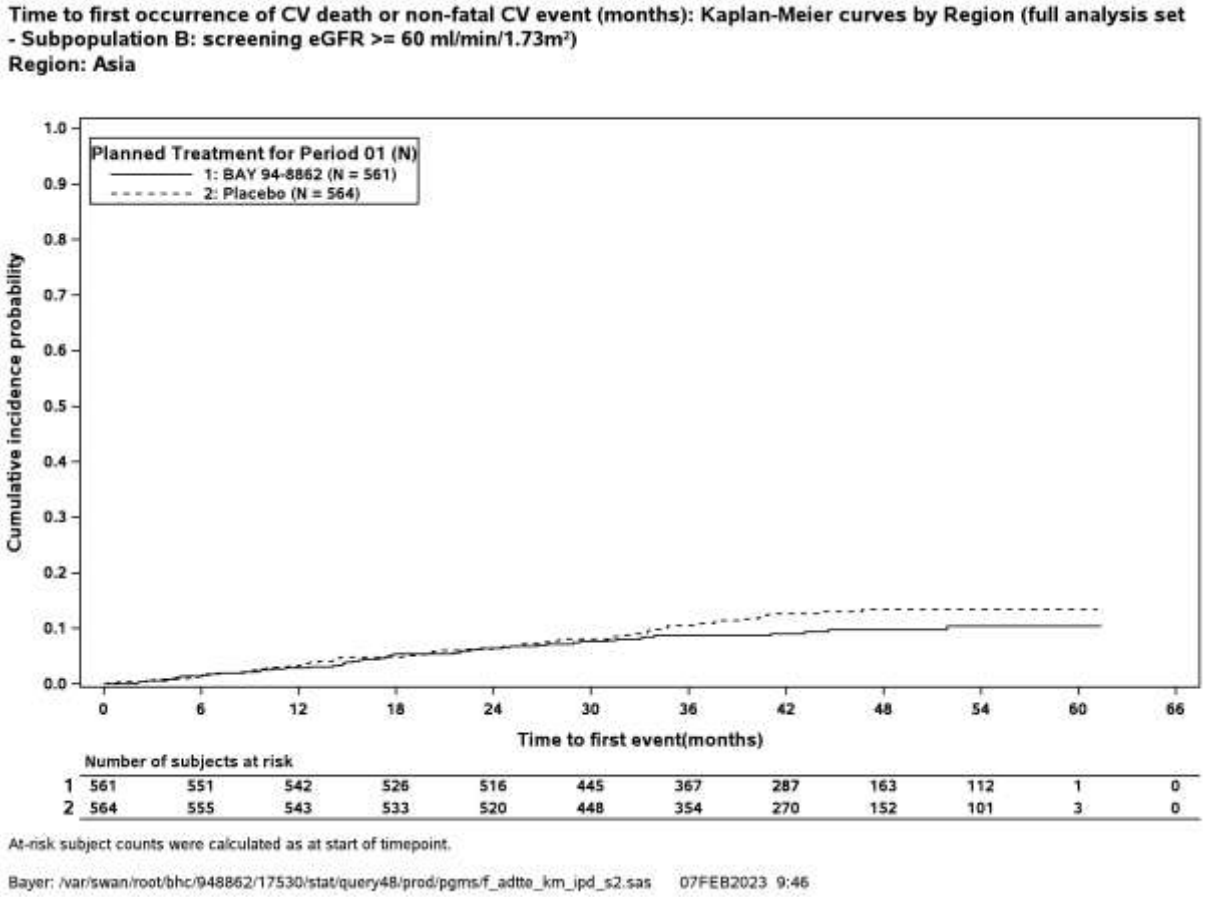


Figure 1.2.1 / 35: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

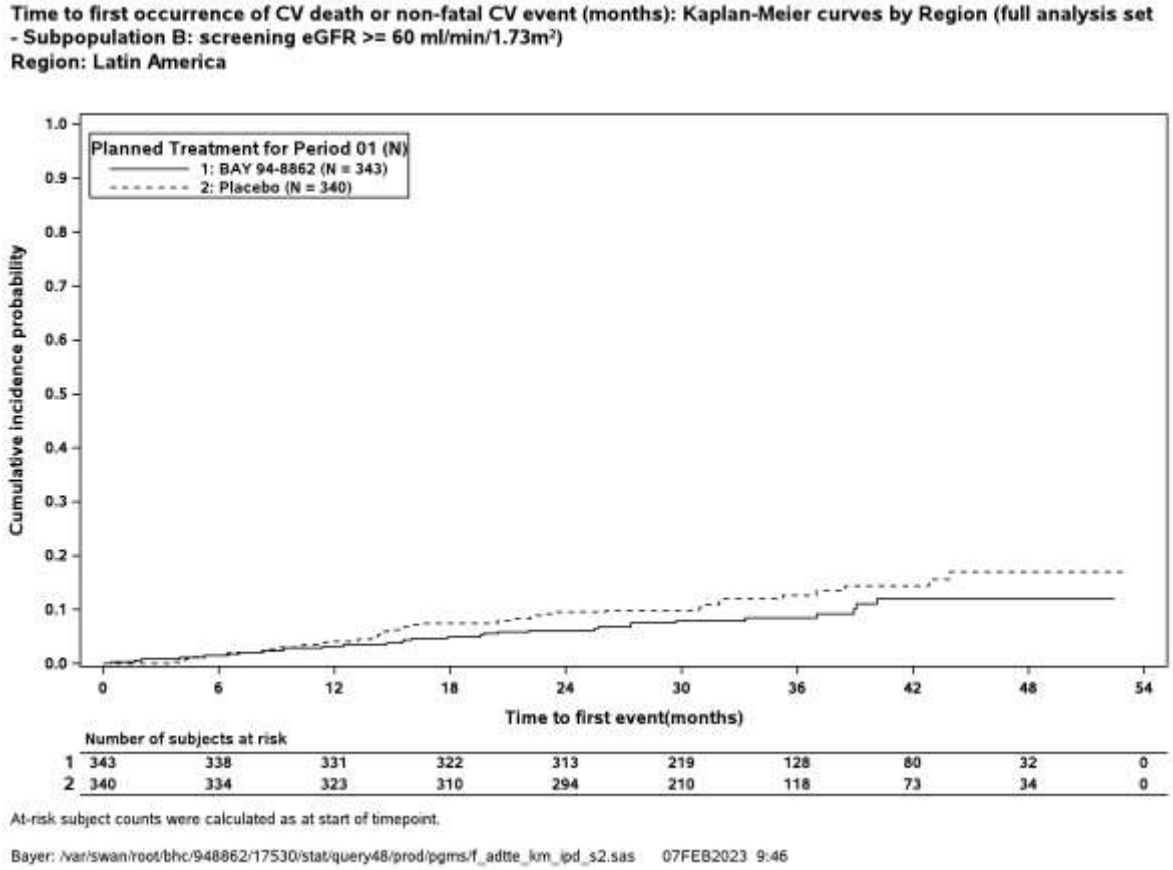


Figure 1.2.1 / 35: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

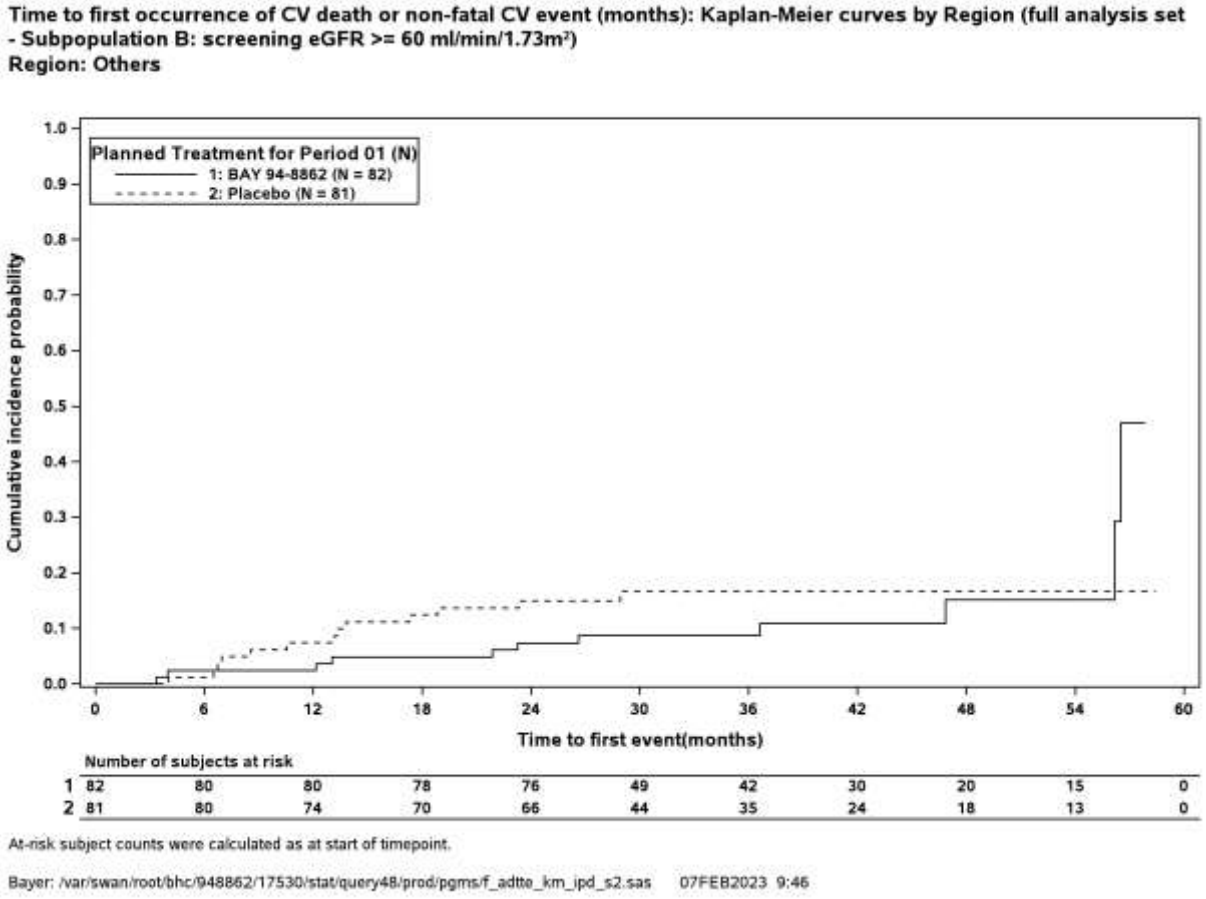


Figure 1.2.1 / 36: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

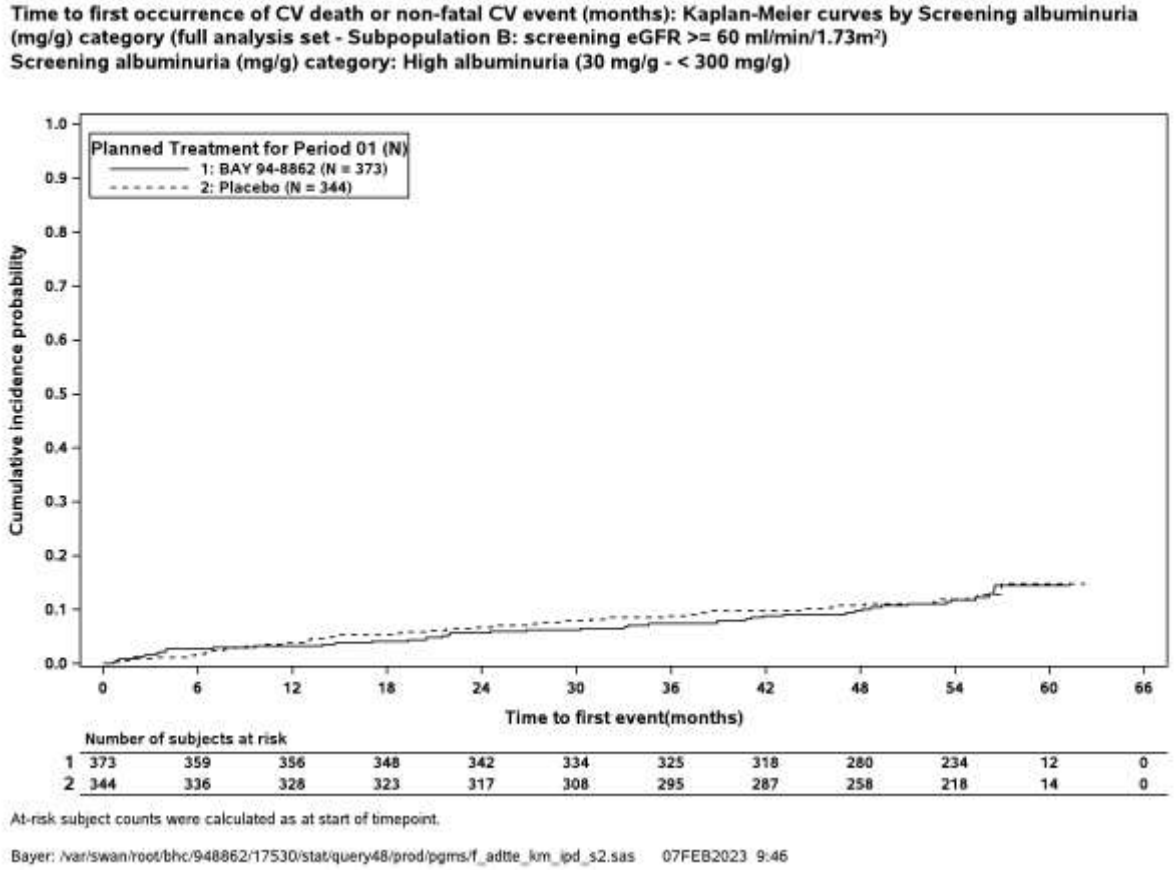


Figure 1.2.1 / 36: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

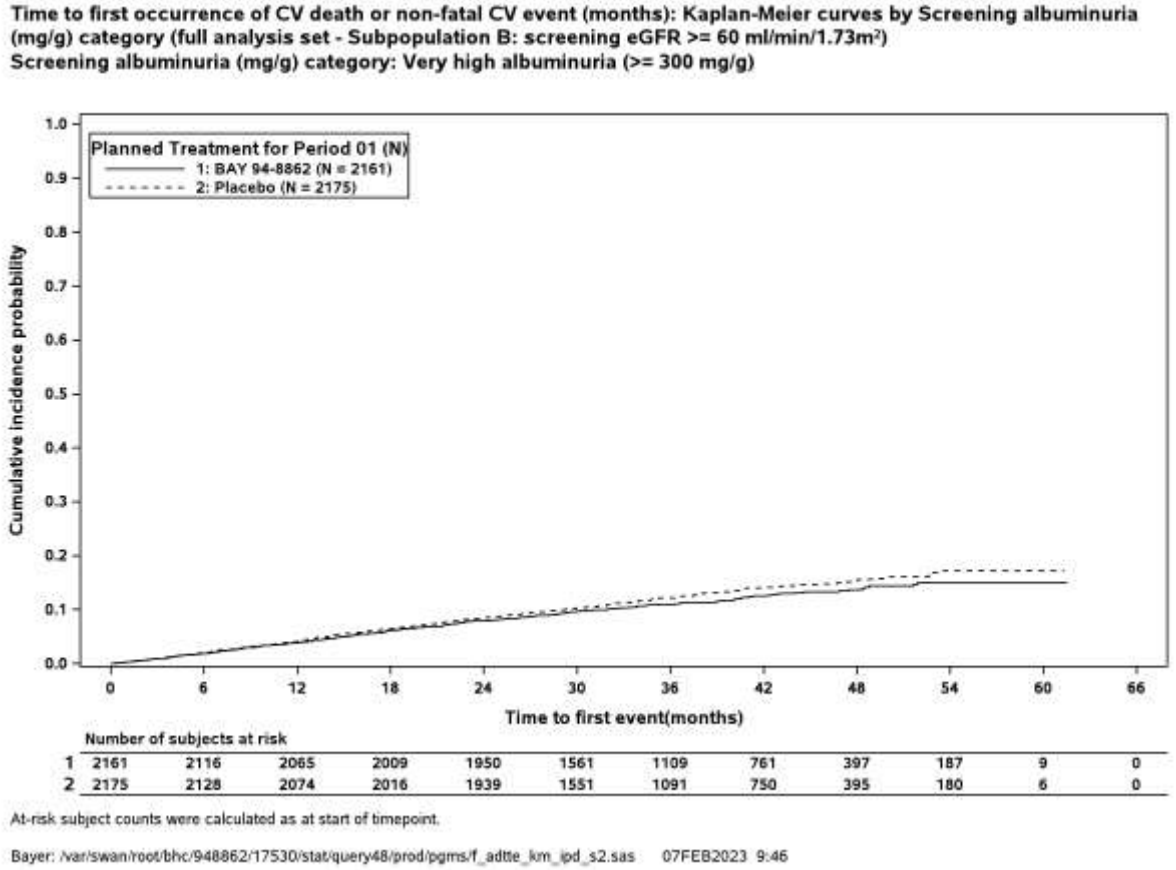


Figure 1.2.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

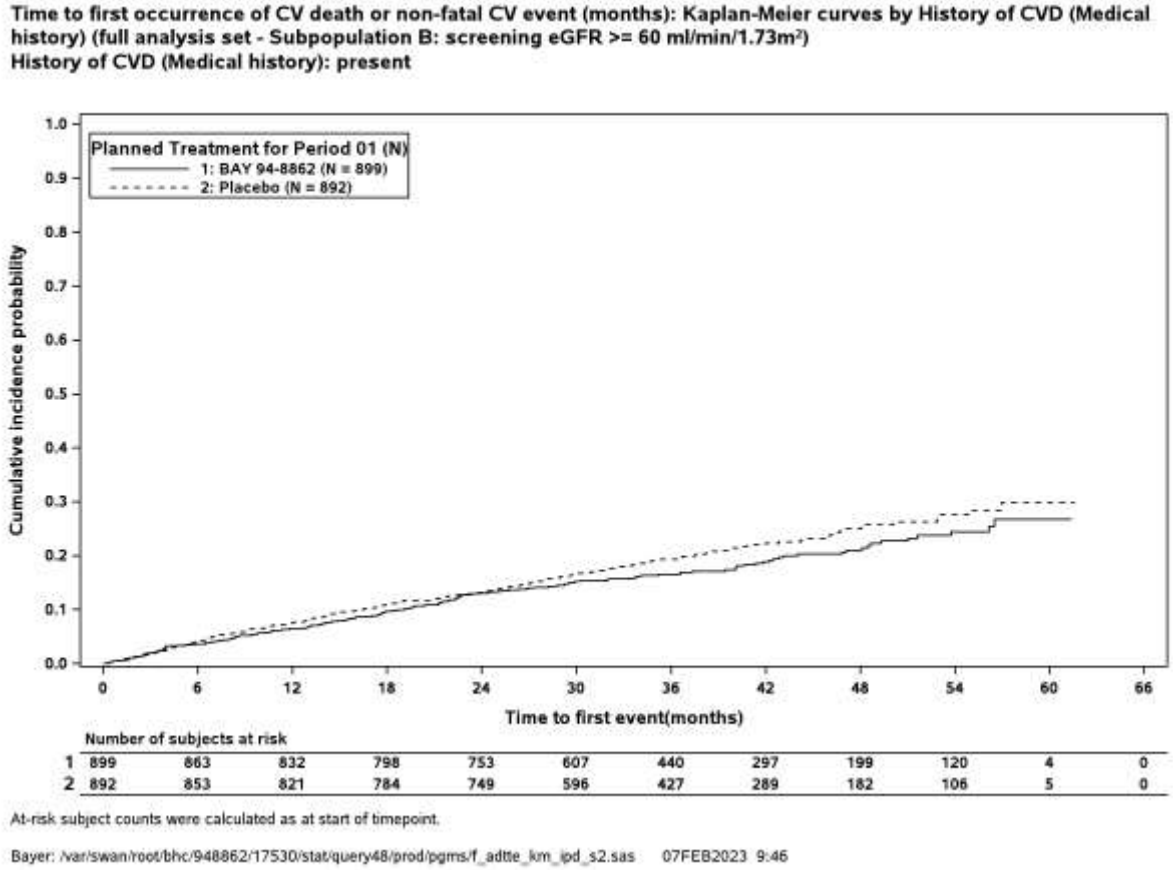


Figure 1.2.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

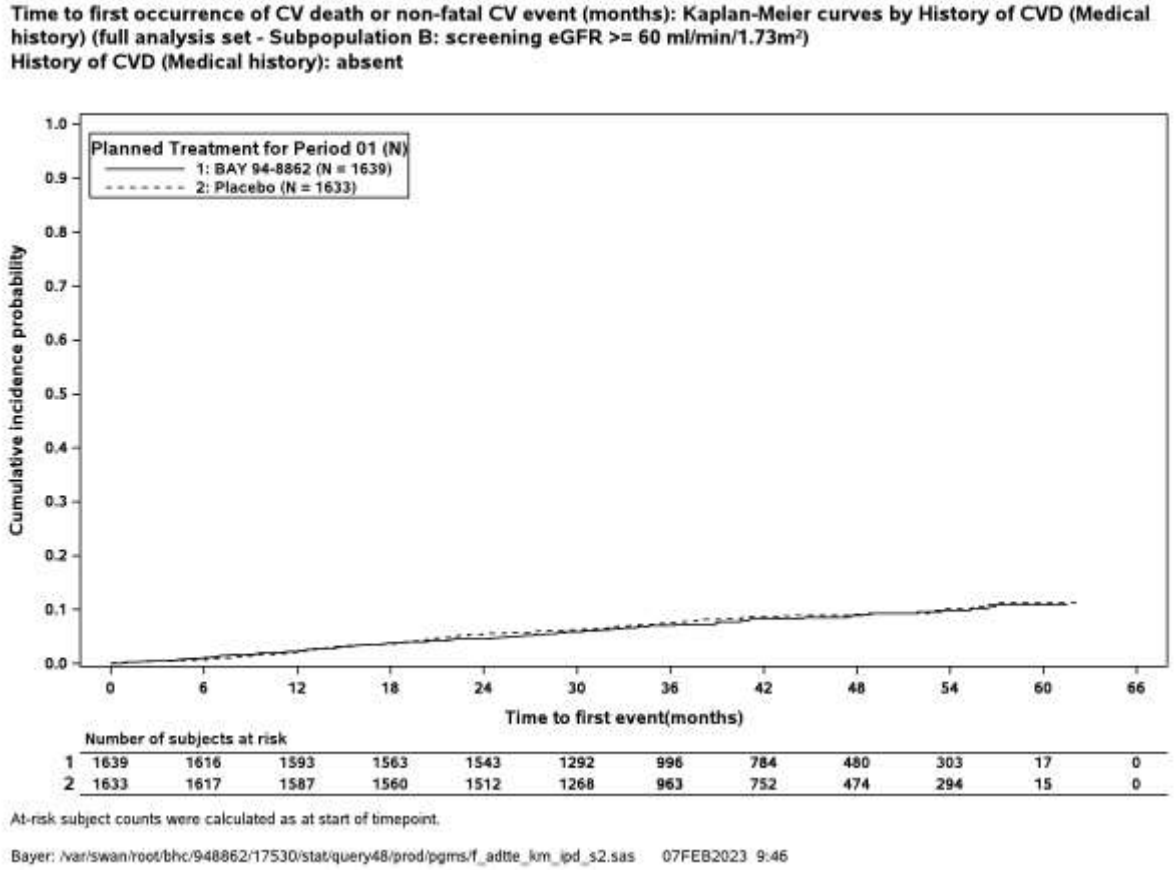


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

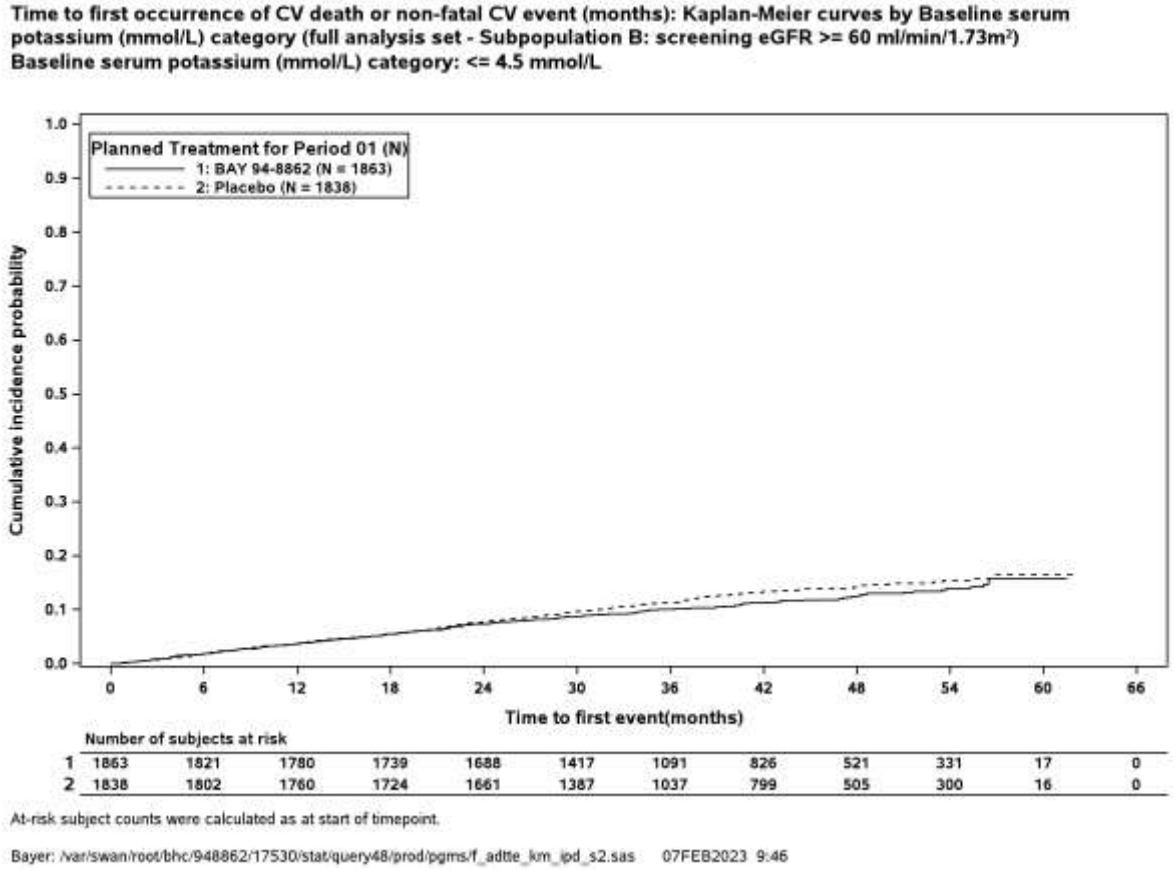
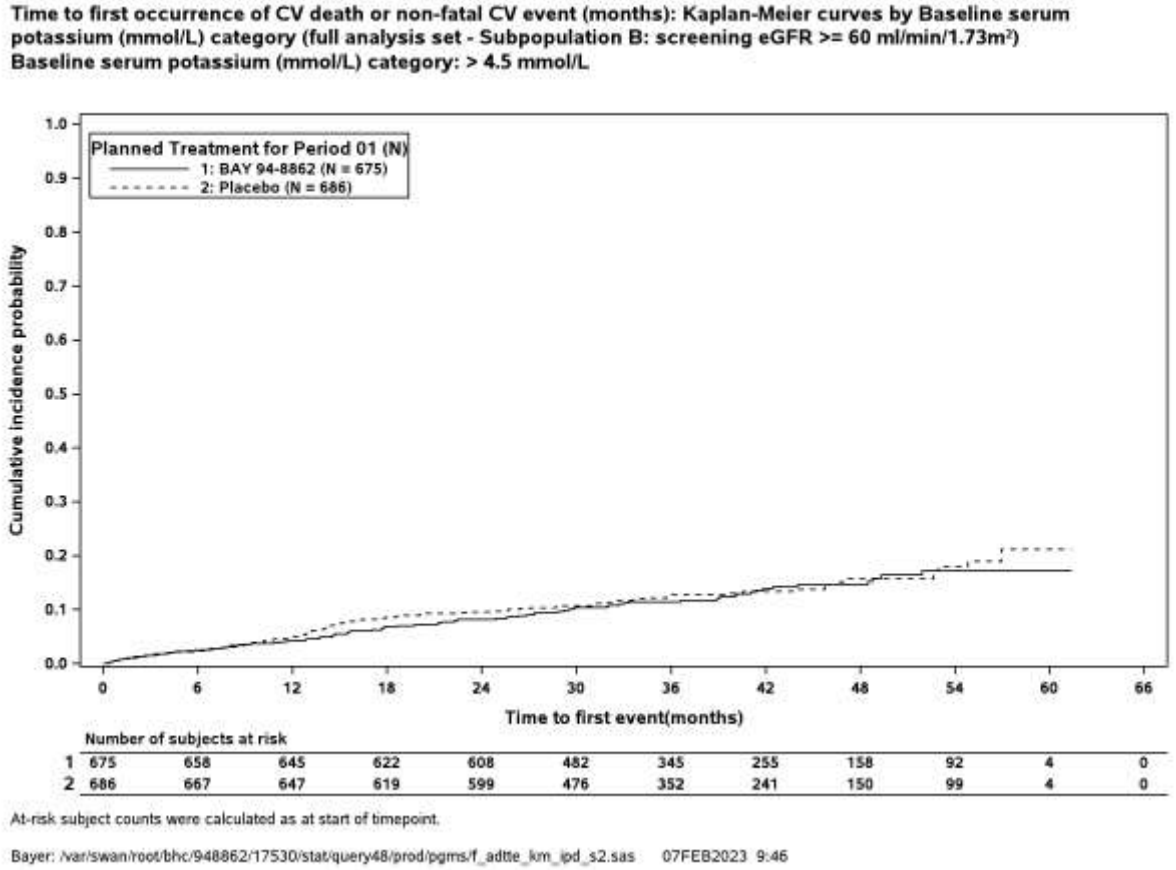


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

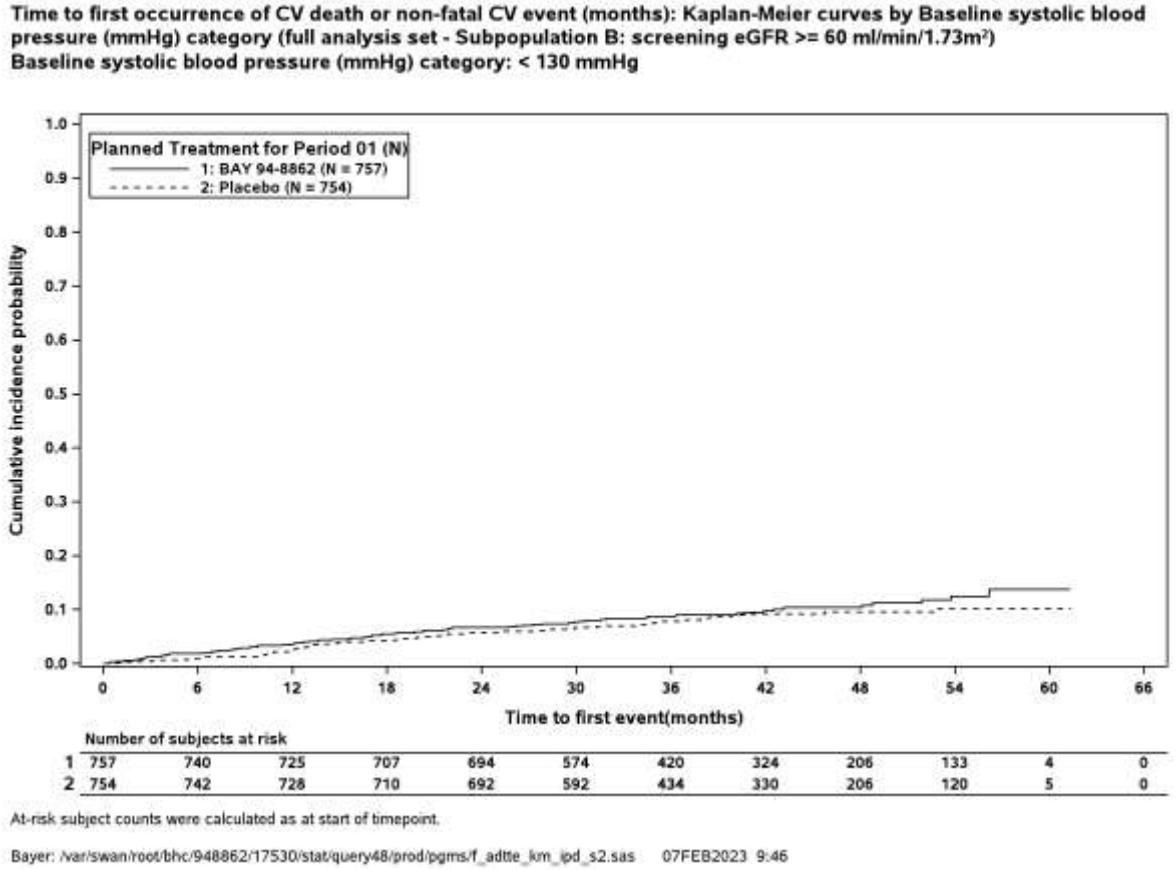


Figure 1.2.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

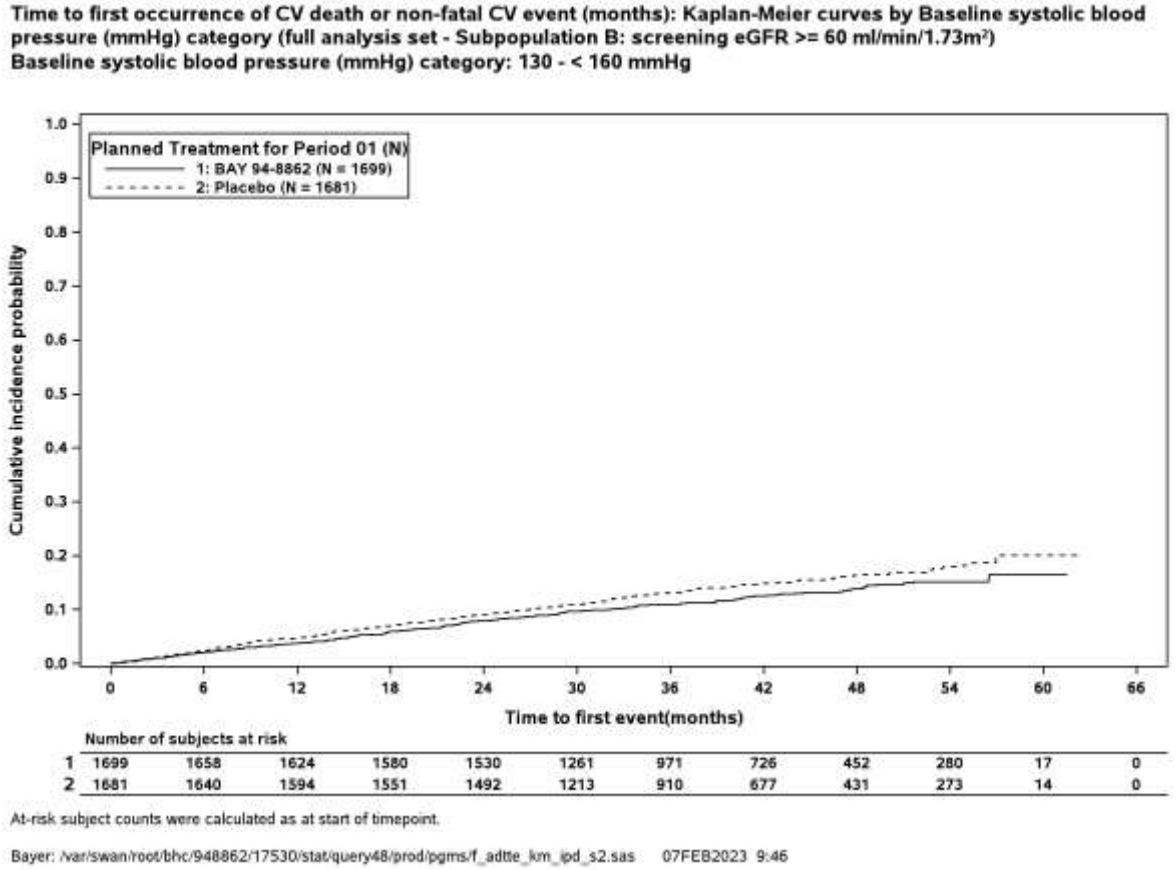


Figure 1.2.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

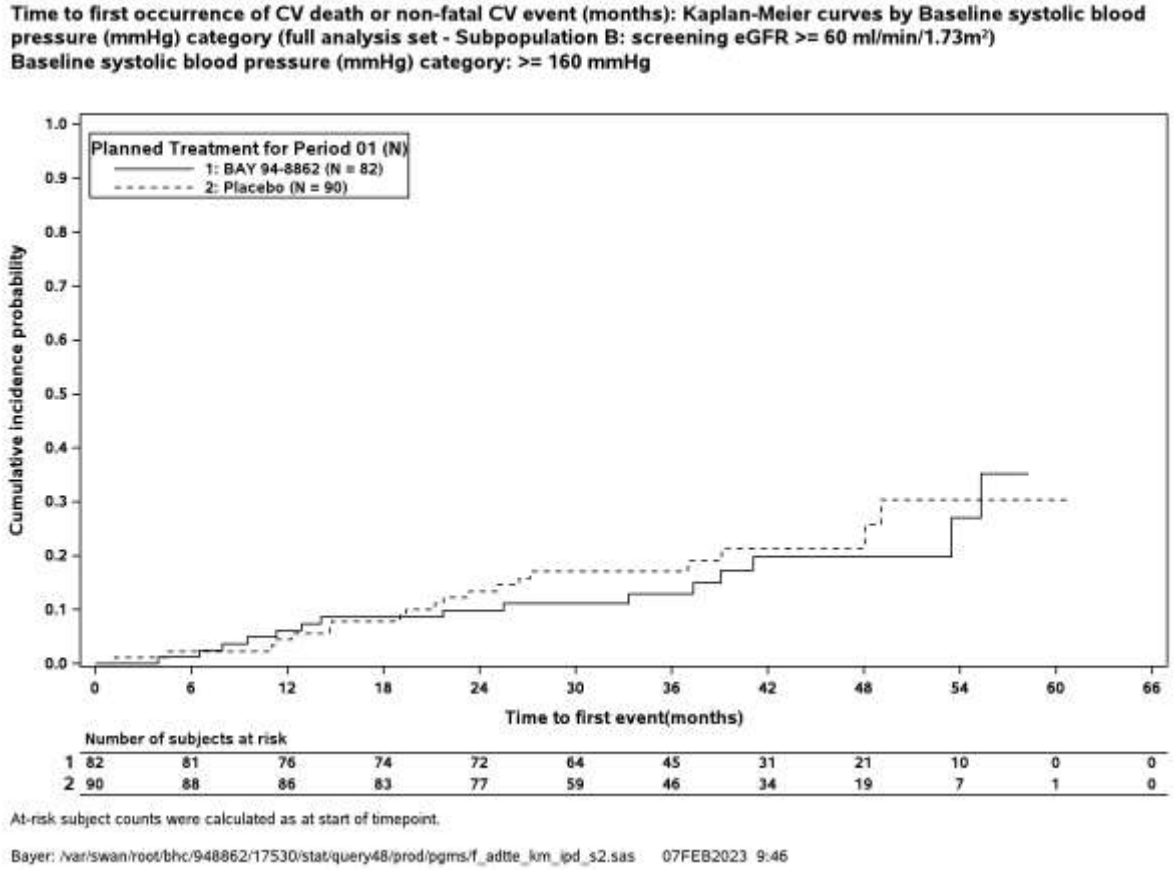


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

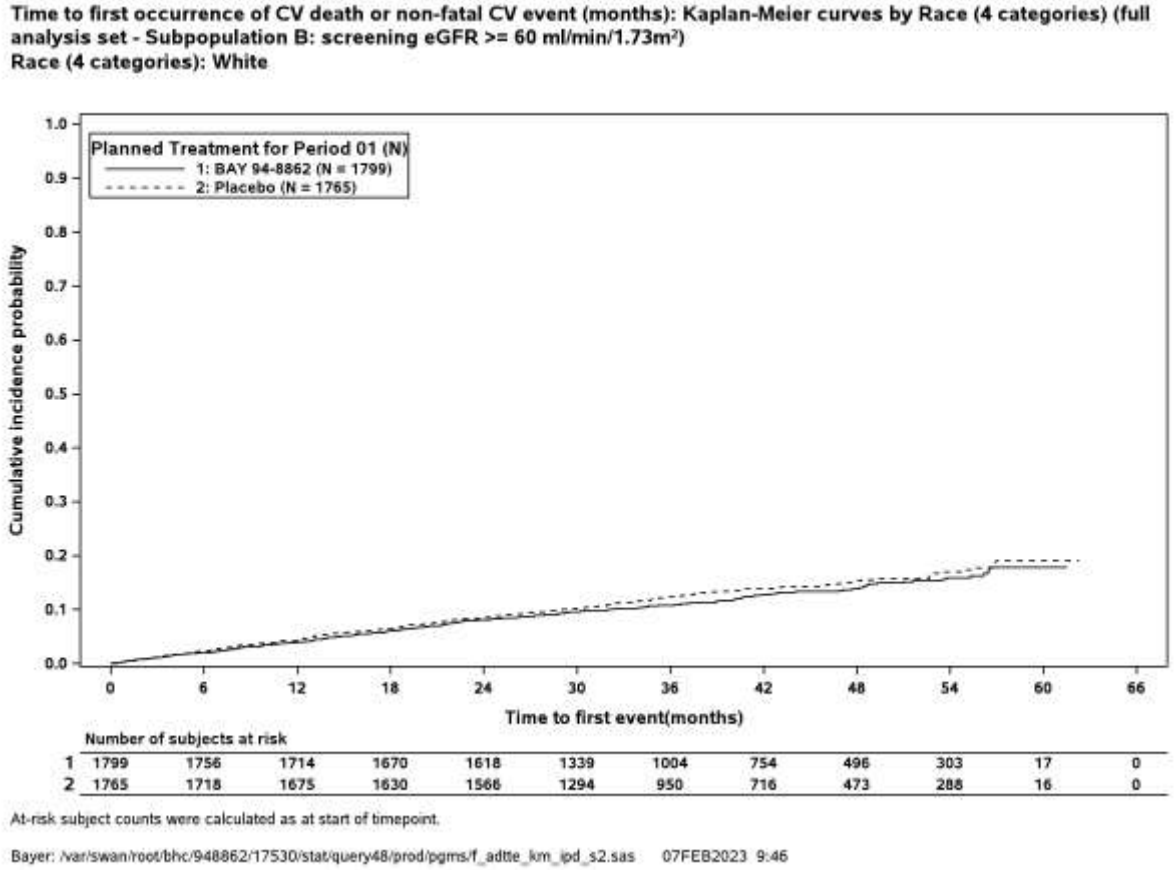


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

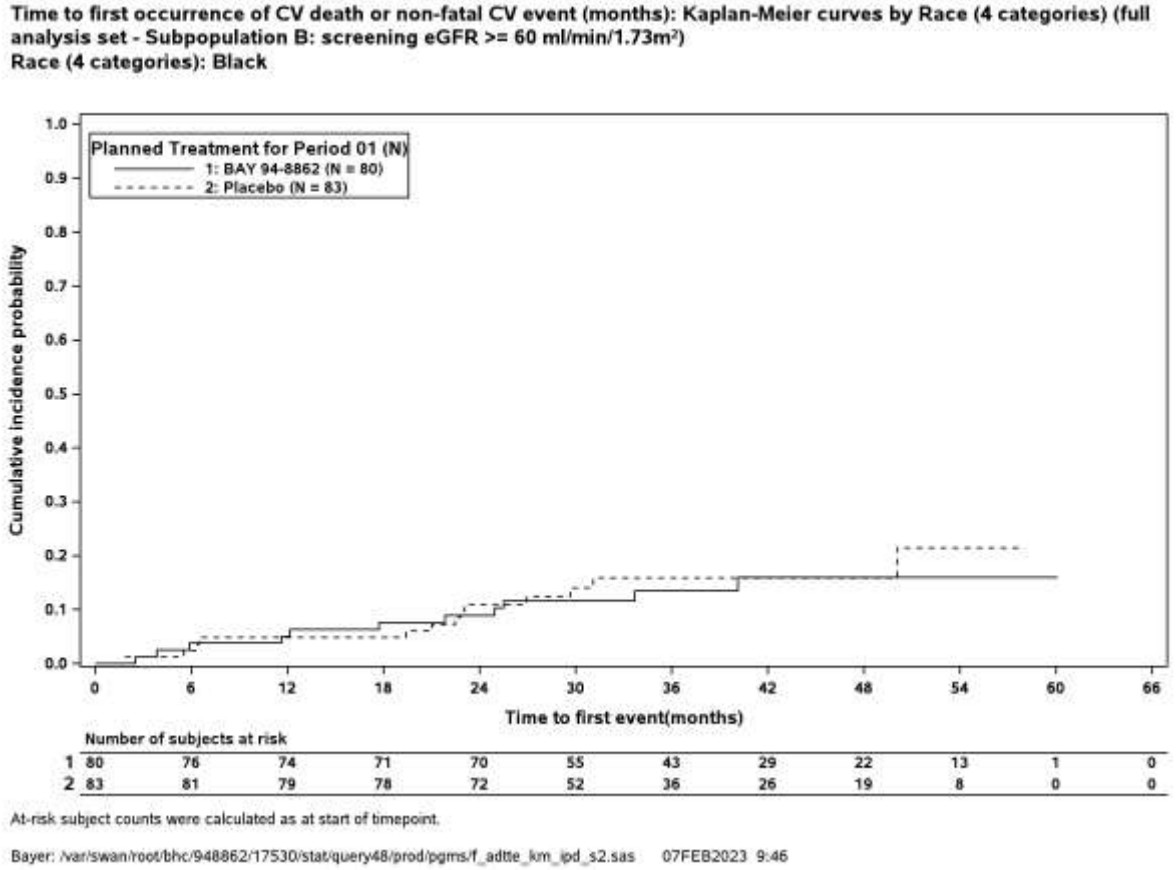


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

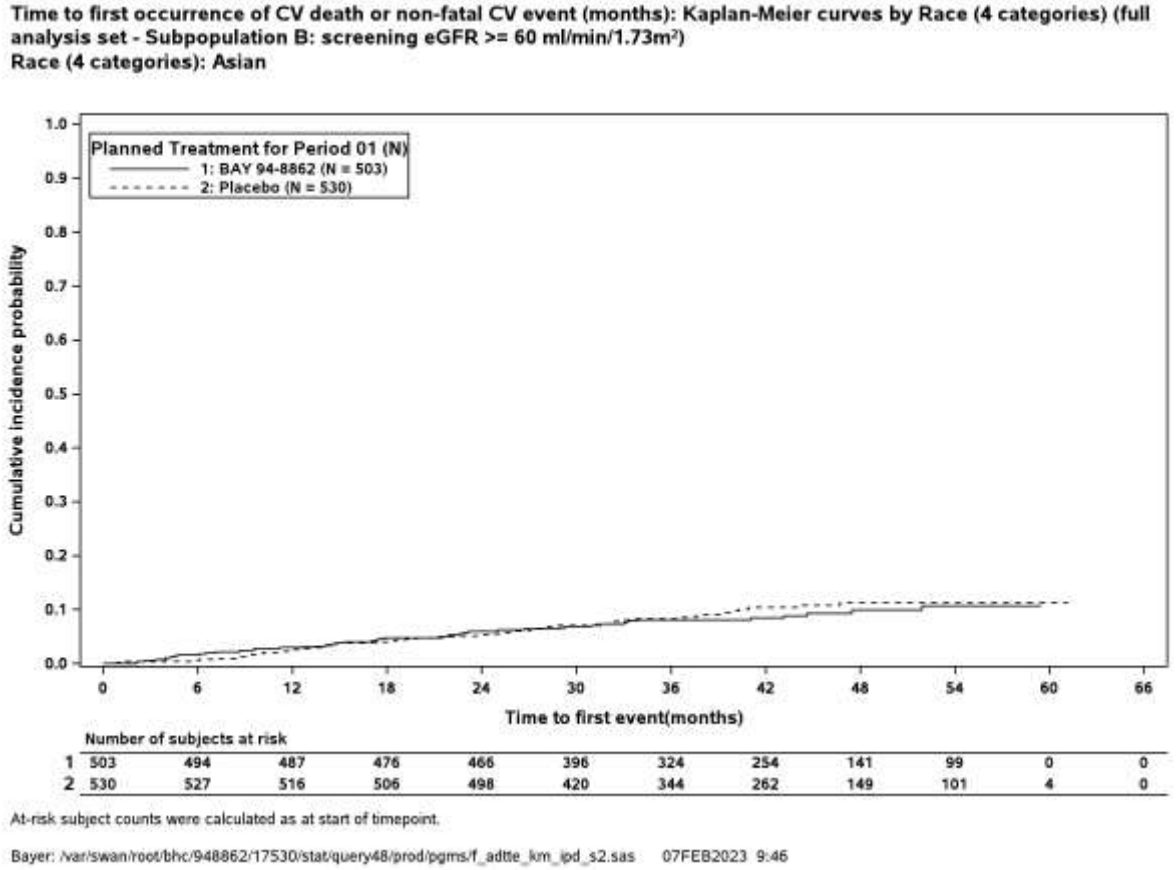


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

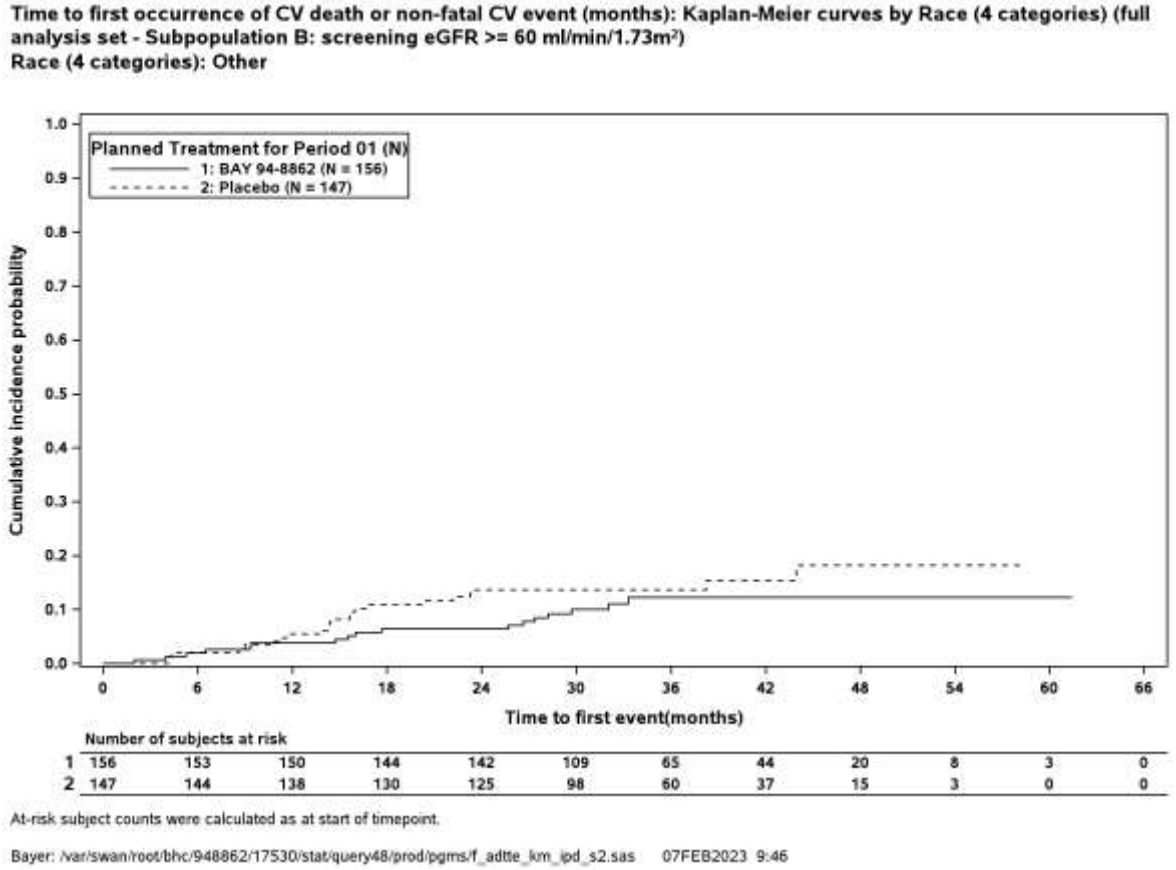


Figure 1.2.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

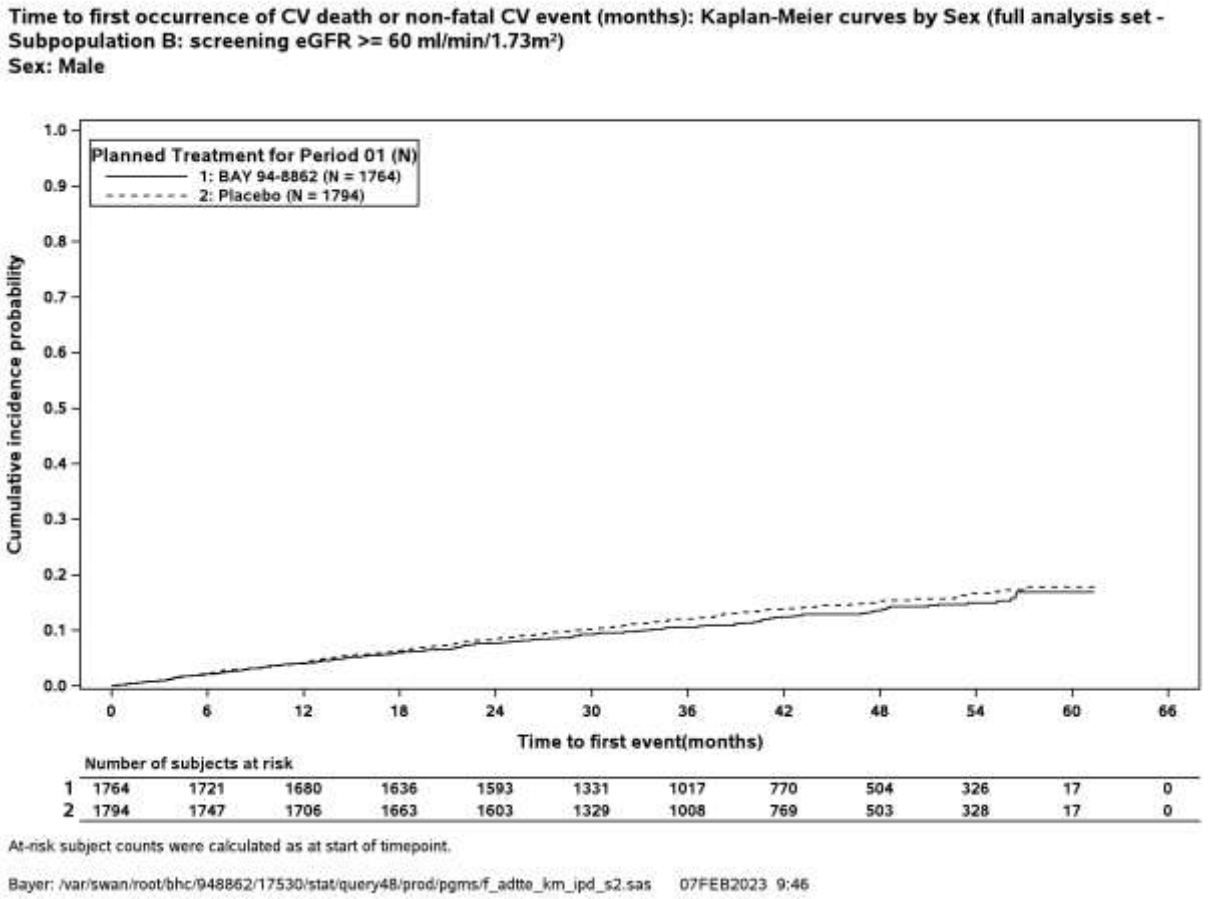


Figure 1.2.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

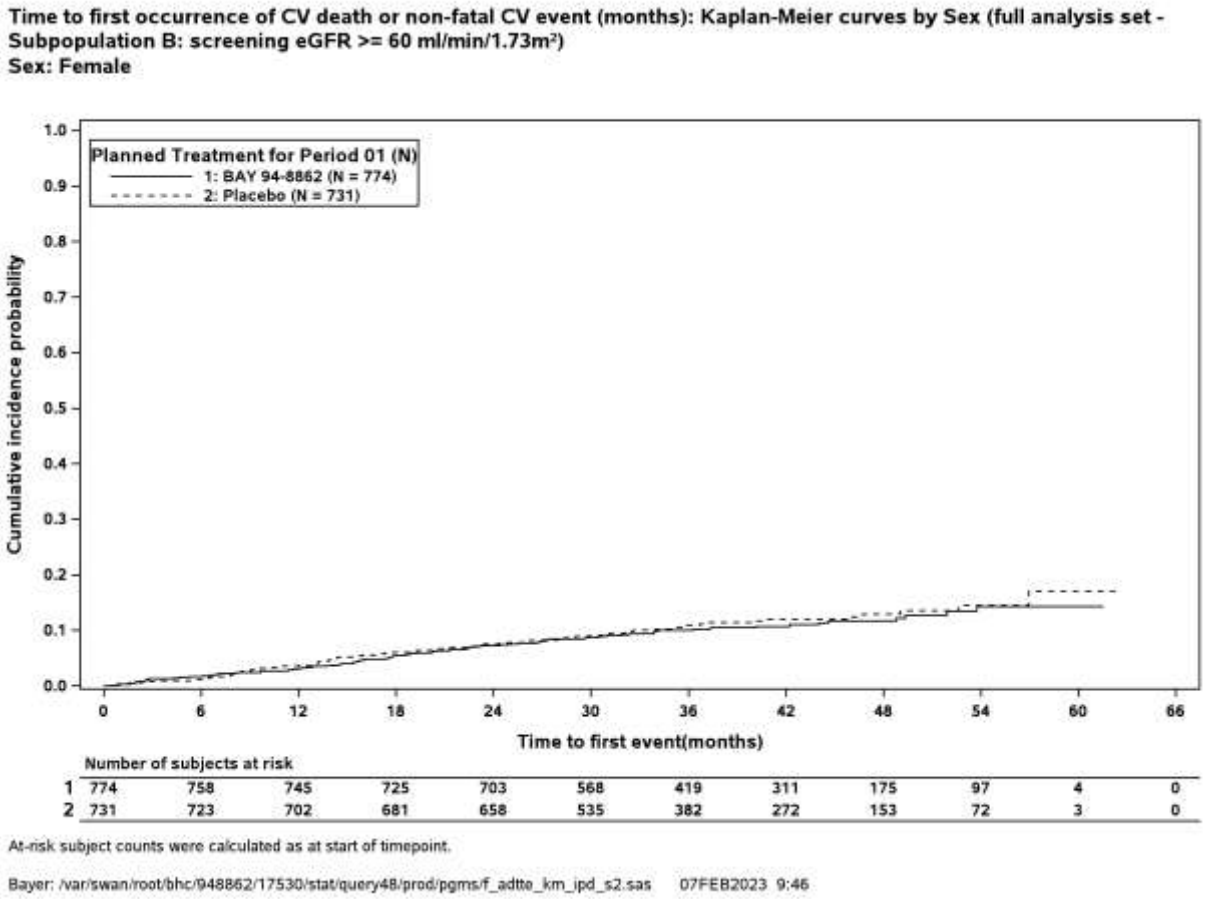


Figure 1.2.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

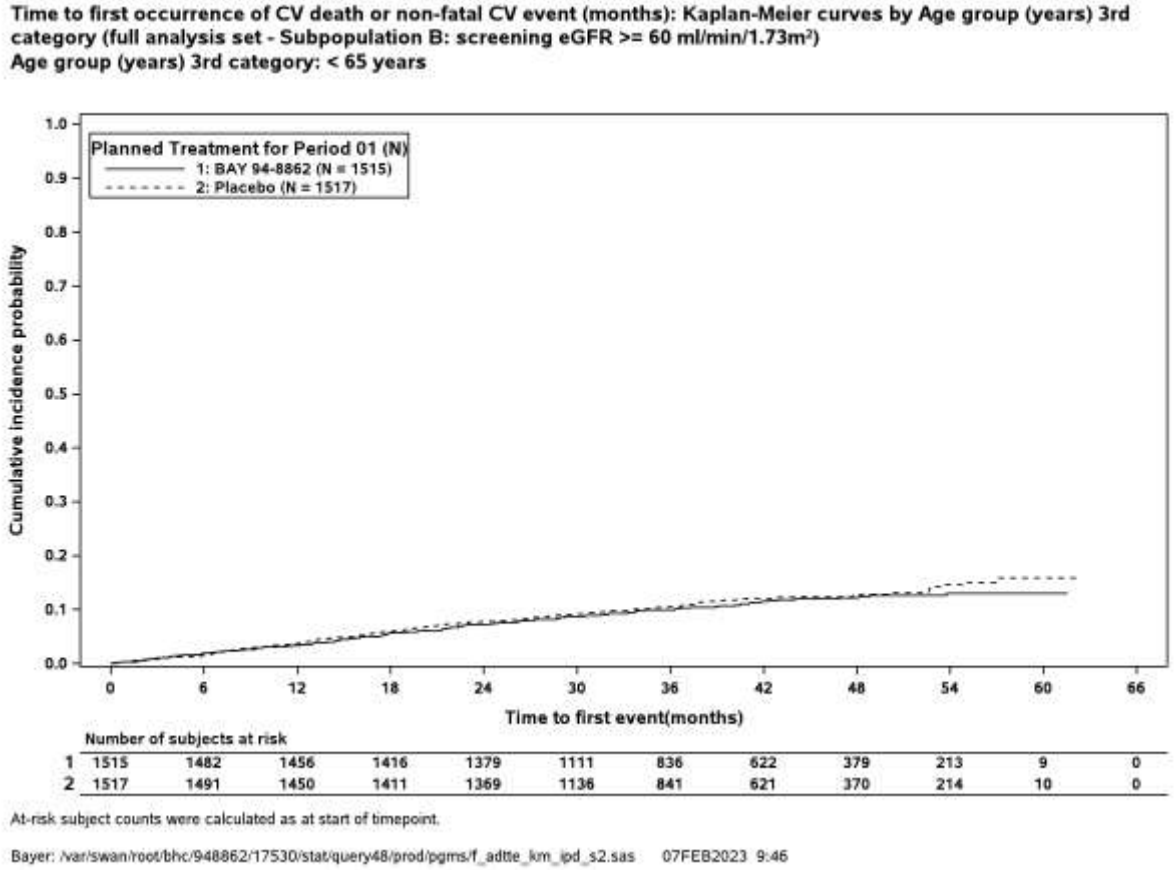


Figure 1.2.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

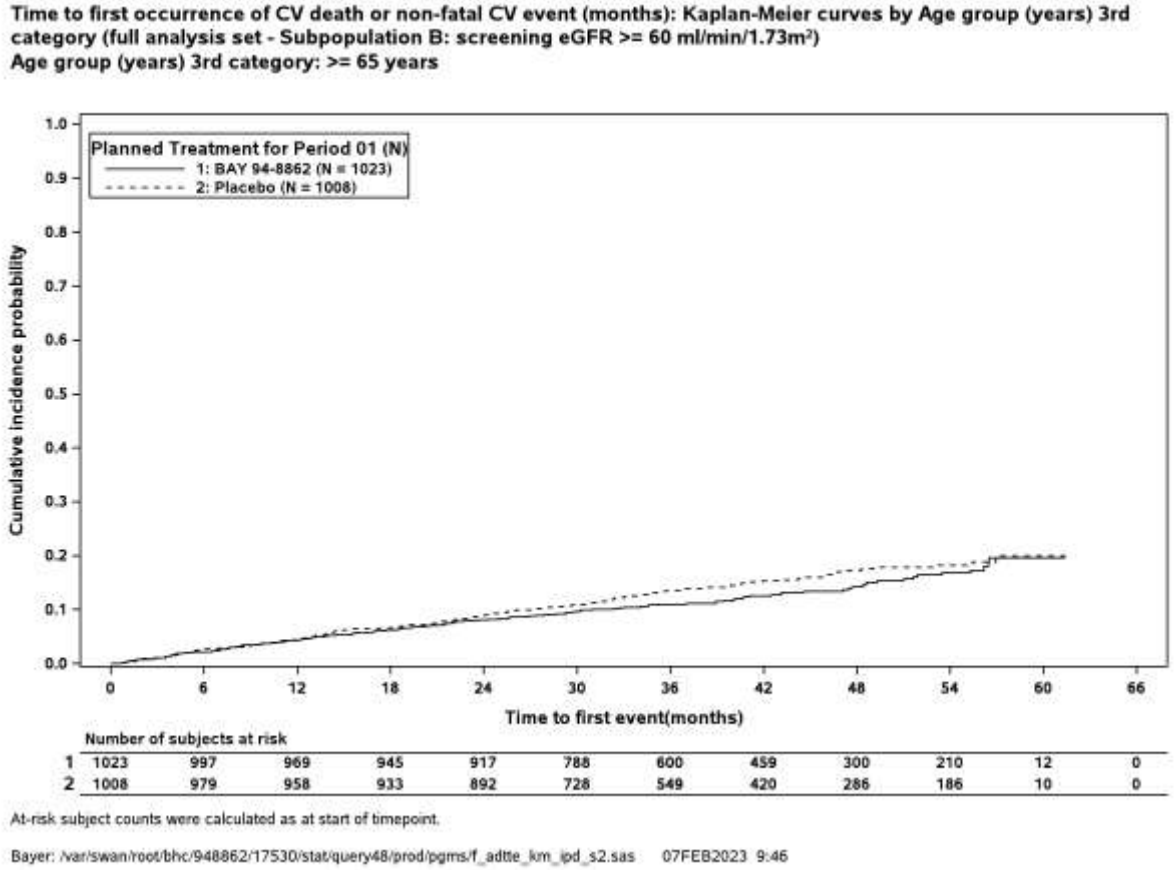


Figure 1.2.1 / 43: Time to CV death (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

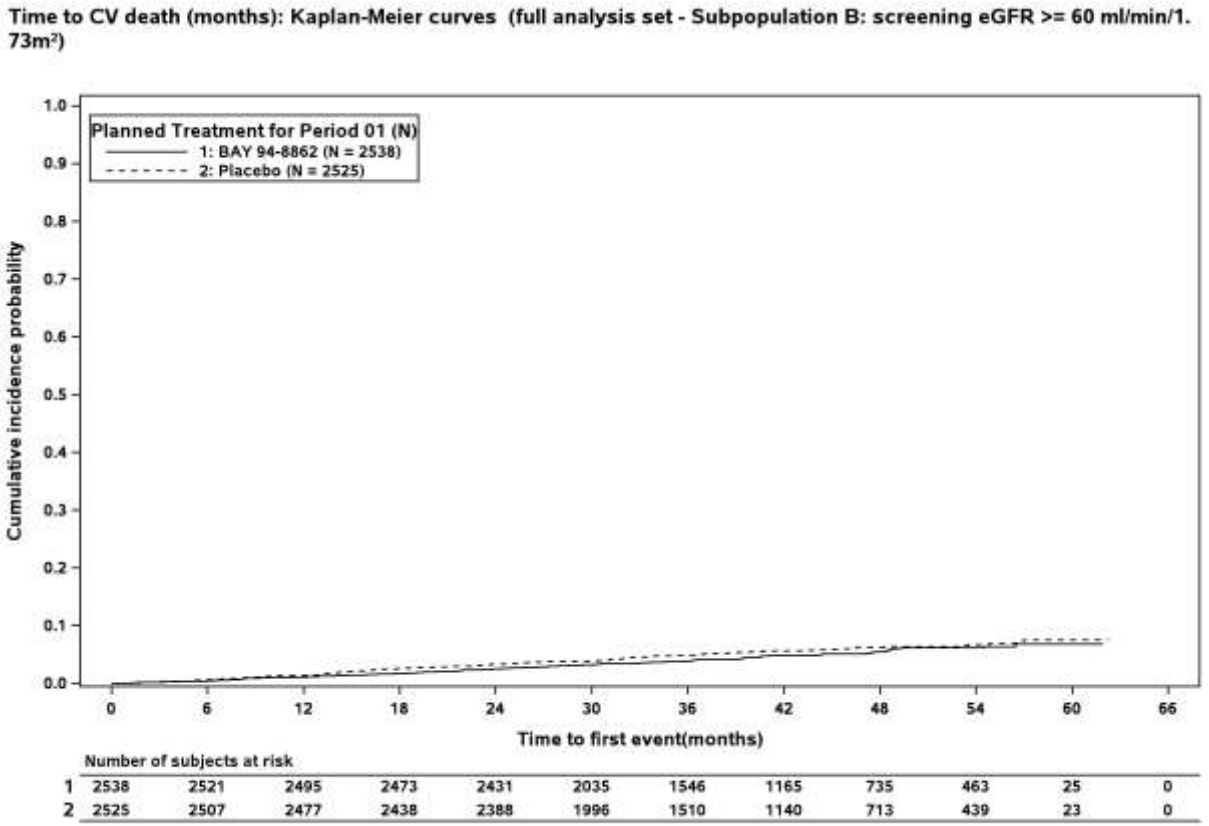


Figure 1.2.1 / 44: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

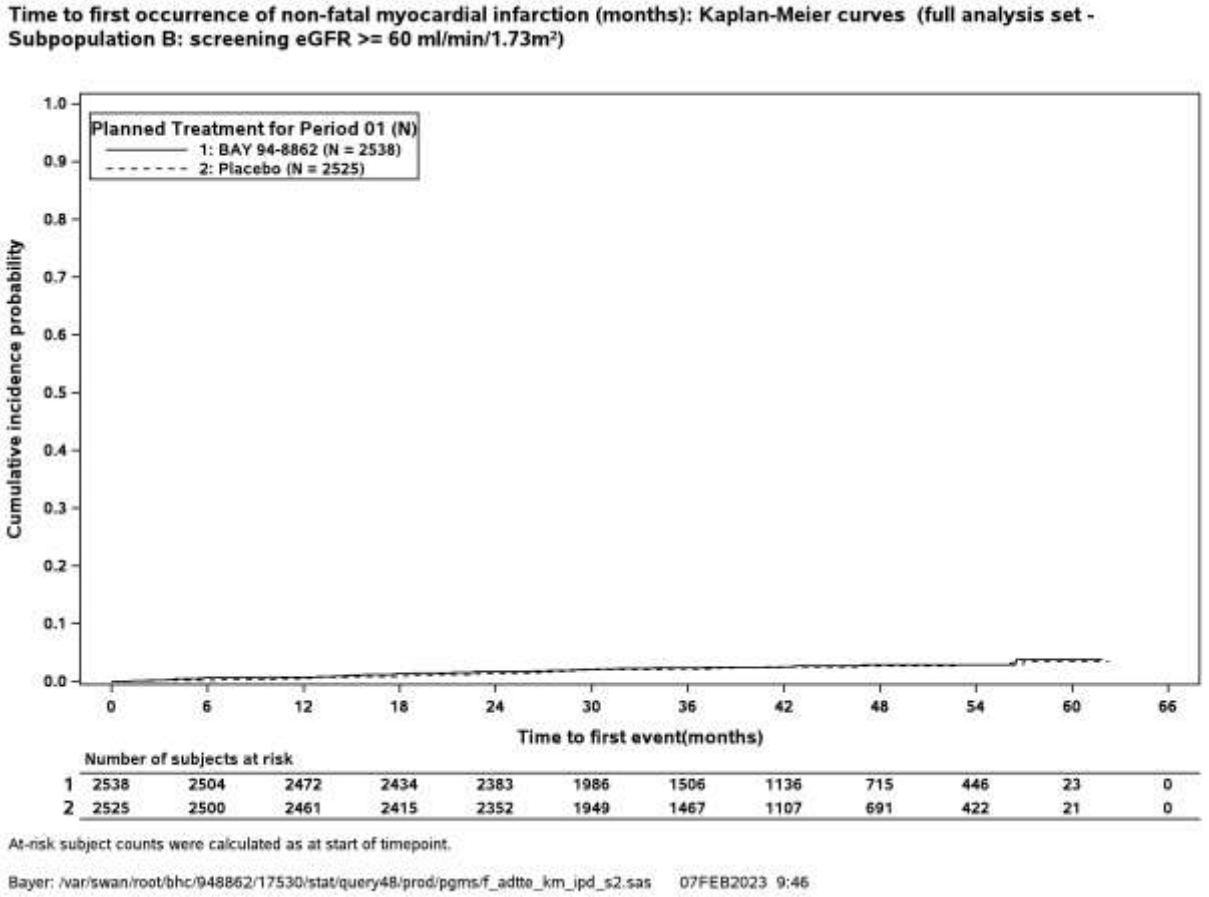
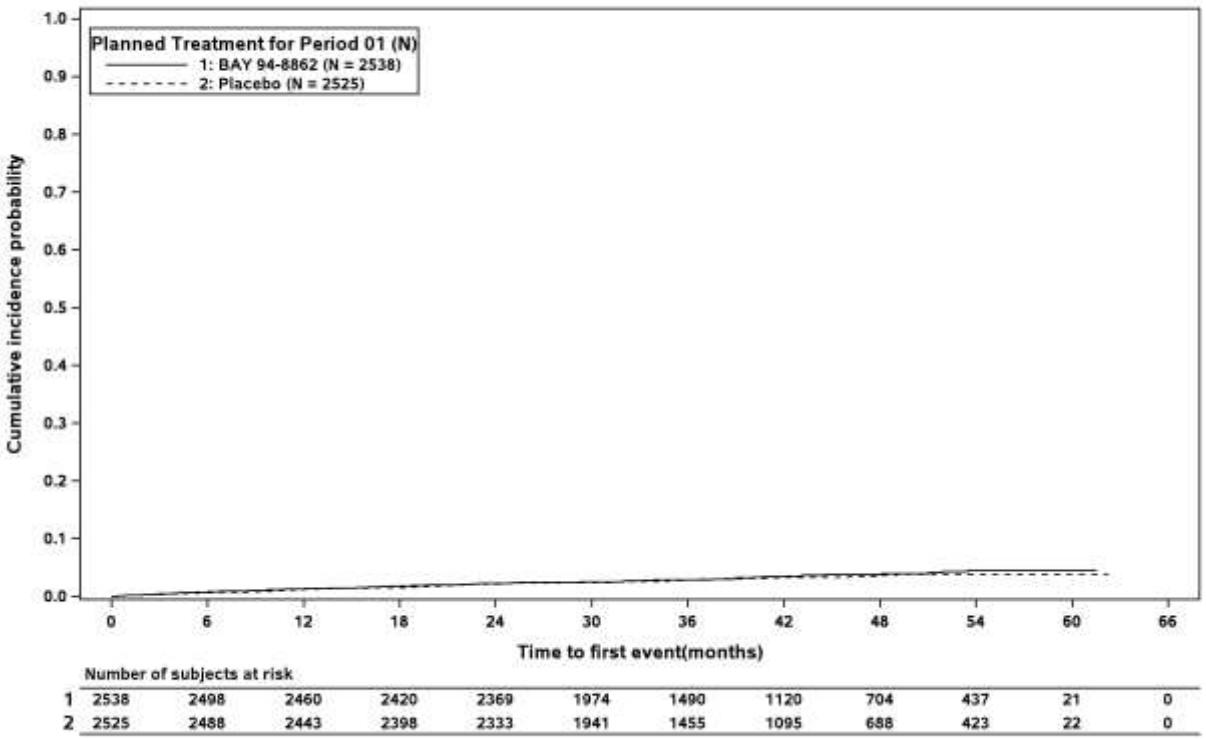


Figure 1.2.1 / 45: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Number of subjects at risk

1	2538	2498	2460	2420	2369	1974	1490	1120	704	437	21	0
2	2525	2488	2443	2398	2333	1941	1455	1095	688	423	22	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 46: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

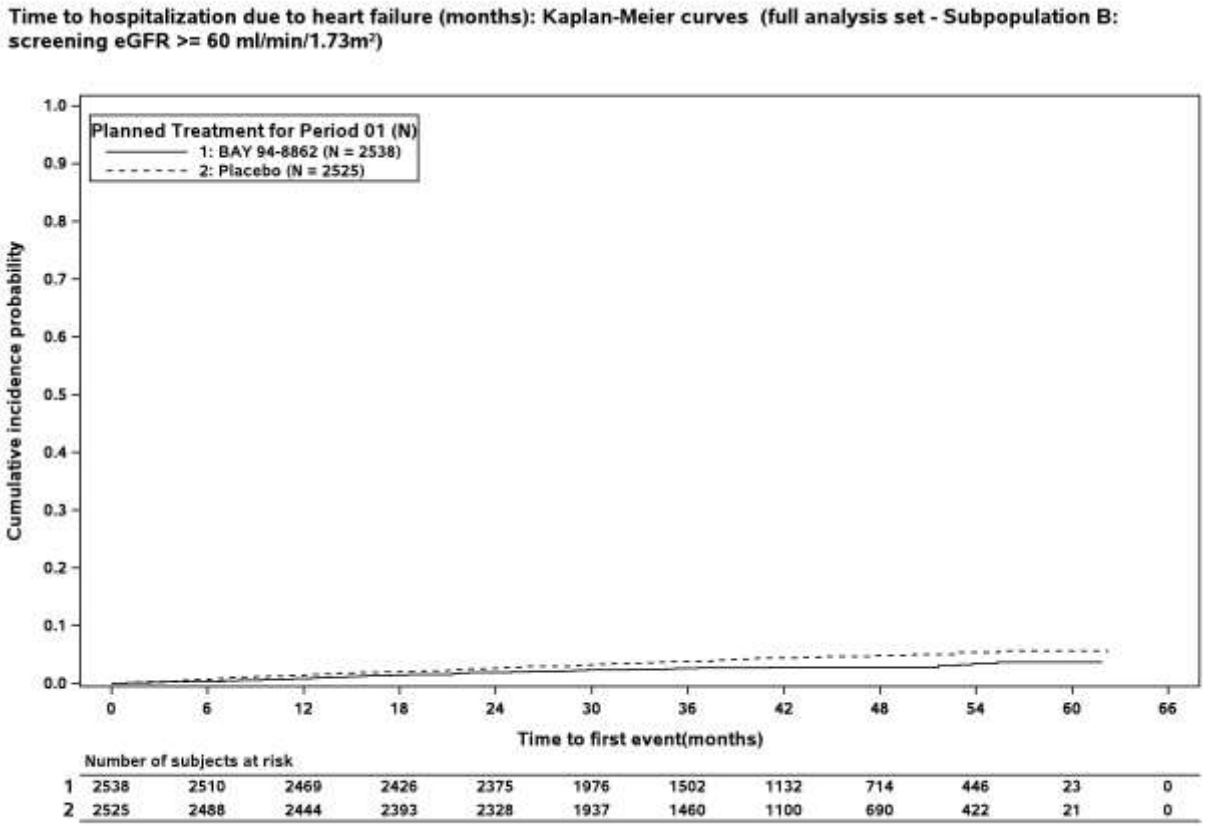


Figure 1.2.1 / 47: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

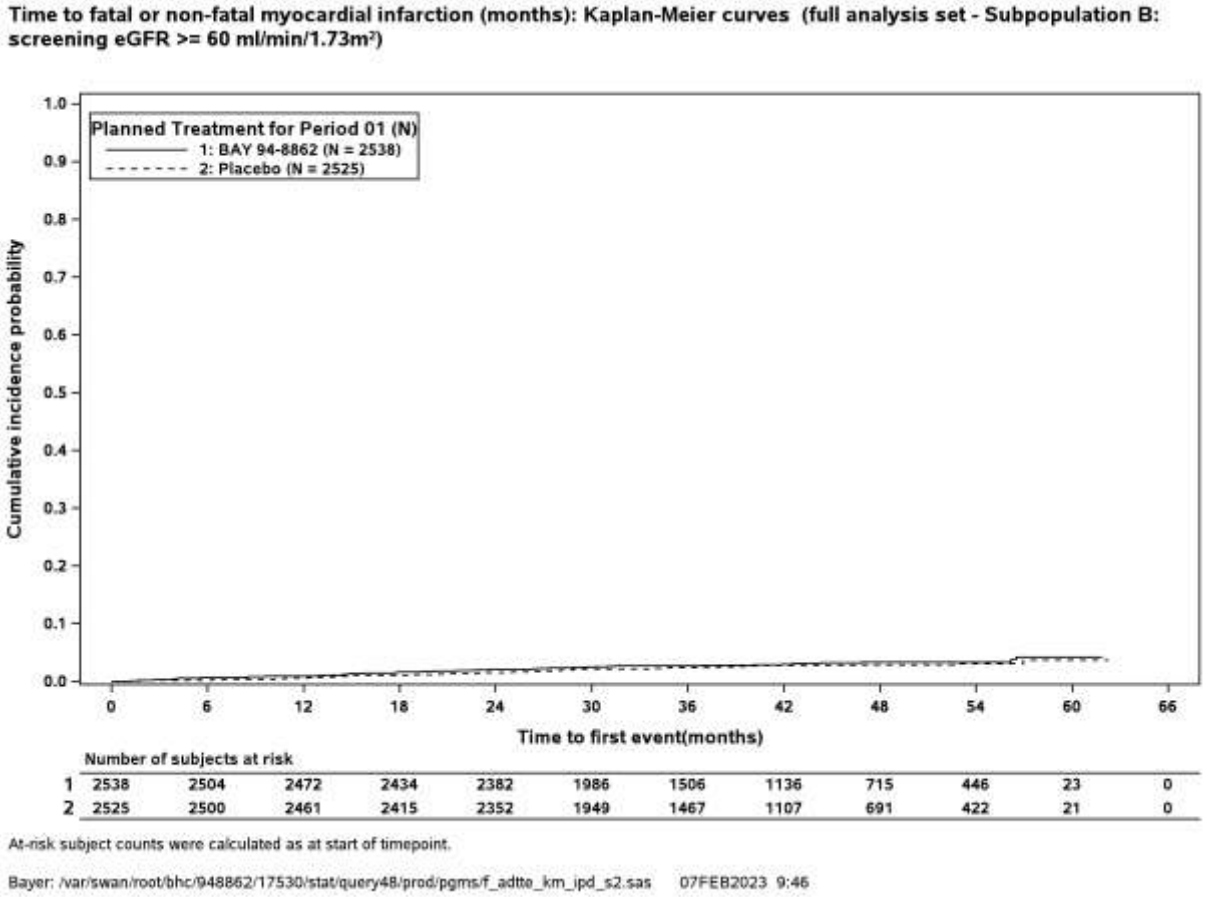


Figure 1.2.1 / 48: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

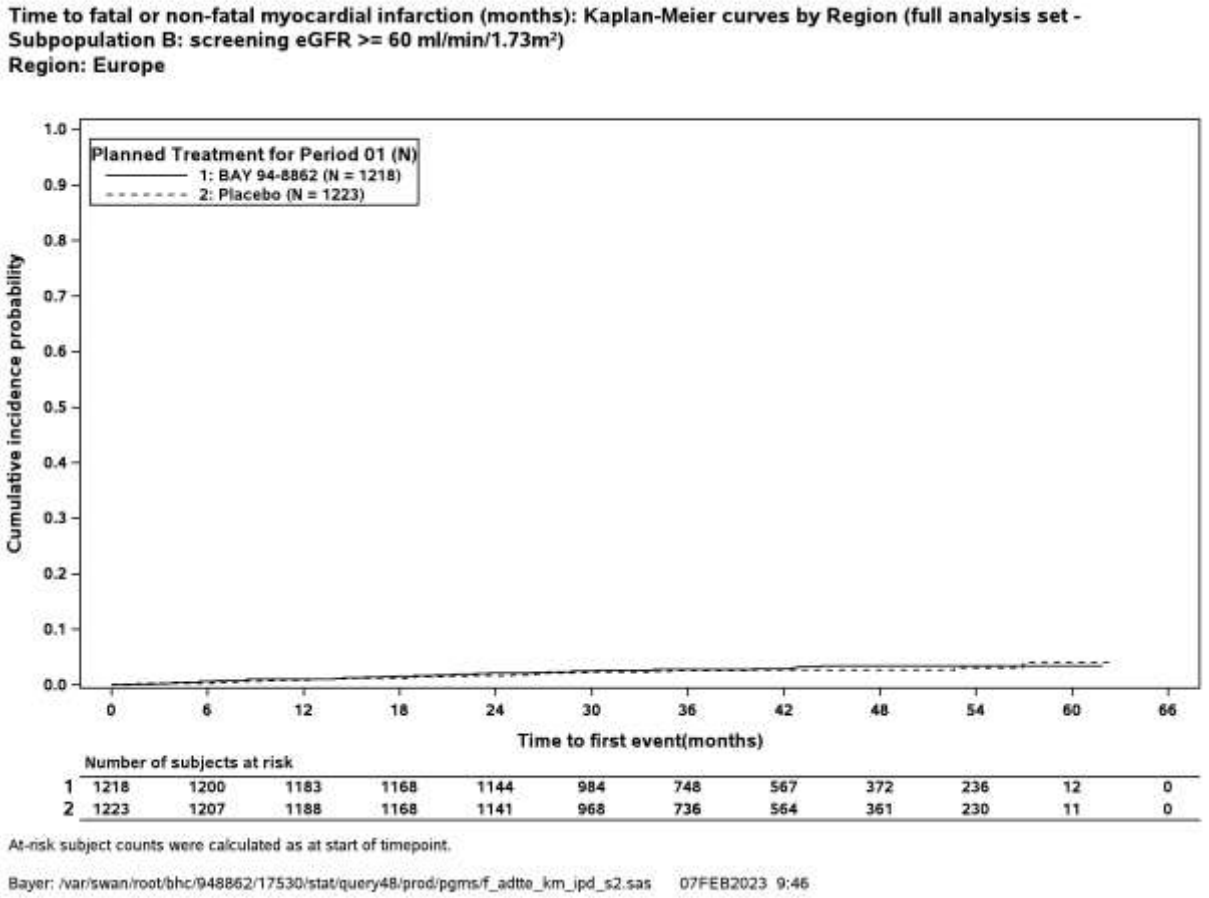


Figure 1.2.1 / 48: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

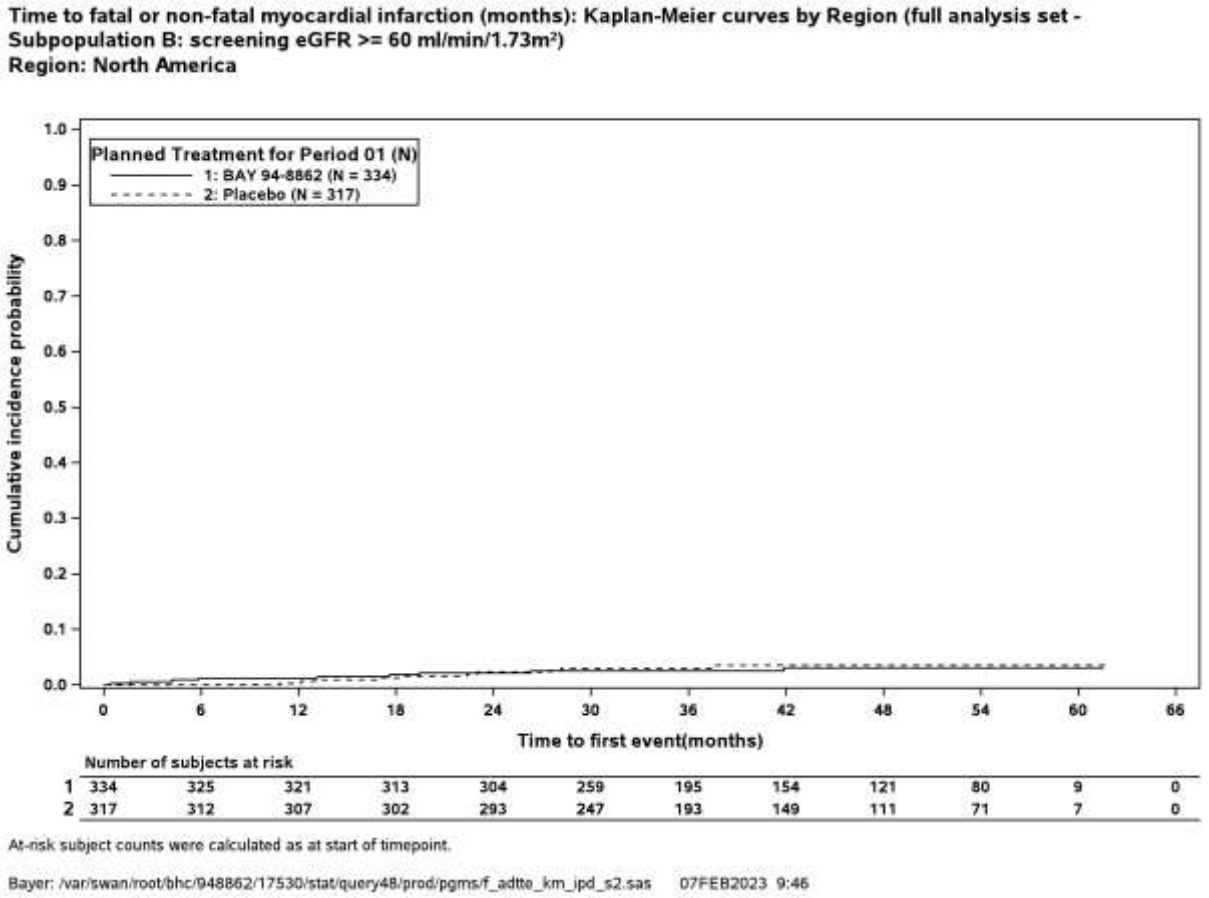


Figure 1.2.1 / 48: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

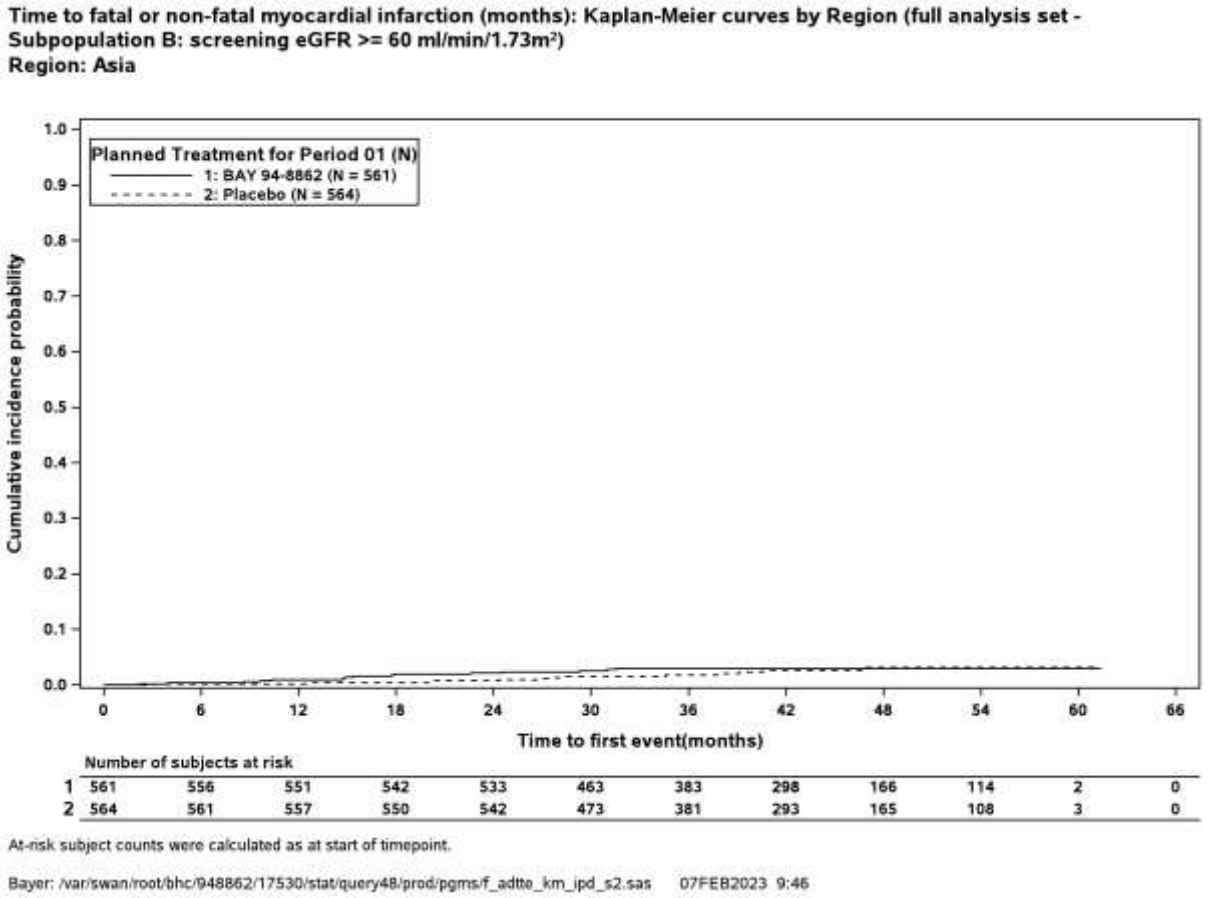


Figure 1.2.1 / 48: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

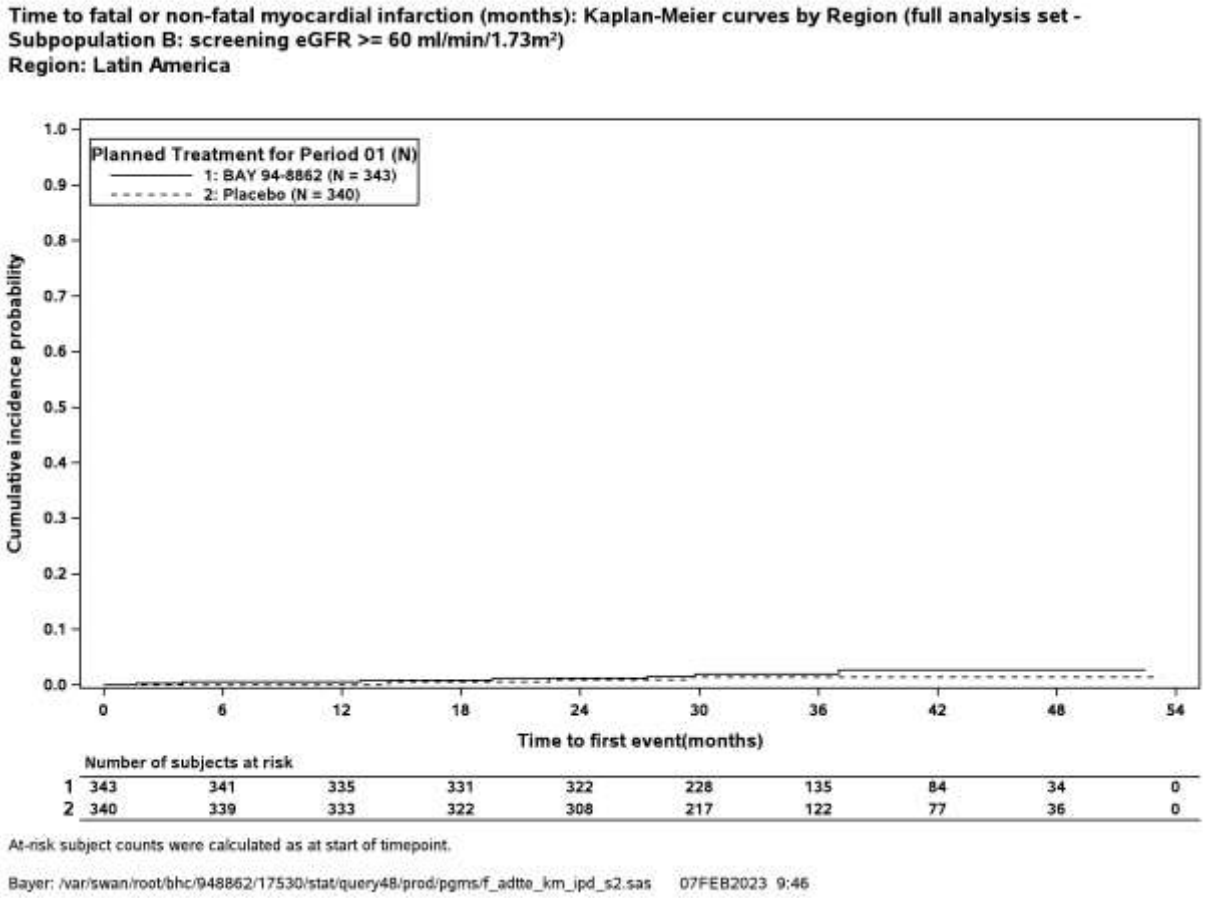


Figure 1.2.1 / 48: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

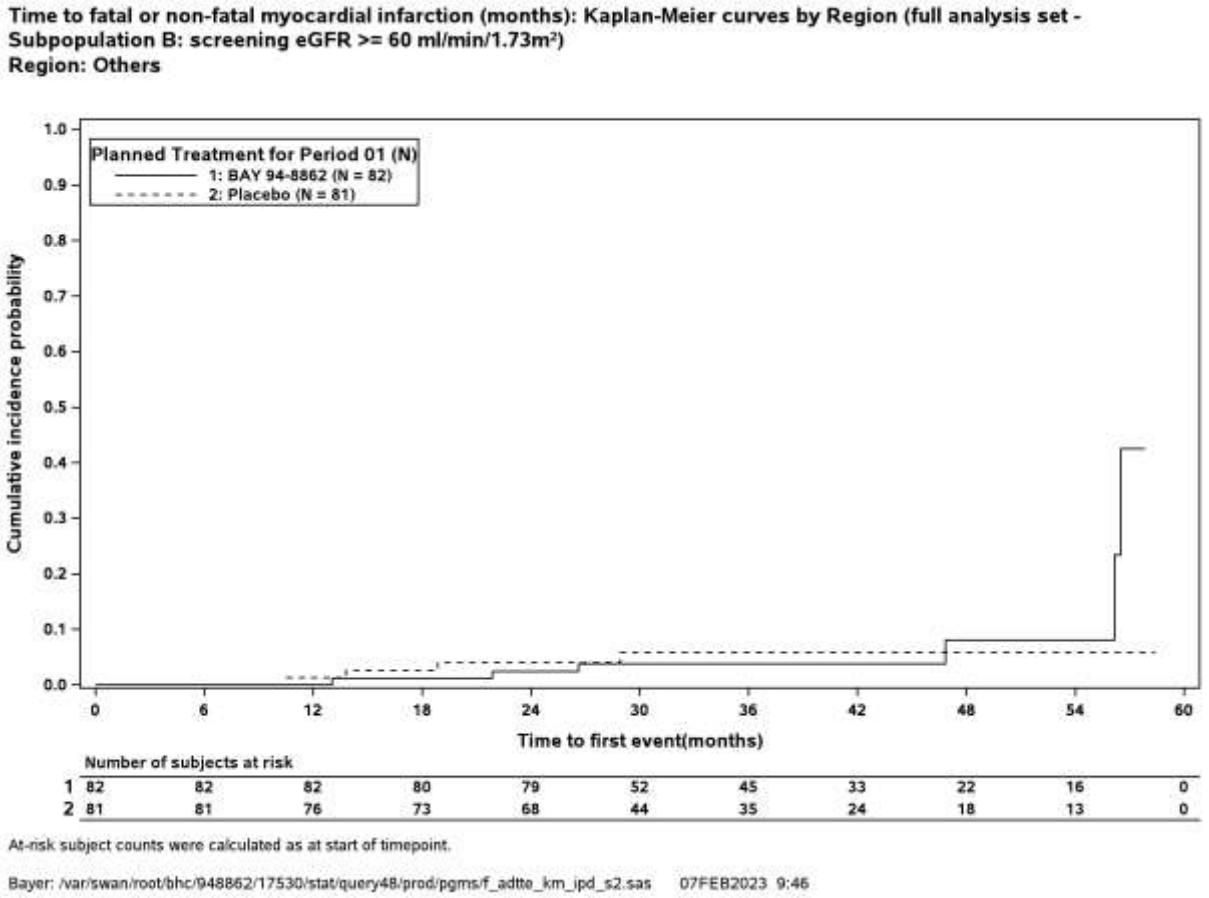


Figure 1.2.1 / 49: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

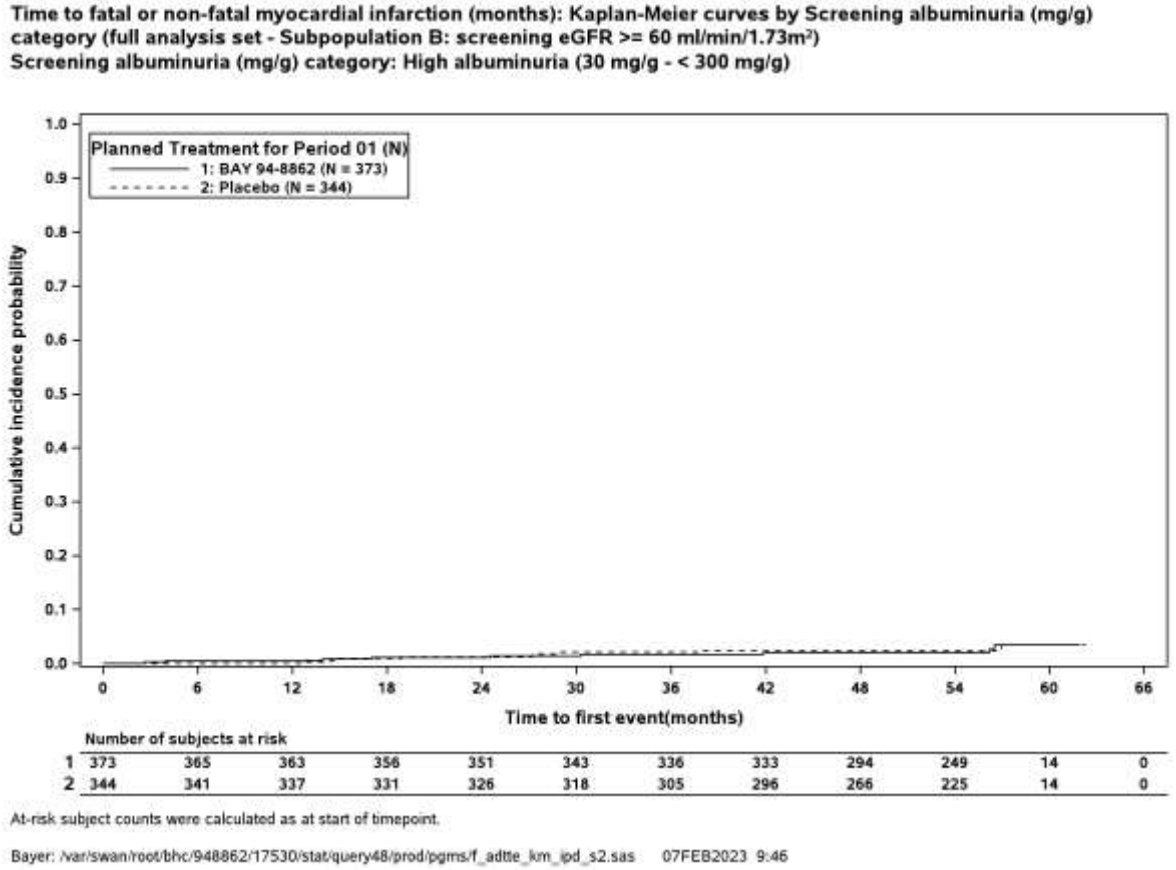


Figure 1.2.1 / 49: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

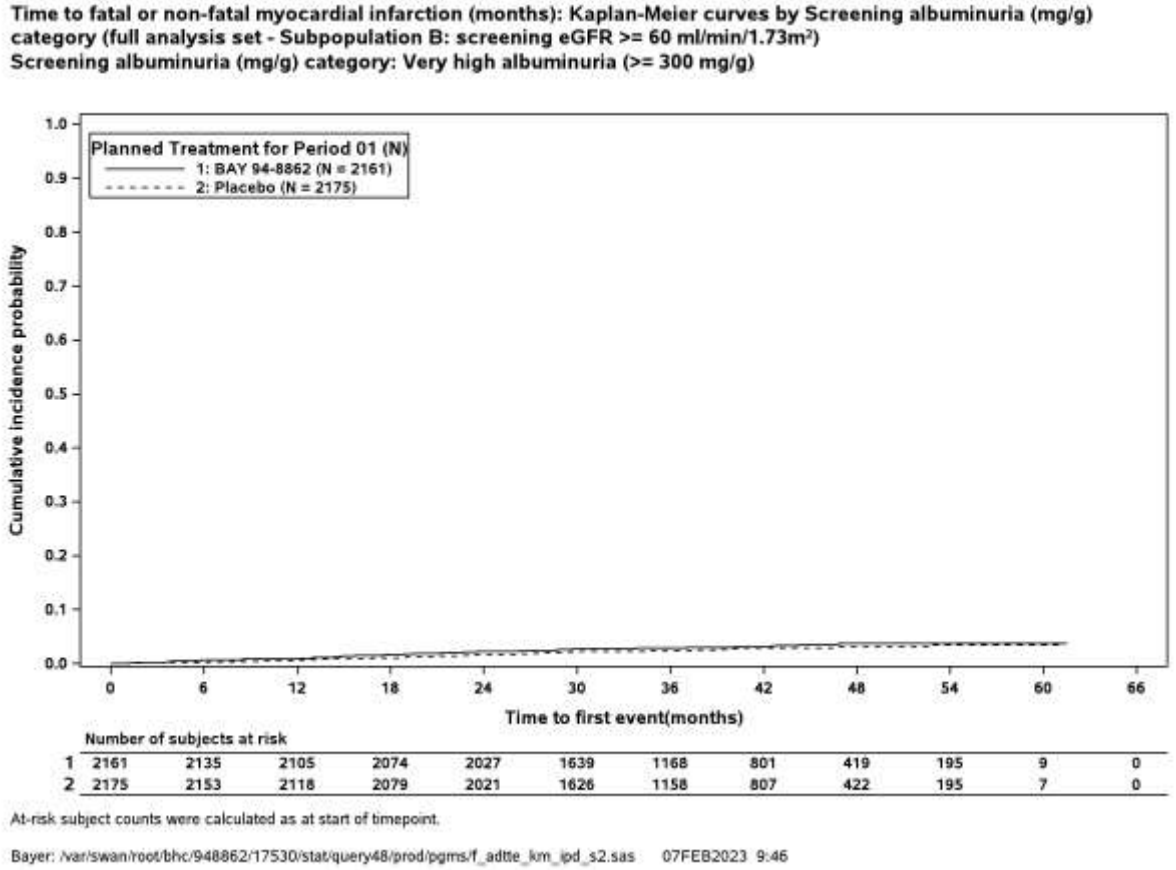


Figure 1.2.1 / 50: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

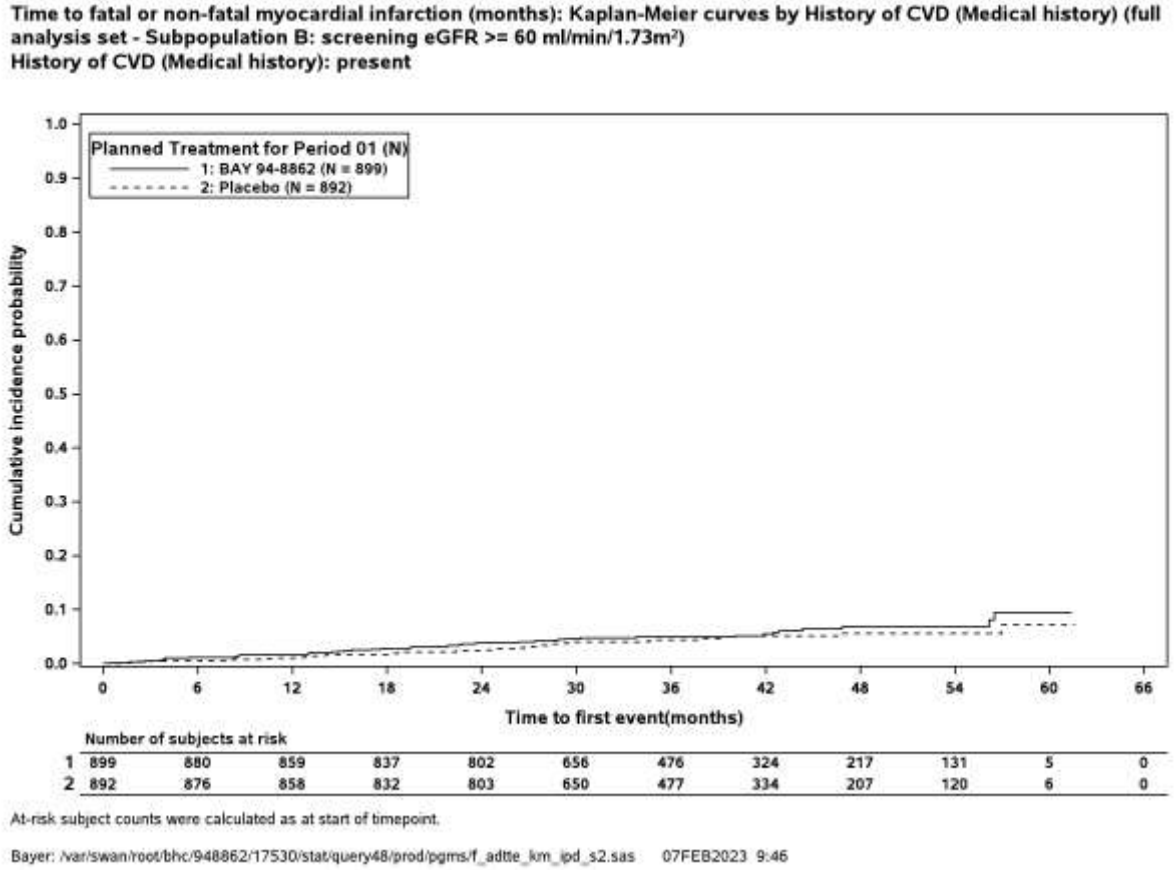


Figure 1.2.1 / 50: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

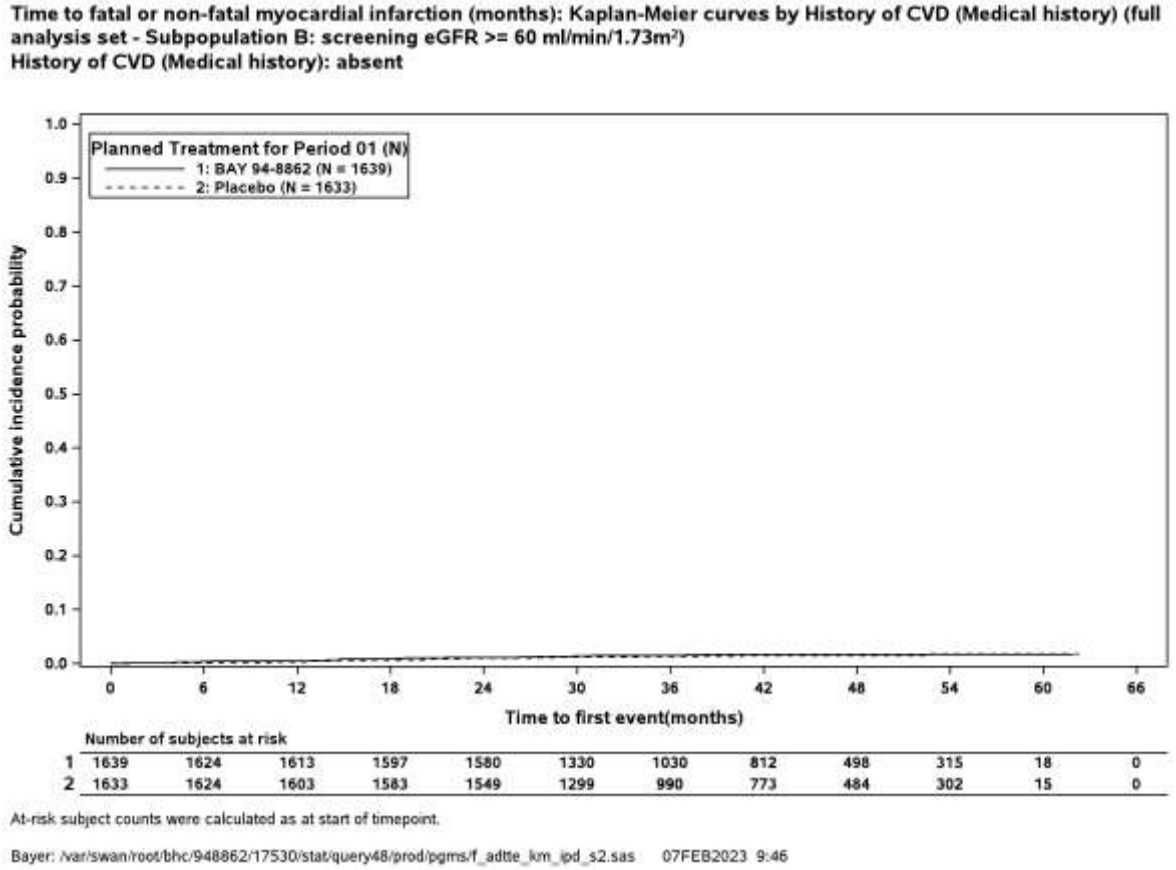


Figure 1.2.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

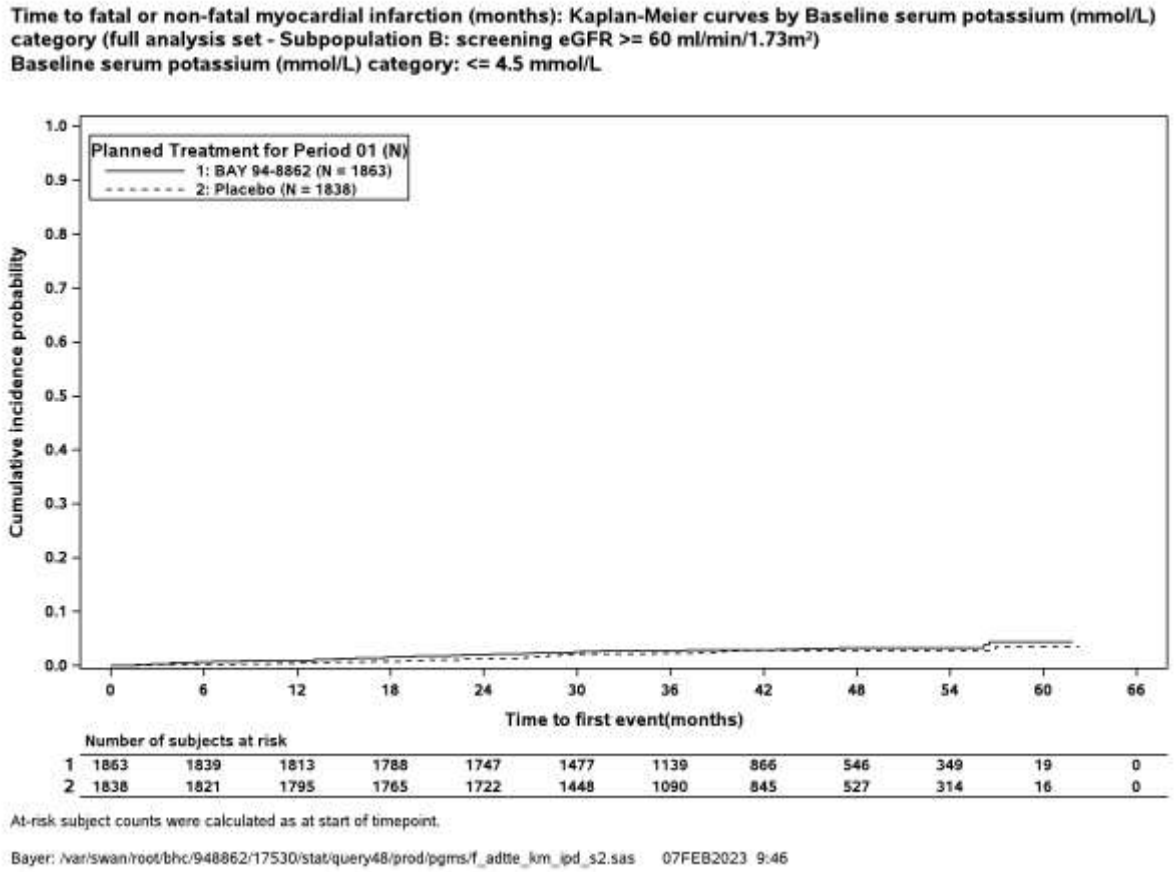


Figure 1.2.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

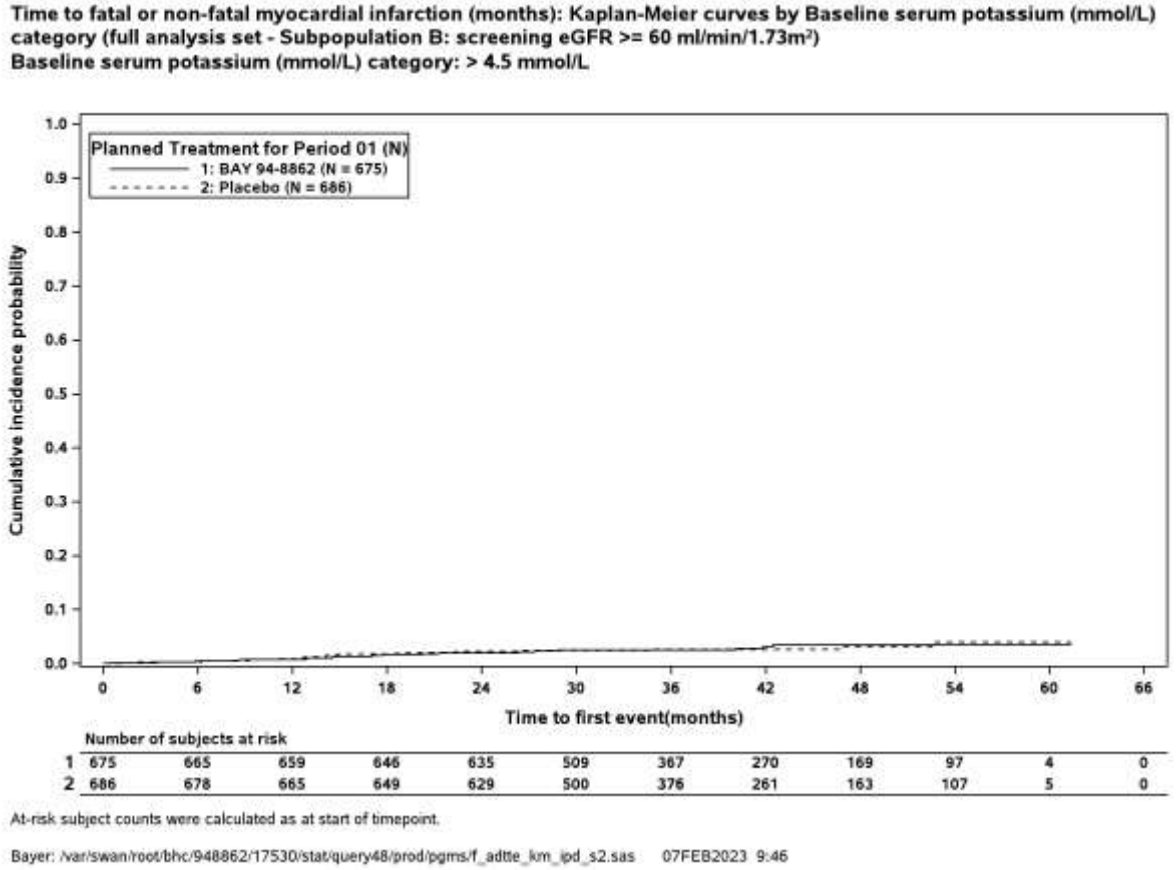


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

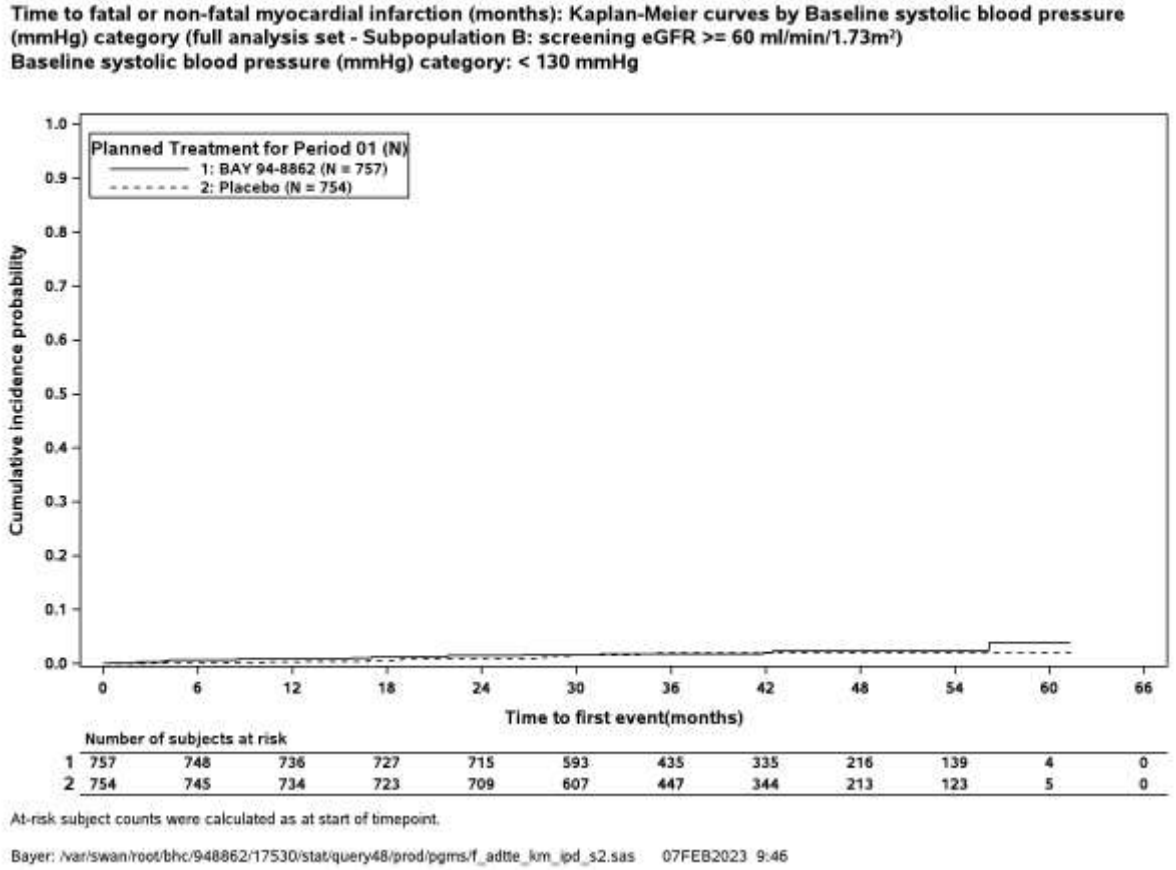


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

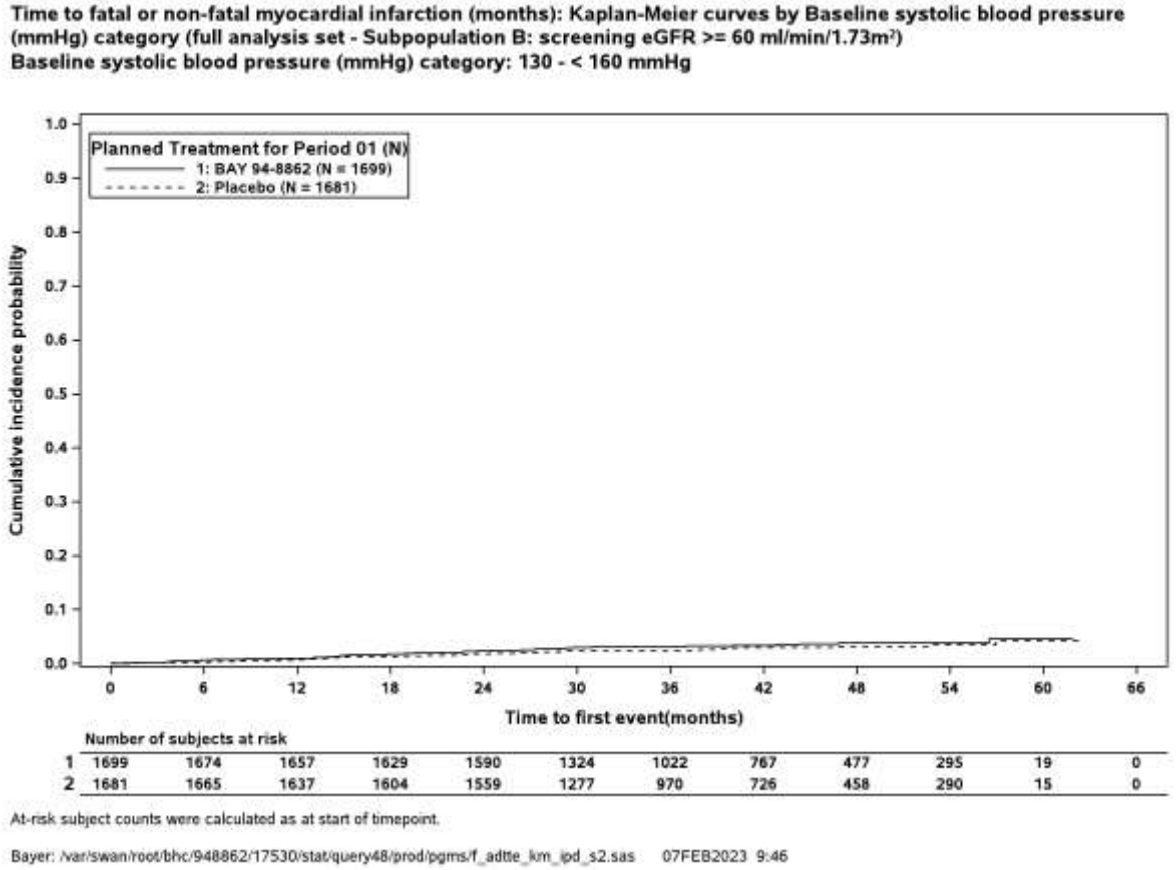


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

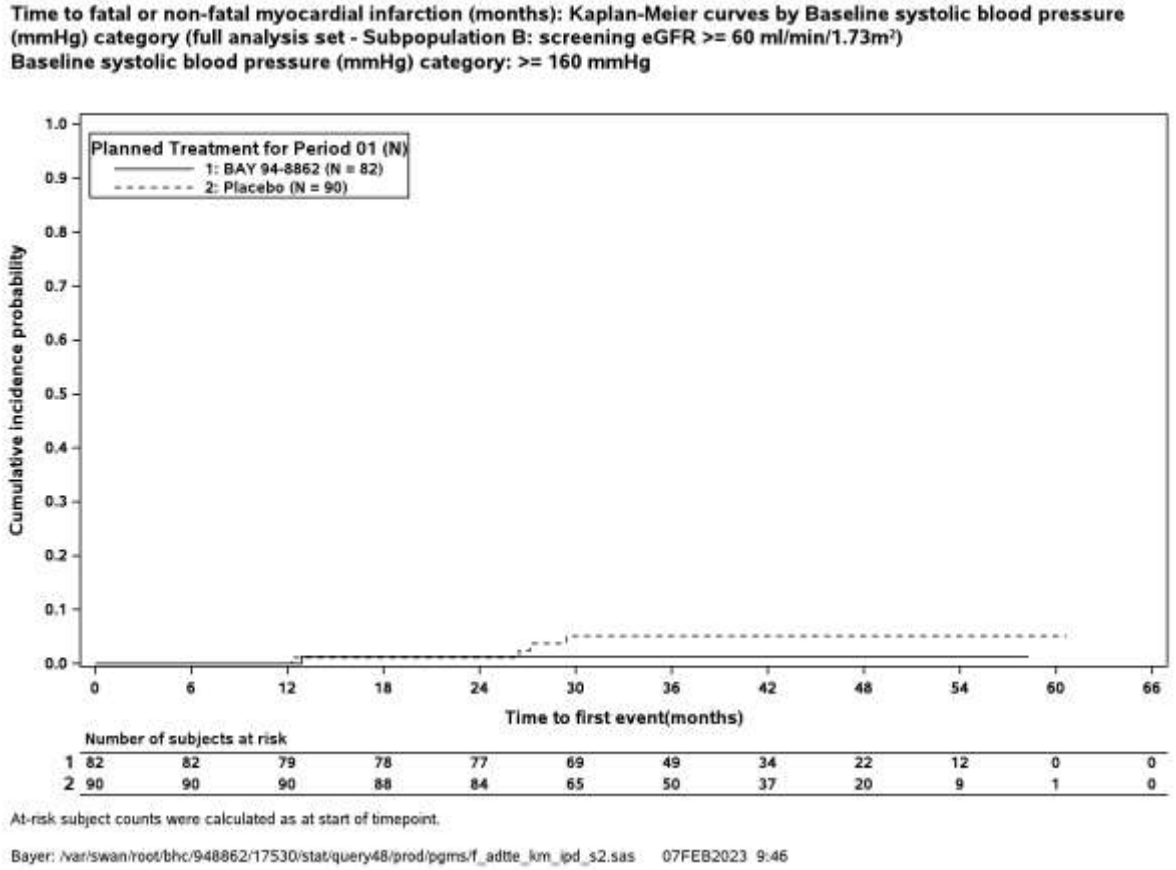


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

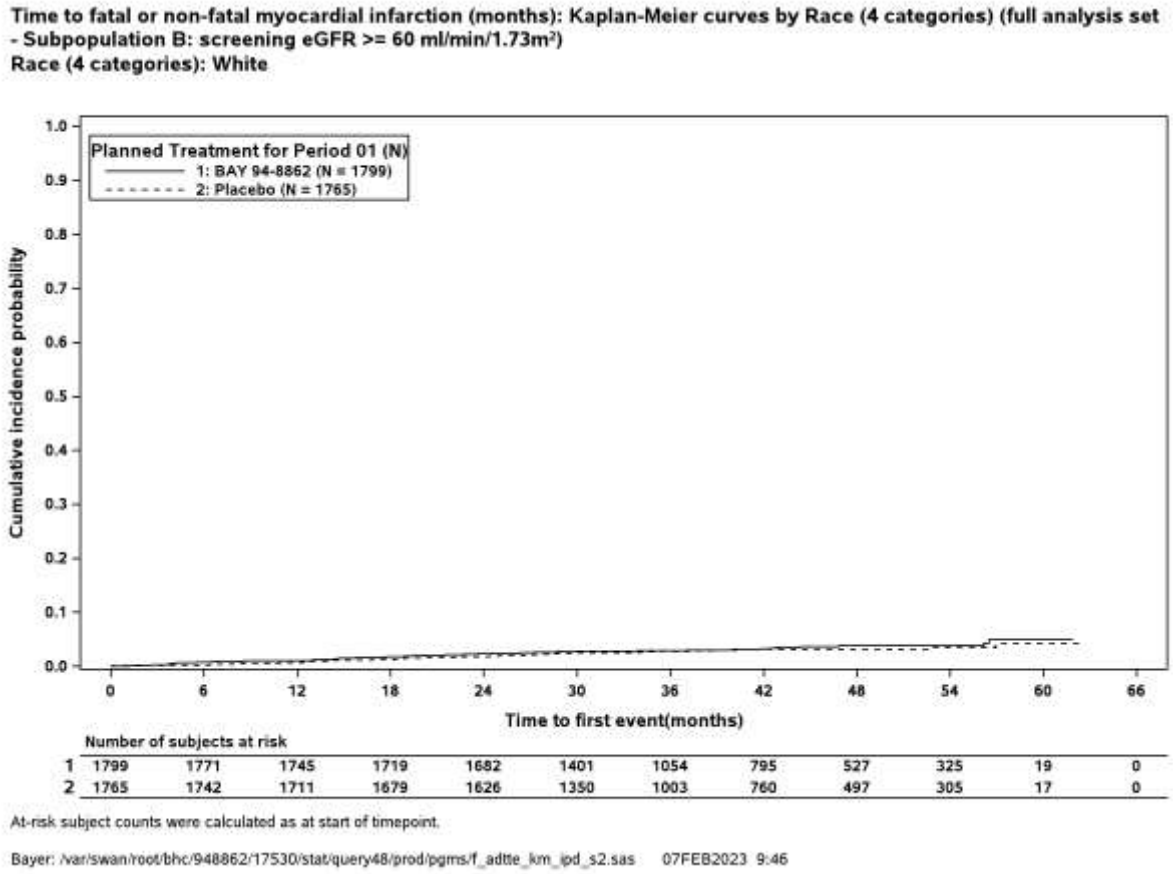


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

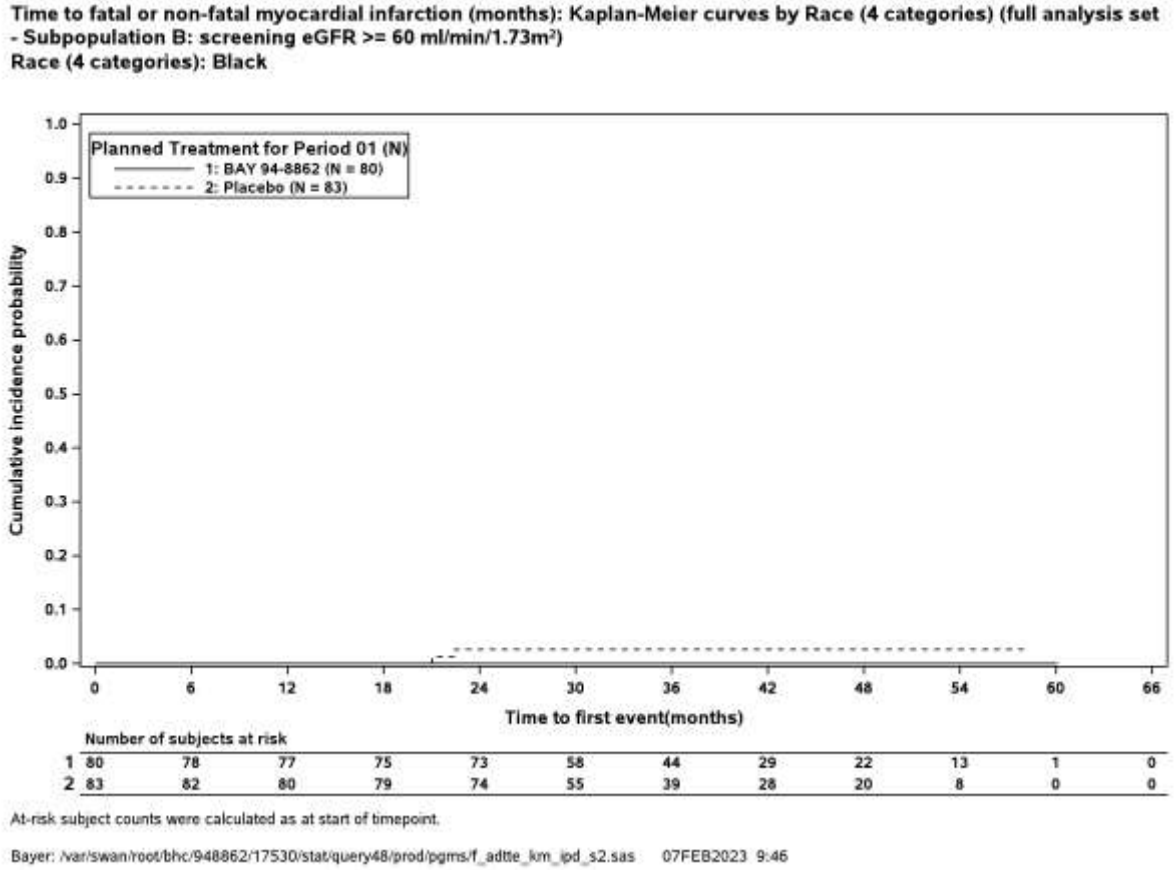


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

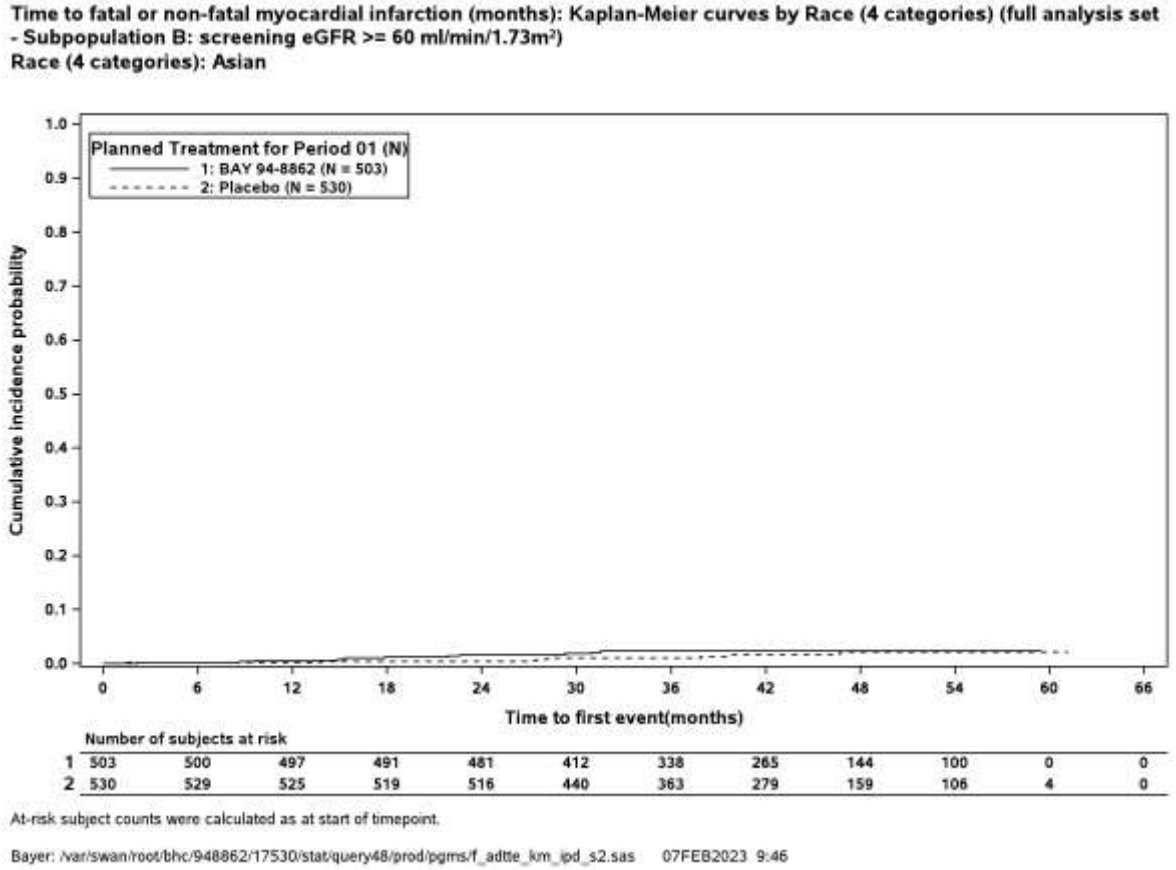


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

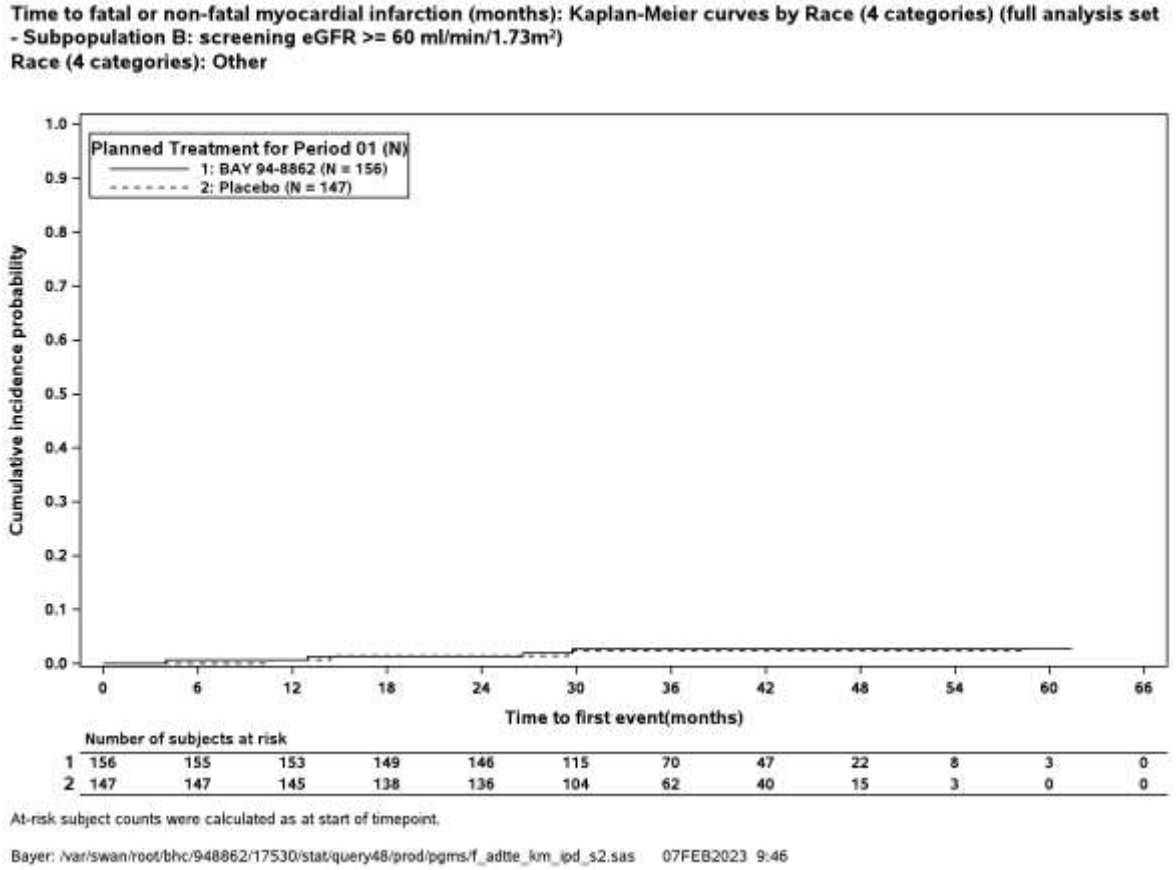


Figure 1.2.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

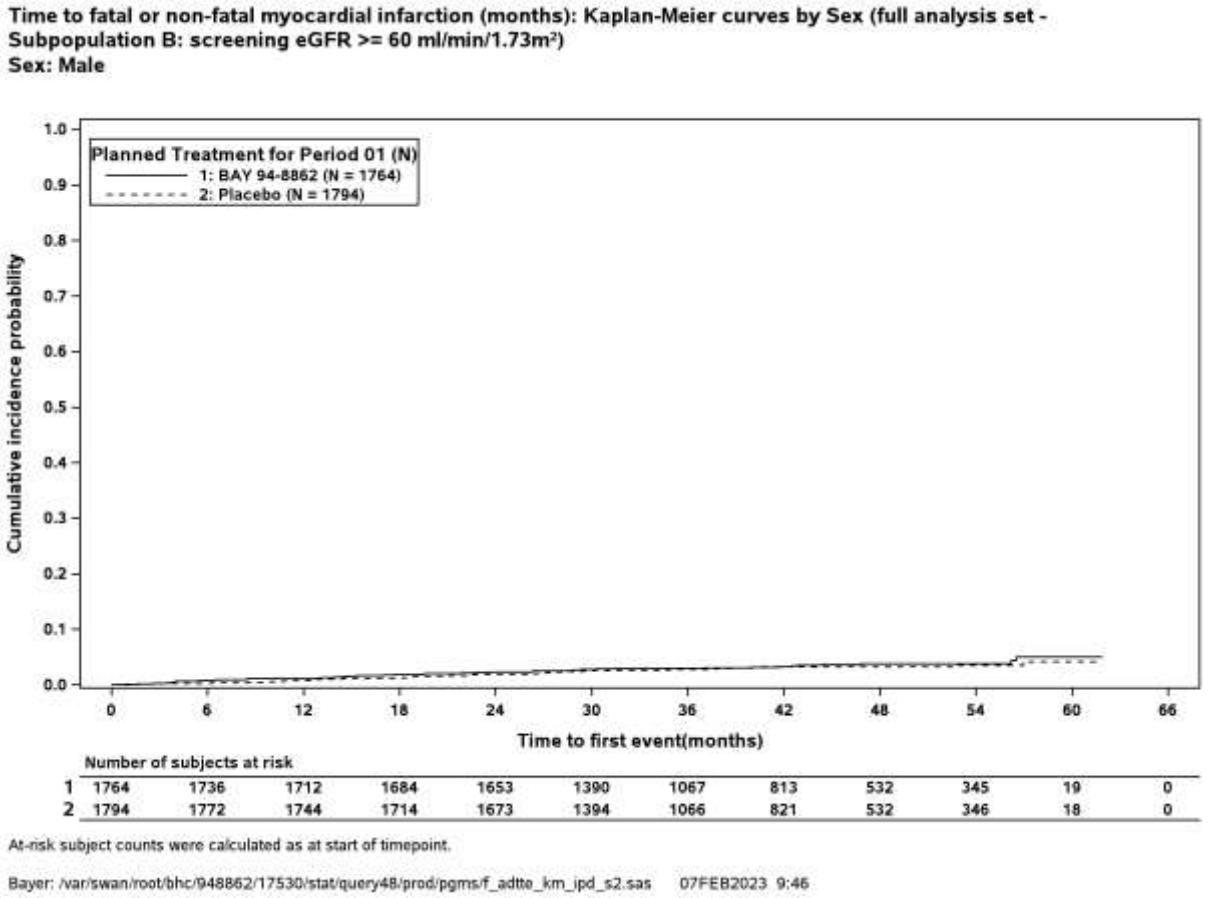


Figure 1.2.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

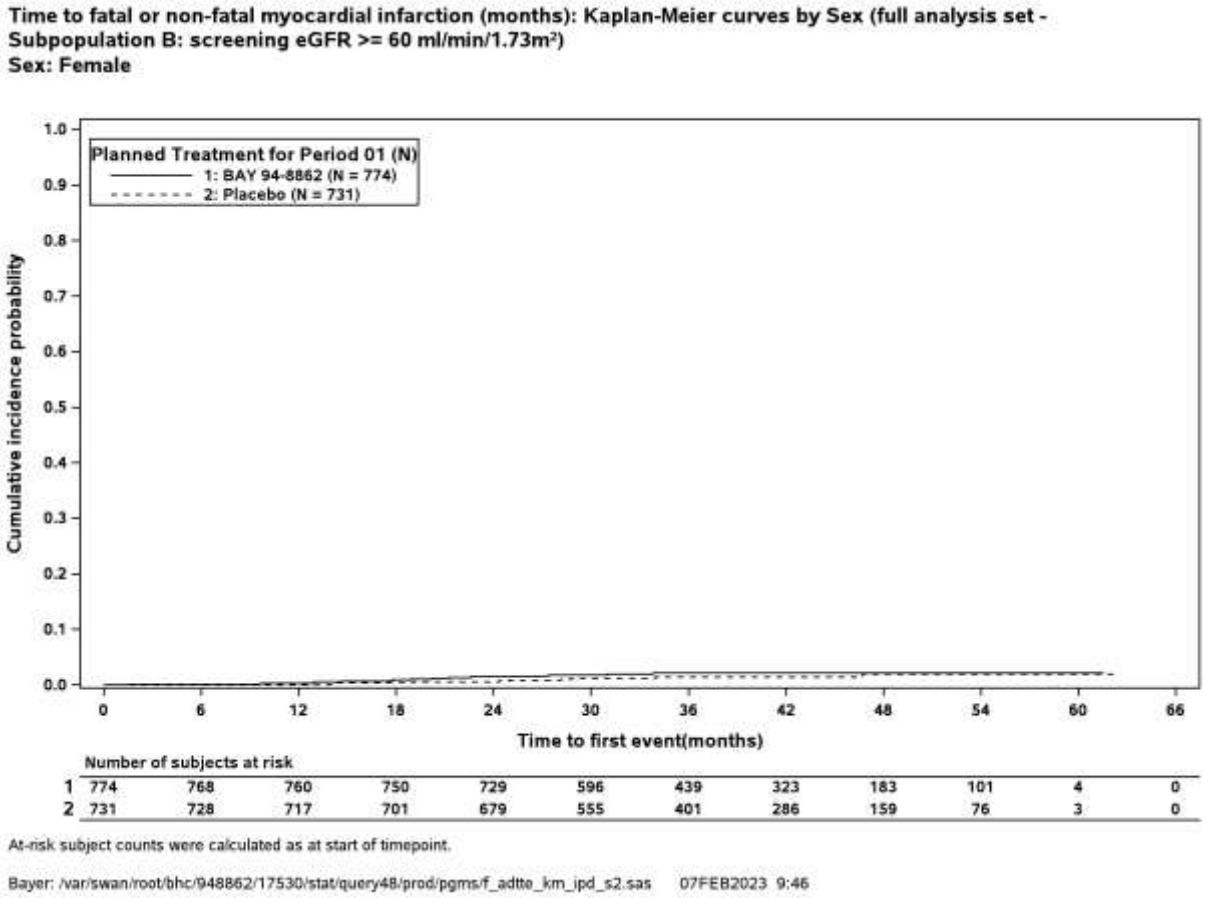


Figure 1.2.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

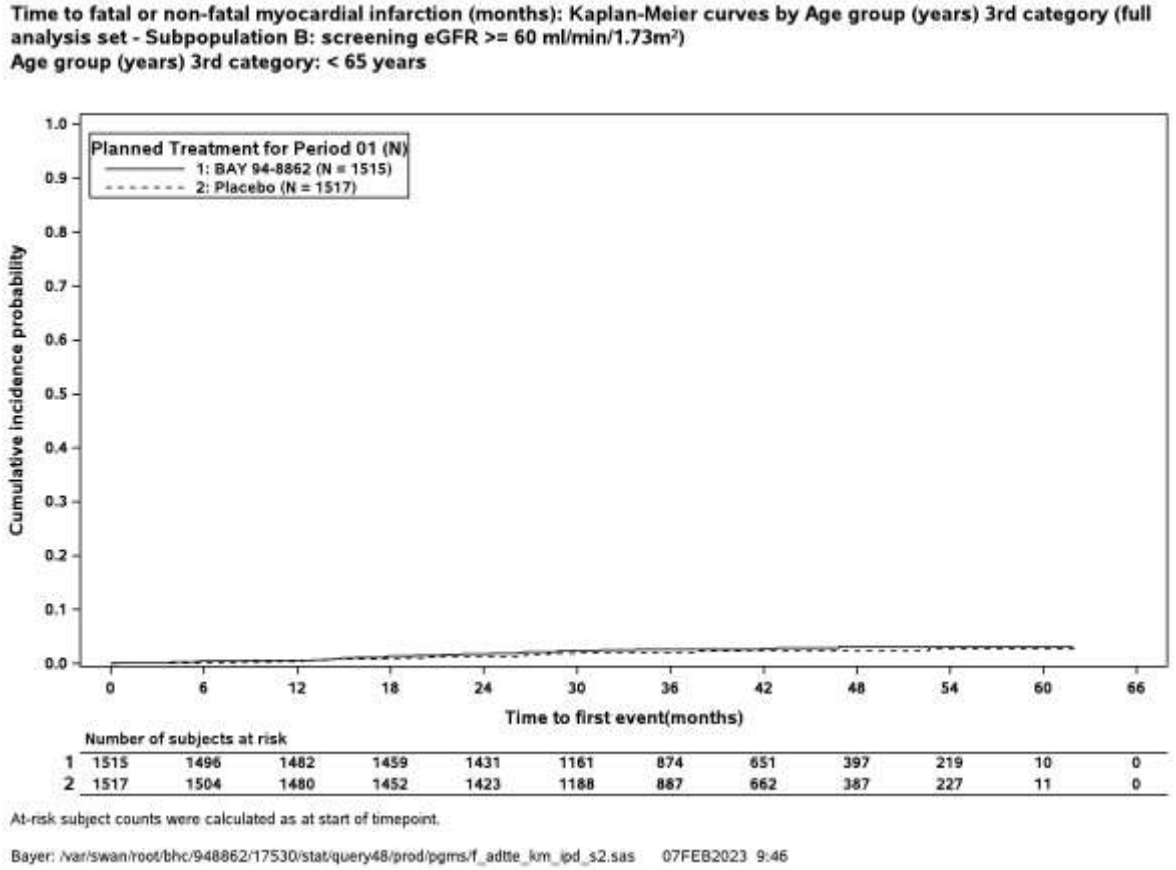


Figure 1.2.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

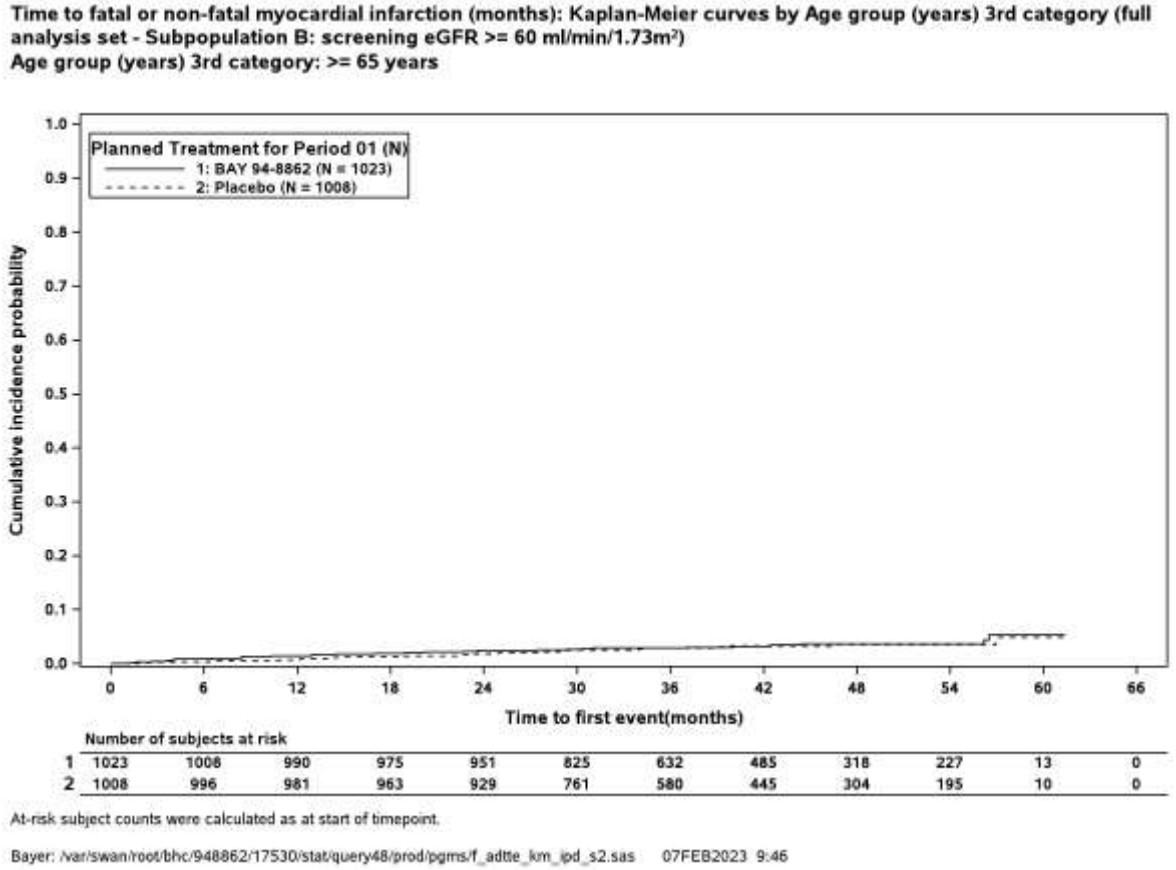


Figure 1.2.1 / 56: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

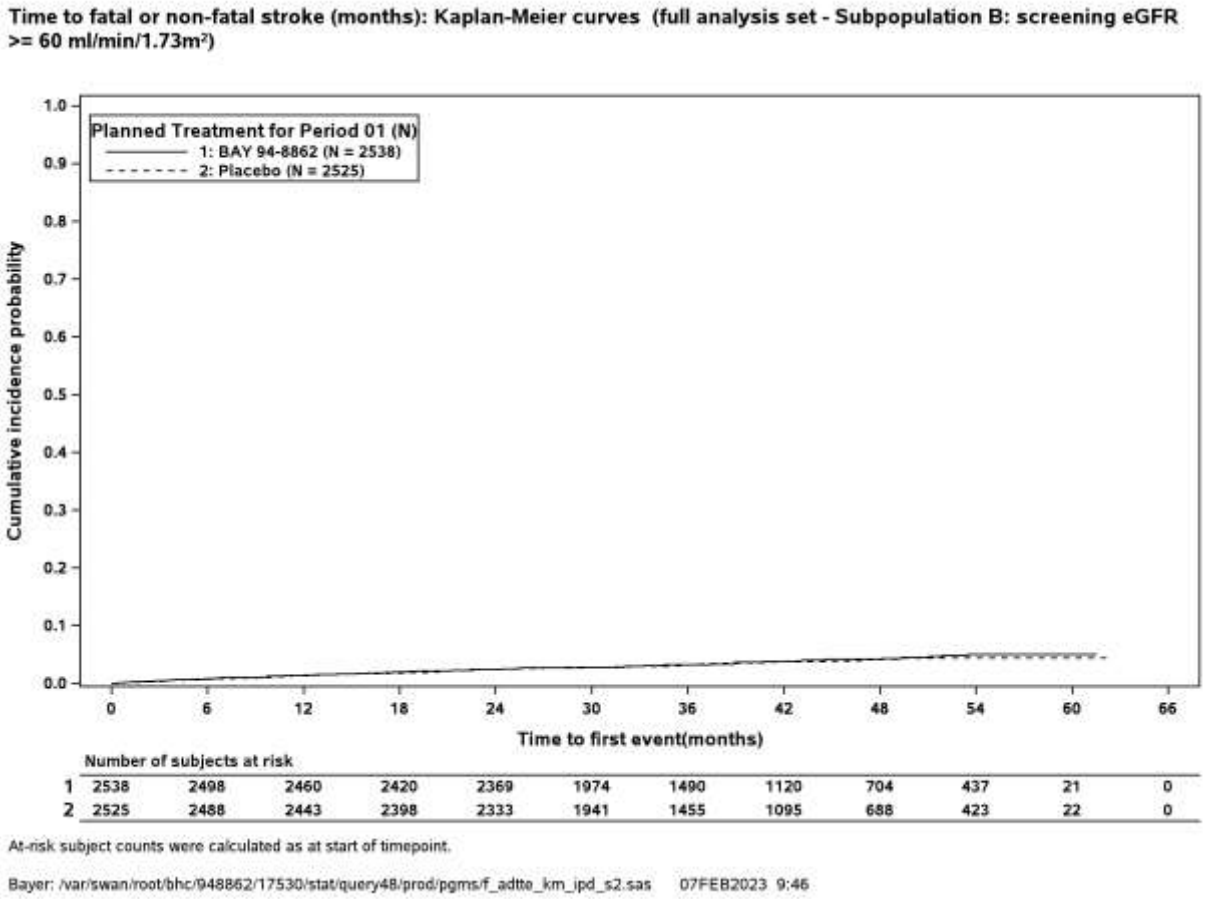


Figure 1.2.1 / 57: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

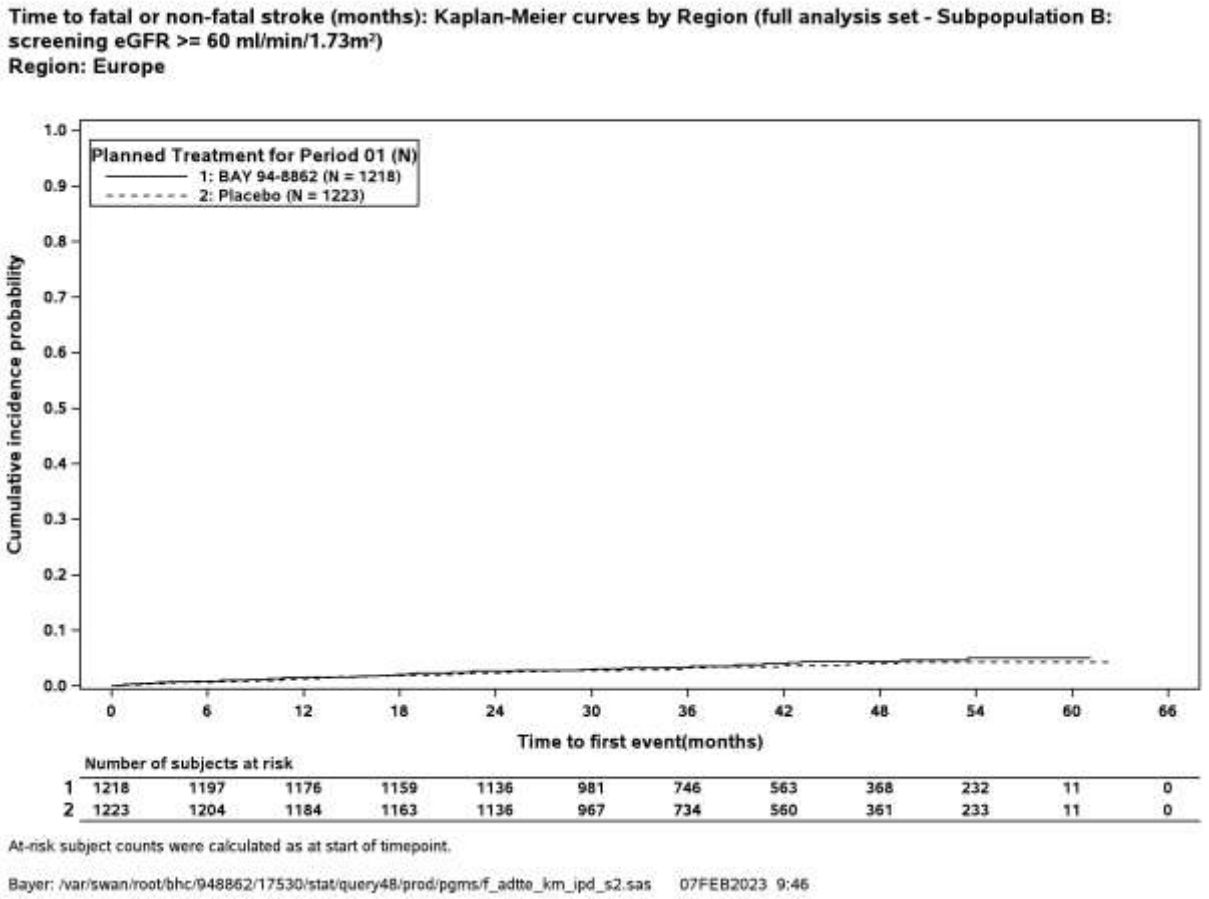


Figure 1.2.1 / 57: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

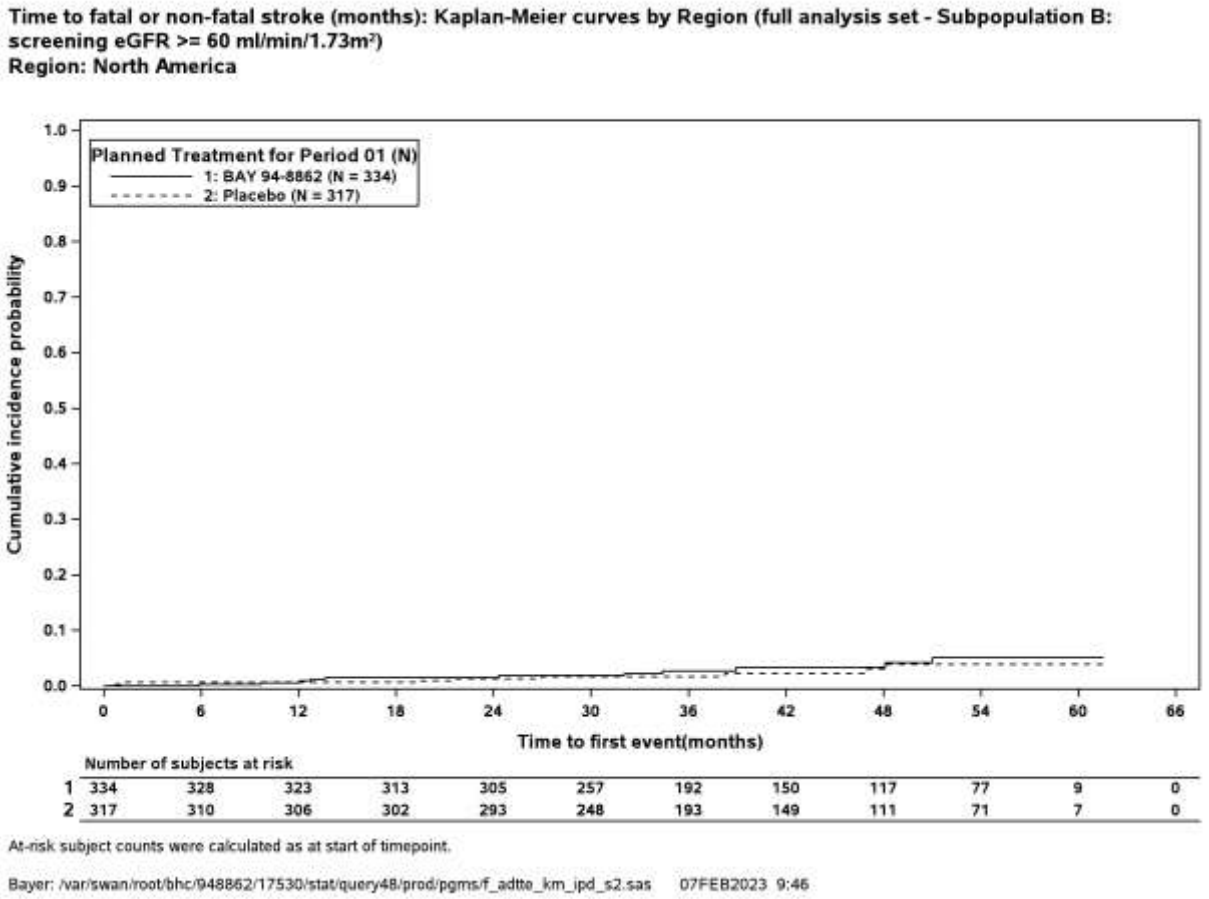


Figure 1.2.1 / 57: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

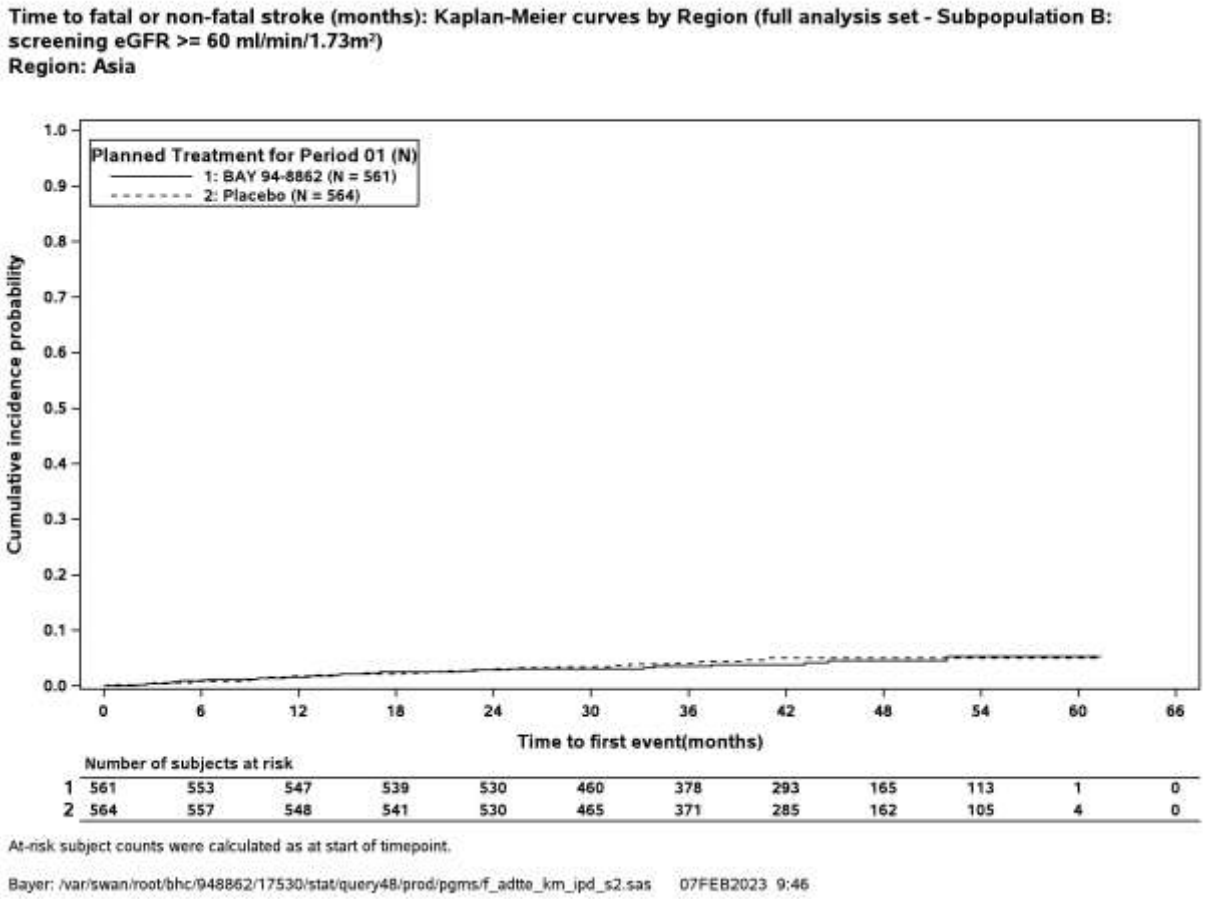


Figure 1.2.1 / 57: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

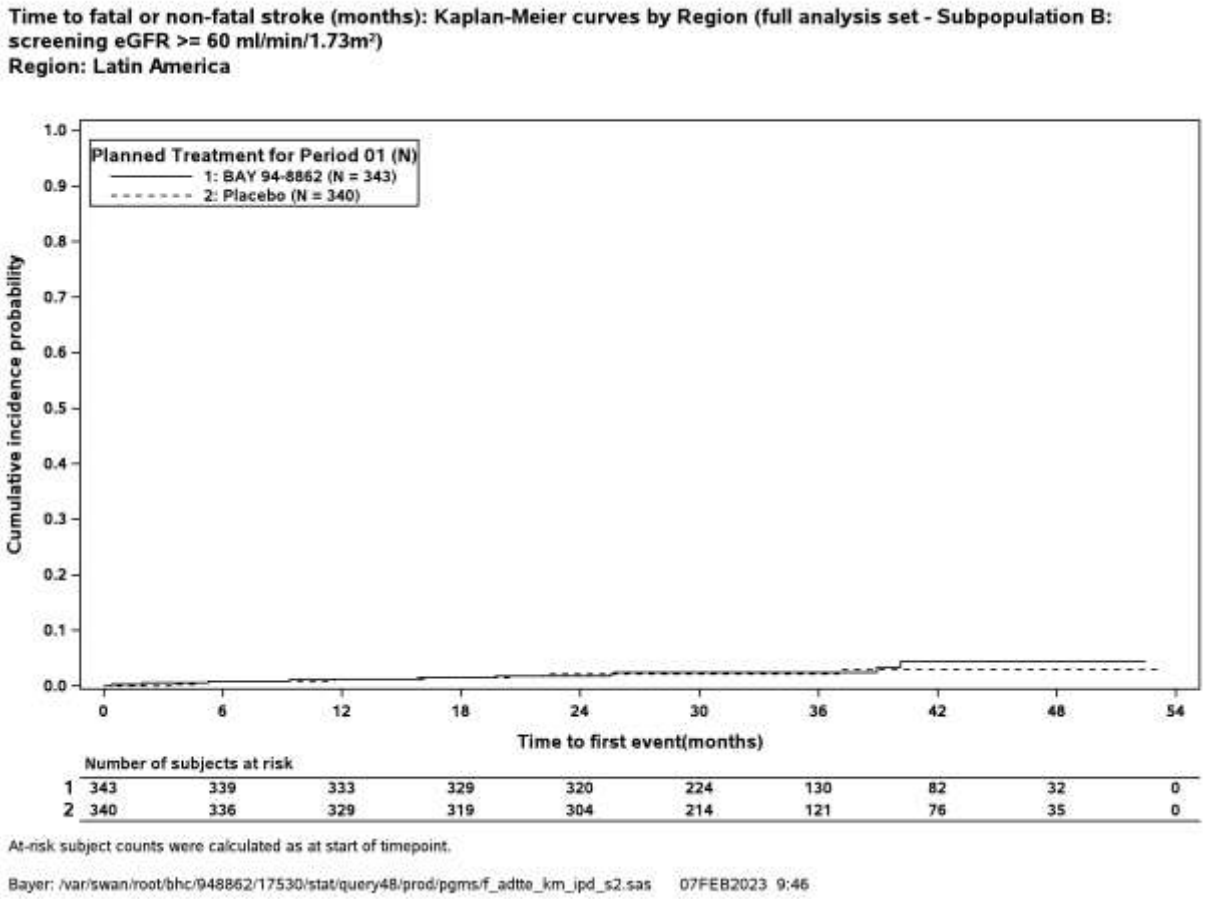


Figure 1.2.1 / 57: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

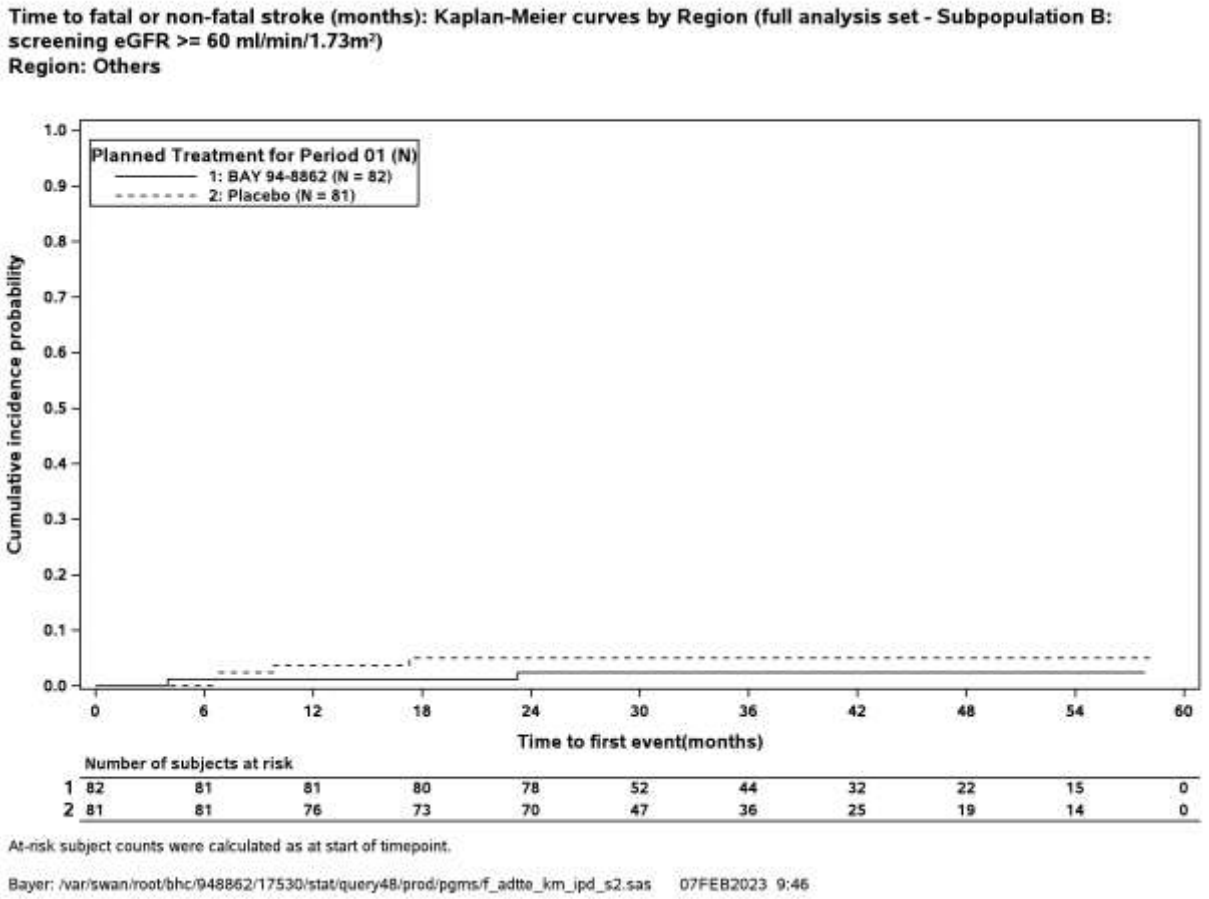


Figure 1.2.1 / 58: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

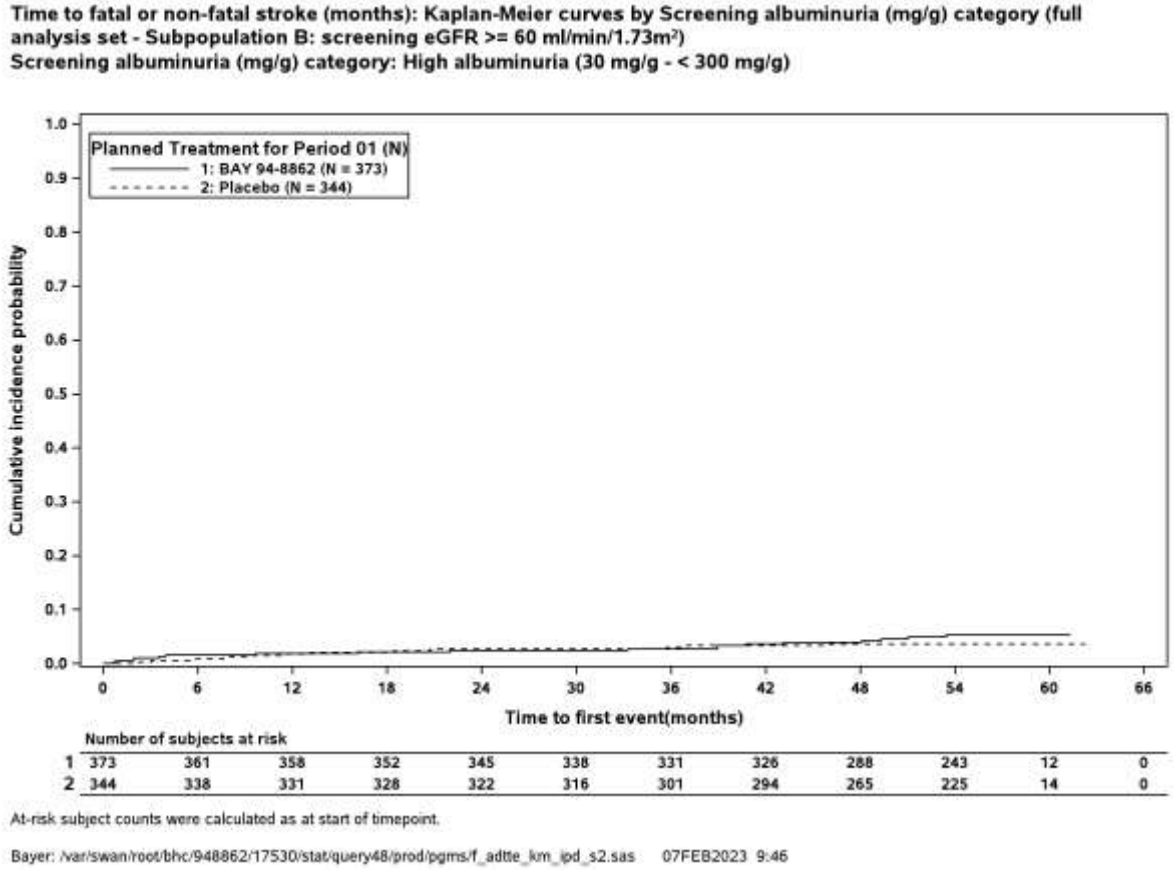


Figure 1.2.1 / 58: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

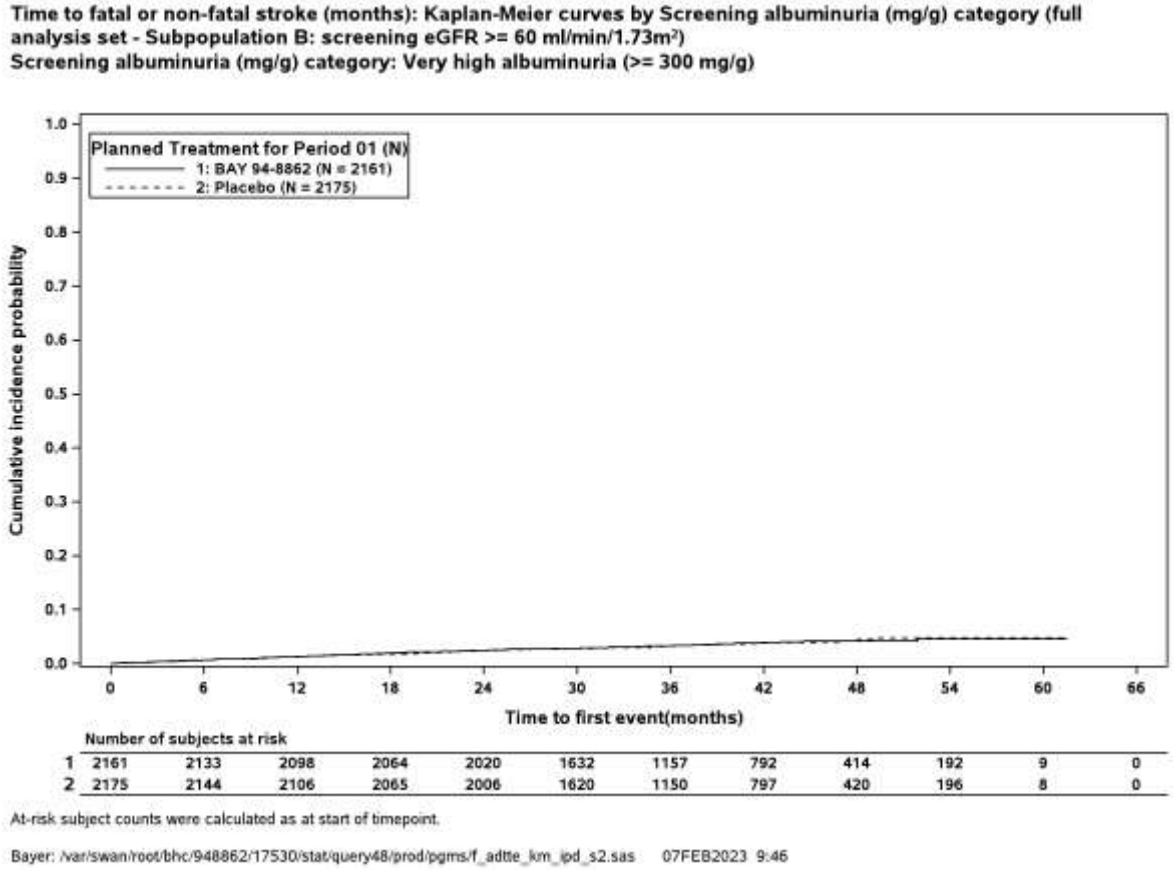


Figure 1.2.1 / 59: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

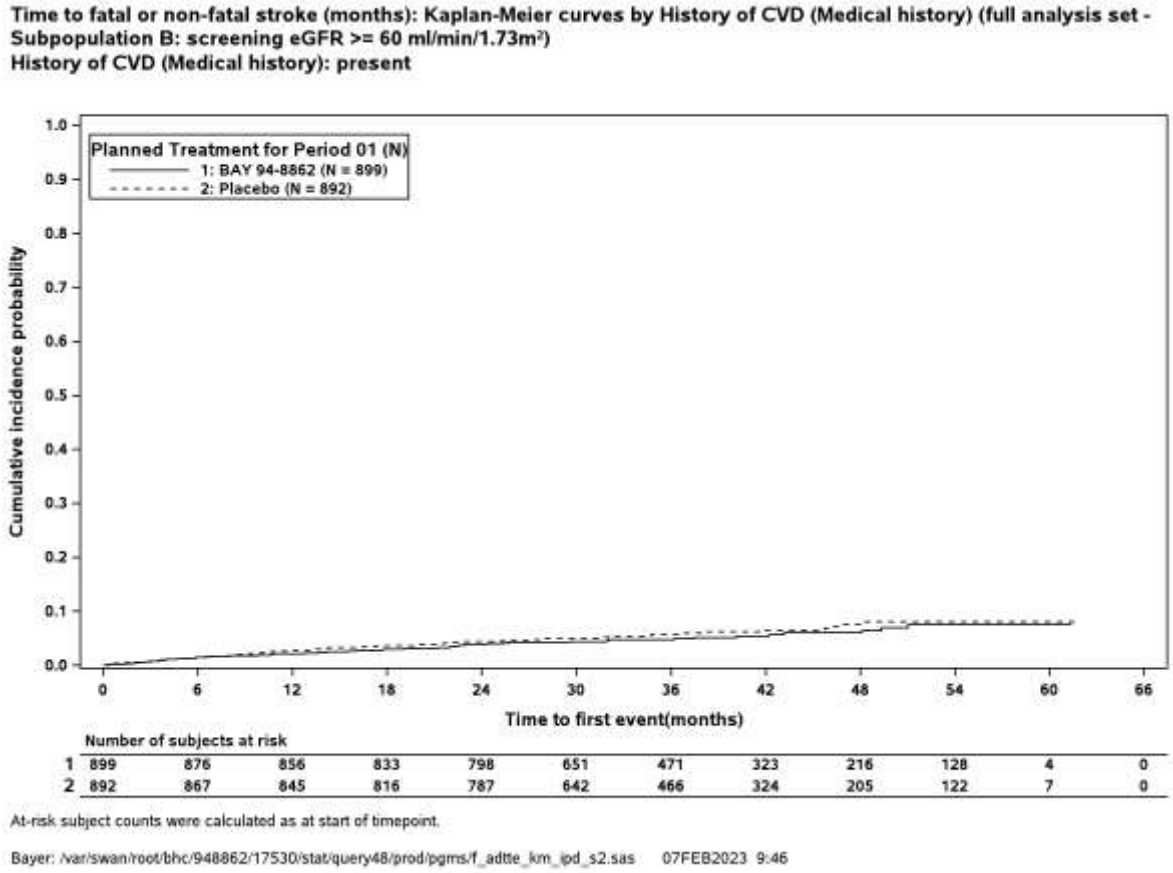


Figure 1.2.1 / 59: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

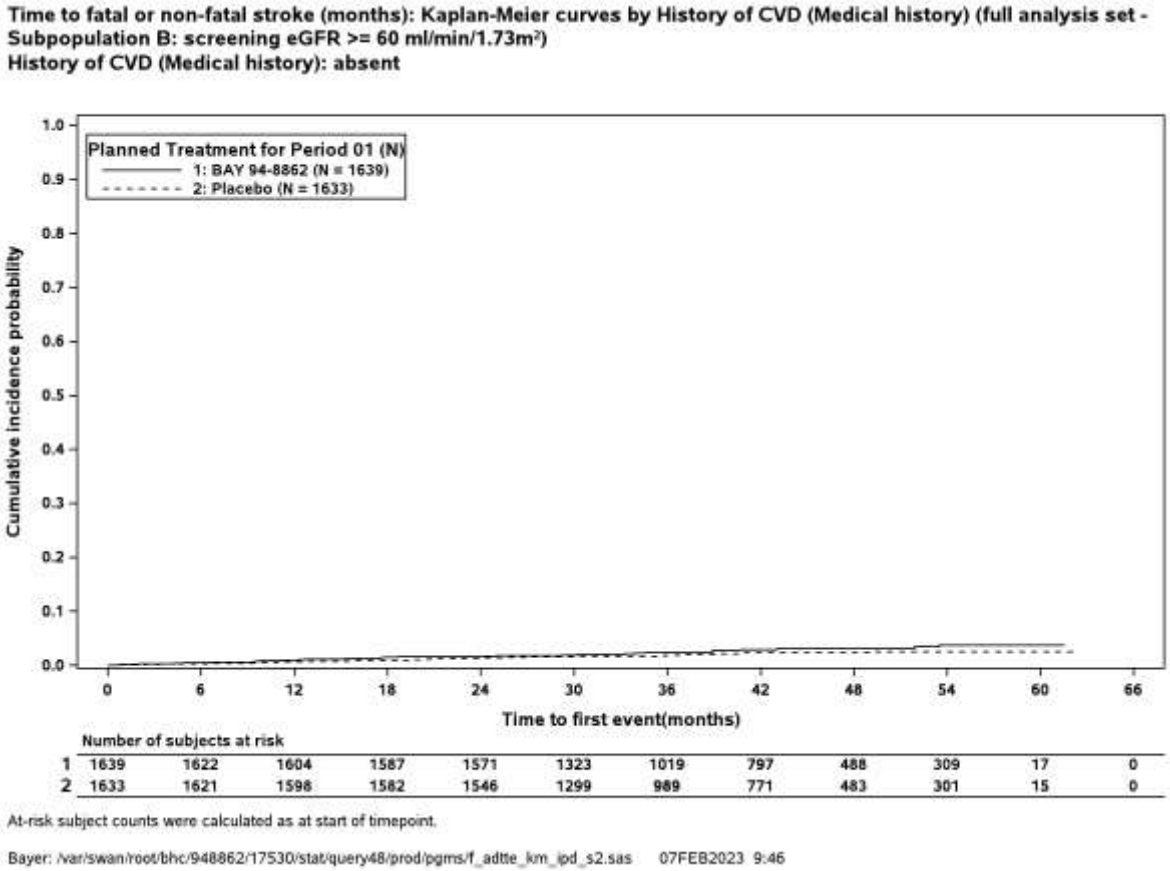


Figure 1.2.1 / 60: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

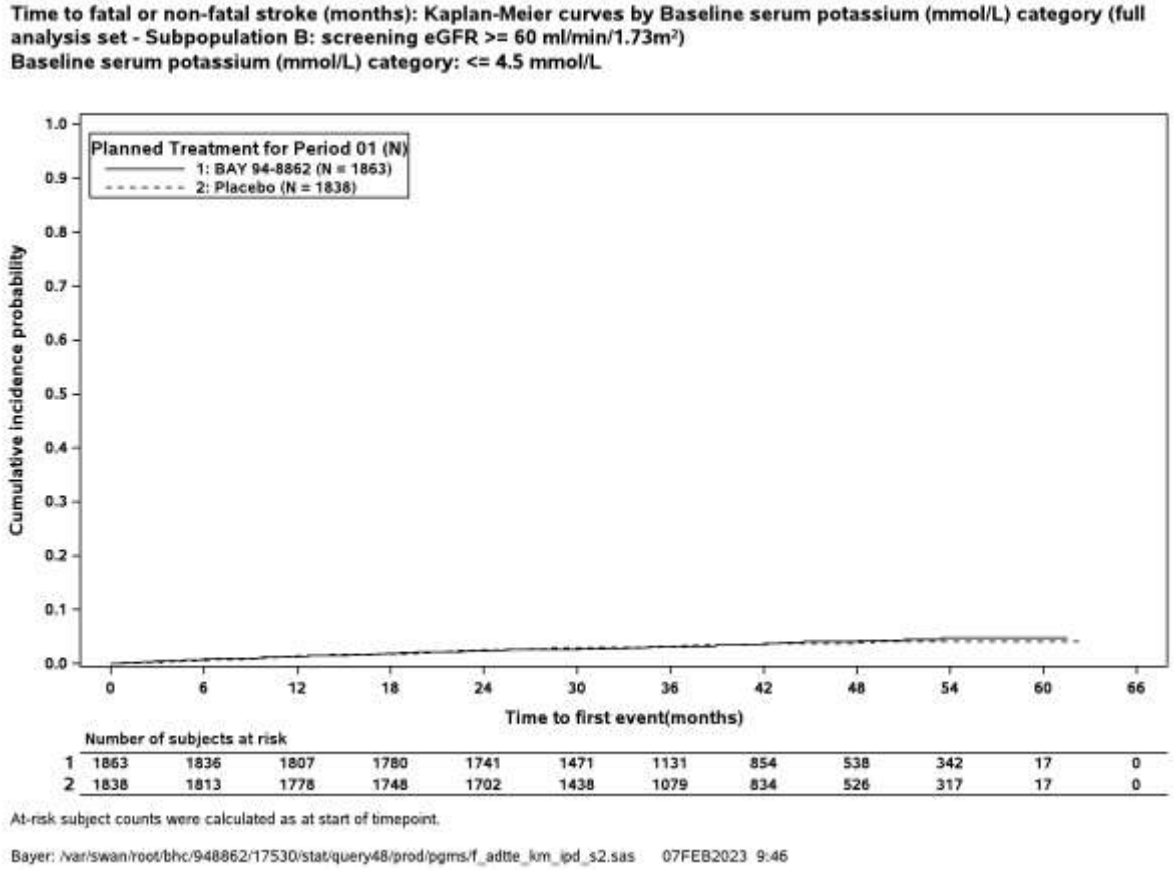


Figure 1.2.1 / 60: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

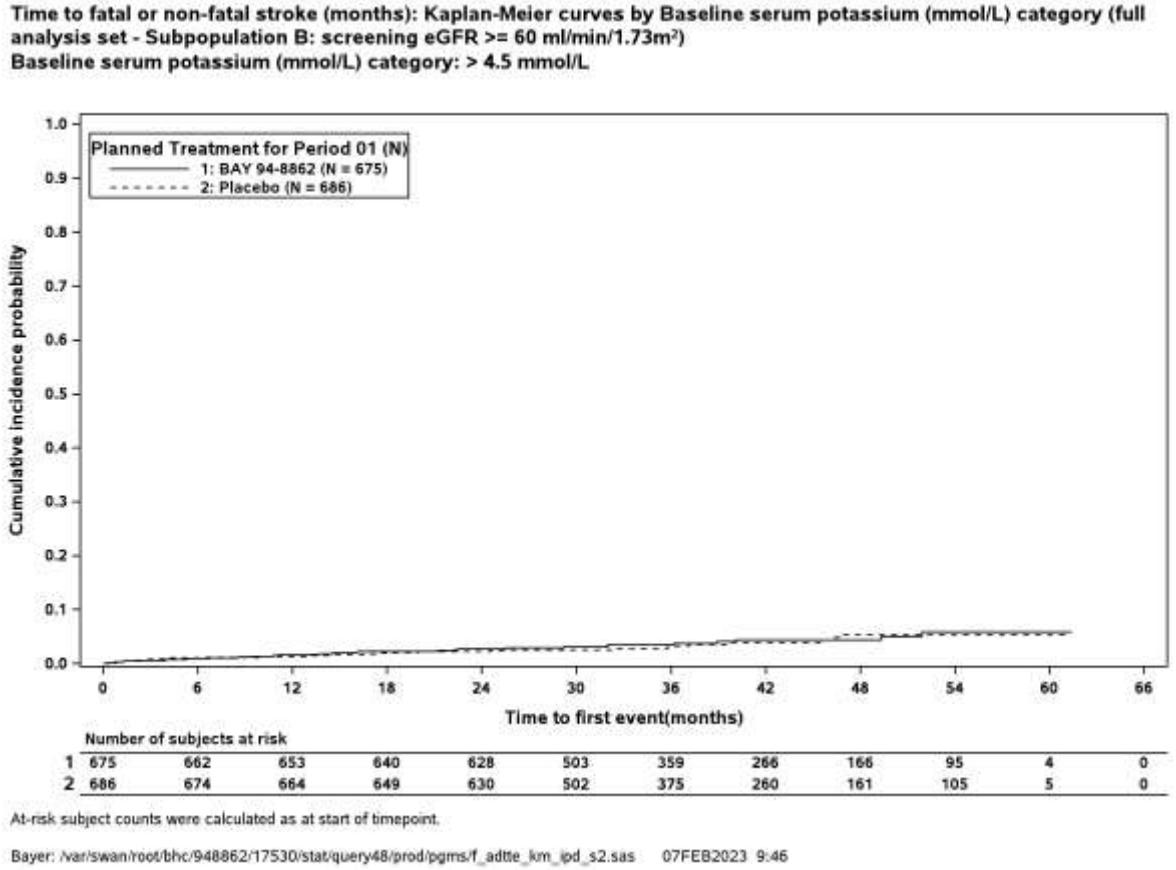
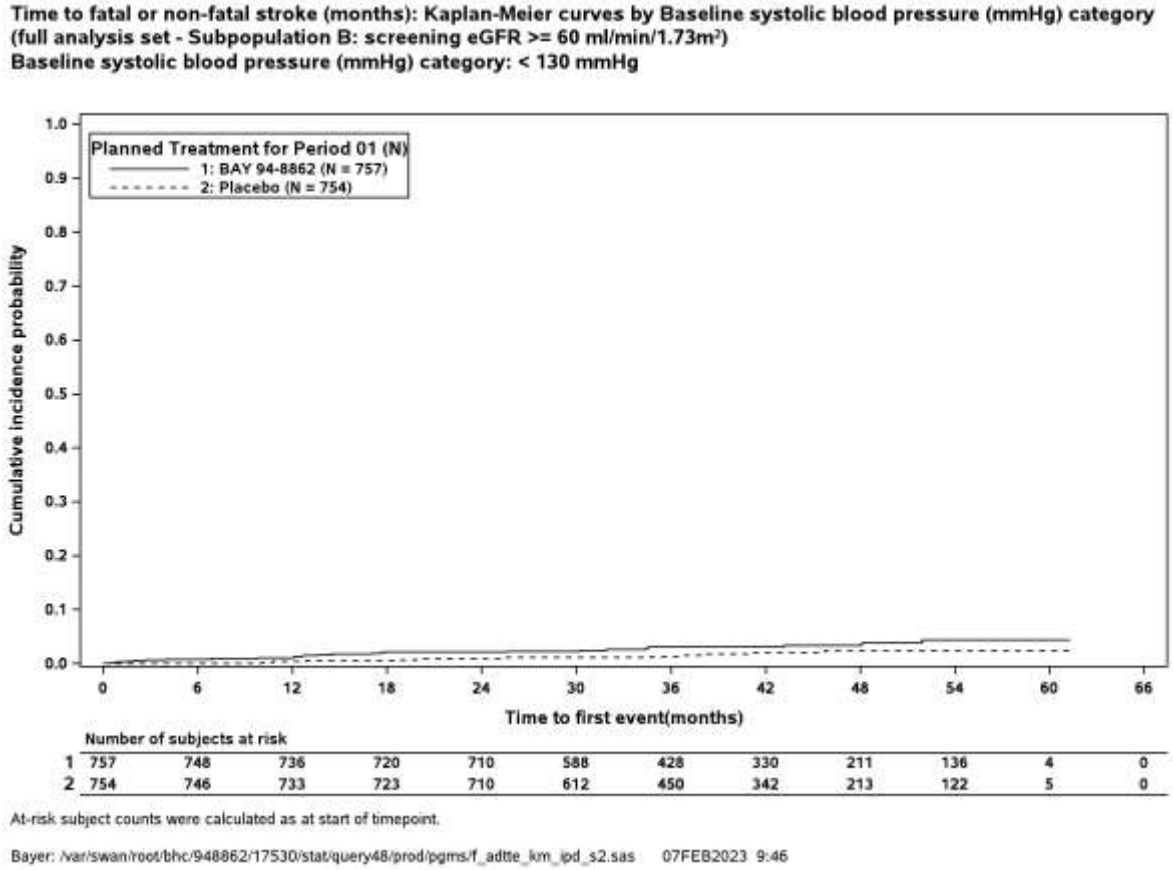


Figure 1.2.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

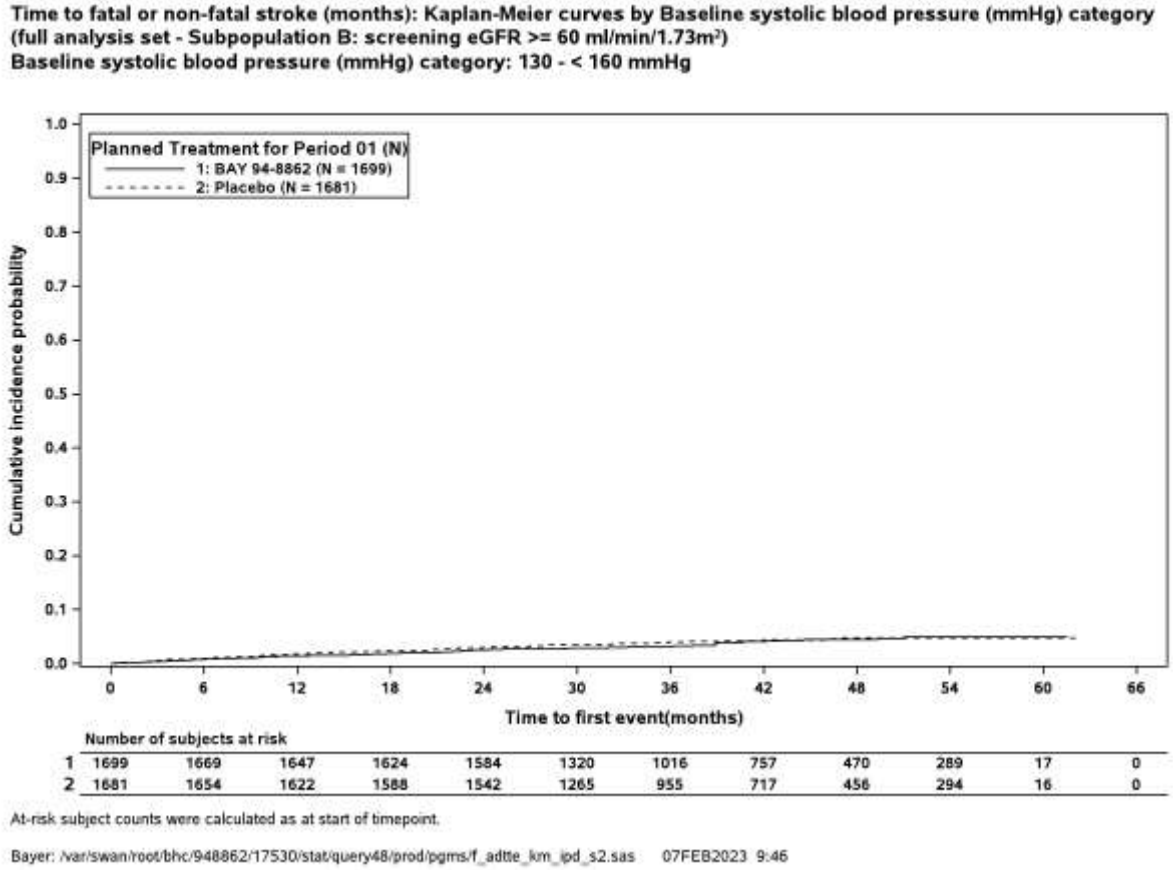


Figure 1.2.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

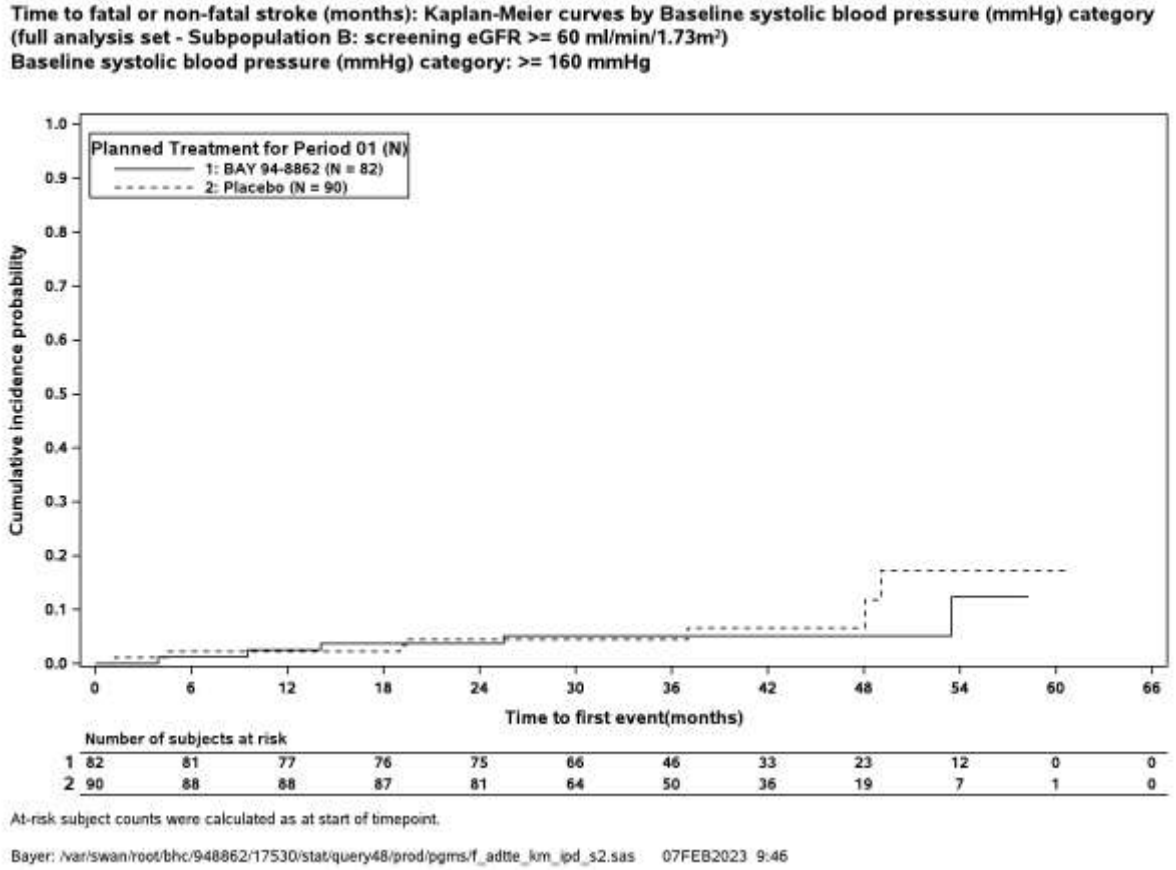


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

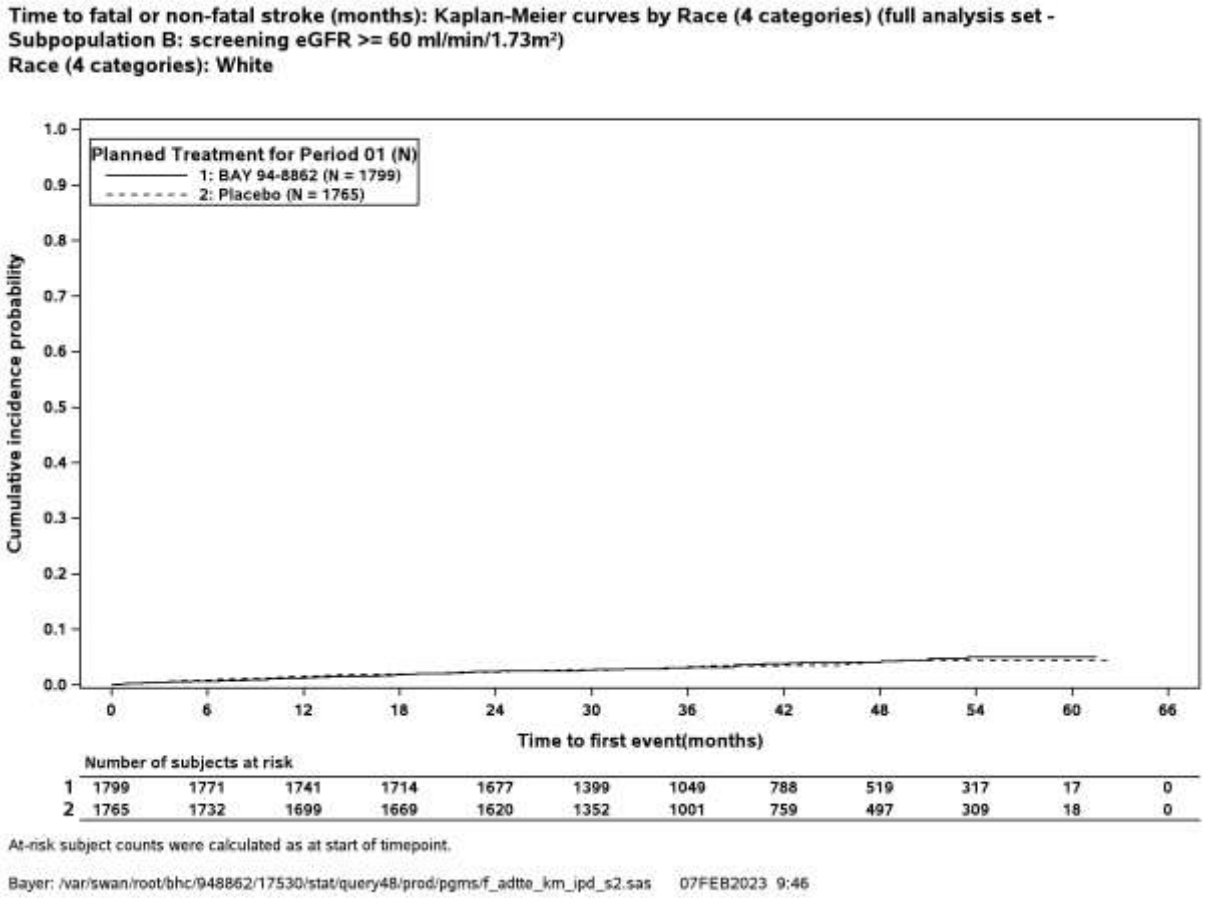


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

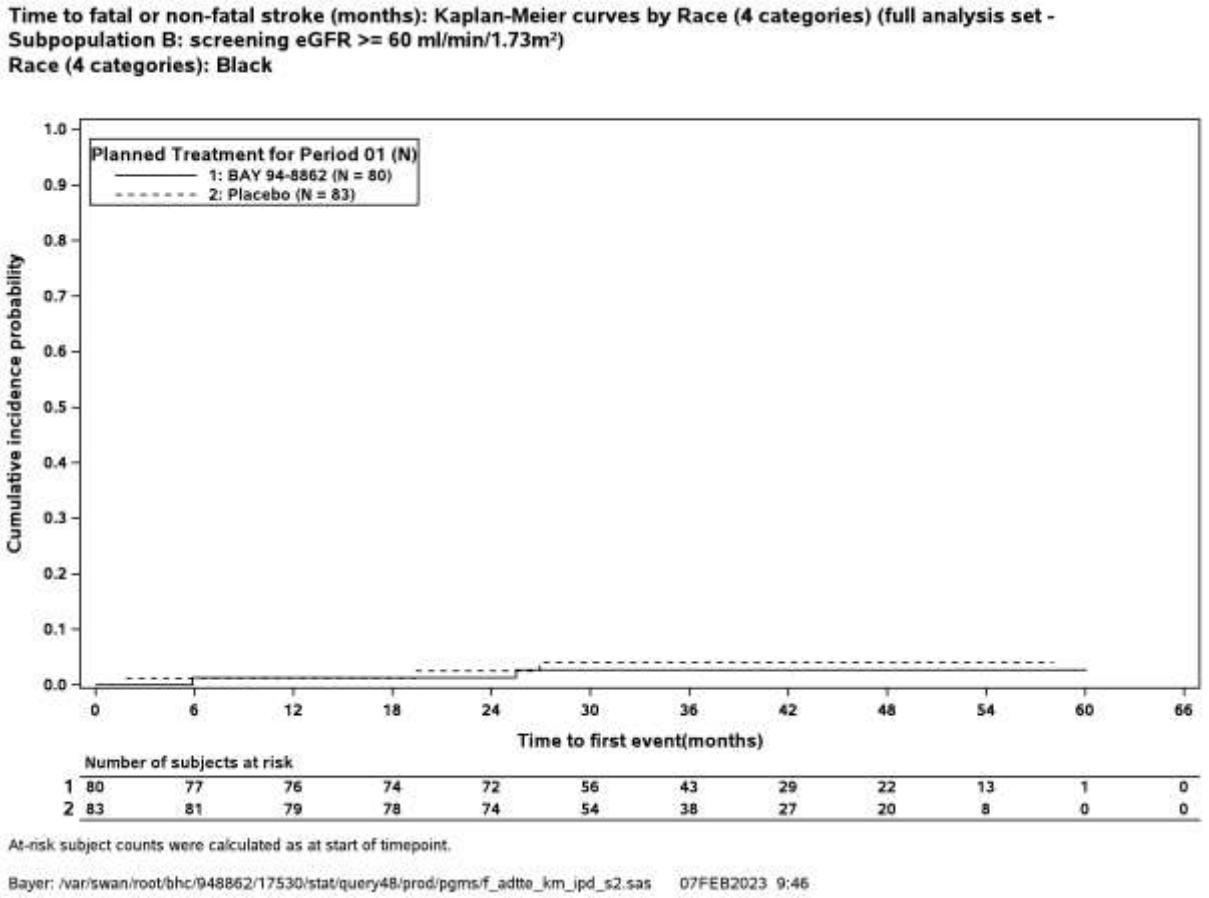
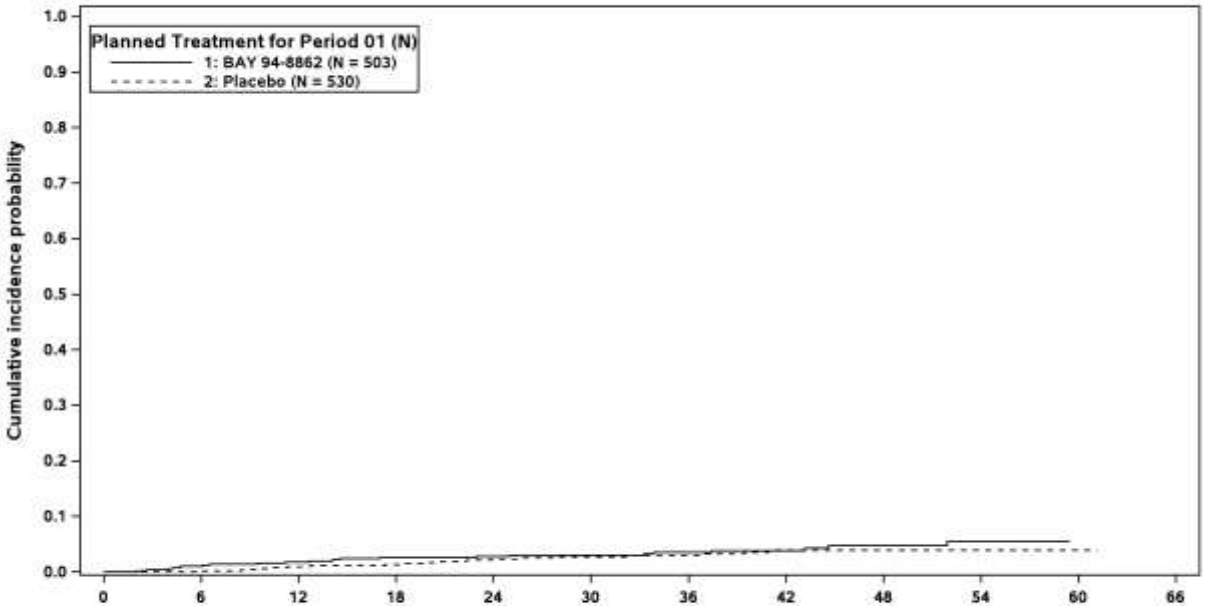


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)
Race (4 categories): Asian



Number of subjects at risk

1	503	496	491	484	475	405	331	259	143	99	0	0
2	530	529	521	514	506	434	355	271	156	103	4	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

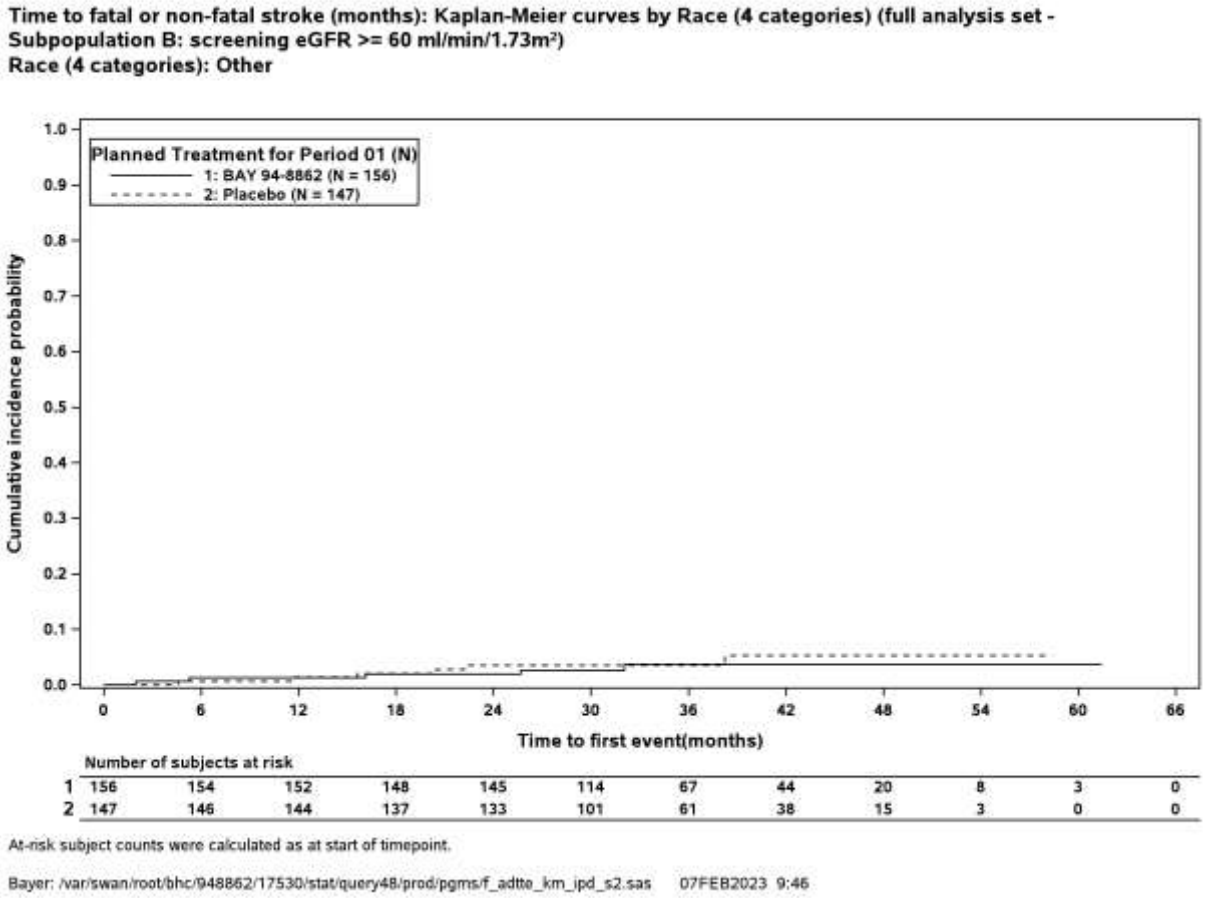


Figure 1.2.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

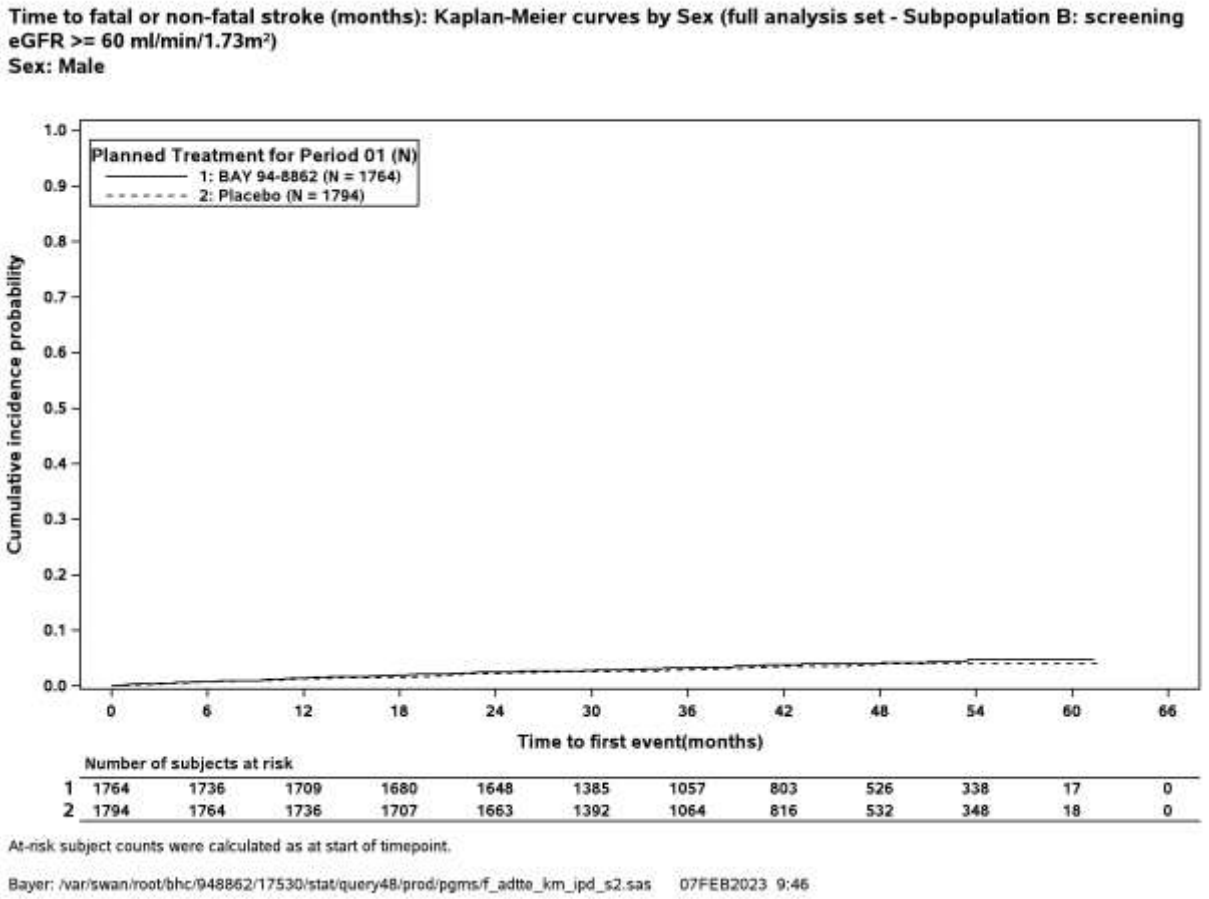


Figure 1.2.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

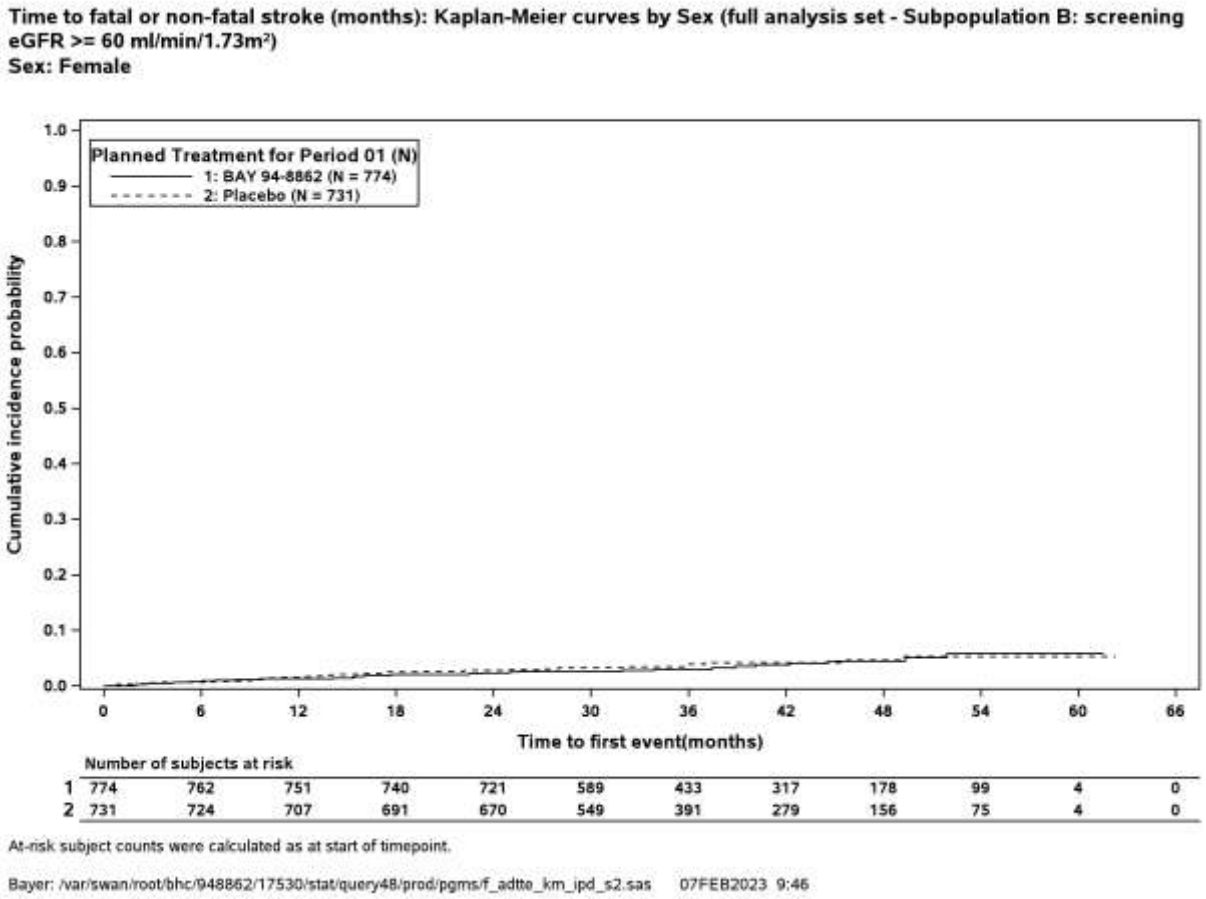


Figure 1.2.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

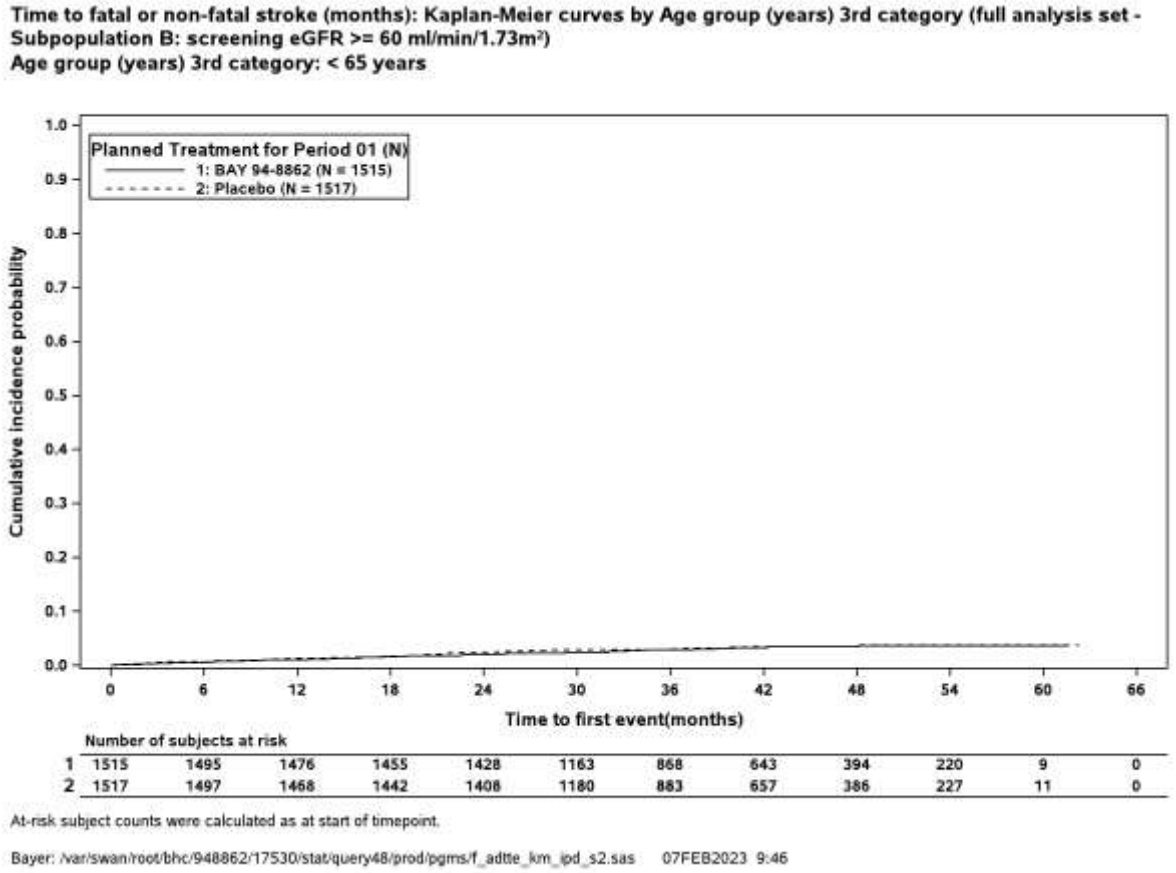


Figure 1.2.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

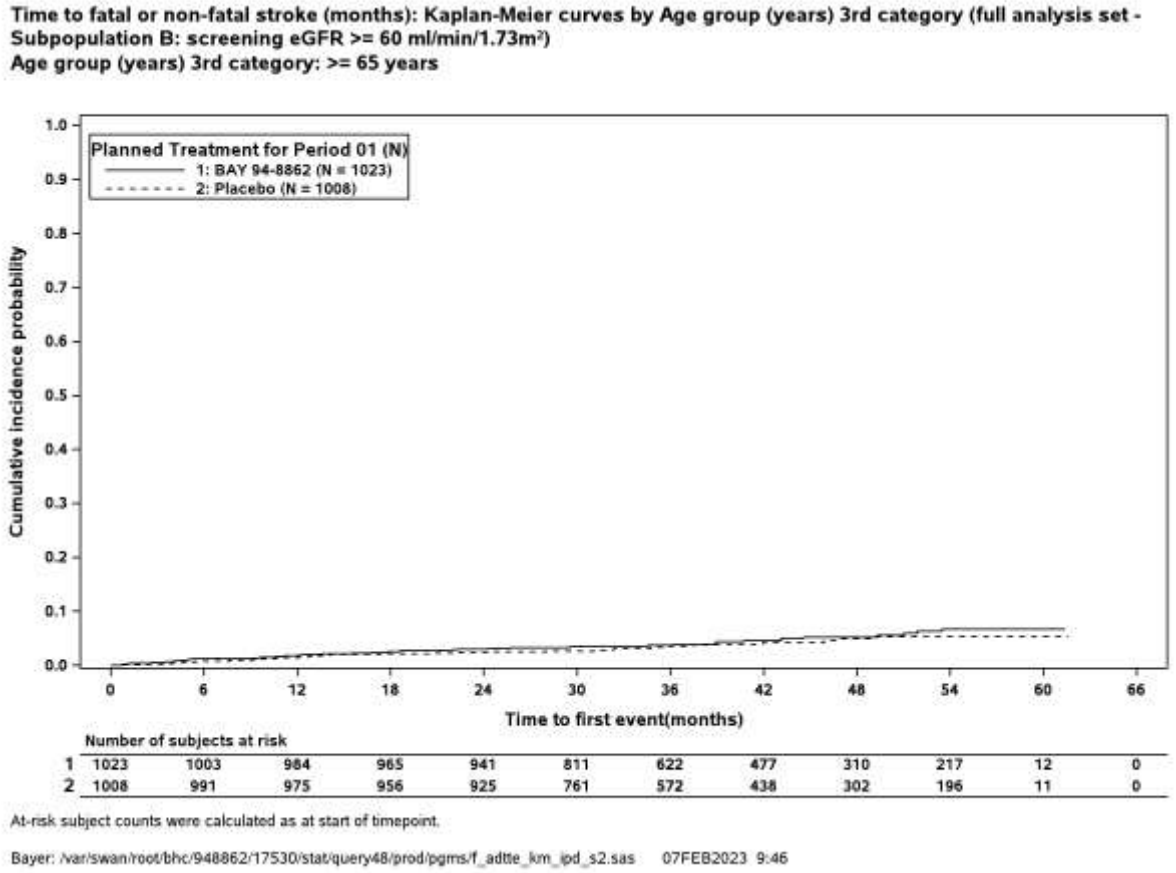


Figure 1.2.1 / 65: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

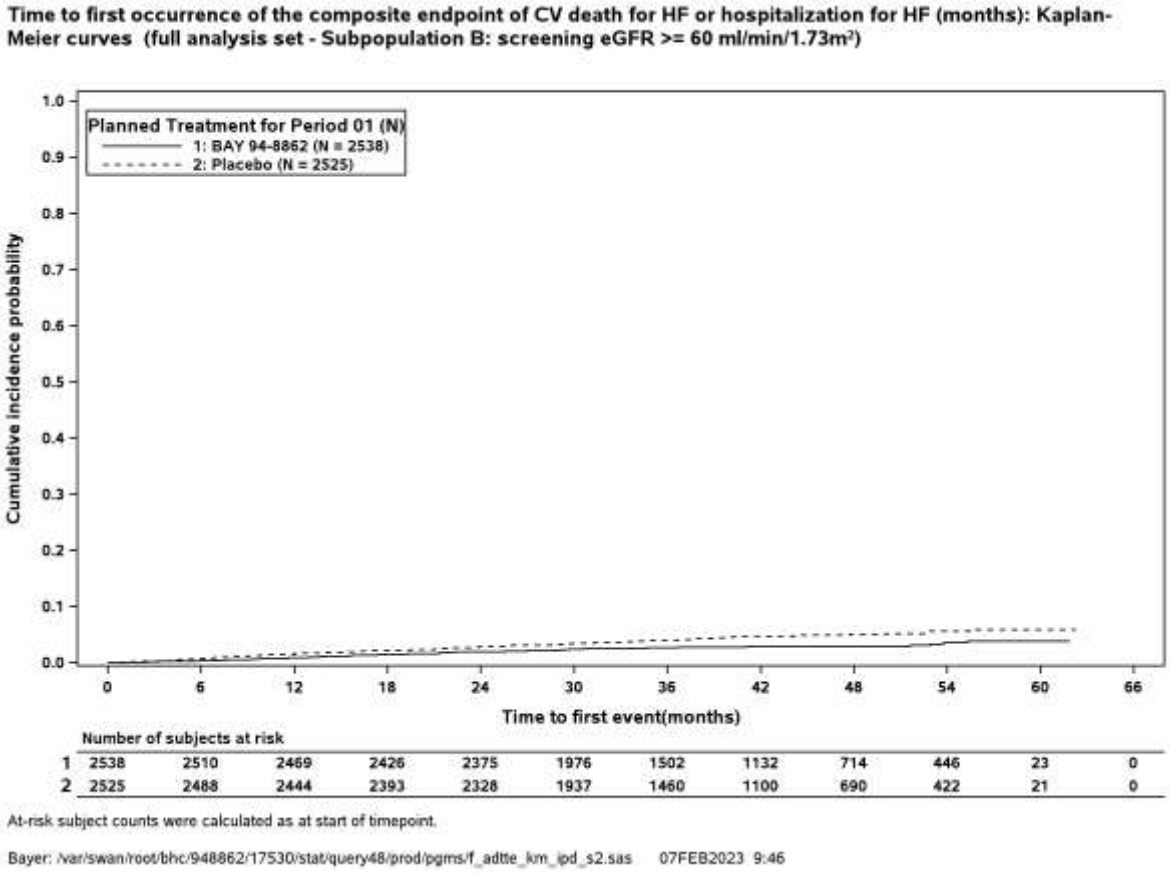


Figure 1.2.1 / 66: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

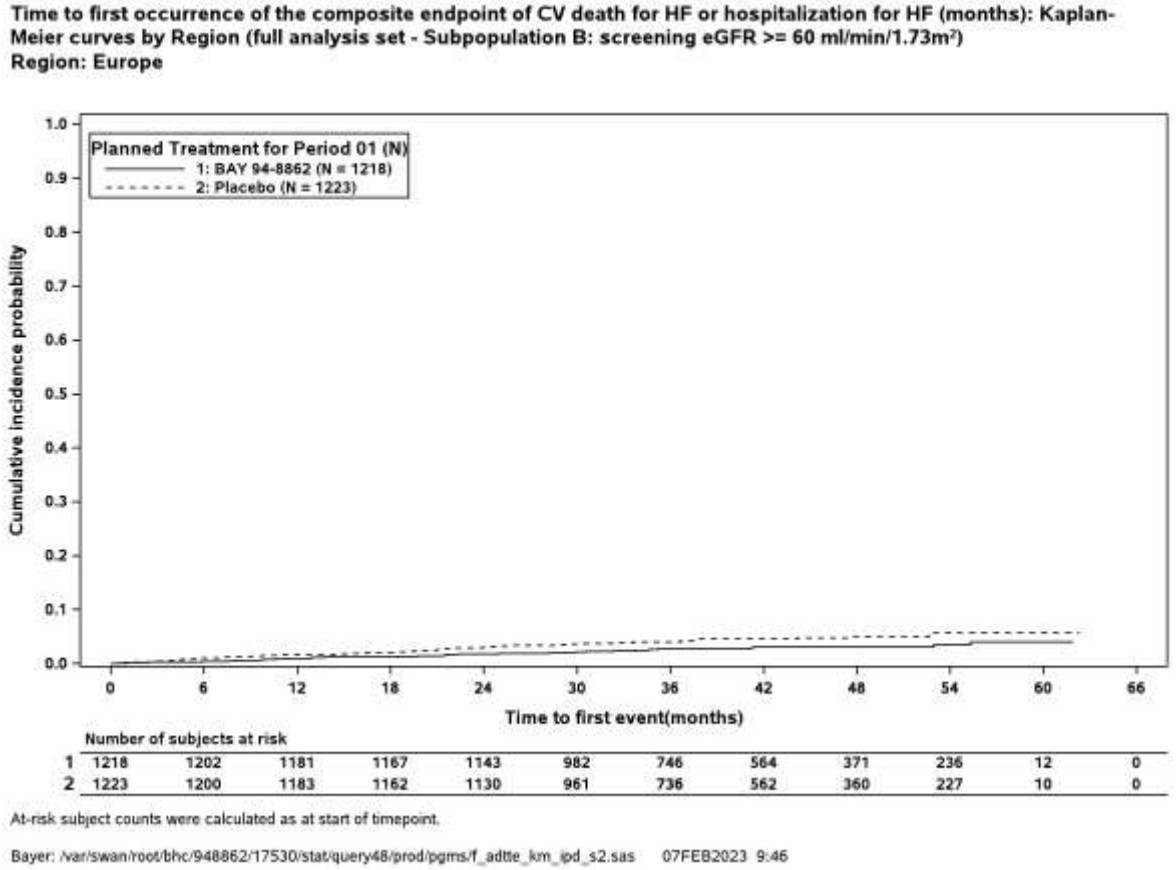


Figure 1.2.1 / 66: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

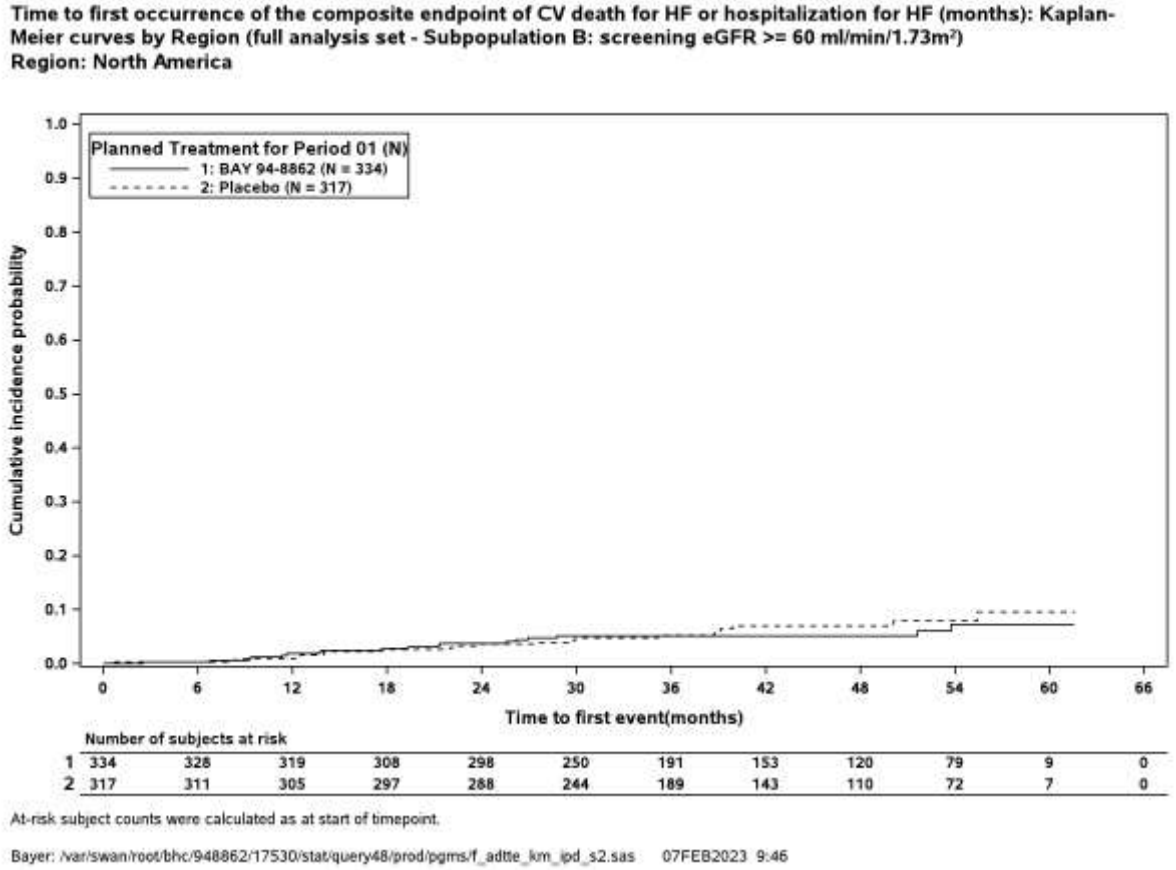


Figure 1.2.1 / 66: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

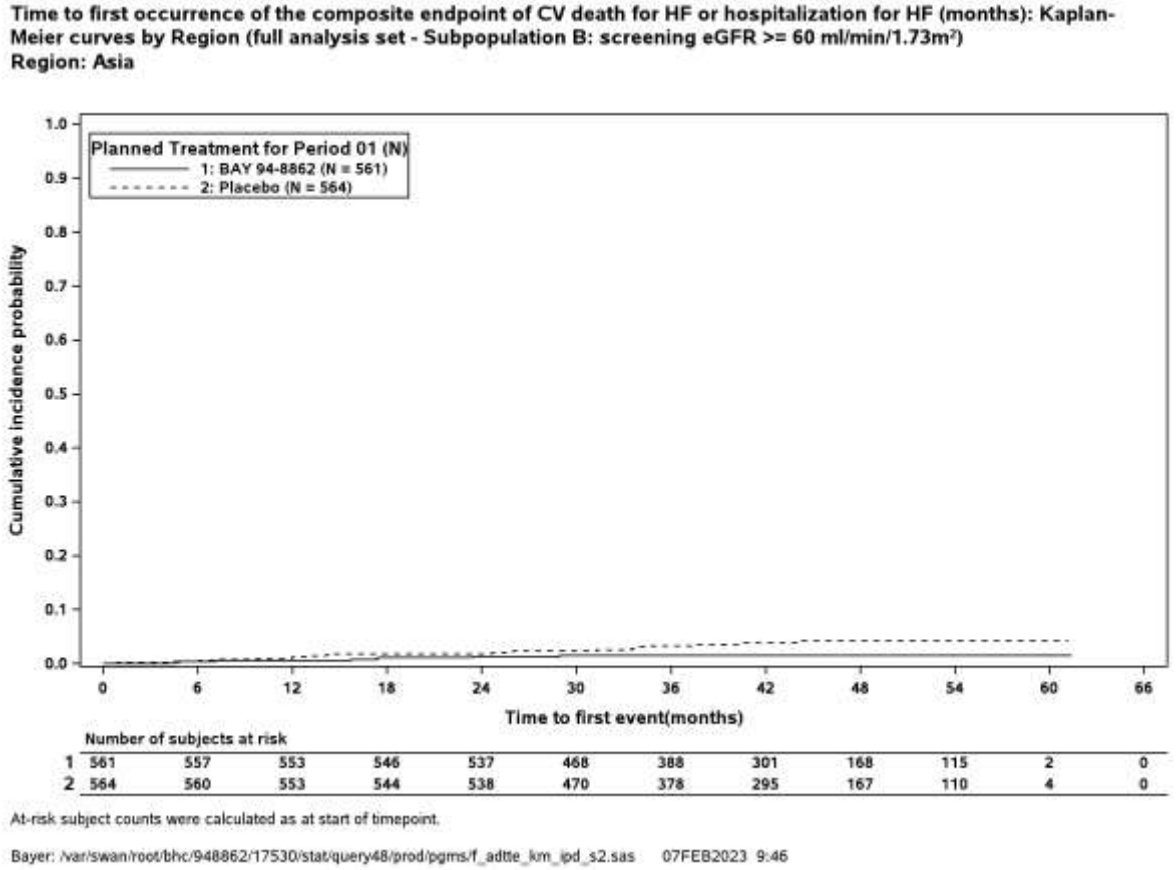


Figure 1.2.1 / 66: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

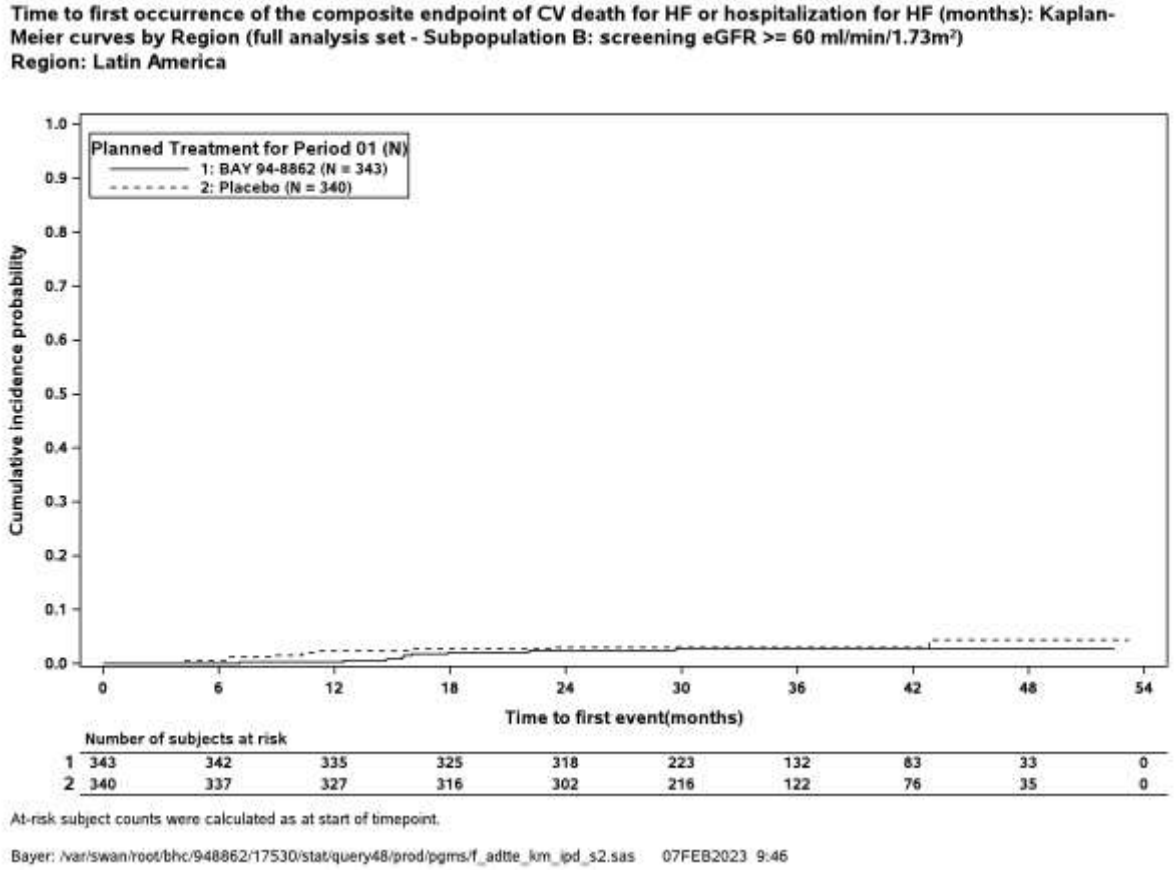


Figure 1.2.1 / 66: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

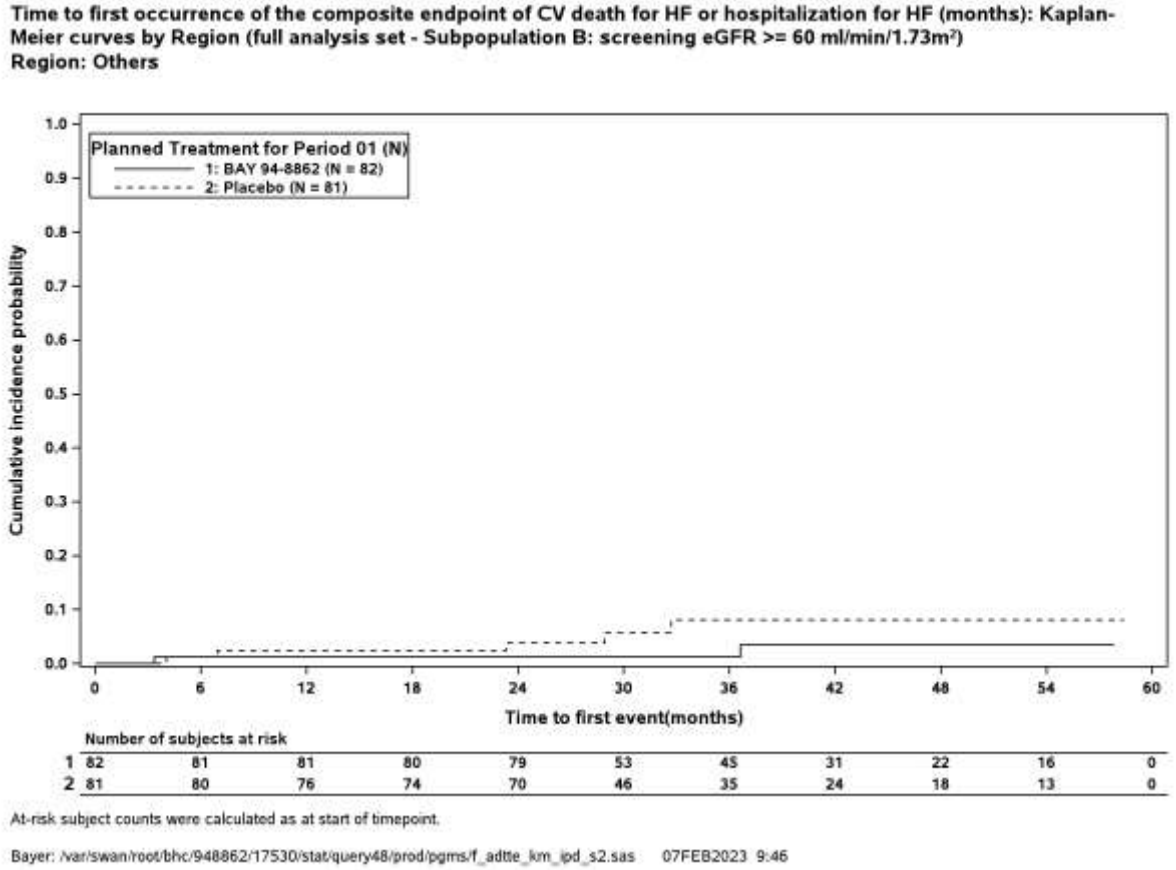


Figure 1.2.1 / 67: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

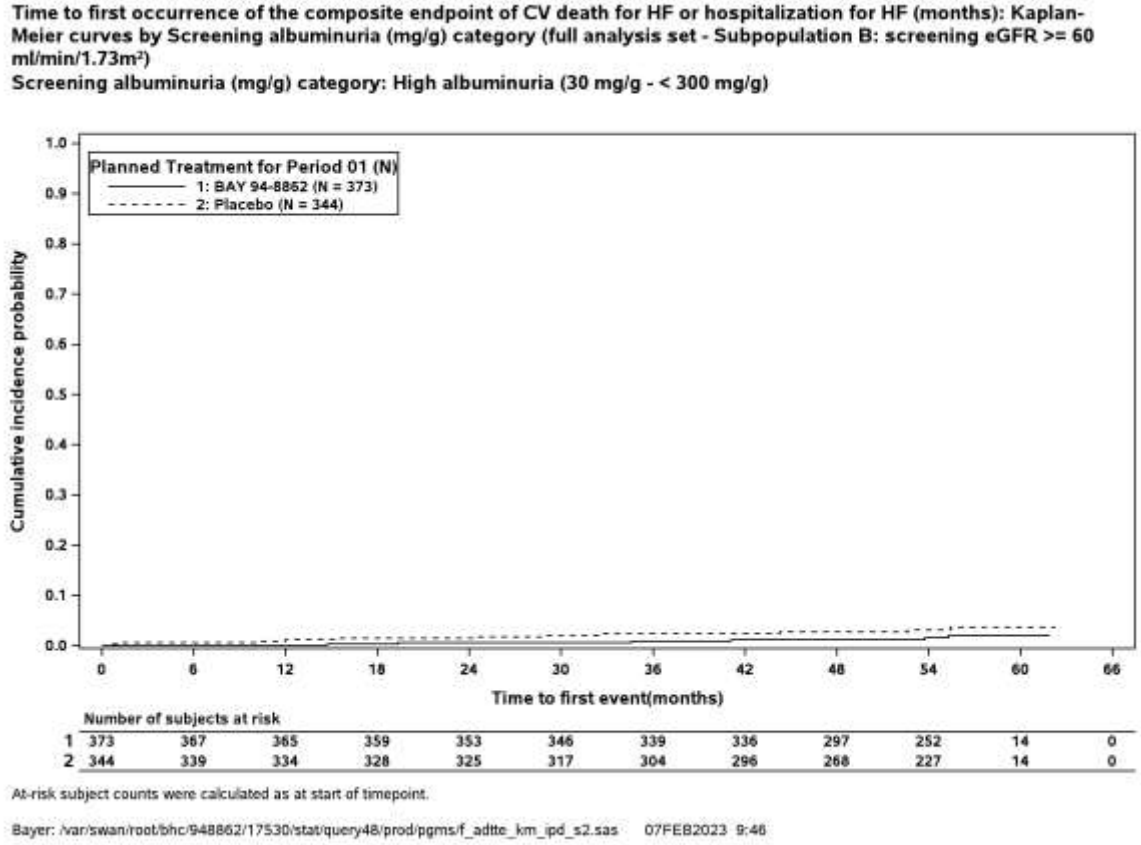
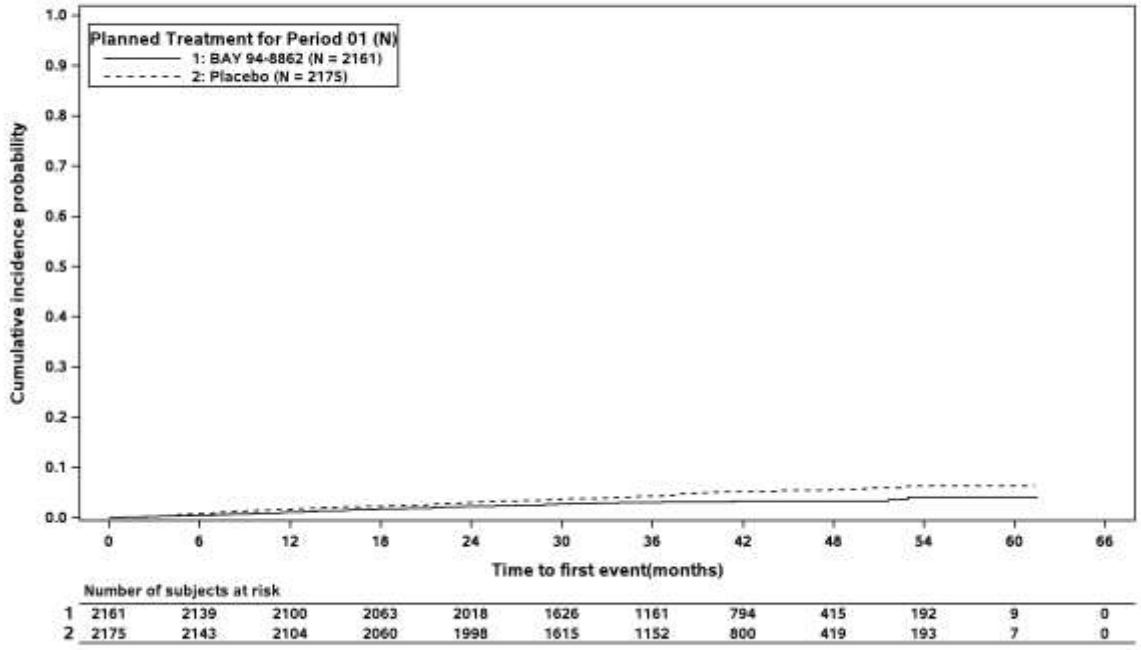


Figure 1.2.1 / 67: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 68: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

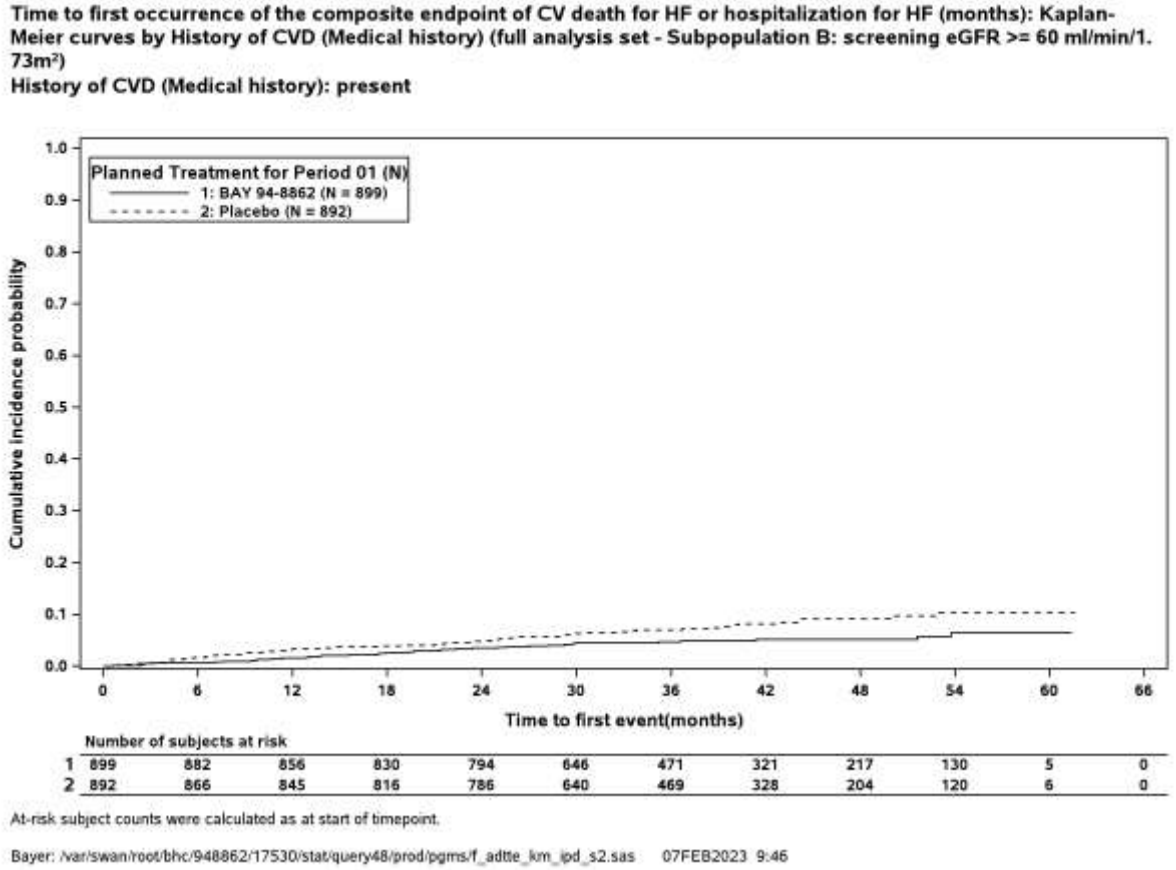


Figure 1.2.1 / 68: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

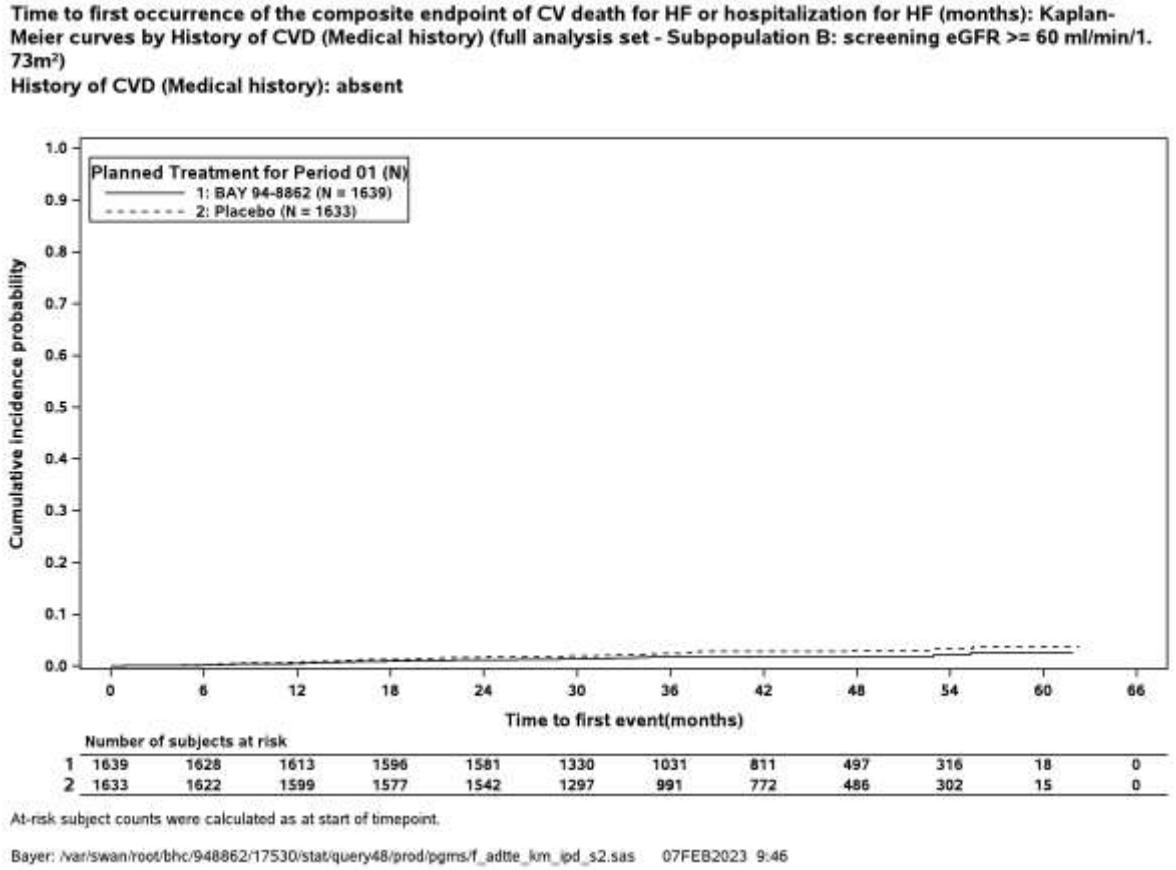


Figure 1.2.1 / 69: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

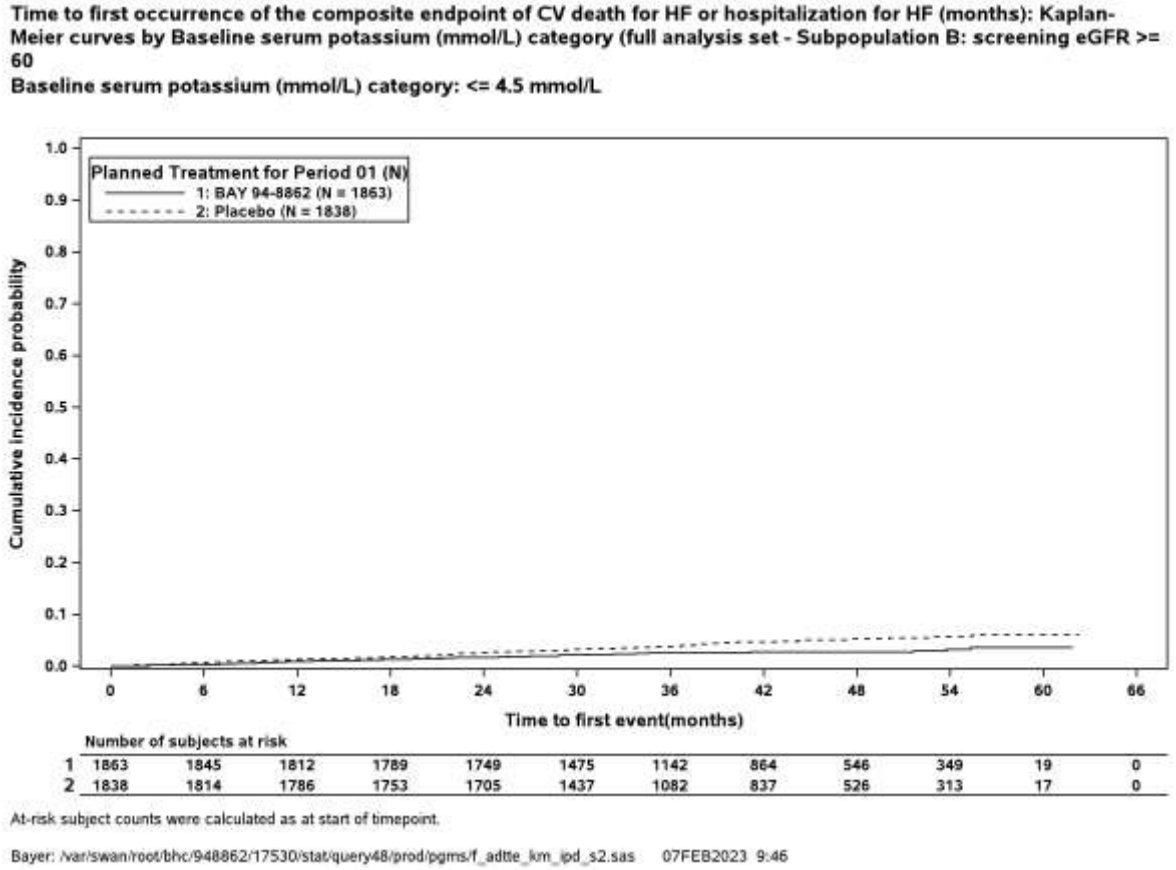
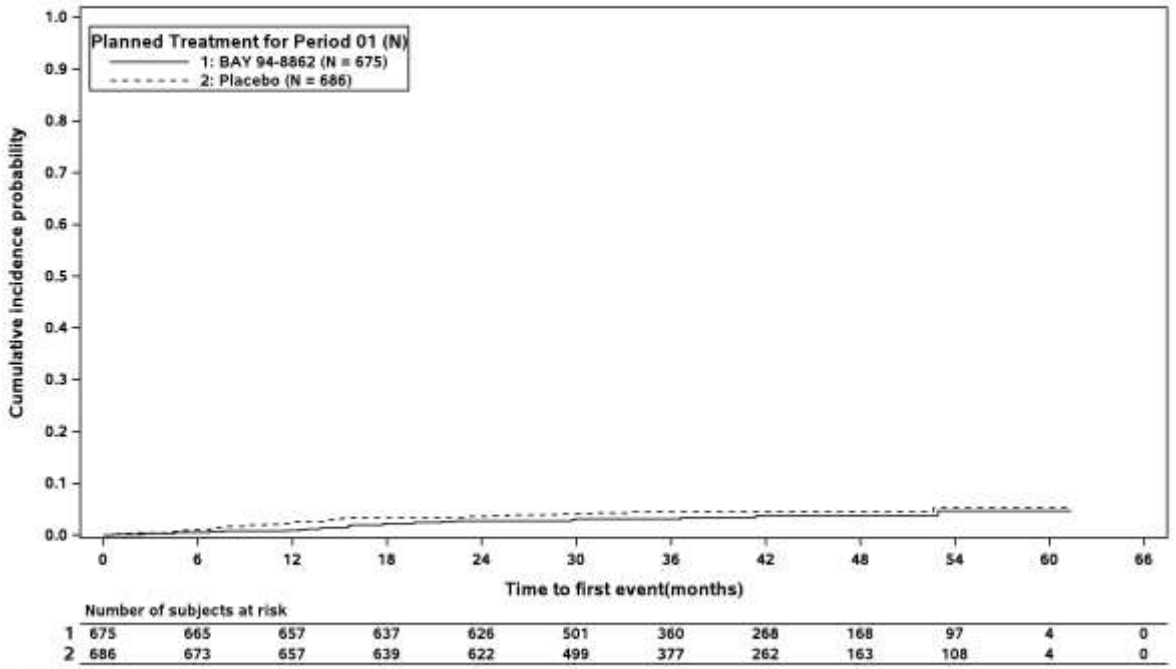


Figure 1.2.1 / 69: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	675	665	657	637	626	501	360	268	168	97	4	0
2	686	673	657	639	622	499	377	262	163	108	4	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 70: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

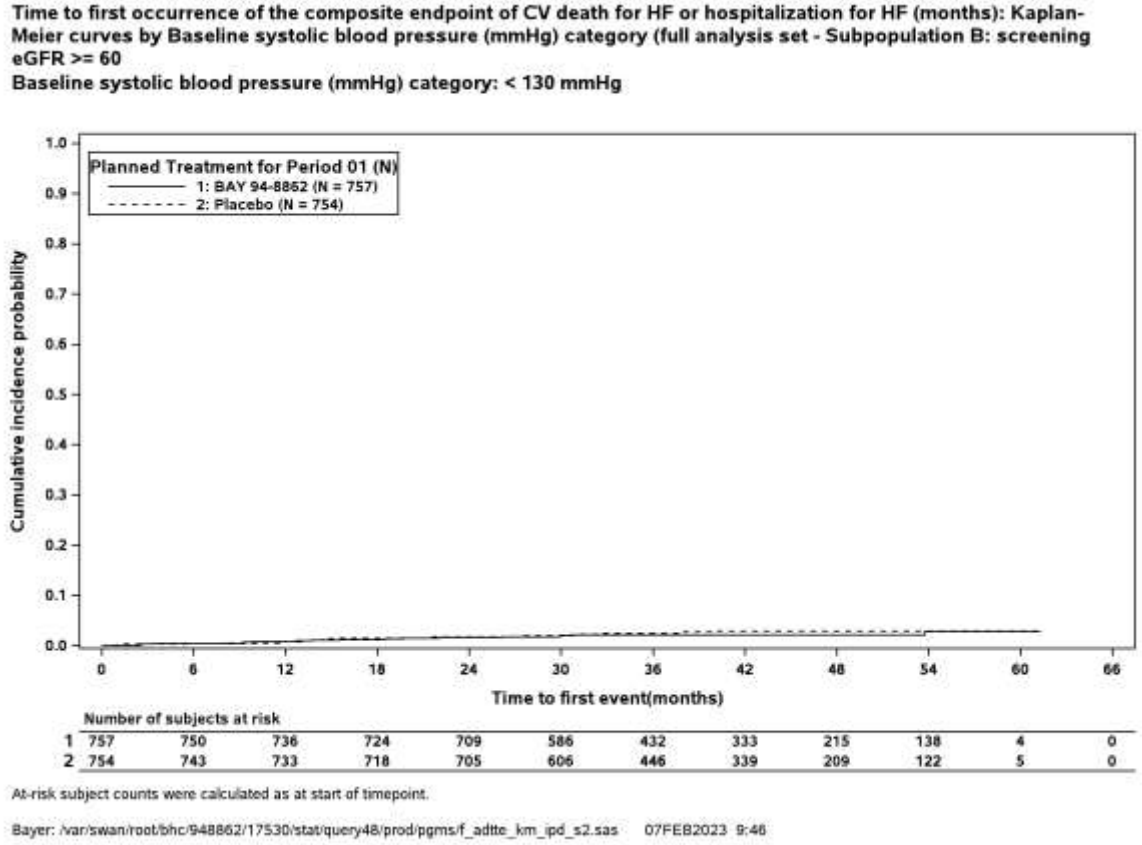
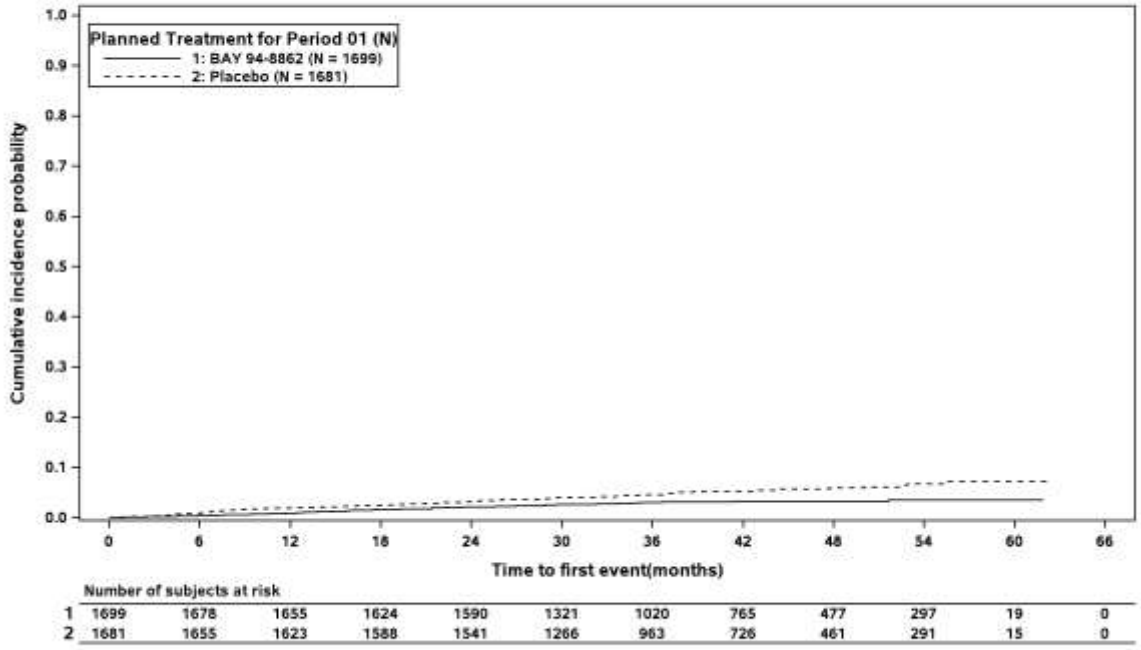


Figure 1.2.1 / 70: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60
Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg



Number of subjects at risk

1	1699	1678	1655	1624	1590	1321	1020	765	477	297	19	0
2	1681	1655	1623	1588	1541	1266	963	726	461	291	15	0

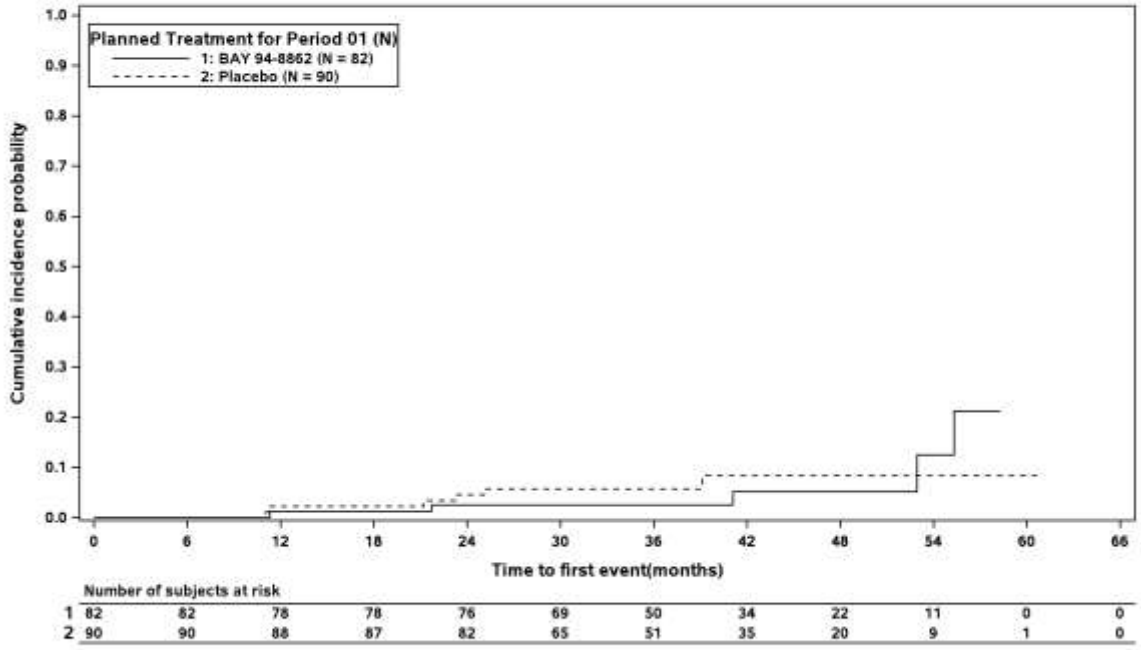
At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 70: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60
Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

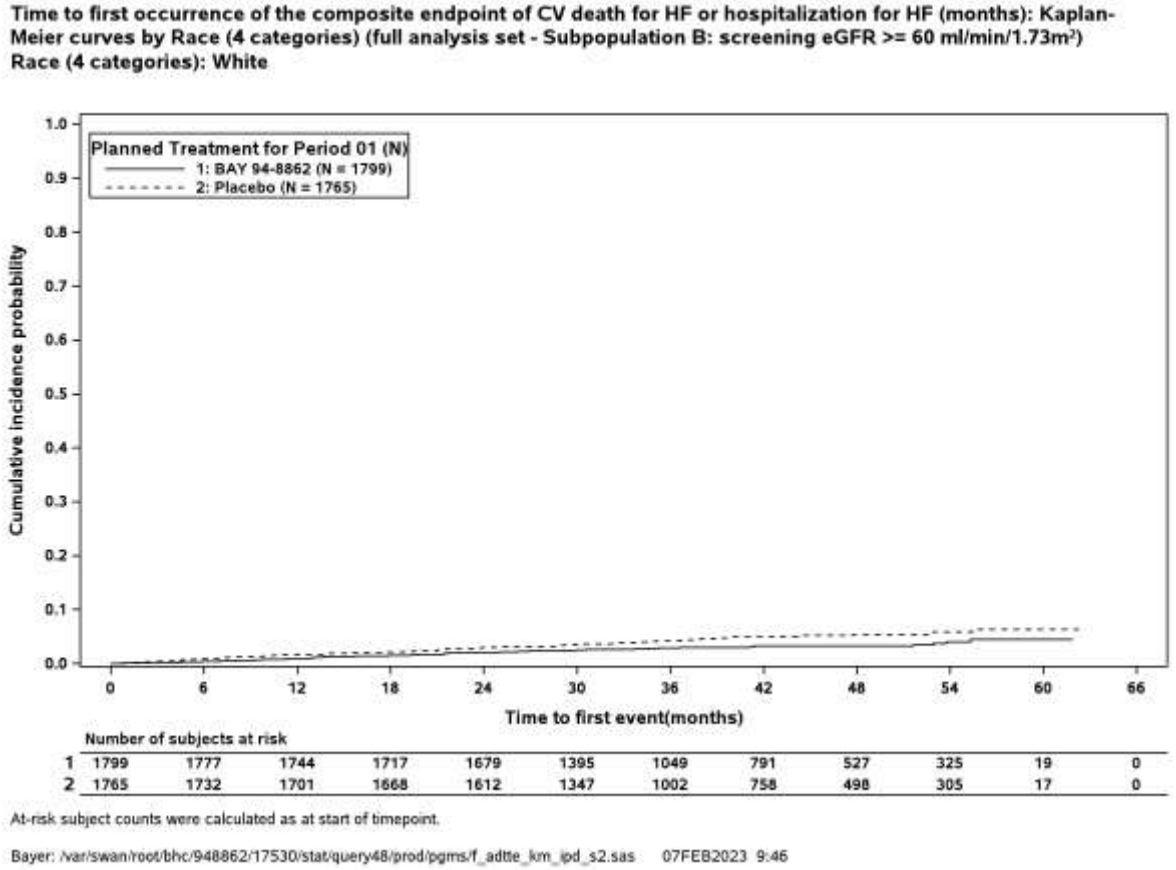


Figure 1.2.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

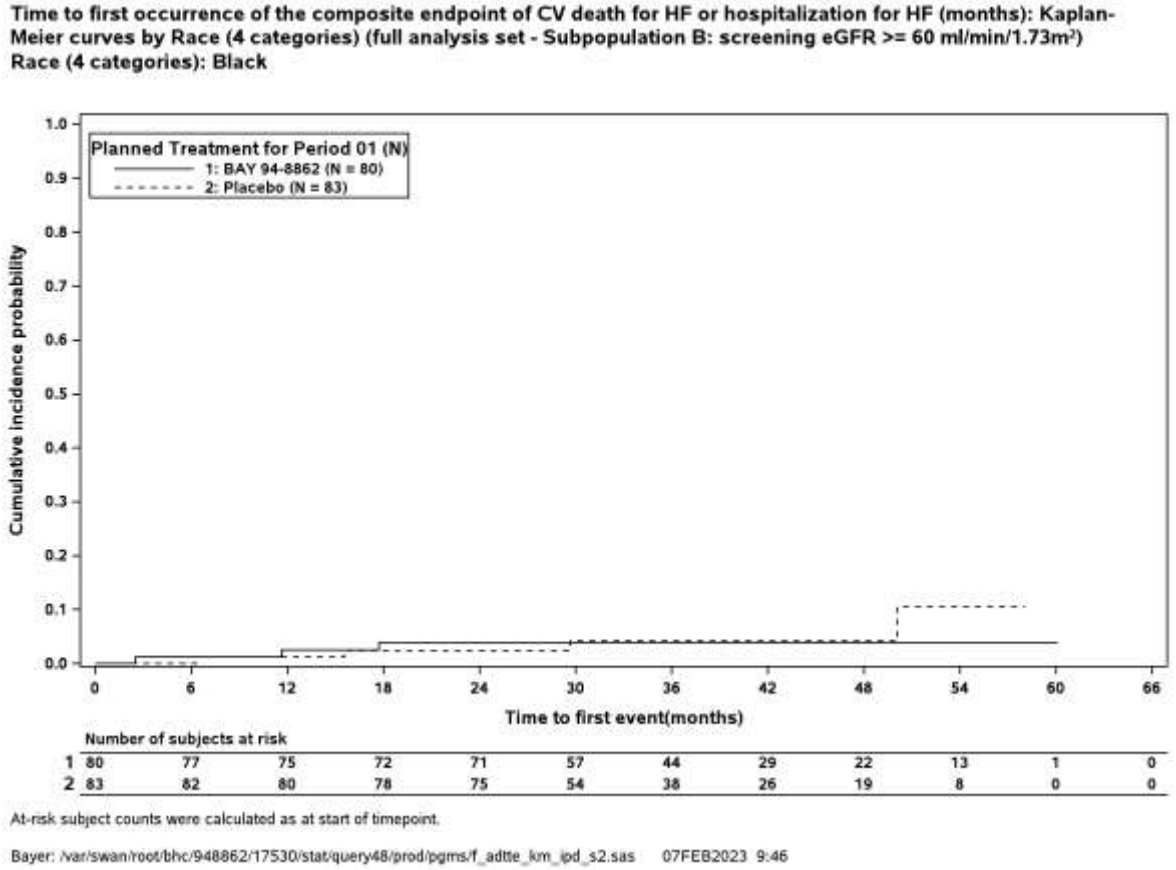


Figure 1.2.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

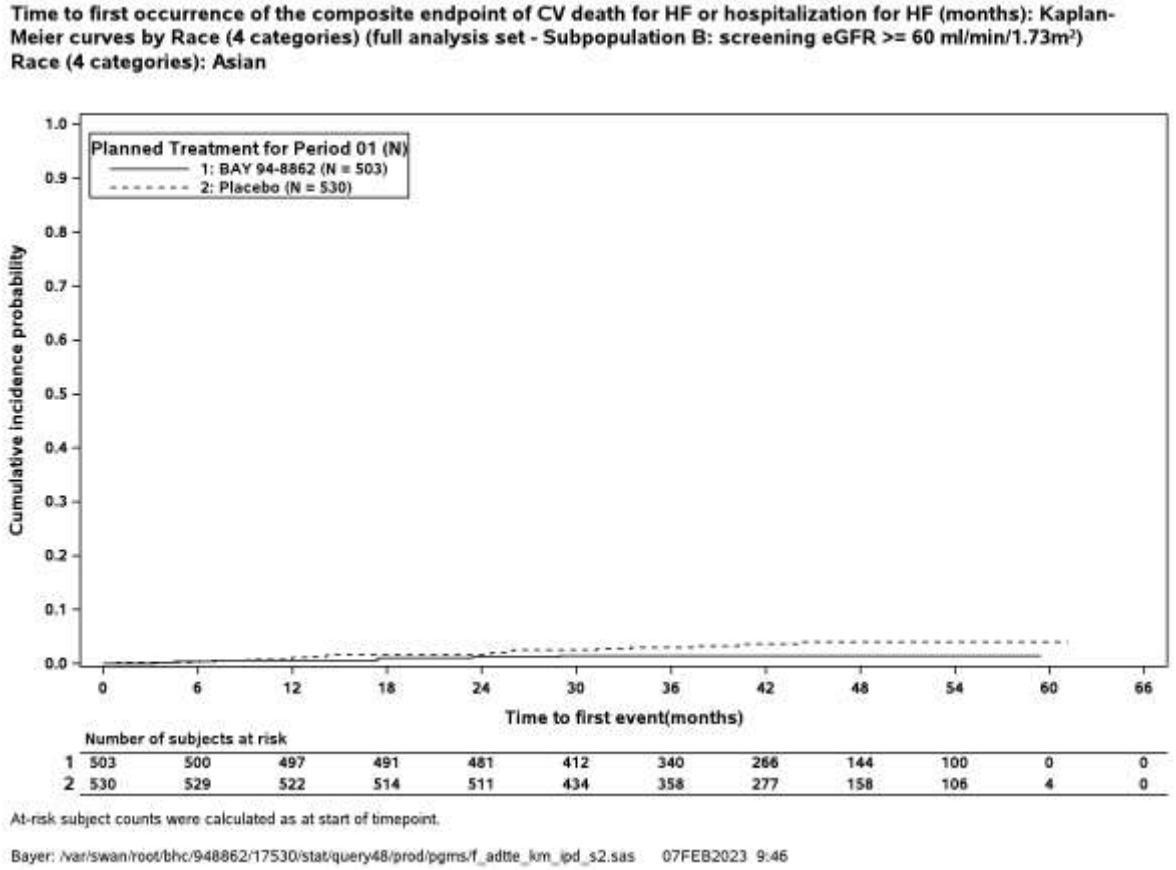


Figure 1.2.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

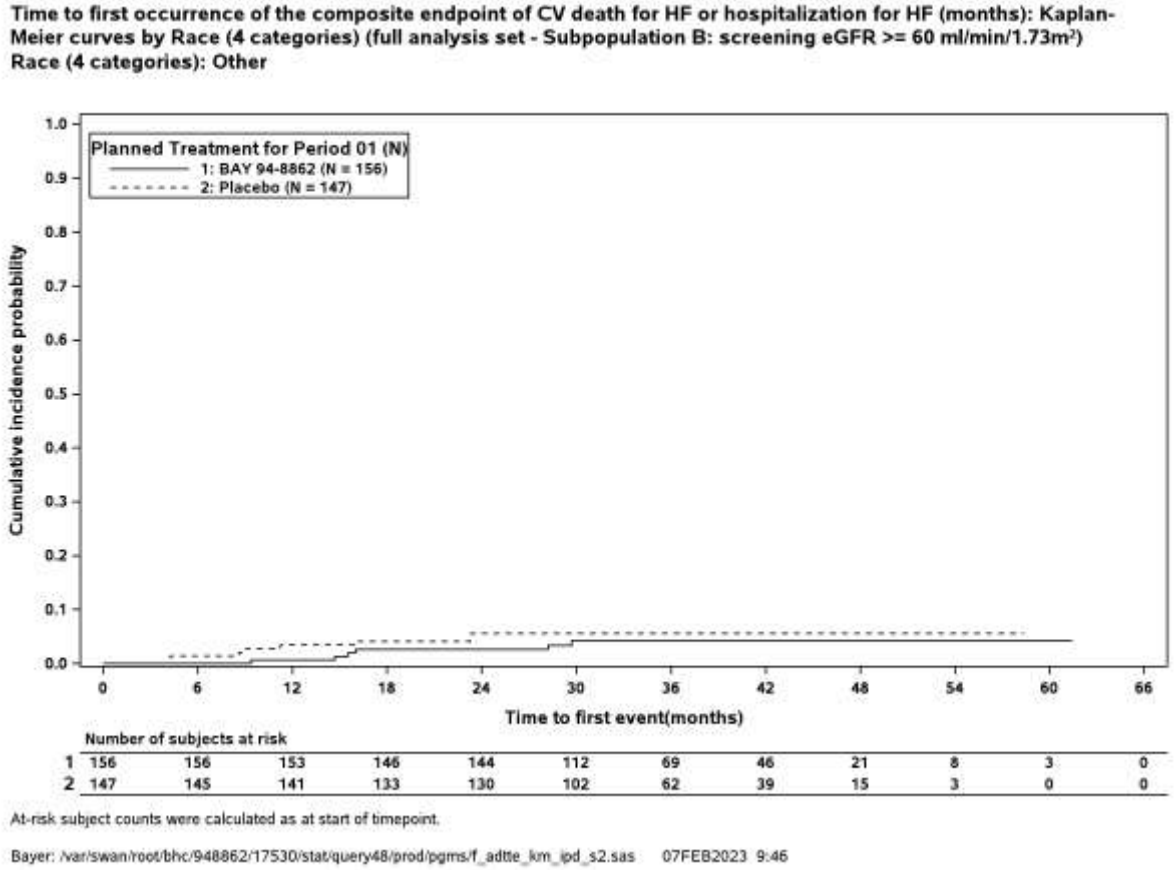


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

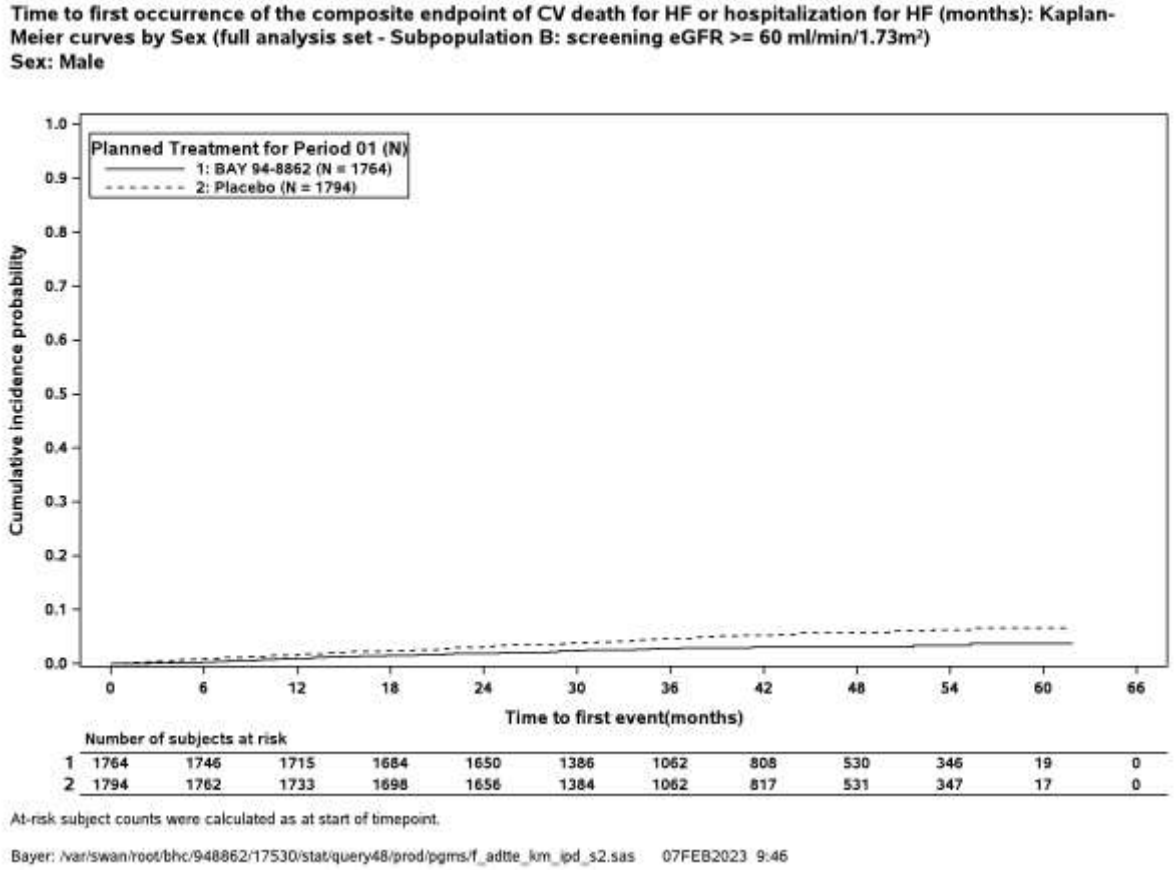


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

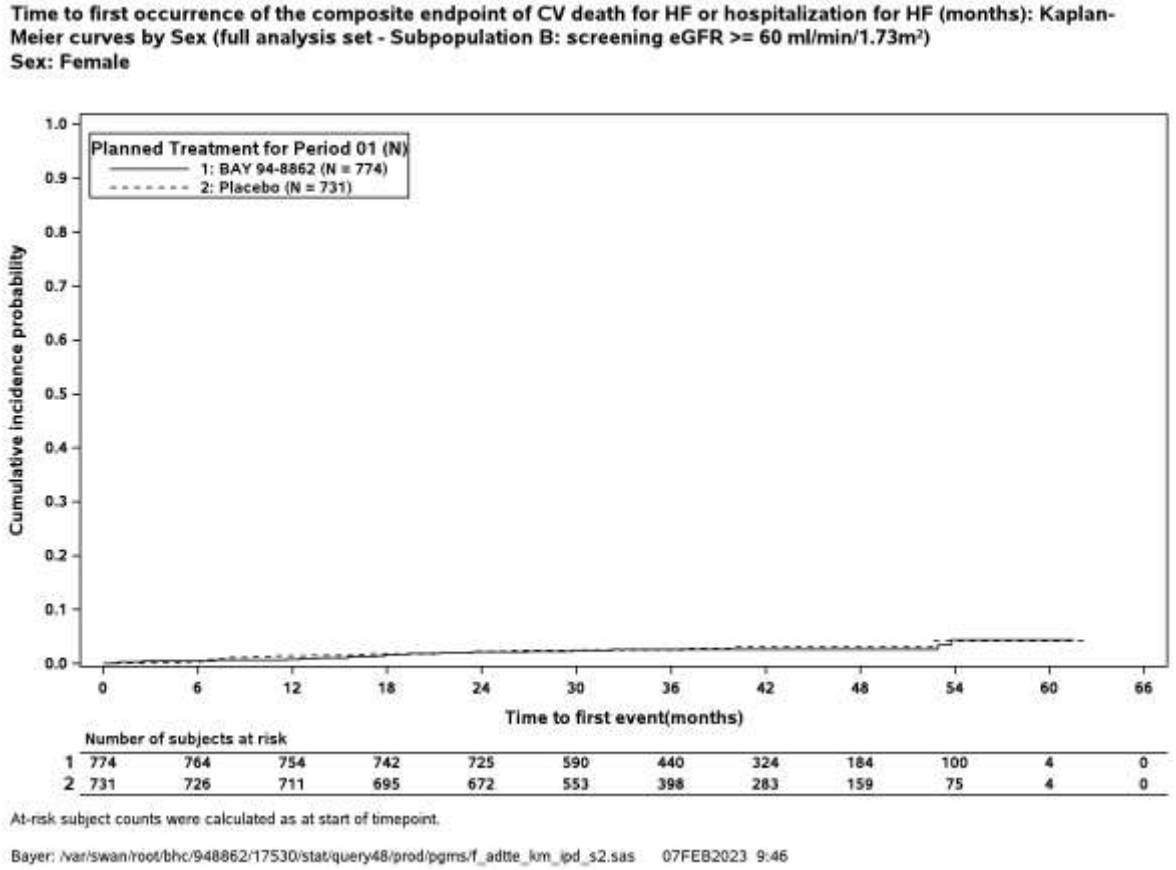


Figure 1.2.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

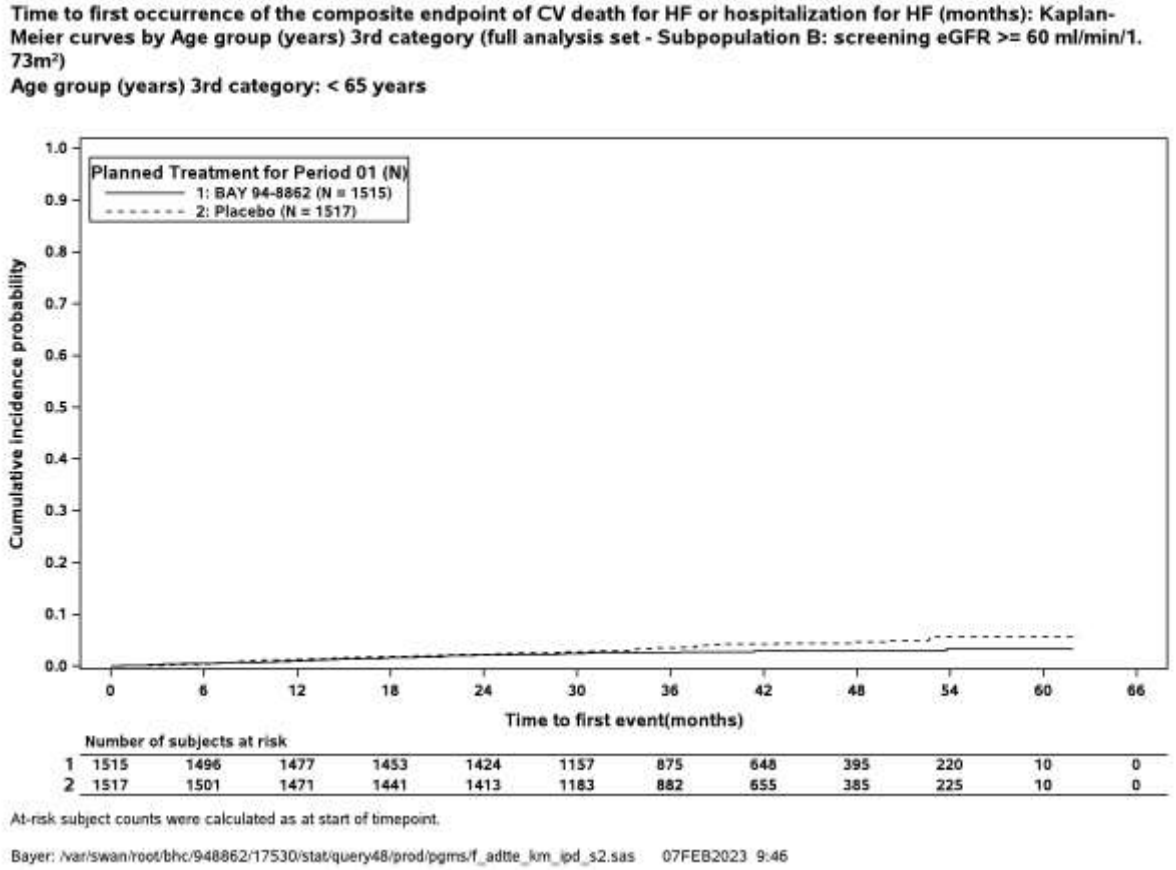


Figure 1.2.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

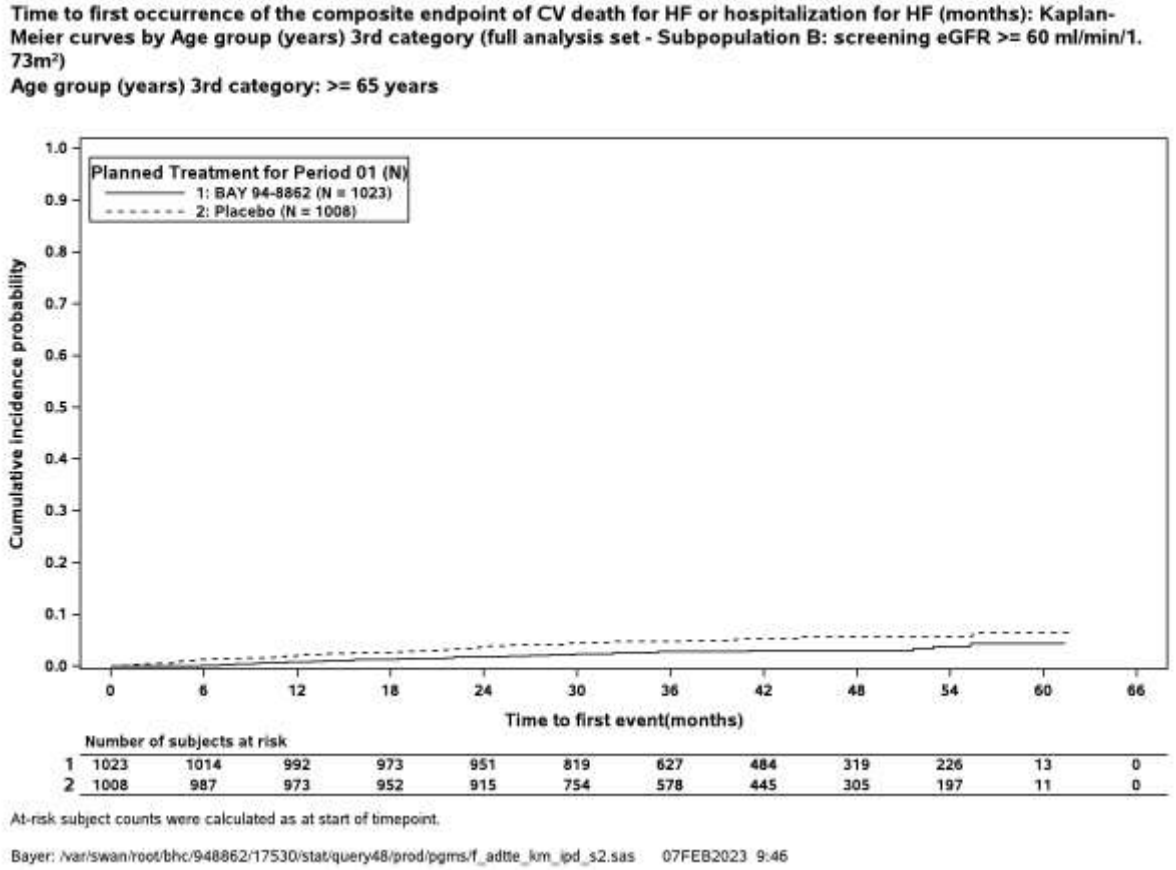


Figure 1.2.1 / 74: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

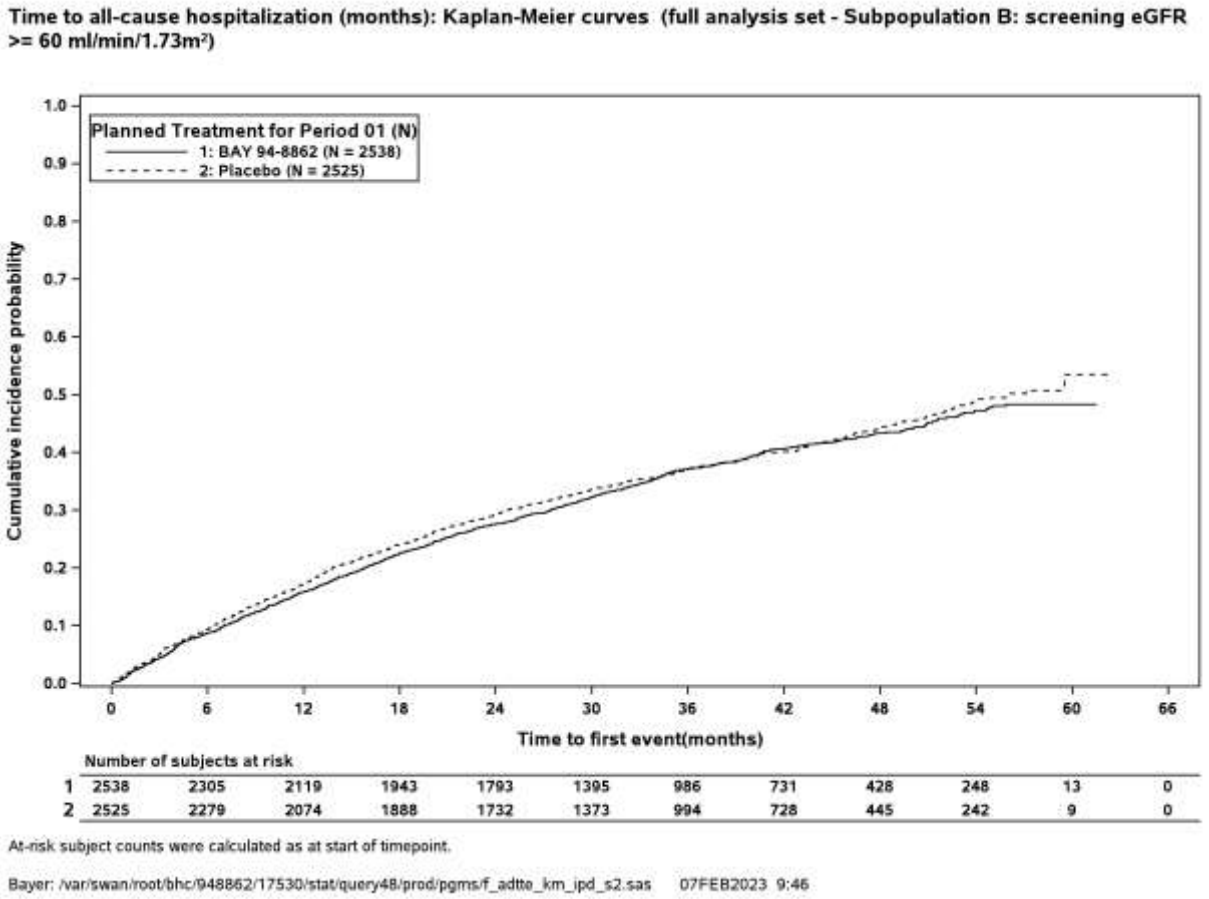


Figure 1.2.1 / 75: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Region: Europe

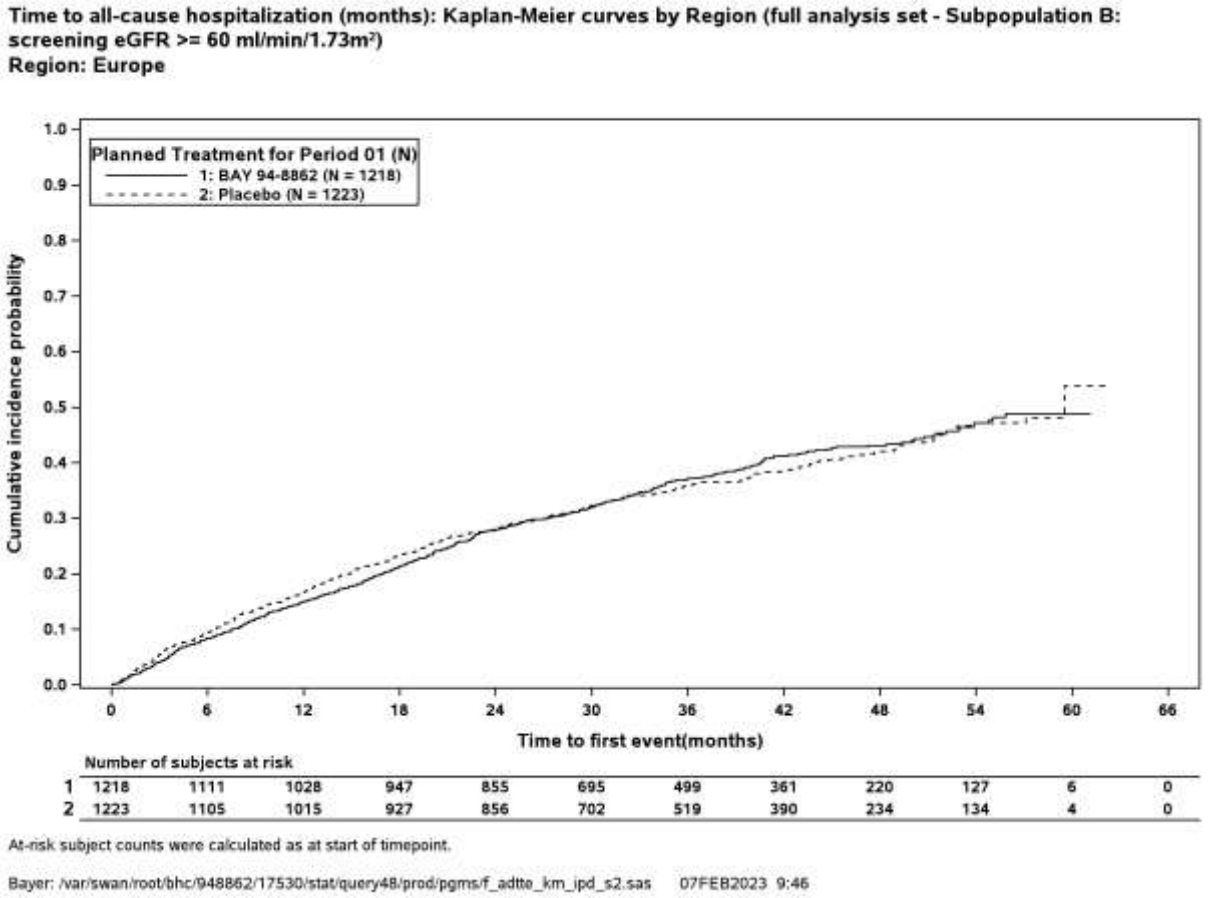


Figure 1.2.1 / 75: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: North America

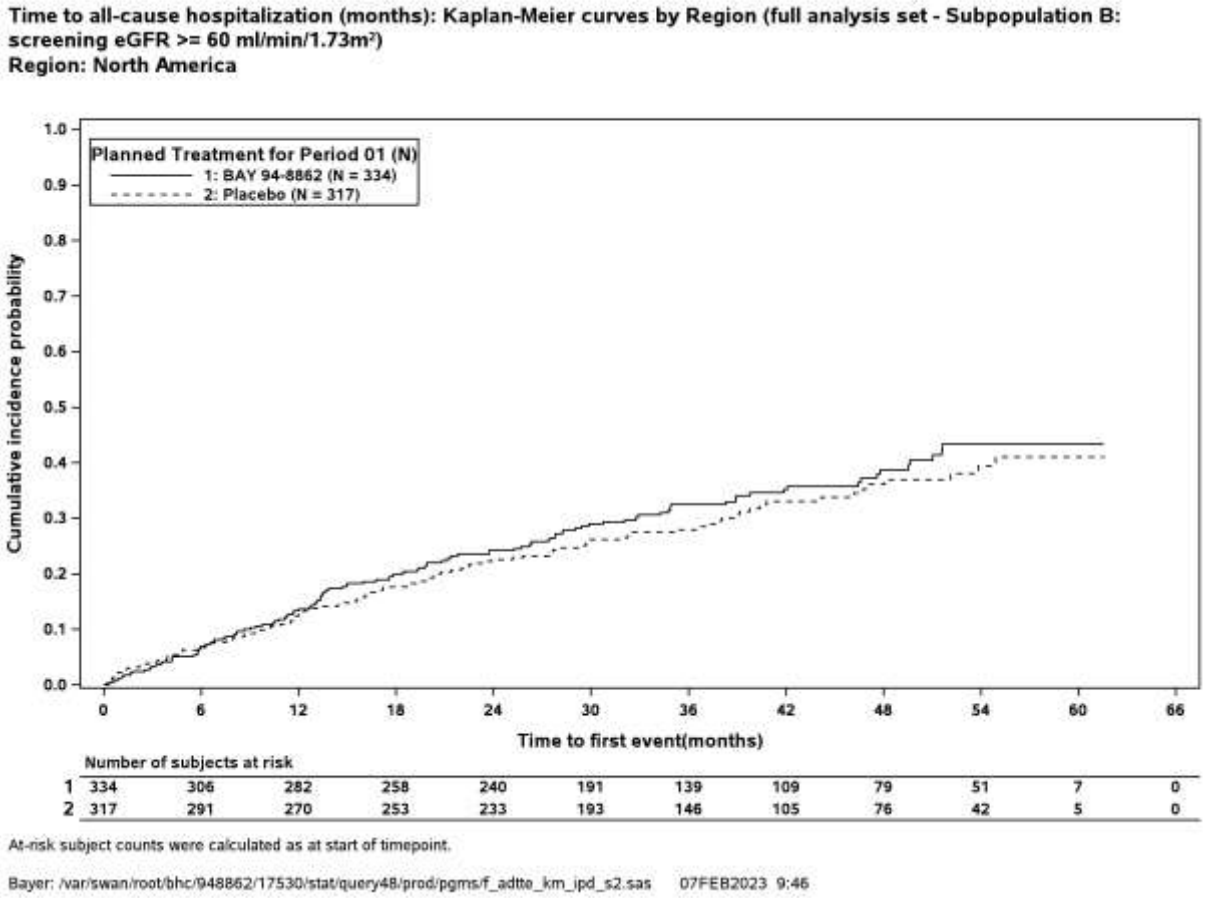


Figure 1.2.1 / 75: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Asia

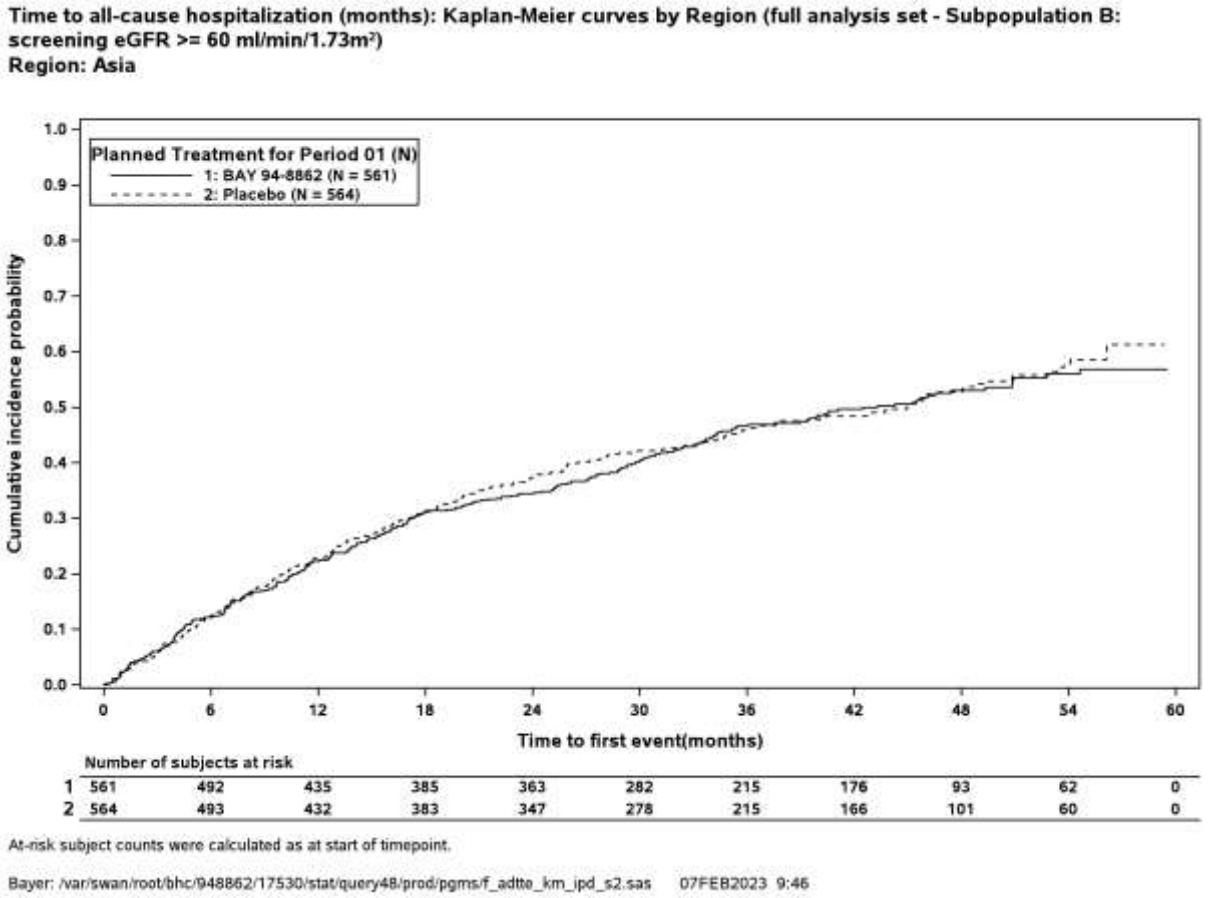


Figure 1.2.1 / 75: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Latin America

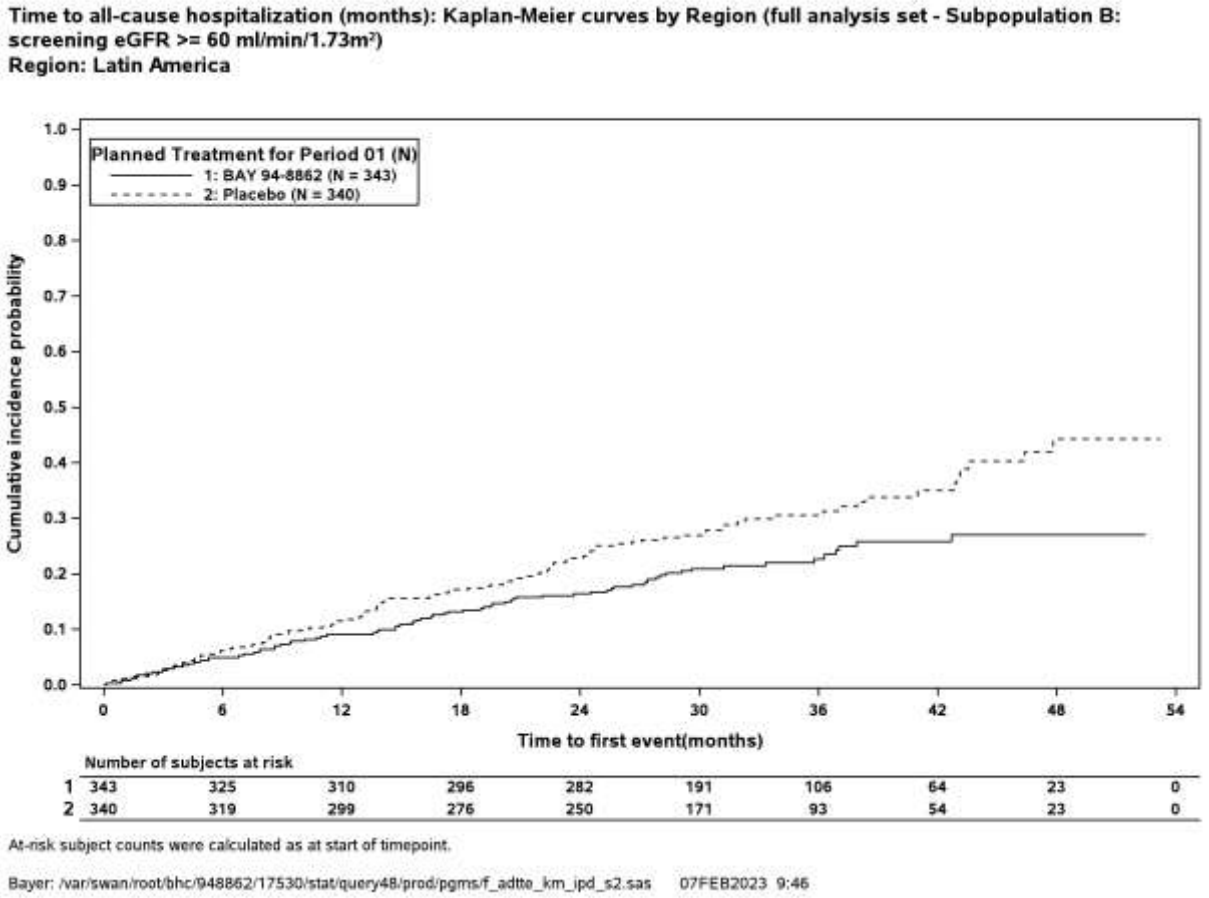


Figure 1.2.1 / 75: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Region: Others

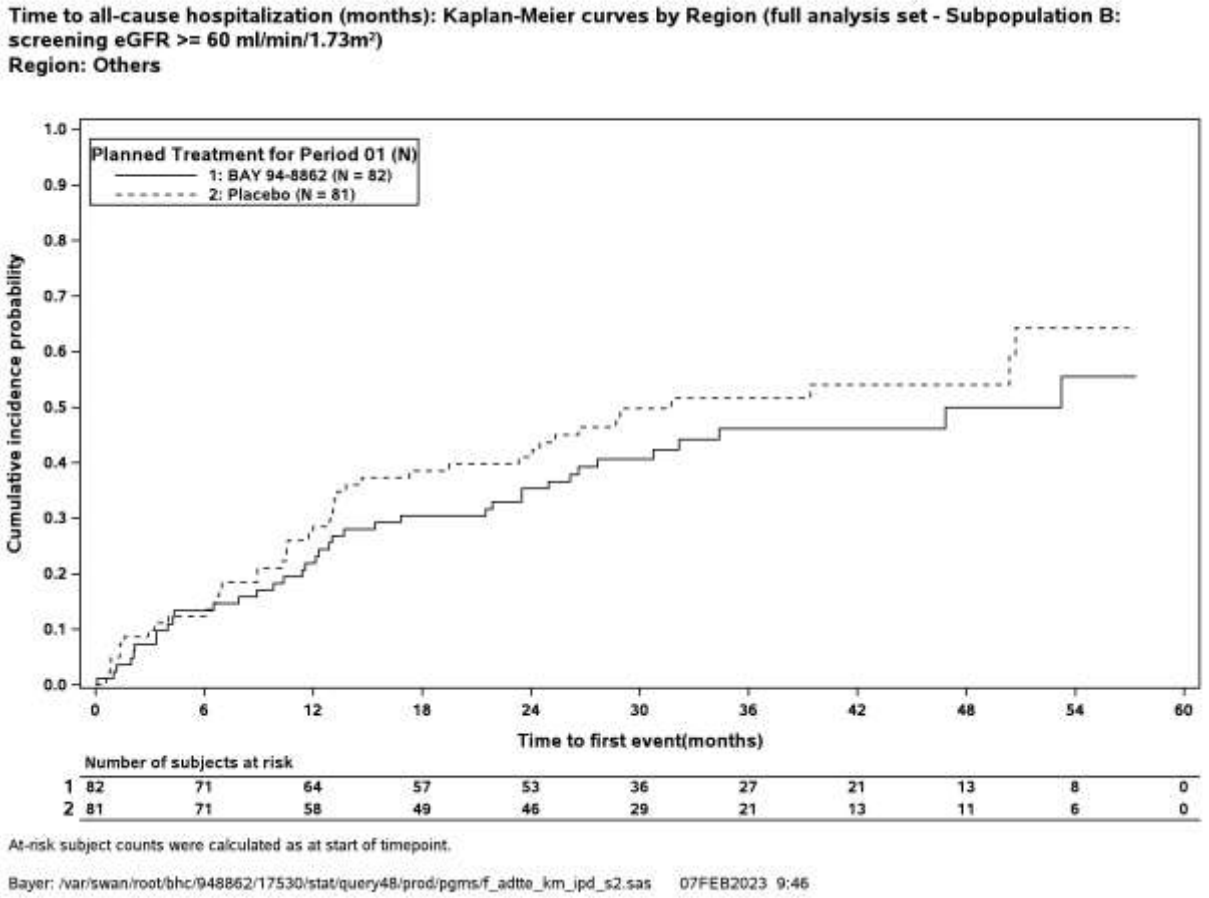


Figure 1.2.1 / 76: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

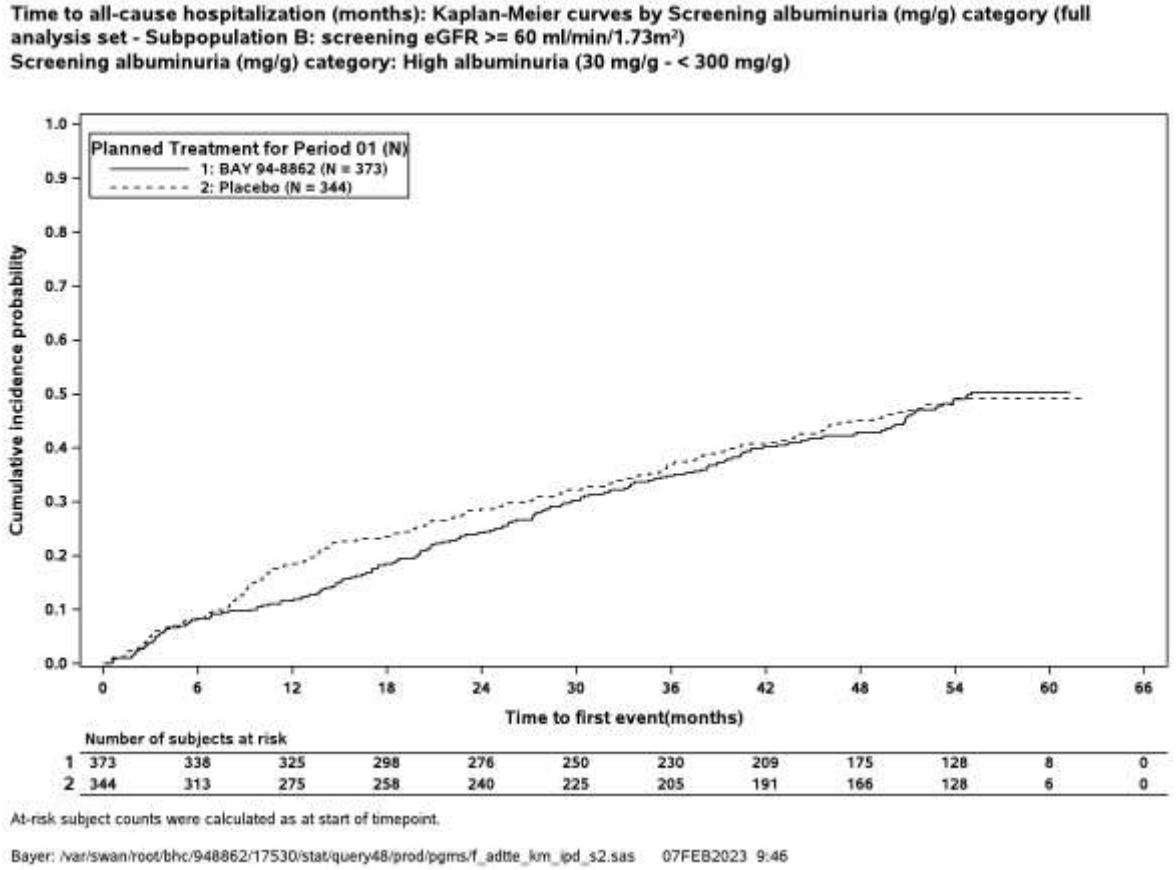


Figure 1.2.1 / 76: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

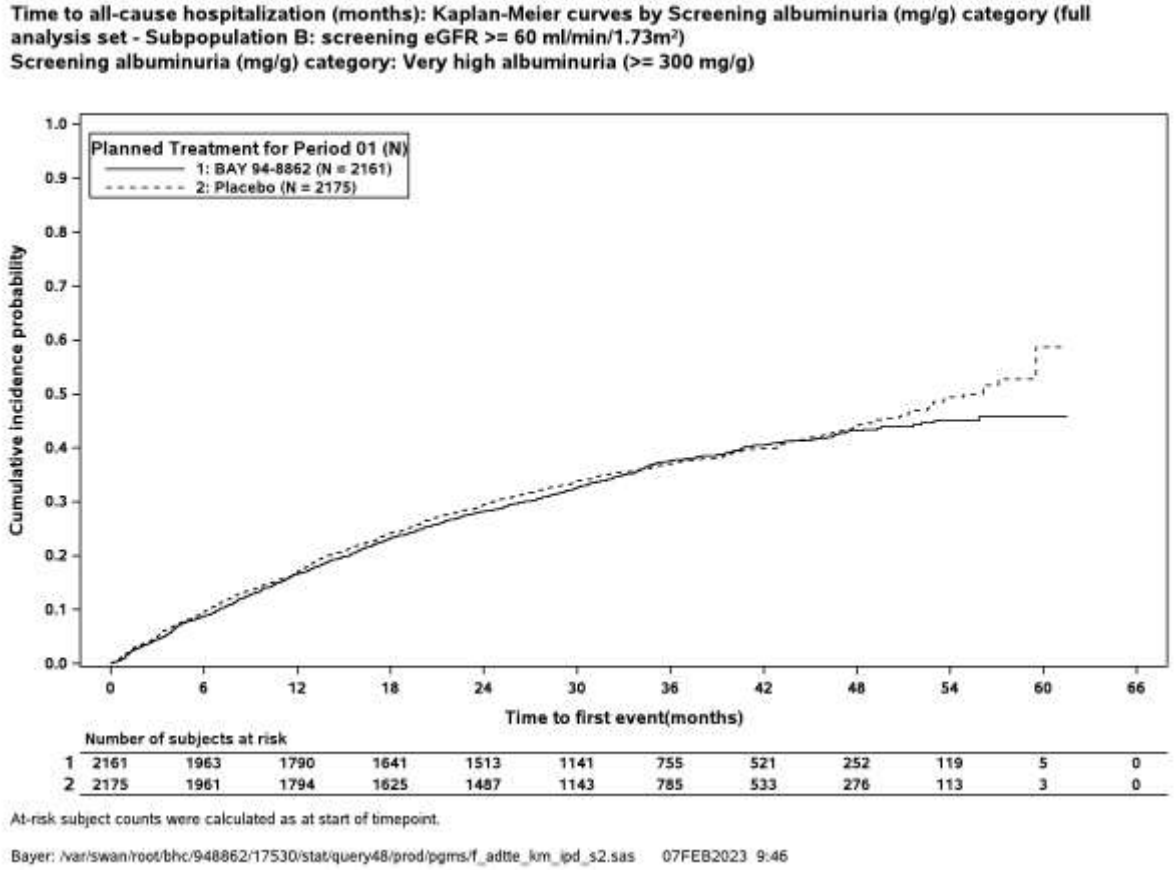


Figure 1.2.1 / 77: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

History of CVD (Medical history): present

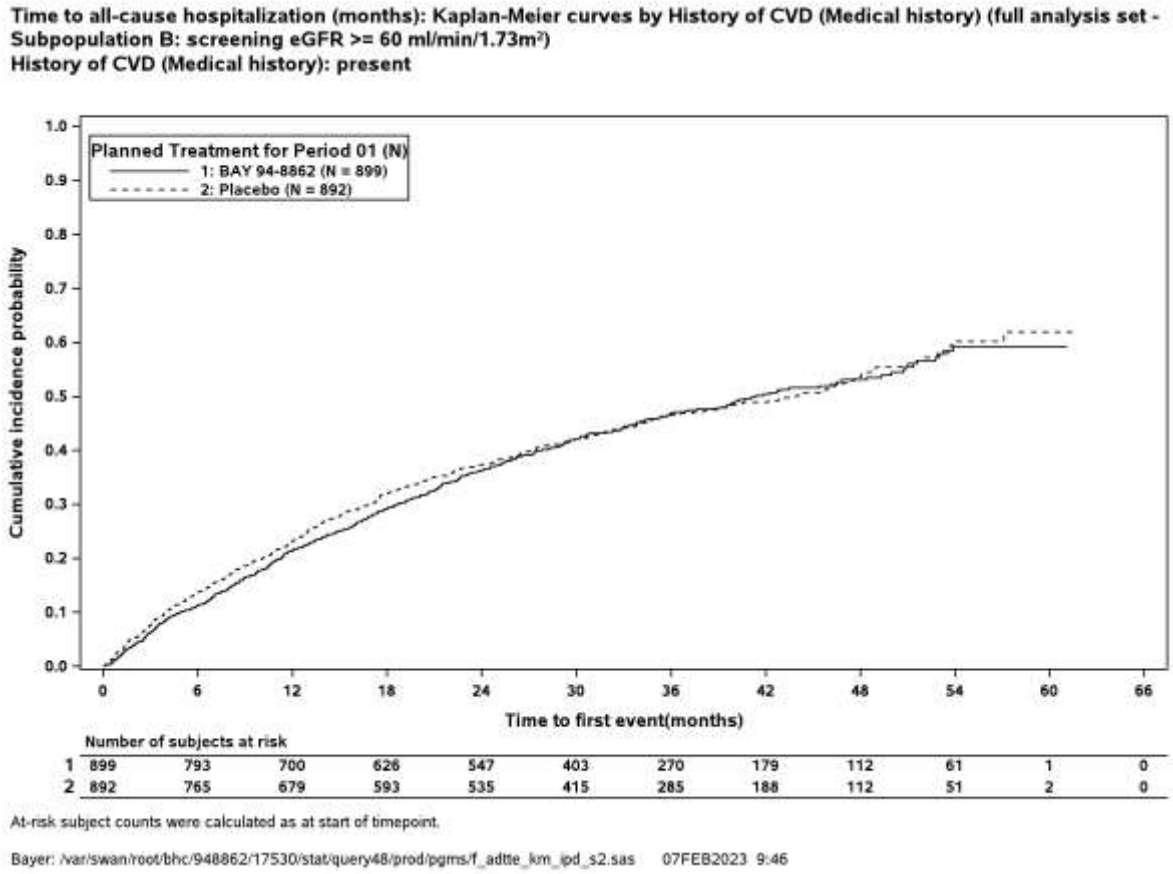


Figure 1.2.1 / 77: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

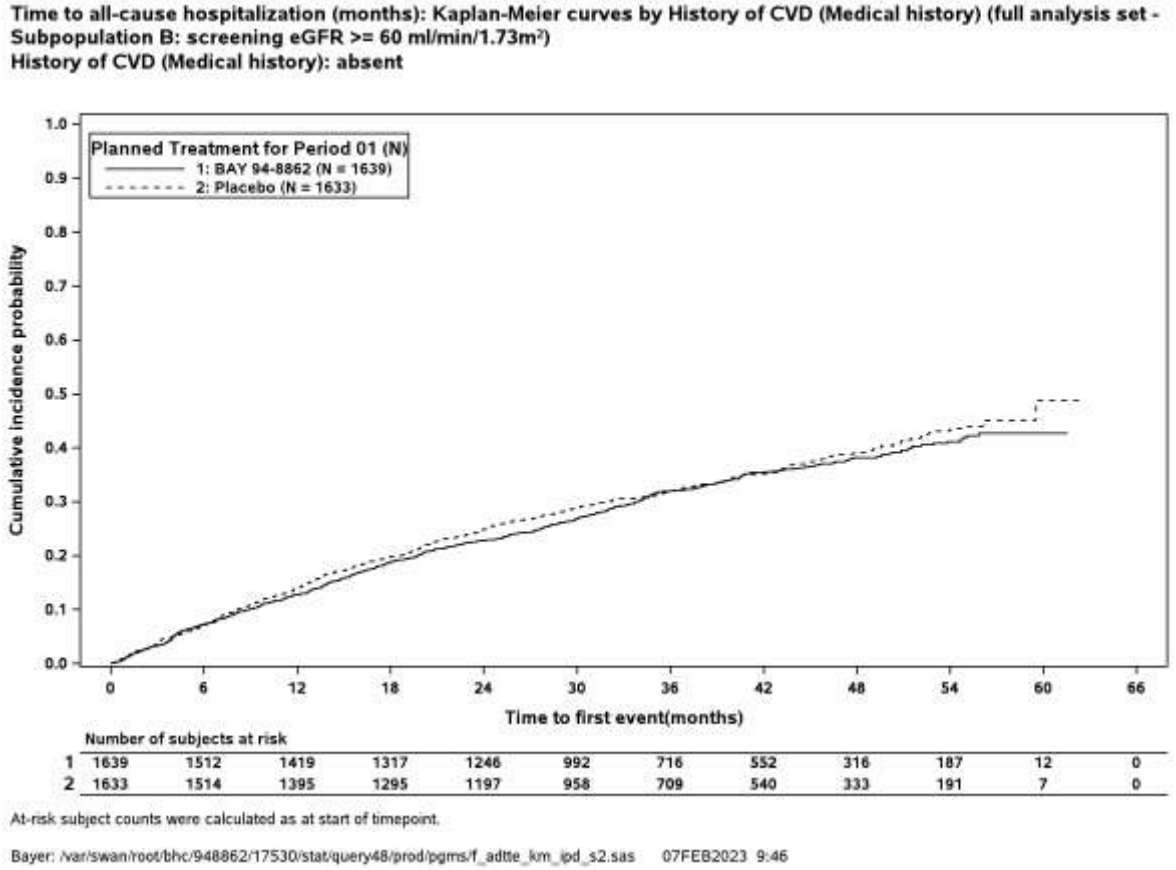


Figure 1.2.1 / 78: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

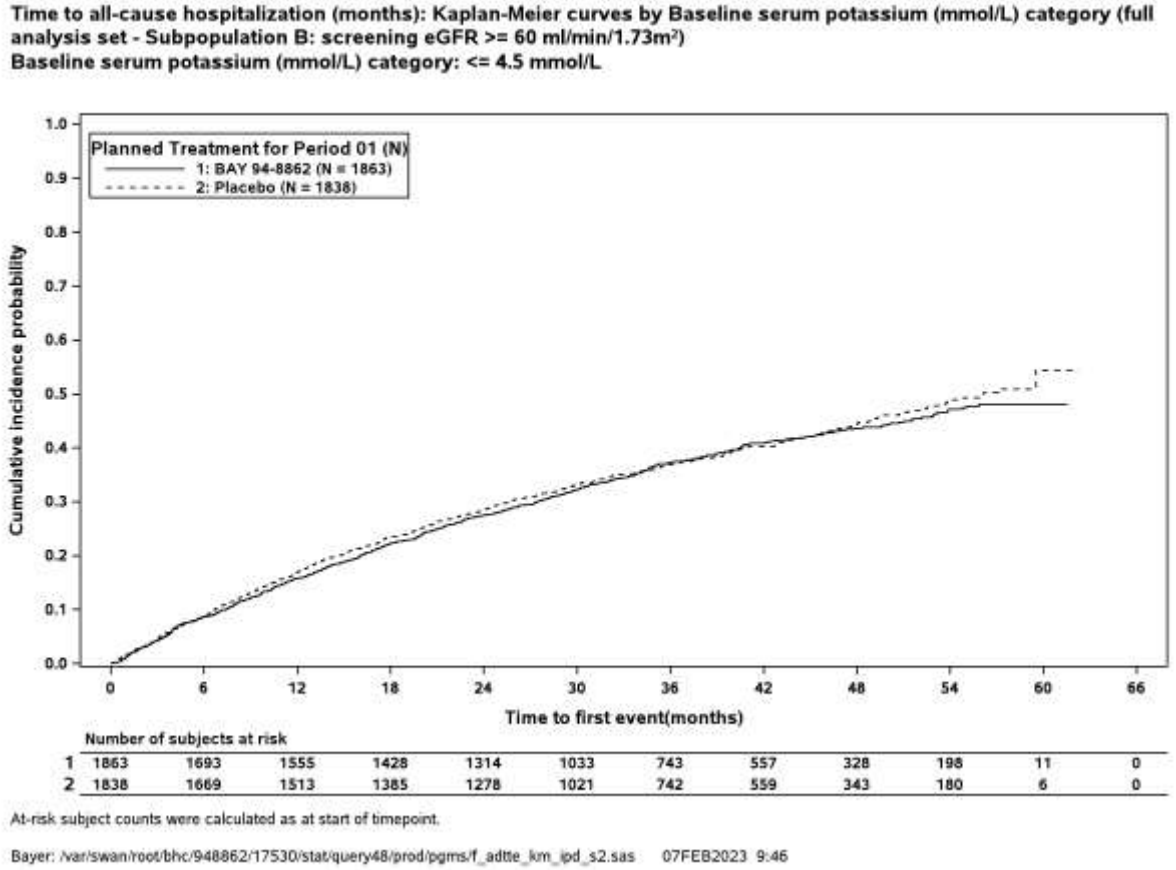
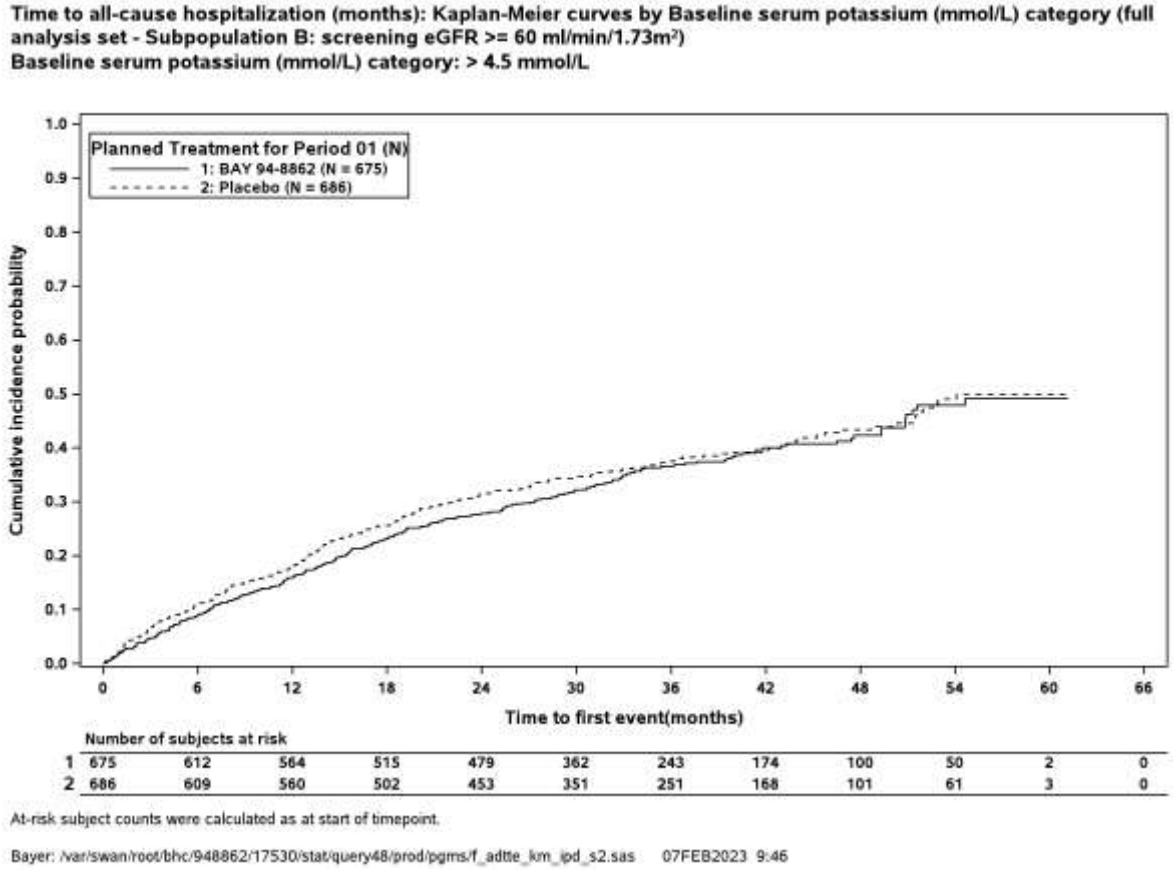


Figure 1.2.1 / 78: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s2.sas 07FEB2023 9:46

Figure 1.2.1 / 79: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

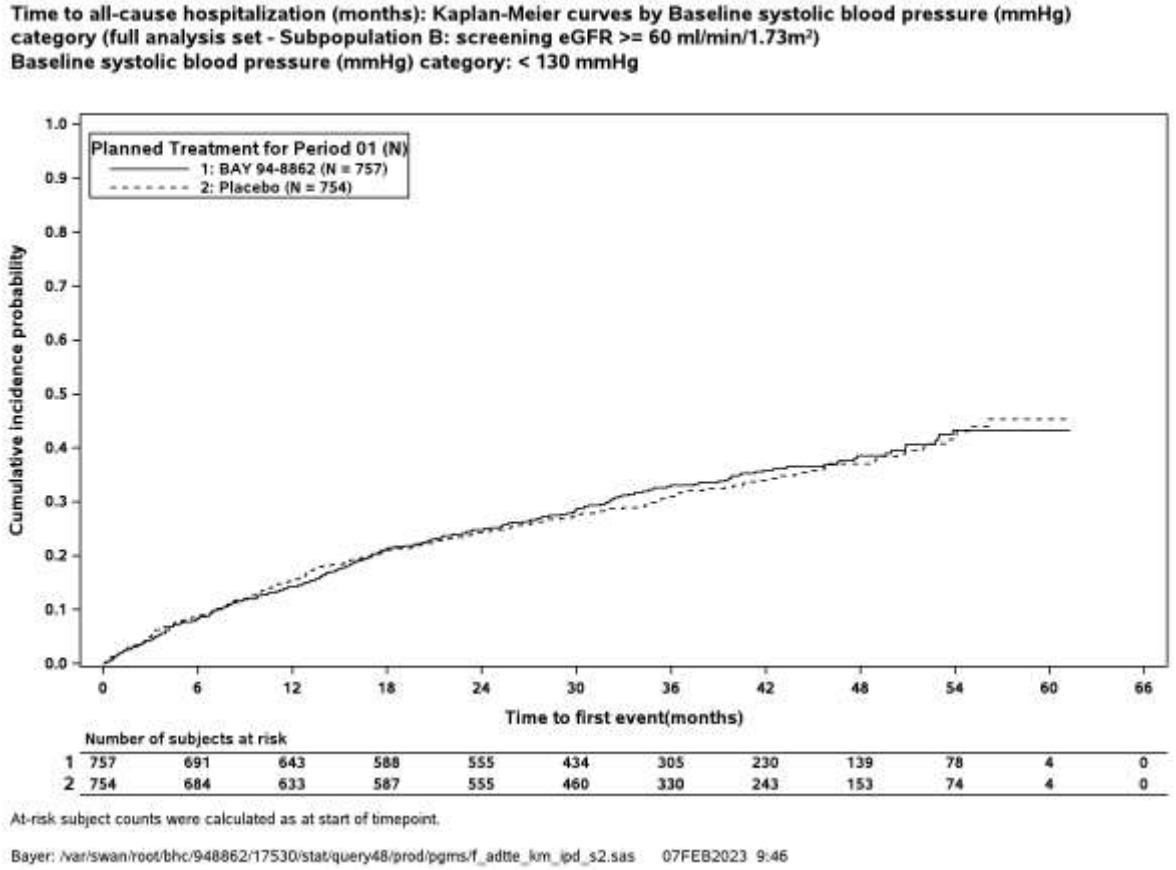


Figure 1.2.1 / 79: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

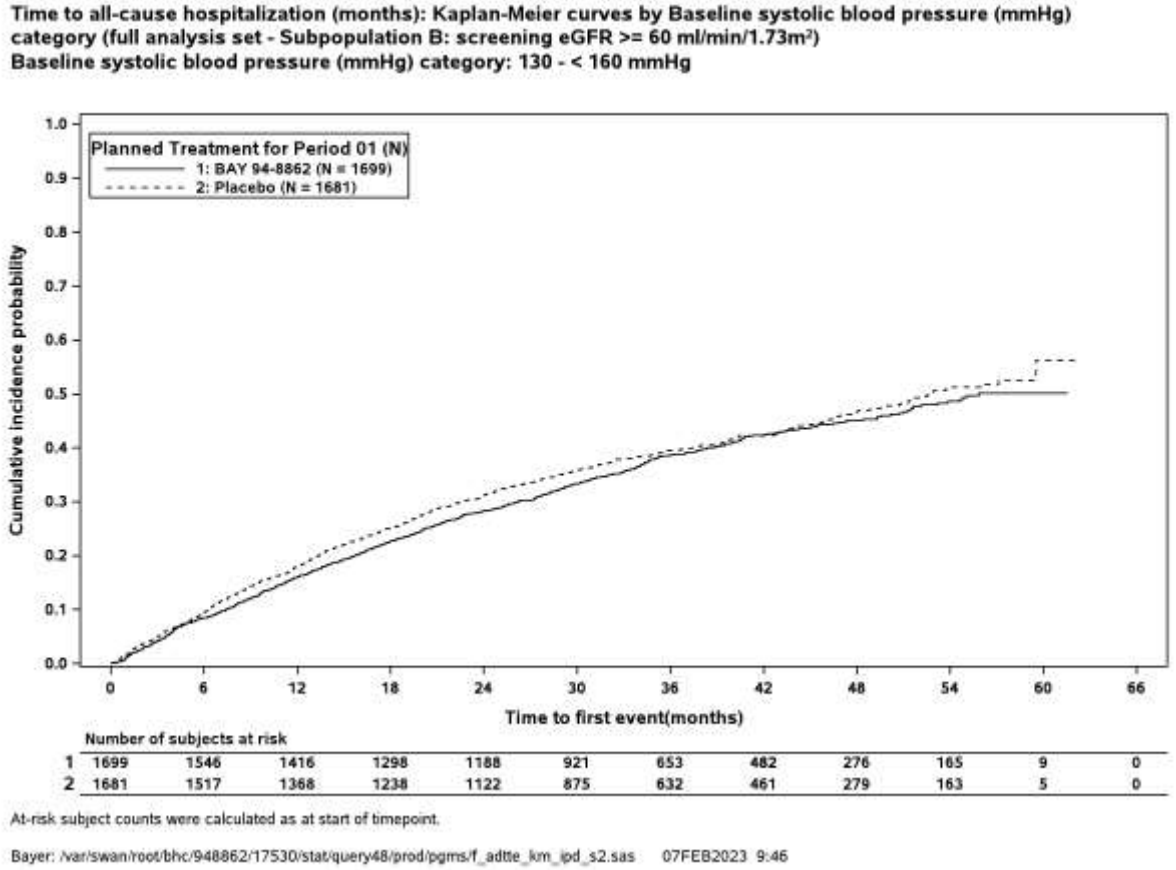


Figure 1.2.1 / 79: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

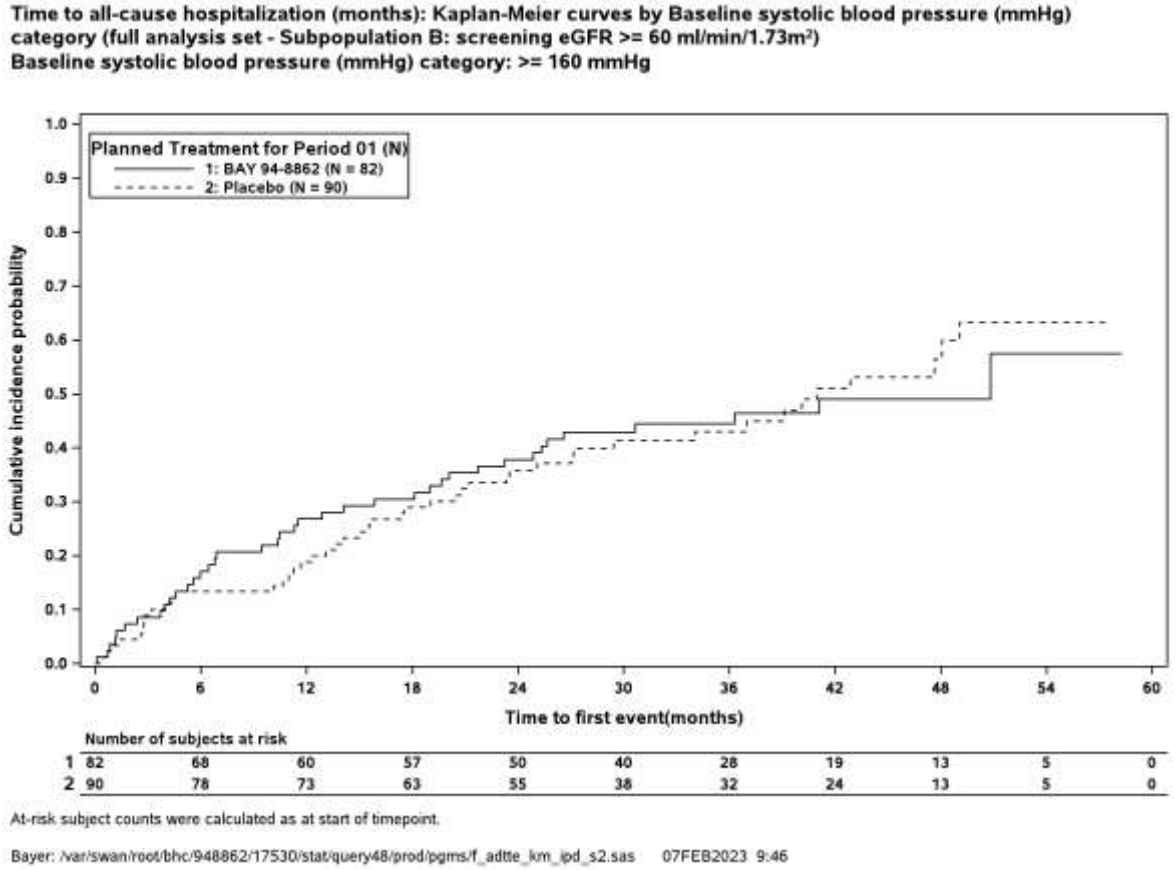


Figure 1.2.1 / 80: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Race (4 categories): White

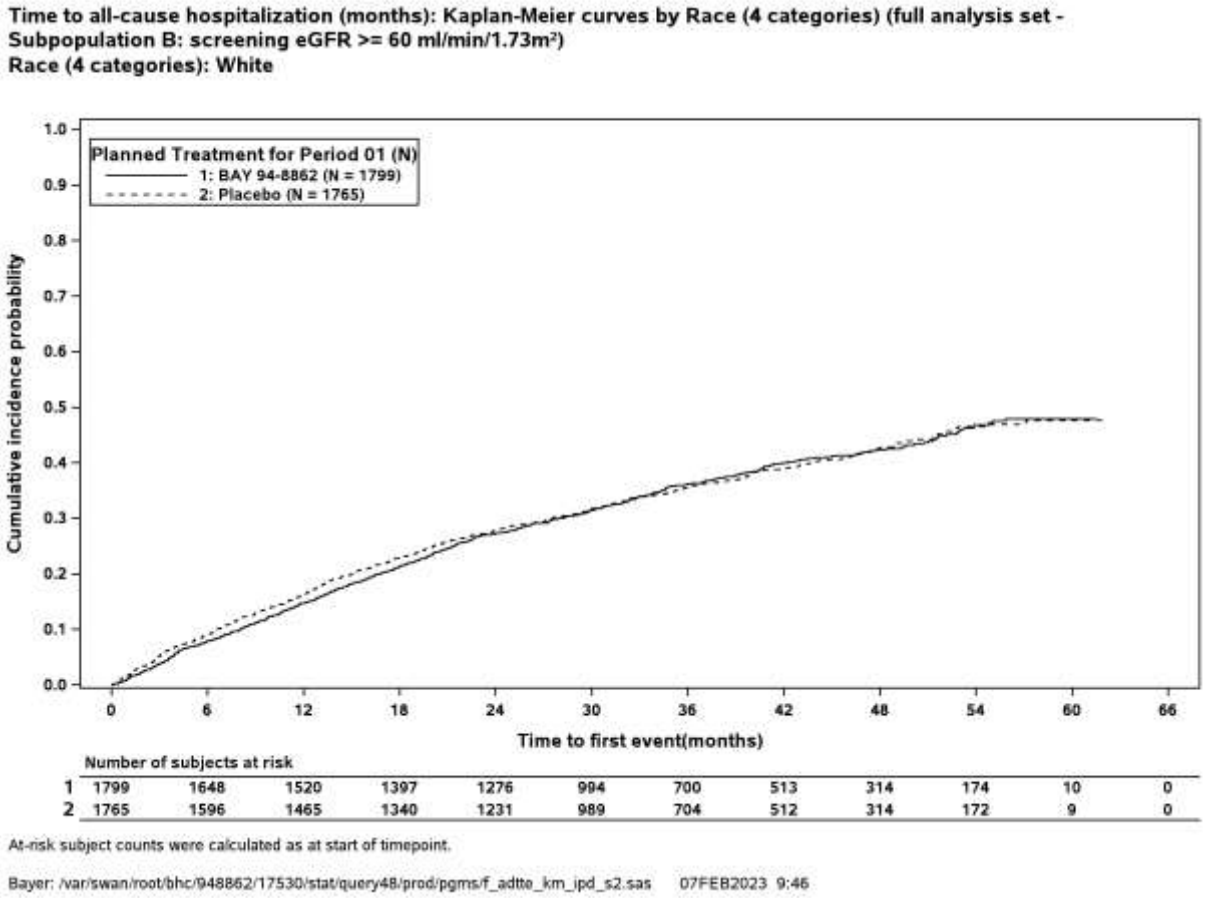


Figure 1.2.1 / 80: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

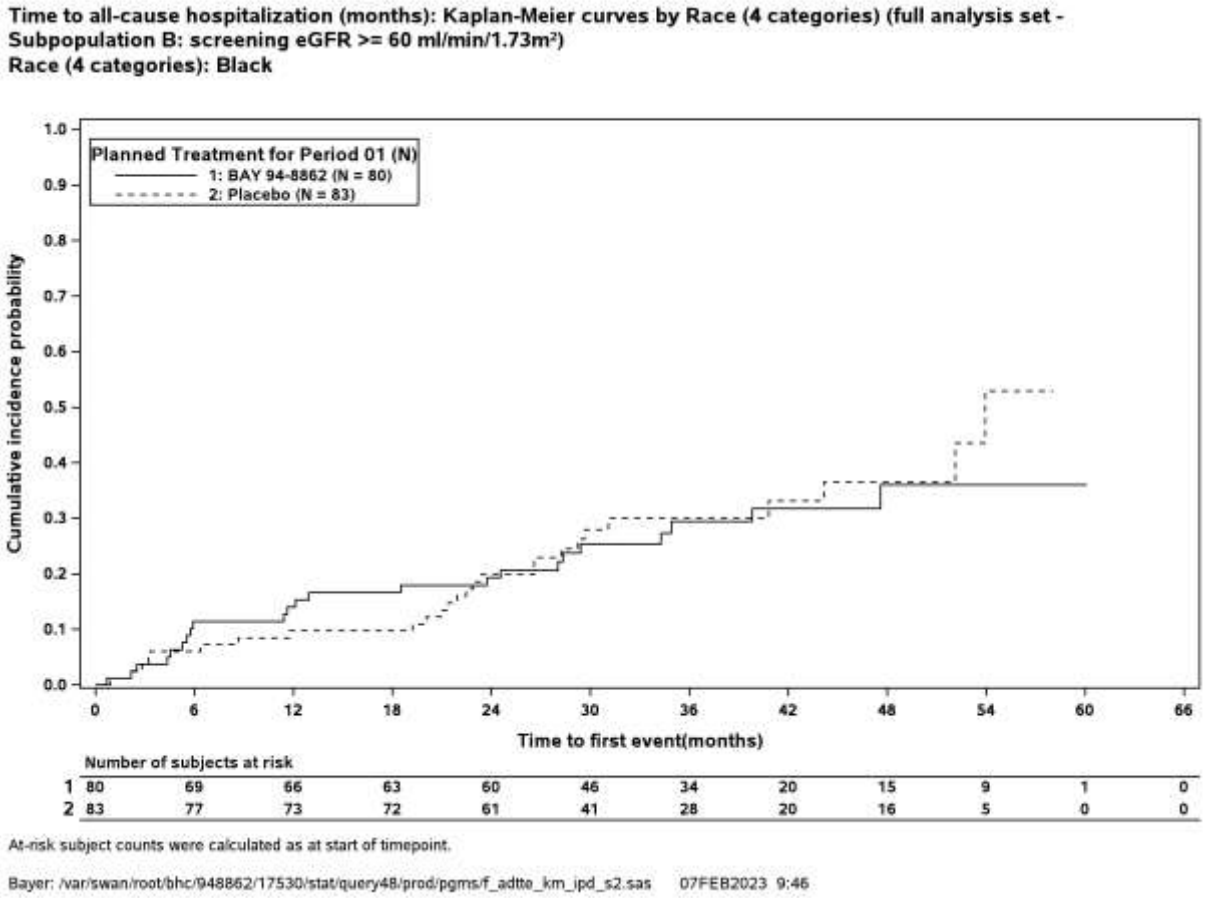


Figure 1.2.1 / 80: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

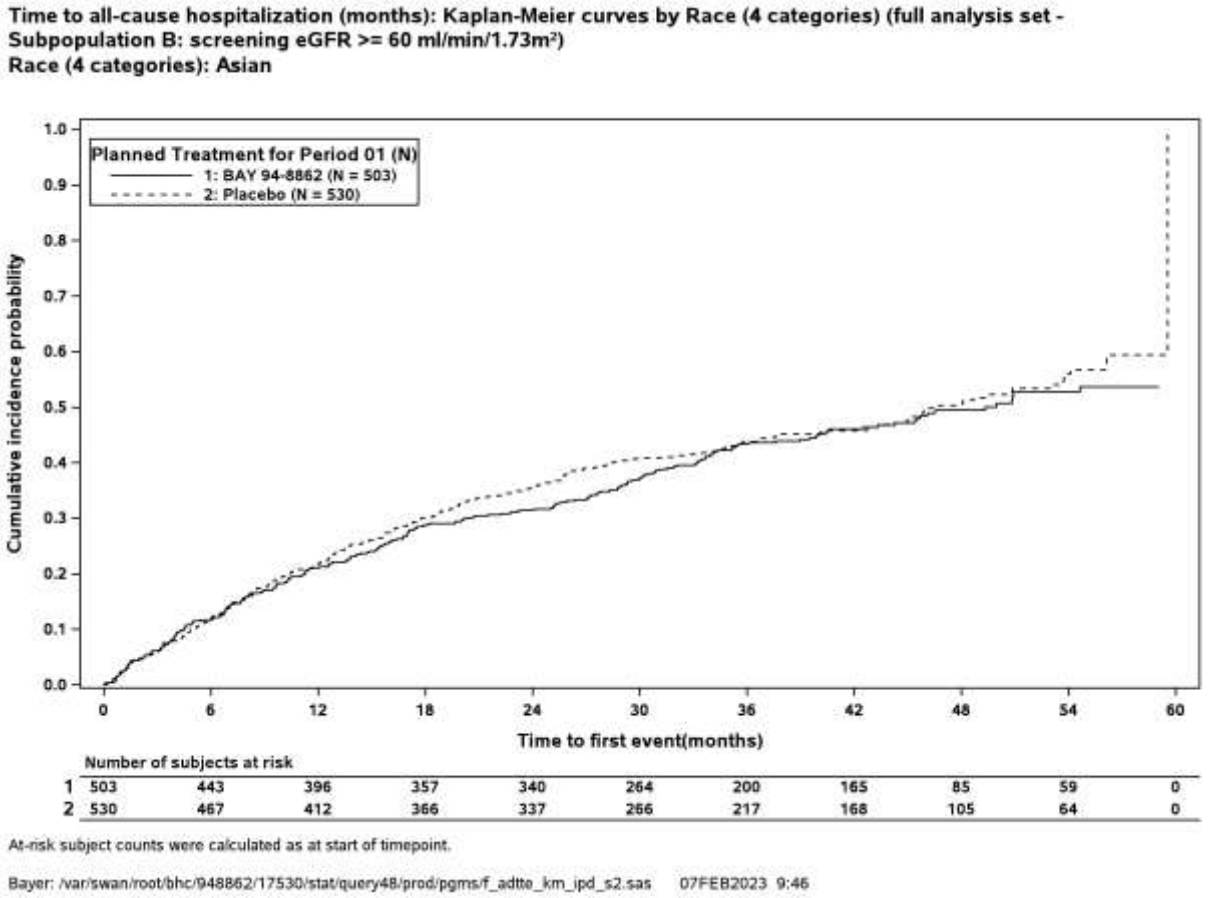


Figure 1.2.1 / 80: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

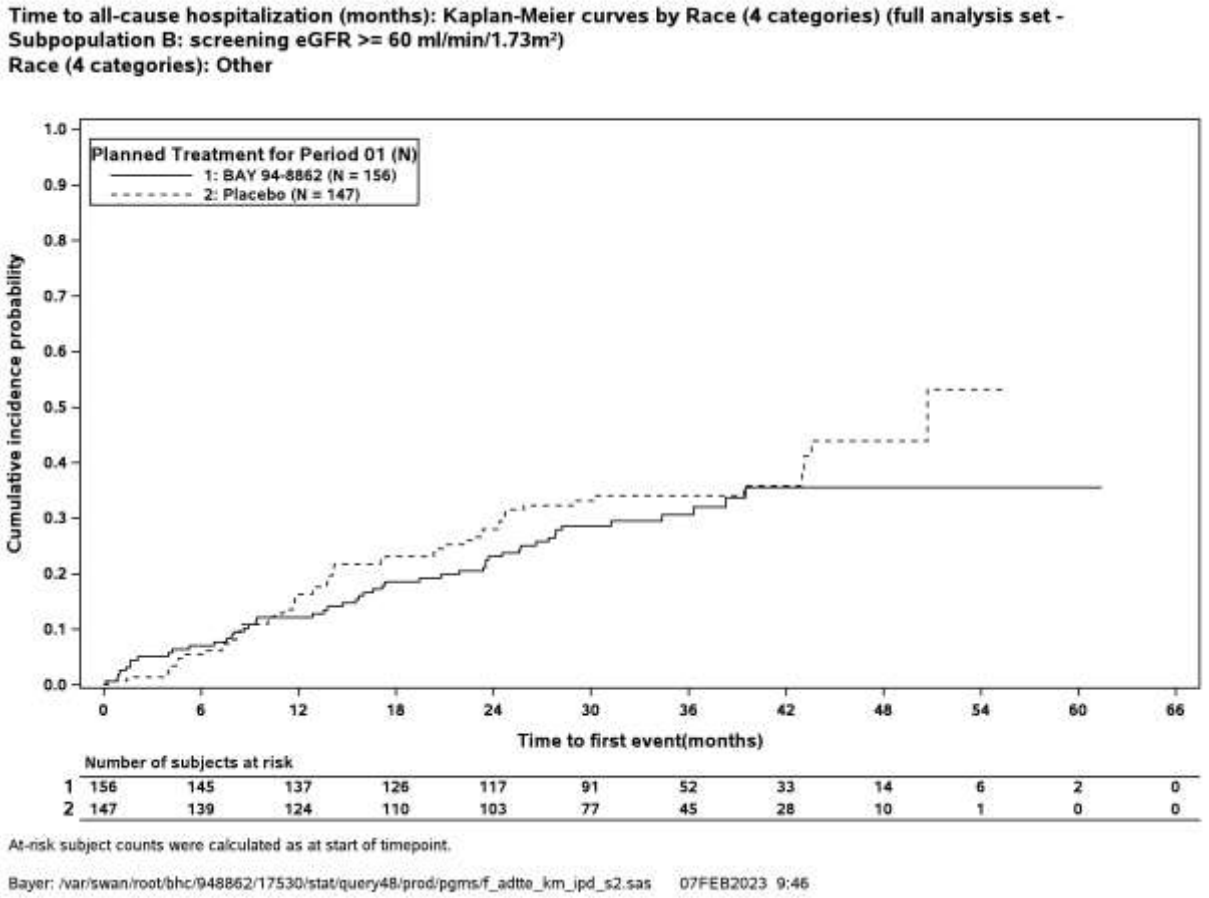


Figure 1.2.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Sex: Male

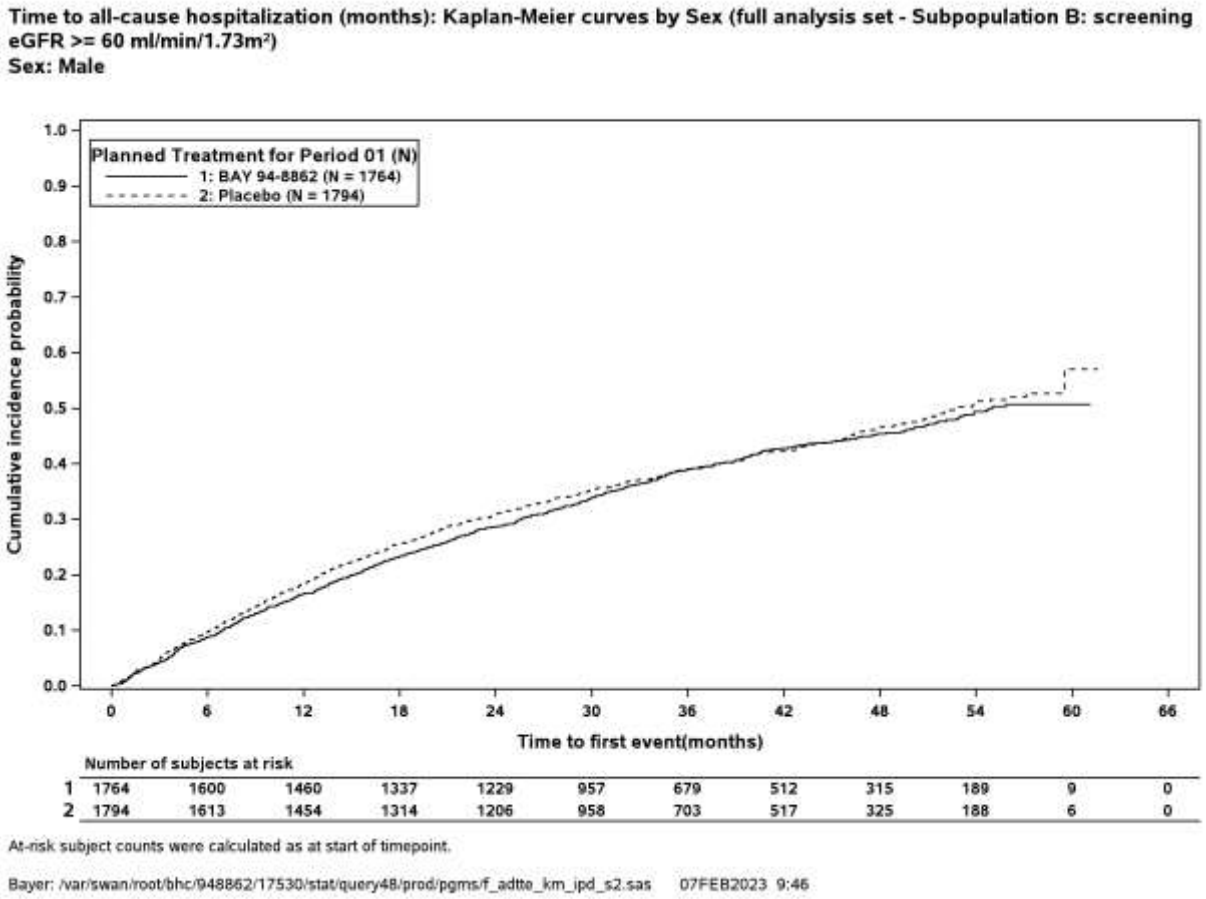


Figure 1.2.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Sex: Female

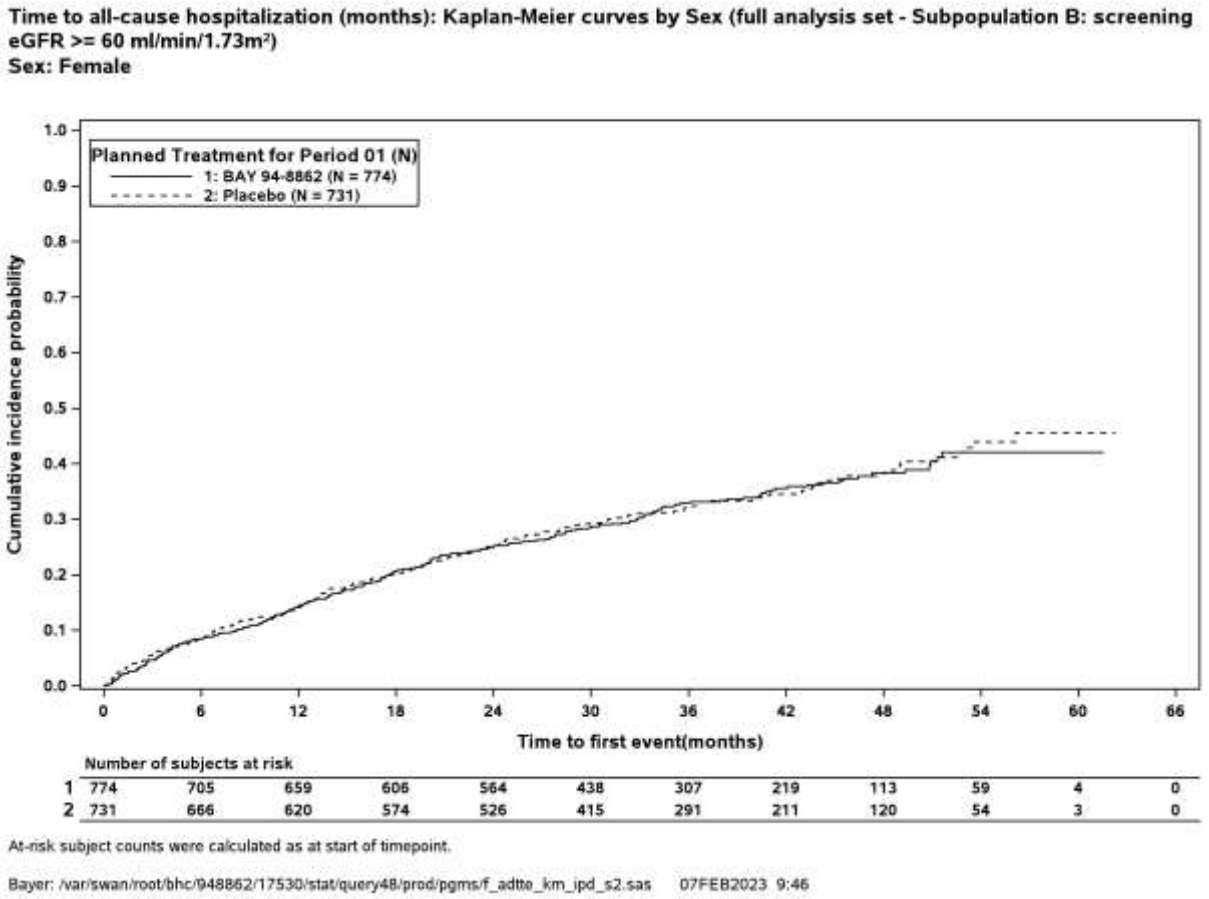


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

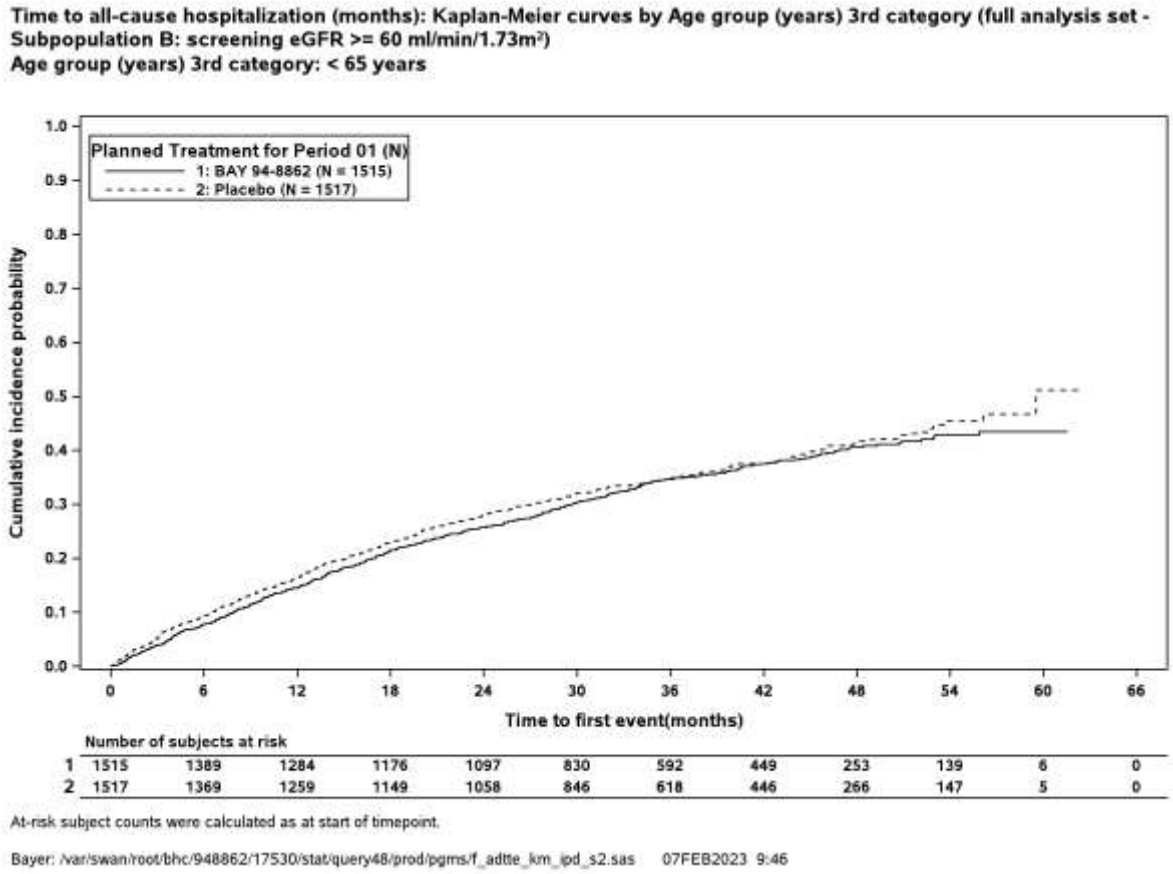
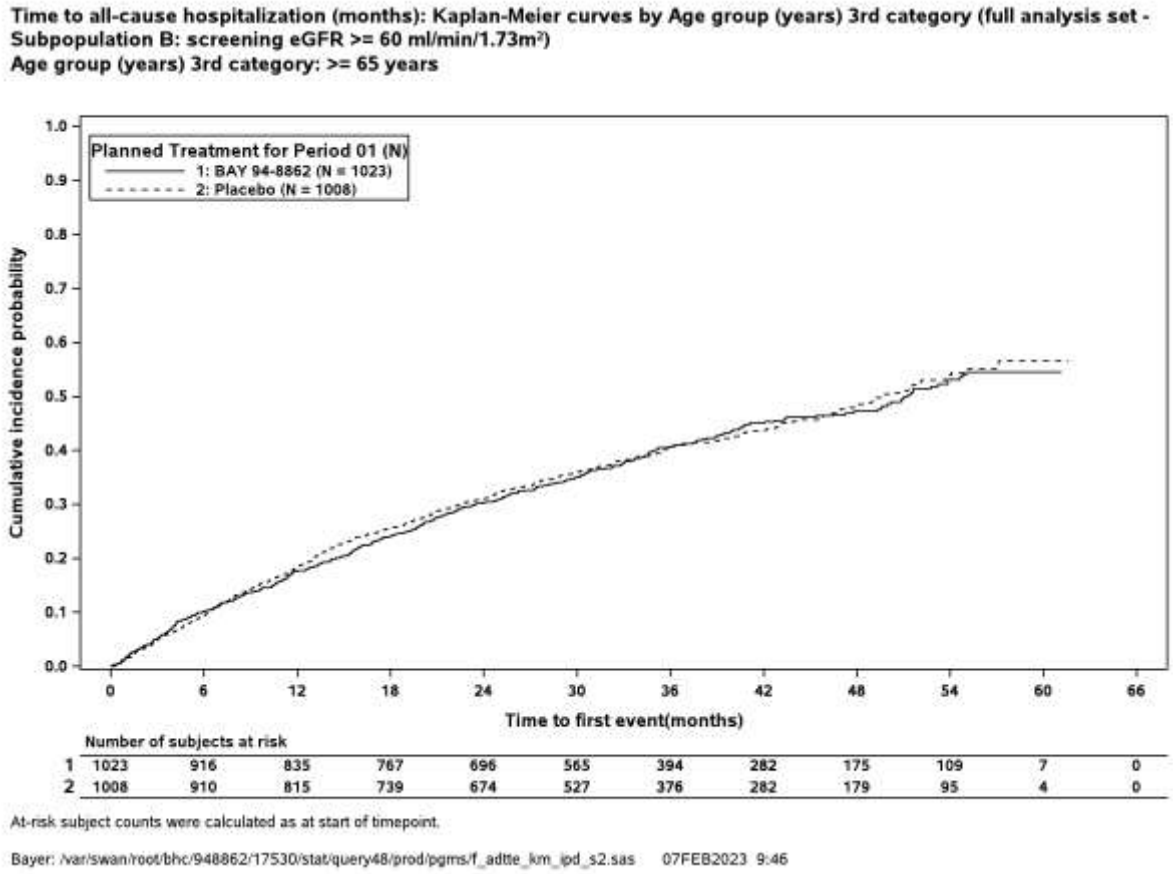


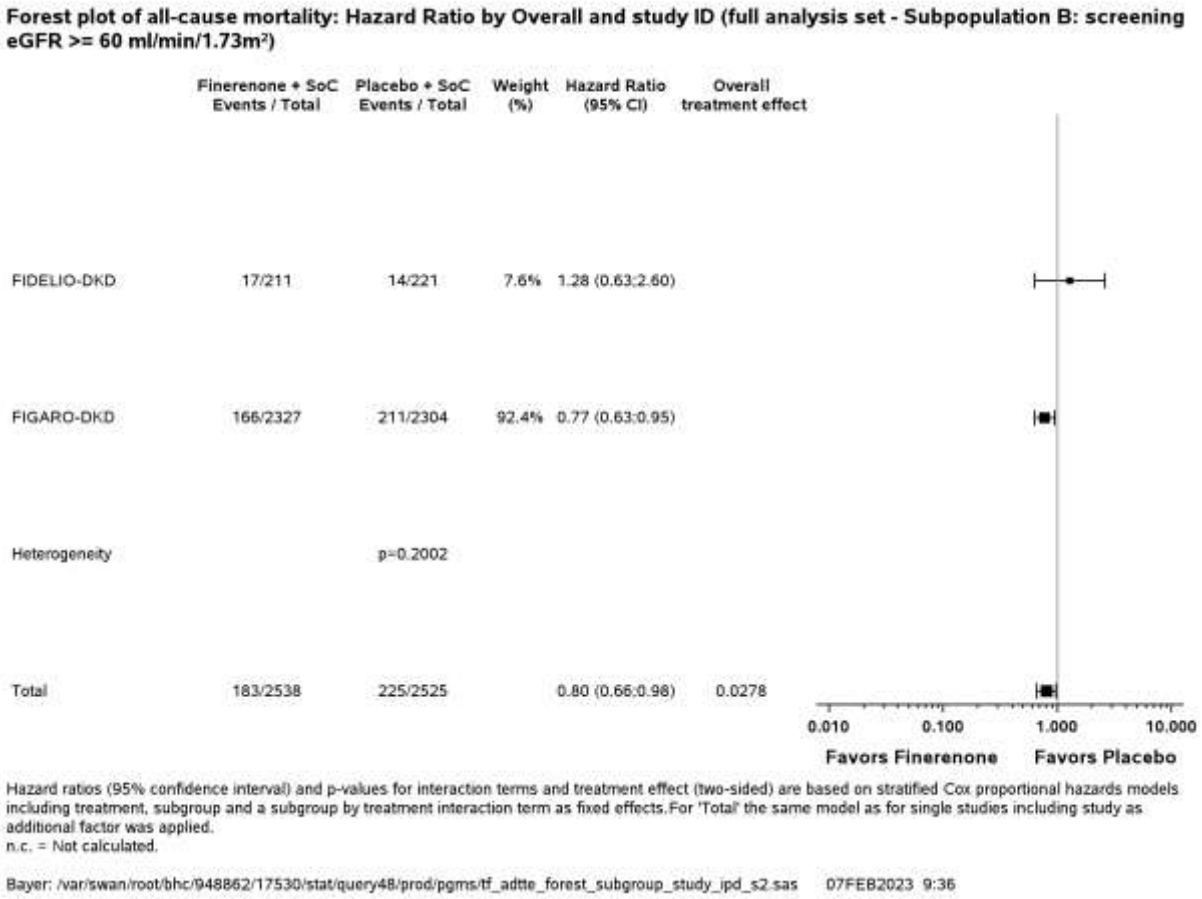
Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years



1.2.2 Forest plots for time-to-event Analyses

Figure 1.2.2 / 1: Forest plot of all-cause mortality: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 2: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=40% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

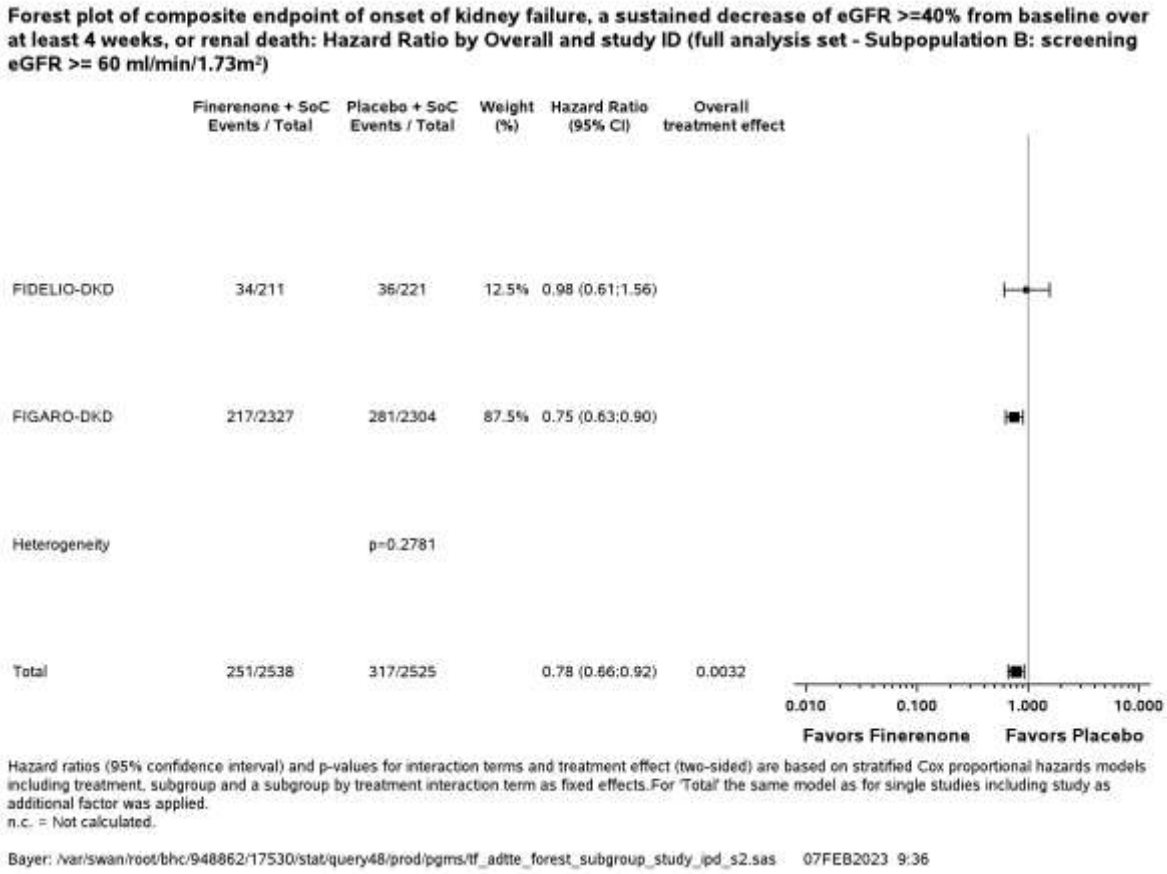


Figure 1.2.2 / 3: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

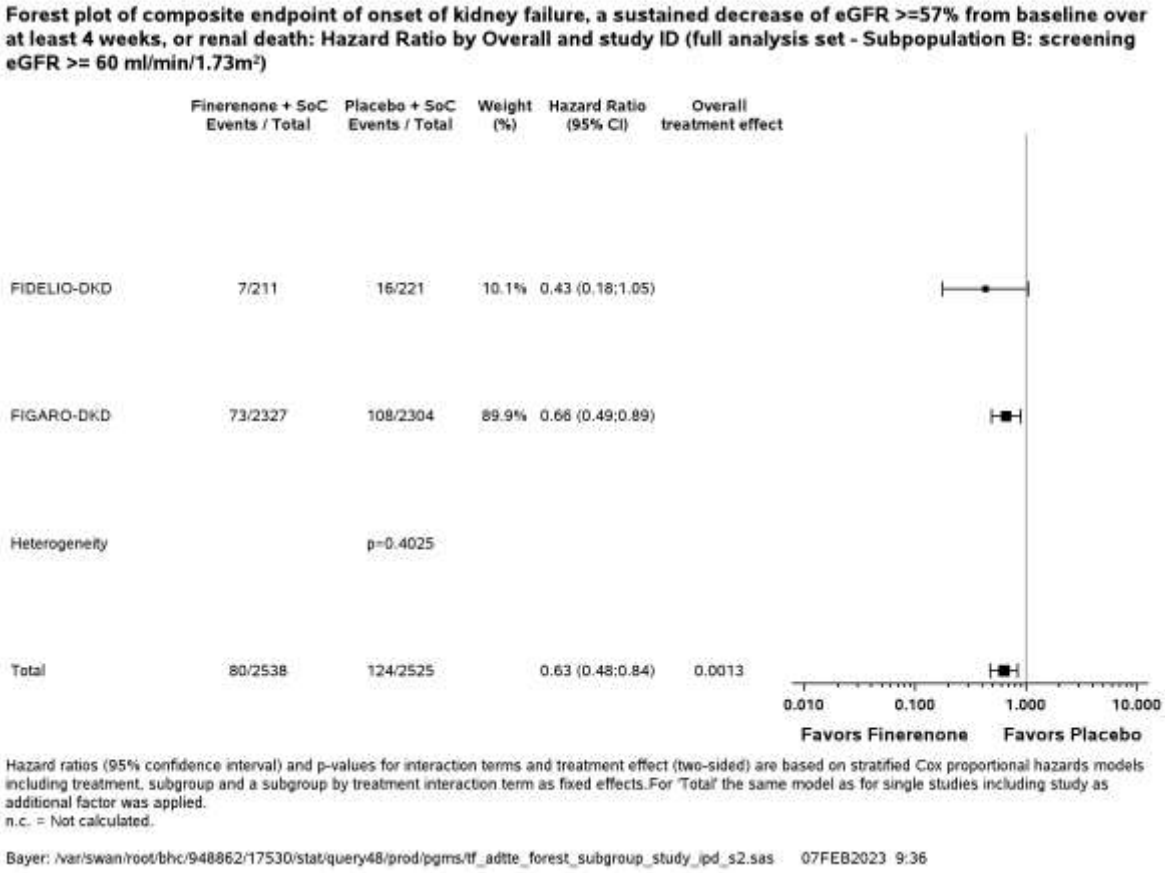
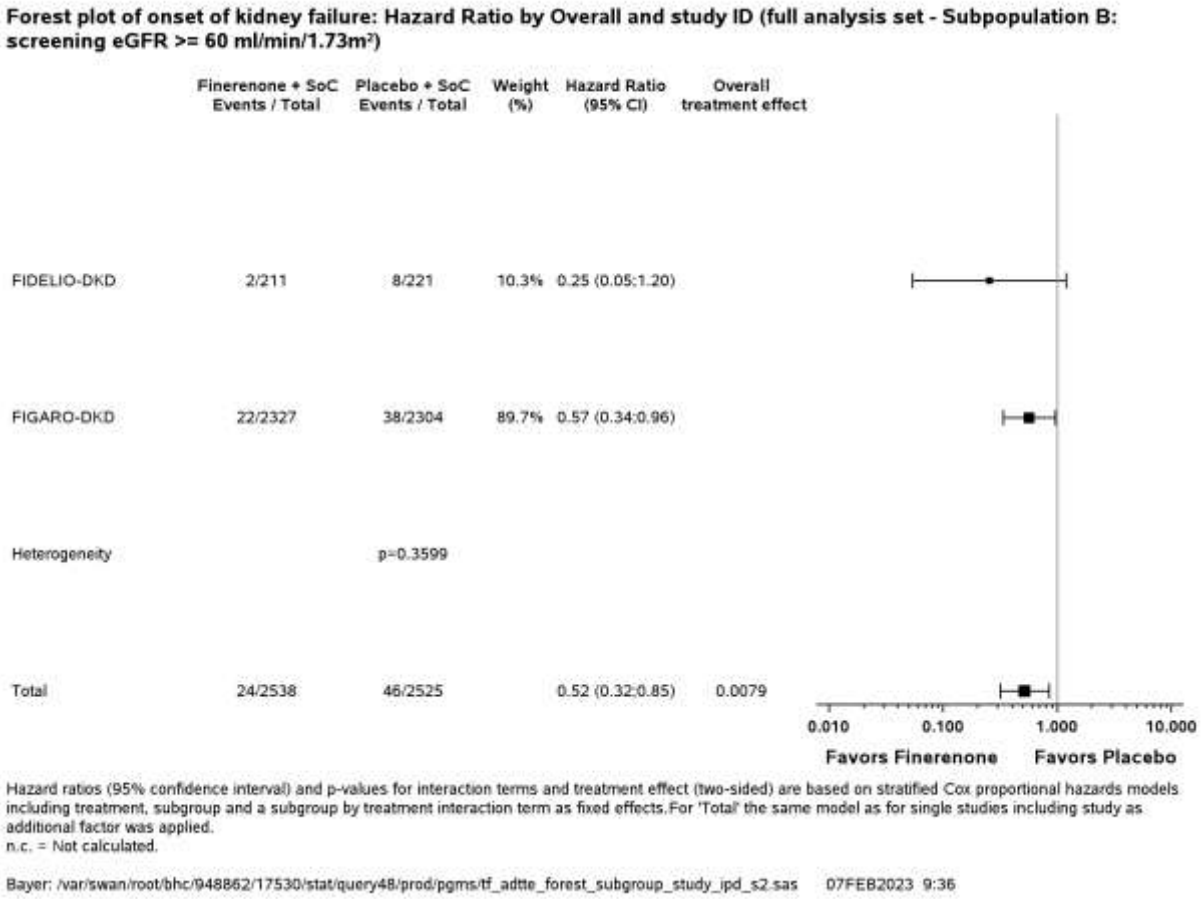


Figure 1.2.2 / 4: Forest plot of onset of kidney failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 5: Forest plot of end-stage renal disease: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

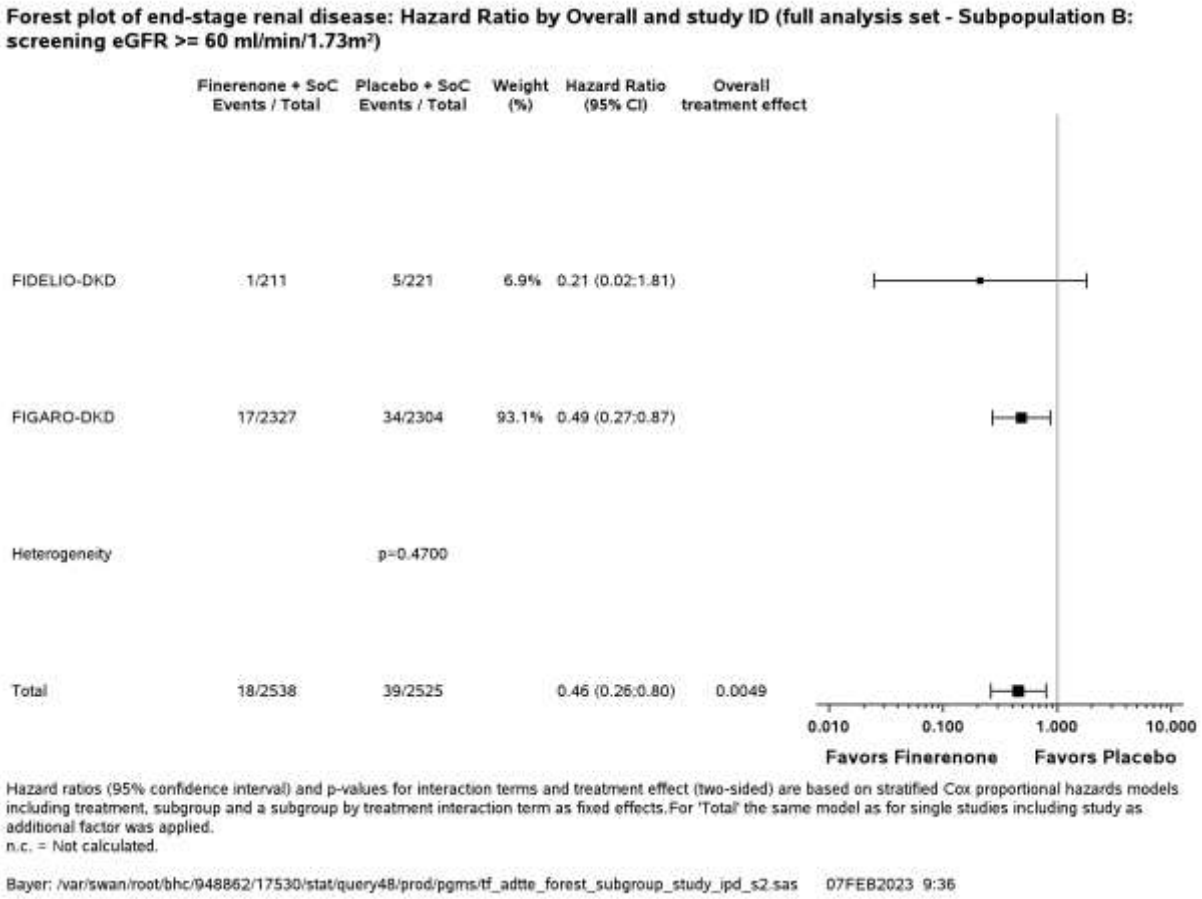
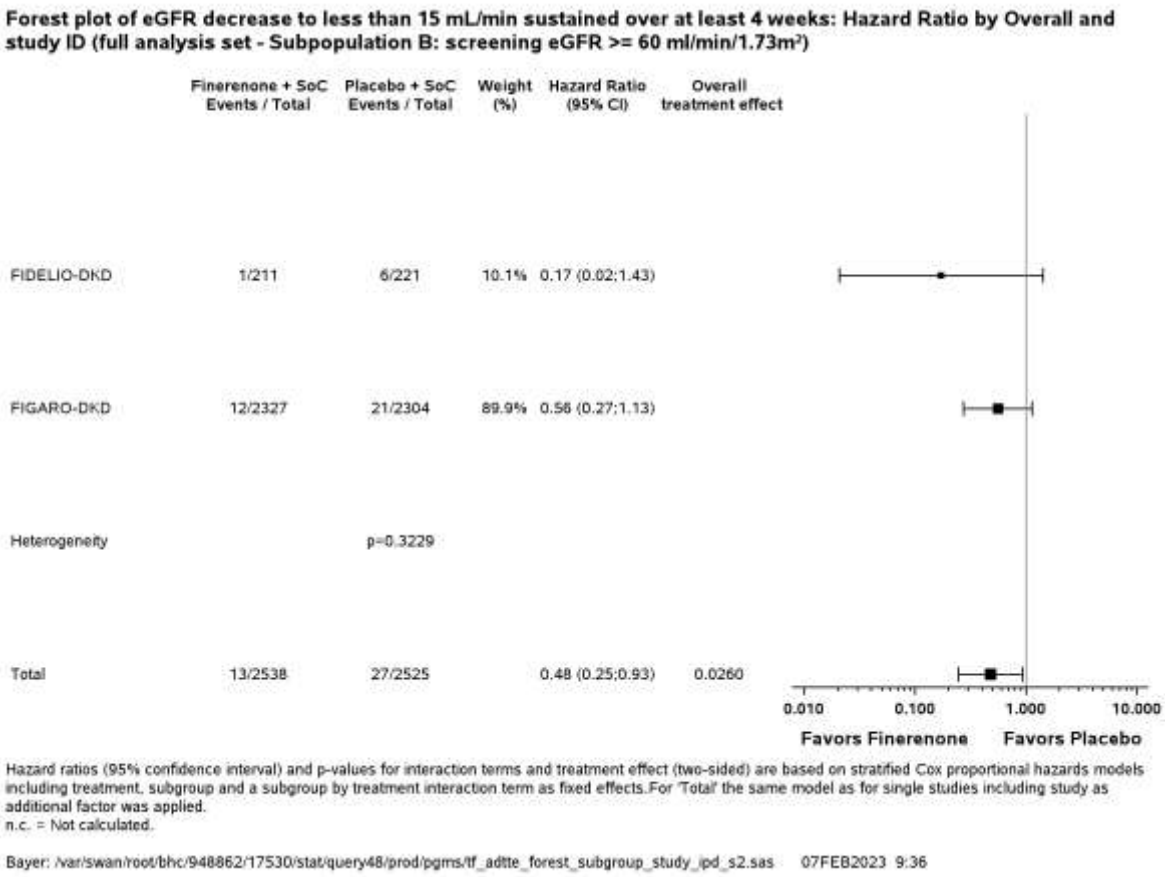


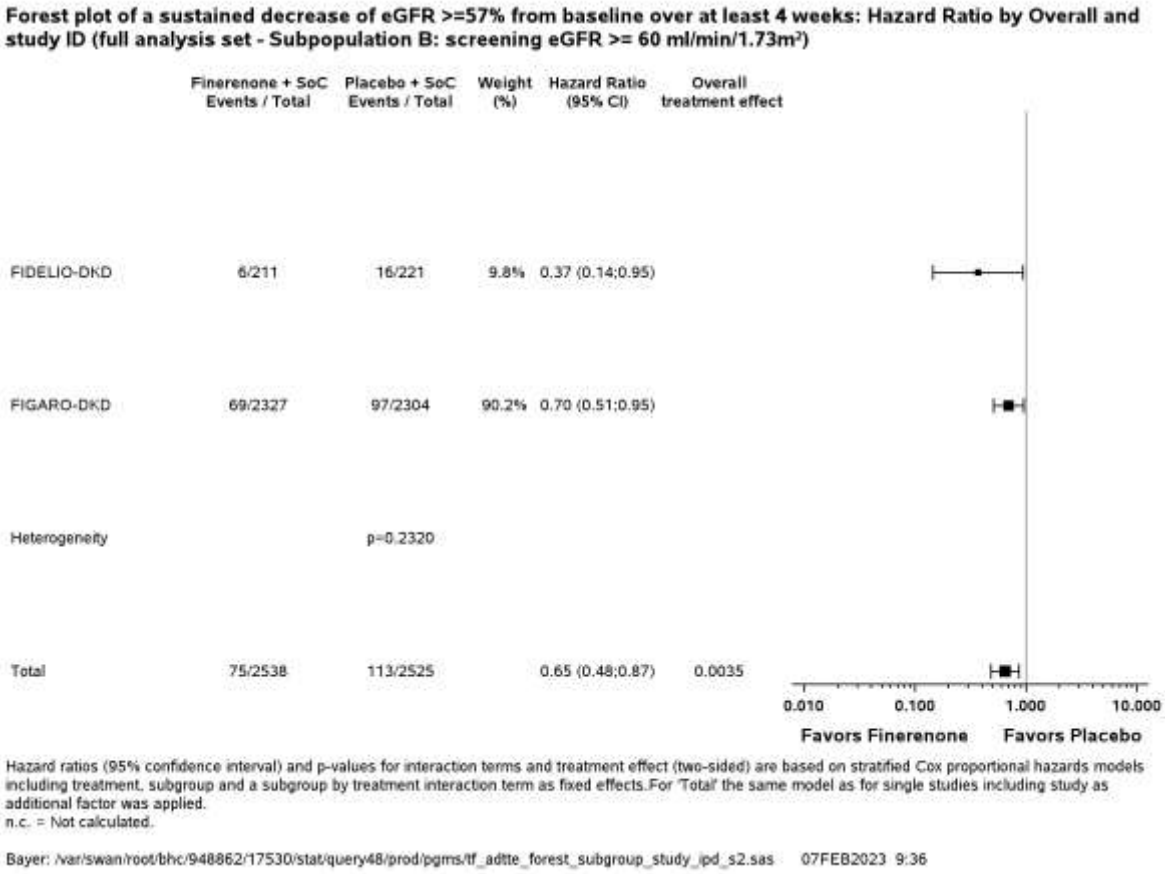
Figure 1.2.2 / 6: Forest plot of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 7: Forest plot of a sustained decrease of eGFR >=57% from baseline over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

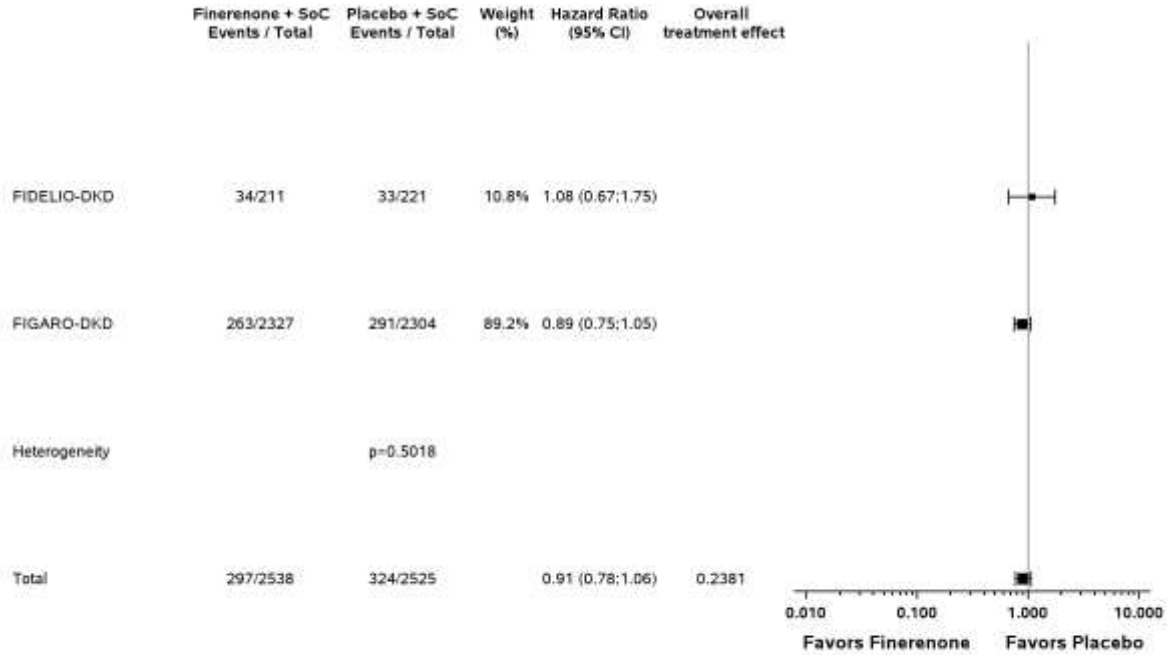


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 8: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 9: Forest plot of cardiovasular (CV) death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

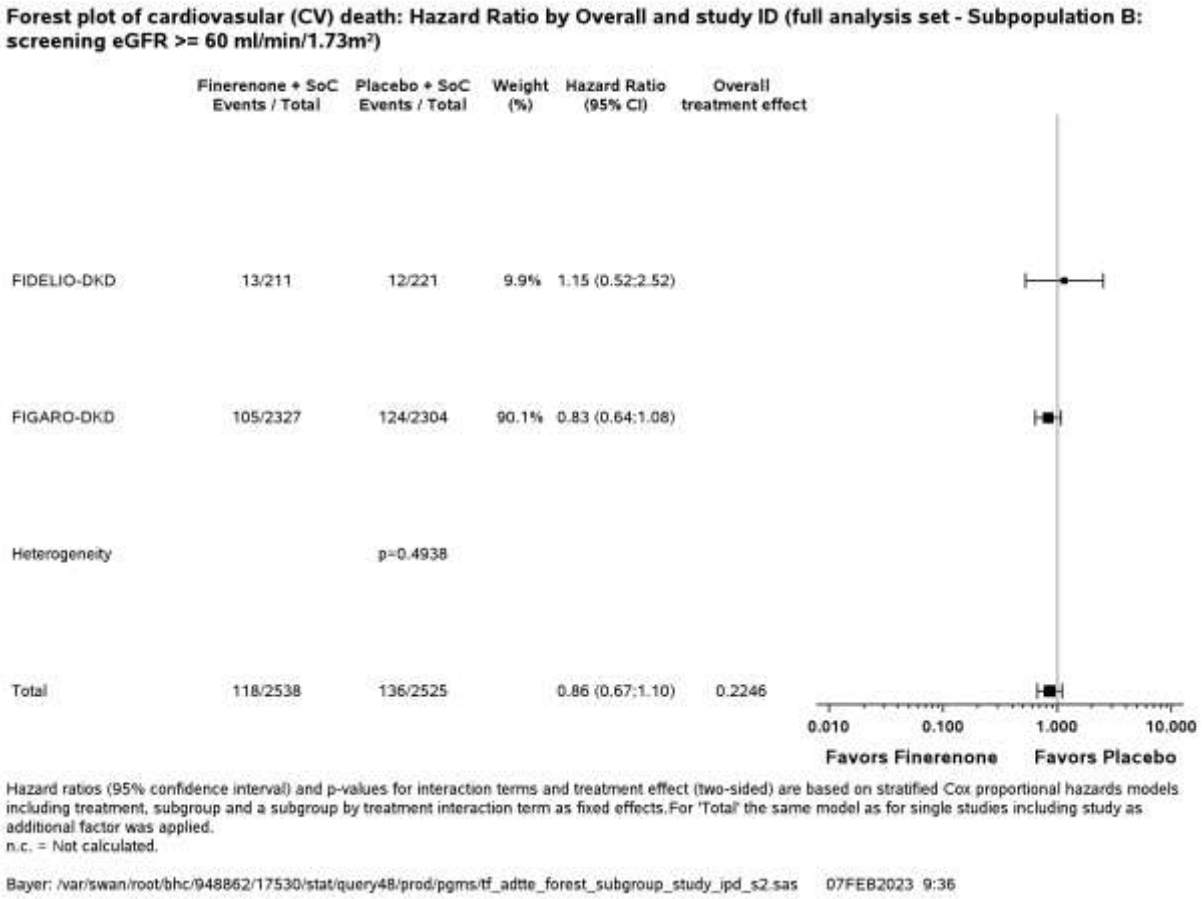
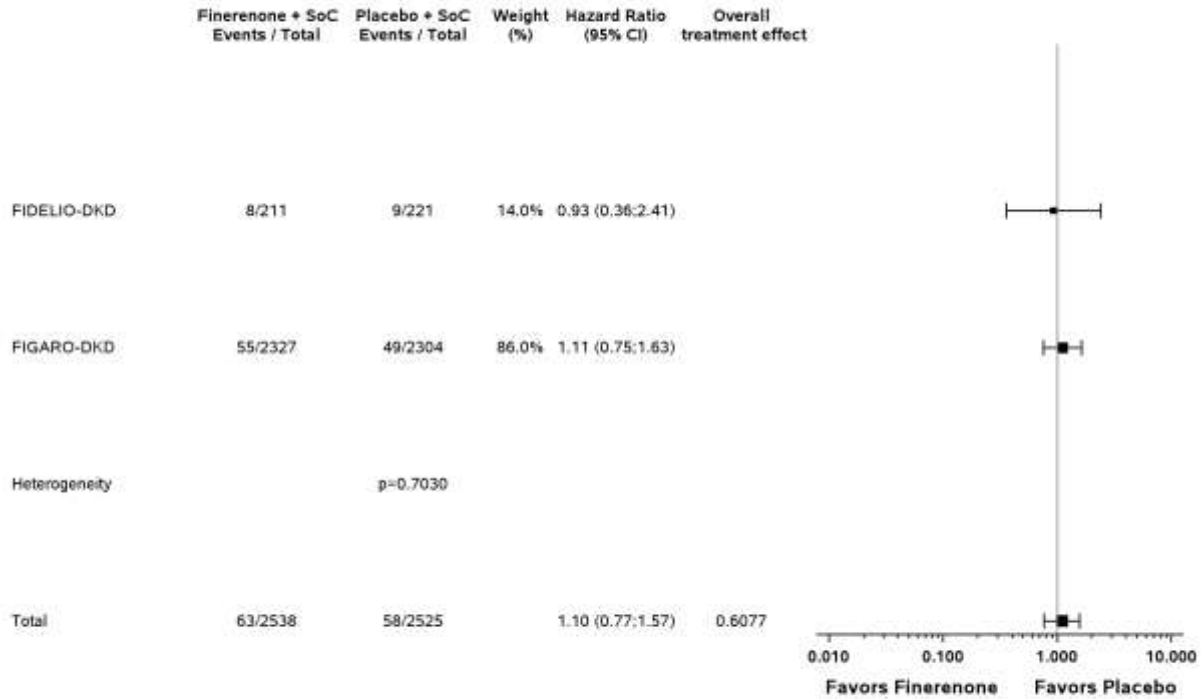


Figure 1.2.2 / 10: Forest plot of non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

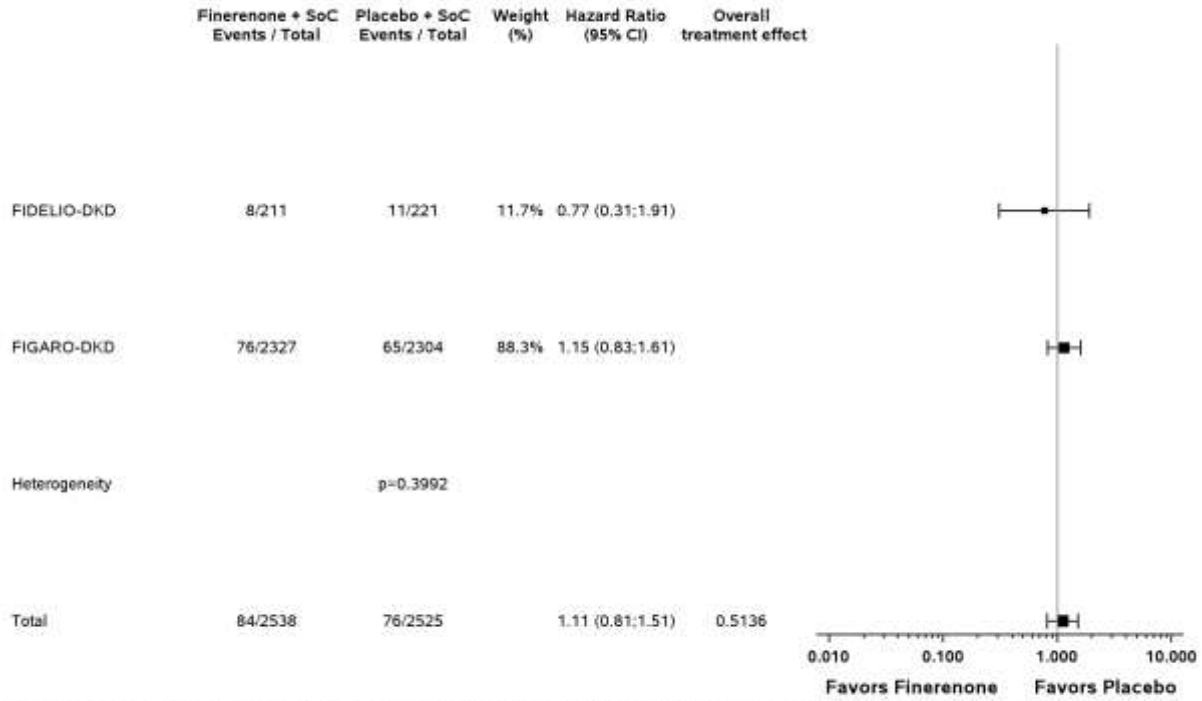


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 11: Forest plot of non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

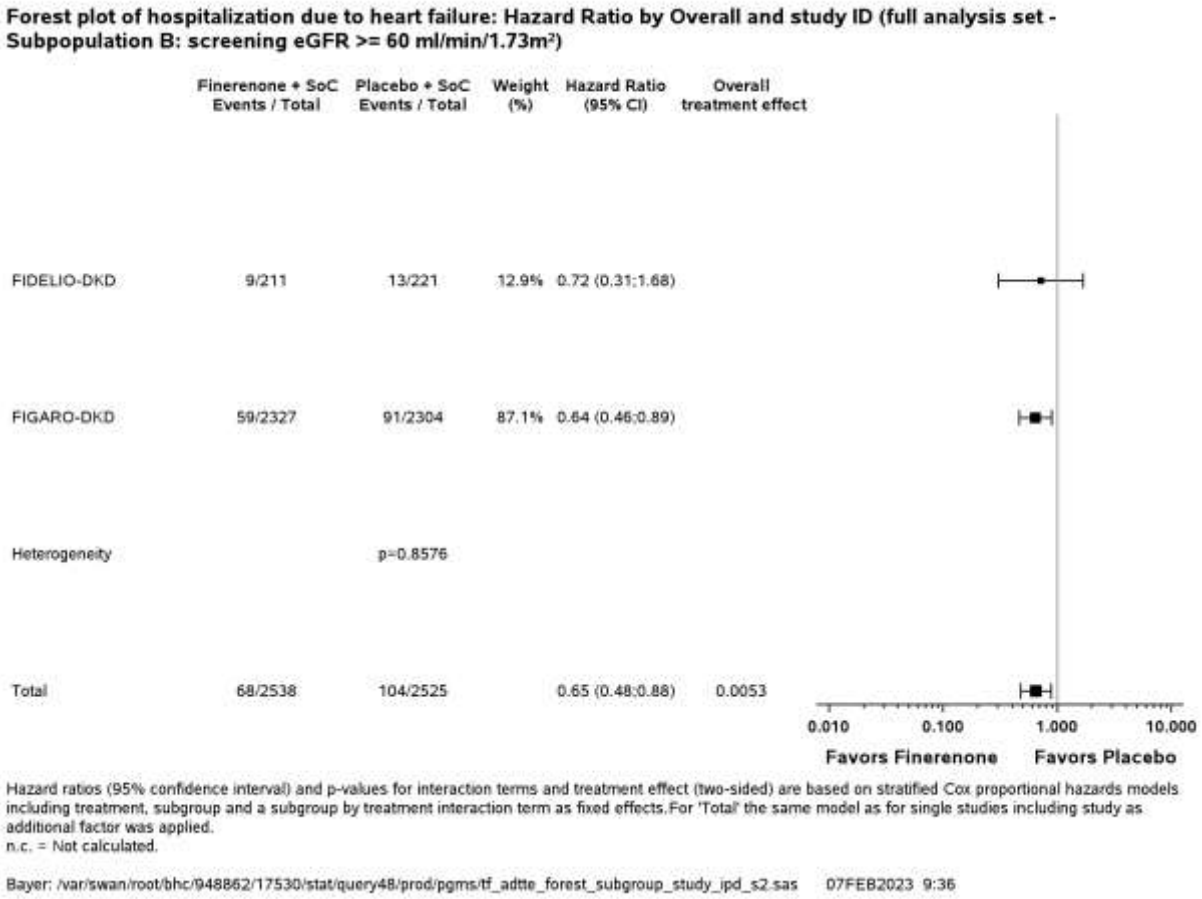
Forest plot of non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 12: Forest plot of hospitalization due to heart failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

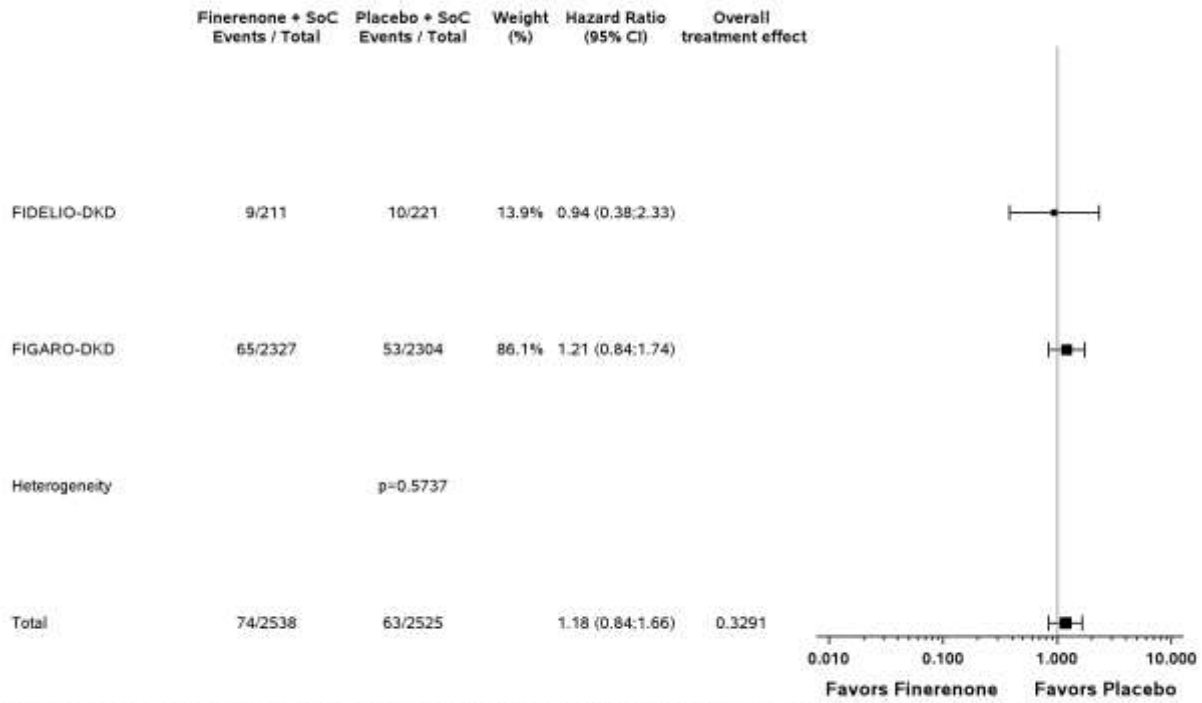


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 13: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

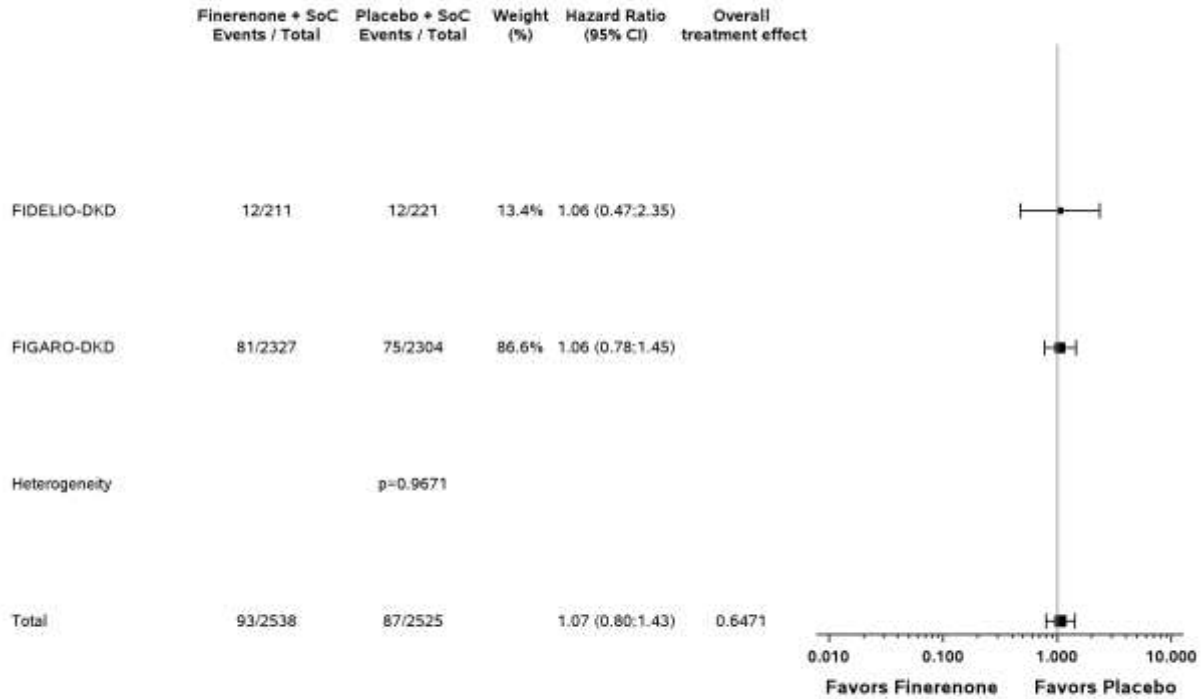


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 14: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

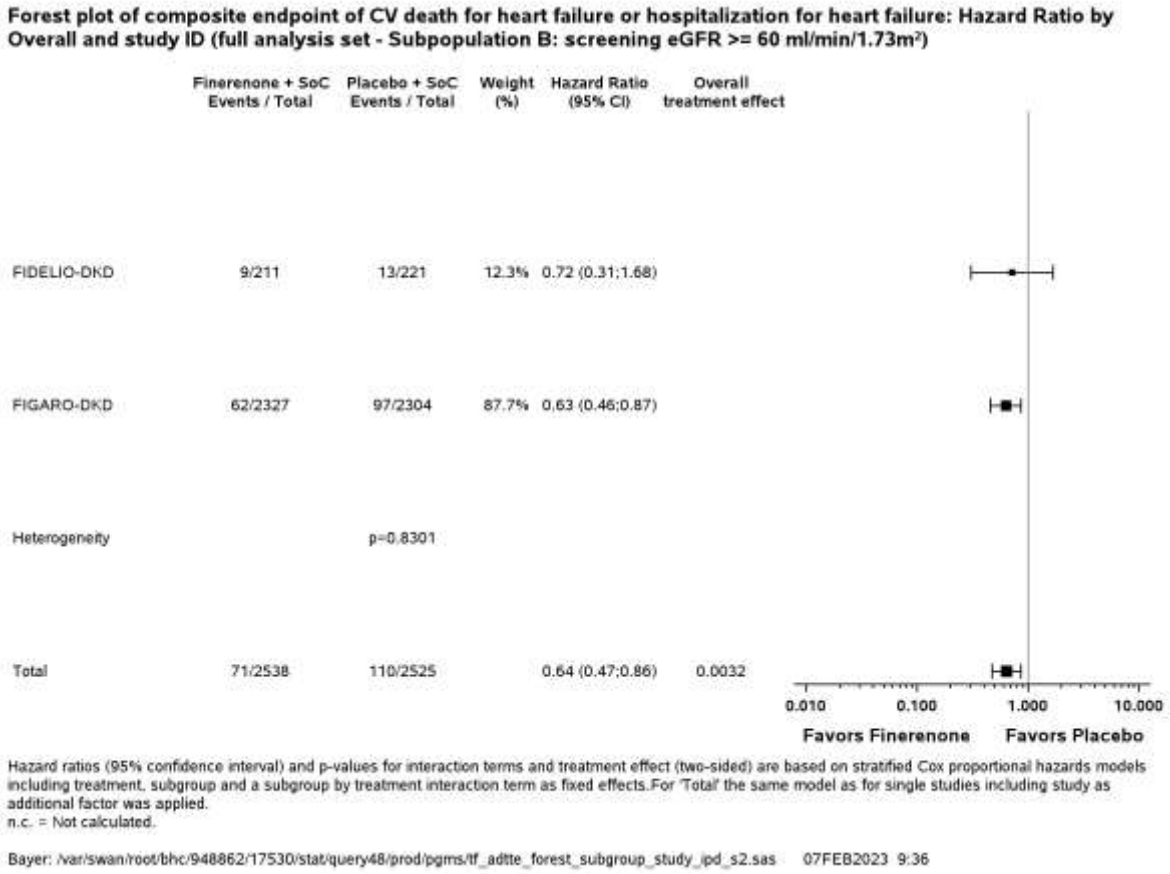
Forest plot of fatal or non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 15: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

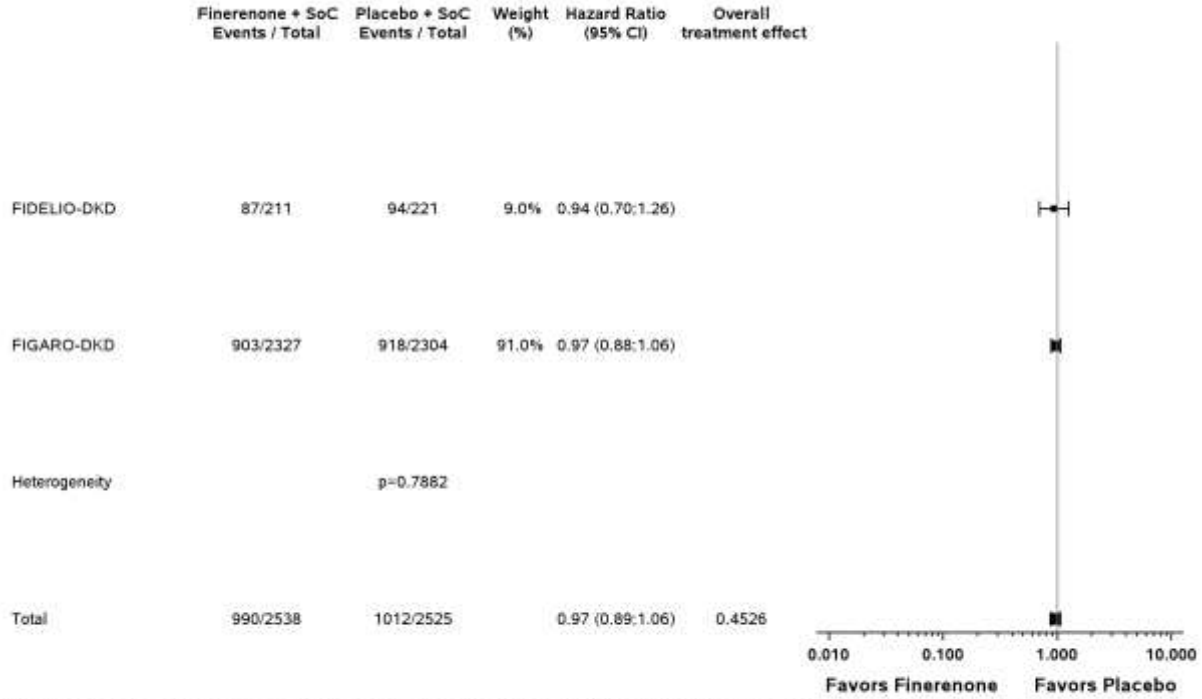


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 16: Forest plot of all-cause hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

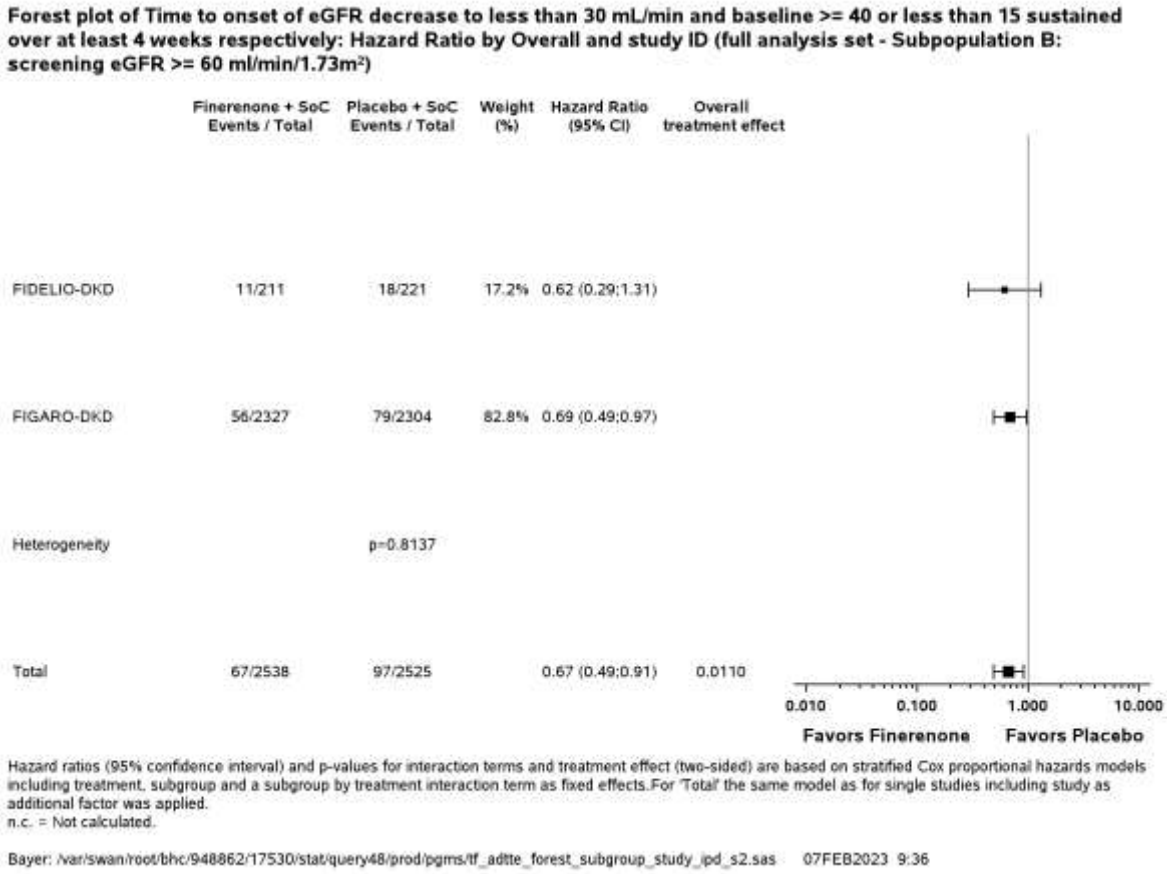
Forest plot of all-cause hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s2.sas 07FEB2023 9:36

Figure 1.2.2 / 17: Forest plot of Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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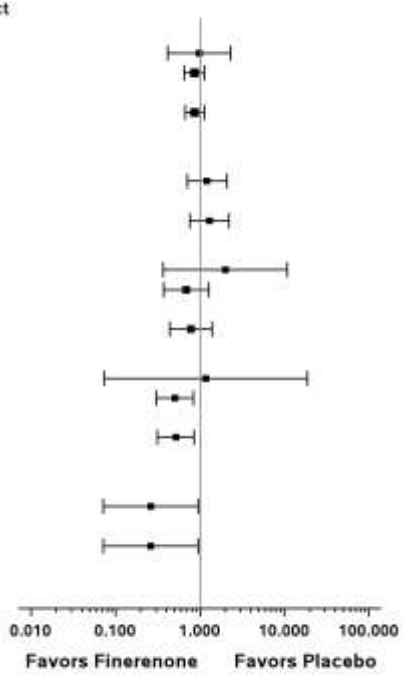
Figure 1.2.2 / 18: Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	10/104	11/112	9.4%	0.97 (0.41;2.29)	
FIGARO-DKD	94/1114	108/1111	90.6%	0.86 (0.65;1.13)	
Heterogeneity		p=0.8048			
Total	104/1218	119/1223		0.87 (0.67;1.13)	0.2912
North America					
FIDELIO-DKD	2/42	0/40		N.C.	
FIGARO-DKD	29/292	24/277	100%	1.21 (0.71;2.09)	
Heterogeneity		p=0.9836			
Total	31/334	24/317		1.29 (0.76;2.21)	0.3421
Asia					
FIDELIO-DKD	4/39	2/41	11.6%	2.00 (0.37;10.9)	
FIGARO-DKD	17/522	25/523	88.4%	0.69 (0.37;1.28)	
Heterogeneity		p=0.1988			
Total	21/561	27/564		0.78 (0.44;1.39)	0.3983
Latin America					
FIDELIO-DKD	1/21	1/24	3.2%	1.17 (0.07;18.7)	
FIGARO-DKD	23/322	44/316	96.8%	0.51 (0.31;0.84)	
Heterogeneity		p=0.5942			
Total	24/343	45/340		0.52 (0.32;0.85)	0.0081
Others					
FIDELIO-DKD	0/5	0/4		N.C.	
FIGARO-DKD	3/77	10/77	100%	0.26 (0.07;0.95)	
Heterogeneity		p=0.9998			
Total	3/82	10/81		0.26 (0.07;0.95)	0.0284
Subgroup Heterogeneity		p=0.0535			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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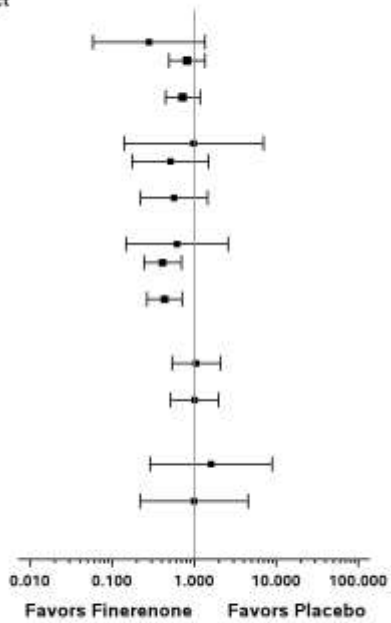
Figure 1.2.2 / 19: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	2/104	7/112	9.5%	0.28 (0.06;1.35)	
FIGARO-DKD	27/1114	33/1111	90.5%	0.82 (0.49;1.36)	
Heterogeneity		p=0.2090			
Total	29/1218	40/1223		0.72 (0.45;1.17)	0.1828
North America					
FIDELIO-DKD	2/42	2/40	23.2%	0.99 (0.14;7.01)	
FIGARO-DKD	5/292	10/277	76.8%	0.51 (0.17;1.50)	
Heterogeneity		p=0.5548			
Total	7/334	12/317		0.57 (0.22;1.46)	0.2333
Asia					
FIDELIO-DKD	3/39	5/41	11.8%	0.61 (0.15;2.57)	
FIGARO-DKD	20/522	47/523	88.2%	0.41 (0.24;0.69)	
Heterogeneity		p=0.5749			
Total	23/561	52/564		0.43 (0.26;0.71)	0.0006
Latin America					
FIDELIO-DKD	0/21	1/24		N.C.	
FIGARO-DKD	17/322	16/316	100%	1.06 (0.53;2.09)	
Heterogeneity		p=0.9900			
Total	17/343	17/340		1.00 (0.51;1.97)	0.9946
Others					
FIDELIO-DKD	0/5	1/4		N.C.	
FIGARO-DKD	4/77	2/77	100%	1.60 (0.29;8.87)	
Heterogeneity		p=0.9949			
Total	4/82	3/81		0.99 (0.22;4.51)	0.9884
Subgroup Heterogeneity		p=0.3125			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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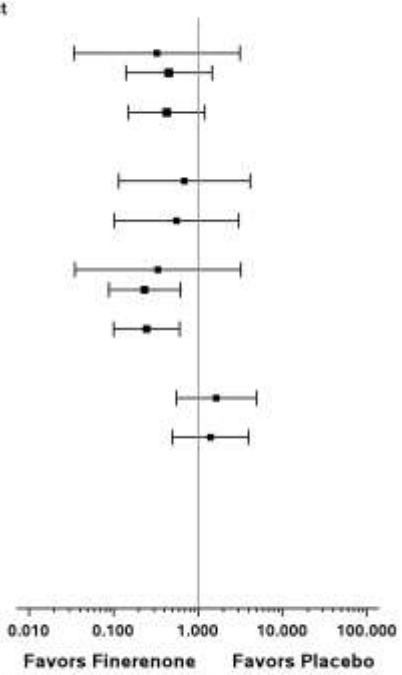
Figure 1.2.2 / 20: Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	1/104	3/112	21.3%	0.32 (0.03;3.12)	
FIGARO-DKD	4/1114	9/1111	78.7%	0.45 (0.14;1.48)	
Heterogeneity		p=0.7949			
Total	5/1218	12/1223		0.43 (0.15;1.21)	0.0996
North America					
FIDELIO-DKD	0/42	1/40		N.C.	
FIGARO-DKD	2/292	3/277	100%	0.69 (0.12;4.15)	
Heterogeneity		p=0.9945			
Total	2/334	4/317		0.56 (0.10;3.07)	0.4976
Asia					
FIDELIO-DKD	1/39	3/41	15.7%	0.34 (0.04;3.24)	
FIGARO-DKD	5/522	21/523	84.3%	0.23 (0.09;0.62)	
Heterogeneity		p=0.6930			
Total	6/561	24/564		0.25 (0.10;0.60)	0.0009
Latin America					
FIDELIO-DKD	0/21	1/24		N.C.	
FIGARO-DKD	9/322	5/316	100%	1.66 (0.55;4.95)	
Heterogeneity		p=0.9928			
Total	9/343	6/340		1.41 (0.50;3.97)	0.5132
Others					
FIDELIO-DKD	0/5	0/4		N.C.	
FIGARO-DKD	2/77	0/77		N.C.	
Heterogeneity		p=0.9994			
Total	2/82	0/81			N.C.
Subgroup Heterogeneity		p=N.C.			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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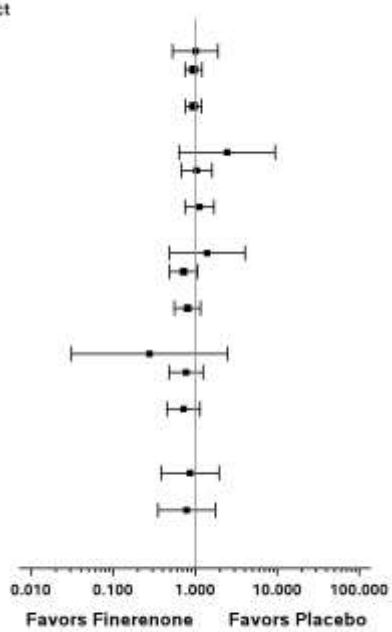
Figure 1.2.2 / 21: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	18/104	19/112	11.8%	1.00 (0.53;1.91)	
FIGARO-DKD	136/1114	141/1111	88.2%	0.95 (0.75;1.21)	
Heterogeneity		p=0.9638			
Total	154/1218	160/1223		0.95 (0.76;1.19)	0.6727
North America					
FIDELIO-DKD	7/42	3/40	9.1%	2.45 (0.63;9.47)	
FIGARO-DKD	43/292	41/277	90.9%	1.04 (0.68;1.59)	
Heterogeneity		p=0.2588			
Total	50/334	44/317		1.12 (0.75;1.69)	0.5726
Asia					
FIDELIO-DKD	8/39	6/41	12.1%	1.40 (0.48;4.02)	
FIGARO-DKD	43/522	59/523	87.9%	0.72 (0.49;1.07)	
Heterogeneity		p=0.1816			
Total	51/561	65/564		0.80 (0.56;1.16)	0.2419
Latin America					
FIDELIO-DKD	1/21	4/24	4.6%	0.28 (0.03;2.48)	
FIGARO-DKD	30/322	38/316	95.4%	0.77 (0.48;1.24)	
Heterogeneity		p=0.3195			
Total	31/343	42/340		0.72 (0.45;1.14)	0.1629
Others					
FIDELIO-DKD	0/5	1/4		N.C.	
FIGARO-DKD	11/77	12/77	100%	0.86 (0.38;1.96)	
Heterogeneity		p=0.9910			
Total	11/82	13/81		0.78 (0.35;1.76)	0.5541
Subgroup Heterogeneity		p=0.5977			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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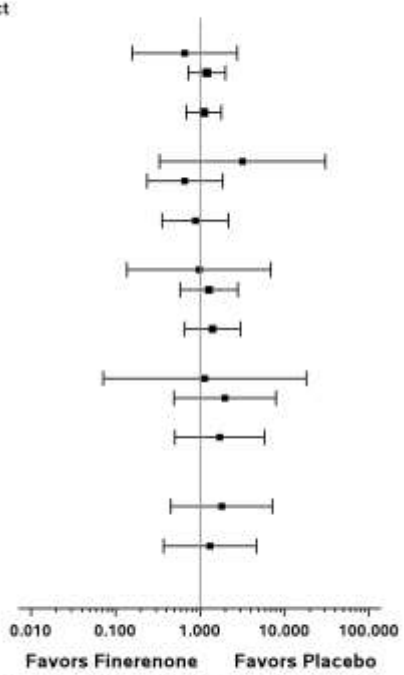
Figure 1.2.2 / 22: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	3/104	5/112	11.2%	0.66 (0.16;2.75)	
FIGARO-DKD	33/1114	27/1111	88.8%	1.21 (0.73;2.01)	
Heterogeneity		p=0.3782			
Total	36/1218	32/1223		1.11 (0.69;1.79)	0.6640
North America					
FIDELIO-DKD	3/42	1/40	17.2%	3.19 (0.33;30.7)	
FIGARO-DKD	6/292	9/277	82.8%	0.66 (0.24;1.86)	
Heterogeneity		p=0.2569			
Total	9/334	10/317		0.88 (0.36;2.17)	0.7838
Asia					
FIDELIO-DKD	2/39	2/41	13.9%	0.97 (0.14;6.94)	
FIGARO-DKD	14/522	11/523	86.1%	1.28 (0.58;2.83)	
Heterogeneity		p=0.9528			
Total	16/561	13/564		1.42 (0.66;3.02)	0.3661
Latin America					
FIDELIO-DKD	1/21	1/24	20.0%	1.15 (0.07;18.3)	
FIGARO-DKD	6/322	3/316	80.0%	1.98 (0.49;7.92)	
Heterogeneity		p=0.6690			
Total	7/343	4/340		1.72 (0.50;5.87)	0.3829
Others					
FIDELIO-DKD	0/5	1/4		N.C.	
FIGARO-DKD	6/77	3/77	100%	1.81 (0.45;7.26)	
Heterogeneity		p=0.9951			
Total	6/82	4/81		1.32 (0.37;4.68)	0.6709
Subgroup Heterogeneity		p=0.8988			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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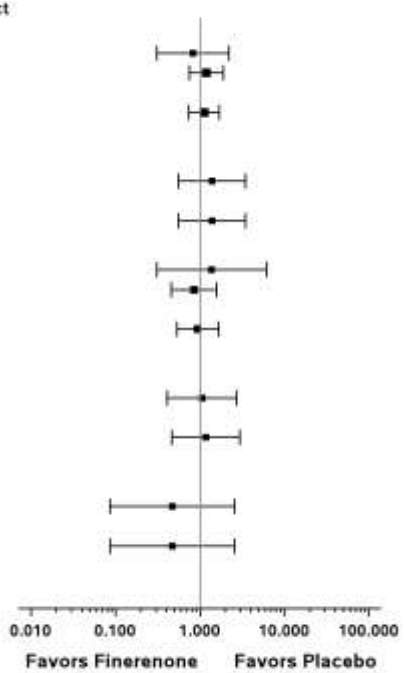
Figure 1.2.2 / 23: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	7/104	9/112	17.9%	0.82 (0.31;2.21)	
FIGARO-DKD	40/1114	33/1111	82.1%	1.20 (0.75;1.90)	
Heterogeneity		p=0.4966			
Total	47/1218	42/1223		1.12 (0.74;1.70)	0.5865
North America					
FIDELIO-DKD	0/42	0/40		N.C.	
FIGARO-DKD	11/292	8/277	100%	1.40 (0.56;3.48)	
Heterogeneity		p=0.9999			
Total	11/334	8/317		1.40 (0.56;3.48)	0.4687
Asia					
FIDELIO-DKD	4/39	3/41	14.4%	1.38 (0.31;6.15)	
FIGARO-DKD	19/522	22/523	85.6%	0.85 (0.46;1.57)	
Heterogeneity		p=0.4452			
Total	23/561	25/564		0.94 (0.53;1.66)	0.8391
Latin America					
FIDELIO-DKD	1/21	0/24		N.C.	
FIGARO-DKD	9/322	8/316	100%	1.06 (0.41;2.75)	
Heterogeneity		p=0.9922			
Total	10/343	8/340		1.17 (0.46;2.98)	0.7353
Others					
FIDELIO-DKD	0/5	0/4		N.C.	
FIGARO-DKD	2/77	4/77	100%	0.47 (0.09;2.57)	
Heterogeneity		p=0.9999			
Total	2/82	4/81		0.47 (0.09;2.57)	0.3726
Subgroup Heterogeneity		p=0.8247			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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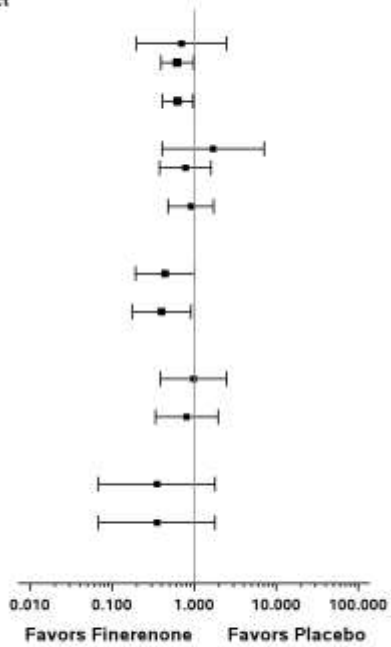
Figure 1.2.2 / 24: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	4/104	6/112	11.5%	0.69 (0.20;2.46)	
FIGARO-DKD	30/1114	48/1111	88.5%	0.62 (0.39;0.98)	
Heterogeneity		p=0.8808			
Total	34/1218	54/1223		0.63 (0.41;0.96)	0.0305
North America					
FIDELIO-DKD	5/42	3/40	20.4%	1.70 (0.41;7.10)	
FIGARO-DKD	13/292	17/277	79.6%	0.78 (0.38;1.61)	
Heterogeneity		p=0.3599			
Total	18/334	20/317		0.91 (0.48;1.72)	0.7679
Asia					
FIDELIO-DKD	0/39	2/41		N.C.	
FIGARO-DKD	8/522	18/523	100%	0.44 (0.19;1.01)	
Heterogeneity		p=0.9906			
Total	8/561	20/564		0.40 (0.18;0.91)	0.0232
Latin America					
FIDELIO-DKD	0/21	2/24		N.C.	
FIGARO-DKD	9/322	9/316	100%	0.98 (0.39;2.47)	
Heterogeneity		p=0.9921			
Total	9/343	11/340		0.81 (0.34;1.96)	0.6384
Others					
FIDELIO-DKD	0/5	0/4		N.C.	
FIGARO-DKD	2/77	5/77	100%	0.35 (0.07;1.80)	
Heterogeneity		p=0.9999			
Total	2/82	5/81		0.35 (0.07;1.80)	0.1877
Subgroup Heterogeneity		p=0.5201			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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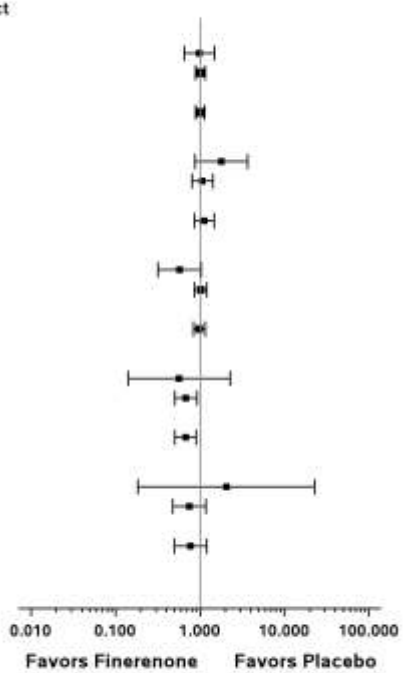
Figure 1.2.2 / 25: Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	44/104	46/112	9.4%	0.98 (0.65;1.49)	
FIGARO-DKD	438/1114	431/1111	90.6%	1.01 (0.88;1.15)	
Heterogeneity		p=0.8487			
Total	482/1218	477/1223		1.01 (0.89;1.14)	0.9202
North America					
FIDELIO-DKD	20/42	12/40	14.0%	1.80 (0.88;3.69)	
FIGARO-DKD	96/292	89/277	86.0%	1.07 (0.80;1.43)	
Heterogeneity		p=0.2556			
Total	116/334	101/317		1.13 (0.87;1.48)	0.3636
Asia					
FIDELIO-DKD	18/39	29/41	7.9%	0.57 (0.32;1.03)	
FIGARO-DKD	259/522	255/523	92.1%	1.02 (0.86;1.22)	
Heterogeneity		p=0.0990			
Total	277/561	284/564		0.99 (0.83;1.16)	0.8633
Latin America					
FIDELIO-DKD	3/21	6/24	4.5%	0.57 (0.14;2.27)	
FIGARO-DKD	74/322	101/316	95.5%	0.68 (0.50;0.92)	
Heterogeneity		p=0.7196			
Total	77/343	107/340		0.67 (0.50;0.91)	0.0082
Others					
FIDELIO-DKD	2/5	1/4	3.4%	2.06 (0.18;23.0)	
FIGARO-DKD	36/77	42/77	96.6%	0.75 (0.48;1.18)	
Heterogeneity		p=0.4563			
Total	38/82	43/81		0.78 (0.50;1.21)	0.2567
Subgroup Heterogeneity		p=0.0751			



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n.c. = Not calculated.

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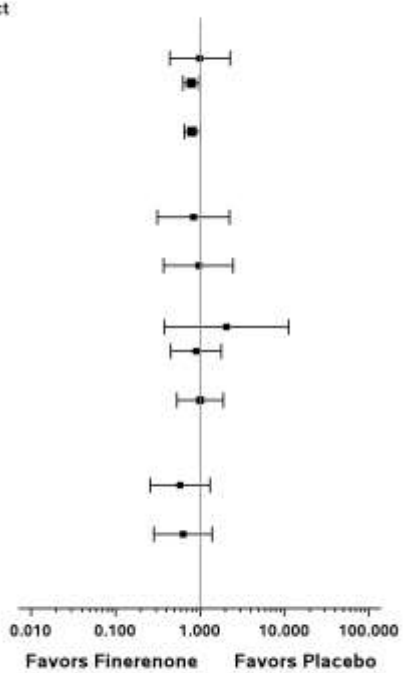
Figure 1.2.2 / 26: Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	11/140	12/152	7.2%	0.99 (0.44;2.26)	
FIGARO-DKD	134/1659	164/1613	92.8%	0.79 (0.63;1.00)	
Heterogeneity		p=0.7030			
Total	145/1799	176/1765		0.81 (0.65;1.01)	0.0554
Black					
FIDELIO-DKD	1/10	0/9		N.C.	
FIGARO-DKD	8/70	12/74	100%	0.84 (0.32;2.26)	
Heterogeneity		p=0.9927			
Total	9/80	12/83		0.96 (0.37;2.49)	0.9318
Asian					
FIDELIO-DKD	4/39	2/44	14.1%	2.05 (0.38;11.2)	
FIGARO-DKD	15/464	18/486	85.9%	0.90 (0.45;1.78)	
Heterogeneity		p=0.3004			
Total	19/503	20/530		1.01 (0.54;1.90)	0.9735
Other					
FIDELIO-DKD	1/22	0/16		N.C.	
FIGARO-DKD	9/134	17/131	100%	0.58 (0.26;1.32)	
Heterogeneity		p=0.9890			
Total	10/156	17/147		0.63 (0.29;1.40)	0.2531
Subgroup Heterogeneity		p=0.7751			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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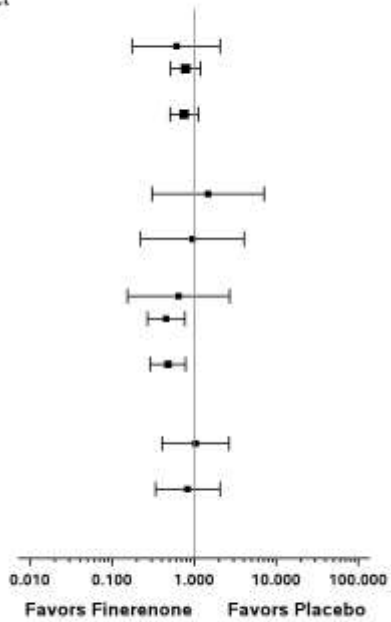
Figure 1.2.2 / 27: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	4/140	7/152	10.6%	0.60 (0.18;2.07)	
FIGARO-DKD	39/1659	48/1613	89.4%	0.78 (0.51;1.19)	
Heterogeneity		p=0.7716			
Total	43/1799	55/1765		0.75 (0.50;1.12)	0.1622
Black					
FIDELIO-DKD	0/10	1/9		N.C.	
FIGARO-DKD	4/70	4/74	100%	1.47 (0.30;7.08)	
Heterogeneity		p=0.9949			
Total	4/80	5/83		0.95 (0.22;4.07)	0.9438
Asian					
FIDELIO-DKD	3/39	6/44	11.9%	0.64 (0.15;2.69)	
FIGARO-DKD	20/464	46/486	88.1%	0.45 (0.27;0.77)	
Heterogeneity		p=0.6608			
Total	23/503	52/530		0.48 (0.29;0.78)	0.0027
Other					
FIDELIO-DKD	0/22	2/16		N.C.	
FIGARO-DKD	10/134	10/131	100%	1.04 (0.41;2.67)	
Heterogeneity		p=0.9904			
Total	10/156	12/147		0.83 (0.34;2.06)	0.6894
Subgroup Heterogeneity		p=0.4022			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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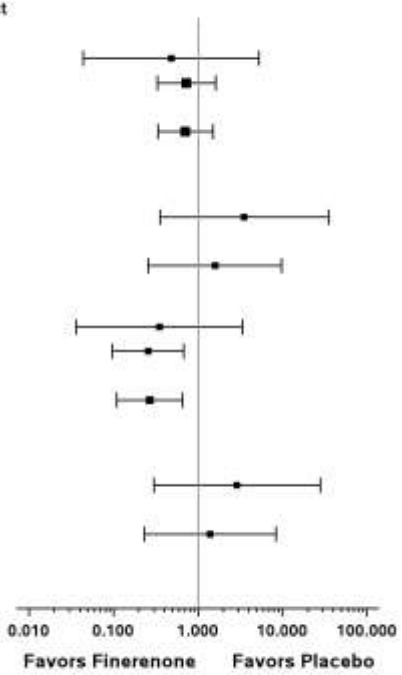
Figure 1.2.2 / 28: Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	1/140	2/152	9.9%	0.48 (0.04;5.32)	
FIGARO-DKD	11/1659	14/1613	90.1%	0.73 (0.33;1.62)	
Heterogeneity		p=0.8334			
Total	12/1799	16/1765		0.71 (0.33;1.51)	0.3701
Black					
FIDELIO-DKD	0/10	1/9		N.C.	
FIGARO-DKD	3/70	1/74	100%	3.54 (0.36;35.1)	
Heterogeneity		p=0.9971			
Total	3/80	2/83		1.59 (0.26;9.82)	0.6138
Asian					
FIDELIO-DKD	1/39	4/44	15.7%	0.35 (0.04;3.35)	
FIGARO-DKD	5/464	22/486	84.3%	0.26 (0.10;0.68)	
Heterogeneity		p=0.7347			
Total	6/503	26/530		0.27 (0.11;0.66)	0.0020
Other					
FIDELIO-DKD	0/22	1/16		N.C.	
FIGARO-DKD	3/134	1/131	100%	2.90 (0.30;28.0)	
Heterogeneity		p=0.9951			
Total	3/156	2/147		1.40 (0.23;8.42)	0.7112
Subgroup Heterogeneity		p=0.1217			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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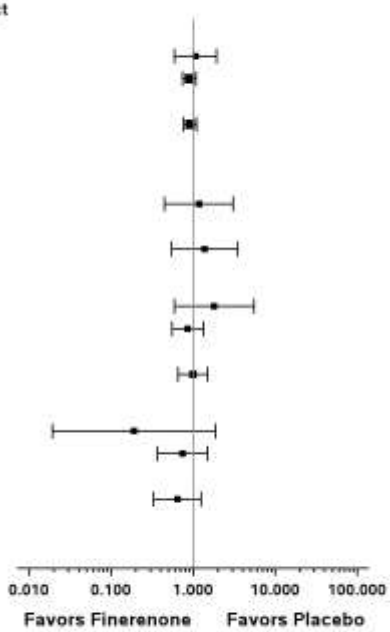
Figure 1.2.2 / 29: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	22/140	22/152	9.5%	1.07 (0.59;1.93)	
FIGARO-DKD	203/1659	216/1613	90.5%	0.90 (0.74;1.09)	
Heterogeneity		p=0.6641			
Total	225/1799	238/1765		0.91 (0.76;1.09)	0.3215
Black					
FIDELIO-DKD	2/10	1/9			
FIGARO-DKD	9/70	12/74	100%	1.17 (0.45;3.06)	
Heterogeneity		p=0.5705			
Total	11/80	13/83		1.37 (0.55;3.45)	0.4994
Asian					
FIDELIO-DKD	8/39	7/44	13.5%	1.79 (0.59;5.48)	
FIGARO-DKD	36/464	44/486	86.5%	0.85 (0.55;1.33)	
Heterogeneity		p=0.2091			
Total	44/503	51/530		0.99 (0.65;1.49)	0.9581
Other					
FIDELIO-DKD	2/22	3/16	8.6%	0.19 (0.02;1.86)	
FIGARO-DKD	15/134	19/131	91.4%	0.74 (0.37;1.49)	
Heterogeneity		p=0.5387			
Total	17/156	22/147		0.64 (0.33;1.25)	0.1890
Subgroup Heterogeneity		p=0.9160			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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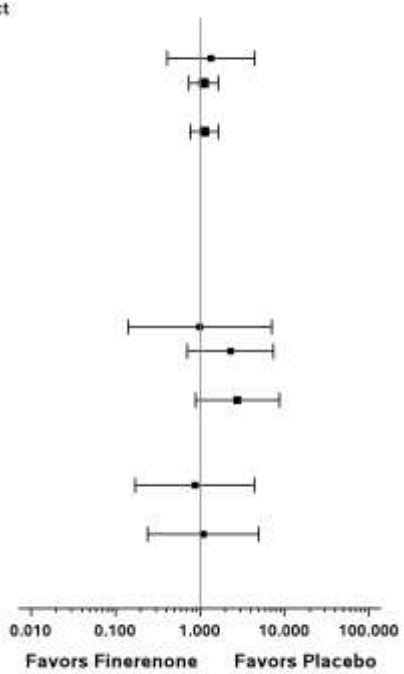
Figure 1.2.2 / 30: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	6/140	5/152	10.1%	1.35 (0.41;4.46)	
FIGARO-DKD	53/1659	45/1613	89.9%	1.10 (0.74;1.65)	
Heterogeneity		p=0.8830			
Total	59/1799	50/1765		1.13 (0.77;1.64)	0.5363
Black					
FIDELIO-DKD	0/10	1/9		N.C.	
FIGARO-DKD	0/70	1/74		N.C.	
Heterogeneity		p=N.C.			
Total	0/80	2/83			N.C.
Asian					
FIDELIO-DKD	2/39	4/44	26.5%	1.00 (0.14;7.08)	
FIGARO-DKD	9/464	4/486	73.5%	2.30 (0.71;7.46)	
Heterogeneity		p=0.4556			
Total	11/503	8/530		2.78 (0.89;8.74)	0.0672
Other					
FIDELIO-DKD	1/22	0/16		N.C.	
FIGARO-DKD	3/134	3/131	100%	0.87 (0.17;4.42)	
Heterogeneity		p=0.9950			
Total	4/156	3/147		1.10 (0.24;5.03)	0.8994
Subgroup Heterogeneity		p=N.C.			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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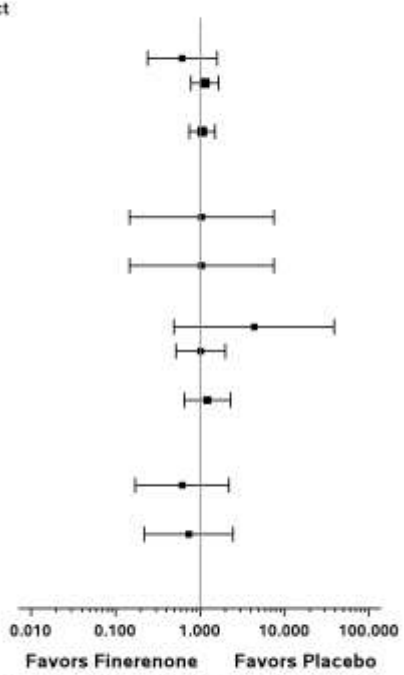
Figure 1.2.2 / 31: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	7/140	11/152	13.8%	0.62 (0.24;1.60)	
FIGARO-DKD	58/1659	49/1613	86.2%	1.14 (0.78;1.67)	
Heterogeneity		p=0.2570			
Total	65/1799	60/1765		1.06 (0.75;1.51)	0.7319
Black					
FIDELIO-DKD	0/10	0/9		N.C.	
FIGARO-DKD	2/70	3/74	100%	1.05 (0.15;7.48)	
Heterogeneity		p=1.0000			
Total	2/80	3/83		1.05 (0.15;7.48)	0.9631
Asian					
FIDELIO-DKD	4/39	1/44	8.6%	4.38 (0.49;39.2)	
FIGARO-DKD	17/464	17/486	91.4%	1.03 (0.52;2.01)	
Heterogeneity		p=0.1897			
Total	21/503	18/530		1.22 (0.65;2.29)	0.5342
Other					
FIDELIO-DKD	1/22	0/16		N.C.	
FIGARO-DKD	4/134	6/131	100%	0.62 (0.17;2.21)	
Heterogeneity		p=0.9932			
Total	5/156	6/147		0.74 (0.22;2.46)	0.6210
Subgroup Heterogeneity		p=0.8401			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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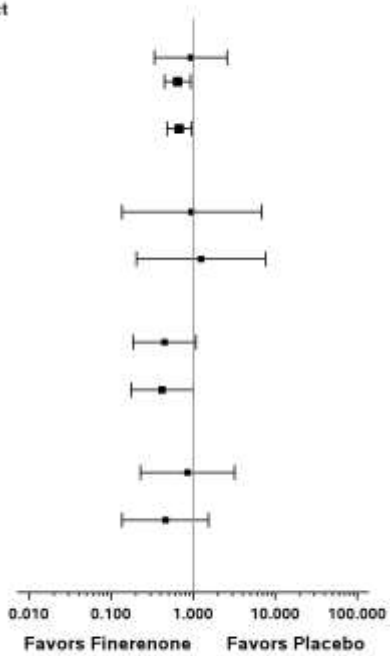
Figure 1.2.2 / 32: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	7/140	8/152	11.5%	0.93 (0.34;2.58)	
FIGARO-DKD	48/1659	72/1613	88.5%	0.64 (0.45;0.93)	
Heterogeneity		p=0.5069			
Total	55/1799	80/1765		0.67 (0.48;0.95)	0.0236
Black					
FIDELIO-DKD	1/10	0/9		N.C.	
FIGARO-DKD	2/70	4/74	100%	0.96 (0.13;6.85)	
Heterogeneity		p=0.9966			
Total	3/80	4/83		1.24 (0.20;7.63)	0.8143
Asian					
FIDELIO-DKD	0/39	2/44		N.C.	
FIGARO-DKD	7/464	16/486	100%	0.45 (0.18;1.08)	
Heterogeneity		p=0.9912			
Total	7/503	18/530		0.42 (0.17;1.01)	0.0451
Other					
FIDELIO-DKD	1/22	3/16			
FIGARO-DKD	5/134	5/131	100%	0.85 (0.23;3.20)	
Heterogeneity		p=0.2885			
Total	6/156	8/147		0.46 (0.14;1.54)	0.1958
Subgroup Heterogeneity		p=0.7575			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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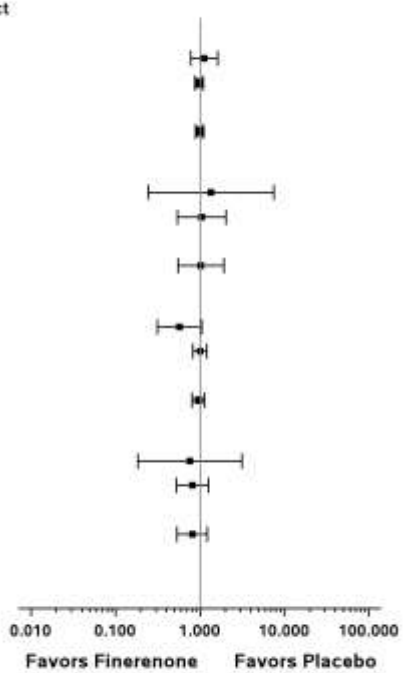
Figure 1.2.2 / 33: Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	61/140	56/152	8.5%	1.12 (0.78;1.62)	
FIGARO-DKD	626/1659	617/1613	91.5%	0.98 (0.87;1.09)	
Heterogeneity		p=0.4920			
Total	687/1799	673/1765		0.99 (0.89;1.10)	0.7997
Black					
FIDELIO-DKD	4/10	4/9	13.1%	1.35 (0.24;7.51)	
FIGARO-DKD	19/70	22/74	86.9%	1.05 (0.54;2.04)	
Heterogeneity		p=0.5379			
Total	23/80	26/83		1.03 (0.55;1.92)	0.9344
Asian					
FIDELIO-DKD	17/39	30/44	8.9%	0.57 (0.31;1.05)	
FIGARO-DKD	214/464	229/486	91.1%	1.00 (0.83;1.21)	
Heterogeneity		p=0.0821			
Total	231/503	259/530		0.96 (0.80;1.15)	0.6580
Other					
FIDELIO-DKD	5/22	4/16	8.4%	0.76 (0.18;3.13)	
FIGARO-DKD	44/134	50/131	91.6%	0.82 (0.53;1.25)	
Heterogeneity		p=0.9547			
Total	49/156	54/147		0.81 (0.54;1.22)	0.3130
Subgroup Heterogeneity		p=0.7094			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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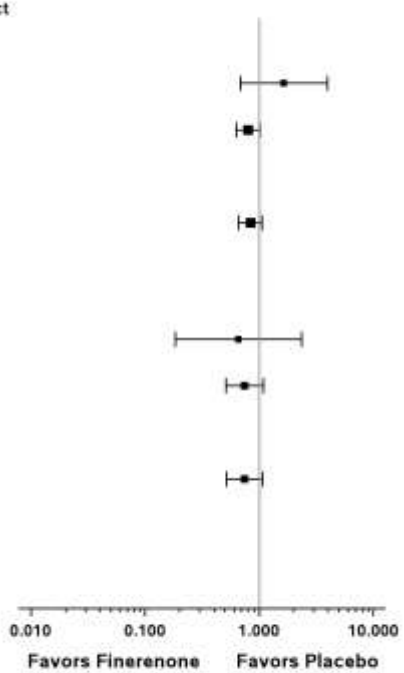
Figure 1.2.2 / 34: Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	13/153	8/154	7.0%	1.64 (0.68;3.96)	
FIGARO-DKD	117/1611	150/1640	93.0%	0.80 (0.63;1.02)	
Heterogeneity		p=0.1348			
Total	130/1764	158/1794		0.84 (0.67;1.06)	0.1388
Female					
FIDELIO-DKD	4/58	6/67	8.1%	0.66 (0.18;2.36)	
FIGARO-DKD	49/716	61/664	91.9%	0.74 (0.51;1.09)	
Heterogeneity		p=0.9539			
Total	53/774	67/731		0.74 (0.51;1.06)	0.1019
Subgroup Heterogeneity		p=0.5215			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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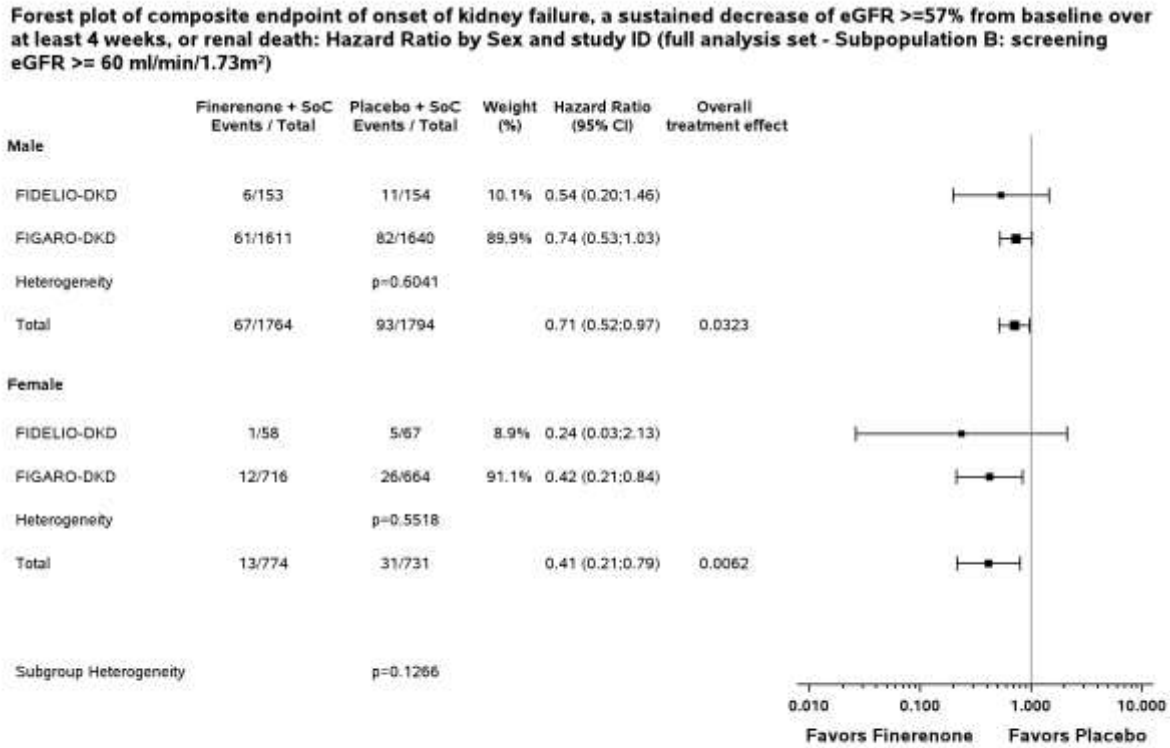
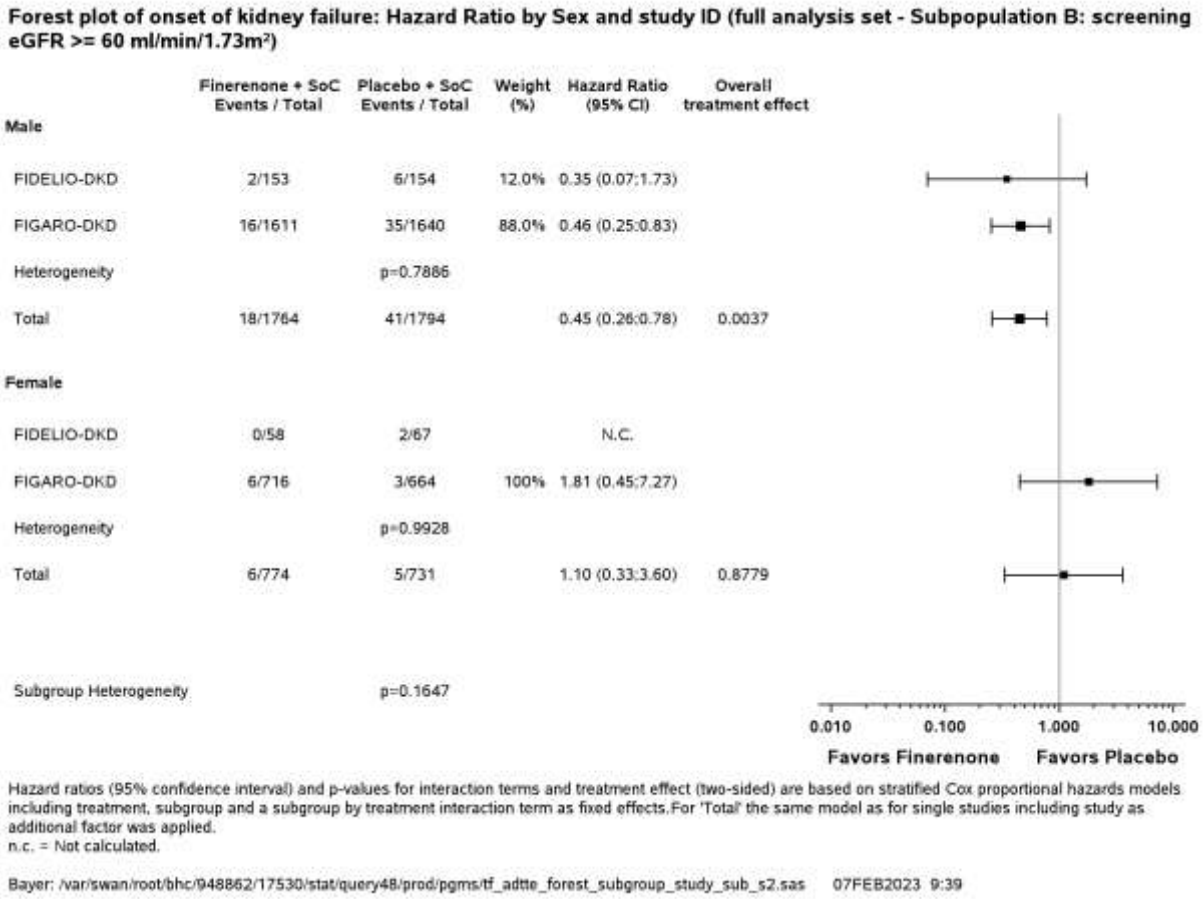
Figure 1.2.2 / 35: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 36: Forest plot of onset of kidney failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



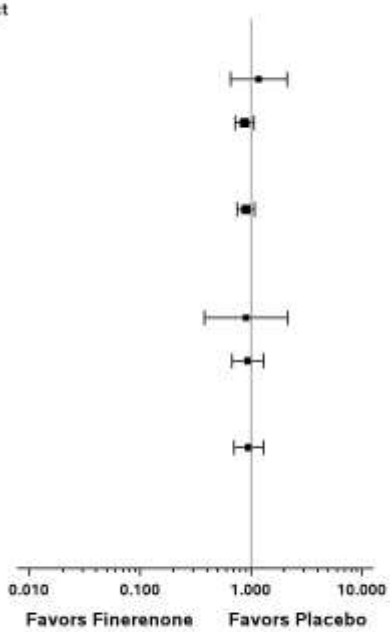
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 37: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	24/153	21/154	9.9%	1.17 (0.65;2.11)	
FIGARO-DKD	190/1611	220/1640	90.1%	0.88 (0.72;1.07)	
Heterogeneity		p=0.4637			
Total	214/1764	241/1794		0.90 (0.75;1.08)	0.2674
Female					
FIDELIO-DKD	10/58	12/67	12.6%	0.90 (0.38;2.15)	
FIGARO-DKD	73/716	71/664	87.4%	0.94 (0.68;1.31)	
Heterogeneity		p=0.9303			
Total	83/774	83/731		0.96 (0.70;1.30)	0.7791
Subgroup Heterogeneity		p=0.8173			



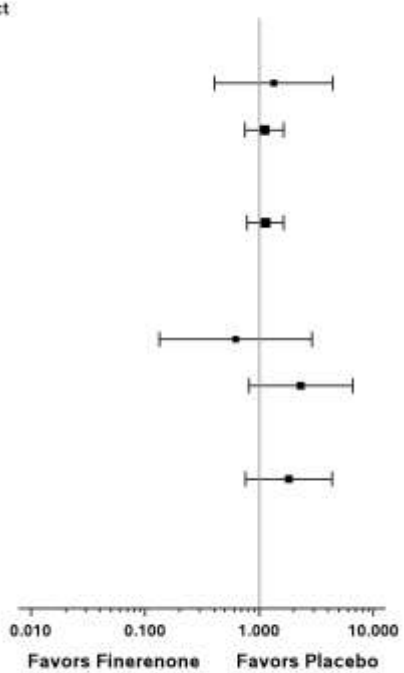
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 38: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	6/153	5/154	9.7%	1.34 (0.41;4.40)	
FIGARO-DKD	53/1611	48/1640	90.3%	1.11 (0.75;1.64)	
Heterogeneity		p=0.9346			
Total	59/1764	53/1794		1.13 (0.78;1.64)	0.5147
Female					
FIDELIO-DKD	3/58	5/67	31.5%	0.62 (0.13;2.89)	
FIGARO-DKD	12/716	5/664	68.5%	2.31 (0.81;6.57)	
Heterogeneity		p=0.1872			
Total	15/774	10/731		1.81 (0.76;4.33)	0.1779
Subgroup Heterogeneity		p=0.5383			



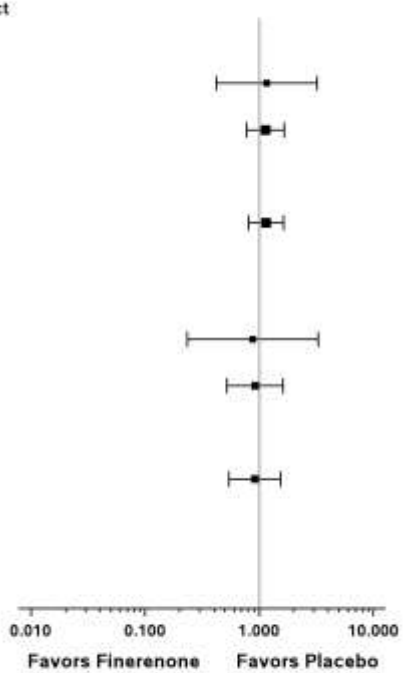
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 39: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

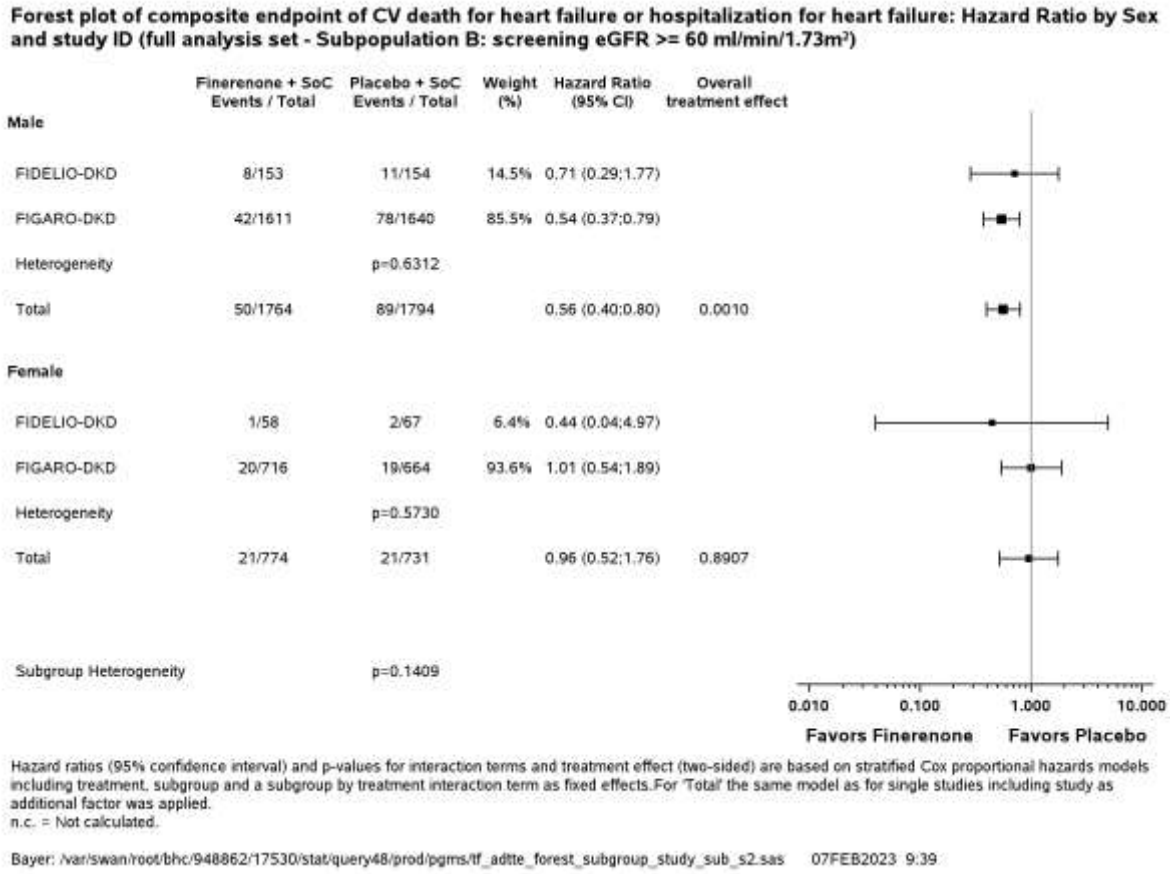
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	8/153	7/154	12.3%	1.16 (0.42;3.20)	
FIGARO-DKD	56/1611	51/1640	87.7%	1.14 (0.78;1.66)	
Heterogeneity		p=0.9734			
Total	64/1764	58/1794		1.15 (0.81;1.64)	0.4385
Female					
FIDELIO-DKD	4/58	5/67	15.5%	0.88 (0.23;3.29)	
FIGARO-DKD	25/716	24/664	84.5%	0.92 (0.52;1.63)	
Heterogeneity		p=0.9762			
Total	29/774	29/731		0.91 (0.54;1.54)	0.7295
Subgroup Heterogeneity		p=0.5029			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 40: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 41: Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	65/153	68/154	8.9%	0.92 (0.66;1.30)	
FIGARO-DKD	664/1611	692/1640	91.1%	0.97 (0.87;1.08)	
Heterogeneity		p=0.6892			
Total	729/1764	760/1794		0.96 (0.87;1.07)	0.4656
Female					
FIDELIO-DKD	22/58	26/67	9.2%	0.94 (0.53;1.68)	
FIGARO-DKD	239/716	226/664	90.8%	1.01 (0.84;1.21)	
Heterogeneity		p=0.7529			
Total	261/774	252/731		1.01 (0.85;1.20)	0.9203
Subgroup Heterogeneity		p=0.7592			

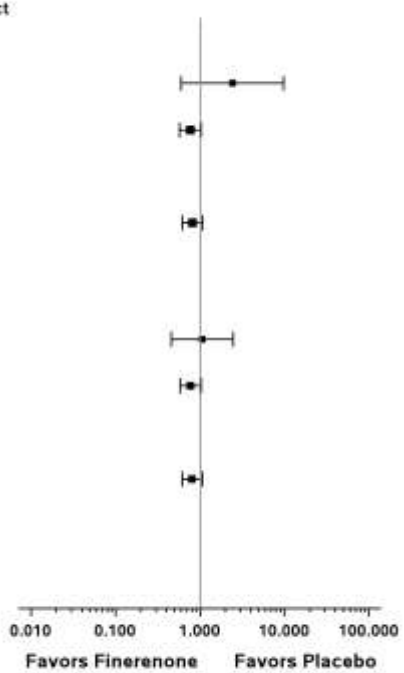
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 42: Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	6/99	3/96	4.2%	2.43 (0.60;9.86)	
FIGARO-DKD	82/1416	104/1421	95.8%	0.77 (0.58;1.03)	
Heterogeneity		p=0.2388			
Total	88/1515	107/1517		0.81 (0.61;1.08)	0.1506
>= 65 years					
FIDELIO-DKD	11/112	11/125	10.4%	1.06 (0.46;2.47)	
FIGARO-DKD	84/911	107/883	89.6%	0.78 (0.58;1.03)	
Heterogeneity		p=0.4401			
Total	95/1023	118/1008		0.81 (0.62;1.06)	0.1234
Subgroup Heterogeneity		p=0.9953			



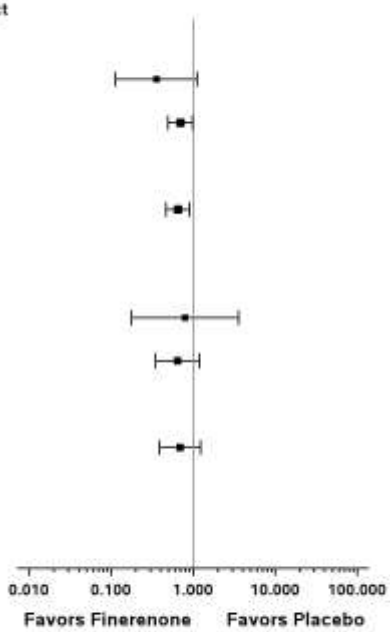
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 43: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	4/99	12/96	8.2%	0.36 (0.11;1.12)	
FIGARO-DKD	56/1416	83/1421	91.8%	0.70 (0.49;0.98)	
Heterogeneity		p=0.2490			
Total	60/1515	95/1517		0.65 (0.47;0.90)	0.0085
>= 65 years					
FIDELIO-DKD	3/112	4/125	14.5%	0.79 (0.18;3.56)	
FIGARO-DKD	17/911	25/883	85.5%	0.64 (0.35;1.20)	
Heterogeneity		p=0.9673			
Total	20/1023	29/1008		0.69 (0.39;1.23)	0.2076
Subgroup Heterogeneity		p=0.9905			



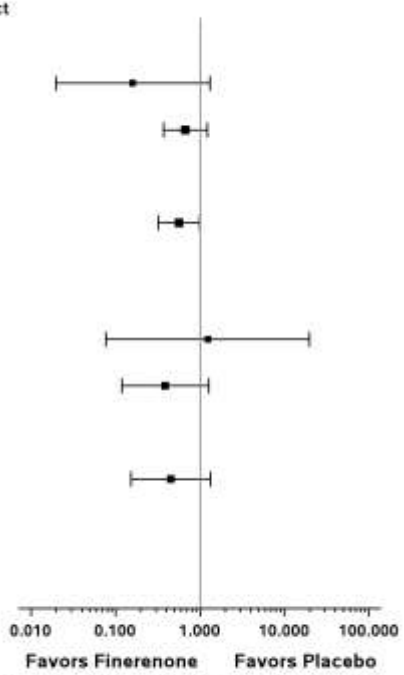
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 44: Forest plot of onset of kidney failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

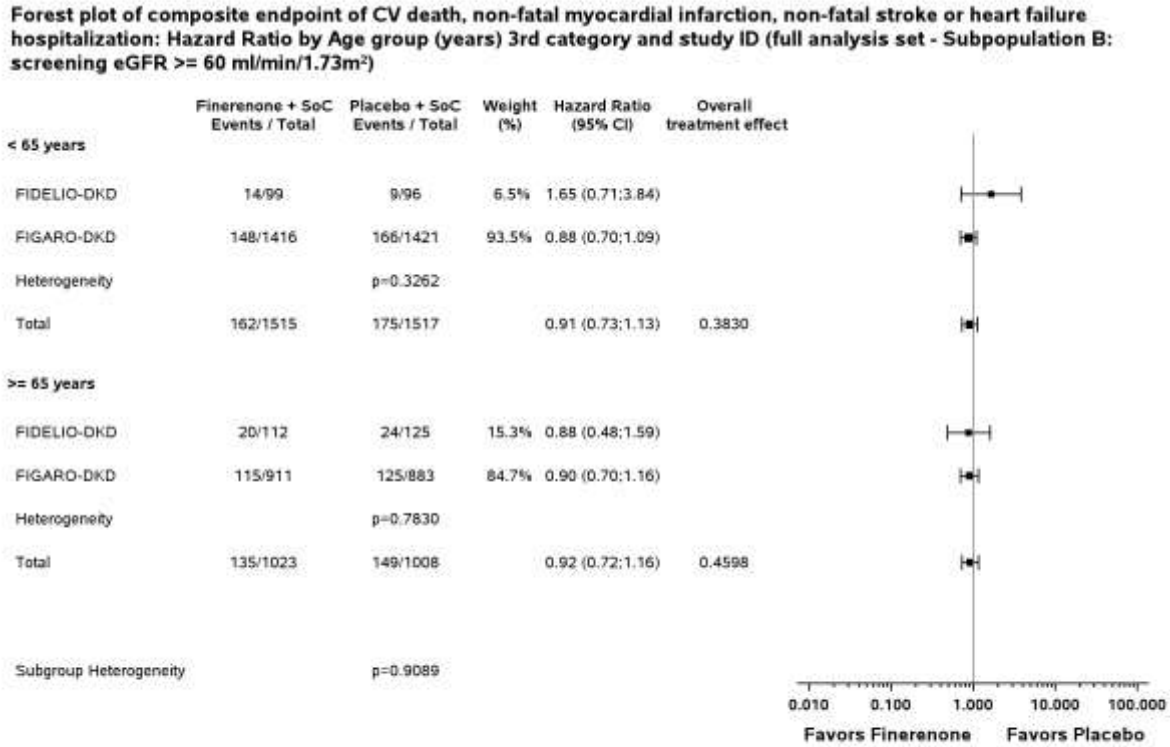
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	1/99	7/96	7.4%	0.16 (0.02;1.31)	
FIGARO-DKD	18/1416	29/1421	92.6%	0.67 (0.37;1.22)	
Heterogeneity		p=0.1947			
Total	19/1515	36/1517		0.57 (0.32;1.00)	0.0470
>= 65 years					
FIDELIO-DKD	1/112	1/125	15.5%	1.24 (0.08;19.9)	
FIGARO-DKD	4/911	9/883	84.5%	0.39 (0.12;1.28)	
Heterogeneity		p=0.4200			
Total	5/1023	10/1008		0.45 (0.15;1.33)	0.1394
Subgroup Heterogeneity		p=0.6485			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

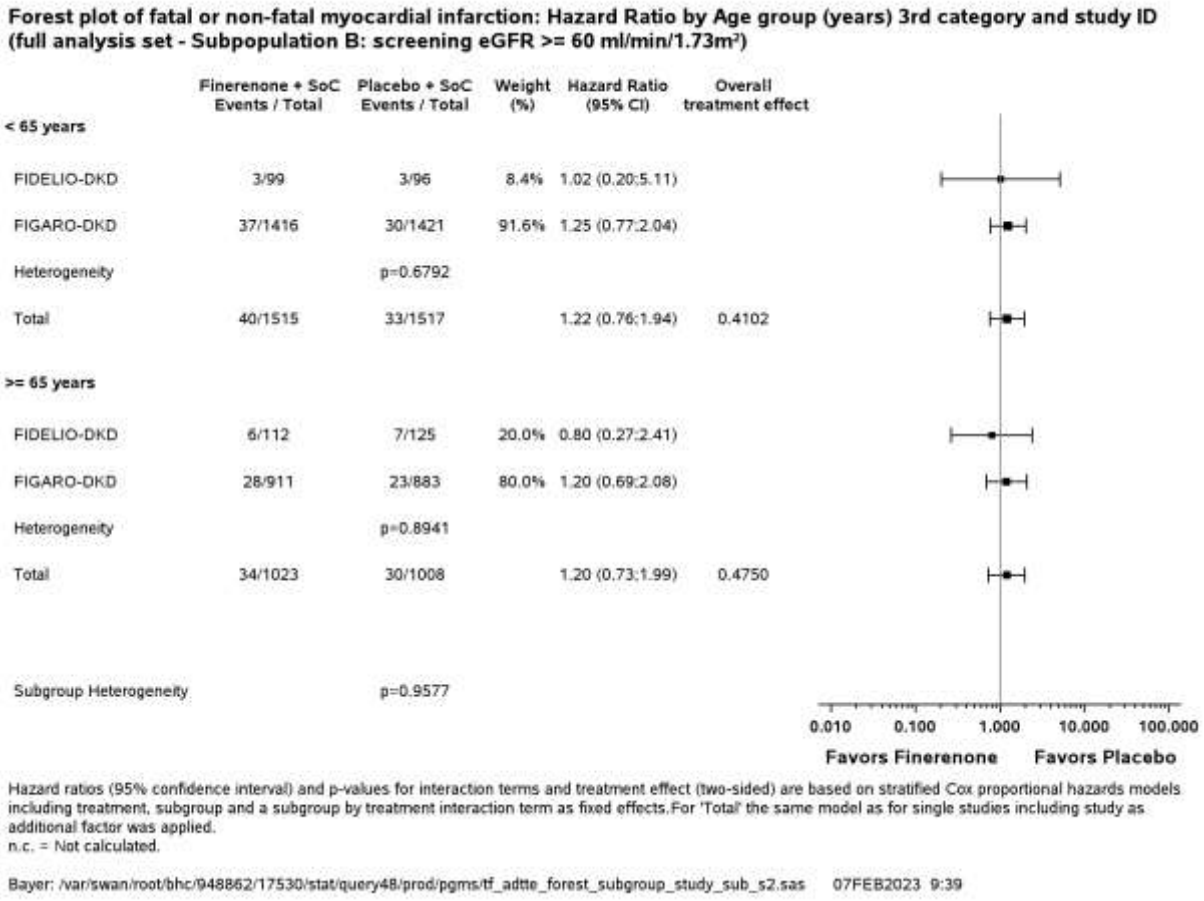
Figure 1.2.2 / 45: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 46: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

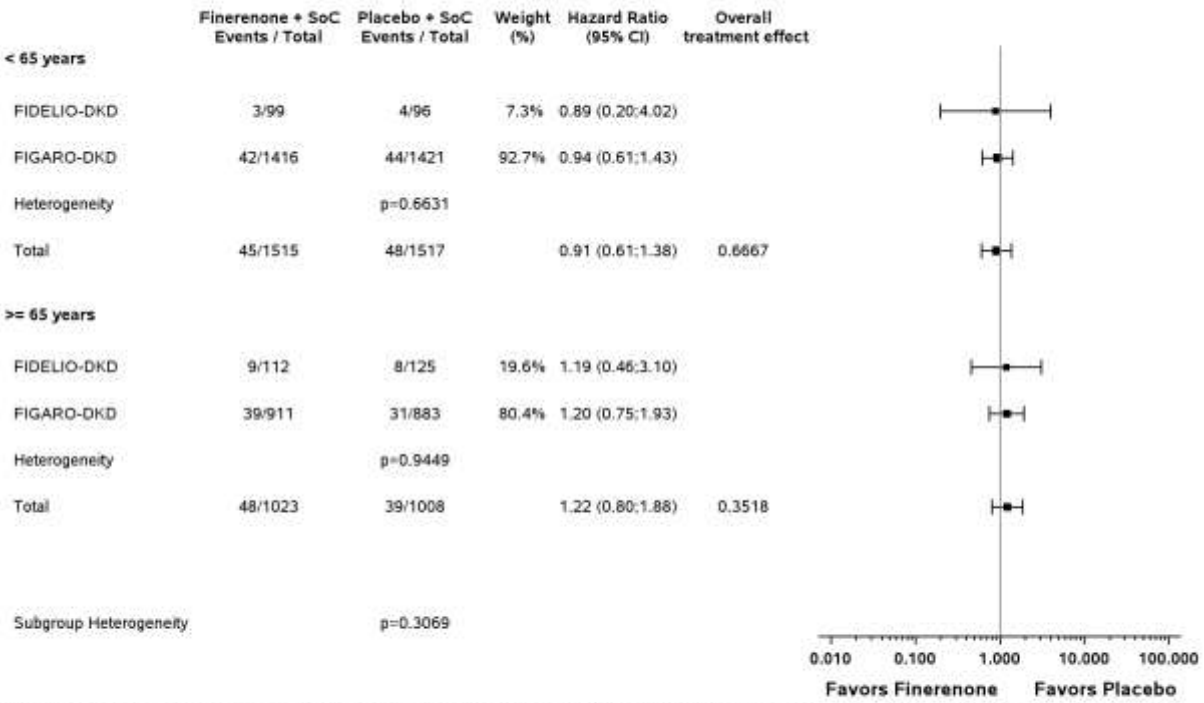


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 47: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



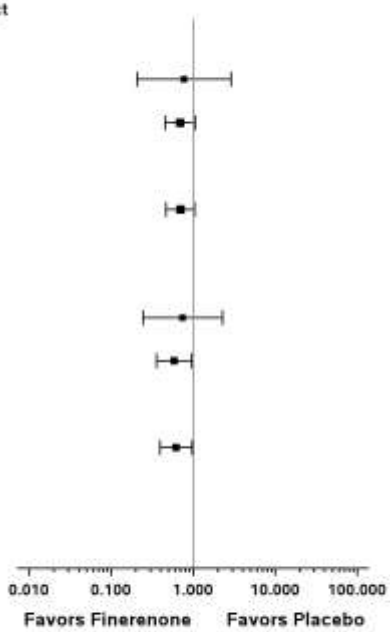
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 48: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	4/99	5/96	9.2%	0.77 (0.20;2.88)	
FIGARO-DKD	37/1416	54/1421	90.8%	0.69 (0.45;1.05)	
Heterogeneity		p=0.9954			
Total	41/1515	59/1517		0.70 (0.47;1.04)	0.0744
>= 65 years					
FIDELIO-DKD	5/112	8/125	16.4%	0.74 (0.24;2.26)	
FIGARO-DKD	25/911	43/883	83.6%	0.58 (0.36;0.96)	
Heterogeneity		p=0.7035			
Total	30/1023	51/1008		0.62 (0.39;0.97)	0.0351
Subgroup Heterogeneity		p=0.6756			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 49: Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	40/99	38/96	6.9%	1.08 (0.69;1.70)	
FIGARO-DKD	501/1416	530/1421	93.1%	0.94 (0.83;1.07)	
Heterogeneity		p=0.7329			
Total	541/1515	568/1517		0.95 (0.84;1.06)	0.3583
>= 65 years					
FIDELIO-DKD	47/112	56/125	11.3%	0.82 (0.56;1.22)	
FIGARO-DKD	402/911	388/883	88.7%	1.02 (0.88;1.17)	
Heterogeneity		p=0.4488			
Total	449/1023	444/1008		1.00 (0.88;1.15)	0.9517
Subgroup Heterogeneity		p=0.5390			

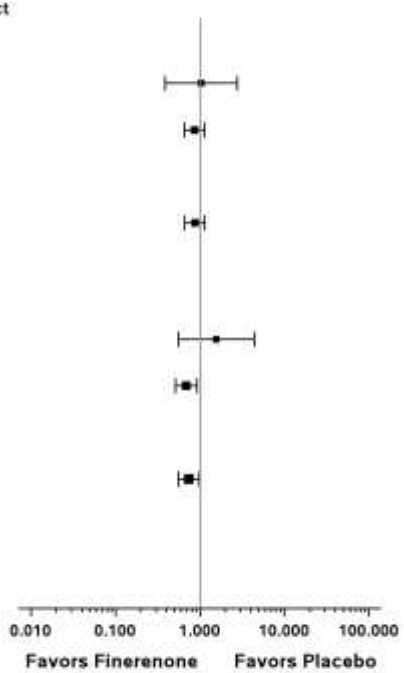
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 50: Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

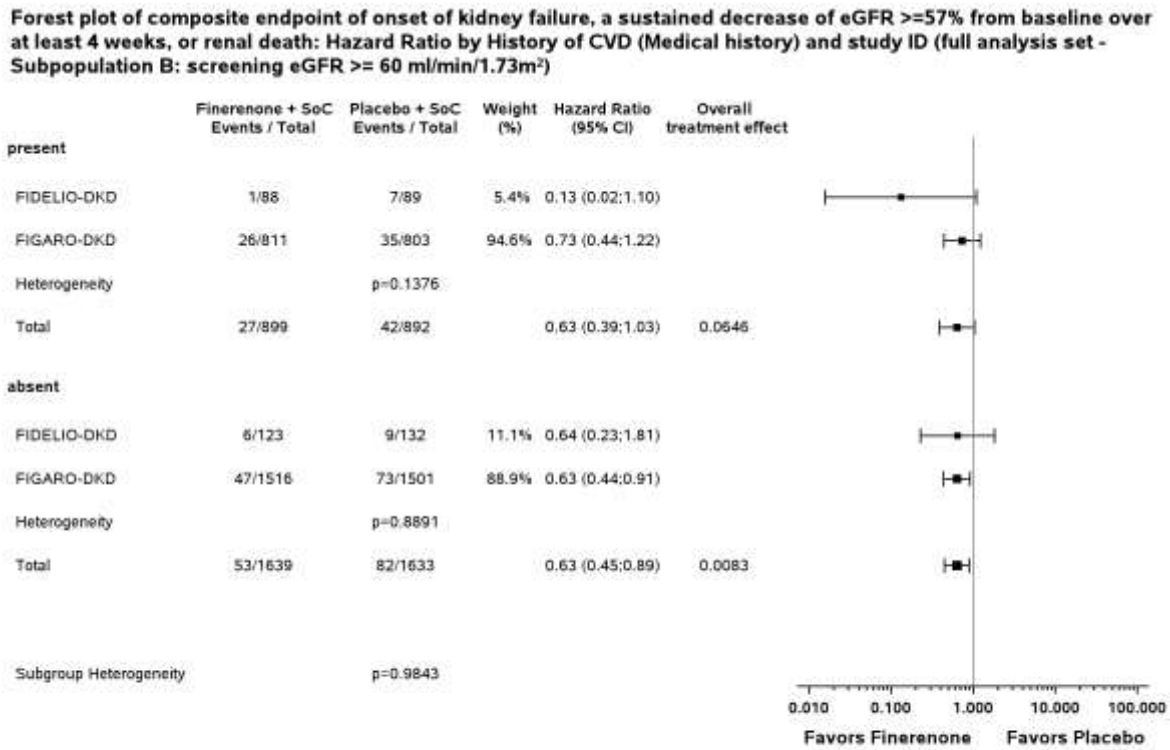
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	8/88	8/89	7.6%	1.03 (0.39;2.76)	
FIGARO-DKD	90/811	104/803	92.4%	0.86 (0.65;1.14)	
Heterogeneity		p=0.8073			
Total	98/899	112/892		0.87 (0.66;1.14)	0.3216
absent					
FIDELIO-DKD	9/123	6/132	7.4%	1.57 (0.55;4.42)	
FIGARO-DKD	76/1516	107/1501	92.6%	0.69 (0.52;0.93)	
Heterogeneity		p=0.1062			
Total	85/1639	113/1633		0.74 (0.56;0.98)	0.0325
Subgroup Heterogeneity		p=0.3972			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 51: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



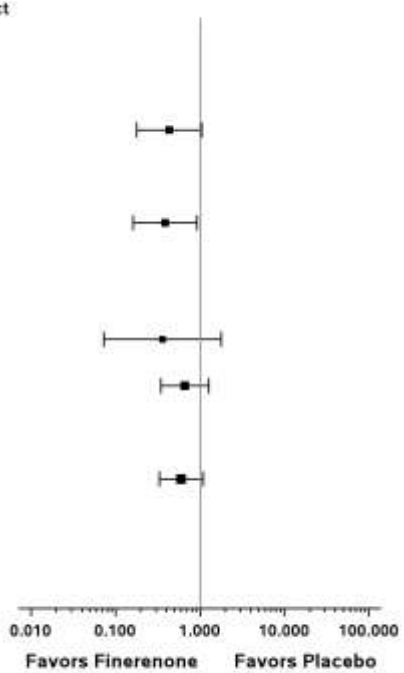
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 52: Forest plot of onset of kidney failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

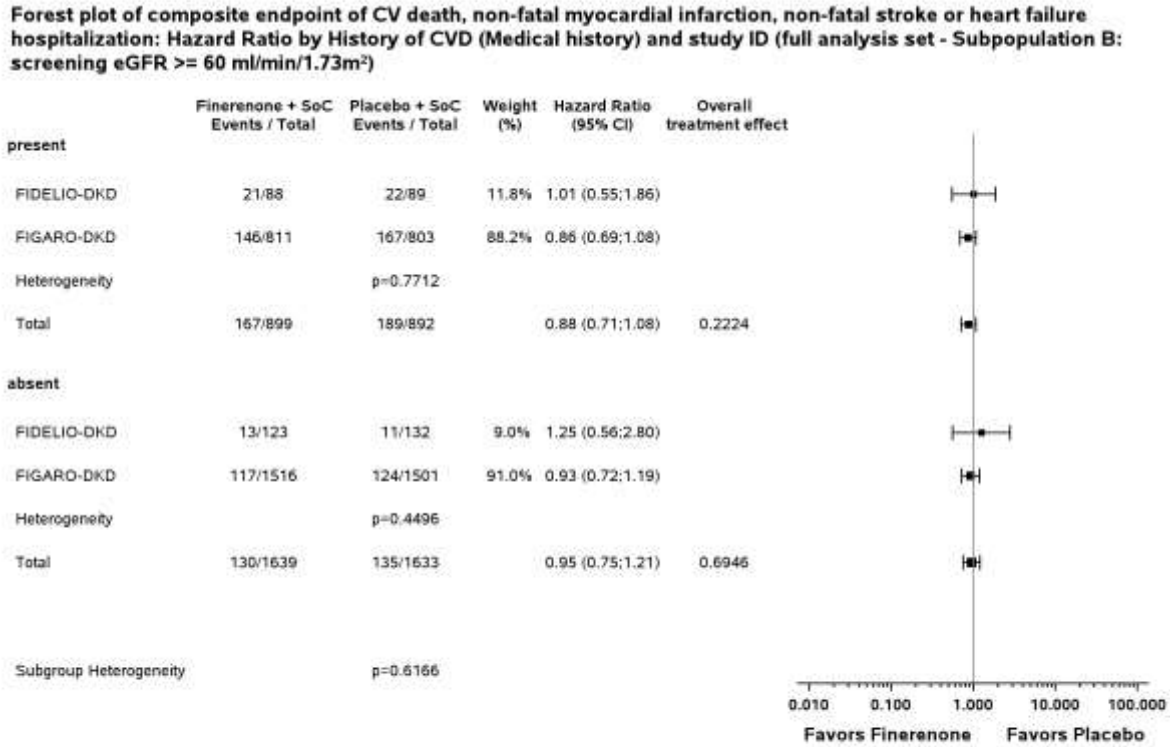
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	0/88	2/89		N.C.	
FIGARO-DKD	7/811	16/803	100%	0.43 (0.18;1.05)	
Heterogeneity		p=0.9905			
Total	7/899	18/892		0.39 (0.16;0.93)	0.0270
absent					
FIDELIO-DKD	2/123	6/132	14.3%	0.36 (0.07;1.80)	
FIGARO-DKD	15/1516	22/1501	85.7%	0.66 (0.34;1.28)	
Heterogeneity		p=0.4470			
Total	17/1639	28/1633		0.60 (0.33;1.10)	0.0963
Subgroup Heterogeneity		p=0.4127			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

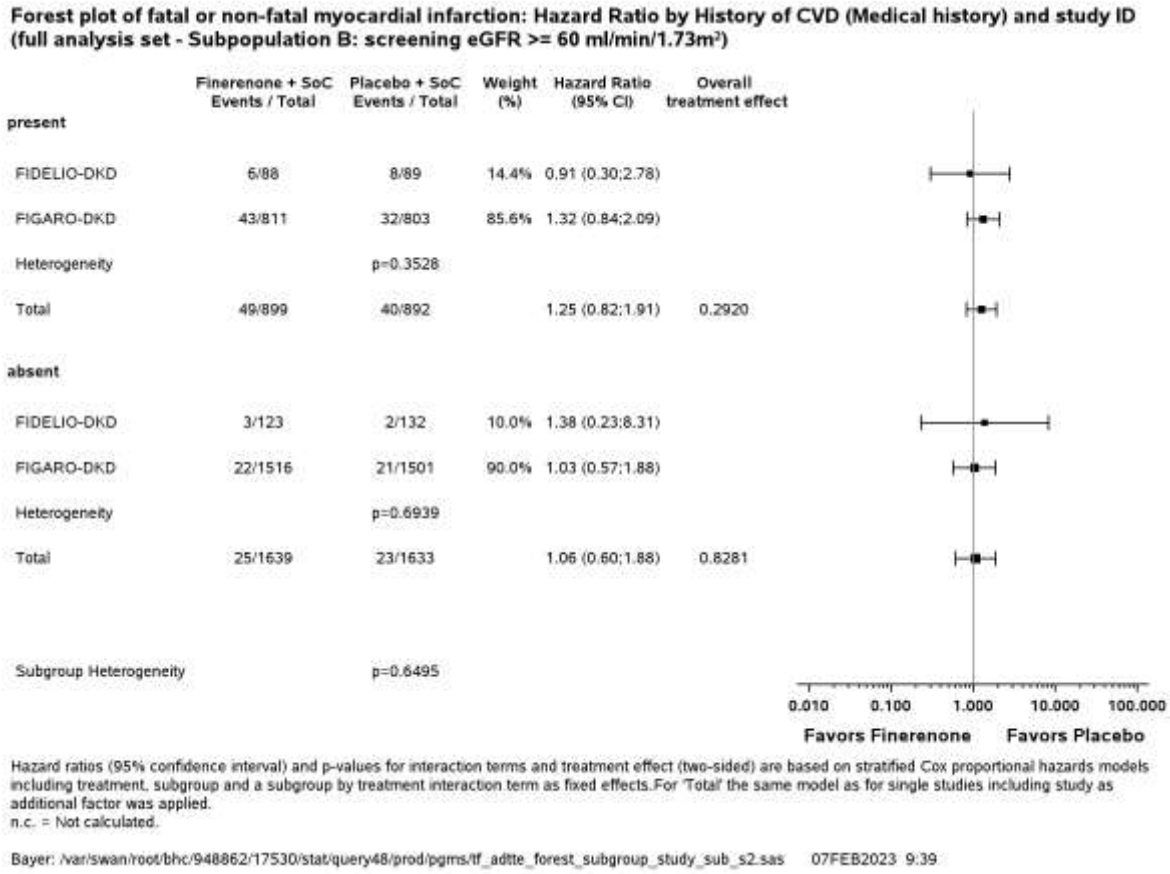
Figure 1.2.2 / 53: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 54: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



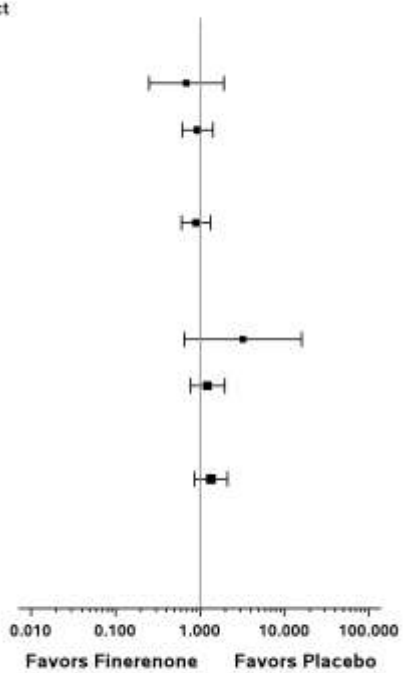
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 55: Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	6/88	10/89	14.7%	0.69 (0.25;1.91)	
FIGARO-DKD	42/811	44/803	85.3%	0.94 (0.62;1.44)	
Heterogeneity		p=0.4427			
Total	48/899	54/892		0.90 (0.61;1.33)	0.5894
absent					
FIDELIO-DKD	6/123	2/132	8.0%	3.23 (0.65;16.0)	
FIGARO-DKD	39/1516	31/1501	92.0%	1.23 (0.77;1.98)	
Heterogeneity		p=0.2560			
Total	45/1639	33/1633		1.35 (0.86;2.12)	0.1898
Subgroup Heterogeneity		p=0.1801			



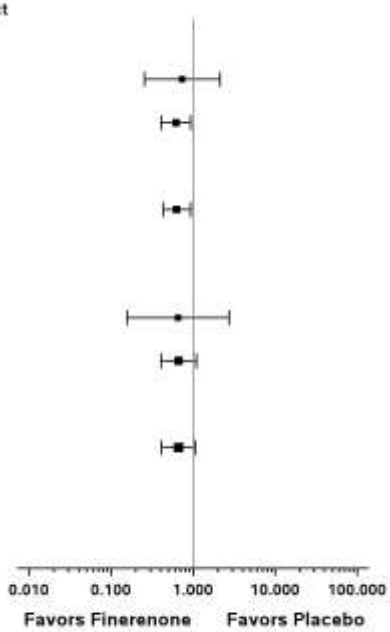
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 56: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	6/88	8/89	13.3%	0.73 (0.25;2.11)	
FIGARO-DKD	36/811	59/803	86.7%	0.61 (0.40;0.93)	
Heterogeneity		p=0.7666			
Total	42/899	67/892		0.63 (0.43;0.92)	0.0169
absent					
FIDELIO-DKD	3/123	5/132	10.8%	0.65 (0.16;2.73)	
FIGARO-DKD	26/1516	38/1501	89.2%	0.66 (0.40;1.09)	
Heterogeneity		p=0.9760			
Total	29/1639	43/1633		0.66 (0.41;1.06)	0.0816
Subgroup Heterogeneity		p=0.8699			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 57: Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	45/88	48/89	10.6%	0.95 (0.63;1.43)	
FIGARO-DKD	386/811	383/803	89.4%	0.99 (0.86;1.14)	
Heterogeneity		p=0.7403			
Total	431/899	431/892		0.98 (0.86;1.13)	0.8203
absent					
FIDELIO-DKD	42/123	46/132	7.6%	0.94 (0.61;1.43)	
FIGARO-DKD	517/1516	535/1501	92.4%	0.96 (0.85;1.08)	
Heterogeneity		p=0.9287			
Total	559/1639	581/1633		0.95 (0.85;1.07)	0.4256
Subgroup Heterogeneity		p=0.7261			

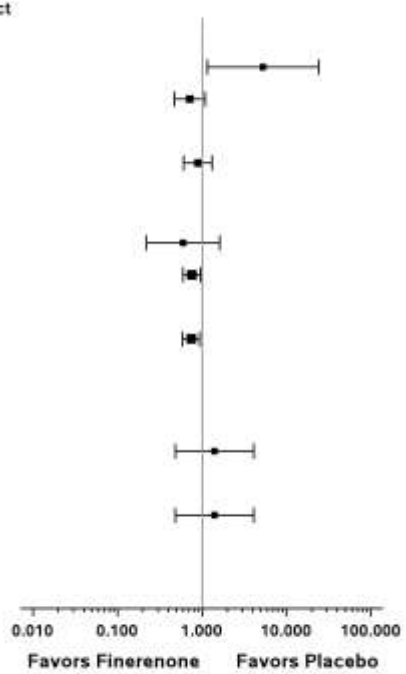
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 58: Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	11/64	2/54	7.1%	5.31 (1.17;24.2)	
FIGARO-DKD	38/693	53/700	92.9%	0.72 (0.47;1.09)	
Heterogeneity		p=0.0191			
Total	49/757	55/754		0.90 (0.61;1.32)	0.5799
130 - < 160 mmHg					
FIDELIO-DKD	6/138	11/156	5.5%	0.60 (0.22;1.61)	
FIGARO-DKD	119/1561	152/1525	94.5%	0.76 (0.60;0.97)	
Heterogeneity		p=0.6240			
Total	125/1699	163/1681		0.75 (0.59;0.94)	0.0145
>= 160 mmHg					
FIDELIO-DKD	0/9	1/11		N.C.	
FIGARO-DKD	9/73	6/79	100%	1.41 (0.49;4.09)	
Heterogeneity		p=0.9942			
Total	9/82	7/90		1.41 (0.49;4.09)	0.5249
Subgroup Heterogeneity		p=0.4038			



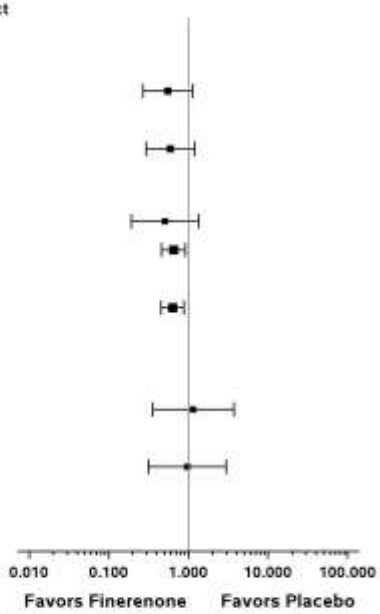
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 59: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

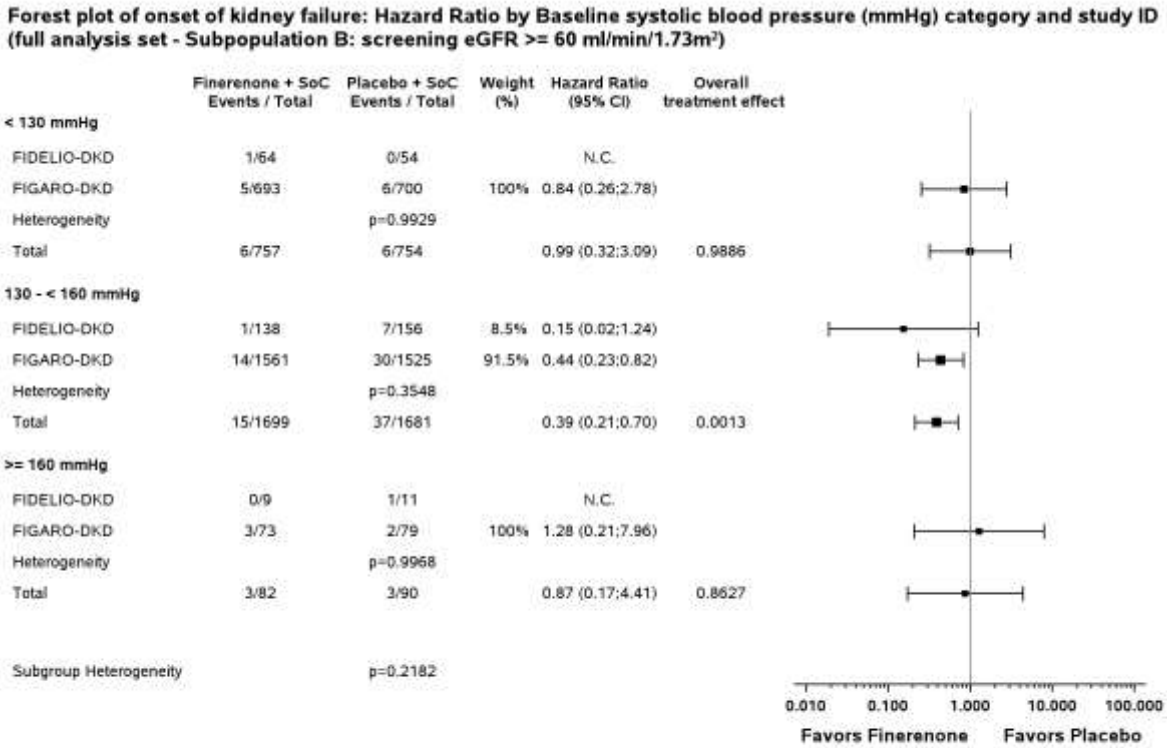
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	1/64	0/54		N.C.	
FIGARO-DKD	12/693	22/700	100%	0.55 (0.27;1.12)	
Heterogeneity		p=0.9891			
Total	13/757	22/754		0.59 (0.29;1.19)	0.1354
130 - < 160 mmHg					
FIDELIO-DKD	6/138	13/156	11.4%	0.50 (0.19;1.33)	
FIGARO-DKD	54/1561	79/1525	88.6%	0.65 (0.46;0.92)	
Heterogeneity		p=0.5483			
Total	60/1699	92/1681		0.63 (0.45;0.87)	0.0052
>= 160 mmHg					
FIDELIO-DKD	0/9	3/11		N.C.	
FIGARO-DKD	7/73	7/79	100%	1.15 (0.36;3.70)	
Heterogeneity		p=0.9927			
Total	7/82	10/90		0.97 (0.31;2.97)	0.9507
Subgroup Heterogeneity		p=0.8331			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 60: Forest plot of onset of kidney failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



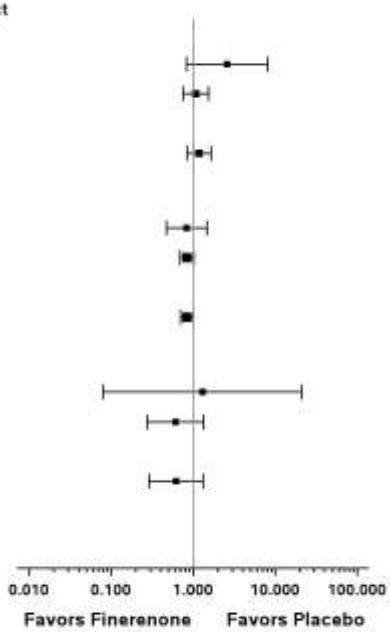
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 61: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

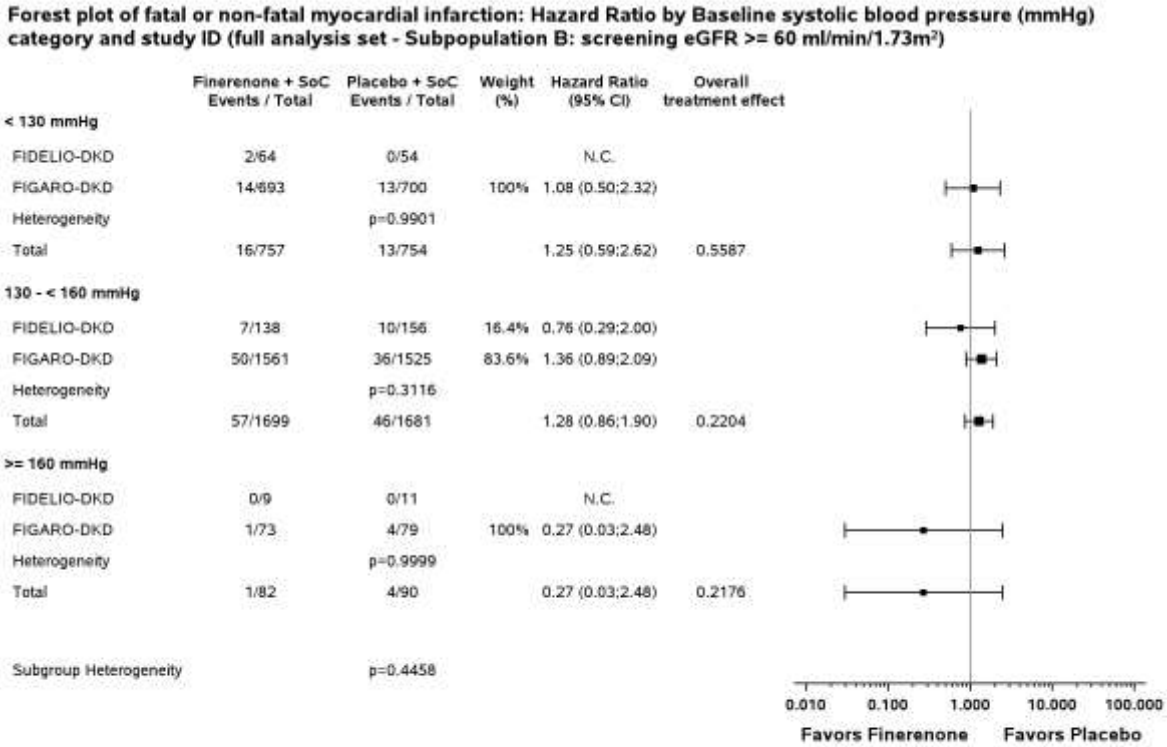
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	12/64	4/54	9.1%	2.59 (0.83;8.07)	
FIGARO-DKD	62/693	59/700	90.9%	1.07 (0.75;1.53)	
Heterogeneity		p=0.2074			
Total	74/757	63/754		1.17 (0.83;1.64)	0.3623
130 - < 160 mmHg					
FIDELIO-DKD	21/138	28/156	10.7%	0.83 (0.47;1.46)	
FIGARO-DKD	187/1561	214/1525	89.3%	0.84 (0.69;1.02)	
Heterogeneity		p=0.9827			
Total	208/1699	242/1681		0.84 (0.70;1.01)	0.0640
>= 160 mmHg					
FIDELIO-DKD	1/9	1/11	7.4%	1.29 (0.08;21.1)	
FIGARO-DKD	14/73	18/79	92.6%	0.60 (0.27;1.33)	
Heterogeneity		p=0.4544			
Total	15/82	19/90		0.62 (0.29;1.32)	0.2097
Subgroup Heterogeneity		p=0.2280			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 62: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



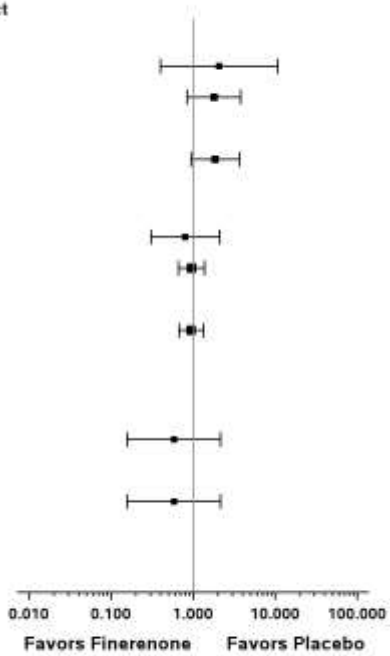
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 63: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	5/64	2/54	17.2%	2.06 (0.40;10.7)	
FIGARO-DKD	19/693	11/700	82.8%	1.78 (0.84;3.77)	
Heterogeneity		p=0.9349			
Total	24/757	13/754		1.85 (0.94;3.66)	0.0727
130 - < 160 mmHg					
FIDELIO-DKD	7/138	10/156	12.6%	0.80 (0.30;2.10)	
FIGARO-DKD	57/1561	57/1525	87.4%	0.95 (0.66;1.37)	
Heterogeneity		p=0.7493			
Total	64/1699	67/1681		0.94 (0.67;1.33)	0.7224
>= 160 mmHg					
FIDELIO-DKD	0/9	0/11		N.C.	
FIGARO-DKD	5/73	7/79	100%	0.58 (0.16;2.15)	
Heterogeneity		p=0.9999			
Total	5/82	7/90		0.58 (0.16;2.15)	0.4096
Subgroup Heterogeneity		p=0.1911			



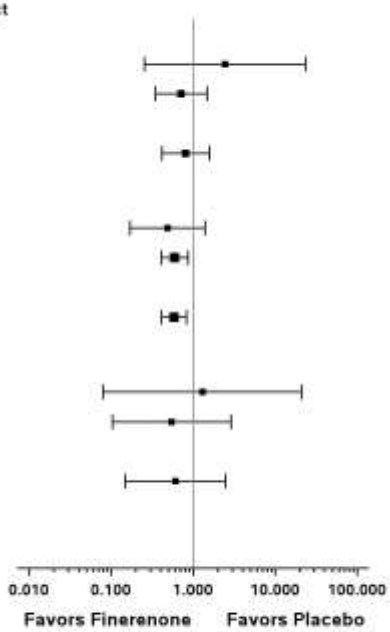
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 64: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	3/64	1/54	9.2%	2.46 (0.26;23.6)	
FIGARO-DKD	13/693	18/700	90.8%	0.71 (0.35;1.47)	
Heterogeneity		p=0.3201			
Total	16/757	19/754		0.81 (0.41;1.59)	0.5363
130 - < 160 mmHg					
FIDELIO-DKD	5/138	11/156	11.0%	0.49 (0.17;1.40)	
FIGARO-DKD	45/1561	74/1525	89.0%	0.59 (0.41;0.86)	
Heterogeneity		p=0.7224			
Total	50/1699	85/1681		0.58 (0.41;0.82)	0.0020
>= 160 mmHg					
FIDELIO-DKD	1/9	1/11	26.2%	1.29 (0.08;21.1)	
FIGARO-DKD	4/73	5/79	73.8%	0.55 (0.10;2.88)	
Heterogeneity		p=0.3054			
Total	5/82	6/90		0.61 (0.15;2.48)	0.4819
Subgroup Heterogeneity		p=0.5023			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 65: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	27/64	15/54	7.2%	1.66 (0.86;3.19)	
FIGARO-DKD	234/693	242/700	92.8%	1.01 (0.84;1.21)	
Heterogeneity		p=0.2404			
Total	261/757	257/754		1.04 (0.87;1.24)	0.6524
130 - < 160 mmHg					
FIDELIO-DKD	56/138	72/156	9.0%	0.82 (0.58;1.16)	
FIGARO-DKD	634/1561	638/1525	91.0%	0.95 (0.85;1.06)	
Heterogeneity		p=0.4990			
Total	690/1699	710/1681		0.94 (0.85;1.05)	0.2611
>= 160 mmHg					
FIDELIO-DKD	4/9	7/11	14.3%	0.65 (0.19;2.23)	
FIGARO-DKD	35/73	38/79	85.7%	1.28 (0.77;2.13)	
Heterogeneity		p=0.4403			
Total	39/82	45/90		1.21 (0.75;1.96)	0.4330
Subgroup Heterogeneity		p=0.6814			

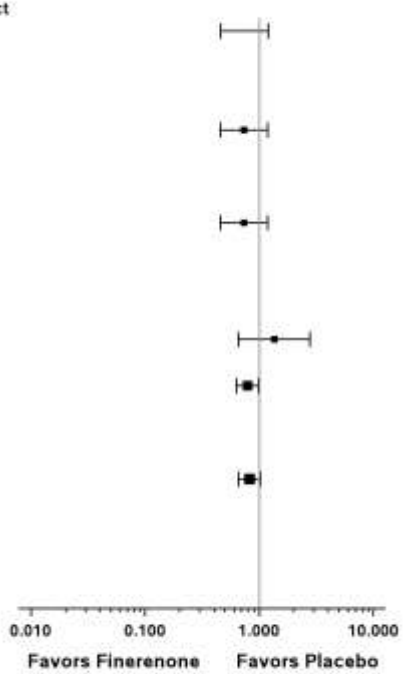
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 66: Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

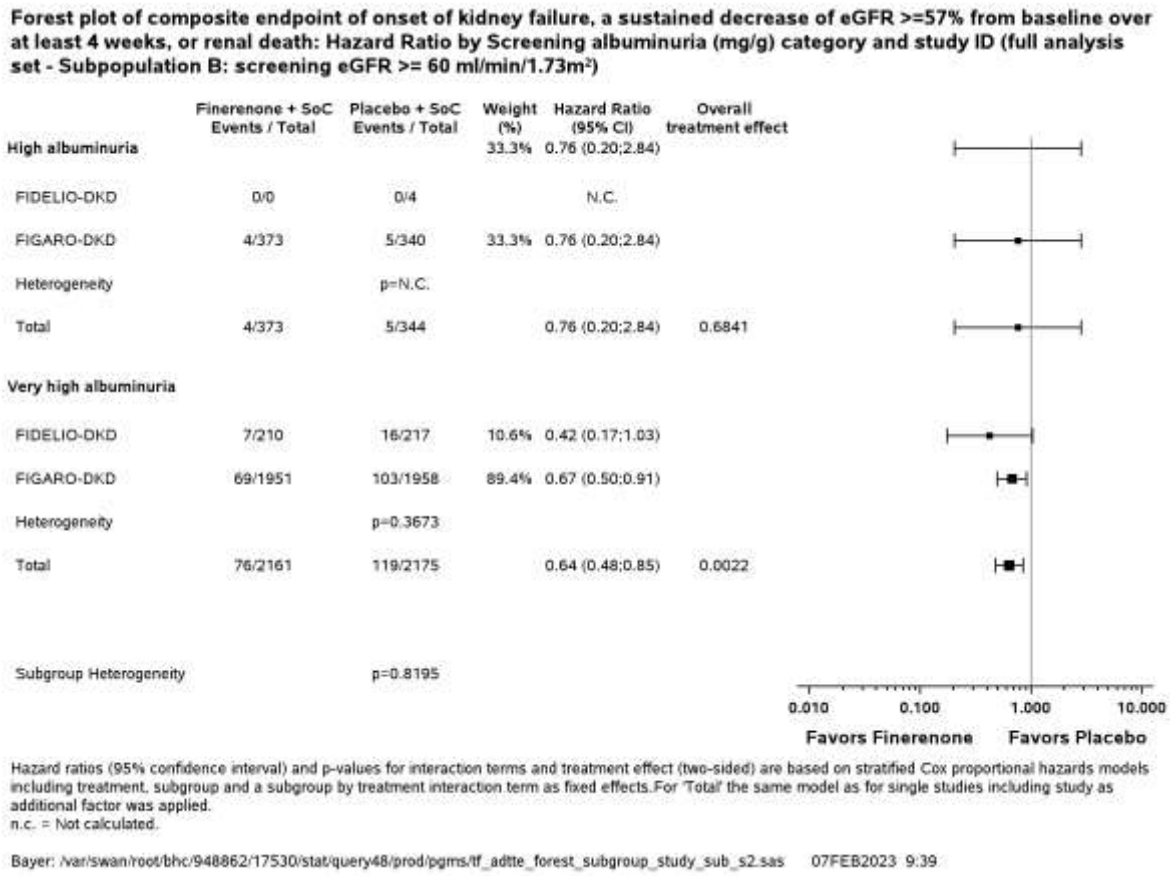
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria			33.4%	0.74 (0.46;1.20)	
FIDELIO-DKD	0/0	1/4		N.C.	
FIGARO-DKD	31/373	37/340	33.3%	0.74 (0.46;1.19)	
Heterogeneity		p=N.C.			
Total	31/373	38/344		0.74 (0.46;1.19)	0.2096
Very high albuminuria					
FIDELIO-DKD	17/210	13/217	8.9%	1.35 (0.66;2.79)	
FIGARO-DKD	135/1951	172/1958	91.1%	0.79 (0.63;0.99)	
Heterogeneity		p=0.1681			
Total	152/2161	185/2175		0.82 (0.66;1.02)	0.0773
Subgroup Heterogeneity		p=0.6847			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

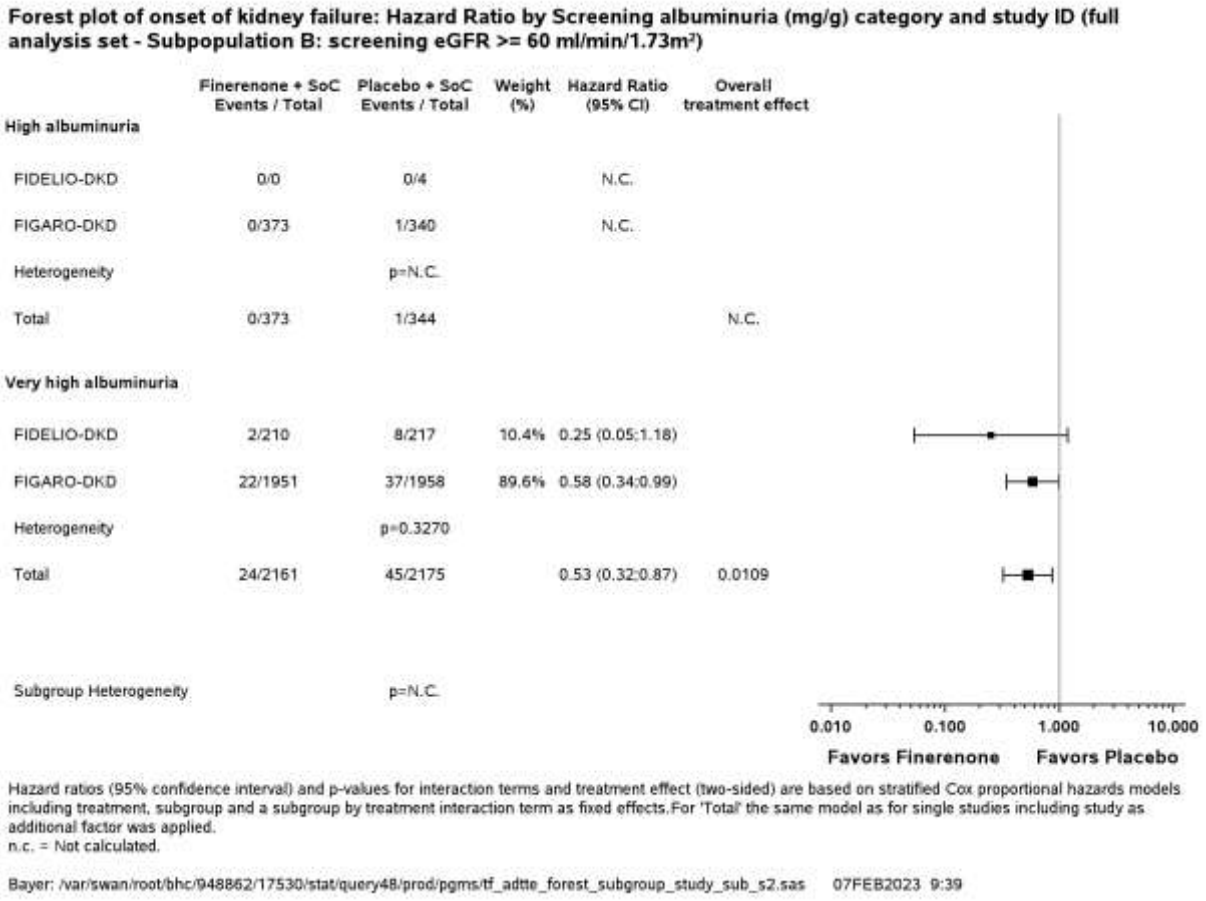
Figure 1.2.2 / 67: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

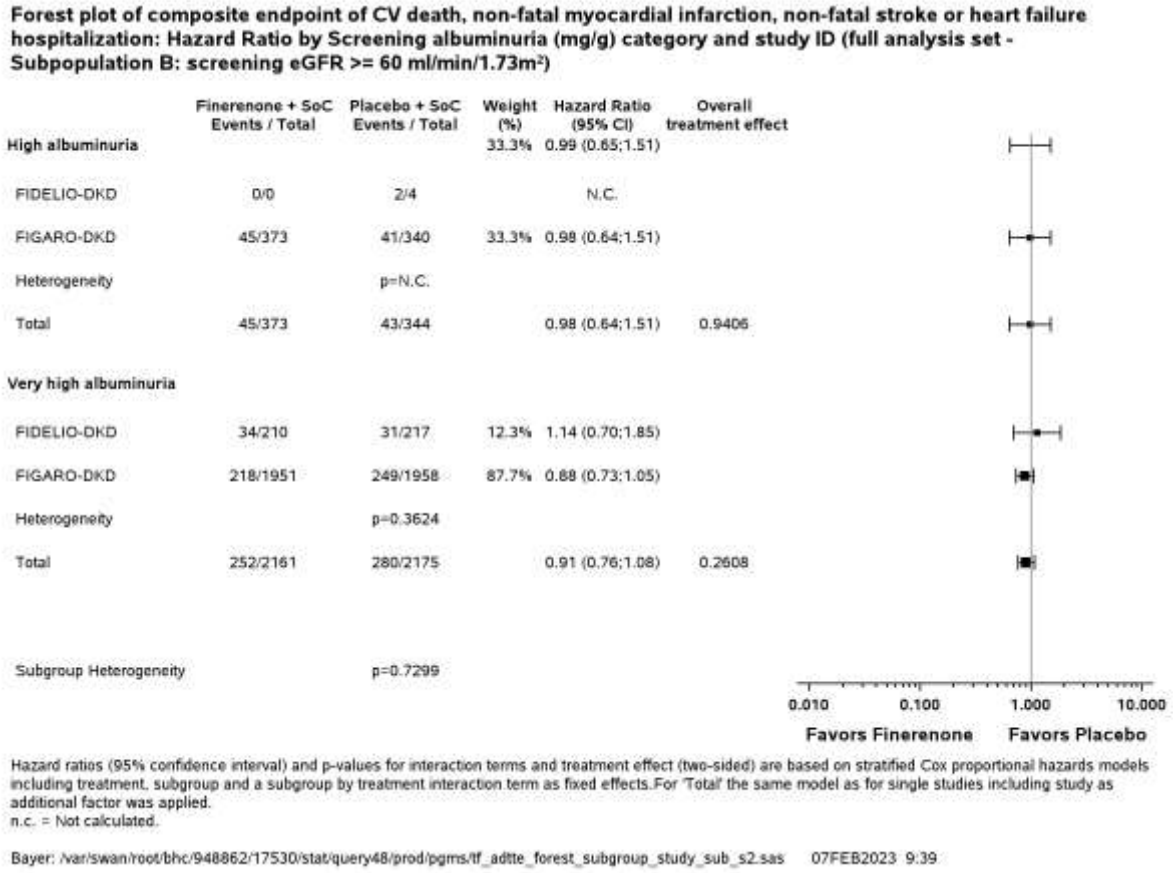
Figure 1.2.2 / 68: Forest plot of onset of kidney failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

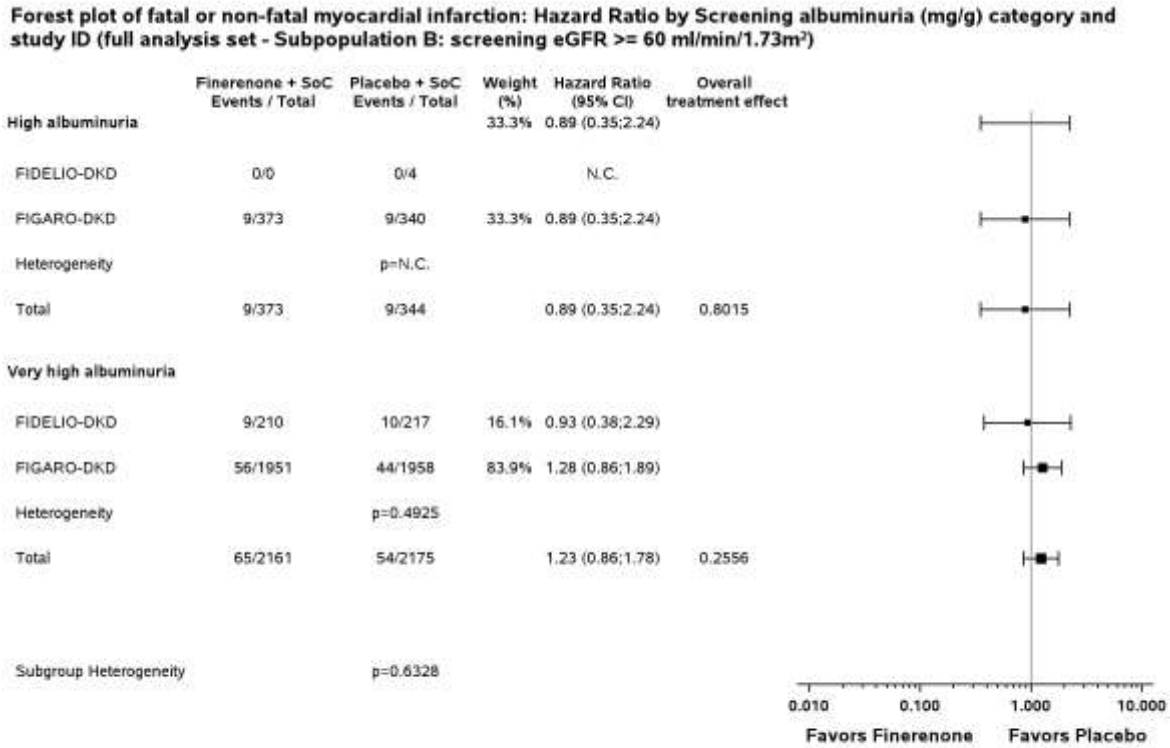
Figure 1.2.2 / 69: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

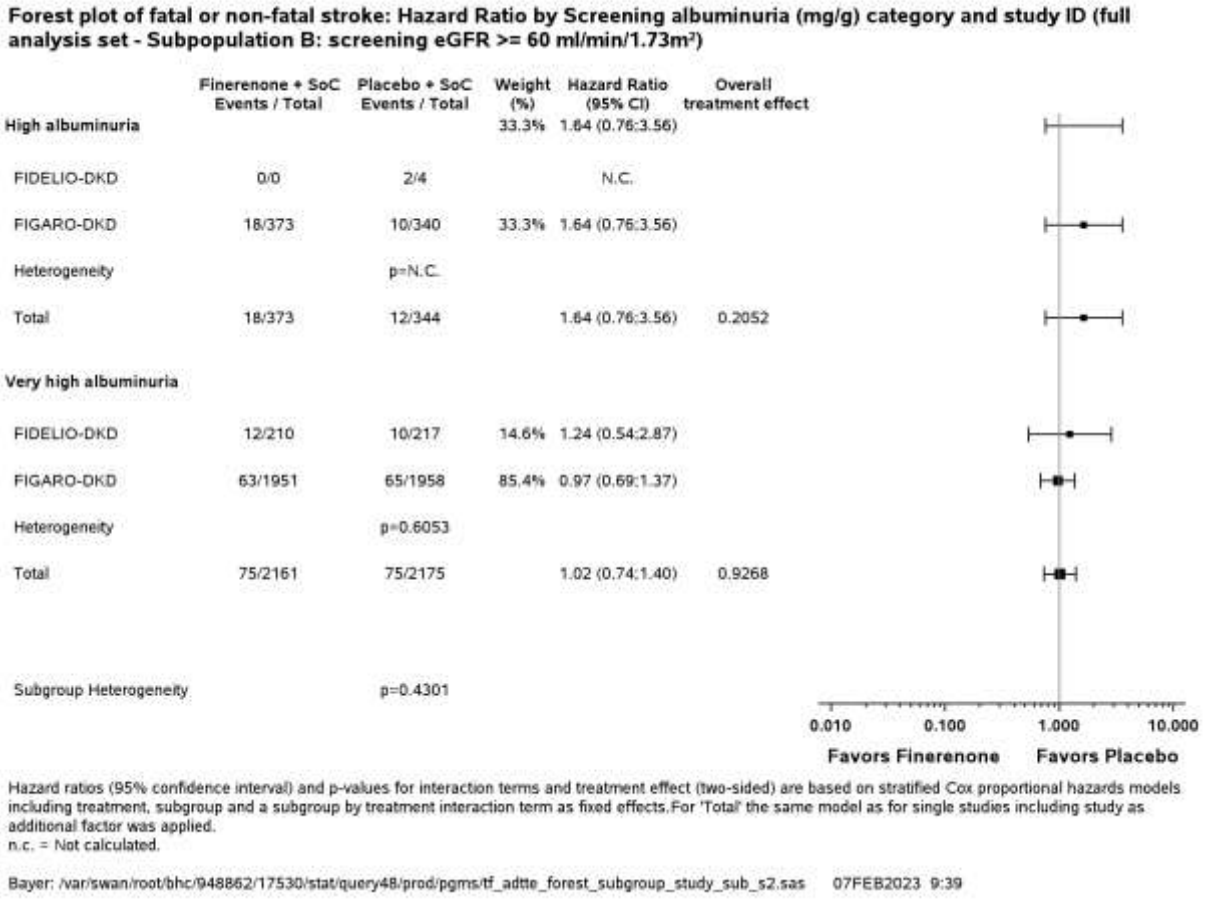
Figure 1.2.2 / 70: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 71: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



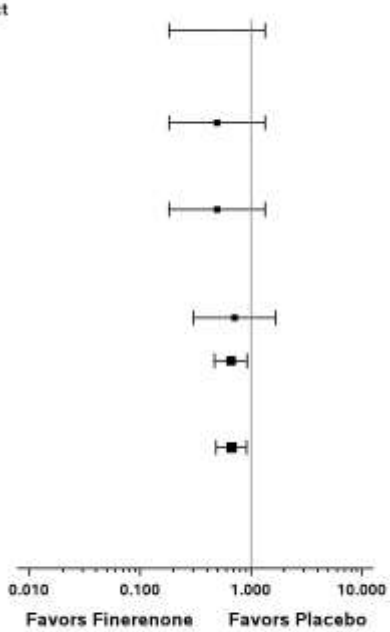
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 72: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

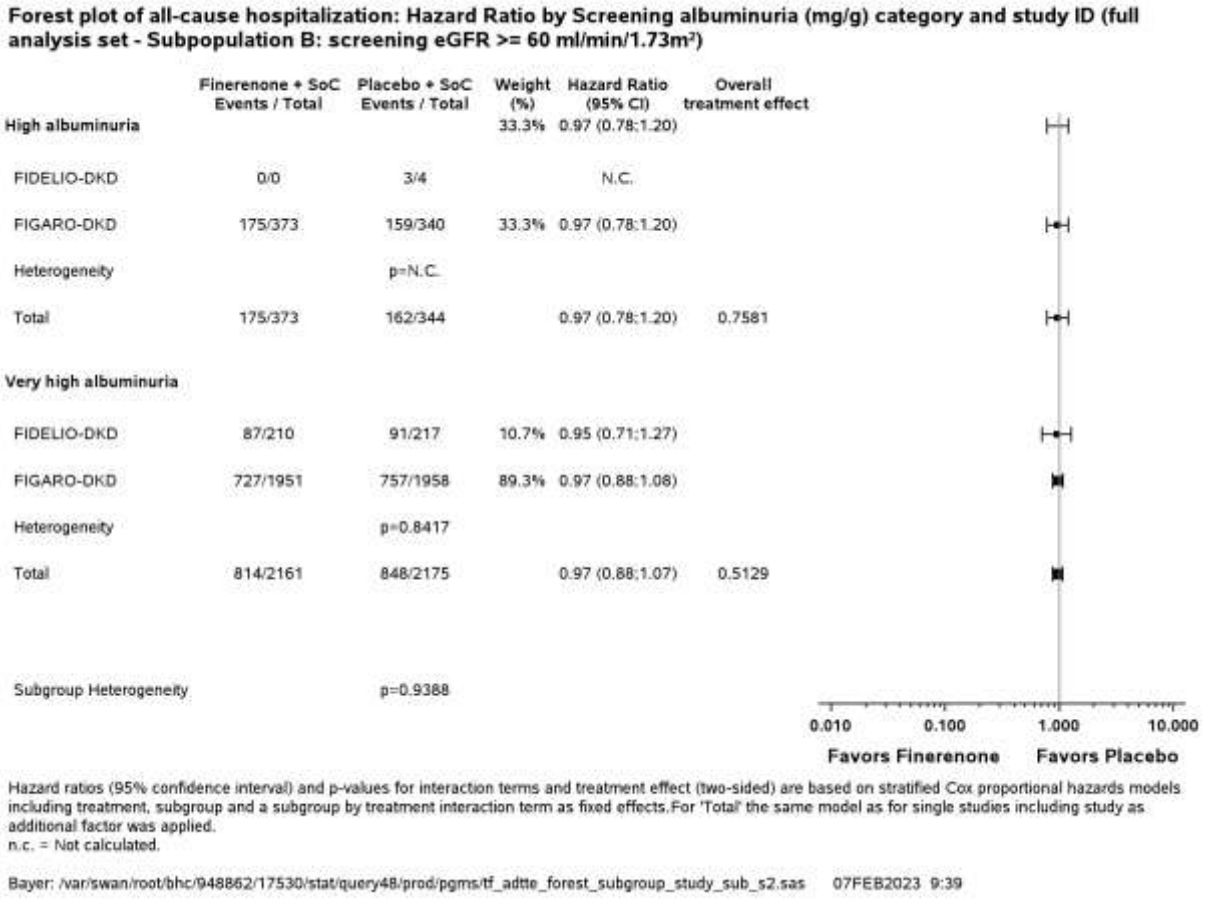
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria			33.3%	0.50 (0.18;1.34)	
FIDELIO-DKD	0/0	0/4	33.3%	N.C.	
FIGARO-DKD	6/373	11/340	33.3%	0.50 (0.18;1.34)	
Heterogeneity		p=N.C.			
Total	6/373	11/344		0.50 (0.18;1.34)	0.1587
Very high albuminuria					
FIDELIO-DKD	9/210	13/217	13.6%	0.71 (0.30;1.67)	
FIGARO-DKD	56/1951	86/1958	86.4%	0.66 (0.47;0.93)	
Heterogeneity		p=0.9147			
Total	65/2161	99/2175		0.67 (0.49;0.91)	0.0104
Subgroup Heterogeneity		p=0.5909			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

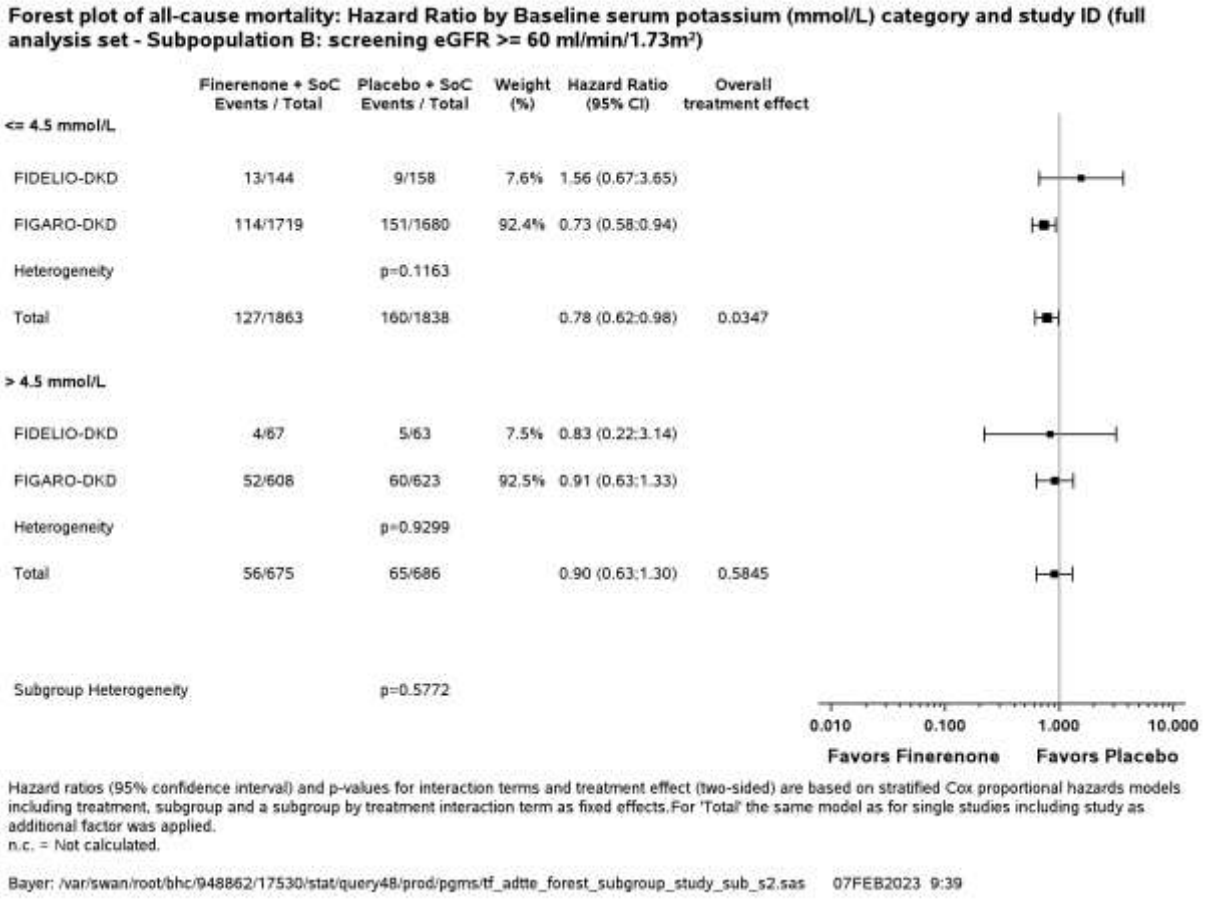
Figure 1.2.2 / 73: Forest plot of all-cause hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

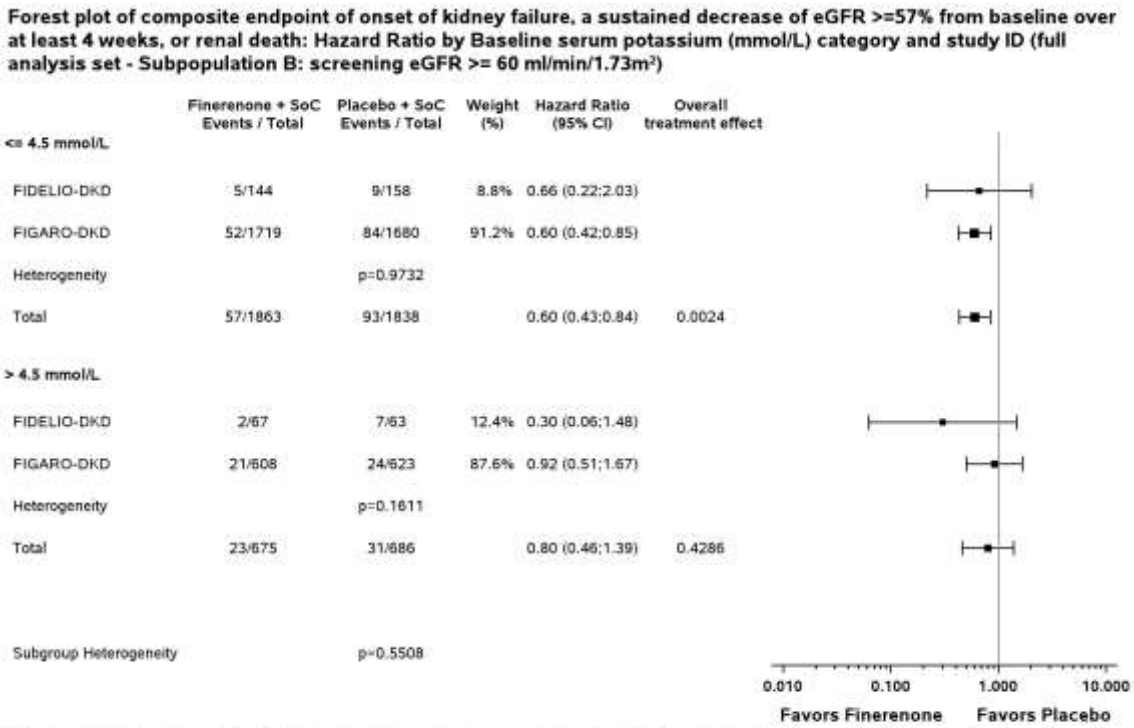
Figure 1.2.2 / 74: Forest plot of all-cause mortality: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

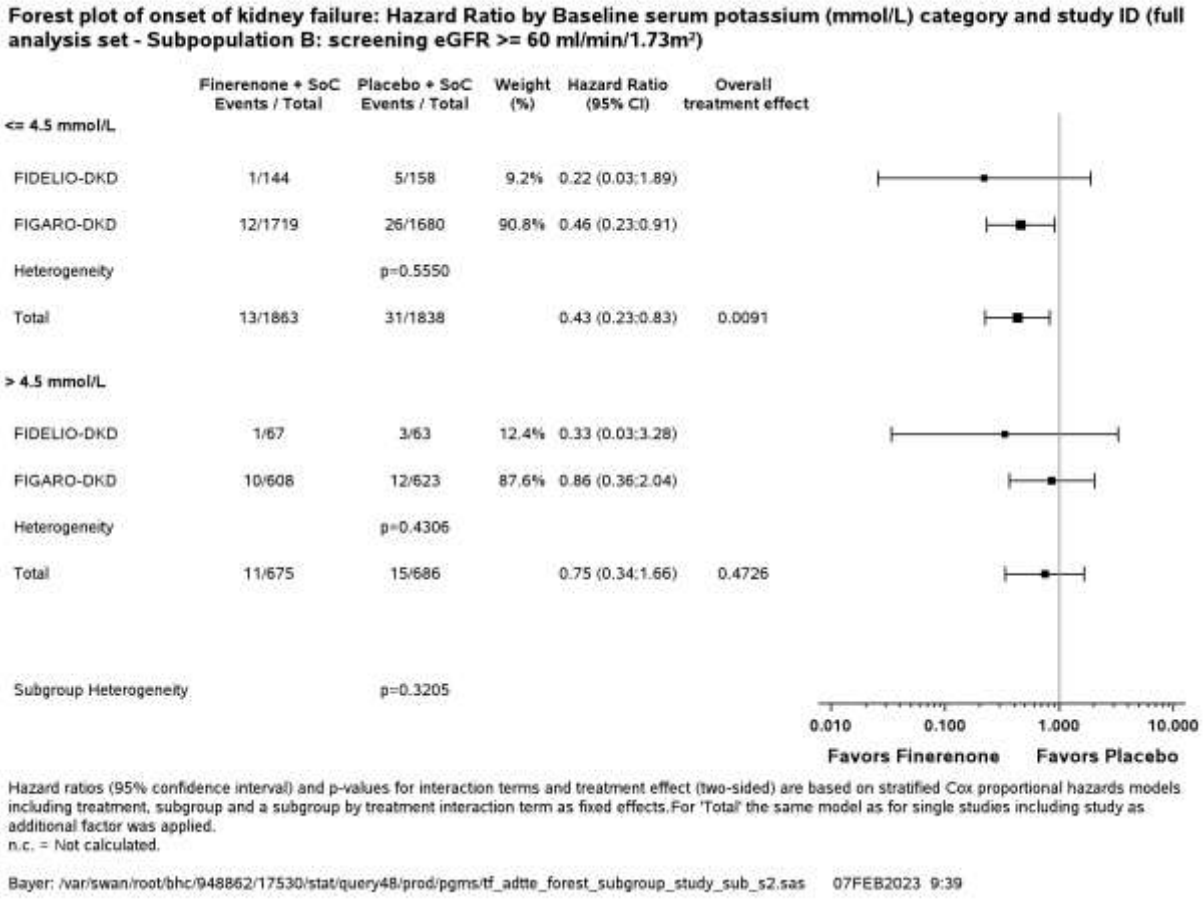
Figure 1.2.2 / 75: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 76: Forest plot of onset of kidney failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



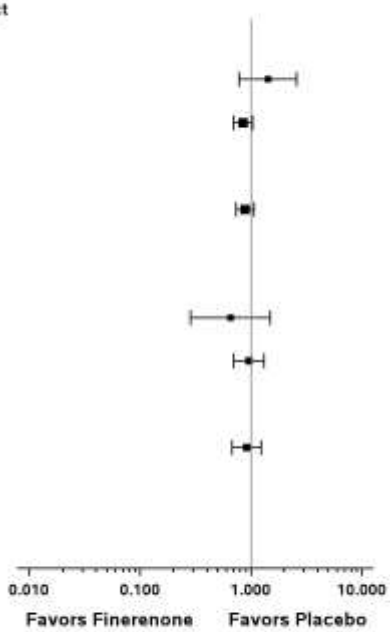
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 77: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

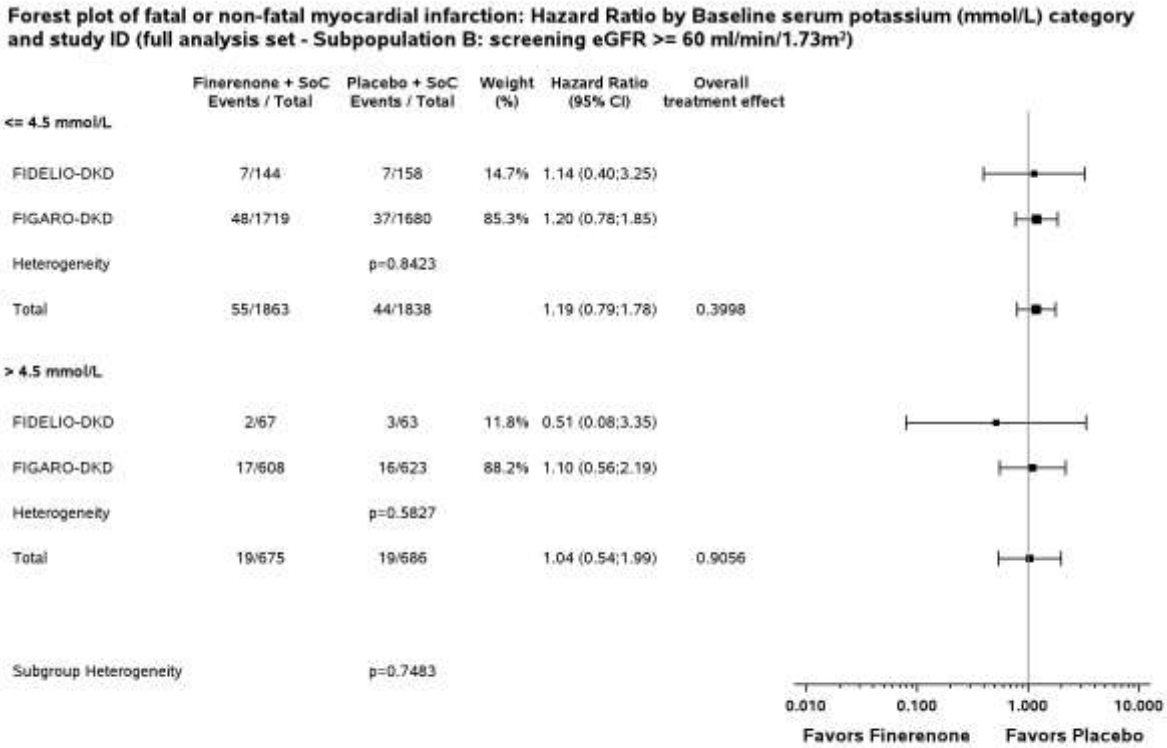
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	24/144	19/158	9.8%	1.42 (0.78;2.60)	
FIGARO-DKD	186/1719	212/1680	90.2%	0.85 (0.69;1.03)	
Heterogeneity		p=0.1254			
Total	210/1863	231/1838		0.89 (0.74;1.07)	0.2203
> 4.5 mmol/L					
FIDELIO-DKD	10/67	14/63	12.9%	0.65 (0.29;1.49)	
FIGARO-DKD	77/608	79/623	87.1%	0.96 (0.70;1.32)	
Heterogeneity		p=0.3792			
Total	87/675	93/686		0.91 (0.68;1.23)	0.5488
Subgroup Heterogeneity		p=0.8072			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

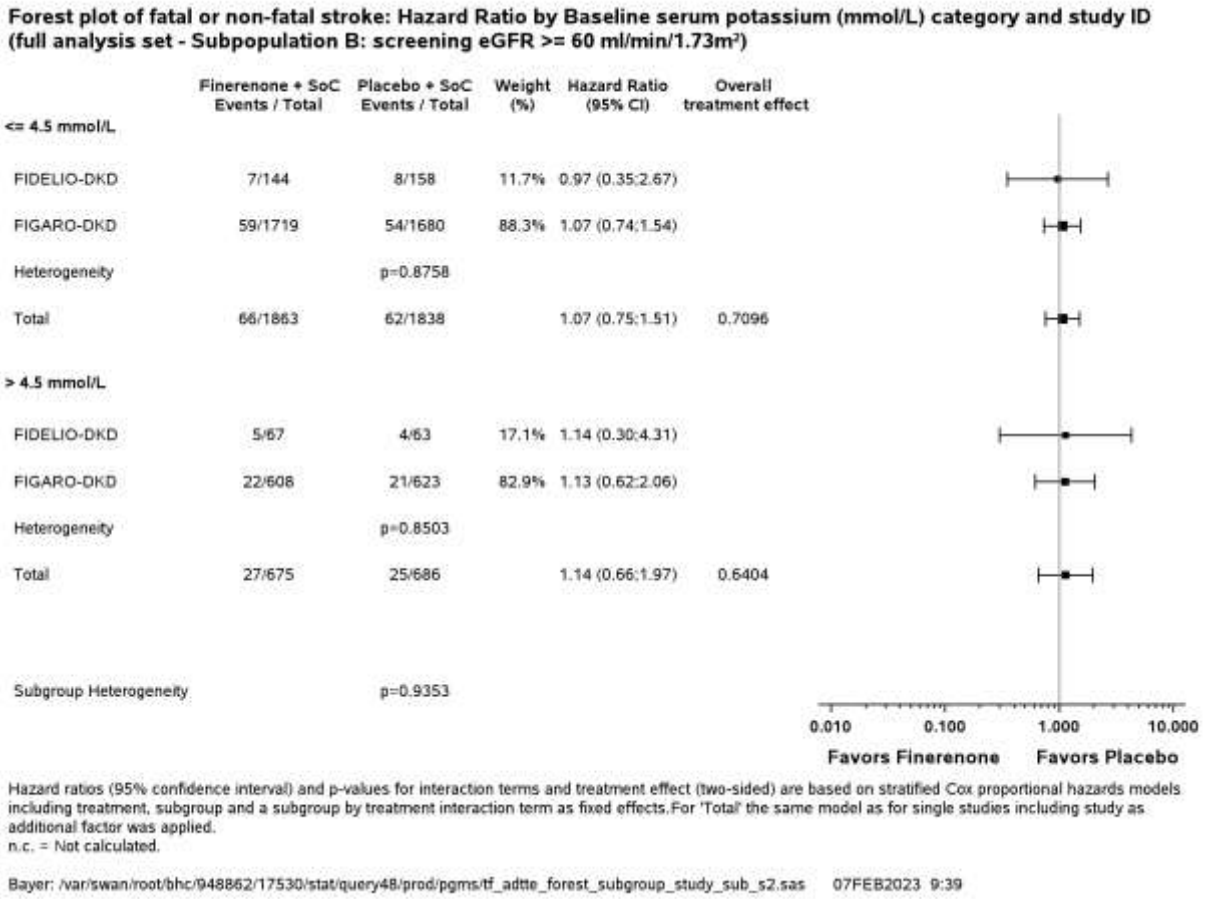
Figure 1.2.2 / 78: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

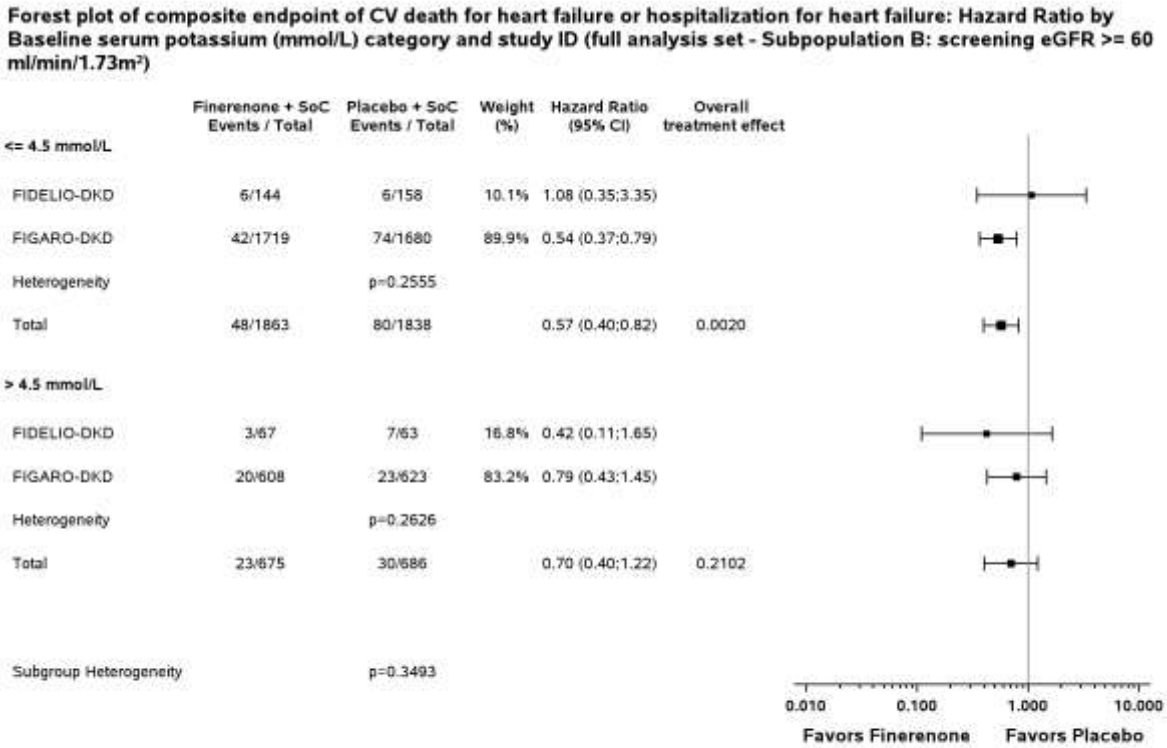
Figure 1.2.2 / 79: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 80: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure 1.2.2 / 81: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation B: screening eGFR >= 60 ml/min/1.73m²)

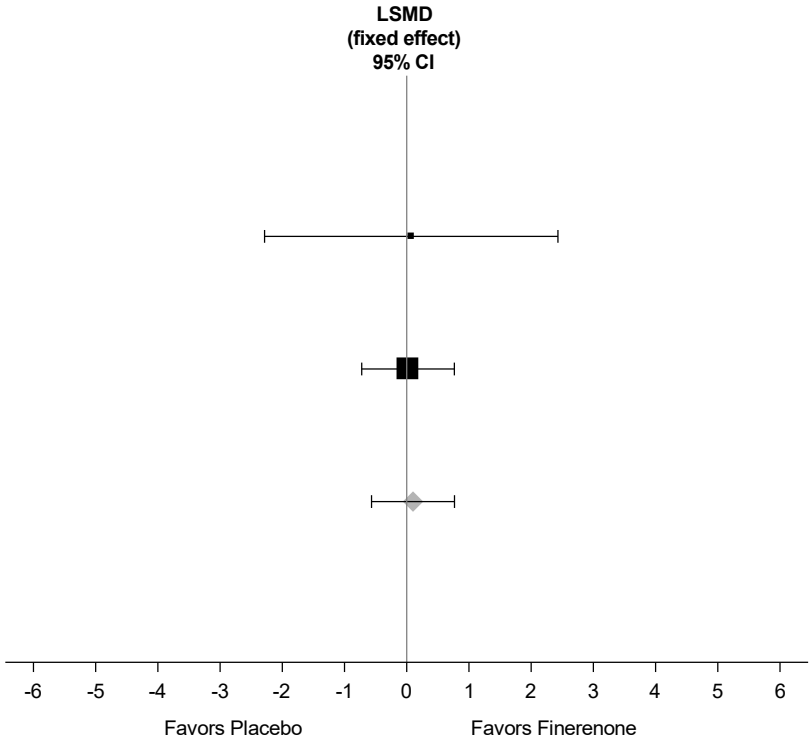
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	61/144	68/158	8.7%	0.98 (0.69;1.39)	
FIGARO-DKD	672/1719	673/1680	91.3%	0.98 (0.88;1.10)	
Heterogeneity		p=0.9581			
Total	733/1863	741/1838		0.98 (0.89;1.09)	0.7468
> 4.5 mmol/L					
FIDELIO-DKD	26/67	26/63	9.6%	0.81 (0.46;1.42)	
FIGARO-DKD	231/608	245/623	90.4%	0.93 (0.78;1.12)	
Heterogeneity		p=0.7446			
Total	257/675	271/686		0.92 (0.77;1.09)	0.3459
Subgroup Heterogeneity		p=0.4951			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s2.sas 07FEB2023 9:39

Figure B3.0.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

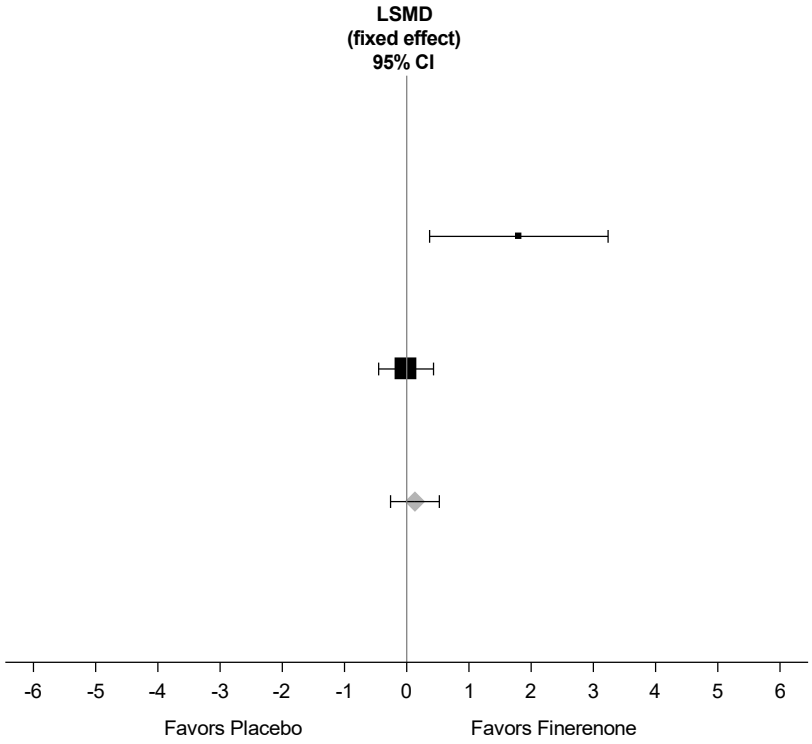
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	9.1	0.07 [-2.28,2.43]	
FIGARO-DKD	2151	2133	90.9	0.02 [-0.72,0.77]	
Total	2345	2338		0.10 [-0.57,0.77]	Z=0.30, p=0.7661
Heterogeneity:	Q=0.04 (df=1)	p=0.8322	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.0.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

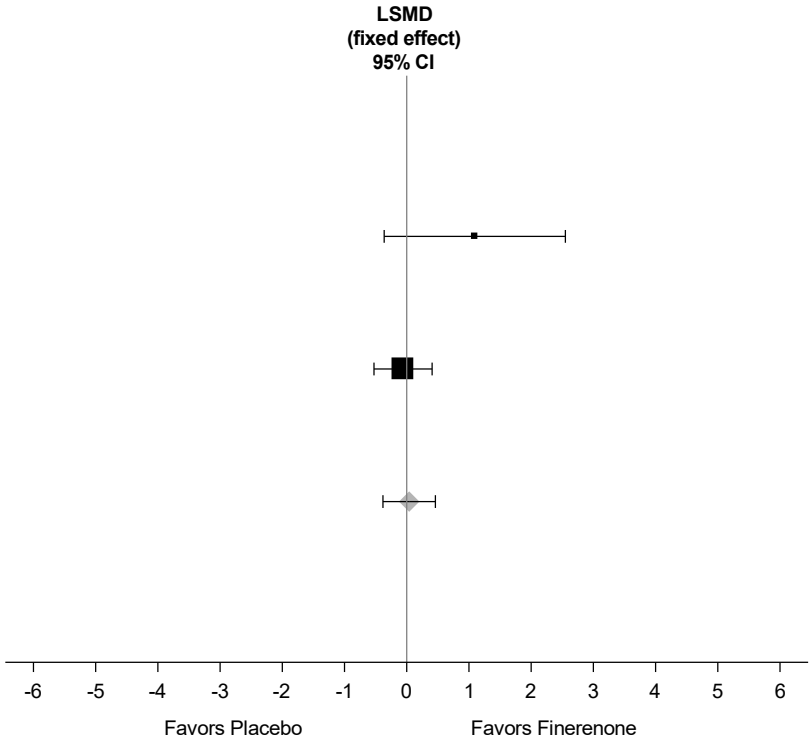
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	193	202	8.7	1.80 [0.37,3.24]	
FIGARO-DKD	2137	2122	91.3	-0.01 [-0.45,0.43]	
Total	2330	2324		0.13 [-0.26,0.52]	Z=0.66, p=0.5091
Heterogeneity:	Q=5.64 (df=1)	p=0.0175	I^2=82.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.0.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

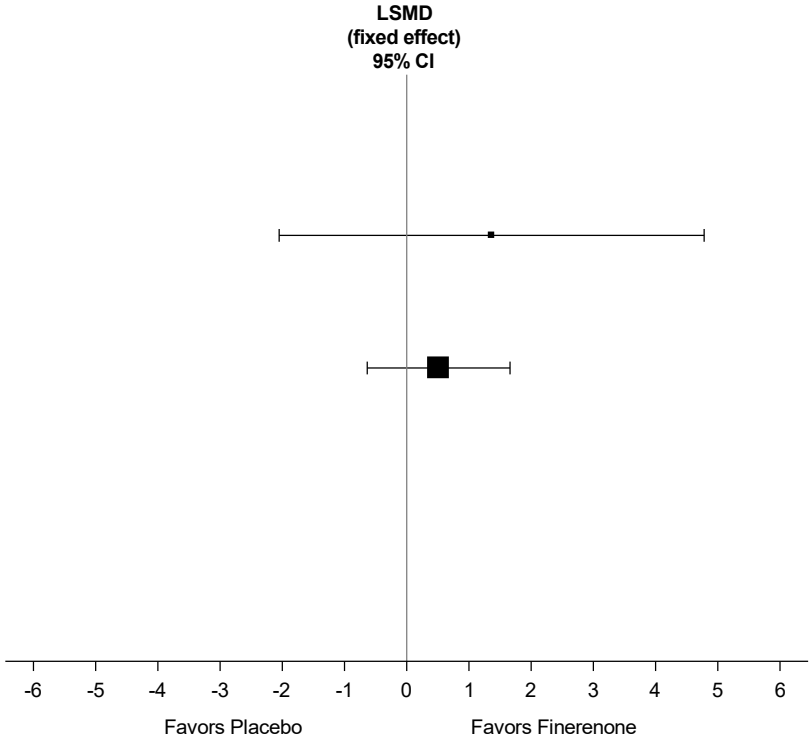
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	193	202	9.4	1.09 [-0.36,2.55]	
FIGARO-DKD	2137	2122	90.6	-0.06 [-0.53,0.41]	
Total	2330	2324		0.04 [-0.38,0.46]	Z=0.18, p=0.8554
Heterogeneity:	Q=2.20 (df=1)	p=0.1381	I^2=54.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.0.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

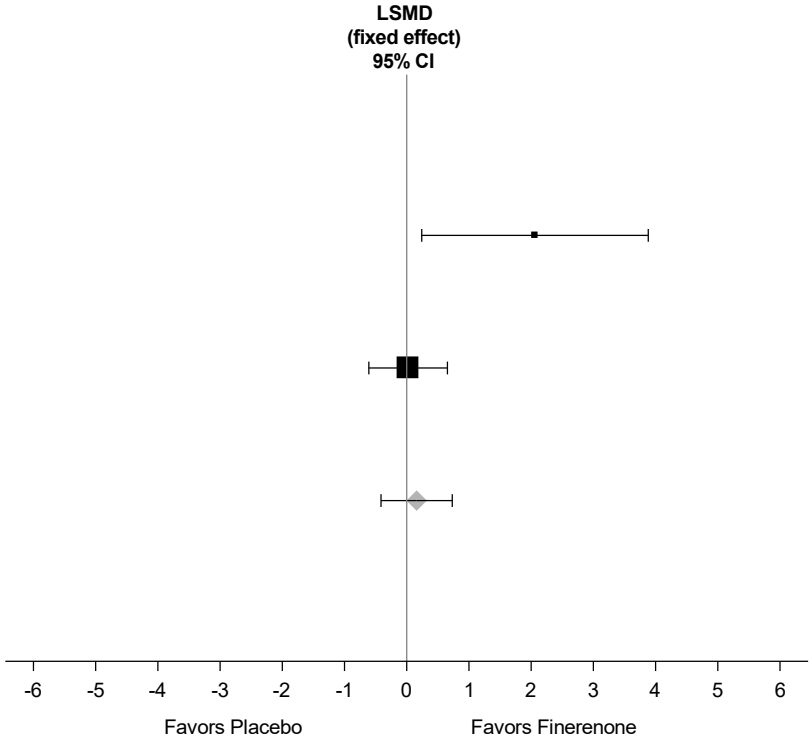
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	10.2	1.37 [-2.05,4.78]	
FIGARO-DKD	2148	2128	89.8	0.51 [-0.63,1.66]	
Total	2342	2333		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.0.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

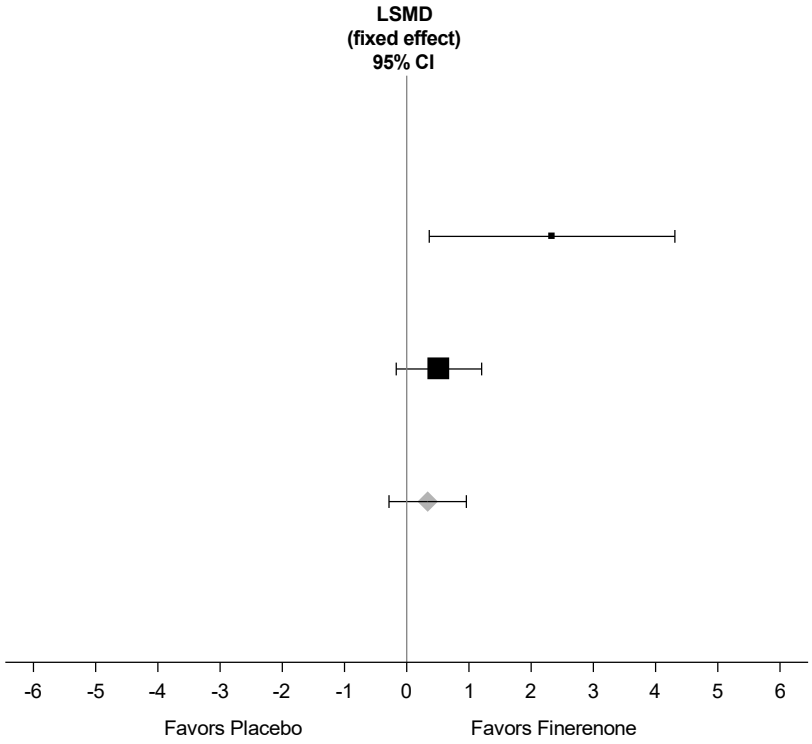
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	10.8	2.06 [0.24,3.88]	
FIGARO-DKD	2151	2133	89.2	0.02 [-0.61,0.65]	
Total	2345	2338		0.16 [-0.41,0.73]	Z=0.55, p=0.5858
Heterogeneity:	Q=4.41 (df=1)	p=0.0358	I^2=77.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.0.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

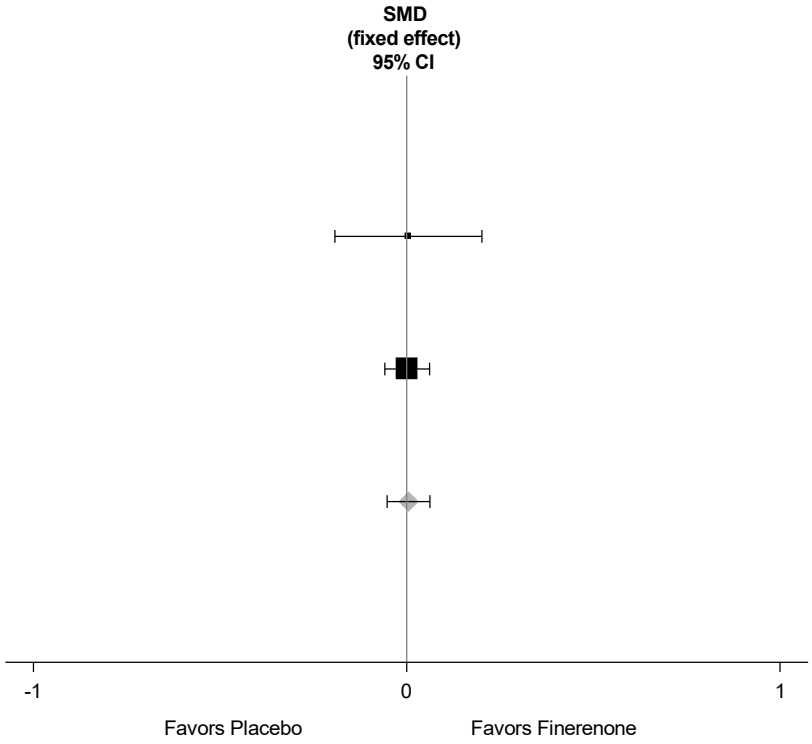
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	10.9	2.34 [0.36,4.31]	
FIGARO-DKD	2143	2128	89.1	0.52 [-0.17,1.20]	
Total	2337	2333		0.34 [-0.28,0.96]	Z=1.06, p=0.2881
Heterogeneity:	Q=4.24 (df=1)	p=0.0395	I^2=76.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

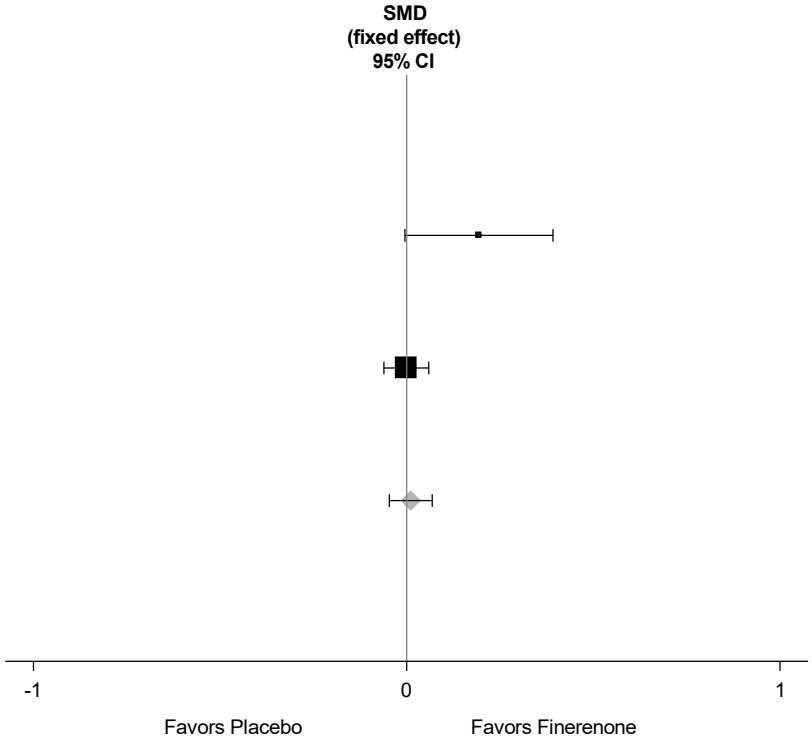
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	8.5	0.00 [-0.19,0.20]	
FIGARO-DKD	2151	2133	91.5	0.00 [-0.06,0.06]	
Total	2345	2338		0.00 [-0.05,0.06]	Z=0.16, p=0.8691
Heterogeneity:	Q=0.01 (df=1)	p=0.9079	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care, VAS=Visual Analogue Scale.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

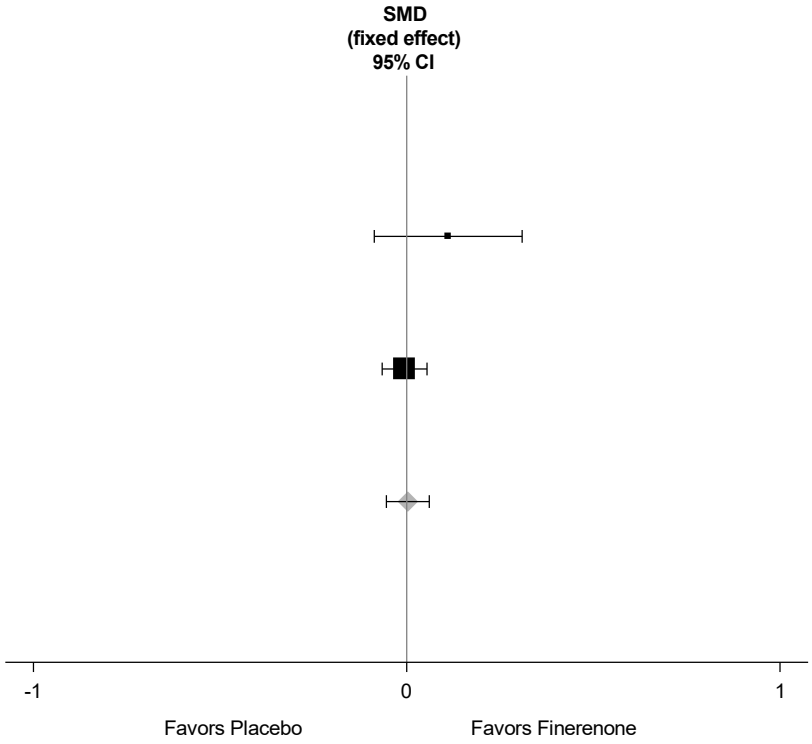
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	193	202	8.4	0.19 [0.00,0.39]	
FIGARO-DKD	2137	2122	91.6	0.00 [-0.06,0.06]	
Total	2330	2324		0.01 [-0.05,0.07]	Z=0.37, p=0.7118
Heterogeneity:	Q=3.43 (df=1)	p=0.0641	I^2=70.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

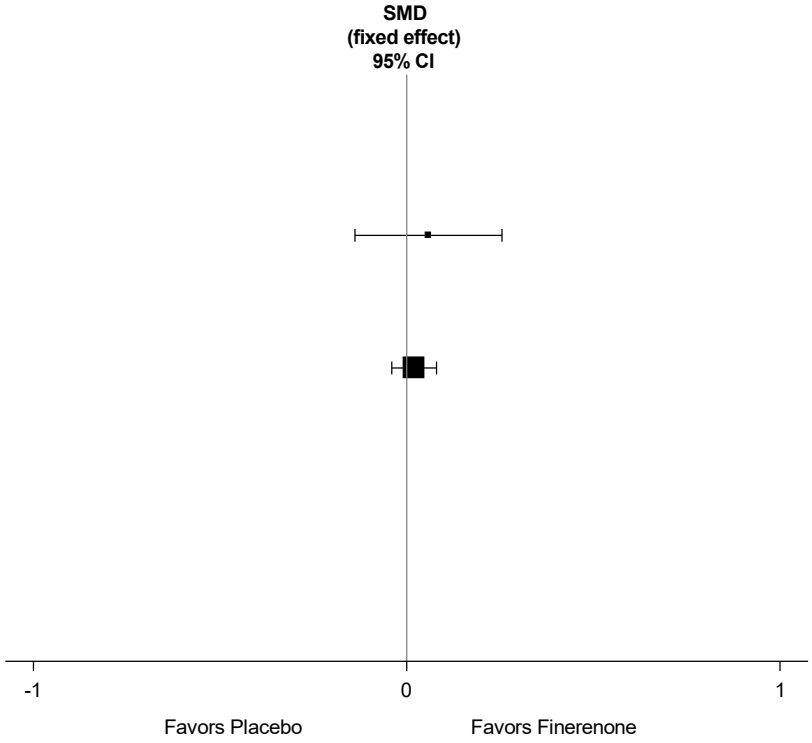
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	193	202	8.5	0.11 [-0.09,0.31]	
FIGARO-DKD	2137	2122	91.5	-0.01 [-0.07,0.05]	
Total	2330	2324		0.00 [-0.05,0.06]	Z=0.10, p=0.9197
Heterogeneity:	Q=1.23 (df=1)	p=0.2668	I^2=18.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

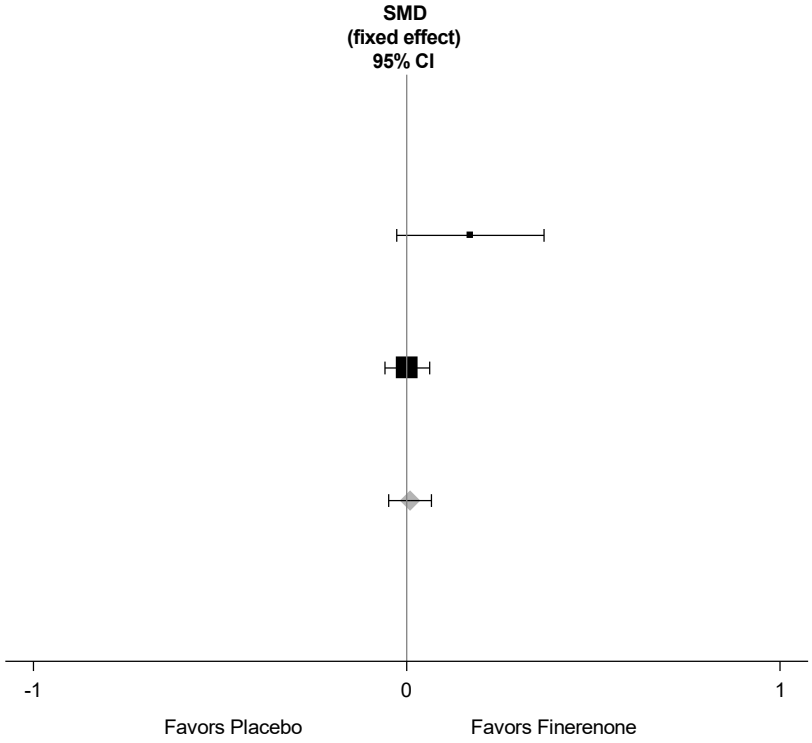
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	8.5	0.06 [-0.14,0.26]	
FIGARO-DKD	2148	2128	91.5	0.02 [-0.04,0.08]	
Total	2342	2333		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

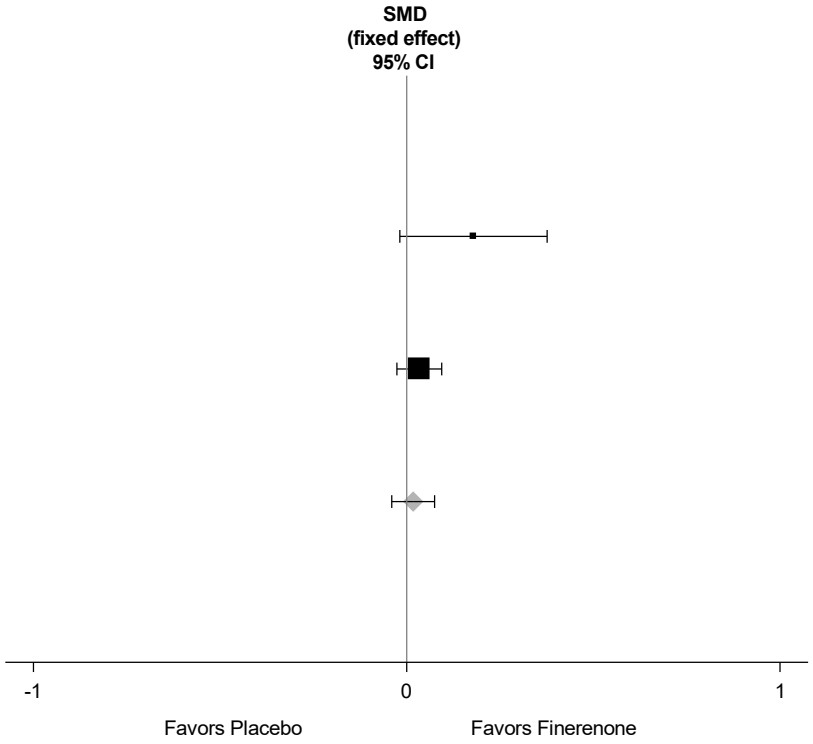
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	8.5	0.17 [-0.03,0.37]	
FIGARO-DKD	2151	2133	91.5	0.00 [-0.06,0.06]	
Total	2345	2338		0.01 [-0.05,0.07]	Z=0.31, p=0.7599
Heterogeneity:	Q=2.65 (df=1)	p=0.1035	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.1.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

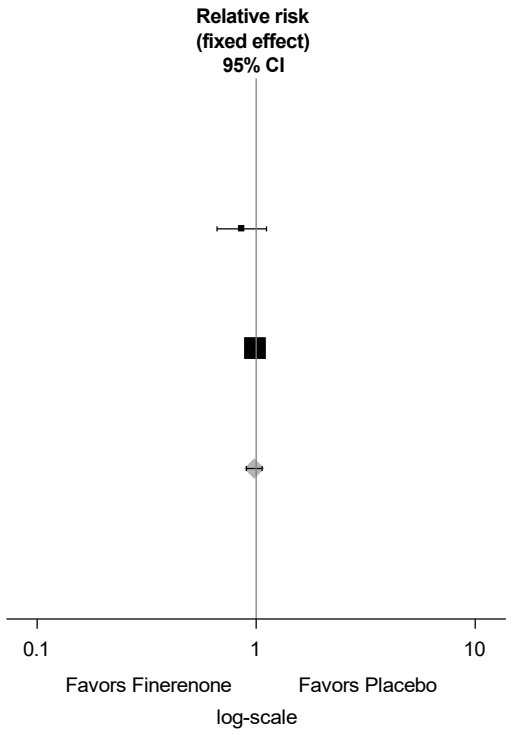
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194	205	8.5	0.18 [-0.02,0.38]	
FIGARO-DKD	2143	2128	91.5	0.03 [-0.03,0.09]	
Total	2337	2333		0.02 [-0.04,0.07]	Z=0.59, p=0.5558
Heterogeneity:	Q=2.88 (df=1)	p=0.0896	I^2=65.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

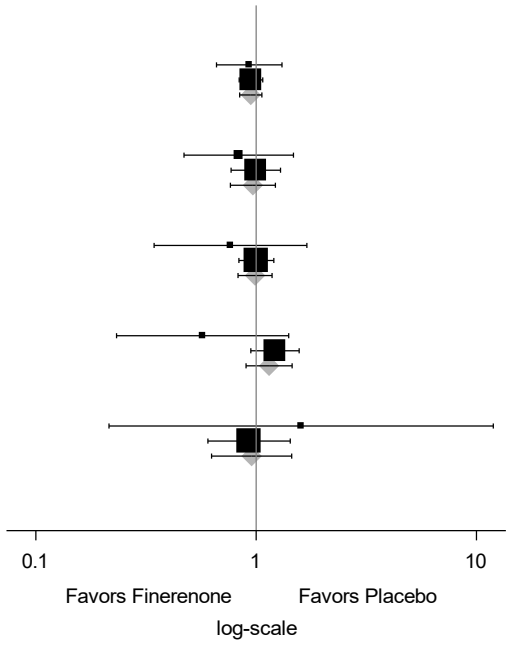
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 211	82 / 221	10.0	0.86 [0.66,1.11]	
FIGARO-DKD	707 / 2327	704 / 2304	90.0	0.99 [0.91,1.08]	
Total	774 / 2538	786 / 2525		0.98 [0.90,1.06]	Z=-0.48, p=0.6295
Heterogeneity:	Q=1.08 (df=1)	p=0.2992	I^2=7.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.1.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

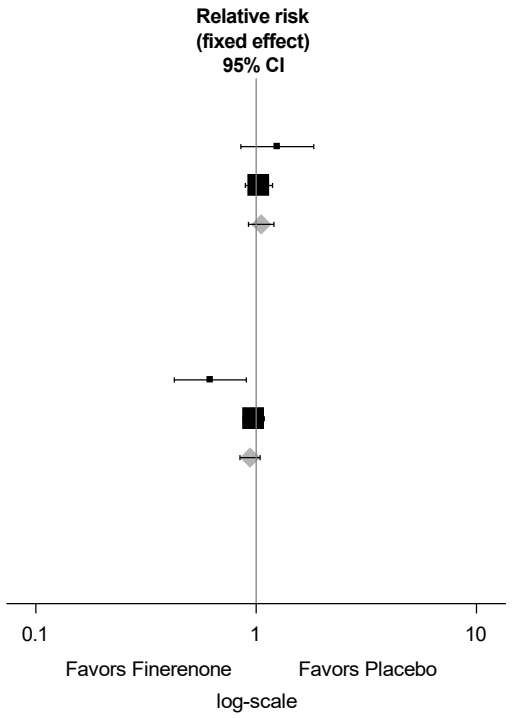
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	38 / 104	44 / 112	11.5	0.93 [0.66,1.31]	
FIGARO-DKD	339 / 1114	357 / 1111	88.5	0.95 [0.84,1.07]	
Total	377 / 1218	401 / 1223		0.95 [0.84,1.06]	Z=-0.96, p=0.3394
Heterogeneity:	Q=0.01 (df=1)	p=0.9225	I^2=0.0%		
North America					
FIDELIO-DKD	14 / 42	16 / 40	16.9	0.83 [0.47,1.48]	
FIGARO-DKD	84 / 292	80 / 277	83.1	1.00 [0.77,1.29]	
Total	98 / 334	96 / 317		0.97 [0.76,1.22]	Z=-0.29, p=0.7749
Heterogeneity:	Q=0.31 (df=1)	p=0.5774	I^2=0.0%		
Asia					
FIDELIO-DKD	8 / 39	11 / 41	5.0	0.76 [0.34,1.70]	
FIGARO-DKD	160 / 522	160 / 523	95.0	1.00 [0.83,1.20]	
Total	168 / 561	171 / 564		0.99 [0.83,1.18]	Z=-0.13, p=0.8964
Heterogeneity:	Q=0.42 (df=1)	p=0.5176	I^2=0.0%		
Latin America					
FIDELIO-DKD	5 / 21	10 / 24	7.3	0.57 [0.23,1.41]	
FIGARO-DKD	98 / 322	79 / 316	92.7	1.22 [0.95,1.57]	
Total	103 / 343	89 / 340		1.14 [0.90,1.46]	Z=1.10, p=0.2720
Heterogeneity:	Q=2.52 (df=1)	p=0.1125	I^2=60.3%		
Others					
FIDELIO-DKD	2 / 5	1 / 4	4.4	1.60 [0.21,11.92]	
FIGARO-DKD	26 / 77	28 / 77	95.6	0.93 [0.60,1.43]	
Total	28 / 82	29 / 81		0.95 [0.63,1.45]	Z=-0.22, p=0.8242
Heterogeneity:	Q=0.27 (df=1)	p=0.6035	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.01 (df=4)	p=0.7339	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.1.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

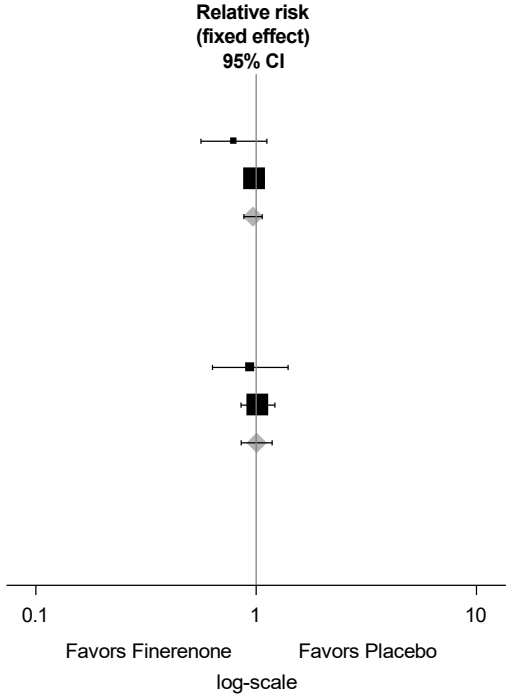
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	37 / 88	30 / 89	12.2	1.25 [0.85,1.83]	
FIGARO-DKD	264 / 811	254 / 803	87.8	1.03 [0.89,1.19]	
Total	301 / 899	284 / 892		1.05 [0.92,1.20]	Z=0.77, p=0.4393
Heterogeneity:	Q=0.86 (df=1)	p=0.3537	I^2=0.0%		
Absent					
FIDELIO-DKD	30 / 123	52 / 132	7.9	0.62 [0.42,0.90]	
FIGARO-DKD	443 / 1516	450 / 1501	92.1	0.97 [0.87,1.09]	
Total	473 / 1639	502 / 1633		0.94 [0.84,1.04]	Z=-1.19, p=0.2335
Heterogeneity:	Q=5.15 (df=1)	p=0.0233	I^2=80.6%		
Subgroup Heterogeneity:	Q=1.81 (df=1)	p=0.1784	I^2=44.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.1.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

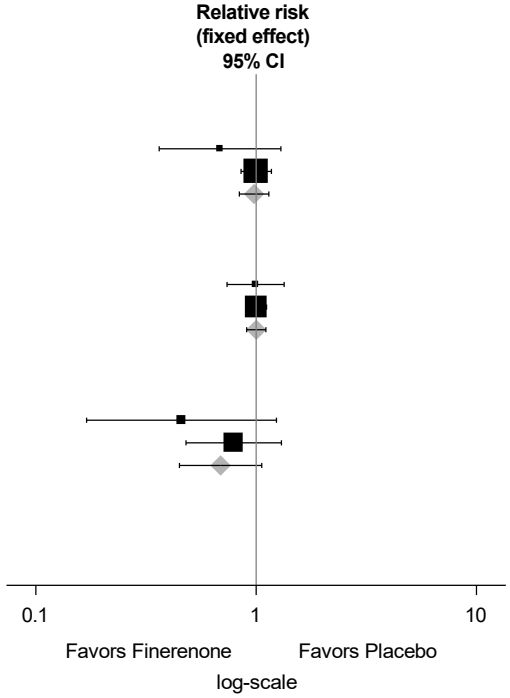
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	39 / 144	54 / 158	7.8	0.79 [0.56,1.12]	
FIGARO-DKD	532 / 1719	528 / 1680	92.2	0.98 [0.89,1.09]	
Total	571 / 1863	582 / 1838		0.97 [0.88,1.07]	Z=-0.67, p=0.5046
Heterogeneity:	Q=1.41 (df=1)	p=0.2351	I^2=29.1%		
> 4.5					
FIDELIO-DKD	28 / 67	28 / 63	16.7	0.94 [0.63,1.40]	
FIGARO-DKD	175 / 608	176 / 623	83.3	1.02 [0.85,1.22]	
Total	203 / 675	204 / 686		1.01 [0.86,1.18]	Z=0.06, p=0.9488
Heterogeneity:	Q=0.13 (df=1)	p=0.7164	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6924	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.1.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

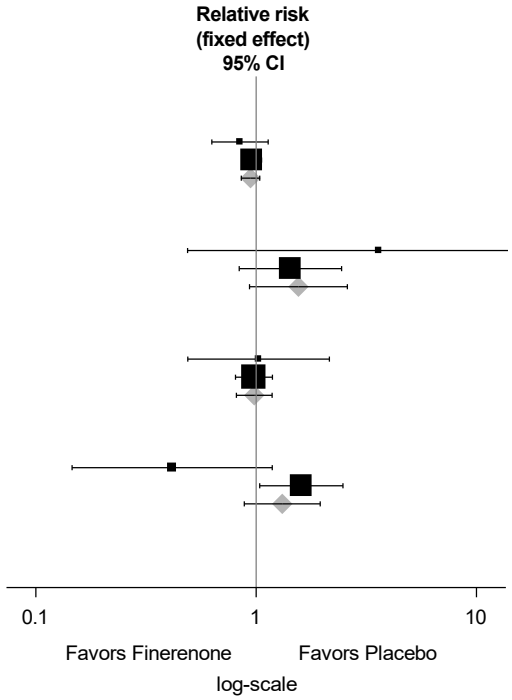
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 64	16 / 54	5.9	0.69 [0.36,1.29]	
FIGARO-DKD	211 / 693	213 / 700	94.1	1.00 [0.85,1.17]	
Total	224 / 757	229 / 754		0.98 [0.84,1.14]	Z=-0.28, p=0.7817
Heterogeneity:	Q=1.28 (df=1)	p=0.2582	I^2=21.8%		
130 - < 160					
FIDELIO-DKD	51 / 138	58 / 156	11.3	0.99 [0.74,1.34]	
FIGARO-DKD	477 / 1561	465 / 1525	88.7	1.00 [0.90,1.11]	
Total	528 / 1699	523 / 1681		1.00 [0.91,1.11]	Z=0.02, p=0.9809
Heterogeneity:	Q=0.00 (df=1)	p=0.9597	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 9	8 / 11	20.2	0.46 [0.17,1.24]	
FIGARO-DKD	19 / 73	26 / 79	79.8	0.79 [0.48,1.30]	
Total	22 / 82	34 / 90		0.69 [0.45,1.06]	Z=-1.69, p=0.0902
Heterogeneity:	Q=0.94 (df=1)	p=0.3320	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.74 (df=2)	p=0.2538	I^2=27.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.1.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

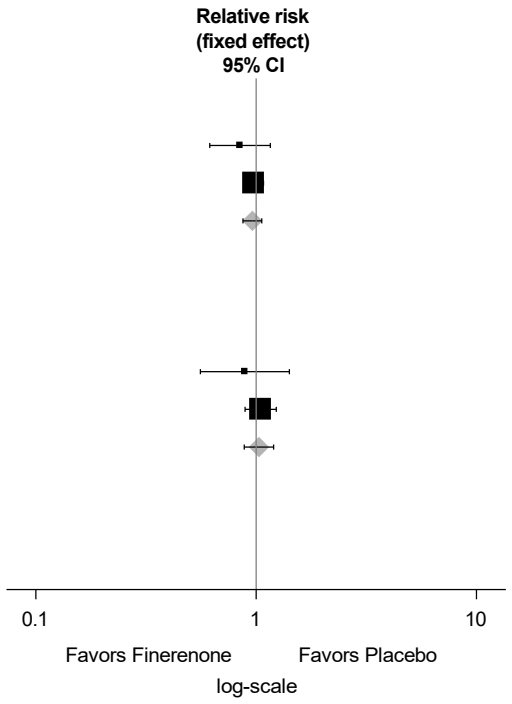
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	49 / 140	63 / 152	10.7	0.84 [0.63,1.13]	
FIGARO-DKD	504 / 1659	513 / 1613	89.3	0.96 [0.86,1.06]	
Total	553 / 1799	576 / 1765		0.94 [0.86,1.04]	Z=-1.20, p=0.2284
Heterogeneity:	Q=0.60 (df=1)	p=0.4381	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	1 / 9	6.7	3.60 [0.49,26.54]	
FIGARO-DKD	23 / 70	17 / 74	93.3	1.43 [0.84,2.44]	
Total	27 / 80	18 / 83		1.56 [0.93,2.59]	Z=1.69, p=0.0903
Heterogeneity:	Q=0.77 (df=1)	p=0.3795	I^2=0.0%		
Asian					
FIDELIO-DKD	10 / 39	11 / 44	6.4	1.03 [0.49,2.15]	
FIGARO-DKD	139 / 464	149 / 486	93.6	0.98 [0.81,1.19]	
Total	149 / 503	160 / 530		0.98 [0.81,1.18]	Z=-0.21, p=0.8332
Heterogeneity:	Q=0.02 (df=1)	p=0.9011	I^2=0.0%		
Others					
FIDELIO-DKD	4 / 22	7 / 16	14.7	0.42 [0.15,1.18]	
FIGARO-DKD	41 / 134	25 / 131	85.3	1.60 [1.04,2.48]	
Total	45 / 156	32 / 147		1.31 [0.88,1.95]	Z=1.35, p=0.1780
Heterogeneity:	Q=5.45 (df=1)	p=0.0195	I^2=81.7%		
Subgroup Heterogeneity:	Q=5.85 (df=3)	p=0.1191	I^2=48.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.1.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

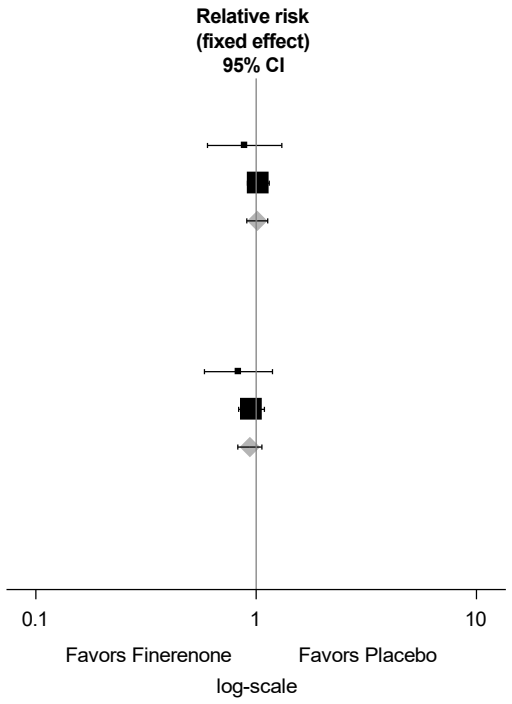
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	47 / 153	56 / 154	9.6	0.84 [0.62,1.16]	
FIGARO-DKD	490 / 1611	512 / 1640	90.4	0.97 [0.88,1.08]	
Total	537 / 1764	568 / 1794		0.96 [0.87,1.06]	Z=-0.80, p=0.4254
Heterogeneity:	Q=0.70 (df=1)	p=0.4013	I^2=0.0%		
Female					
FIDELIO-DKD	20 / 58	26 / 67	10.9	0.89 [0.56,1.41]	
FIGARO-DKD	217 / 716	192 / 664	89.1	1.05 [0.89,1.23]	
Total	237 / 774	218 / 731		1.03 [0.88,1.20]	Z=0.37, p=0.7139
Heterogeneity:	Q=0.43 (df=1)	p=0.5113	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=1)	p=0.4606	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.1.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

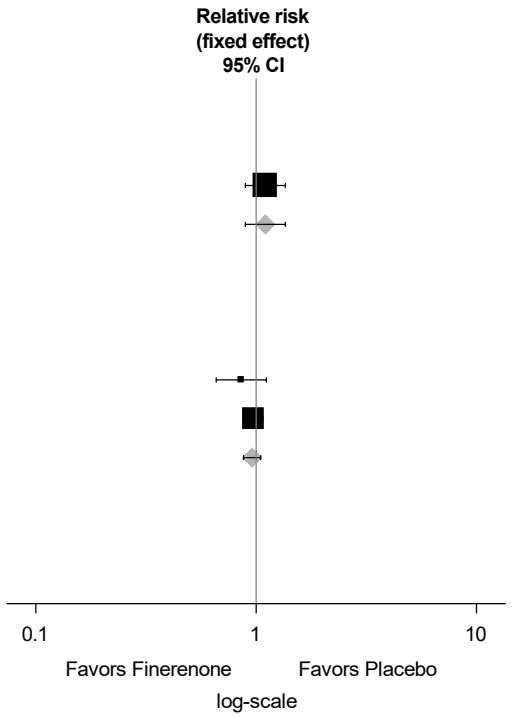
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	32 / 99	35 / 96	7.9	0.89 [0.60,1.31]	
FIGARO-DKD	422 / 1416	414 / 1421	92.1	1.02 [0.91,1.15]	
Total	454 / 1515	449 / 1517		1.01 [0.91,1.13]	Z=0.20, p=0.8390
Heterogeneity:	Q=0.48 (df=1)	p=0.4887	I^2=0.0%		
>= 65					
FIDELIO-DKD	35 / 112	47 / 125	12.6	0.83 [0.58,1.19]	
FIGARO-DKD	285 / 911	290 / 883	87.4	0.95 [0.83,1.09]	
Total	320 / 1023	337 / 1008		0.94 [0.83,1.06]	Z=-1.03, p=0.3042
Heterogeneity:	Q=0.49 (df=1)	p=0.4821	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3633	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.1.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

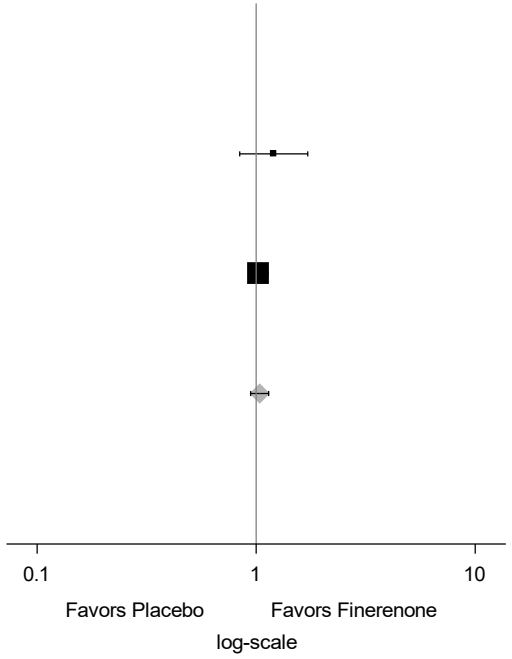
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	127 / 363	109 / 343	100.0	1.10 [0.89,1.36]	
Total	127 / 363	109 / 343		1.10 [0.89,1.36]	Z=0.90, p=0.3673
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	67 / 211	82 / 221	11.8	0.86 [0.66,1.11]	
FIGARO-DKD	580 / 1964	595 / 1961	88.2	0.97 [0.88,1.07]	
Total	647 / 2175	677 / 2182		0.96 [0.88,1.05]	Z=-0.92, p=0.3556
Heterogeneity:	Q=0.82 (df=1)	p=0.3658	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.42 (df=1)	p=0.2328	I^2=29.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

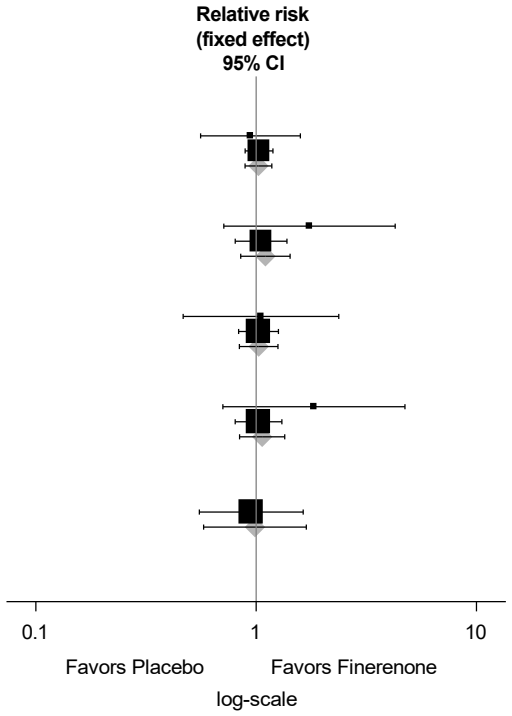
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	50 / 211	44 / 221	7.0	1.20 [0.84,1.72]	
FIGARO-DKD	607 / 2327	584 / 2304	93.0	1.03 [0.93,1.13]	
Total	657 / 2538	628 / 2525		1.04 [0.94,1.14]	Z=0.76, p=0.4447
Heterogeneity:	Q=0.70 (df=1)	p=0.4021	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

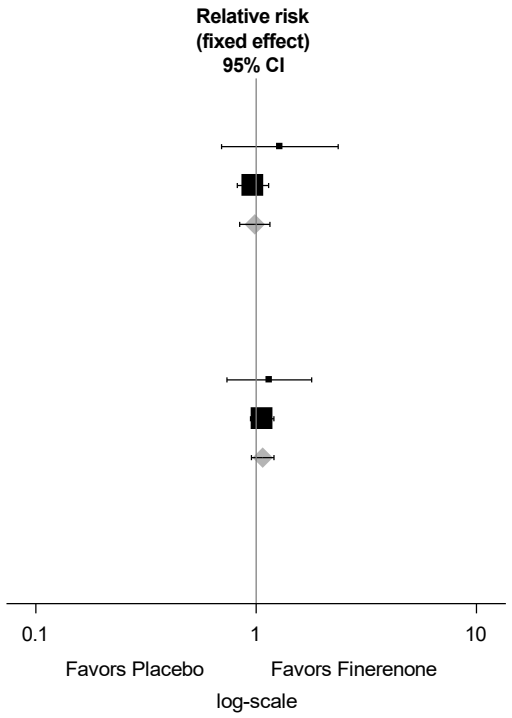
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 104	24 / 112	7.2	0.94 [0.56,1.59]	
FIGARO-DKD	279 / 1114	270 / 1111	92.8	1.03 [0.89,1.19]	
Total	300 / 1218	294 / 1223		1.02 [0.89,1.18]	Z=0.33, p=0.7406
Heterogeneity:	Q=0.11 (df=1)	p=0.7458	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	6 / 40	8.3	1.75 [0.71,4.28]	
FIGARO-DKD	81 / 292	73 / 277	91.7	1.05 [0.80,1.38]	
Total	92 / 334	79 / 317		1.10 [0.85,1.43]	Z=0.73, p=0.4636
Heterogeneity:	Q=1.13 (df=1)	p=0.2888	I^2=11.1%		
Asia					
FIDELIO-DKD	9 / 39	9 / 41	6.1	1.05 [0.47,2.37]	
FIGARO-DKD	134 / 522	131 / 523	93.9	1.02 [0.83,1.26]	
Total	143 / 561	140 / 564		1.03 [0.84,1.26]	Z=0.25, p=0.7995
Heterogeneity:	Q=0.00 (df=1)	p=0.9526	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	5 / 24	6.2	1.83 [0.71,4.74]	
FIGARO-DKD	94 / 322	90 / 316	93.8	1.02 [0.80,1.31]	
Total	102 / 343	95 / 340		1.06 [0.84,1.35]	Z=0.52, p=0.6039
Heterogeneity:	Q=1.33 (df=1)	p=0.2480	I^2=25.1%		
Others					
FIDELIO-DKD	1 / 5	0 / 4	0.0	383E9 [383E9,383E9]	
FIGARO-DKD	19 / 77	20 / 77	100.0	0.95 [0.55,1.63]	
Total	20 / 82	20 / 81		0.99 [0.58,1.69]	Z=-0.05, p=0.9630
Heterogeneity:	Q=0.02 (df=1)	p=0.8892	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=4)	p=0.9880	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

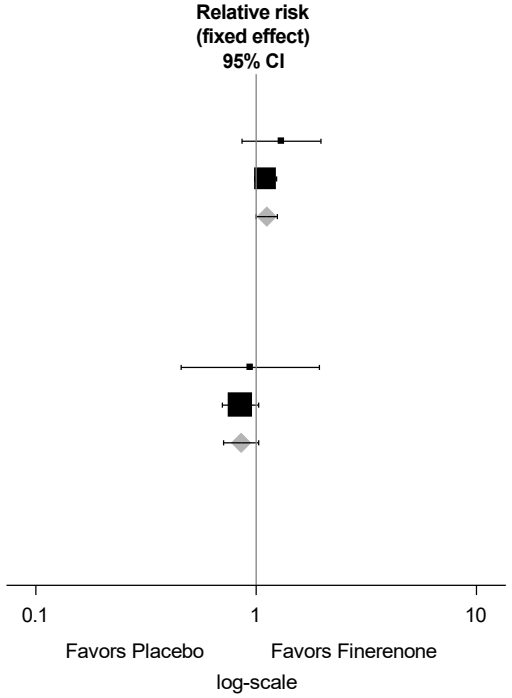
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 88	15 / 89	6.7	1.28 [0.70,2.36]	
FIGARO-DKD	209 / 811	214 / 803	93.3	0.97 [0.82,1.14]	
Total	228 / 899	229 / 892		0.99 [0.84,1.15]	Z=-0.18, p=0.8583
Heterogeneity:	Q=0.76 (df=1)	p=0.3824	I^2=0.0%		
Absent					
FIDELIO-DKD	31 / 123	29 / 132	7.1	1.15 [0.74,1.79]	
FIGARO-DKD	398 / 1516	370 / 1501	92.9	1.07 [0.94,1.20]	
Total	429 / 1639	399 / 1633		1.07 [0.95,1.20]	Z=1.14, p=0.2561
Heterogeneity:	Q=0.10 (df=1)	p=0.7512	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.68 (df=1)	p=0.4111	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.2.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

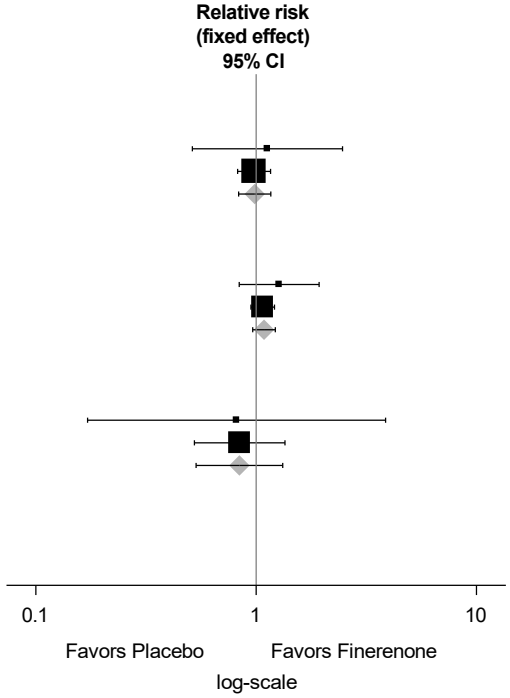
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	38 / 144	32 / 158	7.2	1.30 [0.86,1.97]	
FIGARO-DKD	462 / 1719	409 / 1680	92.8	1.10 [0.98,1.24]	
Total	500 / 1863	441 / 1838		1.12 [1.00,1.25]	Z=1.96, p=0.0495
Heterogeneity:	Q=0.58 (df=1)	p=0.4481	I^2=0.0%		
> 4.5					
FIDELIO-DKD	12 / 67	12 / 63	6.4	0.94 [0.46,1.94]	
FIGARO-DKD	145 / 608	175 / 623	93.6	0.85 [0.70,1.03]	
Total	157 / 675	187 / 686		0.85 [0.71,1.03]	Z=-1.68, p=0.0931
Heterogeneity:	Q=0.07 (df=1)	p=0.7887	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.02 (df=1)	p=0.0142	I^2=83.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.2.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

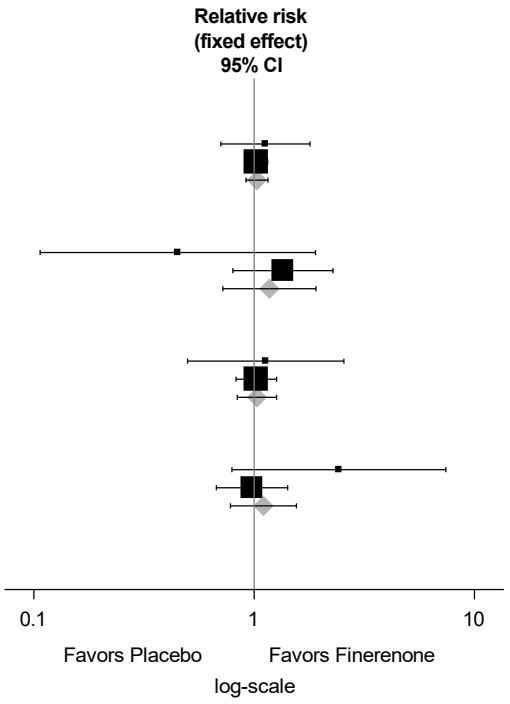
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 64	9 / 54	4.6	1.12 [0.51,2.47]	
FIGARO-DKD	186 / 693	192 / 700	95.4	0.98 [0.82,1.16]	
Total	198 / 757	201 / 754		0.98 [0.83,1.17]	Z=-0.18, p=0.8590
Heterogeneity:	Q=0.12 (df=1)	p=0.7336	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	36 / 138	32 / 156	8.0	1.27 [0.84,1.93]	
FIGARO-DKD	400 / 1561	365 / 1525	92.0	1.07 [0.95,1.21]	
Total	436 / 1699	397 / 1681		1.09 [0.96,1.22]	Z=1.36, p=0.1733
Heterogeneity:	Q=0.60 (df=1)	p=0.4382	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 9	3 / 11	8.5	0.81 [0.17,3.87]	
FIGARO-DKD	21 / 73	27 / 79	91.5	0.84 [0.52,1.35]	
Total	23 / 82	30 / 90		0.84 [0.53,1.32]	Z=-0.76, p=0.4485
Heterogeneity:	Q=0.00 (df=1)	p=0.9688	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=2)	p=0.4129	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.2.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

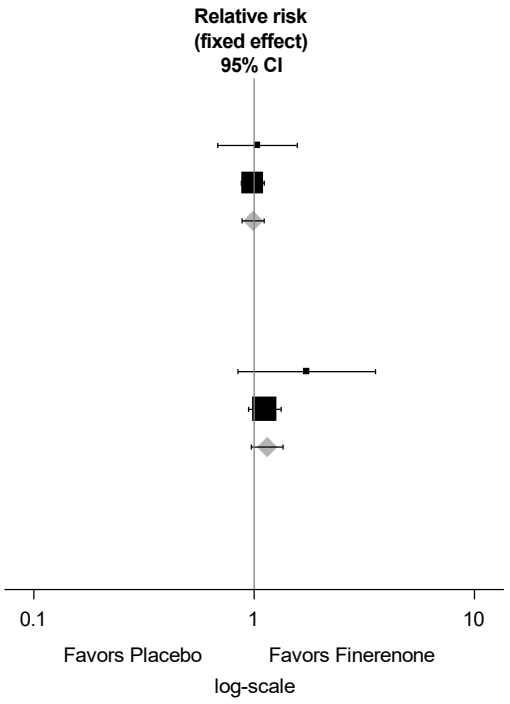
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	29 / 140	28 / 152	6.1	1.12 [0.71,1.79]	
FIGARO-DKD	421 / 1659	400 / 1613	93.9	1.02 [0.91,1.15]	
Total	450 / 1799	428 / 1765		1.03 [0.92,1.15]	Z=0.49, p=0.6233
Heterogeneity:	Q=0.15 (df=1)	p=0.7006	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 10	4 / 9	11.7	0.45 [0.11,1.90]	
FIGARO-DKD	23 / 70	18 / 74	88.3	1.35 [0.80,2.28]	
Total	25 / 80	22 / 83		1.17 [0.72,1.91]	Z=0.64, p=0.5208
Heterogeneity:	Q=1.98 (df=1)	p=0.1591	I^2=49.6%		
Asian					
FIDELIO-DKD	9 / 39	9 / 44	6.3	1.13 [0.50,2.55]	
FIGARO-DKD	124 / 464	127 / 486	93.7	1.02 [0.83,1.26]	
Total	133 / 503	136 / 530		1.03 [0.84,1.26]	Z=0.27, p=0.7848
Heterogeneity:	Q=0.05 (df=1)	p=0.8197	I^2=0.0%		
Others					
FIDELIO-DKD	10 / 22	3 / 16	10.0	2.42 [0.79,7.42]	
FIGARO-DKD	39 / 134	39 / 131	90.0	0.98 [0.67,1.42]	
Total	49 / 156	42 / 147		1.10 [0.78,1.55]	Z=0.55, p=0.5832
Heterogeneity:	Q=2.31 (df=1)	p=0.1289	I^2=56.6%		
Subgroup Heterogeneity:	Q=0.38 (df=3)	p=0.9439	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.2.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

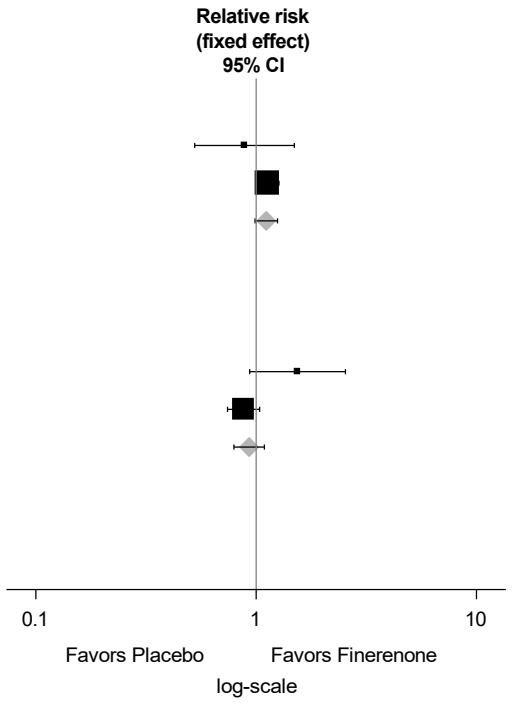
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	35 / 153	34 / 154	7.7	1.04 [0.68,1.57]	
FIGARO-DKD	396 / 1611	409 / 1640	92.3	0.99 [0.87,1.11]	
Total	431 / 1764	443 / 1794		0.99 [0.88,1.11]	Z=-0.18, p=0.8565
Heterogeneity:	Q=0.05 (df=1)	p=0.8209	I^2=0.0%		
Female					
FIDELIO-DKD	15 / 58	10 / 67	5.3	1.73 [0.84,3.56]	
FIGARO-DKD	211 / 716	175 / 664	94.7	1.12 [0.94,1.33]	
Total	226 / 774	185 / 731		1.15 [0.97,1.35]	Z=1.61, p=0.1084
Heterogeneity:	Q=1.35 (df=1)	p=0.2451	I^2=26.0%		
Subgroup Heterogeneity:	Q=2.02 (df=1)	p=0.1550	I^2=50.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.2.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

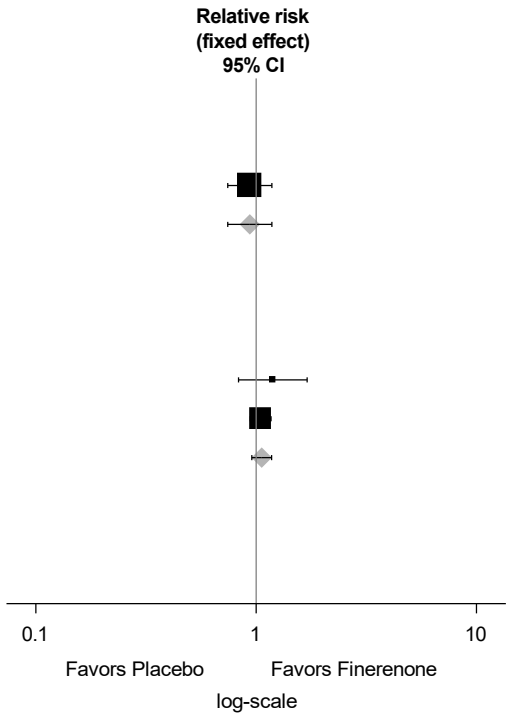
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	21 / 99	23 / 96	5.1	0.89 [0.53,1.49]	
FIGARO-DKD	408 / 1416	364 / 1421	94.9	1.12 [1.00,1.27]	
Total	429 / 1515	387 / 1517		1.11 [0.99,1.25]	Z=1.76, p=0.0785
Heterogeneity:	Q=0.77 (df=1)	p=0.3800	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 112	21 / 125	10.1	1.54 [0.93,2.54]	
FIGARO-DKD	199 / 911	220 / 883	89.9	0.88 [0.74,1.04]	
Total	228 / 1023	241 / 1008		0.93 [0.79,1.09]	Z=-0.90, p=0.3659
Heterogeneity:	Q=4.39 (df=1)	p=0.0362	I^2=77.2%		
Subgroup Heterogeneity:	Q=3.14 (df=1)	p=0.0762	I^2=68.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.2.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

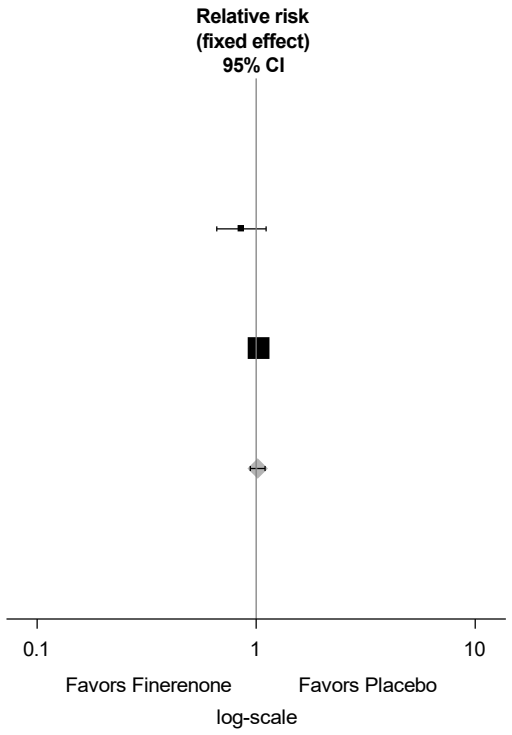
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	102 / 363	103 / 343	100.0	0.94 [0.74,1.18]	
Total	102 / 363	103 / 343		0.94 [0.74,1.18]	Z=-0.56, p=0.5723
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	50 / 211	44 / 221	8.3	1.19 [0.83,1.70]	
FIGARO-DKD	505 / 1964	481 / 1961	91.7	1.05 [0.94,1.17]	
Total	555 / 2175	525 / 2182		1.06 [0.96,1.17]	Z=1.09, p=0.2738
Heterogeneity:	Q=0.44 (df=1)	p=0.5063	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=1)	p=0.3355	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

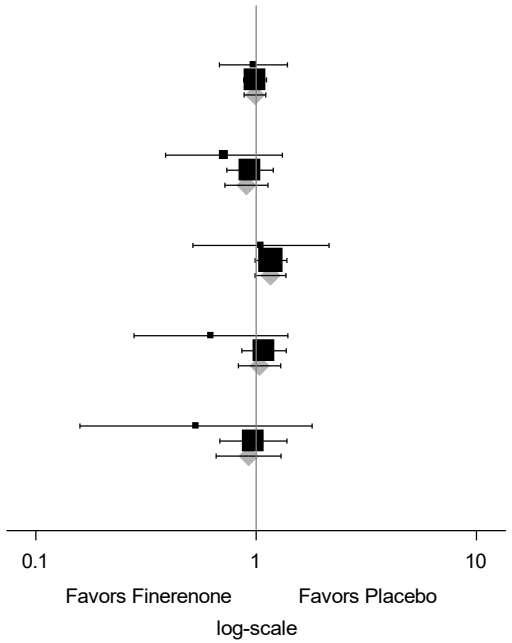
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 211	82 / 221	8.9	0.86 [0.66,1.11]	
FIGARO-DKD	786 / 2327	753 / 2304	91.1	1.03 [0.95,1.12]	
Total	854 / 2538	835 / 2525		1.02 [0.94,1.10]	Z=0.40, p=0.6864
Heterogeneity:	Q=1.82 (df=1)	p=0.1774	I^2=45.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.3.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

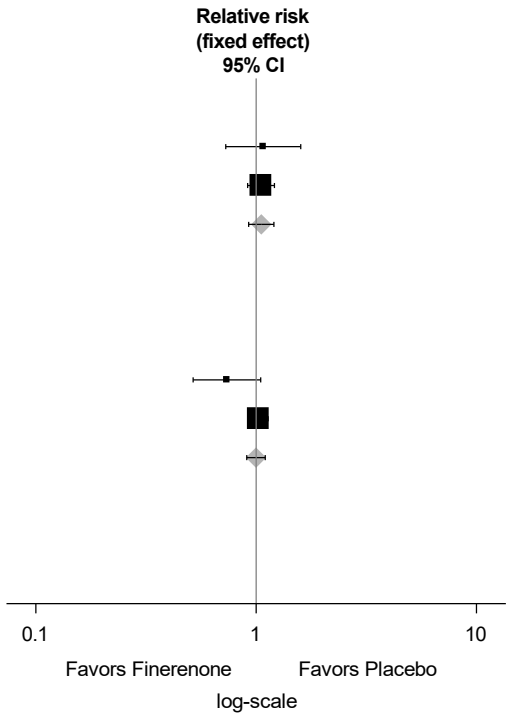
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	37 / 104	41 / 112	10.1	0.97 [0.68,1.39]	
FIGARO-DKD	362 / 1114	365 / 1111	89.9	0.99 [0.88,1.11]	
Total	399 / 1218	406 / 1223		0.99 [0.88,1.11]	Z=-0.22, p=0.8253
Heterogeneity:	Q=0.01 (df=1)	p=0.9267	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 42	16 / 40	13.6	0.71 [0.39,1.32]	
FIGARO-DKD	89 / 292	90 / 277	86.4	0.94 [0.74,1.20]	
Total	101 / 334	106 / 317		0.90 [0.72,1.13]	Z=-0.89, p=0.3750
Heterogeneity:	Q=0.66 (df=1)	p=0.4161	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 39	11 / 41	5.2	1.05 [0.52,2.14]	
FIGARO-DKD	197 / 522	169 / 523	94.8	1.17 [0.99,1.38]	
Total	208 / 561	180 / 564		1.16 [0.99,1.37]	Z=1.82, p=0.0691
Heterogeneity:	Q=0.08 (df=1)	p=0.7778	I^2=0.0%		
Latin America					
FIDELIO-DKD	6 / 21	11 / 24	7.7	0.62 [0.28,1.39]	
FIGARO-DKD	104 / 322	94 / 316	92.3	1.09 [0.86,1.37]	
Total	110 / 343	105 / 340		1.04 [0.83,1.29]	Z=0.32, p=0.7527
Heterogeneity:	Q=1.69 (df=1)	p=0.1935	I^2=40.8%		
Others					
FIDELIO-DKD	2 / 5	3 / 4	7.7	0.53 [0.16,1.79]	
FIGARO-DKD	34 / 77	35 / 77	92.3	0.97 [0.68,1.38]	
Total	36 / 82	38 / 81		0.92 [0.66,1.30]	Z=-0.46, p=0.6461
Heterogeneity:	Q=0.87 (df=1)	p=0.3520	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.27 (df=4)	p=0.3705	I^2=6.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.3.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

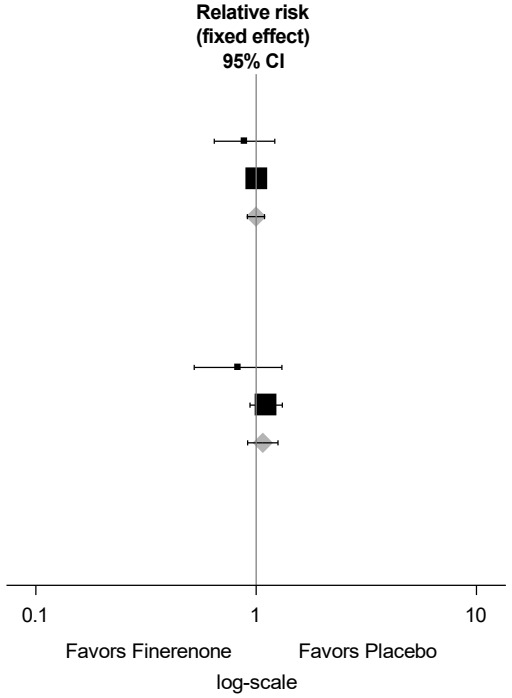
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	33 / 88	31 / 89	11.3	1.08 [0.73,1.59]	
FIGARO-DKD	272 / 811	256 / 803	88.7	1.05 [0.91,1.21]	
Total	305 / 899	287 / 892		1.05 [0.92,1.20]	Z=0.79, p=0.4280
Heterogeneity:	Q=0.01 (df=1)	p=0.9133	I^2=0.0%		
Absent					
FIDELIO-DKD	35 / 123	51 / 132	7.5	0.74 [0.52,1.05]	
FIGARO-DKD	514 / 1516	497 / 1501	92.5	1.02 [0.93,1.13]	
Total	549 / 1639	548 / 1633		1.00 [0.91,1.10]	Z=-0.04, p=0.9695
Heterogeneity:	Q=3.09 (df=1)	p=0.0786	I^2=67.7%		
Subgroup Heterogeneity:	Q=0.44 (df=1)	p=0.5078	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.3.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

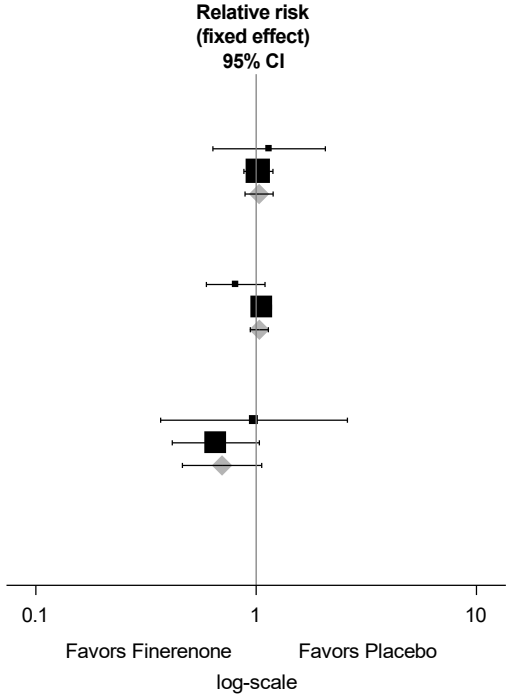
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 144	57 / 158	8.0	0.89 [0.65,1.21]	
FIGARO-DKD	591 / 1719	573 / 1680	92.0	1.01 [0.92,1.11]	
Total	637 / 1863	630 / 1838		1.00 [0.91,1.09]	Z=-0.05, p=0.9567
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
> 4.5					
FIDELIO-DKD	22 / 67	25 / 63	12.0	0.83 [0.52,1.31]	
FIGARO-DKD	195 / 608	180 / 623	88.0	1.11 [0.94,1.31]	
Total	217 / 675	205 / 686		1.07 [0.91,1.26]	Z=0.86, p=0.3921
Heterogeneity:	Q=1.39 (df=1)	p=0.2384	I^2=28.1%		
Subgroup Heterogeneity:	Q=0.60 (df=1)	p=0.4399	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.3.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

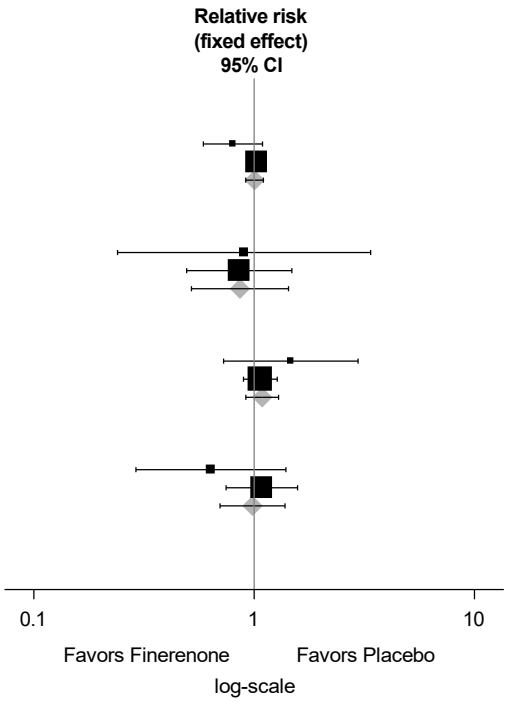
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	19 / 64	14 / 54	6.3	1.15 [0.64,2.06]	
FIGARO-DKD	227 / 693	224 / 700	93.7	1.02 [0.88,1.19]	
Total	246 / 757	238 / 754		1.03 [0.89,1.19]	Z=0.41, p=0.6845
Heterogeneity:	Q=0.13 (df=1)	p=0.7173	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	45 / 138	63 / 156	9.5	0.81 [0.59,1.10]	
FIGARO-DKD	539 / 1561	496 / 1525	90.5	1.06 [0.96,1.17]	
Total	584 / 1699	559 / 1681		1.03 [0.94,1.14]	Z=0.69, p=0.4925
Heterogeneity:	Q=2.77 (df=1)	p=0.0959	I^2=63.9%		
>= 160					
FIDELIO-DKD	4 / 9	5 / 11	17.9	0.98 [0.37,2.59]	
FIGARO-DKD	20 / 73	33 / 79	82.1	0.66 [0.42,1.03]	
Total	24 / 82	38 / 90		0.70 [0.46,1.06]	Z=-1.69, p=0.0918
Heterogeneity:	Q=0.53 (df=1)	p=0.4670	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.26 (df=2)	p=0.1958	I^2=38.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.3.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

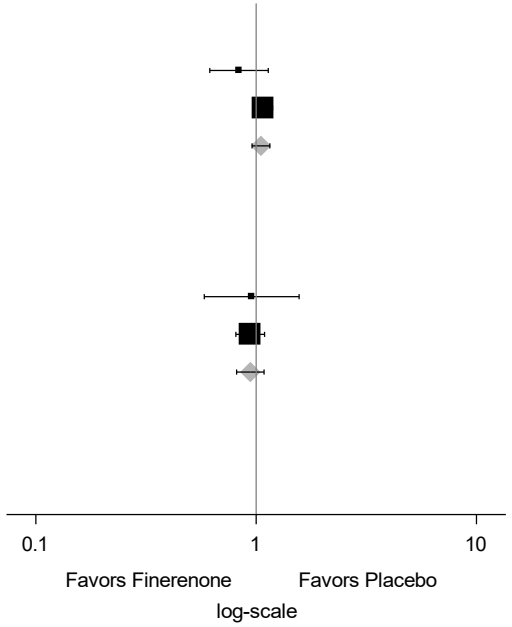
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 140	61 / 152	8.9	0.80 [0.59,1.09]	
FIGARO-DKD	564 / 1659	534 / 1613	91.1	1.03 [0.93,1.13]	
Total	609 / 1799	595 / 1765		1.00 [0.92,1.10]	Z=0.09, p=0.9320
Heterogeneity:	Q=2.26 (df=1)	p=0.1327	I^2=55.8%		
Black					
FIDELIO-DKD	3 / 10	3 / 9	14.7	0.90 [0.24,3.38]	
FIGARO-DKD	17 / 70	21 / 74	85.3	0.86 [0.49,1.48]	
Total	20 / 80	24 / 83		0.86 [0.52,1.43]	Z=-0.57, p=0.5666
Heterogeneity:	Q=0.00 (df=1)	p=0.9450	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 39	10 / 44	5.9	1.47 [0.73,2.96]	
FIGARO-DKD	164 / 464	161 / 486	94.1	1.07 [0.89,1.27]	
Total	177 / 503	171 / 530		1.09 [0.92,1.29]	Z=0.96, p=0.3357
Heterogeneity:	Q=0.74 (df=1)	p=0.3893	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 22	8 / 16	18.5	0.64 [0.29,1.39]	
FIGARO-DKD	41 / 134	37 / 131	81.5	1.08 [0.75,1.57]	
Total	48 / 156	45 / 147		0.98 [0.70,1.38]	Z=-0.10, p=0.9207
Heterogeneity:	Q=1.44 (df=1)	p=0.2298	I^2=30.7%		
Subgroup Heterogeneity:	Q=1.11 (df=3)	p=0.7741	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.3.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

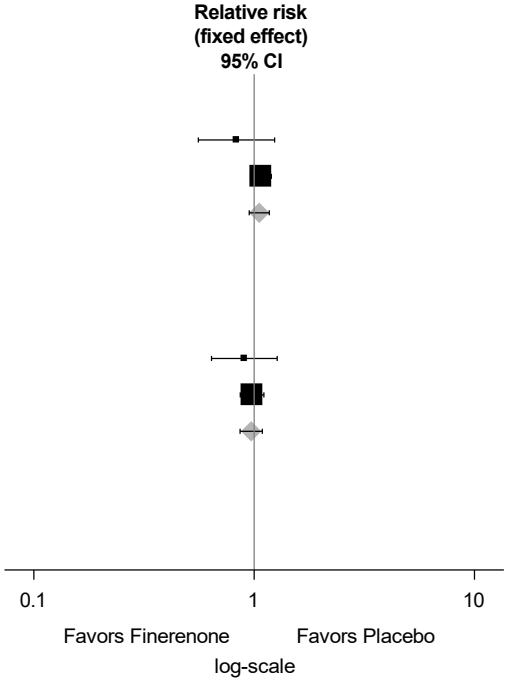
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	49 / 153	59 / 154	9.2	0.84 [0.62,1.13]	
FIGARO-DKD	556 / 1611	526 / 1640	90.8	1.08 [0.98,1.19]	
Total	605 / 1764	585 / 1794		1.05 [0.96,1.15]	Z=1.05, p=0.2921
Heterogeneity:	Q=2.38 (df=1)	p=0.1229	I^2=58.0%		
Female					
FIDELIO-DKD	19 / 58	23 / 67	8.4	0.95 [0.58,1.57]	
FIGARO-DKD	230 / 716	227 / 664	91.6	0.94 [0.81,1.09]	
Total	249 / 774	250 / 731		0.94 [0.82,1.09]	Z=-0.83, p=0.4050
Heterogeneity:	Q=0.00 (df=1)	p=0.9533	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.62 (df=1)	p=0.2037	I^2=38.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.3.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

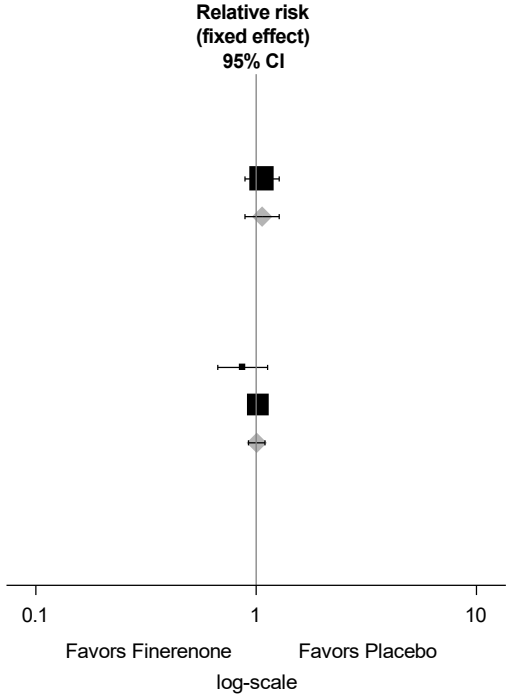
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	30 / 99	35 / 96	6.9	0.83 [0.56,1.24]	
FIGARO-DKD	462 / 1416	432 / 1421	93.1	1.07 [0.96,1.20]	
Total	492 / 1515	467 / 1517		1.05 [0.95,1.17]	Z=0.99, p=0.3219
Heterogeneity:	Q=1.47 (df=1)	p=0.2254	I^2=31.9%		
>= 65					
FIDELIO-DKD	38 / 112	47 / 125	11.5	0.90 [0.64,1.27]	
FIGARO-DKD	324 / 911	321 / 883	88.5	0.98 [0.86,1.11]	
Total	362 / 1023	368 / 1008		0.97 [0.86,1.09]	Z=-0.53, p=0.5980
Heterogeneity:	Q=0.19 (df=1)	p=0.6640	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.11 (df=1)	p=0.2915	I^2=10.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.3.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

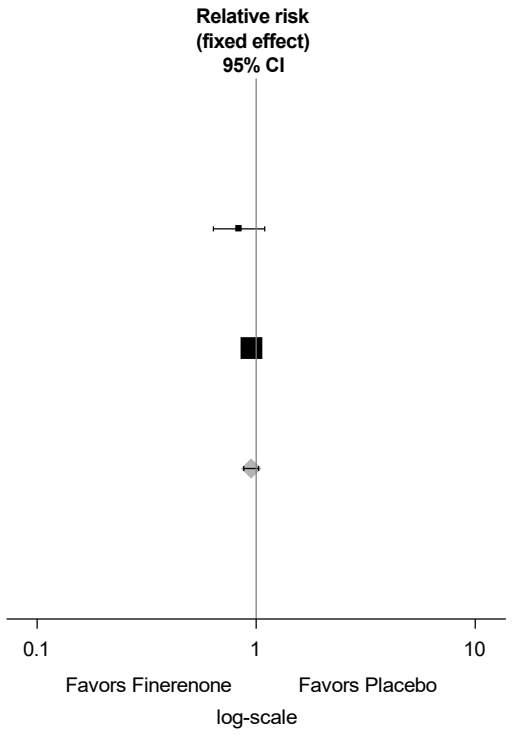
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	152 / 363	135 / 343	100.0	1.06 [0.89,1.27]	
Total	152 / 363	135 / 343		1.06 [0.89,1.27]	Z=0.68, p=0.4970
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	68 / 211	82 / 221	11.0	0.87 [0.67,1.13]	
FIGARO-DKD	634 / 1964	618 / 1961	89.0	1.02 [0.93,1.12]	
Total	702 / 2175	700 / 2182		1.01 [0.92,1.10]	Z=0.13, p=0.8957
Heterogeneity:	Q=1.37 (df=1)	p=0.2413	I^2=27.2%		
Subgroup Heterogeneity:	Q=0.31 (df=1)	p=0.5790	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

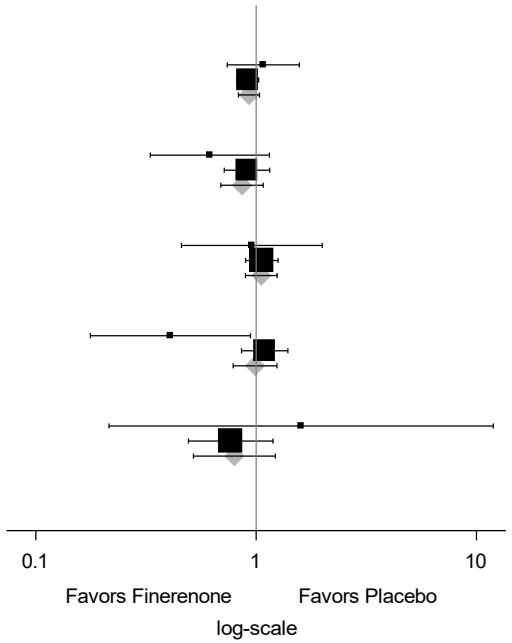
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 211	79 / 221	8.4	0.84 [0.64,1.09]	
FIGARO-DKD	758 / 2327	782 / 2304	91.6	0.96 [0.88,1.04]	
Total	822 / 2538	861 / 2525		0.95 [0.88,1.03]	Z=-1.32, p=0.1854
Heterogeneity:	Q=0.91 (df=1)	p=0.3405	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.4.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

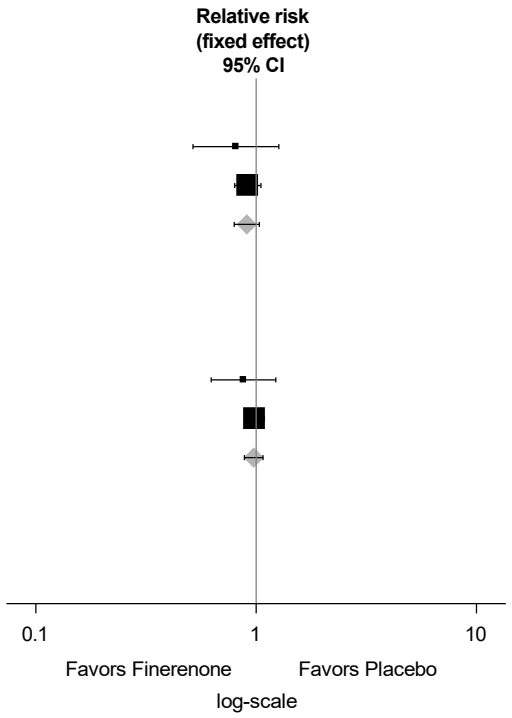
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 104	36 / 112	8.5	1.08 [0.74,1.57]	
FIGARO-DKD	366 / 1114	399 / 1111	91.5	0.91 [0.82,1.03]	
Total	402 / 1218	435 / 1223		0.93 [0.83,1.04]	Z=-1.34, p=0.1801
Heterogeneity:	Q=0.66 (df=1)	p=0.4173	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	17 / 40	12.7	0.62 [0.33,1.15]	
FIGARO-DKD	90 / 292	94 / 277	87.3	0.91 [0.72,1.15]	
Total	101 / 334	111 / 317		0.86 [0.69,1.08]	Z=-1.31, p=0.1904
Heterogeneity:	Q=1.30 (df=1)	p=0.2539	I^2=23.2%		
Asia					
FIDELIO-DKD	10 / 39	11 / 41	5.1	0.96 [0.46,1.99]	
FIGARO-DKD	181 / 522	171 / 523	94.9	1.06 [0.89,1.26]	
Total	191 / 561	182 / 564		1.05 [0.89,1.25]	Z=0.63, p=0.5276
Heterogeneity:	Q=0.07 (df=1)	p=0.7871	I^2=0.0%		
Latin America					
FIDELIO-DKD	5 / 21	14 / 24	7.7	0.41 [0.18,0.94]	
FIGARO-DKD	98 / 322	88 / 316	92.3	1.09 [0.86,1.39]	
Total	103 / 343	102 / 340		0.99 [0.79,1.24]	Z=-0.10, p=0.9192
Heterogeneity:	Q=4.96 (df=1)	p=0.0260	I^2=79.8%		
Others					
FIDELIO-DKD	2 / 5	1 / 4	4.6	1.60 [0.21,11.92]	
FIGARO-DKD	23 / 77	30 / 77	95.4	0.77 [0.49,1.19]	
Total	25 / 82	31 / 81		0.80 [0.52,1.22]	Z=-1.04, p=0.2974
Heterogeneity:	Q=0.49 (df=1)	p=0.4830	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.21 (df=4)	p=0.5234	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.4.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

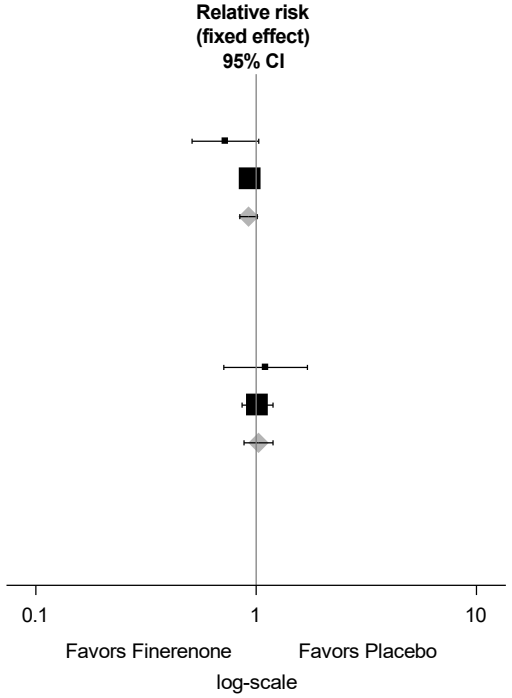
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	24 / 88	30 / 89	8.6	0.81 [0.52,1.27]	
FIGARO-DKD	261 / 811	282 / 803	91.4	0.92 [0.80,1.05]	
Total	285 / 899	312 / 892		0.91 [0.80,1.03]	Z=-1.47, p=0.1429
Heterogeneity:	Q=0.27 (df=1)	p=0.6029	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 123	49 / 132	8.3	0.88 [0.62,1.23]	
FIGARO-DKD	497 / 1516	500 / 1501	91.7	0.98 [0.89,1.09]	
Total	537 / 1639	549 / 1633		0.97 [0.88,1.07]	Z=-0.52, p=0.6045
Heterogeneity:	Q=0.42 (df=1)	p=0.5179	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.75 (df=1)	p=0.3850	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.4.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

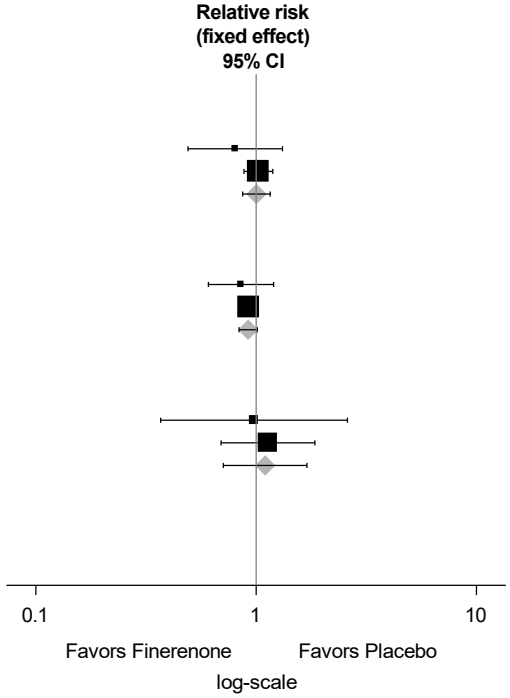
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	37 / 144	56 / 158	6.9	0.72 [0.51,1.03]	
FIGARO-DKD	560 / 1719	582 / 1680	93.1	0.94 [0.86,1.03]	
Total	597 / 1863	638 / 1838		0.92 [0.84,1.01]	Z=-1.72, p=0.0855
Heterogeneity:	Q=1.99 (df=1)	p=0.1579	I^2=49.9%		
> 4.5					
FIDELIO-DKD	27 / 67	23 / 63	12.0	1.10 [0.71,1.71]	
FIGARO-DKD	198 / 608	200 / 623	88.0	1.01 [0.86,1.19]	
Total	225 / 675	223 / 686		1.02 [0.88,1.19]	Z=0.32, p=0.7510
Heterogeneity:	Q=0.13 (df=1)	p=0.7224	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=1)	p=0.2468	I^2=25.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.4.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

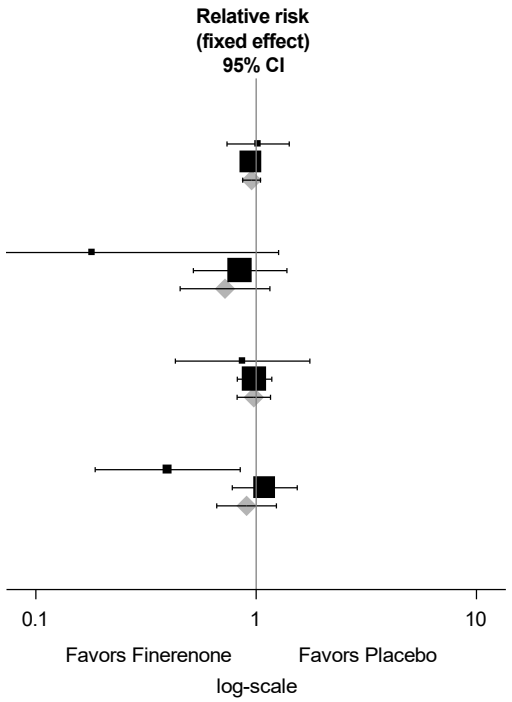
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	20 / 64	21 / 54	8.5	0.80 [0.49,1.32]	
FIGARO-DKD	230 / 693	227 / 700	91.5	1.02 [0.88,1.19]	
Total	250 / 757	248 / 754		1.00 [0.87,1.16]	Z=0.04, p=0.9700
Heterogeneity:	Q=0.84 (df=1)	p=0.3584	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	40 / 138	53 / 156	7.8	0.85 [0.61,1.20]	
FIGARO-DKD	505 / 1561	533 / 1525	92.2	0.93 [0.84,1.02]	
Total	545 / 1699	586 / 1681		0.92 [0.84,1.01]	Z=-1.72, p=0.0847
Heterogeneity:	Q=0.20 (df=1)	p=0.6525	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 9	5 / 11	20.1	0.98 [0.37,2.59]	
FIGARO-DKD	23 / 73	22 / 79	79.9	1.13 [0.69,1.85]	
Total	27 / 82	27 / 90		1.10 [0.71,1.70]	Z=0.42, p=0.6742
Heterogeneity:	Q=0.07 (df=1)	p=0.7934	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.41 (df=2)	p=0.4942	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.4.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

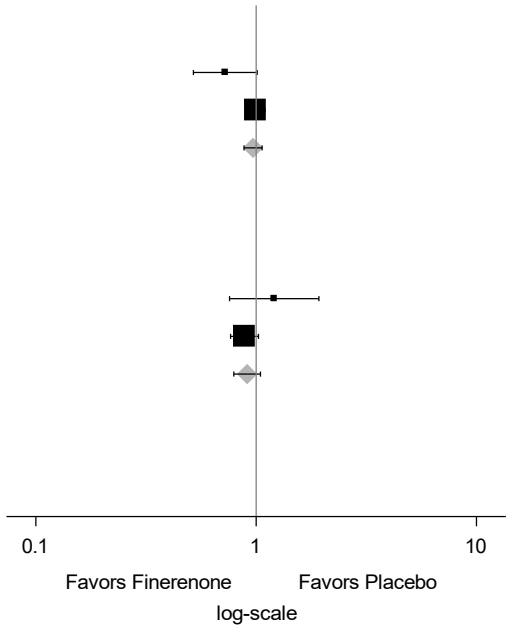
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	47 / 140	50 / 152	8.2	1.02 [0.74,1.41]	
FIGARO-DKD	538 / 1659	552 / 1613	91.8	0.95 [0.86,1.04]	
Total	585 / 1799	602 / 1765		0.95 [0.87,1.05]	Z=-1.01, p=0.3137
Heterogeneity:	Q=0.18 (df=1)	p=0.6685	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	5 / 9	5.9	0.18 [0.03,1.26]	
FIGARO-DKD	20 / 70	25 / 74	94.1	0.85 [0.52,1.38]	
Total	21 / 80	30 / 83		0.72 [0.45,1.15]	Z=-1.36, p=0.1736
Heterogeneity:	Q=2.35 (df=1)	p=0.1250	I^2=57.5%		
Asian					
FIDELIO-DKD	10 / 39	13 / 44	6.2	0.87 [0.43,1.75]	
FIGARO-DKD	153 / 464	163 / 486	93.8	0.98 [0.82,1.18]	
Total	163 / 503	176 / 530		0.98 [0.82,1.16]	Z=-0.28, p=0.7809
Heterogeneity:	Q=0.11 (df=1)	p=0.7361	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 22	11 / 16	16.7	0.40 [0.19,0.85]	
FIGARO-DKD	47 / 134	42 / 131	83.3	1.09 [0.78,1.54]	
Total	53 / 156	53 / 147		0.90 [0.66,1.24]	Z=-0.63, p=0.5283
Heterogeneity:	Q=5.75 (df=1)	p=0.0165	I^2=82.6%		
Subgroup Heterogeneity:	Q=1.50 (df=3)	p=0.6826	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.4.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

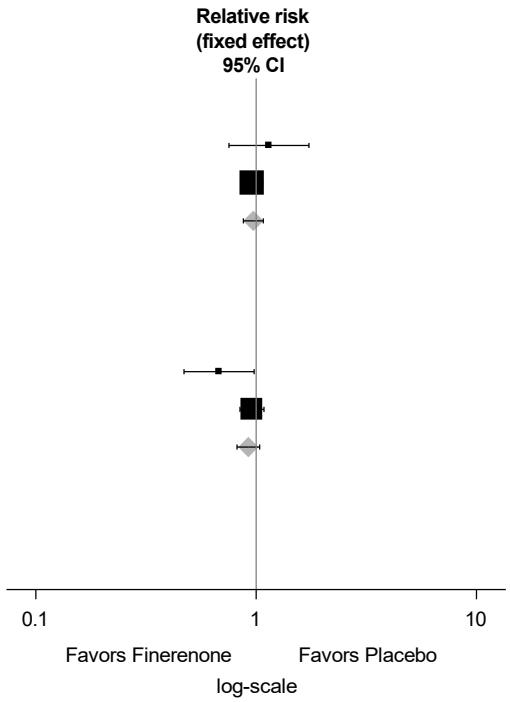
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	41 / 153	57 / 154	8.0	0.72 [0.52,1.01]	
FIGARO-DKD	526 / 1611	539 / 1640	92.0	0.99 [0.90,1.10]	
Total	567 / 1764	596 / 1794		0.97 [0.88,1.06]	Z=-0.68, p=0.4969
Heterogeneity:	Q=3.19 (df=1)	p=0.0743	I^2=68.6%		
Female					
FIDELIO-DKD	23 / 58	22 / 67	8.9	1.21 [0.76,1.93]	
FIGARO-DKD	232 / 716	243 / 664	91.1	0.89 [0.77,1.02]	
Total	255 / 774	265 / 731		0.91 [0.79,1.05]	Z=-1.33, p=0.1834
Heterogeneity:	Q=1.55 (df=1)	p=0.2136	I^2=35.4%		
Subgroup Heterogeneity:	Q=0.52 (df=1)	p=0.4713	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.4.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

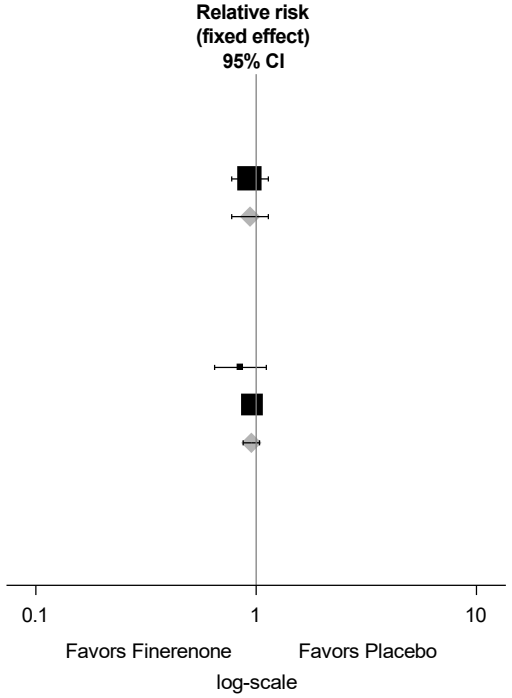
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 99	28 / 96	6.2	1.14 [0.75,1.74]	
FIGARO-DKD	444 / 1416	464 / 1421	93.8	0.96 [0.86,1.07]	
Total	477 / 1515	492 / 1517		0.97 [0.87,1.08]	Z=-0.56, p=0.5752
Heterogeneity:	Q=0.62 (df=1)	p=0.4293	I^2=0.0%		
>= 65					
FIDELIO-DKD	31 / 112	51 / 125	10.5	0.68 [0.47,0.98]	
FIGARO-DKD	314 / 911	318 / 883	89.5	0.96 [0.84,1.09]	
Total	345 / 1023	369 / 1008		0.92 [0.82,1.04]	Z=-1.36, p=0.1743
Heterogeneity:	Q=3.04 (df=1)	p=0.0815	I^2=67.1%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5152	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.4.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

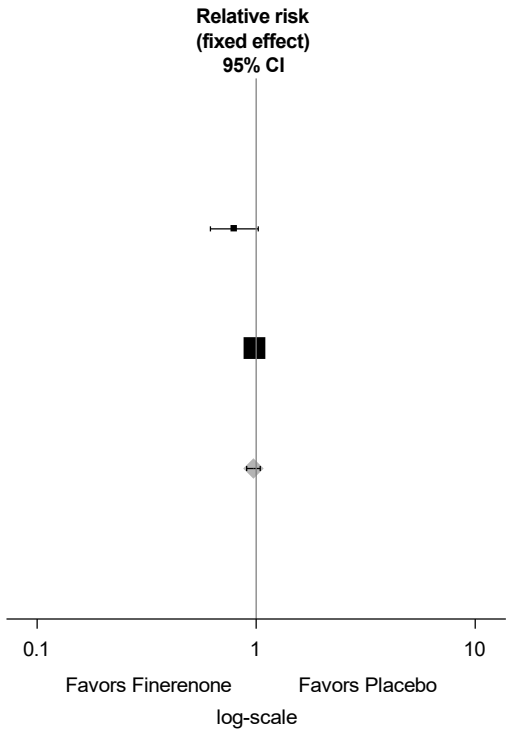
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	131 / 363	132 / 343	100.0	0.94 [0.77,1.14]	
Total	131 / 363	132 / 343		0.94 [0.77,1.14]	Z=-0.66, p=0.5105
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	64 / 211	79 / 221	10.0	0.85 [0.65,1.11]	
FIGARO-DKD	627 / 1964	650 / 1961	90.0	0.96 [0.88,1.05]	
Total	691 / 2175	729 / 2182		0.95 [0.87,1.04]	Z=-1.15, p=0.2482
Heterogeneity:	Q=0.76 (df=1)	p=0.3834	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8963	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

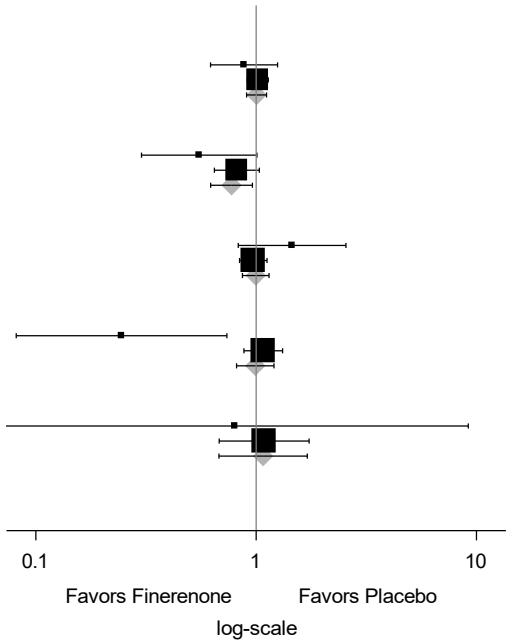
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	69 / 211	91 / 221	8.1	0.79 [0.62,1.02]	
FIGARO-DKD	861 / 2327	861 / 2304	91.9	0.99 [0.92,1.07]	
Total	930 / 2538	952 / 2525		0.97 [0.90,1.04]	Z=-0.79, p=0.4318
Heterogeneity:	Q=2.66 (df=1)	p=0.1032	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.5.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

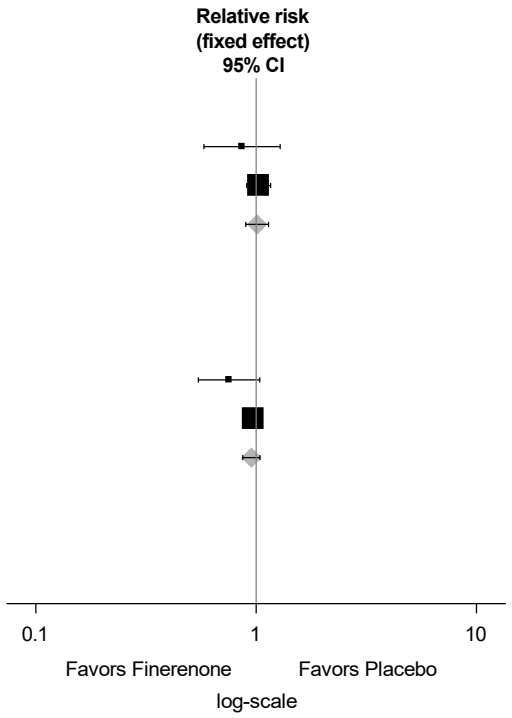
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 104	44 / 112	8.9	0.88 [0.62,1.25]	
FIGARO-DKD	411 / 1114	403 / 1111	91.1	1.02 [0.91,1.13]	
Total	447 / 1218	447 / 1223		1.00 [0.90,1.11]	Z=0.08, p=0.9388
Heterogeneity:	Q=0.59 (df=1)	p=0.4435	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	19 / 40	13.2	0.55 [0.30,1.01]	
FIGARO-DKD	87 / 292	101 / 277	86.8	0.82 [0.65,1.03]	
Total	98 / 334	120 / 317		0.77 [0.62,0.96]	Z=-2.31, p=0.0207
Heterogeneity:	Q=1.42 (df=1)	p=0.2334	I^2=29.6%		
Asia					
FIDELIO-DKD	18 / 39	13 / 41	6.1	1.46 [0.83,2.56]	
FIGARO-DKD	214 / 522	221 / 523	93.9	0.97 [0.84,1.12]	
Total	232 / 561	234 / 564		1.00 [0.87,1.14]	Z=-0.07, p=0.9477
Heterogeneity:	Q=1.87 (df=1)	p=0.1710	I^2=46.7%		
Latin America					
FIDELIO-DKD	3 / 21	14 / 24	3.3	0.24 [0.08,0.74]	
FIGARO-DKD	124 / 322	113 / 316	96.7	1.08 [0.88,1.32]	
Total	127 / 343	127 / 340		0.99 [0.81,1.20]	Z=-0.09, p=0.9244
Heterogeneity:	Q=6.85 (df=1)	p=0.0089	I^2=85.4%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	3.6	0.80 [0.07,9.18]	
FIGARO-DKD	25 / 77	23 / 77	96.4	1.09 [0.68,1.74]	
Total	26 / 82	24 / 81		1.08 [0.68,1.71]	Z=0.31, p=0.7580
Heterogeneity:	Q=0.06 (df=1)	p=0.8090	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.94 (df=4)	p=0.2934	I^2=19.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.5.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

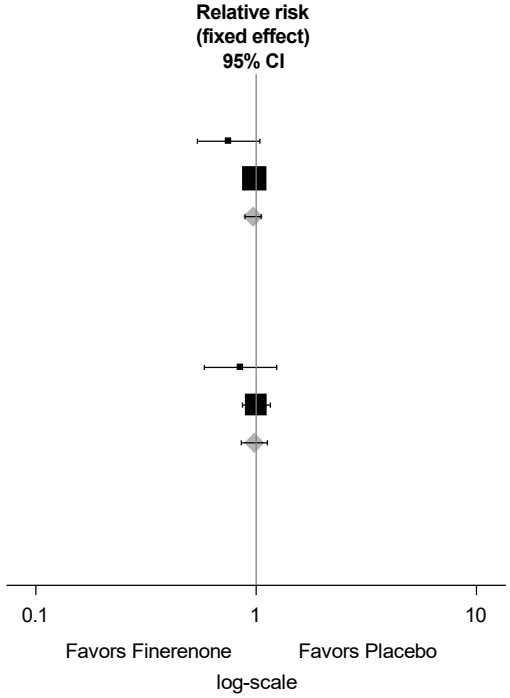
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	29 / 88	34 / 89	8.9	0.86 [0.58,1.28]	
FIGARO-DKD	312 / 811	301 / 803	91.1	1.03 [0.91,1.16]	
Total	341 / 899	335 / 892		1.01 [0.90,1.14]	Z=0.17, p=0.8644
Heterogeneity:	Q=0.67 (df=1)	p=0.4145	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 123	57 / 132	7.8	0.75 [0.55,1.04]	
FIGARO-DKD	549 / 1516	560 / 1501	92.2	0.97 [0.88,1.07]	
Total	589 / 1639	617 / 1633		0.95 [0.87,1.04]	Z=-1.10, p=0.2720
Heterogeneity:	Q=2.21 (df=1)	p=0.1370	I^2=54.8%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4249	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.5.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

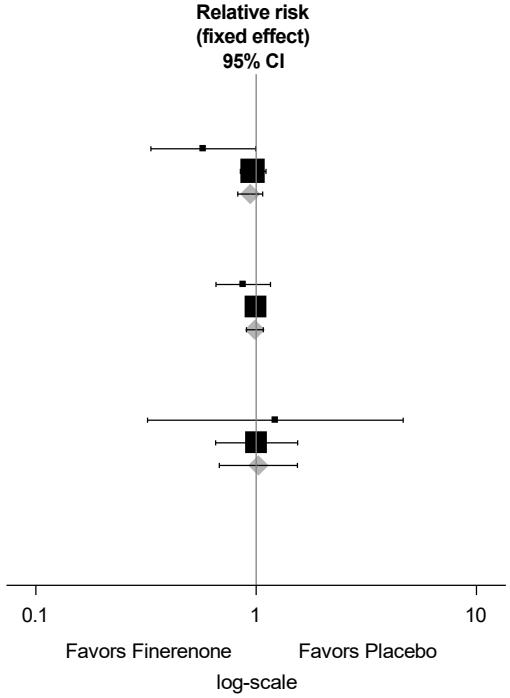
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	41 / 144	60 / 158	6.7	0.75 [0.54,1.04]	
FIGARO-DKD	636 / 1719	630 / 1680	93.3	0.99 [0.90,1.08]	
Total	677 / 1863	690 / 1838		0.97 [0.89,1.05]	Z=-0.75, p=0.4511
Heterogeneity:	Q=2.53 (df=1)	p=0.1116	I^2=60.5%		
> 4.5					
FIDELIO-DKD	28 / 67	31 / 63	13.0	0.85 [0.58,1.24]	
FIGARO-DKD	225 / 608	230 / 623	87.0	1.00 [0.87,1.16]	
Total	253 / 675	261 / 686		0.98 [0.86,1.12]	Z=-0.28, p=0.7823
Heterogeneity:	Q=0.64 (df=1)	p=0.4226	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8720	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.5.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

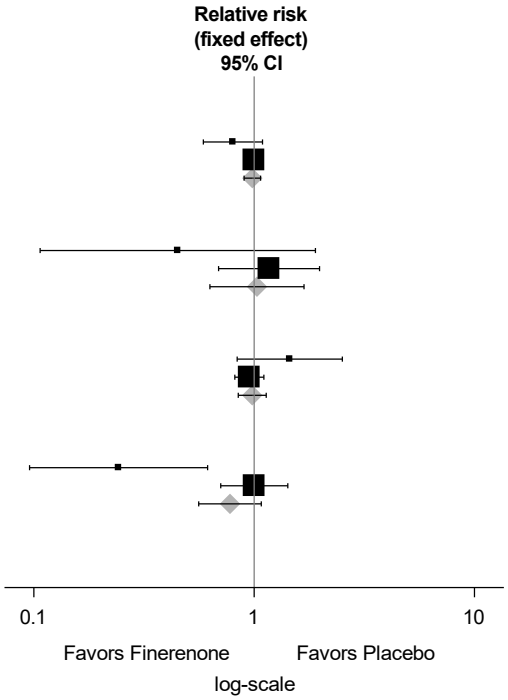
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 64	22 / 54	5.6	0.58 [0.33,0.99]	
FIGARO-DKD	260 / 693	271 / 700	94.4	0.97 [0.85,1.11]	
Total	275 / 757	293 / 754		0.94 [0.83,1.07]	Z=-0.94, p=0.3496
Heterogeneity:	Q=3.29 (df=1)	p=0.0696	I^2=69.6%		
130 - < 160					
FIDELIO-DKD	51 / 138	66 / 156	9.5	0.87 [0.66,1.16]	
FIGARO-DKD	575 / 1561	562 / 1525	90.5	1.00 [0.91,1.10]	
Total	626 / 1699	628 / 1681		0.99 [0.90,1.08]	Z=-0.30, p=0.7635
Heterogeneity:	Q=0.78 (df=1)	p=0.3776	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 9	3 / 11	9.3	1.22 [0.32,4.65]	
FIGARO-DKD	26 / 73	28 / 79	90.7	1.00 [0.65,1.54]	
Total	29 / 82	31 / 90		1.02 [0.68,1.54]	Z=0.11, p=0.9119
Heterogeneity:	Q=0.07 (df=1)	p=0.7845	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=2)	p=0.8072	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.5.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

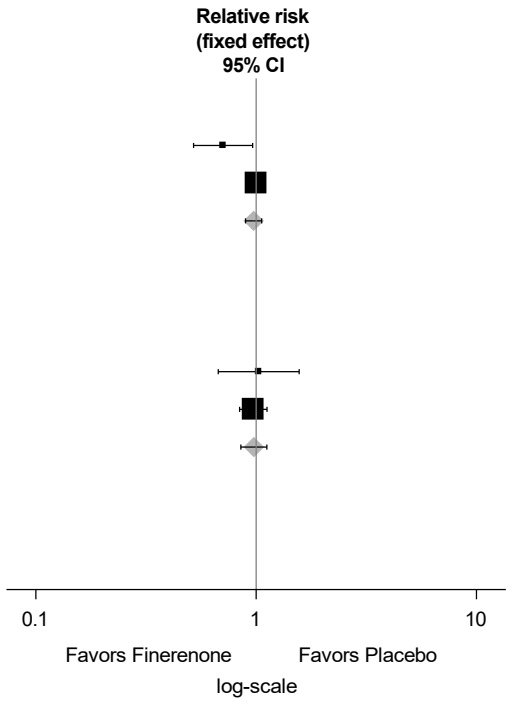
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 140	61 / 152	7.8	0.80 [0.59,1.09]	
FIGARO-DKD	610 / 1659	594 / 1613	92.2	1.00 [0.91,1.09]	
Total	655 / 1799	655 / 1765		0.98 [0.90,1.07]	Z=-0.43, p=0.6644
Heterogeneity:	Q=1.80 (df=1)	p=0.1797	I^2=44.4%		
Black					
FIDELIO-DKD	2 / 10	4 / 9	11.9	0.45 [0.11,1.90]	
FIGARO-DKD	21 / 70	19 / 74	88.1	1.17 [0.69,1.98]	
Total	23 / 80	23 / 83		1.03 [0.63,1.68]	Z=0.12, p=0.9078
Heterogeneity:	Q=1.49 (df=1)	p=0.2219	I^2=33.0%		
Asian					
FIDELIO-DKD	18 / 39	14 / 44	7.1	1.45 [0.84,2.51]	
FIGARO-DKD	187 / 464	206 / 486	92.9	0.95 [0.82,1.11]	
Total	205 / 503	220 / 530		0.98 [0.85,1.13]	Z=-0.27, p=0.7875
Heterogeneity:	Q=2.11 (df=1)	p=0.1465	I^2=52.6%		
Others					
FIDELIO-DKD	4 / 22	12 / 16	12.4	0.24 [0.10,0.61]	
FIGARO-DKD	43 / 134	42 / 131	87.6	1.00 [0.71,1.42]	
Total	47 / 156	54 / 147		0.78 [0.56,1.08]	Z=-1.51, p=0.1299
Heterogeneity:	Q=8.03 (df=1)	p=0.0046	I^2=87.5%		
Subgroup Heterogeneity:	Q=1.92 (df=3)	p=0.5900	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.5.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

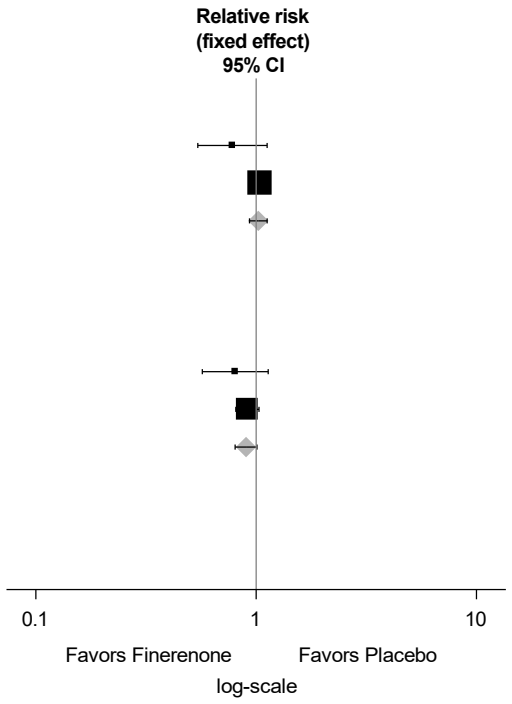
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	45 / 153	64 / 154	7.5	0.71 [0.52,0.96]	
FIGARO-DKD	613 / 1611	624 / 1640	92.5	1.00 [0.92,1.09]	
Total	658 / 1764	688 / 1794		0.97 [0.89,1.06]	Z=-0.62, p=0.5352
Heterogeneity:	Q=4.46 (df=1)	p=0.0347	I^2=77.6%		
Female					
FIDELIO-DKD	24 / 58	27 / 67	10.3	1.03 [0.67,1.57]	
FIGARO-DKD	248 / 716	237 / 664	89.7	0.97 [0.84,1.12]	
Total	272 / 774	264 / 731		0.98 [0.85,1.12]	Z=-0.35, p=0.7267
Heterogeneity:	Q=0.06 (df=1)	p=0.8041	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9761	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.5.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

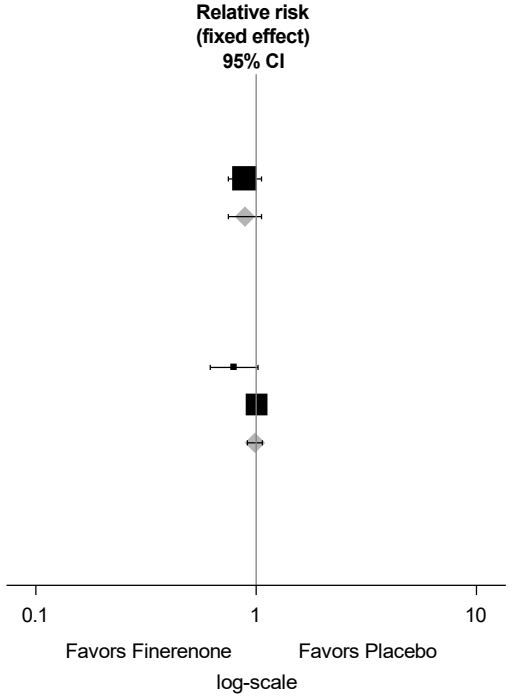
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 99	41 / 96	6.5	0.78 [0.54,1.12]	
FIGARO-DKD	540 / 1416	520 / 1421	93.5	1.04 [0.95,1.15]	
Total	573 / 1515	561 / 1517		1.02 [0.93,1.12]	Z=0.47, p=0.6352
Heterogeneity:	Q=2.29 (df=1)	p=0.1304	I^2=56.3%		
>= 65					
FIDELIO-DKD	36 / 112	50 / 125	11.0	0.80 [0.57,1.13]	
FIGARO-DKD	321 / 911	341 / 883	89.0	0.91 [0.81,1.03]	
Total	357 / 1023	391 / 1008		0.90 [0.80,1.01]	Z=-1.82, p=0.0690
Heterogeneity:	Q=0.47 (df=1)	p=0.4951	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.93 (df=1)	p=0.0867	I^2=65.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.5.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

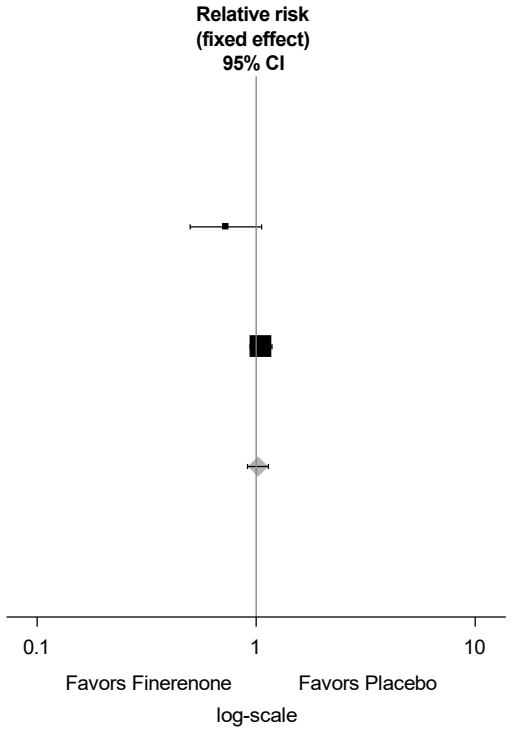
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	144 / 363	153 / 343	100.0	0.89 [0.75,1.06]	
Total	144 / 363	153 / 343		0.89 [0.75,1.06]	Z=-1.33, p=0.1844
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	69 / 211	91 / 221	9.9	0.79 [0.62,1.02]	
FIGARO-DKD	717 / 1964	708 / 1961	90.1	1.01 [0.93,1.10]	
Total	786 / 2175	799 / 2182		0.99 [0.91,1.07]	Z=-0.33, p=0.7388
Heterogeneity:	Q=3.24 (df=1)	p=0.0718	I^2=69.1%		
Subgroup Heterogeneity:	Q=1.15 (df=1)	p=0.2841	I^2=12.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

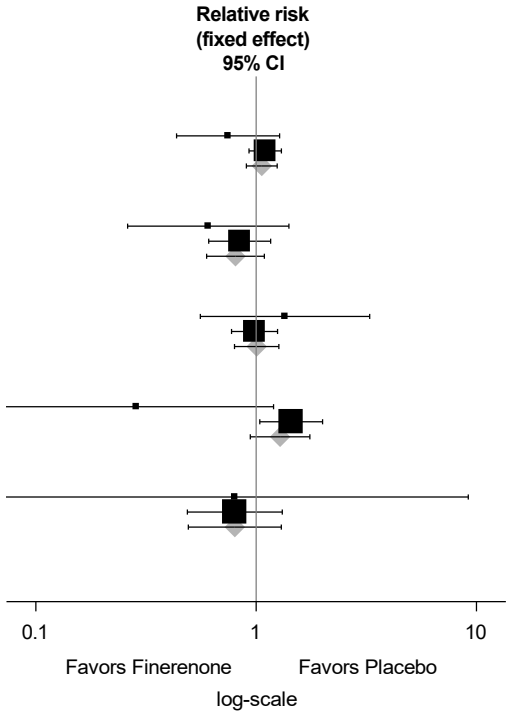
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 211	53 / 221	8.5	0.73 [0.50,1.06]	
FIGARO-DKD	479 / 2327	449 / 2304	91.5	1.05 [0.94,1.18]	
Total	516 / 2538	502 / 2525		1.02 [0.91,1.14]	Z=0.34, p=0.7349
Heterogeneity:	Q=3.40 (df=1)	p=0.0650	I^2=70.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.6.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

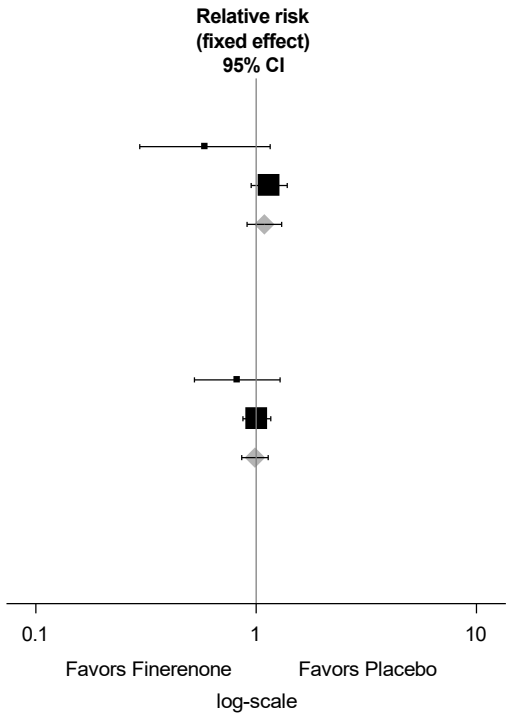
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 104	26 / 112	9.0	0.75 [0.44,1.28]	
FIGARO-DKD	227 / 1114	206 / 1111	91.0	1.10 [0.93,1.30]	
Total	245 / 1218	232 / 1223		1.06 [0.90,1.25]	Z=0.71, p=0.4762
Heterogeneity:	Q=1.82 (df=1)	p=0.1779	I^2=44.9%		
North America					
FIDELIO-DKD	7 / 42	11 / 40	12.9	0.61 [0.26,1.41]	
FIGARO-DKD	55 / 292	62 / 277	87.1	0.84 [0.61,1.16]	
Total	62 / 334	73 / 317		0.81 [0.60,1.09]	Z=-1.41, p=0.1599
Heterogeneity:	Q=0.51 (df=1)	p=0.4761	I^2=0.0%		
Asia					
FIDELIO-DKD	9 / 39	7 / 41	6.9	1.35 [0.56,3.28]	
FIGARO-DKD	105 / 522	107 / 523	93.1	0.98 [0.77,1.25]	
Total	114 / 561	114 / 564		1.01 [0.80,1.27]	Z=0.04, p=0.9648
Heterogeneity:	Q=0.46 (df=1)	p=0.4964	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	8 / 24	5.0	0.29 [0.07,1.20]	
FIGARO-DKD	72 / 322	49 / 316	95.0	1.44 [1.04,2.00]	
Total	74 / 343	57 / 340		1.28 [0.94,1.75]	Z=1.57, p=0.1156
Heterogeneity:	Q=4.70 (df=1)	p=0.0302	I^2=78.7%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	4.0	0.80 [0.07,9.18]	
FIGARO-DKD	20 / 77	25 / 77	96.0	0.80 [0.49,1.31]	
Total	21 / 82	26 / 81		0.80 [0.49,1.30]	Z=-0.90, p=0.3682
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.65 (df=4)	p=0.2269	I^2=29.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.6.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

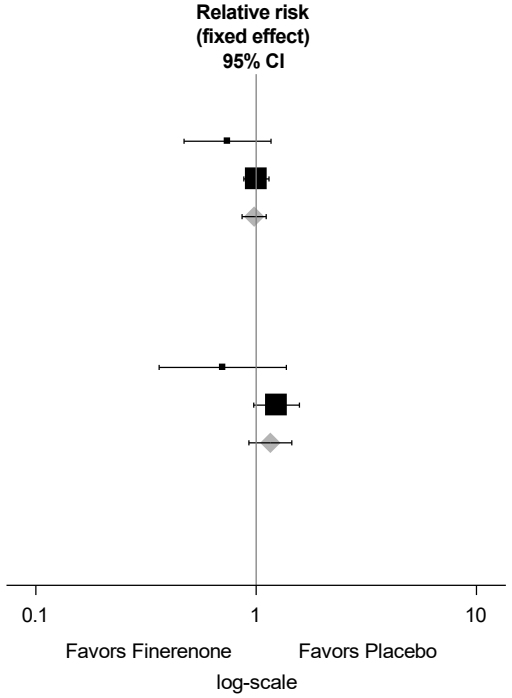
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	11 / 88	19 / 89	7.1	0.59 [0.30,1.16]	
FIGARO-DKD	184 / 811	159 / 803	92.9	1.15 [0.95,1.38]	
Total	195 / 899	178 / 892		1.09 [0.91,1.31]	Z=0.93, p=0.3535
Heterogeneity:	Q=3.46 (df=1)	p=0.0628	I^2=71.1%		
Absent					
FIDELIO-DKD	26 / 123	34 / 132	9.6	0.82 [0.52,1.28]	
FIGARO-DKD	295 / 1516	290 / 1501	90.4	1.01 [0.87,1.16]	
Total	321 / 1639	324 / 1633		0.99 [0.86,1.13]	Z=-0.18, p=0.8573
Heterogeneity:	Q=0.73 (df=1)	p=0.3938	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.72 (df=1)	p=0.3975	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.6.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

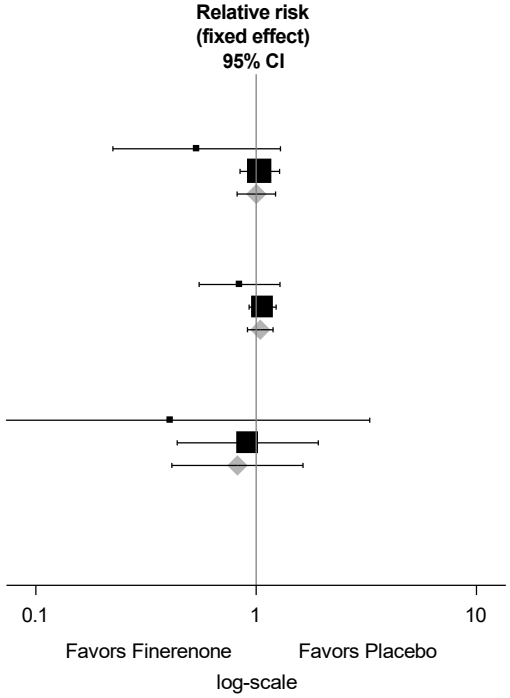
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	37 / 158	7.7	0.74 [0.47,1.17]	
FIGARO-DKD	357 / 1719	348 / 1680	92.3	1.00 [0.88,1.14]	
Total	382 / 1863	385 / 1838		0.98 [0.86,1.11]	Z=-0.33, p=0.7397
Heterogeneity:	Q=1.56 (df=1)	p=0.2111	I^2=36.1%		
> 4.5					
FIDELIO-DKD	12 / 67	16 / 63	11.4	0.71 [0.36,1.37]	
FIGARO-DKD	122 / 608	101 / 623	88.6	1.24 [0.97,1.57]	
Total	134 / 675	117 / 686		1.16 [0.93,1.45]	Z=1.30, p=0.1949
Heterogeneity:	Q=2.44 (df=1)	p=0.1186	I^2=59.0%		
Subgroup Heterogeneity:	Q=1.67 (df=1)	p=0.1961	I^2=40.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.6.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

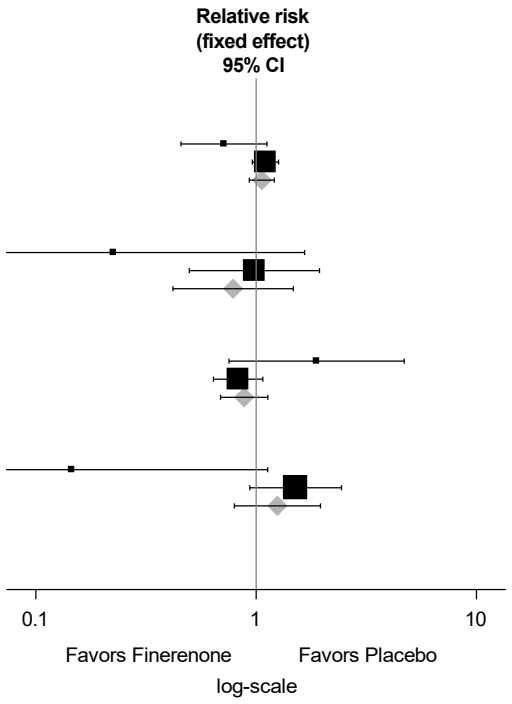
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 64	11 / 54	5.3	0.54 [0.22,1.29]	
FIGARO-DKD	145 / 693	141 / 700	94.7	1.04 [0.84,1.28]	
Total	152 / 757	152 / 754		1.00 [0.82,1.22]	Z=0.02, p=0.9868
Heterogeneity:	Q=2.07 (df=1)	p=0.1506	I^2=51.6%		
130 - < 160					
FIDELIO-DKD	29 / 138	39 / 156	10.0	0.84 [0.55,1.28]	
FIGARO-DKD	323 / 1561	295 / 1525	90.0	1.07 [0.93,1.23]	
Total	352 / 1699	334 / 1681		1.04 [0.91,1.19]	Z=0.63, p=0.5306
Heterogeneity:	Q=1.12 (df=1)	p=0.2890	I^2=11.1%		
>= 160					
FIDELIO-DKD	1 / 9	3 / 11	11.1	0.41 [0.05,3.28]	
FIGARO-DKD	11 / 73	13 / 79	88.9	0.92 [0.44,1.91]	
Total	12 / 82	16 / 90		0.82 [0.41,1.63]	Z=-0.56, p=0.5753
Heterogeneity:	Q=0.52 (df=1)	p=0.4718	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.52 (df=2)	p=0.7717	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.6.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

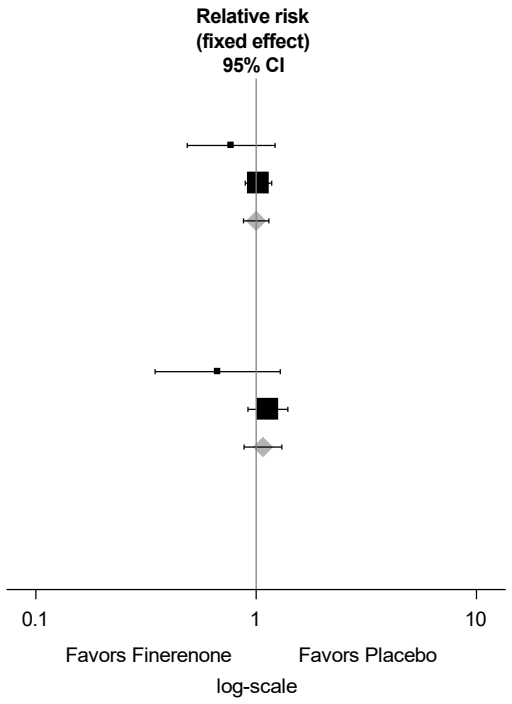
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	25 / 140	38 / 152	8.5	0.71 [0.46,1.12]	
FIGARO-DKD	349 / 1659	308 / 1613	91.5	1.10 [0.96,1.26]	
Total	374 / 1799	346 / 1765		1.06 [0.93,1.21]	Z=0.88, p=0.3784
Heterogeneity:	Q=3.27 (df=1)	p=0.0707	I^2=69.4%		
Black					
FIDELIO-DKD	1 / 10	4 / 9	10.4	0.23 [0.03,1.66]	
FIGARO-DKD	13 / 70	14 / 74	89.6	0.98 [0.50,1.94]	
Total	14 / 80	18 / 83		0.79 [0.42,1.47]	Z=-0.75, p=0.4528
Heterogeneity:	Q=1.92 (df=1)	p=0.1663	I^2=47.8%		
Asian					
FIDELIO-DKD	10 / 39	6 / 44	7.4	1.88 [0.75,4.70]	
FIGARO-DKD	83 / 464	105 / 486	92.6	0.83 [0.64,1.07]	
Total	93 / 503	111 / 530		0.88 [0.69,1.13]	Z=-0.99, p=0.3204
Heterogeneity:	Q=2.86 (df=1)	p=0.0911	I^2=65.0%		
Others					
FIDELIO-DKD	1 / 22	5 / 16	5.2	0.15 [0.02,1.13]	
FIGARO-DKD	34 / 134	22 / 131	94.8	1.51 [0.94,2.44]	
Total	35 / 156	27 / 147		1.25 [0.80,1.96]	Z=0.97, p=0.3335
Heterogeneity:	Q=4.84 (df=1)	p=0.0278	I^2=79.3%		
Subgroup Heterogeneity:	Q=3.10 (df=3)	p=0.3768	I^2=3.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.6.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

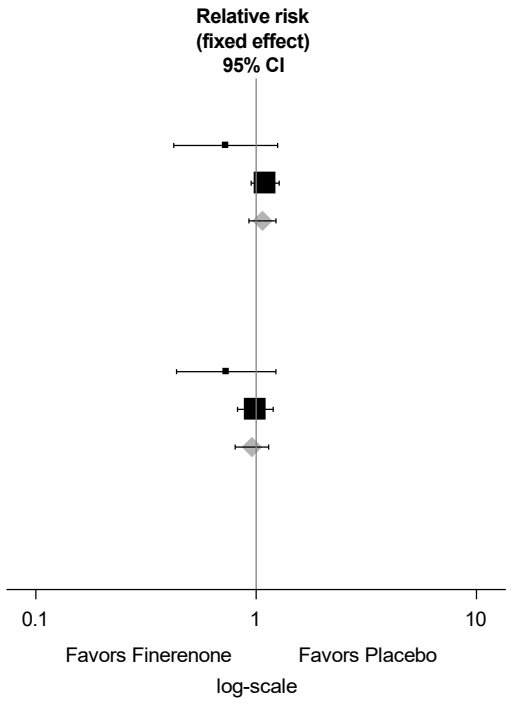
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 153	34 / 154	8.3	0.77 [0.49,1.22]	
FIGARO-DKD	323 / 1611	321 / 1640	91.7	1.02 [0.89,1.18]	
Total	349 / 1764	355 / 1794		1.00 [0.88,1.14]	Z=-0.00, p=0.9989
Heterogeneity:	Q=1.37 (df=1)	p=0.2426	I^2=26.8%		
Female					
FIDELIO-DKD	11 / 58	19 / 67	9.2	0.67 [0.35,1.29]	
FIGARO-DKD	156 / 716	128 / 664	90.8	1.13 [0.92,1.39]	
Total	167 / 774	147 / 731		1.07 [0.88,1.31]	Z=0.71, p=0.4794
Heterogeneity:	Q=2.24 (df=1)	p=0.1341	I^2=55.5%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5564	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.6.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

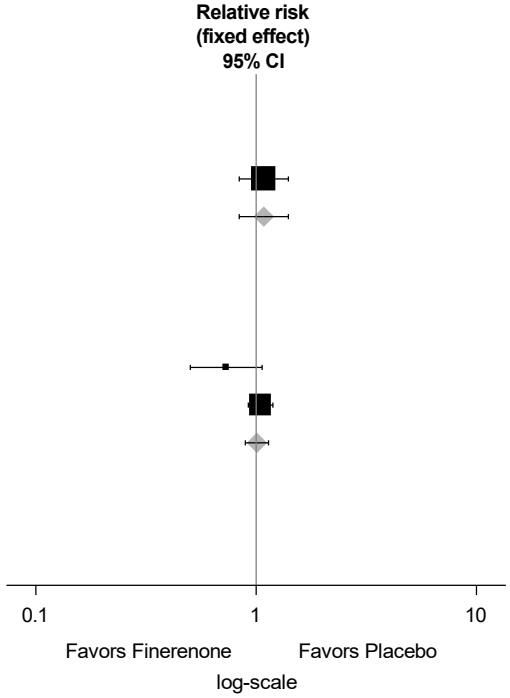
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 99	24 / 96	6.8	0.73 [0.42,1.25]	
FIGARO-DKD	300 / 1416	274 / 1421	93.2	1.10 [0.95,1.27]	
Total	318 / 1515	298 / 1517		1.07 [0.93,1.23]	Z=0.91, p=0.3612
Heterogeneity:	Q=2.07 (df=1)	p=0.1503	I^2=51.7%		
>= 65					
FIDELIO-DKD	19 / 112	29 / 125	11.4	0.73 [0.44,1.23]	
FIGARO-DKD	179 / 911	175 / 883	88.6	0.99 [0.82,1.19]	
Total	198 / 1023	204 / 1008		0.96 [0.80,1.14]	Z=-0.50, p=0.6188
Heterogeneity:	Q=1.17 (df=1)	p=0.2795	I^2=14.5%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3369	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.6.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

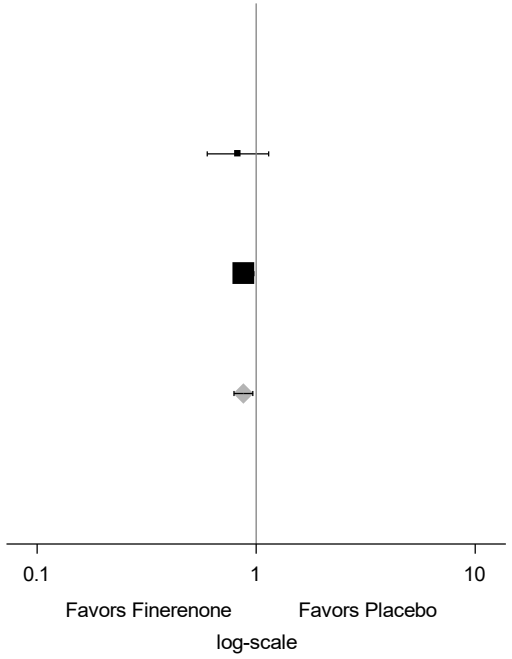
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	94 / 363	82 / 343	100.0	1.08 [0.84,1.40]	
Total	94 / 363	82 / 343		1.08 [0.84,1.40]	Z=0.61, p=0.5419
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	37 / 211	53 / 221	10.5	0.73 [0.50,1.06]	
FIGARO-DKD	385 / 1964	367 / 1961	89.5	1.05 [0.92,1.19]	
Total	422 / 2175	420 / 2182		1.01 [0.89,1.14]	Z=0.12, p=0.9021
Heterogeneity:	Q=3.16 (df=1)	p=0.0756	I^2=68.3%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

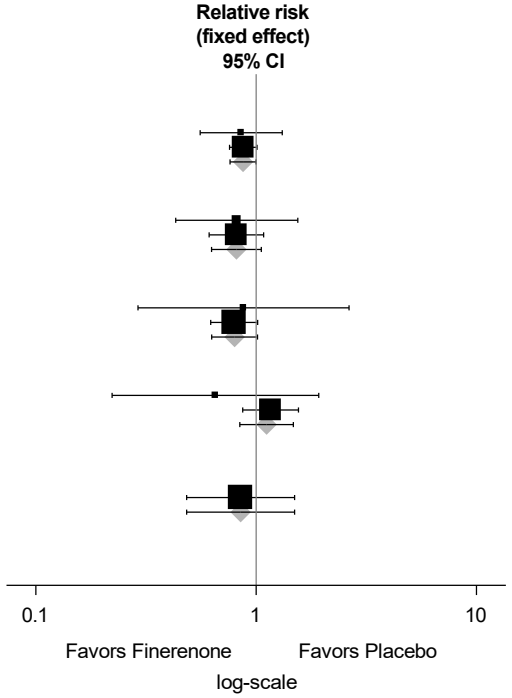
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 211	61 / 221	9.4	0.83 [0.60,1.14]	
FIGARO-DKD	514 / 2327	577 / 2304	90.6	0.88 [0.79,0.98]	
Total	562 / 2538	638 / 2525		0.87 [0.79,0.97]	Z=-2.66, p=0.0077
Heterogeneity:	Q=0.13 (df=1)	p=0.7142	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.7.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

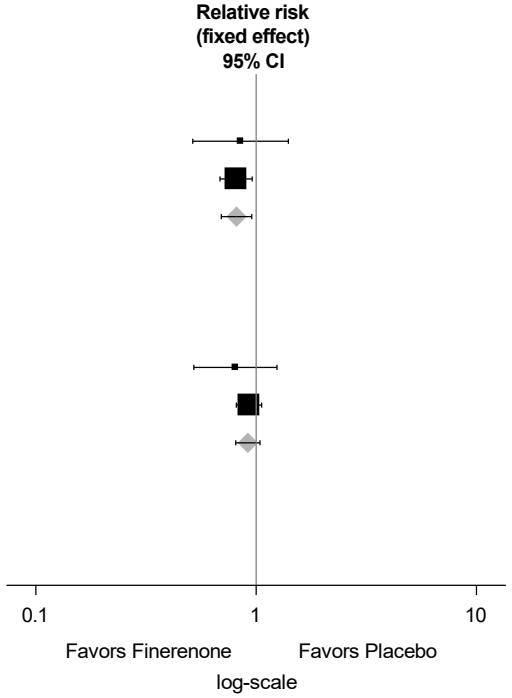
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 104	34 / 112	10.1	0.86 [0.56,1.31]	
FIGARO-DKD	262 / 1114	299 / 1111	89.9	0.87 [0.76,1.01]	
Total	289 / 1218	333 / 1223		0.87 [0.76,1.00]	Z=-1.97, p=0.0486
Heterogeneity:	Q=0.01 (df=1)	p=0.9254	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 42	14 / 40	16.6	0.82 [0.43,1.55]	
FIGARO-DKD	66 / 292	77 / 277	83.4	0.81 [0.61,1.08]	
Total	78 / 334	91 / 317		0.81 [0.63,1.06]	Z=-1.55, p=0.1200
Heterogeneity:	Q=0.00 (df=1)	p=0.9912	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 39	6 / 41	4.7	0.88 [0.29,2.64]	
FIGARO-DKD	92 / 522	116 / 523	95.3	0.79 [0.62,1.02]	
Total	97 / 561	122 / 564		0.80 [0.63,1.01]	Z=-1.84, p=0.0651
Heterogeneity:	Q=0.03 (df=1)	p=0.8656	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 21	7 / 24	6.8	0.65 [0.22,1.92]	
FIGARO-DKD	77 / 322	65 / 316	93.2	1.16 [0.87,1.56]	
Total	81 / 343	72 / 340		1.11 [0.84,1.47]	Z=0.76, p=0.4458
Heterogeneity:	Q=1.02 (df=1)	p=0.3122	I^2=2.1%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	17 / 77	20 / 77	100.0	0.85 [0.48,1.49]	
Total	17 / 82	20 / 81		0.85 [0.48,1.49]	Z=-0.56, p=0.5723
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.76 (df=4)	p=0.4395	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.7.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

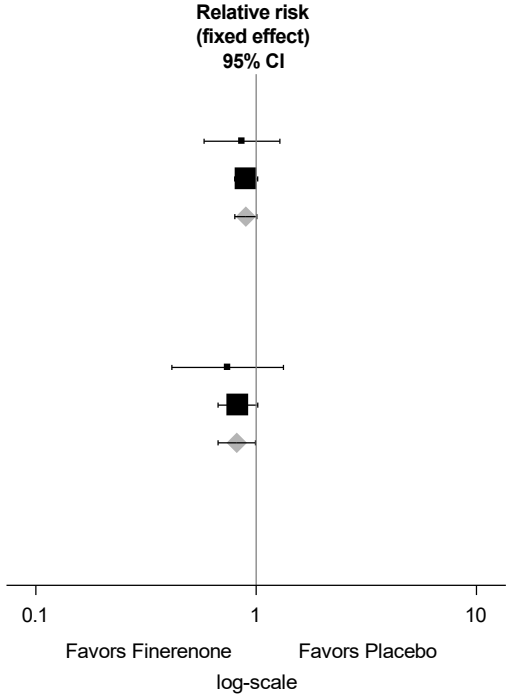
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	21 / 88	25 / 89	10.2	0.85 [0.52,1.40]	
FIGARO-DKD	185 / 811	226 / 803	89.8	0.81 [0.69,0.96]	
Total	206 / 899	251 / 892		0.81 [0.69,0.96]	Z=-2.53, p=0.0115
Heterogeneity:	Q=0.03 (df=1)	p=0.8612	I^2=0.0%		
Absent					
FIDELIO-DKD	27 / 123	36 / 132	8.5	0.80 [0.52,1.24]	
FIGARO-DKD	329 / 1516	351 / 1501	91.5	0.93 [0.81,1.06]	
Total	356 / 1639	387 / 1633		0.92 [0.81,1.04]	Z=-1.35, p=0.1783
Heterogeneity:	Q=0.38 (df=1)	p=0.5388	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.30 (df=1)	p=0.2540	I^2=23.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.7.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

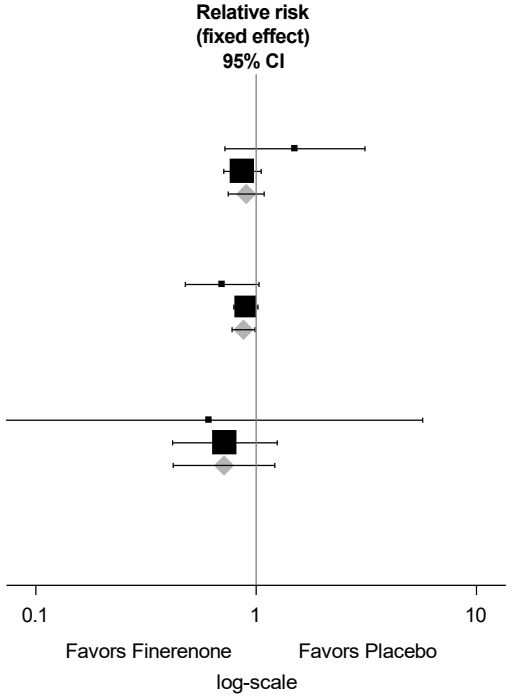
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	33 / 144	42 / 158	8.4	0.86 [0.58,1.28]	
FIGARO-DKD	389 / 1719	422 / 1680	91.6	0.90 [0.80,1.02]	
Total	422 / 1863	464 / 1838		0.90 [0.80,1.01]	Z=-1.84, p=0.0655
Heterogeneity:	Q=0.04 (df=1)	p=0.8349	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 67	19 / 63	11.2	0.74 [0.41,1.33]	
FIGARO-DKD	125 / 608	155 / 623	88.8	0.83 [0.67,1.02]	
Total	140 / 675	174 / 686		0.82 [0.67,0.99]	Z=-2.03, p=0.0419
Heterogeneity:	Q=0.12 (df=1)	p=0.7342	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=1)	p=0.4127	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.7.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	16 / 64	9 / 54	6.7	1.50 [0.72,3.12]	
FIGARO-DKD	145 / 693	169 / 700	93.3	0.87 [0.71,1.05]	
Total	161 / 757	178 / 754		0.90 [0.75,1.09]	Z=-1.09, p=0.2768
Heterogeneity:	Q=2.01 (df=1)	p=0.1558	I^2=50.4%		
130 - < 160					
FIDELIO-DKD	31 / 138	50 / 156	9.7	0.70 [0.48,1.03]	
FIGARO-DKD	353 / 1561	384 / 1525	90.3	0.90 [0.79,1.02]	
Total	384 / 1699	434 / 1681		0.88 [0.78,0.99]	Z=-2.17, p=0.0300
Heterogeneity:	Q=1.44 (df=1)	p=0.2304	I^2=30.5%		
>= 160					
FIDELIO-DKD	1 / 9	2 / 11	5.7	0.61 [0.07,5.70]	
FIGARO-DKD	16 / 73	24 / 79	94.3	0.72 [0.42,1.25]	
Total	17 / 82	26 / 90		0.71 [0.42,1.22]	Z=-1.24, p=0.2146
Heterogeneity:	Q=0.02 (df=1)	p=0.8875	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=2)	p=0.7217	I^2=0.0%		

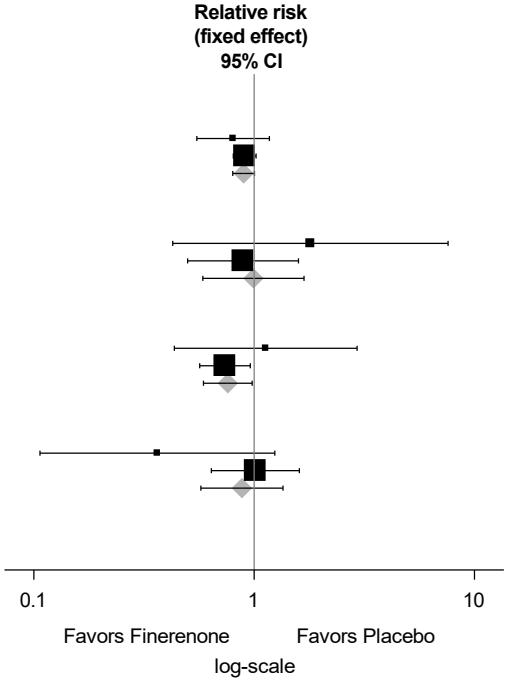


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.7.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race

Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	34 / 140	46 / 152	9.0	0.80 [0.55,1.17]	
FIGARO-DKD	393 / 1659	422 / 1613	91.0	0.91 [0.80,1.02]	
Total	427 / 1799	468 / 1765		0.90 [0.80,1.00]	Z=-1.90, p=0.0569
Heterogeneity:	Q=0.35 (df=1)	p=0.5516	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	2 / 9	13.9	1.80 [0.43,7.59]	
FIGARO-DKD	16 / 70	19 / 74	86.1	0.89 [0.50,1.59]	
Total	20 / 80	21 / 83		0.99 [0.58,1.68]	Z=-0.03, p=0.9766
Heterogeneity:	Q=0.79 (df=1)	p=0.3732	I^2=0.0%		
Asian					
FIDELIO-DKD	7 / 39	7 / 44	7.1	1.13 [0.43,2.93]	
FIGARO-DKD	76 / 464	108 / 486	92.9	0.74 [0.57,0.96]	
Total	83 / 503	115 / 530		0.76 [0.59,0.98]	Z=-2.12, p=0.0339
Heterogeneity:	Q=0.71 (df=1)	p=0.3997	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 22	6 / 16	12.3	0.36 [0.11,1.24]	
FIGARO-DKD	29 / 134	28 / 131	87.7	1.01 [0.64,1.60]	
Total	32 / 156	34 / 147		0.88 [0.57,1.35]	Z=-0.58, p=0.5589
Heterogeneity:	Q=2.35 (df=1)	p=0.1253	I^2=57.4%		
Subgroup Heterogeneity:	Q=1.57 (df=3)	p=0.6657	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.

Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.

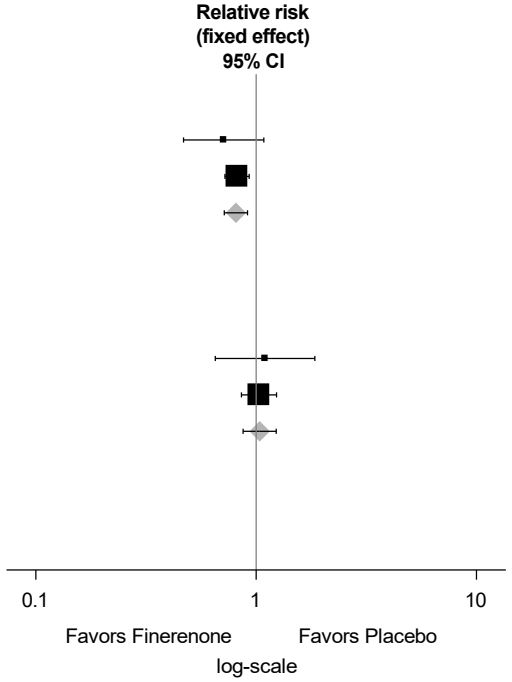
Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure B3.2.7.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

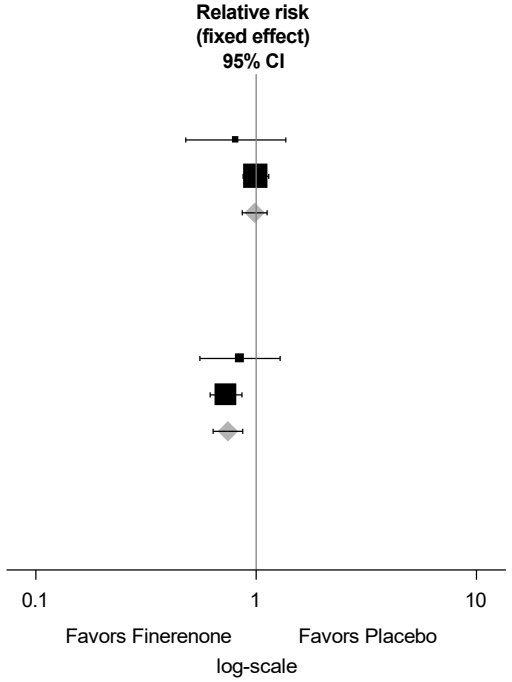
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 153	41 / 154	8.4	0.71 [0.47,1.08]	
FIGARO-DKD	333 / 1611	414 / 1640	91.6	0.82 [0.72,0.93]	
Total	362 / 1764	455 / 1794		0.81 [0.72,0.91]	Z=-3.42, p=0.0006
Heterogeneity:	Q=0.39 (df=1)	p=0.5317	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 58	20 / 67	11.1	1.10 [0.65,1.85]	
FIGARO-DKD	181 / 716	163 / 664	88.9	1.03 [0.86,1.24]	
Total	200 / 774	183 / 731		1.04 [0.87,1.23]	Z=0.41, p=0.6804
Heterogeneity:	Q=0.05 (df=1)	p=0.8212	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.29 (df=1)	p=0.0214	I^2=81.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.7.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

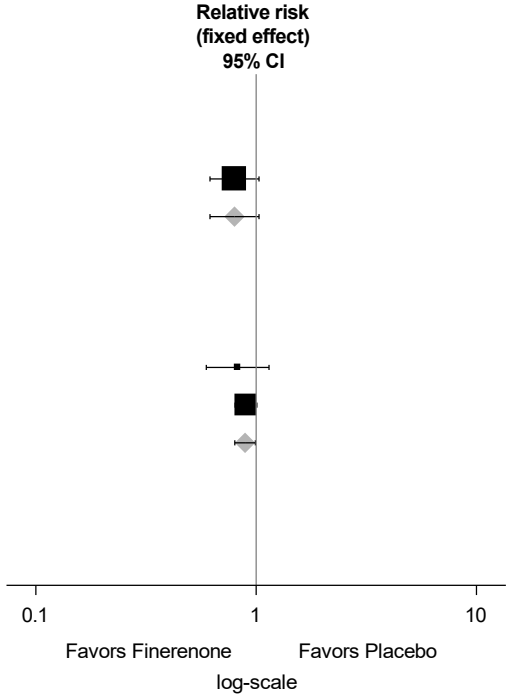
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	20 / 99	24 / 96	6.2	0.81 [0.48,1.36]	
FIGARO-DKD	328 / 1416	330 / 1421	93.8	1.00 [0.87,1.14]	
Total	348 / 1515	354 / 1517		0.98 [0.86,1.12]	Z=-0.24, p=0.8134
Heterogeneity:	Q=0.58 (df=1)	p=0.4445	I^2=0.0%		
>= 65					
FIDELIO-DKD	28 / 112	37 / 125	13.6	0.84 [0.56,1.28]	
FIGARO-DKD	186 / 911	247 / 883	86.4	0.73 [0.62,0.86]	
Total	214 / 1023	284 / 1008		0.74 [0.64,0.87]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.40 (df=1)	p=0.5261	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.38 (df=1)	p=0.0066	I^2=86.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.7.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

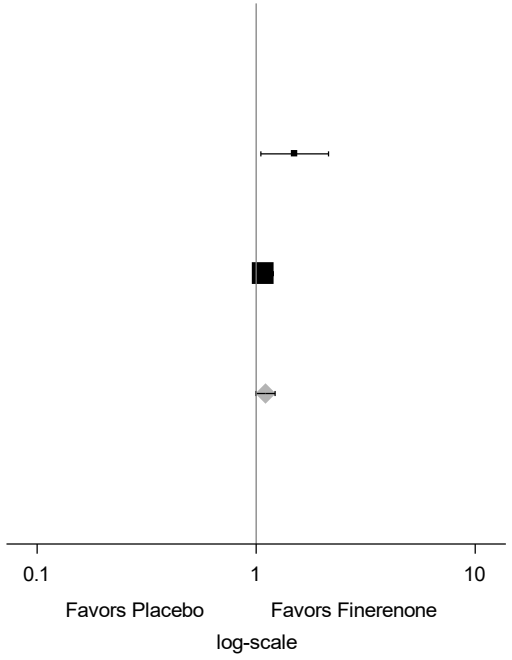
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	81 / 363	96 / 343	100.0	0.80 [0.62,1.03]	
Total	81 / 363	96 / 343		0.80 [0.62,1.03]	Z=-1.73, p=0.0831
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	48 / 211	61 / 221	10.8	0.82 [0.59,1.14]	
FIGARO-DKD	433 / 1964	481 / 1961	89.2	0.90 [0.80,1.01]	
Total	481 / 2175	542 / 2182		0.89 [0.80,0.99]	Z=-2.12, p=0.0343
Heterogeneity:	Q=0.24 (df=1)	p=0.6242	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4356	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

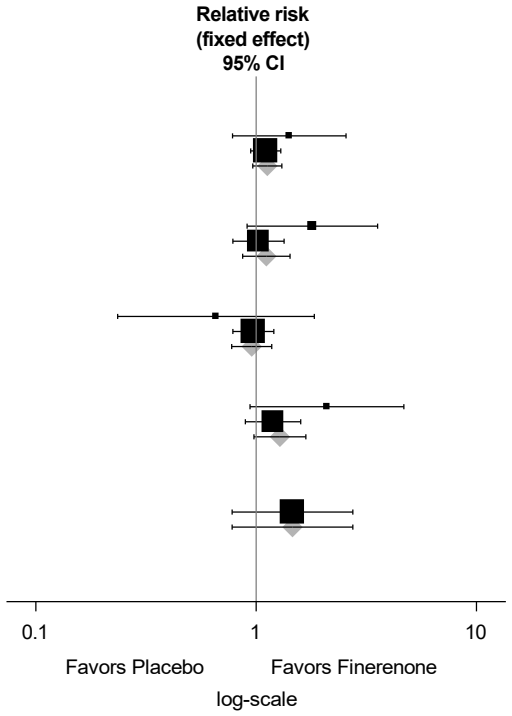
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 211	39 / 221	8.0	1.50 [1.05,2.14]	
FIGARO-DKD	560 / 2327	513 / 2304	92.0	1.08 [0.97,1.20]	
Total	614 / 2538	552 / 2525		1.10 [1.00,1.22]	Z=1.91, p=0.0561
Heterogeneity:	Q=3.04 (df=1)	p=0.0813	I^2=67.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.8.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

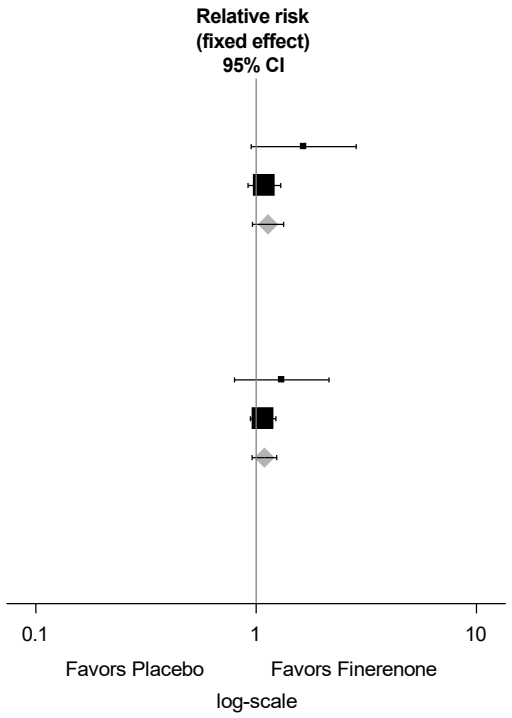
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 104	16 / 112	6.6	1.41 [0.78;2.56]	
FIGARO-DKD	256 / 1114	231 / 1111	93.4	1.11 [0.94;1.29]	
Total	277 / 1218	247 / 1223		1.12 [0.97;1.31]	Z=1.50, p=0.1332
Heterogeneity:	Q=0.62 (df=1)	p=0.4320	I^2=0.0%		
North America					
FIDELIO-DKD	17 / 42	9 / 40	13.3	1.80 [0.91;3.56]	
FIGARO-DKD	81 / 292	75 / 277	86.7	1.02 [0.78;1.34]	
Total	98 / 334	84 / 317		1.11 [0.87;1.42]	Z=0.84, p=0.4001
Heterogeneity:	Q=2.27 (df=1)	p=0.1318	I^2=56.0%		
Asia					
FIDELIO-DKD	5 / 39	8 / 41	4.2	0.66 [0.24;1.84]	
FIGARO-DKD	125 / 522	129 / 523	95.8	0.97 [0.78;1.20]	
Total	130 / 561	137 / 564		0.95 [0.77;1.18]	Z=-0.44, p=0.6634
Heterogeneity:	Q=0.53 (df=1)	p=0.4661	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 21	6 / 24	11.5	2.10 [0.94;4.68]	
FIGARO-DKD	79 / 322	65 / 316	88.5	1.19 [0.89;1.59]	
Total	90 / 343	71 / 340		1.28 [0.98;1.68]	Z=1.79, p=0.0731
Heterogeneity:	Q=1.67 (df=1)	p=0.1959	I^2=40.2%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	19 / 77	13 / 77	100.0	1.46 [0.78;2.75]	
Total	19 / 82	13 / 81		1.46 [0.78;2.75]	Z=1.18, p=0.2383
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.83 (df=4)	p=0.4300	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.8.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

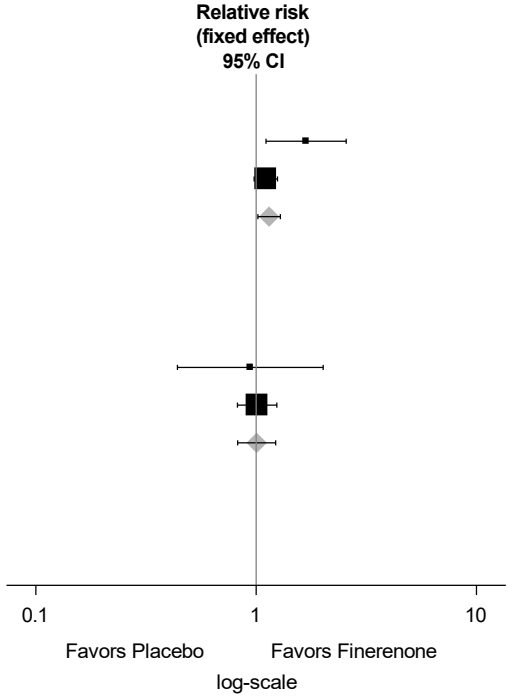
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 88	16 / 89	8.9	1.64 [0.95,2.84]	
FIGARO-DKD	208 / 811	189 / 803	91.1	1.09 [0.92,1.29]	
Total	234 / 899	205 / 892		1.13 [0.96,1.33]	Z=1.49, p=0.1358
Heterogeneity:	Q=1.96 (df=1)	p=0.1610	I^2=49.1%		
Absent					
FIDELIO-DKD	28 / 123	23 / 132	6.8	1.31 [0.80,2.14]	
FIGARO-DKD	352 / 1516	324 / 1501	93.2	1.08 [0.94,1.23]	
Total	380 / 1639	347 / 1633		1.09 [0.96,1.24]	Z=1.32, p=0.1882
Heterogeneity:	Q=0.55 (df=1)	p=0.4563	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.8.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

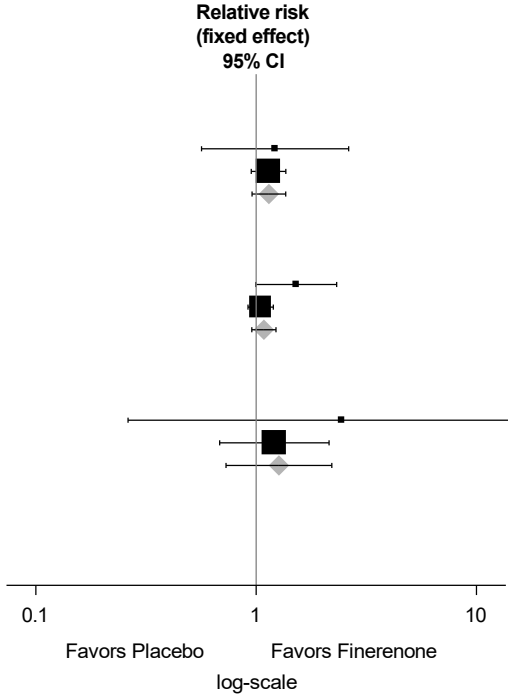
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	43 / 144	28 / 158	7.8	1.69 [1.11,2.56]	
FIGARO-DKD	421 / 1719	372 / 1680	92.2	1.11 [0.98,1.25]	
Total	464 / 1863	400 / 1838		1.14 [1.02,1.29]	Z=2.26, p=0.0238
Heterogeneity:	Q=3.57 (df=1)	p=0.0587	I^2=72.0%		
> 4.5					
FIDELIO-DKD	11 / 67	11 / 63	6.8	0.94 [0.44,2.01]	
FIGARO-DKD	139 / 608	141 / 623	93.2	1.01 [0.82,1.24]	
Total	150 / 675	152 / 686		1.01 [0.82,1.23]	Z=0.05, p=0.9590
Heterogeneity:	Q=0.03 (df=1)	p=0.8587	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.22 (df=1)	p=0.2696	I^2=17.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.8.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

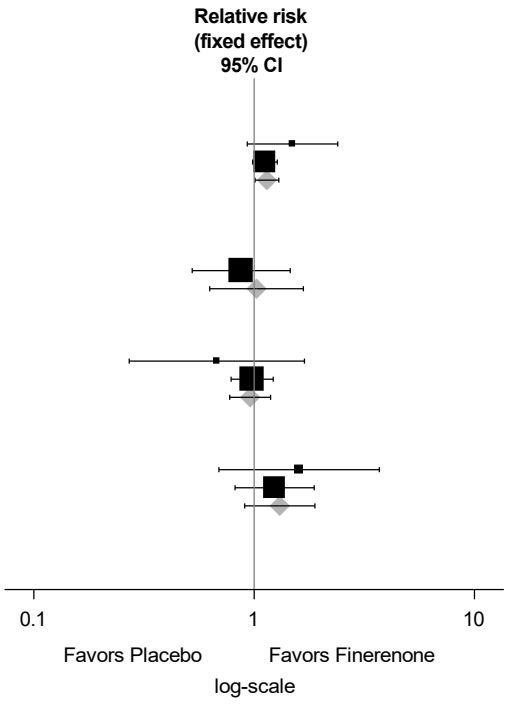
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 64	9 / 54	5.2	1.22 [0.56,2.63]	
FIGARO-DKD	187 / 693	166 / 700	94.8	1.14 [0.95,1.36]	
Total	200 / 757	175 / 754		1.14 [0.96,1.36]	Z=1.48, p=0.1389
Heterogeneity:	Q=0.03 (df=1)	p=0.8647	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	39 / 138	29 / 156	8.9	1.52 [1.00,2.32]	
FIGARO-DKD	354 / 1561	330 / 1525	91.1	1.05 [0.92,1.20]	
Total	393 / 1699	359 / 1681		1.08 [0.96,1.23]	Z=1.25, p=0.2097
Heterogeneity:	Q=2.71 (df=1)	p=0.0996	I^2=63.1%		
>= 160					
FIDELIO-DKD	2 / 9	1 / 11	6.2	2.44 [0.26,22.80]	
FIGARO-DKD	19 / 73	17 / 79	93.8	1.21 [0.68,2.14]	
Total	21 / 82	18 / 90		1.27 [0.73,2.20]	Z=0.84, p=0.3993
Heterogeneity:	Q=0.36 (df=1)	p=0.5495	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=2)	p=0.7958	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.8.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

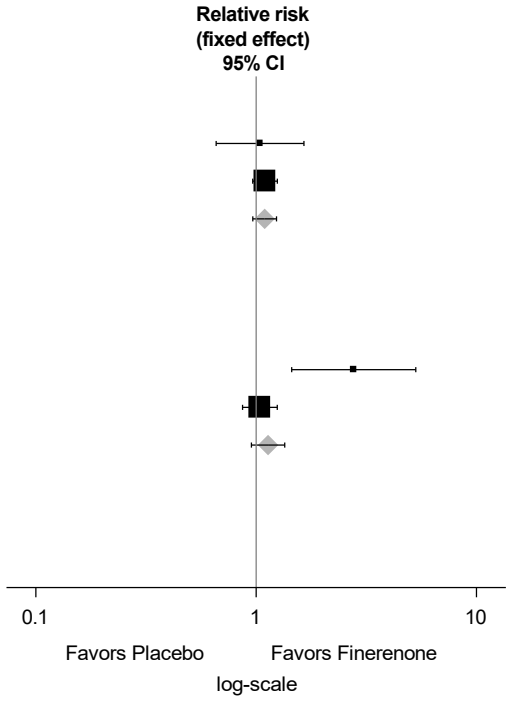
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	33 / 140	24 / 152	6.9	1.49 [0.93,2.40]	
FIGARO-DKD	388 / 1659	337 / 1613	93.1	1.12 [0.98,1.27]	
Total	421 / 1799	361 / 1765		1.14 [1.01,1.29]	Z=2.10, p=0.0359
Heterogeneity:	Q=1.32 (df=1)	p=0.2498	I^2=24.5%		
Black					
FIDELIO-DKD	4 / 10	0 / 9	0.0	282E9 [282E9,282E9]	
FIGARO-DKD	19 / 70	23 / 74	100.0	0.87 [0.52,1.46]	
Total	23 / 80	23 / 83		1.03 [0.63,1.67]	Z=0.10, p=0.9204
Heterogeneity:	Q=0.38 (df=1)	p=0.5394	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 39	10 / 44	5.5	0.68 [0.27,1.69]	
FIGARO-DKD	115 / 464	123 / 486	94.5	0.98 [0.79,1.22]	
Total	121 / 503	133 / 530		0.96 [0.77,1.19]	Z=-0.39, p=0.6998
Heterogeneity:	Q=0.59 (df=1)	p=0.4422	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 22	5 / 16	19.6	1.60 [0.69,3.70]	
FIGARO-DKD	38 / 134	30 / 131	80.4	1.24 [0.82,1.87]	
Total	49 / 156	35 / 147		1.31 [0.91,1.89]	Z=1.43, p=0.1530
Heterogeneity:	Q=0.29 (df=1)	p=0.5909	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.86 (df=3)	p=0.4136	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.8.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

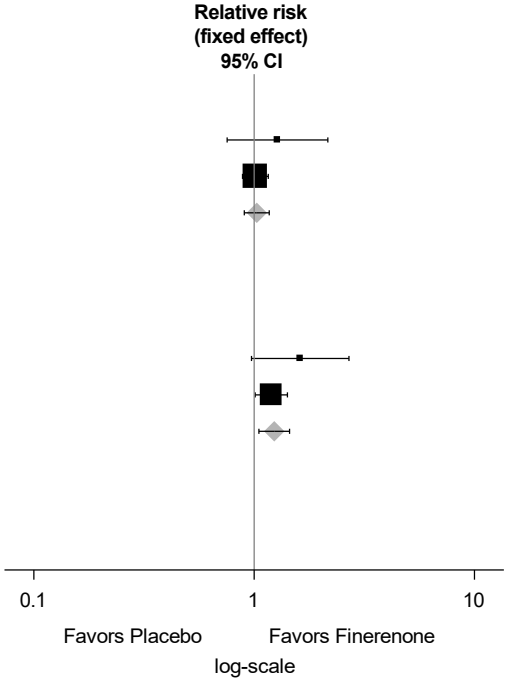
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	30 / 153	29 / 154	7.3	1.04 [0.66,1.65]	
FIGARO-DKD	375 / 1611	348 / 1640	92.7	1.10 [0.96,1.25]	
Total	405 / 1764	377 / 1794		1.09 [0.97,1.24]	Z=1.40, p=0.1602
Heterogeneity:	Q=0.05 (df=1)	p=0.8301	I^2=0.0%		
Female					
FIDELIO-DKD	24 / 58	10 / 67	7.3	2.77 [1.45,5.30]	
FIGARO-DKD	185 / 716	165 / 664	92.7	1.04 [0.87,1.25]	
Total	209 / 774	175 / 731		1.13 [0.95,1.35]	Z=1.40, p=0.1617
Heterogeneity:	Q=8.17 (df=1)	p=0.0043	I^2=87.8%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7444	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.8.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

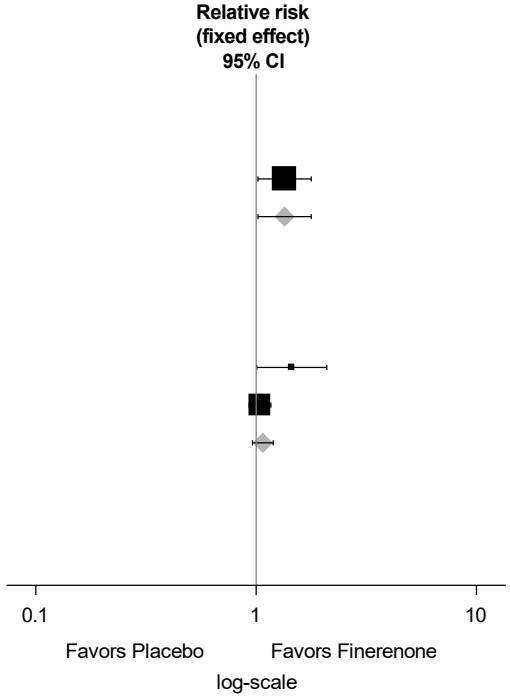
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	25 / 99	19 / 96	6.1	1.28 [0.75,2.16]	
FIGARO-DKD	328 / 1416	325 / 1421	93.9	1.01 [0.89,1.16]	
Total	353 / 1515	344 / 1517		1.03 [0.90,1.17]	Z=0.41, p=0.6835
Heterogeneity:	Q=0.69 (df=1)	p=0.4047	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 112	20 / 125	9.9	1.62 [0.97,2.69]	
FIGARO-DKD	232 / 911	188 / 883	90.1	1.20 [1.01,1.42]	
Total	261 / 1023	208 / 1008		1.23 [1.05,1.45]	Z=2.57, p=0.0102
Heterogeneity:	Q=1.22 (df=1)	p=0.2695	I^2=18.0%		
Subgroup Heterogeneity:	Q=3.01 (df=1)	p=0.0829	I^2=66.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.8.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

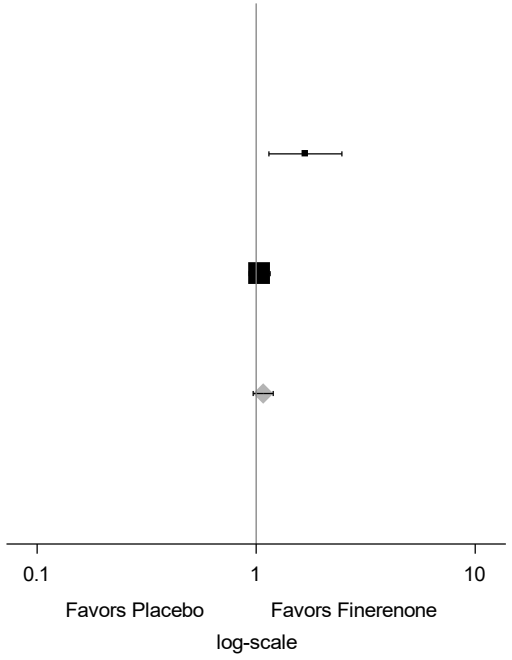
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	94 / 363	66 / 343	100.0	1.35 [1.02,1.78]	
Total	94 / 363	66 / 343		1.35 [1.02,1.78]	Z=2.09, p=0.0363
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 211	39 / 221	8.8	1.45 [1.01,2.09]	
FIGARO-DKD	466 / 1964	447 / 1961	91.2	1.04 [0.93,1.17]	
Total	520 / 2175	486 / 2182		1.07 [0.96,1.20]	Z=1.26, p=0.2064
Heterogeneity:	Q=2.87 (df=1)	p=0.0900	I^2=65.2%		
Subgroup Heterogeneity:	Q=2.22 (df=1)	p=0.1359	I^2=55.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

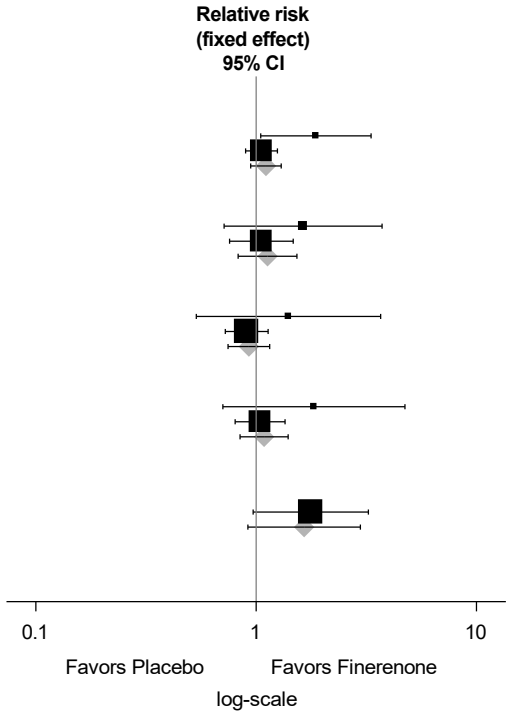
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 211	34 / 221	7.6	1.68 [1.14,2.46]	
FIGARO-DKD	510 / 2327	488 / 2304	92.4	1.04 [0.93,1.16]	
Total	564 / 2538	522 / 2525		1.08 [0.97,1.20]	Z=1.37, p=0.1705
Heterogeneity:	Q=5.57 (df=1)	p=0.0183	I^2=82.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.9.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

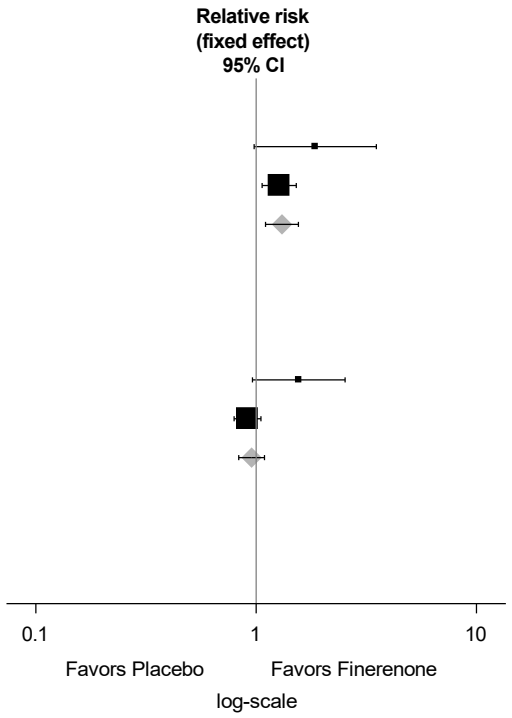
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 104	15 / 112	7.7	1.87 [1.05,3.32]	
FIGARO-DKD	229 / 1114	216 / 1111	92.3	1.06 [0.90,1.25]	
Total	255 / 1218	231 / 1223		1.11 [0.94,1.30]	Z=1.26, p=0.2091
Heterogeneity:	Q=3.45 (df=1)	p=0.0634	I^2=71.0%		
North America					
FIDELIO-DKD	12 / 42	7 / 40	14.0	1.63 [0.72,3.73]	
FIGARO-DKD	59 / 292	53 / 277	86.0	1.06 [0.76,1.47]	
Total	71 / 334	60 / 317		1.13 [0.83,1.53]	Z=0.76, p=0.4494
Heterogeneity:	Q=0.92 (df=1)	p=0.3372	I^2=0.0%		
Asia					
FIDELIO-DKD	8 / 39	6 / 41	5.1	1.40 [0.53,3.67]	
FIGARO-DKD	113 / 522	125 / 523	94.9	0.91 [0.72,1.13]	
Total	121 / 561	131 / 564		0.93 [0.75,1.15]	Z=-0.69, p=0.4920
Heterogeneity:	Q=0.75 (df=1)	p=0.3868	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	5 / 24	7.0	1.83 [0.71,4.74]	
FIGARO-DKD	86 / 322	81 / 316	93.0	1.04 [0.80,1.35]	
Total	94 / 343	86 / 340		1.09 [0.84,1.40]	Z=0.65, p=0.5188
Heterogeneity:	Q=1.25 (df=1)	p=0.2638	I^2=19.9%		
Others					
FIDELIO-DKD	0 / 5	1 / 4	0.0	0.00 [0.00,38E295]	
FIGARO-DKD	23 / 77	13 / 77	100.0	1.77 [0.97,3.23]	
Total	23 / 82	14 / 81		1.65 [0.92,2.97]	Z=1.67, p=0.0947
Heterogeneity:	Q=0.05 (df=1)	p=0.8217	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.06 (df=4)	p=0.3973	I^2=1.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.9.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

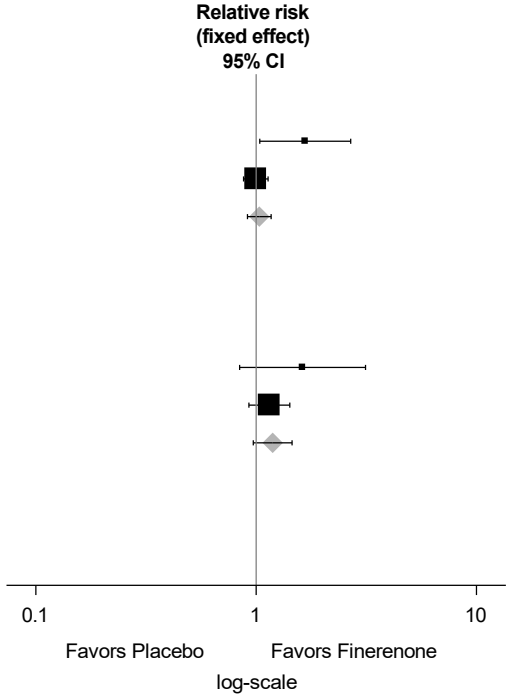
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	22 / 88	12 / 89	7.2	1.85 [0.98,3.51]	
FIGARO-DKD	212 / 811	165 / 803	92.8	1.27 [1.06,1.52]	
Total	234 / 899	177 / 892		1.31 [1.10,1.56]	Z=3.08, p=0.0021
Heterogeneity:	Q=1.24 (df=1)	p=0.2655	I^2=19.3%		
Absent					
FIDELIO-DKD	32 / 123	22 / 132	7.8	1.56 [0.96,2.53]	
FIGARO-DKD	298 / 1516	323 / 1501	92.2	0.91 [0.79,1.05]	
Total	330 / 1639	345 / 1633		0.95 [0.83,1.09]	Z=-0.70, p=0.4870
Heterogeneity:	Q=4.34 (df=1)	p=0.0372	I^2=77.0%		
Subgroup Heterogeneity:	Q=8.13 (df=1)	p=0.0044	I^2=87.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.9.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

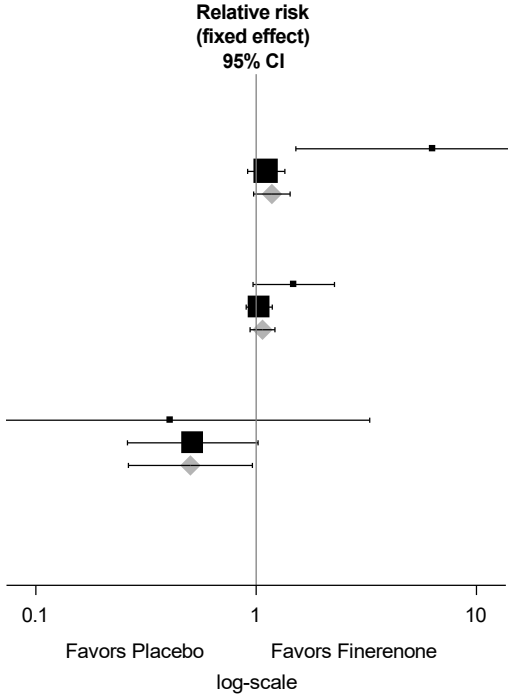
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	35 / 144	23 / 158	6.8	1.67 [1.04,2.69]	
FIGARO-DKD	370 / 1719	363 / 1680	93.2	1.00 [0.88,1.13]	
Total	405 / 1863	386 / 1838		1.03 [0.91,1.17]	Z=0.52, p=0.6054
Heterogeneity:	Q=4.23 (df=1)	p=0.0397	I^2=76.4%		
> 4.5					
FIDELIO-DKD	19 / 67	11 / 63	9.5	1.62 [0.84,3.14]	
FIGARO-DKD	140 / 608	125 / 623	90.5	1.15 [0.93,1.42]	
Total	159 / 675	136 / 686		1.19 [0.97,1.46]	Z=1.67, p=0.0954
Heterogeneity:	Q=0.97 (df=1)	p=0.3252	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2483	I^2=25.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.9.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

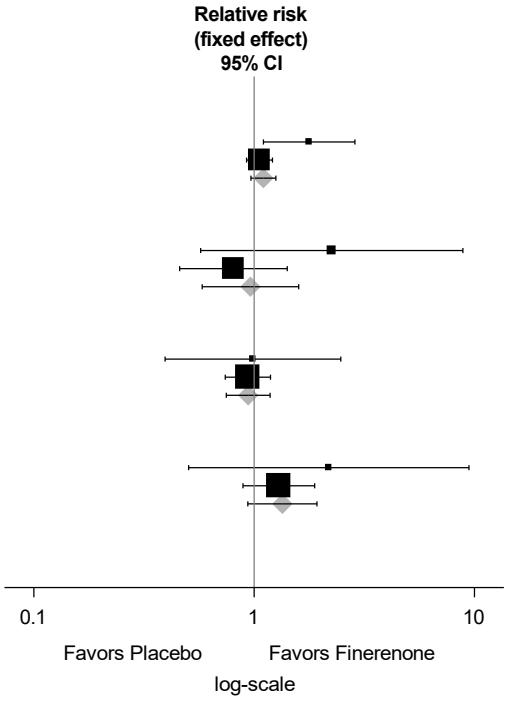
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 64	2 / 54	1.8	6.33 [1.51,26.45]	
FIGARO-DKD	165 / 693	150 / 700	98.2	1.11 [0.91,1.35]	
Total	180 / 757	152 / 754		1.18 [0.97,1.43]	Z=1.69, p=0.0916
Heterogeneity:	Q=5.66 (df=1)	p=0.0174	I^2=82.3%		
130 - < 160					
FIDELIO-DKD	38 / 138	29 / 156	9.3	1.48 [0.97,2.27]	
FIGARO-DKD	335 / 1561	317 / 1525	90.7	1.03 [0.90,1.18]	
Total	373 / 1699	346 / 1681		1.07 [0.94,1.22]	Z=1.00, p=0.3184
Heterogeneity:	Q=2.51 (df=1)	p=0.1133	I^2=60.1%		
>= 160					
FIDELIO-DKD	1 / 9	3 / 11	9.7	0.41 [0.05,3.28]	
FIGARO-DKD	10 / 73	21 / 79	90.3	0.52 [0.26,1.02]	
Total	11 / 82	24 / 90		0.50 [0.26,0.96]	Z=-2.08, p=0.0376
Heterogeneity:	Q=0.04 (df=1)	p=0.8336	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.17 (df=2)	p=0.0456	I^2=67.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.9.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

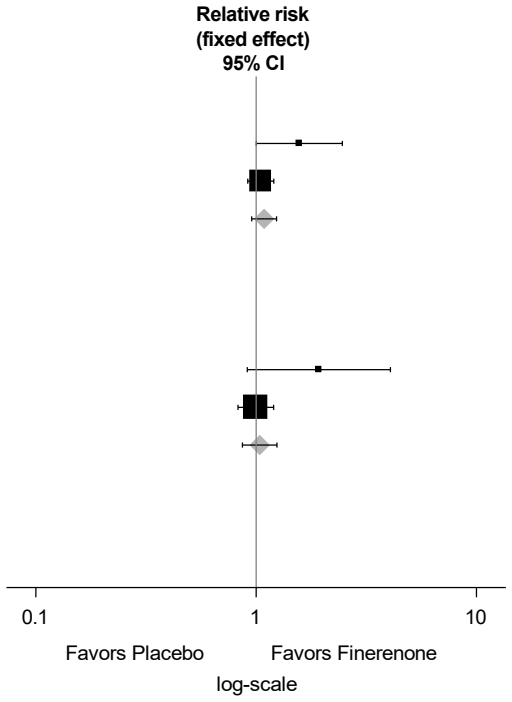
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	36 / 140	22 / 152	7.4	1.78 [1.10,2.87]	
FIGARO-DKD	348 / 1659	320 / 1613	92.6	1.06 [0.92,1.21]	
Total	384 / 1799	342 / 1765		1.10 [0.97,1.25]	Z=1.45, p=0.1467
Heterogeneity:	Q=4.19 (df=1)	p=0.0407	I^2=76.1%		
Black					
FIDELIO-DKD	5 / 10	2 / 9	14.4	2.25 [0.57,8.86]	
FIGARO-DKD	16 / 70	21 / 74	85.6	0.81 [0.46,1.41]	
Total	21 / 80	23 / 83		0.96 [0.58,1.59]	Z=-0.15, p=0.8796
Heterogeneity:	Q=1.86 (df=1)	p=0.1727	I^2=46.2%		
Asian					
FIDELIO-DKD	7 / 39	8 / 44	6.2	0.99 [0.39,2.47]	
FIGARO-DKD	101 / 464	113 / 486	93.8	0.94 [0.74,1.19]	
Total	108 / 503	121 / 530		0.94 [0.75,1.18]	Z=-0.54, p=0.5916
Heterogeneity:	Q=0.01 (df=1)	p=0.9127	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 22	2 / 16	6.1	2.18 [0.50,9.44]	
FIGARO-DKD	45 / 134	34 / 131	93.9	1.29 [0.89,1.88]	
Total	51 / 156	36 / 147		1.34 [0.94,1.93]	Z=1.60, p=0.1099
Heterogeneity:	Q=0.46 (df=1)	p=0.4979	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.11 (df=3)	p=0.3750	I^2=3.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.9.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

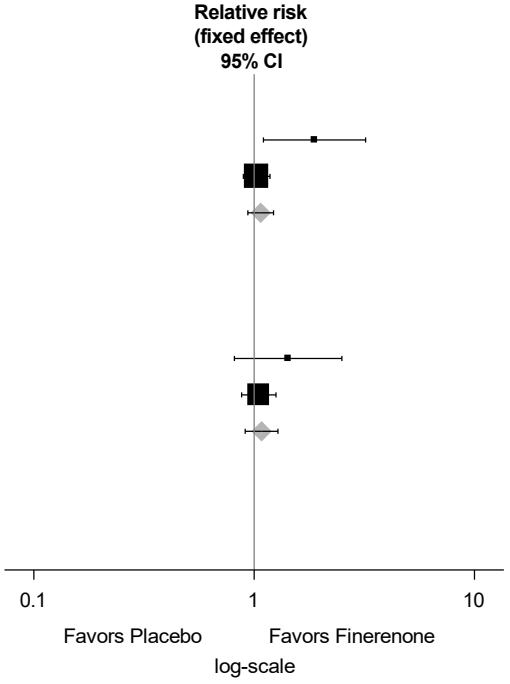
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	39 / 153	25 / 154	8.4	1.57 [1.00,2.46]	
FIGARO-DKD	336 / 1611	326 / 1640	91.6	1.05 [0.92,1.20]	
Total	375 / 1764	351 / 1794		1.09 [0.95,1.24]	Z=1.26, p=0.2094
Heterogeneity:	Q=2.83 (df=1)	p=0.0925	I^2=64.7%		
Female					
FIDELIO-DKD	15 / 58	9 / 67	5.8	1.93 [0.91,4.07]	
FIGARO-DKD	174 / 716	162 / 664	94.2	1.00 [0.83,1.20]	
Total	189 / 774	171 / 731		1.04 [0.87,1.24]	Z=0.40, p=0.6893
Heterogeneity:	Q=2.81 (df=1)	p=0.0937	I^2=64.4%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6828	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.9.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

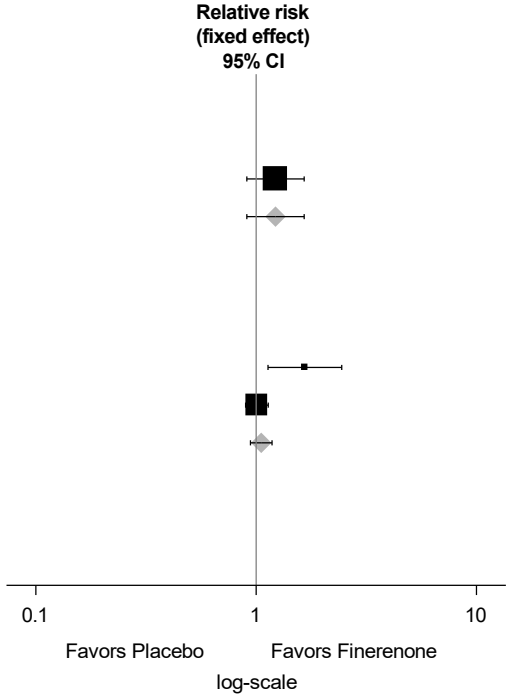
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	31 / 99	16 / 96	6.3	1.88 [1.10,3.20]	
FIGARO-DKD	314 / 1416	307 / 1421	93.7	1.03 [0.89,1.18]	
Total	345 / 1515	323 / 1517		1.07 [0.94,1.22]	Z=1.00, p=0.3190
Heterogeneity:	Q=4.61 (df=1)	p=0.0317	I^2=78.3%		
>= 65					
FIDELIO-DKD	23 / 112	18 / 125	9.3	1.43 [0.81,2.50]	
FIGARO-DKD	196 / 911	181 / 883	90.7	1.05 [0.88,1.26]	
Total	219 / 1023	199 / 1008		1.08 [0.91,1.28]	Z=0.88, p=0.3764
Heterogeneity:	Q=1.04 (df=1)	p=0.3082	I^2=3.7%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9347	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.9.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

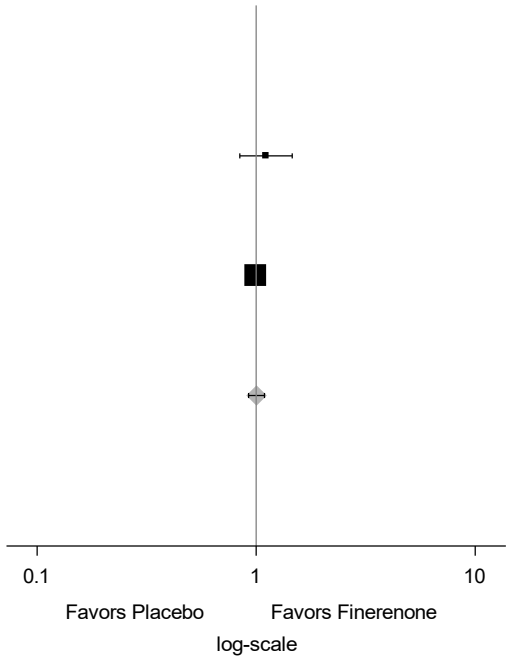
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	79 / 363	61 / 343	100.0	1.22 [0.91,1.65]	
Total	79 / 363	61 / 343		1.22 [0.91,1.65]	Z=1.32, p=0.1867
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 211	34 / 221	8.6	1.66 [1.13,2.45]	
FIGARO-DKD	431 / 1964	427 / 1961	91.4	1.01 [0.90,1.13]	
Total	485 / 2175	461 / 2182		1.05 [0.94,1.18]	Z=0.92, p=0.3580
Heterogeneity:	Q=5.94 (df=1)	p=0.0148	I^2=83.2%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3619	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.10: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

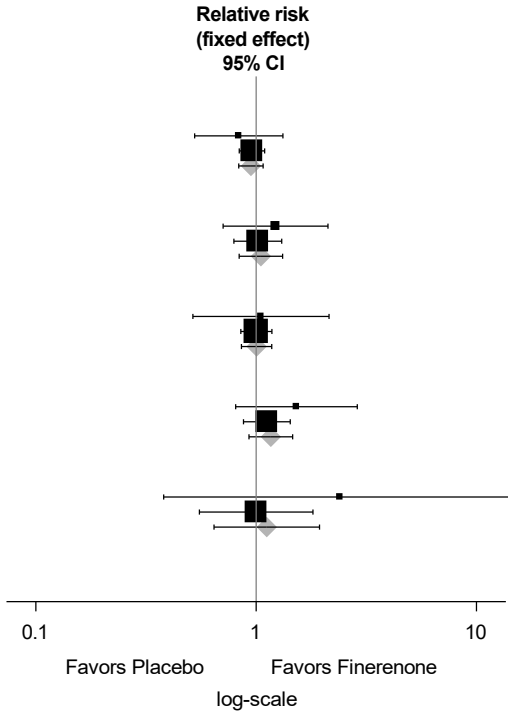
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 211	66 / 221	9.1	1.11 [0.84,1.46]	
FIGARO-DKD	698 / 2327	693 / 2304	90.9	1.00 [0.91,1.09]	
Total	766 / 2538	759 / 2525		1.00 [0.92,1.09]	Z=0.09, p=0.9280
Heterogeneity:	Q=0.53 (df=1)	p=0.4679	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.10.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

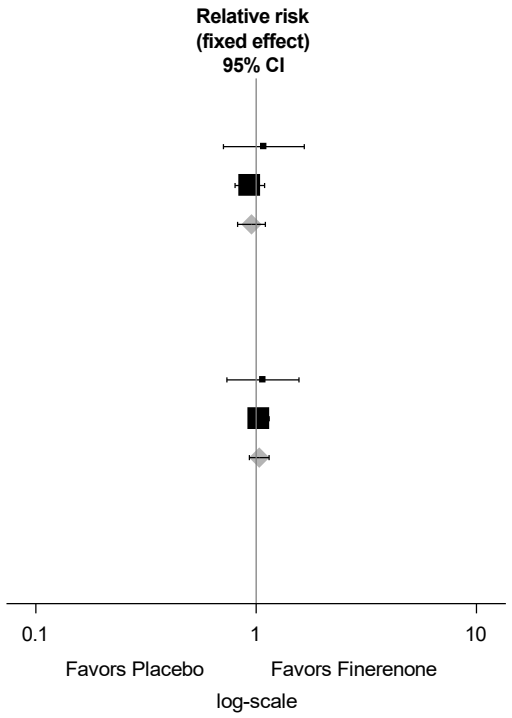
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	24 / 104	31 / 112	7.6	0.83 [0.53,1.32]	
FIGARO-DKD	307 / 1114	320 / 1111	92.4	0.96 [0.84,1.09]	
Total	331 / 1218	351 / 1223		0.95 [0.83,1.08]	Z=-0.84, p=0.3994
Heterogeneity:	Q=0.32 (df=1)	p=0.5740	I^2=0.0%		
North America					
FIDELIO-DKD	18 / 42	14 / 40	17.2	1.22 [0.71,2.12]	
FIGARO-DKD	89 / 292	83 / 277	82.8	1.02 [0.79,1.31]	
Total	107 / 334	97 / 317		1.05 [0.84,1.32]	Z=0.43, p=0.6695
Heterogeneity:	Q=0.36 (df=1)	p=0.5461	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 39	11 / 41	5.0	1.05 [0.52,2.14]	
FIGARO-DKD	187 / 522	187 / 523	95.0	1.00 [0.85,1.18]	
Total	198 / 561	198 / 564		1.00 [0.86,1.18]	Z=0.05, p=0.9576
Heterogeneity:	Q=0.02 (df=1)	p=0.8972	I^2=0.0%		
Latin America					
FIDELIO-DKD	12 / 21	9 / 24	12.9	1.52 [0.81,2.88]	
FIGARO-DKD	98 / 322	86 / 316	87.1	1.12 [0.88,1.43]	
Total	110 / 343	95 / 340		1.17 [0.93,1.46]	Z=1.32, p=0.1883
Heterogeneity:	Q=0.79 (df=1)	p=0.3732	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 5	1 / 4	9.4	2.40 [0.38,15.14]	
FIGARO-DKD	17 / 77	17 / 77	90.6	1.00 [0.55,1.81]	
Total	20 / 82	18 / 81		1.12 [0.64,1.94]	Z=0.39, p=0.6941
Heterogeneity:	Q=0.80 (df=1)	p=0.3724	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=4)	p=0.6004	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.10.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

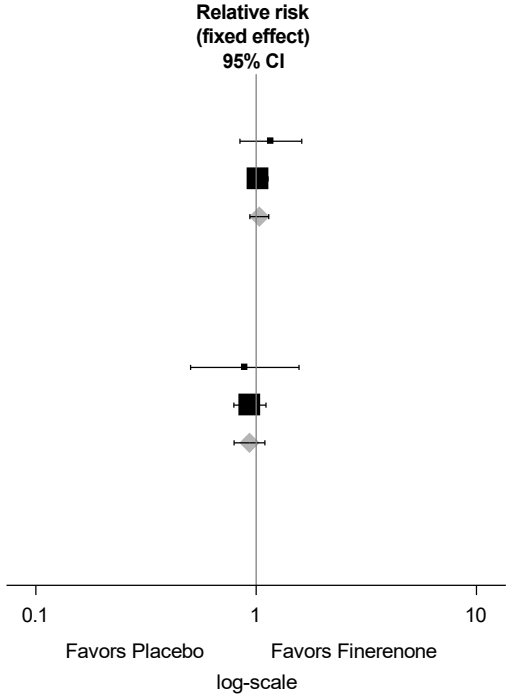
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	30 / 88	28 / 89	11.8	1.08 [0.71,1.65]	
FIGARO-DKD	224 / 811	237 / 803	88.2	0.94 [0.80,1.09]	
Total	254 / 899	265 / 892		0.95 [0.82,1.10]	Z=-0.66, p=0.5073
Heterogeneity:	Q=0.41 (df=1)	p=0.5228	I^2=0.0%		
Absent					
FIDELIO-DKD	38 / 123	38 / 132	7.5	1.07 [0.74,1.56]	
FIGARO-DKD	474 / 1516	456 / 1501	92.5	1.03 [0.92,1.15]	
Total	512 / 1639	494 / 1633		1.03 [0.93,1.14]	Z=0.61, p=0.5435
Heterogeneity:	Q=0.04 (df=1)	p=0.8341	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.80 (df=1)	p=0.3722	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.10.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

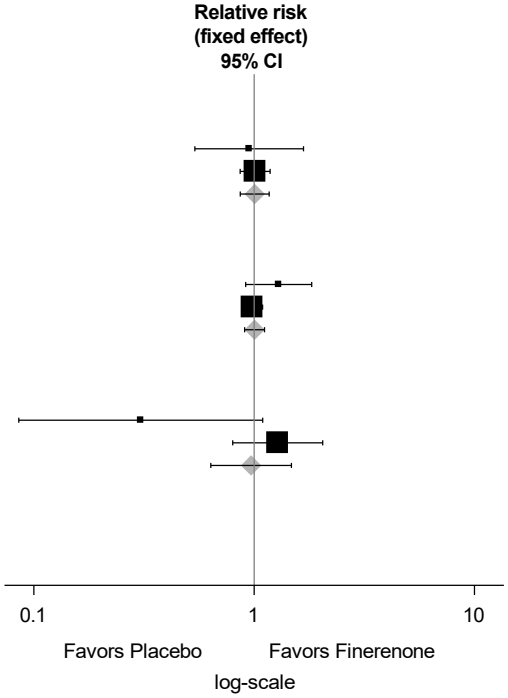
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	51 / 144	48 / 158	9.3	1.17 [0.84,1.61]	
FIGARO-DKD	517 / 1719	495 / 1680	90.7	1.02 [0.92,1.13]	
Total	568 / 1863	543 / 1838		1.03 [0.94,1.14]	Z=0.65, p=0.5127
Heterogeneity:	Q=0.59 (df=1)	p=0.4426	I^2=0.0%		
> 4.5					
FIDELIO-DKD	17 / 67	18 / 63	8.1	0.89 [0.50,1.57]	
FIGARO-DKD	181 / 608	198 / 623	91.9	0.94 [0.79,1.11]	
Total	198 / 675	216 / 686		0.93 [0.79,1.10]	Z=-0.85, p=0.3958
Heterogeneity:	Q=0.03 (df=1)	p=0.8596	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.14 (df=1)	p=0.2864	I^2=12.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.10.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

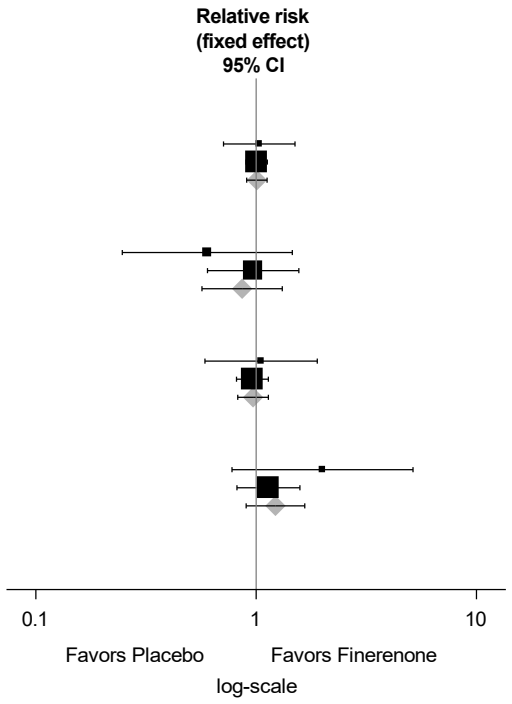
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	18 / 64	16 / 54	7.1	0.95 [0.54,1.67]	
FIGARO-DKD	216 / 693	216 / 700	92.9	1.01 [0.86,1.18]	
Total	234 / 757	232 / 754		1.01 [0.86,1.17]	Z=0.07, p=0.9414
Heterogeneity:	Q=0.04 (df=1)	p=0.8361	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	48 / 138	42 / 156	9.1	1.29 [0.91,1.82]	
FIGARO-DKD	456 / 1561	455 / 1525	90.9	0.98 [0.88,1.09]	
Total	504 / 1699	497 / 1681		1.00 [0.90,1.11]	Z=0.08, p=0.9381
Heterogeneity:	Q=2.26 (df=1)	p=0.1331	I^2=55.7%		
>= 160					
FIDELIO-DKD	2 / 9	8 / 11	12.0	0.31 [0.09,1.09]	
FIGARO-DKD	26 / 73	22 / 79	88.0	1.28 [0.80,2.05]	
Total	28 / 82	30 / 90		0.97 [0.64,1.48]	Z=-0.15, p=0.8815
Heterogeneity:	Q=4.49 (df=1)	p=0.0341	I^2=77.7%		
Subgroup Heterogeneity:	Q=0.03 (df=2)	p=0.9860	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.10.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

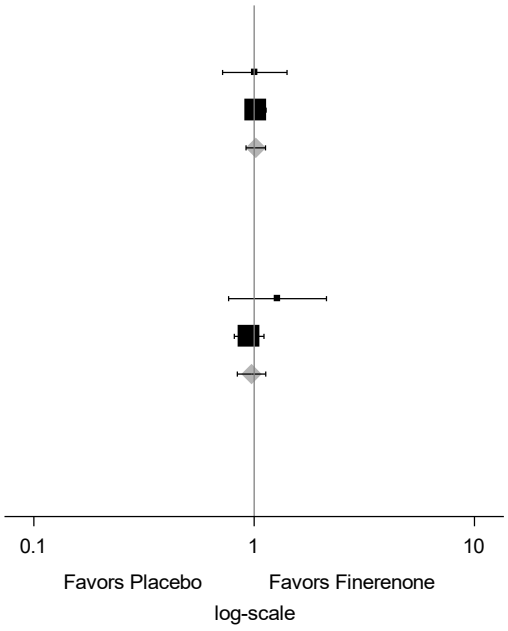
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	39 / 140	41 / 152	8.1	1.03 [0.71,1.50]	
FIGARO-DKD	458 / 1659	443 / 1613	91.9	1.01 [0.90,1.12]	
Total	497 / 1799	484 / 1765		1.01 [0.91,1.12]	Z=0.14, p=0.8920
Heterogeneity:	Q=0.02 (df=1)	p=0.8918	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	6 / 9	22.4	0.60 [0.25,1.46]	
FIGARO-DKD	22 / 70	24 / 74	77.6	0.97 [0.60,1.56]	
Total	26 / 80	30 / 83		0.86 [0.57,1.31]	Z=-0.69, p=0.4928
Heterogeneity:	Q=0.87 (df=1)	p=0.3512	I^2=0.0%		
Asian					
FIDELIO-DKD	14 / 39	15 / 44	7.4	1.05 [0.59,1.89]	
FIGARO-DKD	168 / 464	183 / 486	92.6	0.96 [0.81,1.14]	
Total	182 / 503	198 / 530		0.97 [0.82,1.14]	Z=-0.40, p=0.6909
Heterogeneity:	Q=0.09 (df=1)	p=0.7705	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 22	4 / 16	10.8	2.00 [0.78,5.15]	
FIGARO-DKD	50 / 134	43 / 131	89.2	1.14 [0.82,1.58]	
Total	61 / 156	47 / 147		1.22 [0.90,1.66]	Z=1.29, p=0.1971
Heterogeneity:	Q=1.23 (df=1)	p=0.2677	I^2=18.6%		
Subgroup Heterogeneity:	Q=2.30 (df=3)	p=0.5130	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.10.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

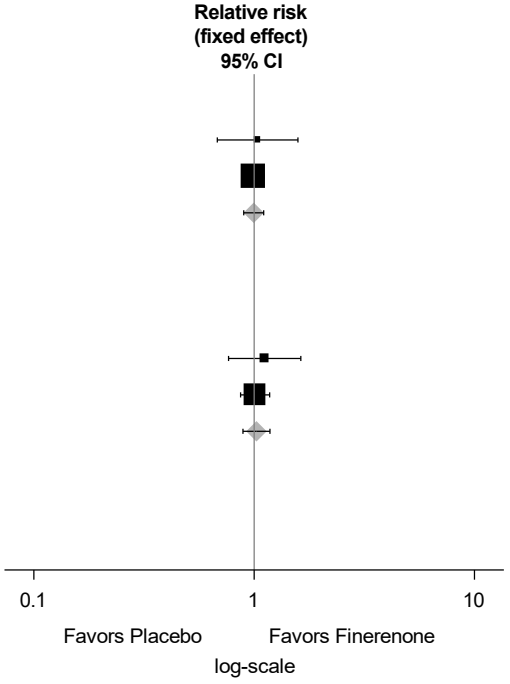
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	47 / 153	47 / 154	9.1	1.01 [0.72,1.41]	
FIGARO-DKD	477 / 1611	477 / 1640	90.9	1.02 [0.91,1.13]	
Total	524 / 1764	524 / 1794		1.02 [0.92,1.13]	Z=0.32, p=0.7460
Heterogeneity:	Q=0.00 (df=1)	p=0.9499	I^2=0.0%		
Female					
FIDELIO-DKD	21 / 58	19 / 67	8.4	1.28 [0.77,2.13]	
FIGARO-DKD	221 / 716	216 / 664	91.6	0.95 [0.81,1.11]	
Total	242 / 774	235 / 731		0.97 [0.84,1.13]	Z=-0.36, p=0.7158
Heterogeneity:	Q=1.19 (df=1)	p=0.2763	I^2=15.6%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6288	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.10.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

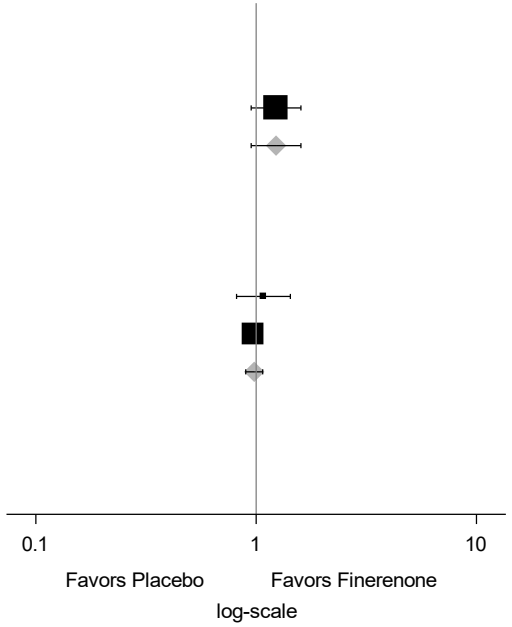
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	31 / 99	29 / 96	6.1	1.04 [0.68,1.58]	
FIGARO-DKD	450 / 1416	455 / 1421	93.9	0.99 [0.89,1.11]	
Total	481 / 1515	484 / 1517		1.00 [0.90,1.10]	Z=-0.09, p=0.9271
Heterogeneity:	Q=0.04 (df=1)	p=0.8448	I^2=0.0%		
>= 65					
FIDELIO-DKD	37 / 112	37 / 125	13.9	1.12 [0.77,1.63]	
FIGARO-DKD	248 / 911	238 / 883	86.1	1.01 [0.87,1.18]	
Total	285 / 1023	275 / 1008		1.02 [0.89,1.18]	Z=0.33, p=0.7404
Heterogeneity:	Q=0.23 (df=1)	p=0.6306	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7483	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.10.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

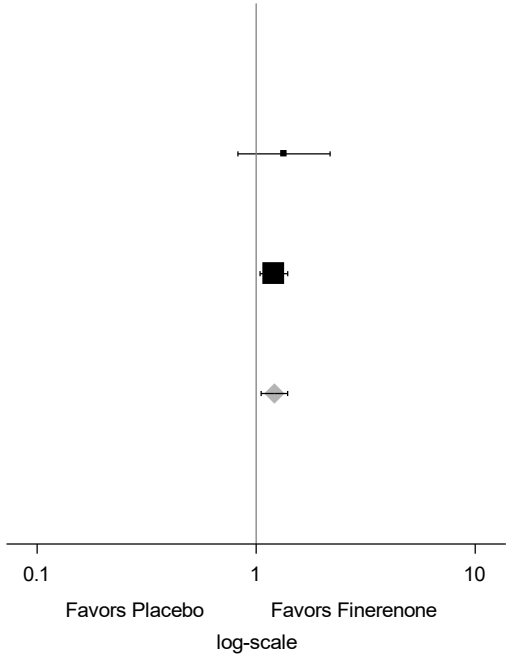
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	99 / 363	76 / 343	100.0	1.23 [0.95,1.60]	
Total	99 / 363	76 / 343		1.23 [0.95,1.60]	Z=1.57, p=0.1173
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	68 / 211	66 / 221	9.9	1.08 [0.81,1.43]	
FIGARO-DKD	599 / 1964	617 / 1961	90.1	0.97 [0.88,1.06]	
Total	667 / 2175	683 / 2182		0.98 [0.90,1.07]	Z=-0.45, p=0.6506
Heterogeneity:	Q=0.50 (df=1)	p=0.4780	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.65 (df=1)	p=0.1034	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.11: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

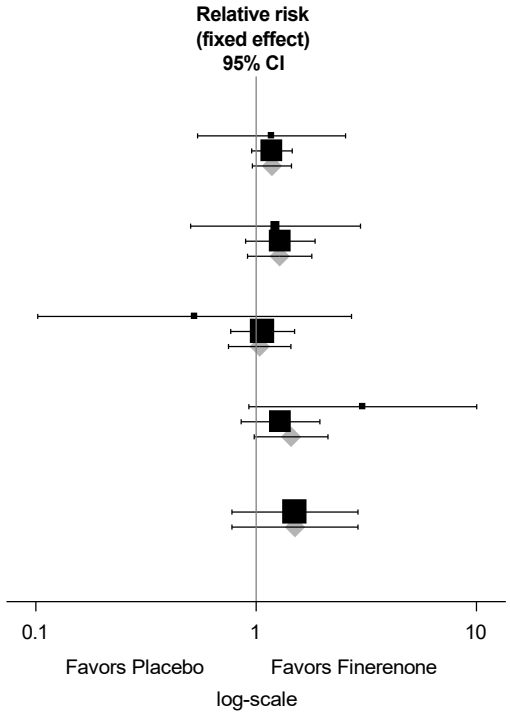
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 211	25 / 221	8.3	1.34 [0.83,2.18]	
FIGARO-DKD	346 / 2327	285 / 2304	91.7	1.20 [1.04,1.39]	
Total	377 / 2538	310 / 2525		1.21 [1.05,1.39]	Z=2.69, p=0.0071
Heterogeneity:	Q=0.17 (df=1)	p=0.6778	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.11.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

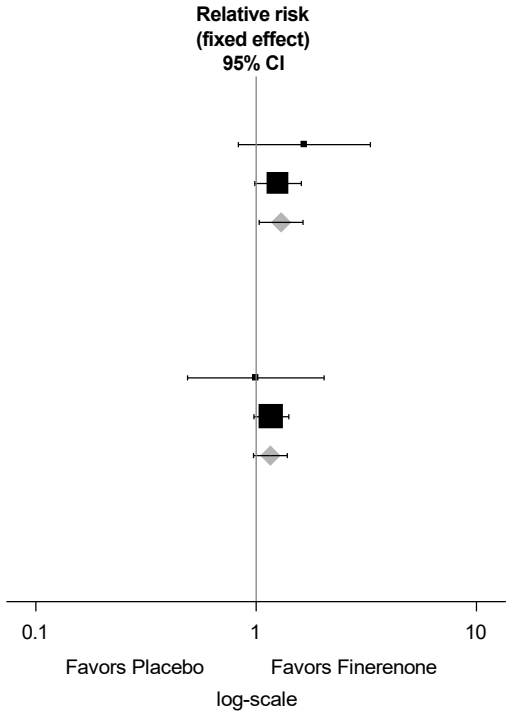
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 104	11 / 112	7.0	1.17 [0.54,2.55]	
FIGARO-DKD	162 / 1114	137 / 1111	93.0	1.18 [0.95,1.46]	
Total	174 / 1218	148 / 1223		1.18 [0.96,1.45]	Z=1.58, p=0.1141
Heterogeneity:	Q=0.00 (df=1)	p=0.9926	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	7 / 40	14.3	1.22 [0.50,2.98]	
FIGARO-DKD	57 / 292	42 / 277	85.7	1.29 [0.90,1.85]	
Total	66 / 334	49 / 317		1.28 [0.91,1.79]	Z=1.43, p=0.1522
Heterogeneity:	Q=0.01 (df=1)	p=0.9184	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	4 / 41	4.0	0.53 [0.10,2.71]	
FIGARO-DKD	63 / 522	59 / 523	96.0	1.07 [0.77,1.49]	
Total	65 / 561	63 / 564		1.04 [0.75,1.44]	Z=0.22, p=0.8249
Heterogeneity:	Q=0.69 (df=1)	p=0.4051	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	3 / 24	10.7	3.05 [0.93,10.02]	
FIGARO-DKD	46 / 322	35 / 316	89.3	1.29 [0.85,1.95]	
Total	54 / 343	38 / 340		1.44 [0.98,2.12]	Z=1.86, p=0.0636
Heterogeneity:	Q=1.80 (df=1)	p=0.1799	I^2=44.4%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	18 / 77	12 / 77	100.0	1.50 [0.78,2.90]	
Total	18 / 82	12 / 81		1.50 [0.78,2.90]	Z=1.21, p=0.2276
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.21 (df=4)	p=0.6966	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.11.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

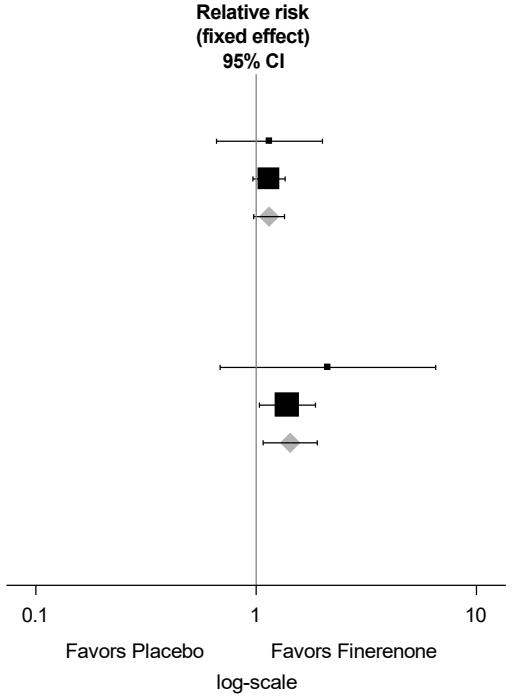
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	18 / 88	11 / 89	11.1	1.65 [0.83,3.30]	
FIGARO-DKD	127 / 811	100 / 803	88.9	1.26 [0.99,1.60]	
Total	145 / 899	111 / 892		1.30 [1.03,1.63]	Z=2.23, p=0.0259
Heterogeneity:	Q=0.54 (df=1)	p=0.4617	I^2=0.0%		
Absent					
FIDELIO-DKD	13 / 123	14 / 132	6.1	1.00 [0.49,2.03]	
FIGARO-DKD	219 / 1516	185 / 1501	93.9	1.17 [0.98,1.41]	
Total	232 / 1639	199 / 1633		1.16 [0.97,1.38]	Z=1.65, p=0.0984
Heterogeneity:	Q=0.19 (df=1)	p=0.6660	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4494	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.11.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

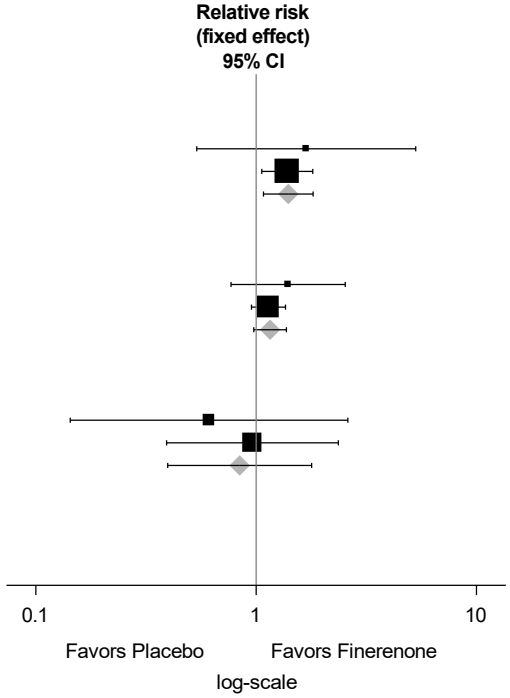
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 144	21 / 158	8.5	1.15 [0.66,2.00]	
FIGARO-DKD	254 / 1719	217 / 1680	91.5	1.14 [0.97,1.35]	
Total	276 / 1863	238 / 1838		1.14 [0.97,1.34]	Z=1.64, p=0.1005
Heterogeneity:	Q=0.00 (df=1)	p=0.9870	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 67	4 / 63	6.3	2.12 [0.69,6.53]	
FIGARO-DKD	92 / 608	68 / 623	93.7	1.39 [1.03,1.86]	
Total	101 / 675	72 / 686		1.43 [1.08,1.89]	Z=2.46, p=0.0138
Heterogeneity:	Q=0.51 (df=1)	p=0.4765	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.76 (df=1)	p=0.1841	I^2=43.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.11.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

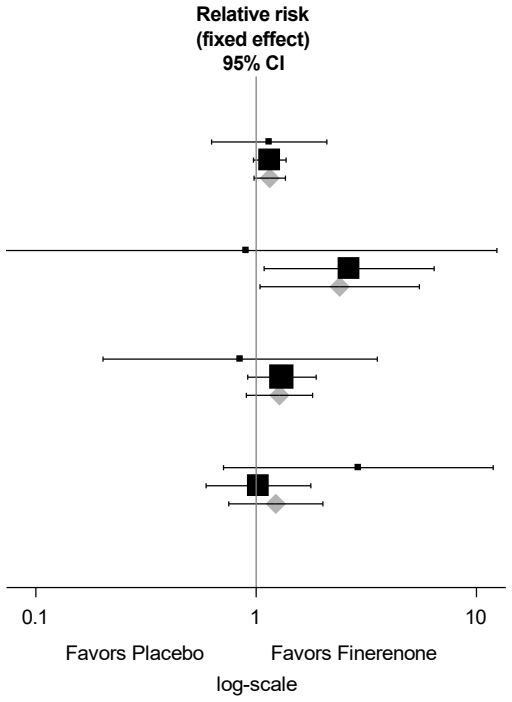
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 64	4 / 54	5.1	1.69 [0.54,5.30]	
FIGARO-DKD	111 / 693	81 / 700	94.9	1.38 [1.06,1.81]	
Total	119 / 757	85 / 754		1.40 [1.08,1.81]	Z=2.54, p=0.0112
Heterogeneity:	Q=0.11 (df=1)	p=0.7410	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	21 / 138	17 / 156	8.2	1.40 [0.77,2.54]	
FIGARO-DKD	227 / 1561	195 / 1525	91.8	1.14 [0.95,1.36]	
Total	248 / 1699	212 / 1681		1.16 [0.98,1.37]	Z=1.67, p=0.0945
Heterogeneity:	Q=0.42 (df=1)	p=0.5183	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 9	4 / 11	27.7	0.61 [0.14,2.61]	
FIGARO-DKD	8 / 73	9 / 79	72.3	0.96 [0.39,2.36]	
Total	10 / 82	13 / 90		0.84 [0.40,1.79]	Z=-0.45, p=0.6531
Heterogeneity:	Q=0.27 (df=1)	p=0.6019	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.37 (df=2)	p=0.3064	I^2=15.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.11.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

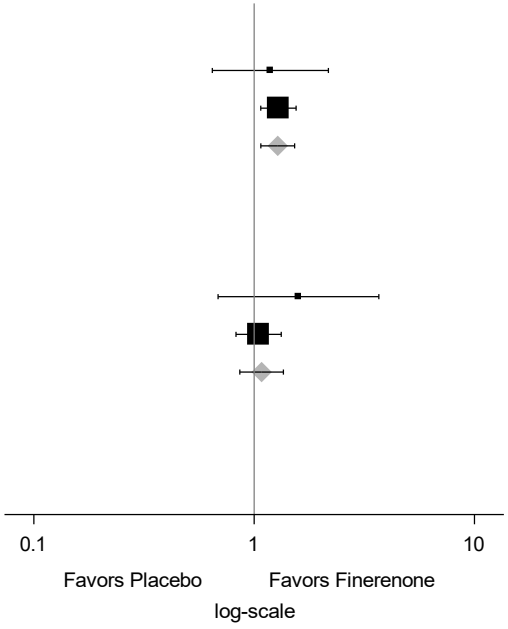
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	19 / 140	18 / 152	7.4	1.15 [0.63,2.09]	
FIGARO-DKD	249 / 1659	210 / 1613	92.6	1.15 [0.97,1.37]	
Total	268 / 1799	228 / 1765		1.15 [0.98,1.36]	Z=1.70, p=0.0900
Heterogeneity:	Q=0.00 (df=1)	p=0.9852	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	10.3	0.90 [0.07,12.38]	
FIGARO-DKD	15 / 70	6 / 74	89.7	2.64 [1.09,6.43]	
Total	16 / 80	7 / 83		2.39 [1.04,5.51]	Z=2.05, p=0.0400
Heterogeneity:	Q=0.58 (df=1)	p=0.4453	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	4 / 44	5.9	0.85 [0.20,3.55]	
FIGARO-DKD	60 / 464	48 / 486	94.1	1.31 [0.92,1.87]	
Total	63 / 503	52 / 530		1.28 [0.90,1.80]	Z=1.38, p=0.1680
Heterogeneity:	Q=0.34 (df=1)	p=0.5625	I^2=0.0%		
Others					
FIDELIO-DKD	8 / 22	2 / 16	13.1	2.91 [0.71,11.91]	
FIGARO-DKD	22 / 134	21 / 131	86.9	1.02 [0.59,1.77]	
Total	30 / 156	23 / 147		1.23 [0.75,2.01]	Z=0.82, p=0.4132
Heterogeneity:	Q=1.86 (df=1)	p=0.1725	I^2=46.3%		
Subgroup Heterogeneity:	Q=3.00 (df=3)	p=0.3911	I^2=0.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.11.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

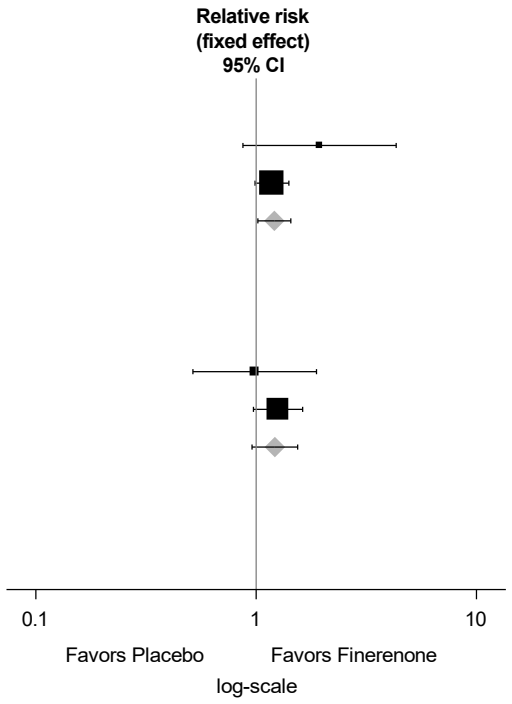
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	20 / 153	17 / 154	8.5	1.18 [0.65,2.17]	
FIGARO-DKD	224 / 1611	177 / 1640	91.5	1.29 [1.07,1.55]	
Total	244 / 1764	194 / 1794		1.28 [1.07,1.53]	Z=2.73, p=0.0063
Heterogeneity:	Q=0.07 (df=1)	p=0.7944	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 58	8 / 67	7.3	1.59 [0.69,3.68]	
FIGARO-DKD	122 / 716	108 / 664	92.7	1.05 [0.83,1.33]	
Total	133 / 774	116 / 731		1.08 [0.86,1.36]	Z=0.67, p=0.5035
Heterogeneity:	Q=0.87 (df=1)	p=0.3499	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.31 (df=1)	p=0.2519	I^2=23.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.11.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

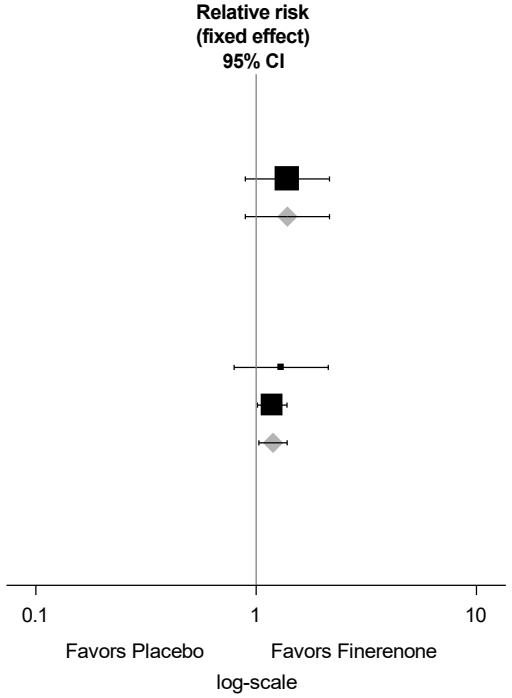
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	16 / 99	8 / 96	4.6	1.94 [0.87,4.32]	
FIGARO-DKD	228 / 1416	194 / 1421	95.4	1.18 [0.99,1.41]	
Total	244 / 1515	202 / 1517		1.21 [1.02,1.44]	Z=2.16, p=0.0308
Heterogeneity:	Q=1.41 (df=1)	p=0.2346	I^2=29.2%		
>= 65					
FIDELIO-DKD	15 / 112	17 / 125	13.7	0.98 [0.52,1.88]	
FIGARO-DKD	118 / 911	91 / 883	86.3	1.26 [0.97,1.63]	
Total	133 / 1023	108 / 1008		1.22 [0.96,1.54]	Z=1.60, p=0.1087
Heterogeneity:	Q=0.47 (df=1)	p=0.4916	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9719	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.11.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

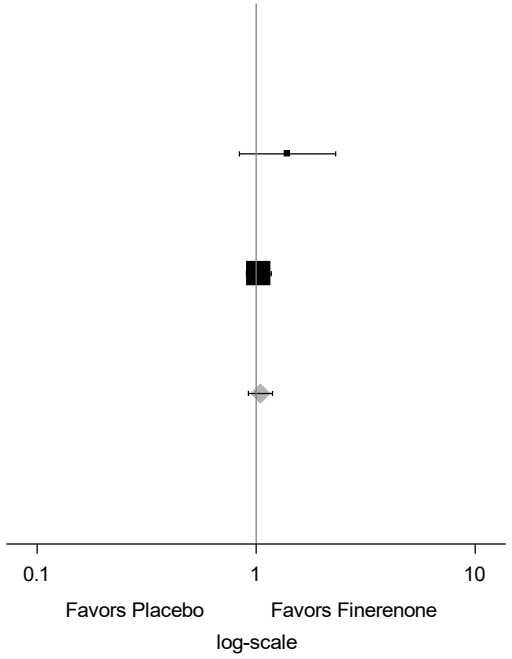
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	44 / 363	30 / 343	100.0	1.39 [0.89,2.15]	
Total	44 / 363	30 / 343		1.39 [0.89,2.15]	Z=1.45, p=0.1460
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	31 / 211	25 / 221	9.0	1.30 [0.79,2.12]	
FIGARO-DKD	302 / 1964	255 / 1961	91.0	1.18 [1.01,1.38]	
Total	333 / 2175	280 / 2182		1.19 [1.03,1.38]	Z=2.34, p=0.0192
Heterogeneity:	Q=0.13 (df=1)	p=0.7215	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=1)	p=0.5257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.12: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

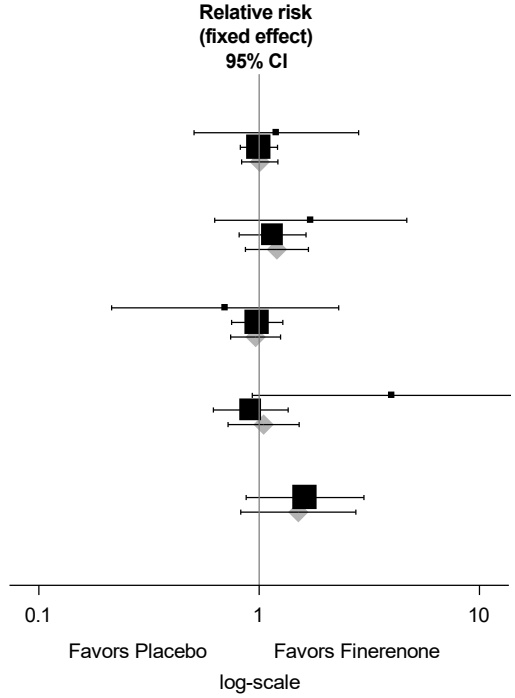
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 211	23 / 221	6.3	1.39 [0.84,2.31]	
FIGARO-DKD	380 / 2327	367 / 2304	93.7	1.03 [0.90,1.17]	
Total	410 / 2538	390 / 2525		1.05 [0.92,1.19]	Z=0.70, p=0.4864
Heterogeneity:	Q=1.28 (df=1)	p=0.2579	I^2=21.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.2.12.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

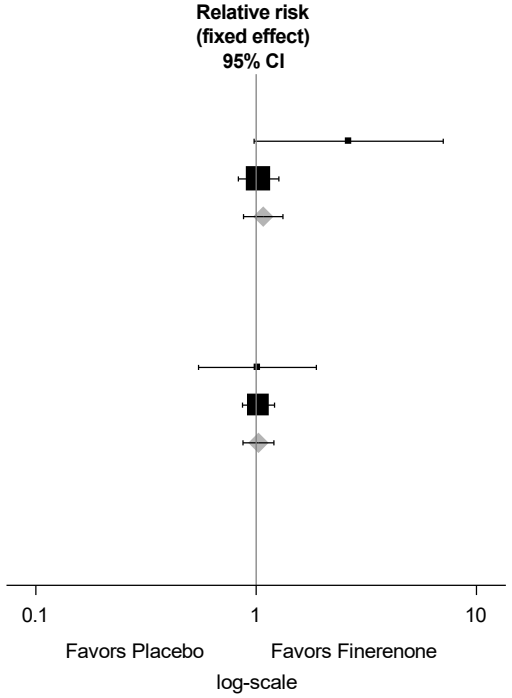
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 104	9 / 112	4.9	1.20 [0.51,2.83]	
FIGARO-DKD	172 / 1114	172 / 1111	95.1	1.00 [0.82,1.21]	
Total	182 / 1218	181 / 1223		1.01 [0.83,1.22]	Z=0.06, p=0.9491
Heterogeneity:	Q=0.16 (df=1)	p=0.6855	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	5 / 40	10.8	1.71 [0.63,4.68]	
FIGARO-DKD	57 / 292	47 / 277	89.2	1.15 [0.81,1.63]	
Total	66 / 334	52 / 317		1.20 [0.87,1.67]	Z=1.10, p=0.2694
Heterogeneity:	Q=0.54 (df=1)	p=0.4620	I^2=0.0%		
Asia					
FIDELIO-DKD	4 / 39	6 / 41	4.8	0.70 [0.21,2.30]	
FIGARO-DKD	88 / 522	90 / 523	95.2	0.98 [0.75,1.28]	
Total	92 / 561	96 / 564		0.96 [0.74,1.25]	Z=-0.28, p=0.7797
Heterogeneity:	Q=0.29 (df=1)	p=0.5895	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 21	2 / 24	6.7	4.00 [0.93,17.19]	
FIGARO-DKD	42 / 322	45 / 316	93.3	0.92 [0.62,1.35]	
Total	49 / 343	47 / 340		1.05 [0.72,1.52]	Z=0.24, p=0.8070
Heterogeneity:	Q=3.70 (df=1)	p=0.0545	I^2=72.9%		
Others					
FIDELIO-DKD	0 / 5	1 / 4	0.0	0.00 [0.00,38E295]	
FIGARO-DKD	21 / 77	13 / 77	100.0	1.62 [0.87,2.99]	
Total	21 / 82	14 / 81		1.51 [0.82,2.75]	Z=1.33, p=0.1826
Heterogeneity:	Q=0.05 (df=1)	p=0.8222	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.65 (df=4)	p=0.6180	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.12.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

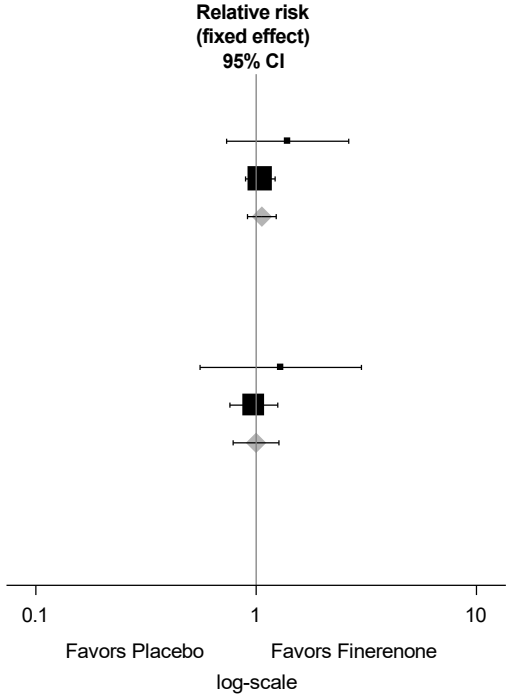
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 88	5 / 89	4.4	2.63 [0.98,7.07]	
FIGARO-DKD	144 / 811	139 / 803	95.6	1.03 [0.83,1.27]	
Total	157 / 899	144 / 892		1.08 [0.88,1.32]	Z=0.70, p=0.4827
Heterogeneity:	Q=3.34 (df=1)	p=0.0678	I^2=70.0%		
Absent					
FIDELIO-DKD	17 / 123	18 / 132	6.9	1.01 [0.55,1.88]	
FIGARO-DKD	236 / 1516	228 / 1501	93.1	1.02 [0.87,1.21]	
Total	253 / 1639	246 / 1633		1.02 [0.87,1.20]	Z=0.29, p=0.7730
Heterogeneity:	Q=0.00 (df=1)	p=0.9728	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7083	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.12.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

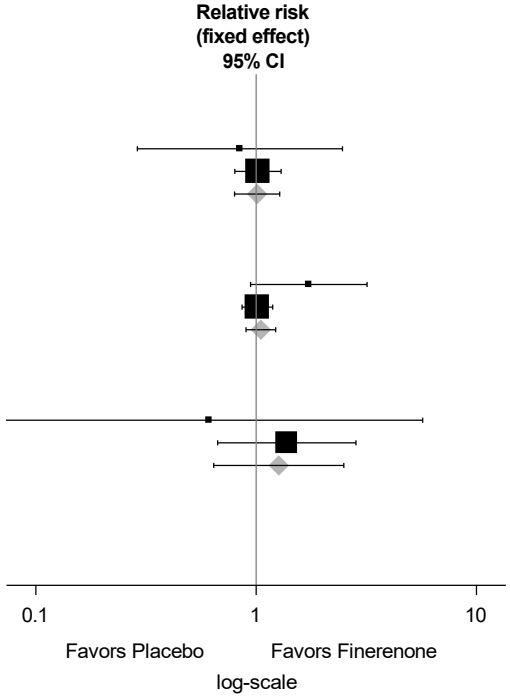
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 144	15 / 158	5.5	1.39 [0.73,2.63]	
FIGARO-DKD	280 / 1719	262 / 1680	94.5	1.04 [0.89,1.22]	
Total	299 / 1863	277 / 1838		1.06 [0.91,1.23]	Z=0.78, p=0.4374
Heterogeneity:	Q=0.73 (df=1)	p=0.3938	I^2=0.0%		
> 4.5					
FIDELIO-DKD	11 / 67	8 / 63	8.1	1.29 [0.56,3.00]	
FIGARO-DKD	100 / 608	105 / 623	91.9	0.98 [0.76,1.25]	
Total	111 / 675	113 / 686		1.00 [0.79,1.27]	Z=-0.01, p=0.9916
Heterogeneity:	Q=0.39 (df=1)	p=0.5307	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6733	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.12.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 64	6 / 54	4.8	0.84 [0.29,2.46]	
FIGARO-DKD	111 / 693	110 / 700	95.2	1.02 [0.80,1.30]	
Total	117 / 757	116 / 754		1.01 [0.80,1.28]	Z=0.08, p=0.9340
Heterogeneity:	Q=0.11 (df=1)	p=0.7361	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 138	15 / 156	6.5	1.73 [0.94,3.19]	
FIGARO-DKD	255 / 1561	246 / 1525	93.5	1.01 [0.86,1.19]	
Total	278 / 1699	261 / 1681		1.05 [0.90,1.23]	Z=0.62, p=0.5372
Heterogeneity:	Q=2.80 (df=1)	p=0.0943	I^2=64.3%		
>= 160					
FIDELIO-DKD	1 / 9	2 / 11	9.5	0.61 [0.07,5.70]	
FIGARO-DKD	14 / 73	11 / 79	90.5	1.38 [0.67,2.84]	
Total	15 / 82	13 / 90		1.27 [0.64,2.50]	Z=0.68, p=0.4955
Heterogeneity:	Q=0.46 (df=1)	p=0.4972	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.39 (df=2)	p=0.8224	I^2=0.0%		

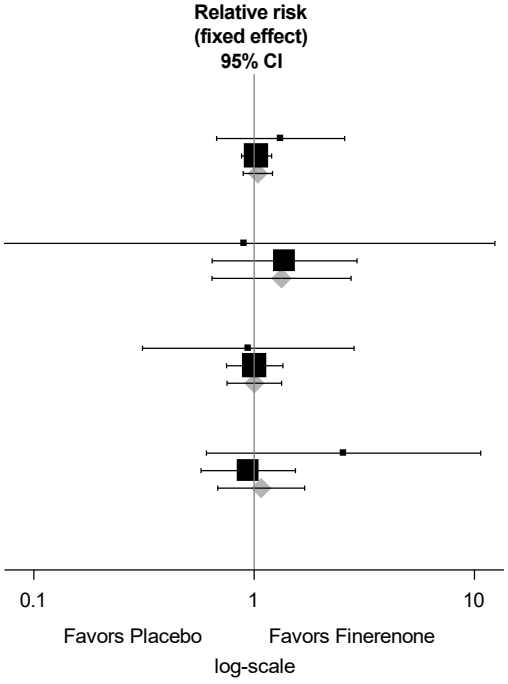


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.2.12.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race

Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 140	14 / 152	5.2	1.32 [0.68,2.57]	
FIGARO-DKD	269 / 1659	255 / 1613	94.8	1.03 [0.88,1.20]	
Total	286 / 1799	269 / 1765		1.04 [0.89,1.21]	Z=0.49, p=0.6212
Heterogeneity:	Q=0.51 (df=1)	p=0.4740	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	7.7	0.90 [0.07,12.38]	
FIGARO-DKD	13 / 70	10 / 74	92.3	1.37 [0.64,2.93]	
Total	14 / 80	11 / 83		1.33 [0.64,2.75]	Z=0.77, p=0.4406
Heterogeneity:	Q=0.09 (df=1)	p=0.7611	I^2=0.0%		
Asian					
FIDELIO-DKD	5 / 39	6 / 44	6.6	0.94 [0.31,2.84]	
FIGARO-DKD	73 / 464	76 / 486	93.4	1.01 [0.75,1.35]	
Total	78 / 503	82 / 530		1.00 [0.75,1.33]	Z=0.01, p=0.9916
Heterogeneity:	Q=0.01 (df=1)	p=0.9076	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 22	2 / 16	10.6	2.55 [0.61,10.67]	
FIGARO-DKD	25 / 134	26 / 131	89.4	0.94 [0.57,1.54]	
Total	32 / 156	28 / 147		1.08 [0.68,1.69]	Z=0.32, p=0.7520
Heterogeneity:	Q=1.67 (df=1)	p=0.1957	I^2=40.3%		
Subgroup Heterogeneity:	Q=0.53 (df=3)	p=0.9122	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.

Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.

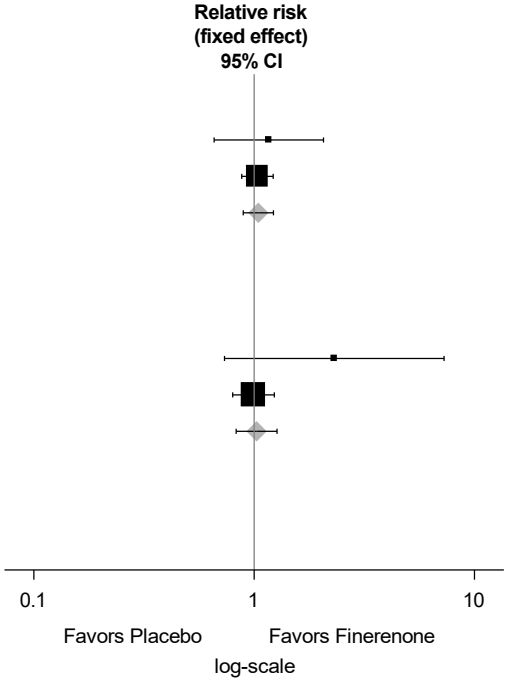
Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure B3.2.12.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

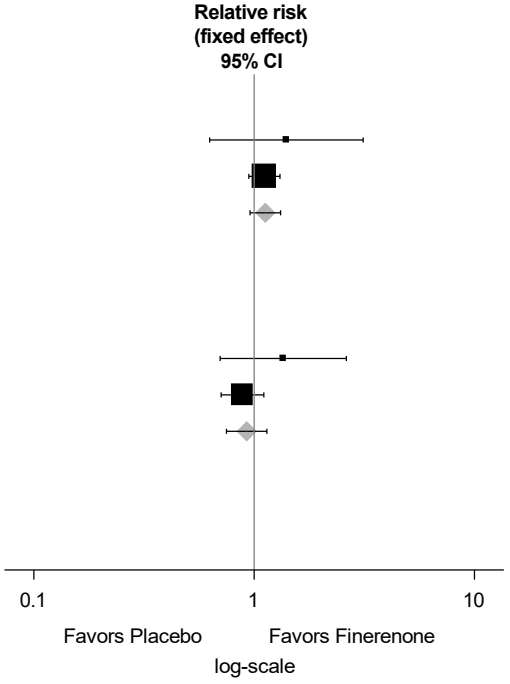
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	22 / 153	19 / 154	7.6	1.17 [0.66,2.06]	
FIGARO-DKD	244 / 1611	240 / 1640	92.4	1.03 [0.88,1.22]	
Total	266 / 1764	259 / 1794		1.04 [0.89,1.22]	Z=0.54, p=0.5896
Heterogeneity:	Q=0.15 (df=1)	p=0.6956	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 58	4 / 67	3.5	2.31 [0.73,7.28]	
FIGARO-DKD	136 / 716	127 / 664	96.5	0.99 [0.80,1.23]	
Total	144 / 774	131 / 731		1.03 [0.83,1.27]	Z=0.23, p=0.8168
Heterogeneity:	Q=2.01 (df=1)	p=0.1565	I^2=50.2%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8929	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.12.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

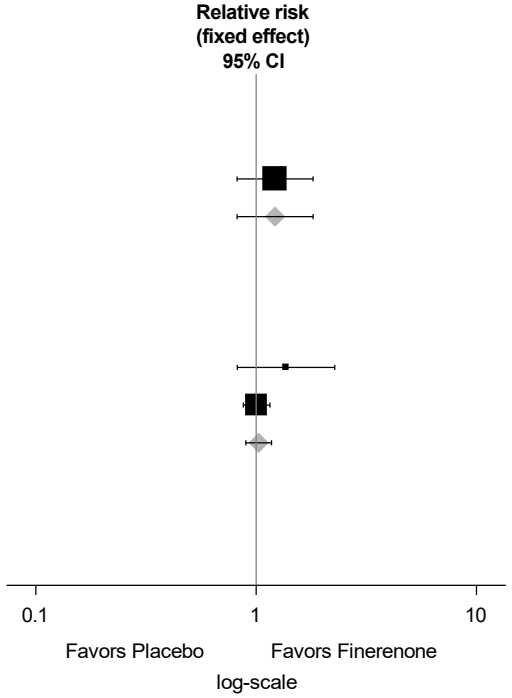
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	13 / 99	9 / 96	4.0	1.40 [0.63,3.12]	
FIGARO-DKD	254 / 1416	229 / 1421	96.0	1.11 [0.95,1.31]	
Total	267 / 1515	238 / 1517		1.12 [0.96,1.32]	Z=1.43, p=0.1525
Heterogeneity:	Q=0.30 (df=1)	p=0.5821	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 112	14 / 125	10.3	1.36 [0.70,2.62]	
FIGARO-DKD	126 / 911	138 / 883	89.7	0.88 [0.71,1.11]	
Total	143 / 1023	152 / 1008		0.92 [0.75,1.14]	Z=-0.73, p=0.4676
Heterogeneity:	Q=1.44 (df=1)	p=0.2304	I^2=30.5%		
Subgroup Heterogeneity:	Q=2.08 (df=1)	p=0.1493	I^2=51.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.2.12.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

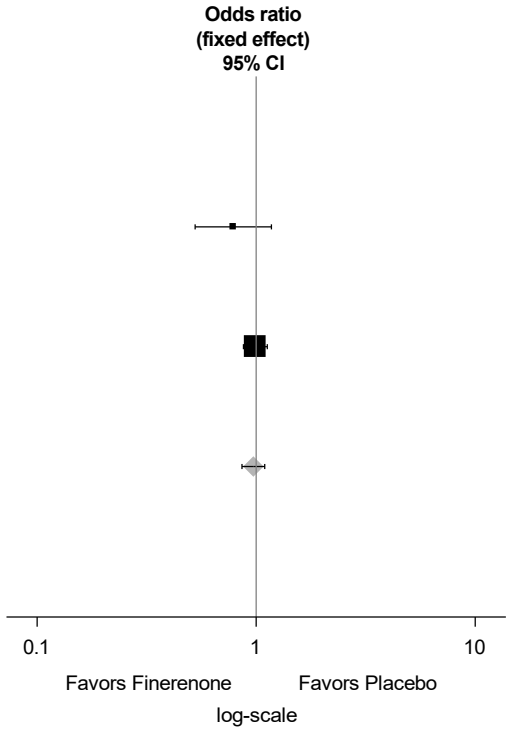
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	49 / 363	38 / 343	100.0	1.22 [0.82,1.81]	
Total	49 / 363	38 / 343		1.22 [0.82,1.81]	Z=0.98, p=0.3295
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	30 / 211	23 / 221	6.9	1.37 [0.82,2.27]	
FIGARO-DKD	331 / 1964	329 / 1961	93.1	1.00 [0.87,1.15]	
Total	361 / 2175	352 / 2182		1.03 [0.90,1.17]	Z=0.38, p=0.7021
Heterogeneity:	Q=1.30 (df=1)	p=0.2538	I^2=23.2%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4229	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

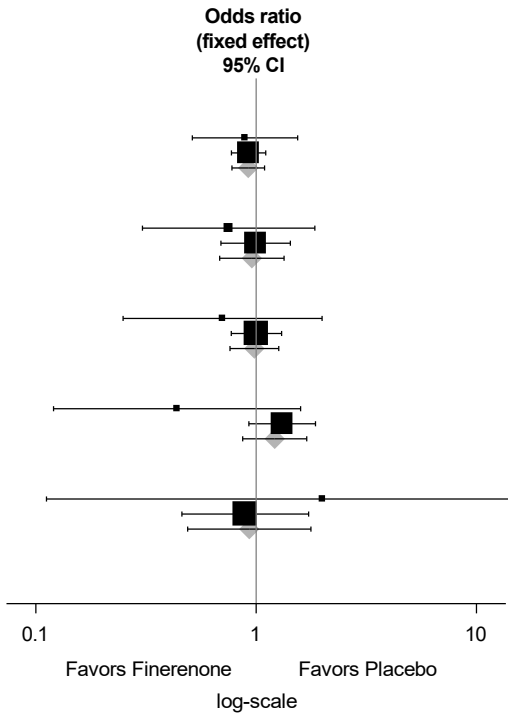
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 211	82 / 221	8.9	0.79 [0.53,1.17]	
FIGARO-DKD	707 / 2327	704 / 2304	91.1	0.99 [0.87,1.12]	
Total	774 / 2538	786 / 2525		0.97 [0.86,1.09]	Z=-0.49, p=0.6269
Heterogeneity:	Q=1.17 (df=1)	p=0.2787	I^2=14.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.1.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

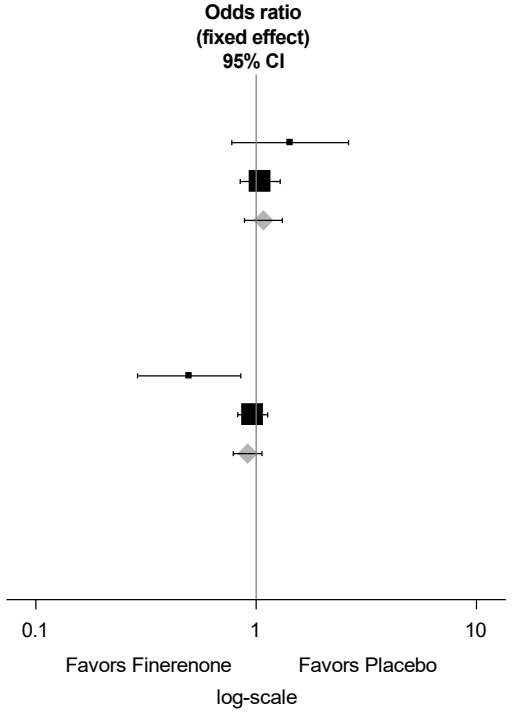
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	38 / 104	44 / 112	9.6	0.89 [0.51,1.54]	
FIGARO-DKD	339 / 1114	357 / 1111	90.4	0.92 [0.77,1.11]	
Total	377 / 1218	401 / 1223		0.92 [0.78,1.09]	Z=-0.95, p=0.3411
Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		
North America					
FIDELIO-DKD	14 / 42	16 / 40	14.0	0.75 [0.30,1.85]	
FIGARO-DKD	84 / 292	80 / 277	86.0	0.99 [0.69,1.43]	
Total	98 / 334	96 / 317		0.96 [0.68,1.34]	Z=-0.26, p=0.7931
Heterogeneity:	Q=0.32 (df=1)	p=0.5691	I^2=0.0%		
Asia					
FIDELIO-DKD	8 / 39	11 / 41	6.0	0.70 [0.25,1.99]	
FIGARO-DKD	160 / 522	160 / 523	94.0	1.00 [0.77,1.30]	
Total	168 / 561	171 / 564		0.98 [0.76,1.27]	Z=-0.14, p=0.8853
Heterogeneity:	Q=0.42 (df=1)	p=0.5177	I^2=0.0%		
Latin America					
FIDELIO-DKD	5 / 21	10 / 24	6.8	0.44 [0.12,1.59]	
FIGARO-DKD	98 / 322	79 / 316	93.2	1.31 [0.93,1.86]	
Total	103 / 343	89 / 340		1.21 [0.87,1.70]	Z=1.14, p=0.2563
Heterogeneity:	Q=2.59 (df=1)	p=0.1073	I^2=61.4%		
Others					
FIDELIO-DKD	2 / 5	1 / 4	5.0	2.00 [0.11,35.81]	
FIGARO-DKD	26 / 77	28 / 77	95.0	0.89 [0.46,1.73]	
Total	28 / 82	29 / 81		0.93 [0.49,1.77]	Z=-0.22, p=0.8266
Heterogeneity:	Q=0.29 (df=1)	p=0.5930	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.12 (df=4)	p=0.7141	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.1.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

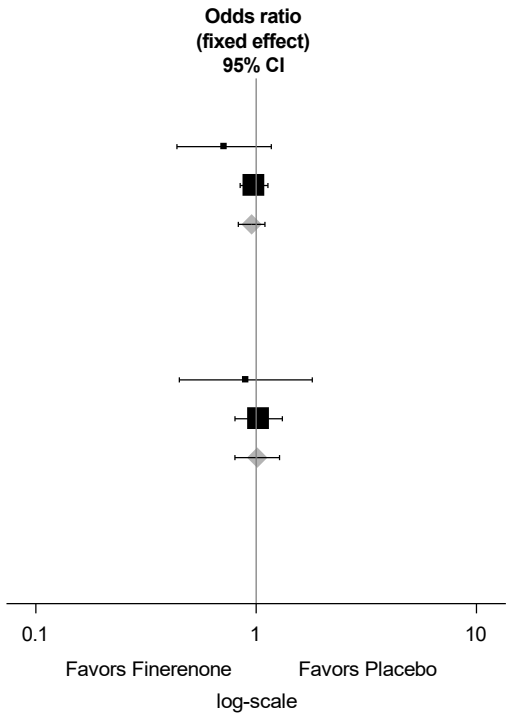
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	37 / 88	30 / 89	10.5	1.43 [0.78,2.63]	
FIGARO-DKD	264 / 811	254 / 803	89.5	1.04 [0.85,1.29]	
Total	301 / 899	284 / 892		1.08 [0.88,1.31]	Z=0.75, p=0.4552
Heterogeneity:	Q=0.91 (df=1)	p=0.3413	I^2=0.0%		
Absent					
FIDELIO-DKD	30 / 123	52 / 132	7.7	0.50 [0.29,0.85]	
FIGARO-DKD	443 / 1516	450 / 1501	92.3	0.96 [0.82,1.13]	
Total	473 / 1639	502 / 1633		0.91 [0.79,1.06]	Z=-1.17, p=0.2430
Heterogeneity:	Q=5.37 (df=1)	p=0.0205	I^2=81.4%		
Subgroup Heterogeneity:	Q=1.69 (df=1)	p=0.1934	I^2=40.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.1.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

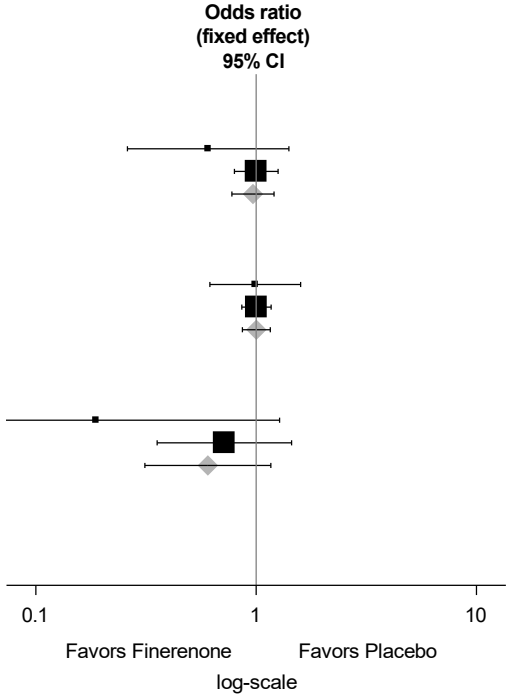
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	39 / 144	54 / 158	8.0	0.72 [0.44,1.17]	
FIGARO-DKD	532 / 1719	528 / 1680	92.0	0.98 [0.85,1.13]	
Total	571 / 1863	582 / 1838		0.95 [0.83,1.10]	Z=-0.67, p=0.5034
Heterogeneity:	Q=1.42 (df=1)	p=0.2333	I^2=29.6%		
> 4.5					
FIDELIO-DKD	28 / 67	28 / 63	11.3	0.90 [0.45,1.80]	
FIGARO-DKD	175 / 608	176 / 623	88.7	1.03 [0.80,1.31]	
Total	203 / 675	204 / 686		1.01 [0.80,1.28]	Z=0.09, p=0.9264
Heterogeneity:	Q=0.13 (df=1)	p=0.7211	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6728	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.1.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

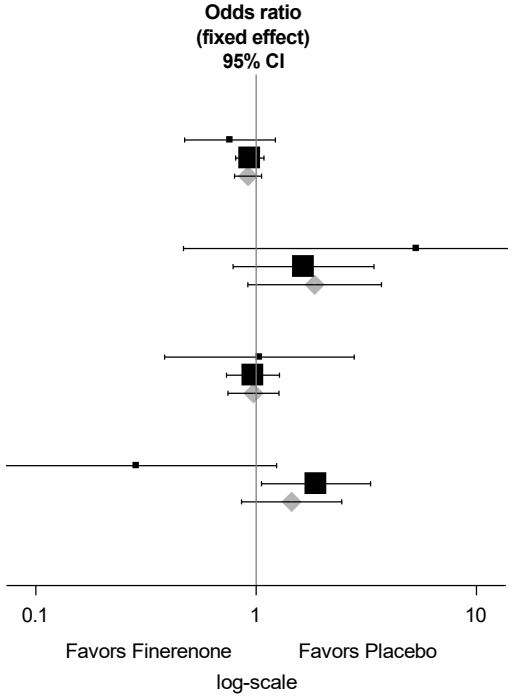
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 64	16 / 54	6.8	0.61 [0.26,1.41]	
FIGARO-DKD	211 / 693	213 / 700	93.2	1.00 [0.80,1.26]	
Total	224 / 757	229 / 754		0.97 [0.78,1.21]	Z=-0.30, p=0.7647
Heterogeneity:	Q=1.27 (df=1)	p=0.2596	I^2=21.3%		
130 - < 160					
FIDELIO-DKD	51 / 138	58 / 156	9.5	0.99 [0.62,1.59]	
FIGARO-DKD	477 / 1561	465 / 1525	90.5	1.00 [0.86,1.17]	
Total	528 / 1699	523 / 1681		1.00 [0.87,1.16]	Z=0.03, p=0.9797
Heterogeneity:	Q=0.00 (df=1)	p=0.9603	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 9	8 / 11	11.8	0.19 [0.03,1.28]	
FIGARO-DKD	19 / 73	26 / 79	88.2	0.72 [0.36,1.45]	
Total	22 / 82	34 / 90		0.60 [0.31,1.17]	Z=-1.50, p=0.1327
Heterogeneity:	Q=1.66 (df=1)	p=0.1979	I^2=39.7%		
Subgroup Heterogeneity:	Q=2.18 (df=2)	p=0.3363	I^2=8.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.1.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

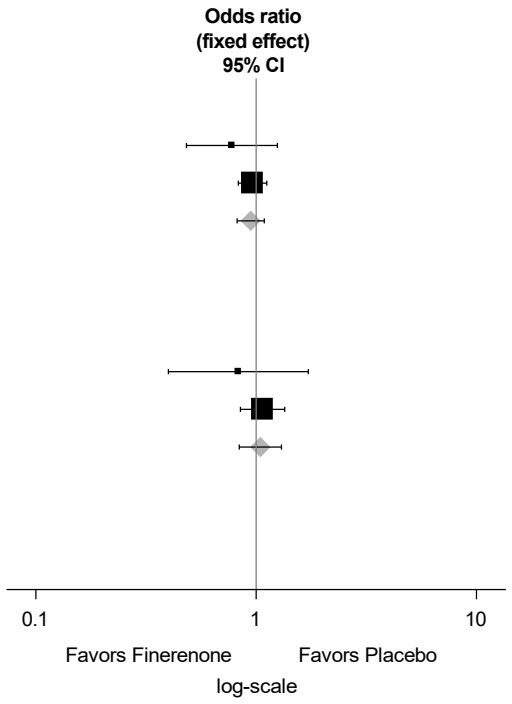
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	49 / 140	63 / 152	8.9	0.76 [0.47,1.22]	
FIGARO-DKD	504 / 1659	513 / 1613	91.1	0.94 [0.81,1.09]	
Total	553 / 1799	576 / 1765		0.92 [0.80,1.06]	Z=-1.18, p=0.2387
Heterogeneity:	Q=0.67 (df=1)	p=0.4139	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	1 / 9	8.4	5.33 [0.47,60.80]	
FIGARO-DKD	23 / 70	17 / 74	91.6	1.64 [0.79,3.43]	
Total	27 / 80	18 / 83		1.84 [0.92,3.71]	Z=1.72, p=0.0862
Heterogeneity:	Q=0.83 (df=1)	p=0.3628	I^2=0.0%		
Asian					
FIDELIO-DKD	10 / 39	11 / 44	7.2	1.03 [0.38,2.79]	
FIGARO-DKD	139 / 464	149 / 486	92.8	0.97 [0.73,1.28]	
Total	149 / 503	160 / 530		0.97 [0.74,1.27]	Z=-0.21, p=0.8349
Heterogeneity:	Q=0.02 (df=1)	p=0.8983	I^2=0.0%		
Others					
FIDELIO-DKD	4 / 22	7 / 16	13.1	0.29 [0.07,1.24]	
FIGARO-DKD	41 / 134	25 / 131	86.9	1.87 [1.06,3.31]	
Total	45 / 156	32 / 147		1.45 [0.86,2.45]	Z=1.39, p=0.1654
Heterogeneity:	Q=5.48 (df=1)	p=0.0193	I^2=81.7%		
Subgroup Heterogeneity:	Q=6.07 (df=3)	p=0.1083	I^2=50.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.1.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

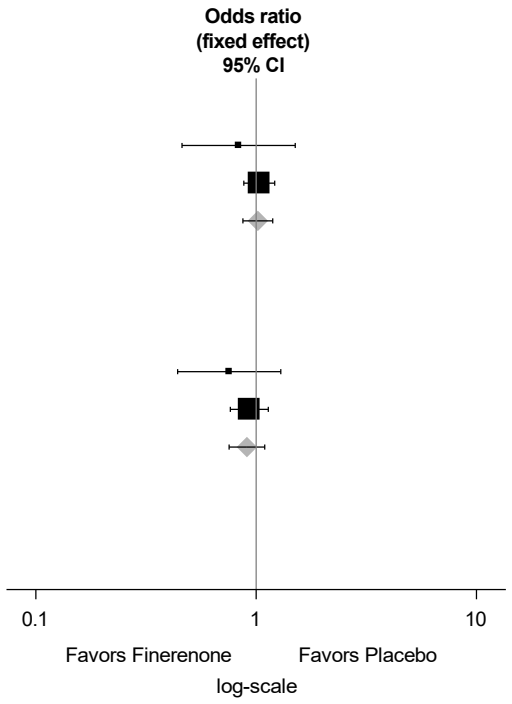
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	47 / 153	56 / 154	8.9	0.78 [0.48,1.25]	
FIGARO-DKD	490 / 1611	512 / 1640	91.1	0.96 [0.83,1.12]	
Total	537 / 1764	568 / 1794		0.94 [0.82,1.09]	Z=-0.79, p=0.4311
Heterogeneity:	Q=0.72 (df=1)	p=0.3953	I^2=0.0%		
Female					
FIDELIO-DKD	20 / 58	26 / 67	9.1	0.83 [0.40,1.72]	
FIGARO-DKD	217 / 716	192 / 664	90.9	1.07 [0.85,1.35]	
Total	237 / 774	218 / 731		1.04 [0.84,1.30]	Z=0.39, p=0.6980
Heterogeneity:	Q=0.42 (df=1)	p=0.5176	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4517	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.1.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

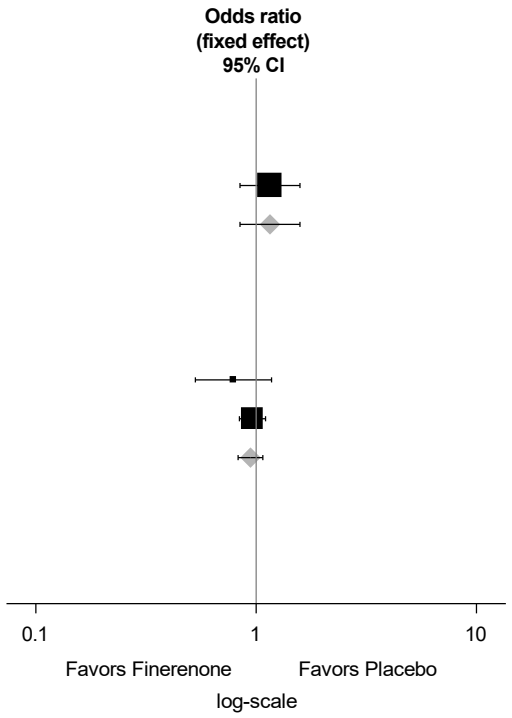
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	32 / 99	35 / 96	6.9	0.83 [0.46,1.50]	
FIGARO-DKD	422 / 1416	414 / 1421	93.1	1.03 [0.88,1.21]	
Total	454 / 1515	449 / 1517		1.02 [0.87,1.19]	Z=0.22, p=0.8288
Heterogeneity:	Q=0.47 (df=1)	p=0.4909	I^2=0.0%		
>= 65					
FIDELIO-DKD	35 / 112	47 / 125	11.9	0.75 [0.44,1.29]	
FIGARO-DKD	285 / 911	290 / 883	88.1	0.93 [0.76,1.14]	
Total	320 / 1023	337 / 1008		0.91 [0.75,1.09]	Z=-1.02, p=0.3082
Heterogeneity:	Q=0.52 (df=1)	p=0.4729	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.85 (df=1)	p=0.3575	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.1.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

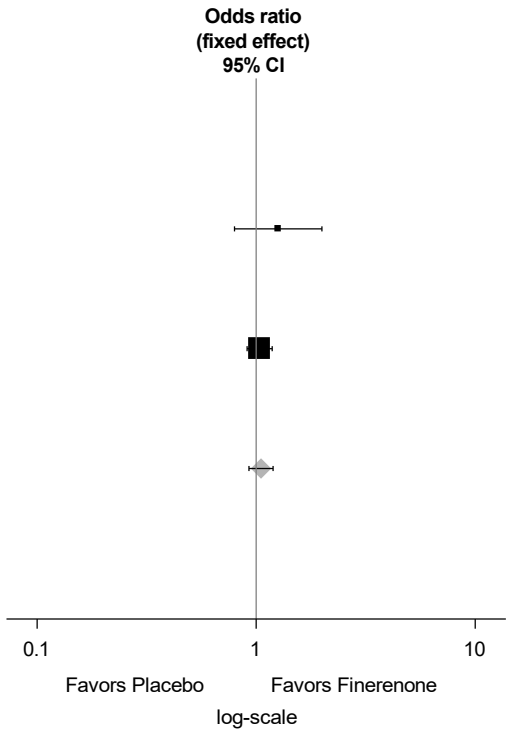
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	127 / 363	109 / 343	100.0	1.16 [0.84,1.58]	
Total	127 / 363	109 / 343		1.16 [0.84,1.58]	Z=0.90, p=0.3666
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	67 / 211	82 / 221	10.5	0.79 [0.53,1.17]	
FIGARO-DKD	580 / 1964	595 / 1961	89.5	0.96 [0.84,1.10]	
Total	647 / 2175	677 / 2182		0.94 [0.83,1.07]	Z=-0.90, p=0.3657
Heterogeneity:	Q=0.86 (df=1)	p=0.3547	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.39 (df=1)	p=0.2382	I^2=28.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

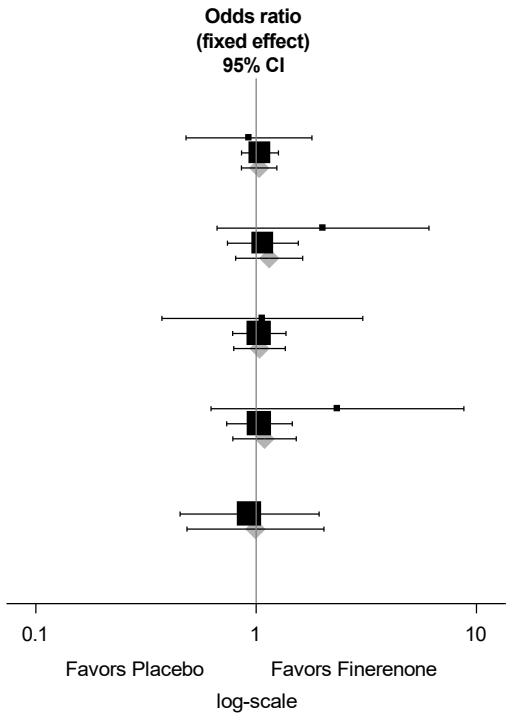
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	50 / 211	44 / 221	7.6	1.26 [0.80,2.00]	
FIGARO-DKD	607 / 2327	584 / 2304	92.4	1.04 [0.91,1.18]	
Total	657 / 2538	628 / 2525		1.05 [0.93,1.19]	Z=0.79, p=0.4319
Heterogeneity:	Q=0.64 (df=1)	p=0.4235	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.2.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

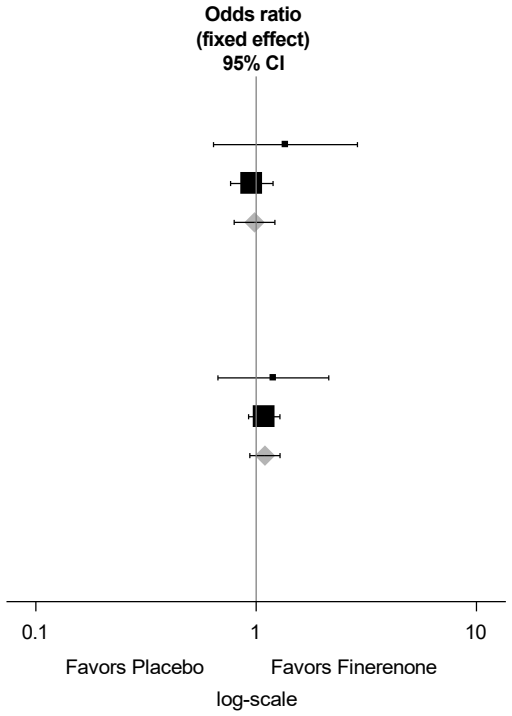
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 104	24 / 112	7.9	0.93 [0.48,1.79]	
FIGARO-DKD	279 / 1114	270 / 1111	92.1	1.04 [0.86,1.26]	
Total	300 / 1218	294 / 1223		1.03 [0.86,1.24]	Z=0.33, p=0.7438
Heterogeneity:	Q=0.11 (df=1)	p=0.7424	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	6 / 40	10.1	2.01 [0.66,6.09]	
FIGARO-DKD	81 / 292	73 / 277	89.9	1.07 [0.74,1.55]	
Total	92 / 334	79 / 317		1.15 [0.81,1.63]	Z=0.76, p=0.4472
Heterogeneity:	Q=1.11 (df=1)	p=0.2916	I^2=10.1%		
Asia					
FIDELIO-DKD	9 / 39	9 / 41	6.6	1.07 [0.37,3.05]	
FIGARO-DKD	134 / 522	131 / 523	93.4	1.03 [0.78,1.37]	
Total	143 / 561	140 / 564		1.04 [0.79,1.36]	Z=0.25, p=0.7991
Heterogeneity:	Q=0.00 (df=1)	p=0.9545	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	5 / 24	6.3	2.34 [0.62,8.77]	
FIGARO-DKD	94 / 322	90 / 316	93.7	1.04 [0.73,1.46]	
Total	102 / 343	95 / 340		1.09 [0.78,1.52]	Z=0.52, p=0.6042
Heterogeneity:	Q=1.37 (df=1)	p=0.2420	I^2=26.9%		
Others					
FIDELIO-DKD	1 / 5	0 / 4	0.0	192E9 [192E9,192E9]	
FIGARO-DKD	19 / 77	20 / 77	100.0	0.93 [0.45,1.93]	
Total	20 / 82	20 / 81		0.99 [0.49,2.03]	Z=-0.02, p=0.9838
Heterogeneity:	Q=0.03 (df=1)	p=0.8687	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=4)	p=0.9859	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.2.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

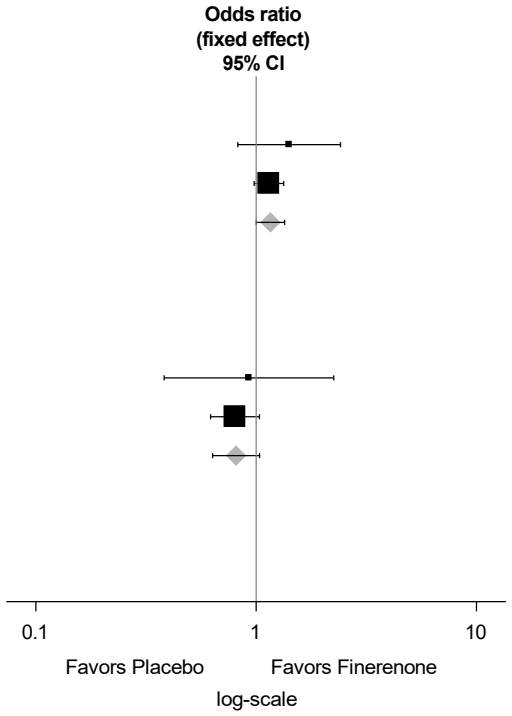
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 88	15 / 89	8.0	1.36 [0.64,2.88]	
FIGARO-DKD	209 / 811	214 / 803	92.0	0.96 [0.77,1.19]	
Total	228 / 899	229 / 892		0.98 [0.79,1.22]	Z=-0.16, p=0.8748
Heterogeneity:	Q=0.77 (df=1)	p=0.3793	I^2=0.0%		
Absent					
FIDELIO-DKD	31 / 123	29 / 132	7.4	1.20 [0.67,2.14]	
FIGARO-DKD	398 / 1516	370 / 1501	92.6	1.09 [0.92,1.28]	
Total	429 / 1639	399 / 1633		1.10 [0.94,1.28]	Z=1.14, p=0.2552
Heterogeneity:	Q=0.10 (df=1)	p=0.7568	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4212	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.2.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

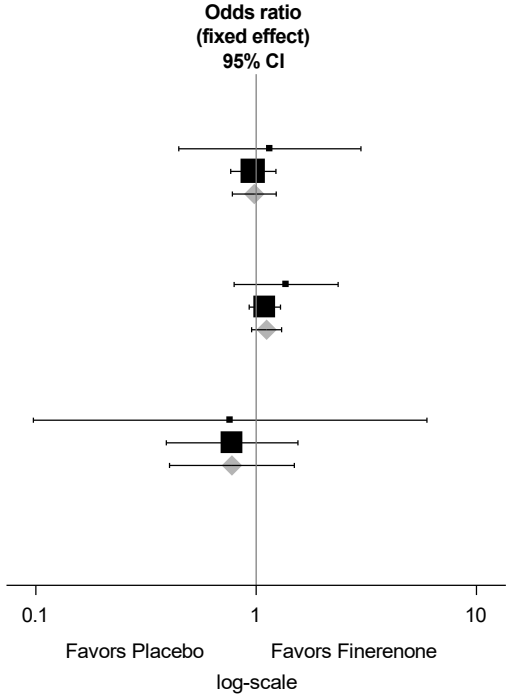
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	38 / 144	32 / 158	7.6	1.41 [0.83,2.41]	
FIGARO-DKD	462 / 1719	409 / 1680	92.4	1.14 [0.98,1.33]	
Total	500 / 1863	441 / 1838		1.16 [1.00,1.35]	Z=1.97, p=0.0486
Heterogeneity:	Q=0.55 (df=1)	p=0.4572	I^2=0.0%		
> 4.5					
FIDELIO-DKD	12 / 67	12 / 63	7.7	0.93 [0.38,2.25]	
FIGARO-DKD	145 / 608	175 / 623	92.3	0.80 [0.62,1.04]	
Total	157 / 675	187 / 686		0.81 [0.63,1.04]	Z=-1.68, p=0.0939
Heterogeneity:	Q=0.10 (df=1)	p=0.7572	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.02 (df=1)	p=0.0142	I^2=83.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.2.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

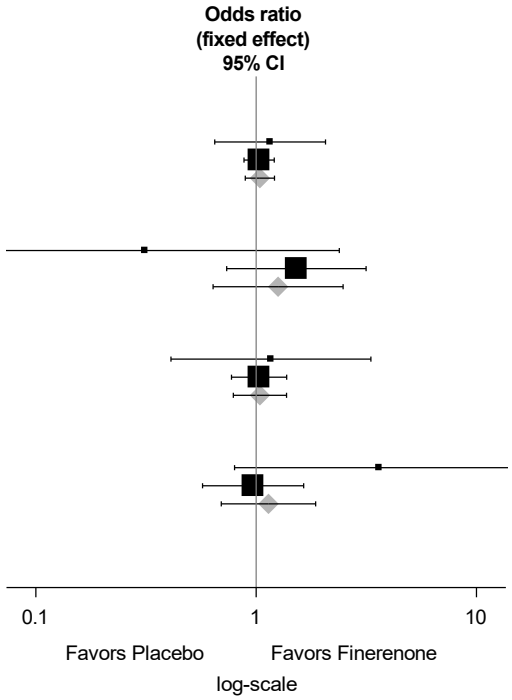
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 64	9 / 54	5.8	1.15 [0.45,2.99]	
FIGARO-DKD	186 / 693	192 / 700	94.2	0.97 [0.77,1.23]	
Total	198 / 757	201 / 754		0.98 [0.78,1.23]	Z=-0.17, p=0.8663
Heterogeneity:	Q=0.12 (df=1)	p=0.7297	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	36 / 138	32 / 156	8.3	1.37 [0.79,2.36]	
FIGARO-DKD	400 / 1561	365 / 1525	91.7	1.09 [0.93,1.29]	
Total	436 / 1699	397 / 1681		1.12 [0.95,1.30]	Z=1.37, p=0.1717
Heterogeneity:	Q=0.59 (df=1)	p=0.4425	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 9	3 / 11	10.1	0.76 [0.10,5.96]	
FIGARO-DKD	21 / 73	27 / 79	89.9	0.78 [0.39,1.55]	
Total	23 / 82	30 / 90		0.78 [0.40,1.49]	Z=-0.76, p=0.4464
Heterogeneity:	Q=0.00 (df=1)	p=0.9851	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.73 (df=2)	p=0.4217	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.2.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

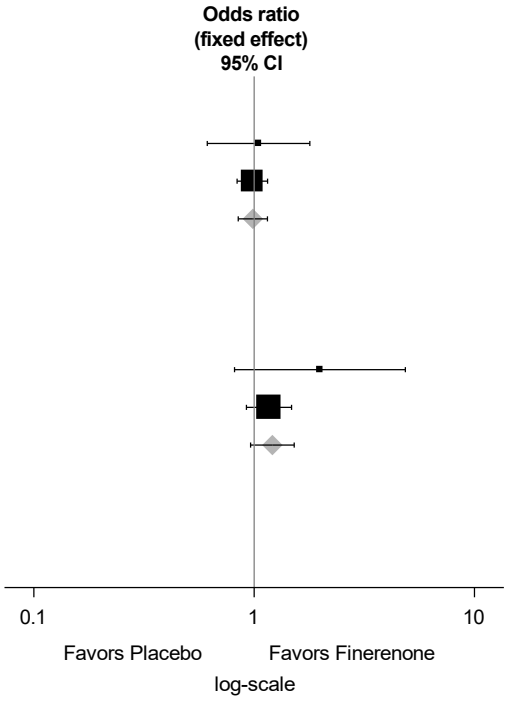
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	29 / 140	28 / 152	6.9	1.16 [0.65,2.06]	
FIGARO-DKD	421 / 1659	400 / 1613	93.1	1.03 [0.88,1.21]	
Total	450 / 1799	428 / 1765		1.04 [0.89,1.21]	Z=0.50, p=0.6185
Heterogeneity:	Q=0.14 (df=1)	p=0.7071	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 10	4 / 9	11.4	0.31 [0.04,2.38]	
FIGARO-DKD	23 / 70	18 / 74	88.6	1.52 [0.73,3.15]	
Total	25 / 80	22 / 83		1.26 [0.64,2.48]	Z=0.66, p=0.5086
Heterogeneity:	Q=2.07 (df=1)	p=0.1504	I^2=51.6%		
Asian					
FIDELIO-DKD	9 / 39	9 / 44	7.1	1.17 [0.41,3.32]	
FIGARO-DKD	124 / 464	127 / 486	92.9	1.03 [0.77,1.38]	
Total	133 / 503	136 / 530		1.04 [0.79,1.37]	Z=0.28, p=0.7822
Heterogeneity:	Q=0.05 (df=1)	p=0.8230	I^2=0.0%		
Others					
FIDELIO-DKD	10 / 22	3 / 16	10.9	3.61 [0.80,16.35]	
FIGARO-DKD	39 / 134	39 / 131	89.1	0.97 [0.57,1.64]	
Total	49 / 156	42 / 147		1.14 [0.69,1.86]	Z=0.51, p=0.6098
Heterogeneity:	Q=2.60 (df=1)	p=0.1066	I^2=61.6%		
Subgroup Heterogeneity:	Q=0.39 (df=3)	p=0.9422	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.2.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

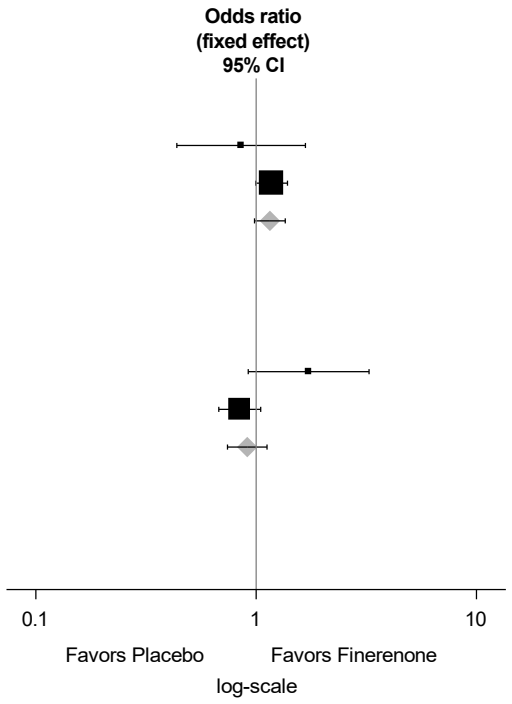
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	35 / 153	34 / 154	8.1	1.05 [0.61,1.79]	
FIGARO-DKD	396 / 1611	409 / 1640	91.9	0.98 [0.84,1.15]	
Total	431 / 1764	443 / 1794		0.99 [0.85,1.15]	Z=-0.18, p=0.8580
Heterogeneity:	Q=0.05 (df=1)	p=0.8197	I^2=0.0%		
Female					
FIDELIO-DKD	15 / 58	10 / 67	6.5	1.99 [0.81,4.86]	
FIGARO-DKD	211 / 716	175 / 664	93.5	1.17 [0.92,1.48]	
Total	226 / 774	185 / 731		1.21 [0.96,1.52]	Z=1.64, p=0.1016
Heterogeneity:	Q=1.28 (df=1)	p=0.2584	I^2=21.7%		
Subgroup Heterogeneity:	Q=2.13 (df=1)	p=0.1444	I^2=53.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.2.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

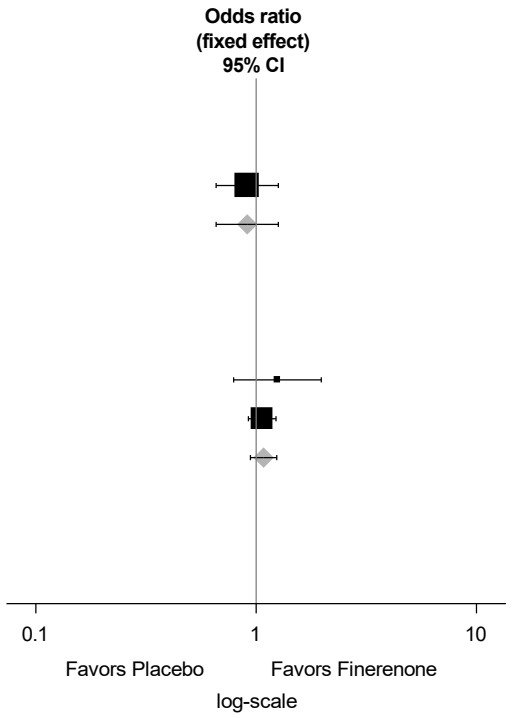
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	21 / 99	23 / 96	5.7	0.85 [0.44,1.67]	
FIGARO-DKD	408 / 1416	364 / 1421	94.3	1.18 [1.00,1.39]	
Total	429 / 1515	387 / 1517		1.15 [0.98,1.36]	Z=1.75, p=0.0805
Heterogeneity:	Q=0.81 (df=1)	p=0.3667	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 112	21 / 125	10.7	1.73 [0.92,3.25]	
FIGARO-DKD	199 / 911	220 / 883	89.3	0.84 [0.68,1.05]	
Total	228 / 1023	241 / 1008		0.91 [0.74,1.12]	Z=-0.88, p=0.3763
Heterogeneity:	Q=4.46 (df=1)	p=0.0347	I^2=77.6%		
Subgroup Heterogeneity:	Q=3.14 (df=1)	p=0.0765	I^2=68.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.2.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

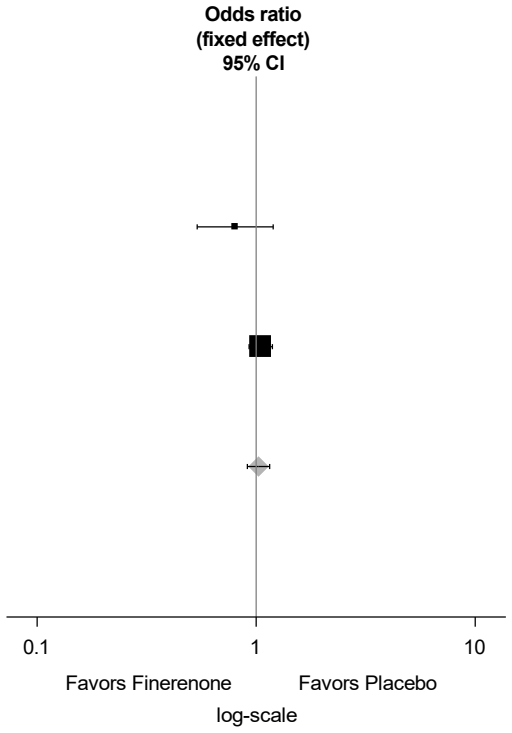
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	102 / 363	103 / 343	100.0	0.91 [0.66,1.26]	
Total	102 / 363	103 / 343		0.91 [0.66,1.26]	Z=-0.56, p=0.5724
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	50 / 211	44 / 221	9.0	1.25 [0.79,1.97]	
FIGARO-DKD	505 / 1964	481 / 1961	91.0	1.07 [0.92,1.23]	
Total	555 / 2175	525 / 2182		1.08 [0.94,1.24]	Z=1.10, p=0.2702
Heterogeneity:	Q=0.42 (df=1)	p=0.5147	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.90 (df=1)	p=0.3422	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

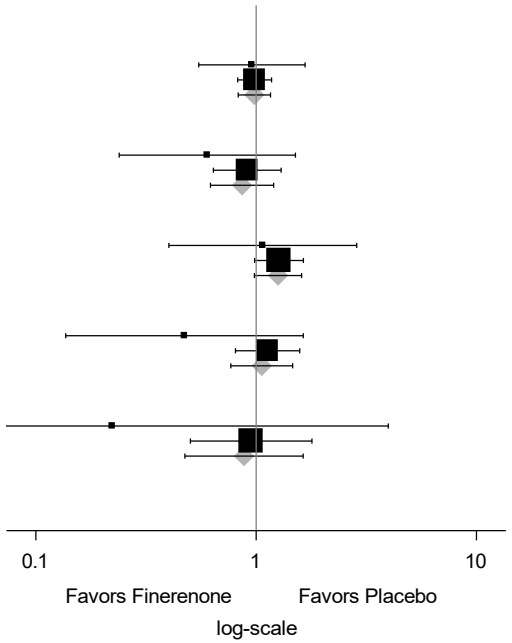
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 211	82 / 221	8.6	0.80 [0.54,1.20]	
FIGARO-DKD	786 / 2327	753 / 2304	91.4	1.05 [0.93,1.19]	
Total	854 / 2538	835 / 2525		1.02 [0.91,1.15]	Z=0.41, p=0.6809
Heterogeneity:	Q=1.59 (df=1)	p=0.2076	I^2=37.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.3.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

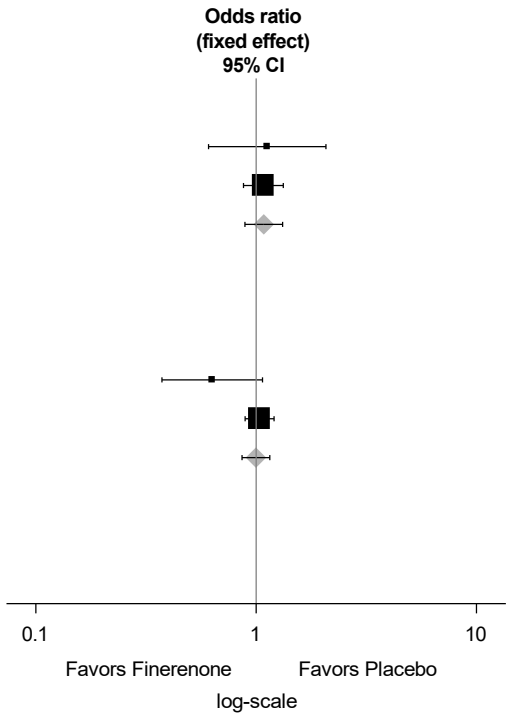
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	37 / 104	41 / 112	9.2	0.96 [0.55,1.67]	
FIGARO-DKD	362 / 1114	365 / 1111	90.8	0.98 [0.82,1.17]	
Total	399 / 1218	406 / 1223		0.98 [0.83,1.16]	Z=-0.22, p=0.8265
Heterogeneity:	Q=0.01 (df=1)	p=0.9240	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 42	16 / 40	12.9	0.60 [0.24,1.51]	
FIGARO-DKD	89 / 292	90 / 277	87.1	0.91 [0.64,1.30]	
Total	101 / 334	106 / 317		0.86 [0.62,1.20]	Z=-0.88, p=0.3812
Heterogeneity:	Q=0.69 (df=1)	p=0.4069	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 39	11 / 41	6.3	1.07 [0.40,2.86]	
FIGARO-DKD	197 / 522	169 / 523	93.7	1.27 [0.98,1.64]	
Total	208 / 561	180 / 564		1.26 [0.98,1.61]	Z=1.81, p=0.0698
Heterogeneity:	Q=0.11 (df=1)	p=0.7428	I^2=0.0%		
Latin America					
FIDELIO-DKD	6 / 21	11 / 24	6.8	0.47 [0.14,1.64]	
FIGARO-DKD	104 / 322	94 / 316	93.2	1.13 [0.81,1.58]	
Total	110 / 343	105 / 340		1.06 [0.77,1.46]	Z=0.35, p=0.7247
Heterogeneity:	Q=1.75 (df=1)	p=0.1856	I^2=42.9%		
Others					
FIDELIO-DKD	2 / 5	3 / 4	4.6	0.22 [0.01,3.98]	
FIGARO-DKD	34 / 77	35 / 77	95.4	0.95 [0.50,1.79]	
Total	36 / 82	38 / 81		0.88 [0.47,1.63]	Z=-0.40, p=0.6872
Heterogeneity:	Q=0.93 (df=1)	p=0.3354	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.19 (df=4)	p=0.3815	I^2=4.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.3.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

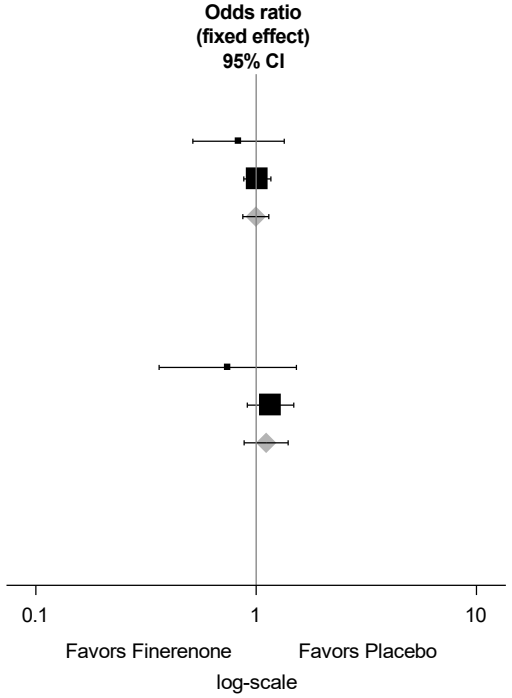
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	33 / 88	31 / 89	10.3	1.12 [0.61,2.07]	
FIGARO-DKD	272 / 811	256 / 803	89.7	1.08 [0.88,1.33]	
Total	305 / 899	287 / 892		1.08 [0.89,1.32]	Z=0.79, p=0.4289
Heterogeneity:	Q=0.01 (df=1)	p=0.9030	I^2=0.0%		
Absent					
FIDELIO-DKD	35 / 123	51 / 132	7.6	0.63 [0.37,1.07]	
FIGARO-DKD	514 / 1516	497 / 1501	92.4	1.04 [0.89,1.21]	
Total	549 / 1639	548 / 1633		1.00 [0.86,1.15]	Z=-0.04, p=0.9707
Heterogeneity:	Q=3.15 (df=1)	p=0.0760	I^2=68.2%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5102	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

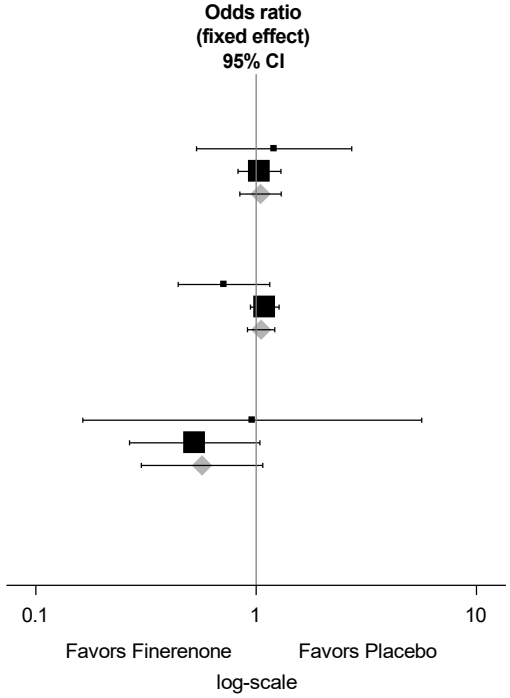
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 144	57 / 158	8.1	0.83 [0.52,1.34]	
FIGARO-DKD	591 / 1719	573 / 1680	91.9	1.01 [0.88,1.17]	
Total	637 / 1863	630 / 1838		1.00 [0.87,1.14]	Z=-0.05, p=0.9563
Heterogeneity:	Q=0.60 (df=1)	p=0.4398	I^2=0.0%		
> 4.5					
FIDELIO-DKD	22 / 67	25 / 63	10.3	0.74 [0.36,1.52]	
FIGARO-DKD	195 / 608	180 / 623	89.7	1.16 [0.91,1.48]	
Total	217 / 675	205 / 686		1.11 [0.88,1.40]	Z=0.89, p=0.3752
Heterogeneity:	Q=1.34 (df=1)	p=0.2473	I^2=25.3%		
Subgroup Heterogeneity:	Q=0.63 (df=1)	p=0.4287	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

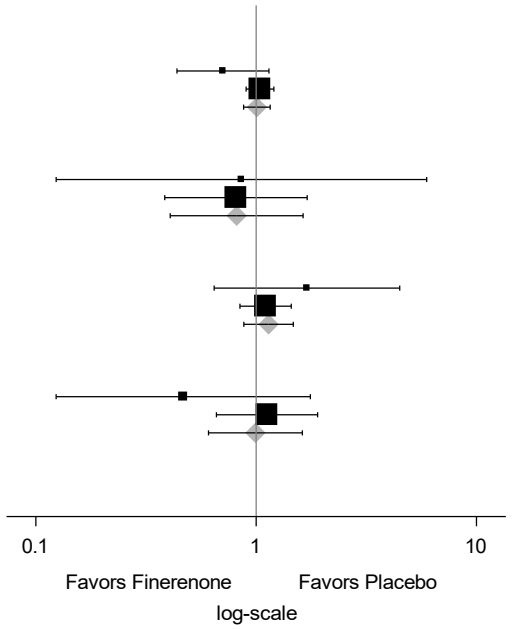
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	19 / 64	14 / 54	7.1	1.21 [0.54,2.71]	
FIGARO-DKD	227 / 693	224 / 700	92.9	1.04 [0.83,1.30]	
Total	246 / 757	238 / 754		1.05 [0.84,1.30]	Z=0.41, p=0.6803
Heterogeneity:	Q=0.13 (df=1)	p=0.7215	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	45 / 138	63 / 156	8.9	0.71 [0.44,1.15]	
FIGARO-DKD	539 / 1561	496 / 1525	91.1	1.09 [0.94,1.27]	
Total	584 / 1699	559 / 1681		1.05 [0.91,1.21]	Z=0.71, p=0.4773
Heterogeneity:	Q=2.78 (df=1)	p=0.0955	I^2=64.0%		
>= 160					
FIDELIO-DKD	4 / 9	5 / 11	12.9	0.96 [0.16,5.64]	
FIGARO-DKD	20 / 73	33 / 79	87.1	0.53 [0.27,1.04]	
Total	24 / 82	38 / 90		0.57 [0.30,1.07]	Z=-1.75, p=0.0806
Heterogeneity:	Q=0.39 (df=1)	p=0.5344	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.49 (df=2)	p=0.1744	I^2=42.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

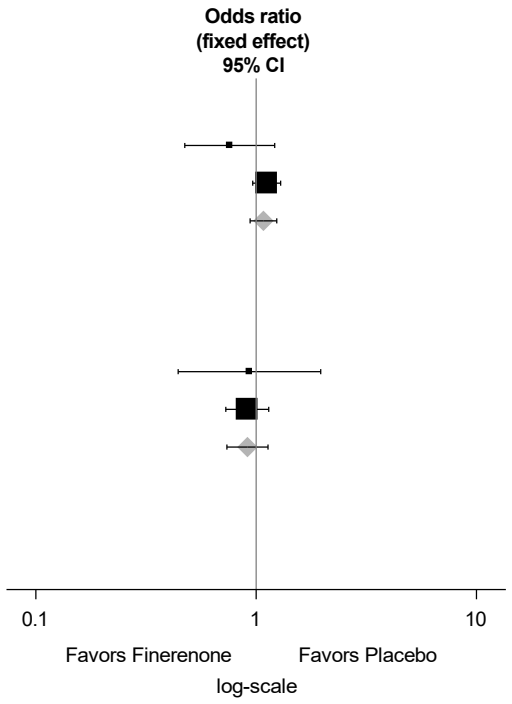
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 140	61 / 152	8.4	0.71 [0.44,1.14]	
FIGARO-DKD	564 / 1659	534 / 1613	91.6	1.04 [0.90,1.20]	
Total	609 / 1799	595 / 1765		1.01 [0.88,1.16]	Z=0.10, p=0.9176
Heterogeneity:	Q=2.28 (df=1)	p=0.1307	I^2=56.2%		
Black					
FIDELIO-DKD	3 / 10	3 / 9	12.9	0.86 [0.12,5.94]	
FIGARO-DKD	17 / 70	21 / 74	87.1	0.81 [0.38,1.70]	
Total	20 / 80	24 / 83		0.82 [0.41,1.63]	Z=-0.58, p=0.5649
Heterogeneity:	Q=0.00 (df=1)	p=0.9569	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 39	10 / 44	7.1	1.70 [0.64,4.48]	
FIGARO-DKD	164 / 464	161 / 486	92.9	1.10 [0.84,1.44]	
Total	177 / 503	171 / 530		1.14 [0.88,1.47]	Z=0.98, p=0.3259
Heterogeneity:	Q=0.71 (df=1)	p=0.3999	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 22	8 / 16	13.7	0.47 [0.12,1.76]	
FIGARO-DKD	41 / 134	37 / 131	86.3	1.12 [0.66,1.90]	
Total	48 / 156	45 / 147		0.99 [0.61,1.62]	Z=-0.03, p=0.9749
Heterogeneity:	Q=1.44 (df=1)	p=0.2302	I^2=30.6%		
Subgroup Heterogeneity:	Q=1.13 (df=3)	p=0.7710	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

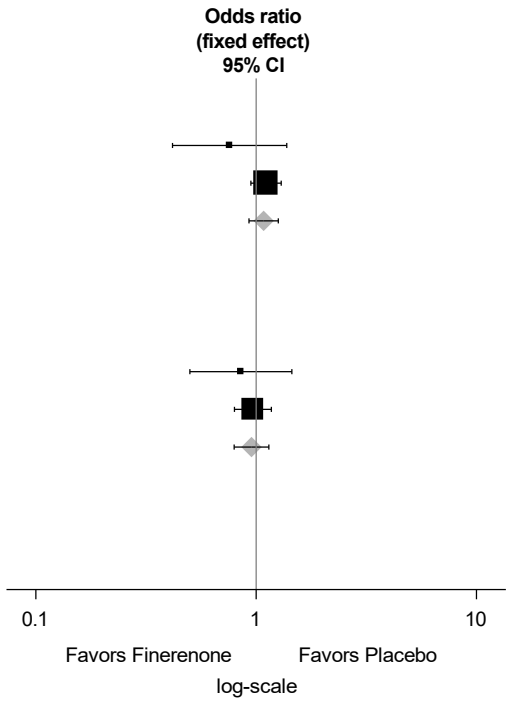
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	49 / 153	59 / 154	8.8	0.76 [0.47,1.21]	
FIGARO-DKD	556 / 1611	526 / 1640	91.2	1.12 [0.96,1.29]	
Total	605 / 1764	585 / 1794		1.08 [0.94,1.24]	Z=1.07, p=0.2864
Heterogeneity:	Q=2.36 (df=1)	p=0.1241	I^2=57.7%		
Female					
FIDELIO-DKD	19 / 58	23 / 67	8.3	0.93 [0.44,1.96]	
FIGARO-DKD	230 / 716	227 / 664	91.7	0.91 [0.73,1.14]	
Total	249 / 774	250 / 731		0.91 [0.74,1.13]	Z=-0.83, p=0.4050
Heterogeneity:	Q=0.00 (df=1)	p=0.9544	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.64 (df=1)	p=0.2010	I^2=38.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

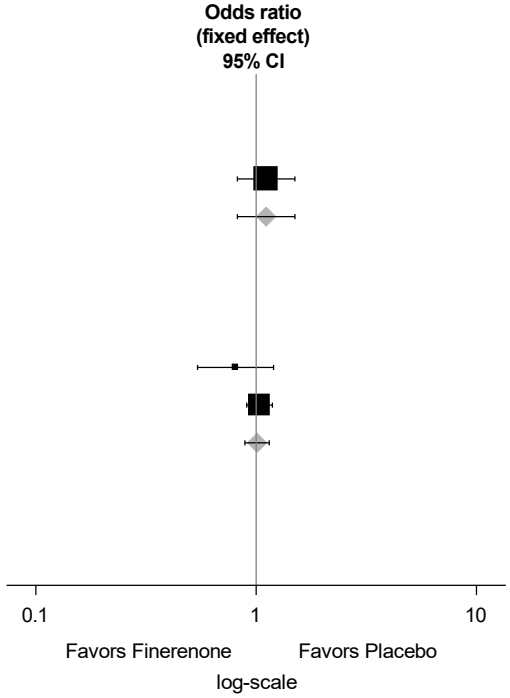
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	30 / 99	35 / 96	6.6	0.76 [0.42,1.38]	
FIGARO-DKD	462 / 1416	432 / 1421	93.4	1.11 [0.95,1.30]	
Total	492 / 1515	467 / 1517		1.08 [0.93,1.26]	Z=1.00, p=0.3179
Heterogeneity:	Q=1.46 (df=1)	p=0.2273	I^2=31.4%		
>= 65					
FIDELIO-DKD	38 / 112	47 / 125	11.6	0.85 [0.50,1.45]	
FIGARO-DKD	324 / 911	321 / 883	88.4	0.97 [0.80,1.17]	
Total	362 / 1023	368 / 1008		0.95 [0.79,1.14]	Z=-0.53, p=0.5978
Heterogeneity:	Q=0.19 (df=1)	p=0.6638	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.10 (df=1)	p=0.2949	I^2=8.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

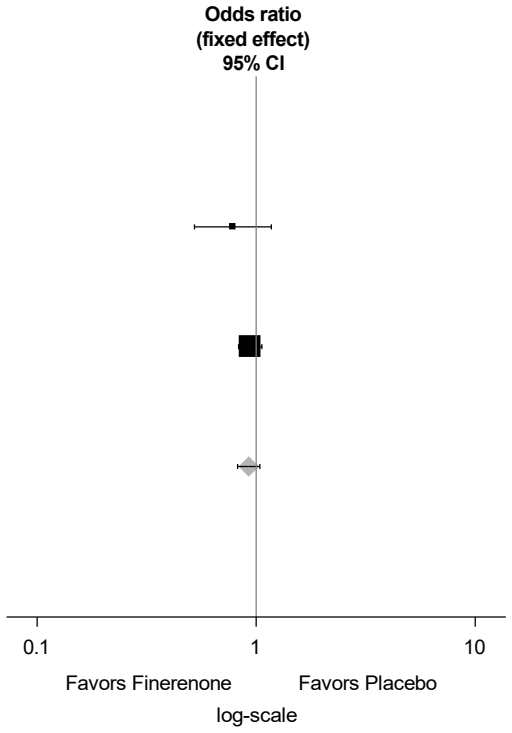
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	152 / 363	135 / 343	100.0	1.11 [0.82,1.50]	
Total	152 / 363	135 / 343		1.11 [0.82,1.50]	Z=0.68, p=0.4966
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	68 / 211	82 / 221	10.2	0.81 [0.54,1.20]	
FIGARO-DKD	634 / 1964	618 / 1961	89.8	1.04 [0.91,1.18]	
Total	702 / 2175	700 / 2182		1.01 [0.89,1.15]	Z=0.15, p=0.8836
Heterogeneity:	Q=1.37 (df=1)	p=0.2410	I^2=27.3%		
Subgroup Heterogeneity:	Q=0.32 (df=1)	p=0.5693	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

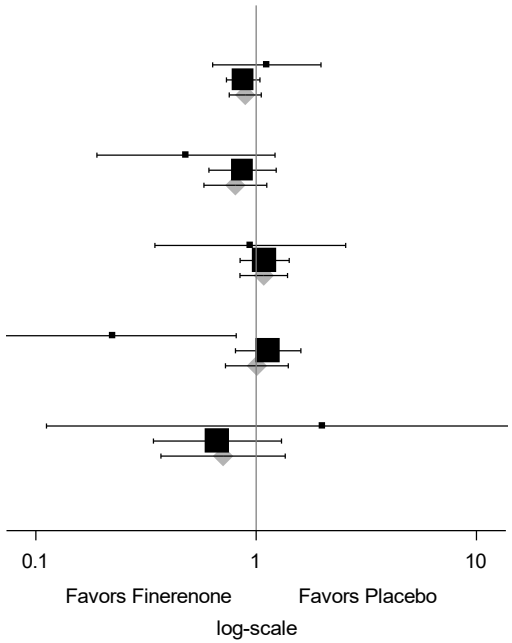
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 211	79 / 221	8.4	0.78 [0.52,1.17]	
FIGARO-DKD	758 / 2327	782 / 2304	91.6	0.94 [0.83,1.06]	
Total	822 / 2538	861 / 2525		0.92 [0.82,1.04]	Z=-1.31, p=0.1906
Heterogeneity:	Q=0.71 (df=1)	p=0.3979	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.4.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

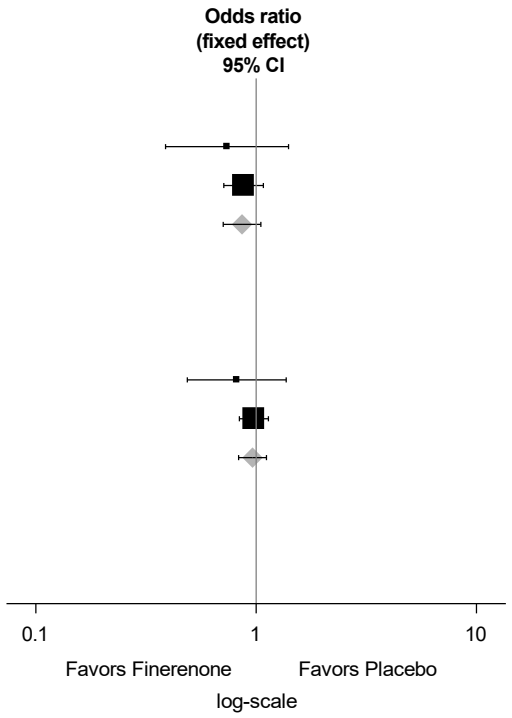
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 104	36 / 112	8.7	1.12 [0.63,1.97]	
FIGARO-DKD	366 / 1114	399 / 1111	91.3	0.87 [0.73,1.04]	
Total	402 / 1218	435 / 1223		0.89 [0.75,1.05]	Z=-1.34, p=0.1811
Heterogeneity:	Q=0.67 (df=1)	p=0.4142	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	17 / 40	12.5	0.48 [0.19,1.22]	
FIGARO-DKD	90 / 292	94 / 277	87.5	0.87 [0.61,1.23]	
Total	101 / 334	111 / 317		0.80 [0.58,1.12]	Z=-1.30, p=0.1940
Heterogeneity:	Q=1.36 (df=1)	p=0.2438	I^2=26.4%		
Asia					
FIDELIO-DKD	10 / 39	11 / 41	6.2	0.94 [0.35,2.55]	
FIGARO-DKD	181 / 522	171 / 523	93.8	1.09 [0.85,1.41]	
Total	191 / 561	182 / 564		1.08 [0.84,1.39]	Z=0.63, p=0.5320
Heterogeneity:	Q=0.08 (df=1)	p=0.7752	I^2=0.0%		
Latin America					
FIDELIO-DKD	5 / 21	14 / 24	6.6	0.22 [0.06,0.81]	
FIGARO-DKD	98 / 322	88 / 316	93.4	1.13 [0.81,1.60]	
Total	103 / 343	102 / 340		1.01 [0.73,1.40]	Z=0.04, p=0.9654
Heterogeneity:	Q=5.69 (df=1)	p=0.0171	I^2=82.4%		
Others					
FIDELIO-DKD	2 / 5	1 / 4	5.1	2.00 [0.11,35.81]	
FIGARO-DKD	23 / 77	30 / 77	94.9	0.67 [0.34,1.30]	
Total	25 / 82	31 / 81		0.71 [0.37,1.36]	Z=-1.04, p=0.2968
Heterogeneity:	Q=0.53 (df=1)	p=0.4675	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.32 (df=4)	p=0.5053	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.4.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

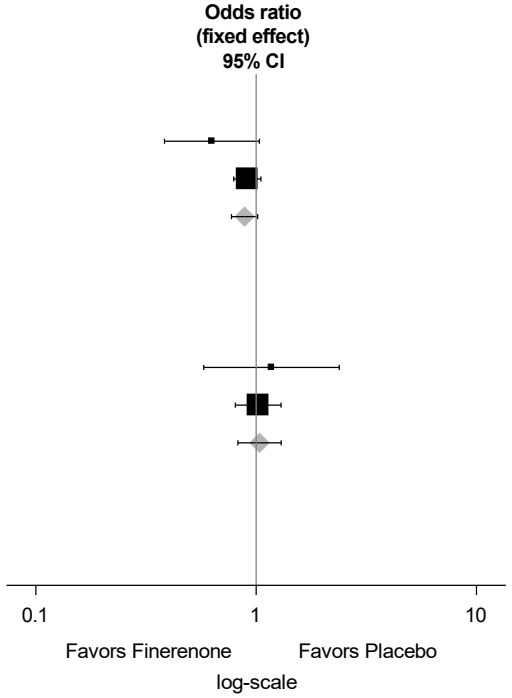
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	24 / 88	30 / 89	9.4	0.74 [0.39,1.40]	
FIGARO-DKD	261 / 811	282 / 803	90.6	0.88 [0.71,1.08]	
Total	285 / 899	312 / 892		0.86 [0.71,1.05]	Z=-1.47, p=0.1408
Heterogeneity:	Q=0.25 (df=1)	p=0.6157	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 123	49 / 132	7.9	0.82 [0.49,1.37]	
FIGARO-DKD	497 / 1516	500 / 1501	92.1	0.98 [0.84,1.14]	
Total	537 / 1639	549 / 1633		0.96 [0.83,1.11]	Z=-0.51, p=0.6080
Heterogeneity:	Q=0.42 (df=1)	p=0.5145	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3795	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.4.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

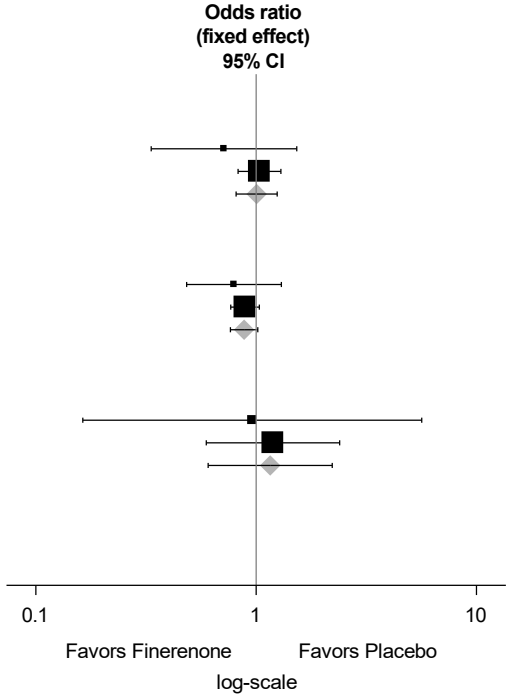
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	37 / 144	56 / 158	7.6	0.63 [0.38,1.03]	
FIGARO-DKD	560 / 1719	582 / 1680	92.4	0.91 [0.79,1.05]	
Total	597 / 1863	638 / 1838		0.89 [0.77,1.02]	Z=-1.74, p=0.0826
Heterogeneity:	Q=1.97 (df=1)	p=0.1603	I^2=49.3%		
> 4.5					
FIDELIO-DKD	27 / 67	23 / 63	10.2	1.17 [0.58,2.38]	
FIGARO-DKD	198 / 608	200 / 623	89.8	1.02 [0.80,1.30]	
Total	225 / 675	223 / 686		1.04 [0.83,1.30]	Z=0.31, p=0.7591
Heterogeneity:	Q=0.13 (df=1)	p=0.7151	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.35 (df=1)	p=0.2460	I^2=25.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.4.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

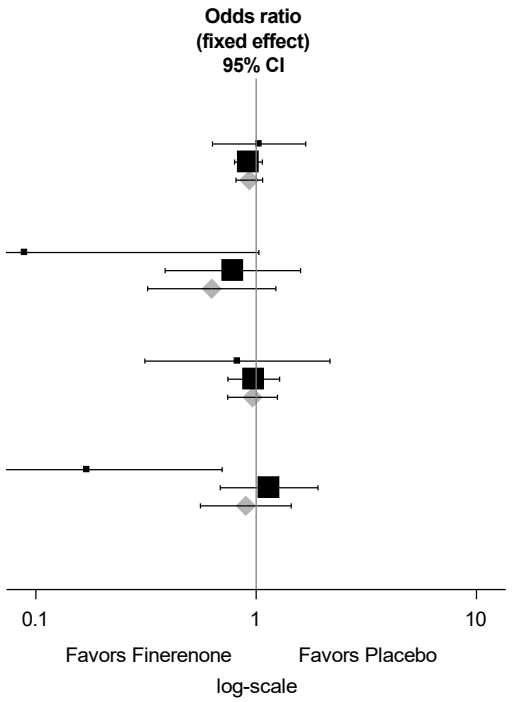
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	20 / 64	21 / 54	8.0	0.71 [0.33,1.53]	
FIGARO-DKD	230 / 693	227 / 700	92.0	1.04 [0.83,1.29]	
Total	250 / 757	248 / 754		1.00 [0.81,1.25]	Z=0.04, p=0.9641
Heterogeneity:	Q=0.84 (df=1)	p=0.3592	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	40 / 138	53 / 156	8.4	0.79 [0.48,1.30]	
FIGARO-DKD	505 / 1561	533 / 1525	91.6	0.89 [0.77,1.03]	
Total	545 / 1699	586 / 1681		0.88 [0.76,1.02]	Z=-1.73, p=0.0839
Heterogeneity:	Q=0.19 (df=1)	p=0.6624	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 9	5 / 11	13.4	0.96 [0.16,5.64]	
FIGARO-DKD	23 / 73	22 / 79	86.6	1.19 [0.59,2.39]	
Total	27 / 82	27 / 90		1.16 [0.61,2.21]	Z=0.44, p=0.6580
Heterogeneity:	Q=0.05 (df=1)	p=0.8237	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.47 (df=2)	p=0.4798	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.4.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

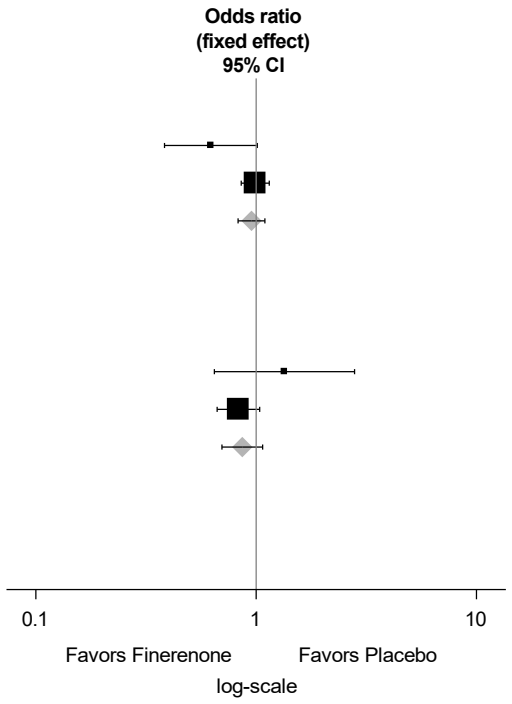
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	47 / 140	50 / 152	8.2	1.03 [0.63,1.68]	
FIGARO-DKD	538 / 1659	552 / 1613	91.8	0.92 [0.80,1.07]	
Total	585 / 1799	602 / 1765		0.93 [0.81,1.07]	Z=-1.01, p=0.3138
Heterogeneity:	Q=0.18 (df=1)	p=0.6683	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	5 / 9	7.7	0.09 [0.01,1.03]	
FIGARO-DKD	20 / 70	25 / 74	92.3	0.78 [0.39,1.59]	
Total	21 / 80	30 / 83		0.63 [0.32,1.23]	Z=-1.36, p=0.1742
Heterogeneity:	Q=2.83 (df=1)	p=0.0928	I^2=64.6%		
Asian					
FIDELIO-DKD	10 / 39	13 / 44	7.2	0.82 [0.31,2.16]	
FIGARO-DKD	153 / 464	163 / 486	92.8	0.97 [0.74,1.28]	
Total	163 / 503	176 / 530		0.96 [0.74,1.25]	Z=-0.28, p=0.7757
Heterogeneity:	Q=0.11 (df=1)	p=0.7398	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 22	11 / 16	11.5	0.17 [0.04,0.70]	
FIGARO-DKD	47 / 134	42 / 131	88.5	1.14 [0.69,1.91]	
Total	53 / 156	53 / 147		0.90 [0.56,1.44]	Z=-0.45, p=0.6550
Heterogeneity:	Q=6.18 (df=1)	p=0.0129	I^2=83.8%		
Subgroup Heterogeneity:	Q=1.39 (df=3)	p=0.7071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.4.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

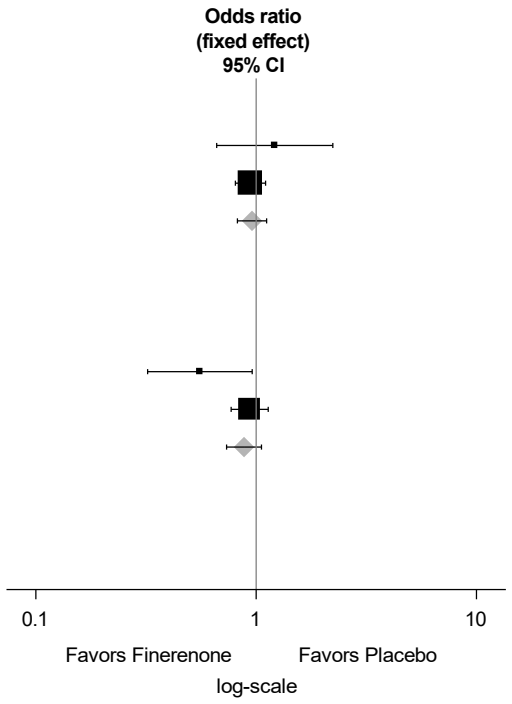
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	41 / 153	57 / 154	8.4	0.62 [0.38,1.01]	
FIGARO-DKD	526 / 1611	539 / 1640	91.6	0.99 [0.86,1.15]	
Total	567 / 1764	596 / 1794		0.95 [0.83,1.10]	Z=-0.69, p=0.4930
Heterogeneity:	Q=3.22 (df=1)	p=0.0728	I^2=68.9%		
Female					
FIDELIO-DKD	23 / 58	22 / 67	8.4	1.34 [0.65,2.80]	
FIGARO-DKD	232 / 716	243 / 664	91.6	0.83 [0.66,1.04]	
Total	255 / 774	265 / 731		0.86 [0.70,1.07]	Z=-1.34, p=0.1811
Heterogeneity:	Q=1.52 (df=1)	p=0.2177	I^2=34.2%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4594	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.4.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

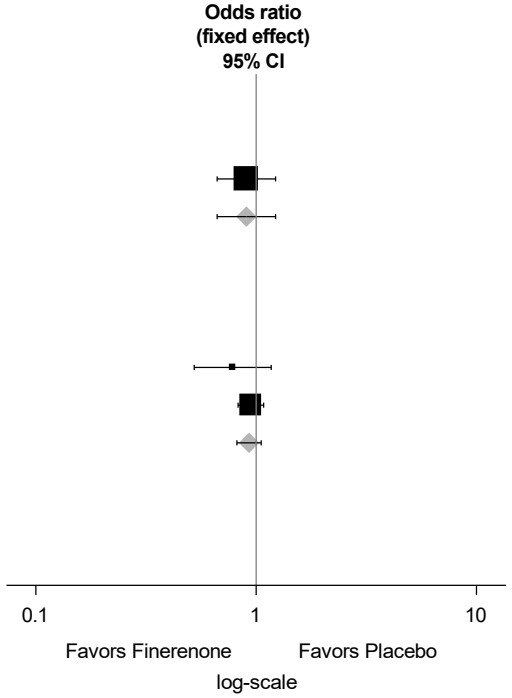
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 99	28 / 96	6.3	1.21 [0.66,2.23]	
FIGARO-DKD	444 / 1416	464 / 1421	93.7	0.94 [0.80,1.10]	
Total	477 / 1515	492 / 1517		0.96 [0.82,1.12]	Z=-0.56, p=0.5766
Heterogeneity:	Q=0.63 (df=1)	p=0.4277	I^2=0.0%		
>= 65					
FIDELIO-DKD	31 / 112	51 / 125	11.2	0.56 [0.32,0.96]	
FIGARO-DKD	314 / 911	318 / 883	88.8	0.93 [0.77,1.13]	
Total	345 / 1023	369 / 1008		0.88 [0.73,1.06]	Z=-1.36, p=0.1723
Heterogeneity:	Q=3.10 (df=1)	p=0.0785	I^2=67.7%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4915	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.4.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

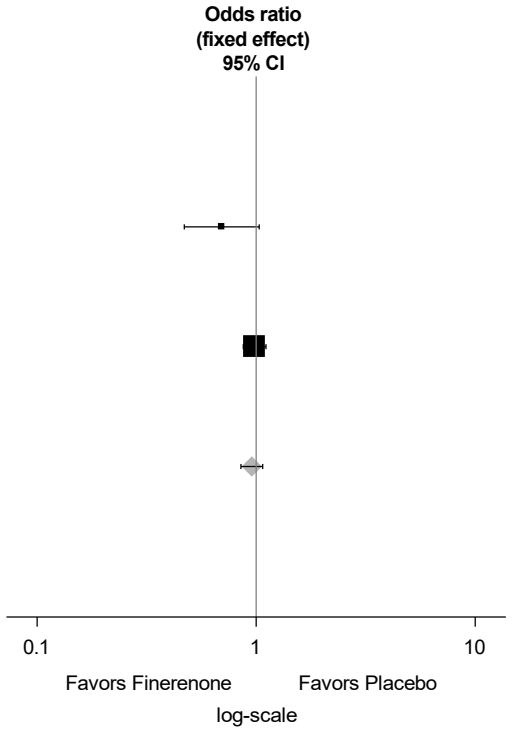
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	131 / 363	132 / 343	100.0	0.90 [0.67,1.22]	
Total	131 / 363	132 / 343		0.90 [0.67,1.22]	Z=-0.66, p=0.5105
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	64 / 211	79 / 221	9.9	0.78 [0.52,1.17]	
FIGARO-DKD	627 / 1964	650 / 1961	90.1	0.95 [0.83,1.08]	
Total	691 / 2175	729 / 2182		0.93 [0.82,1.05]	Z=-1.15, p=0.2490
Heterogeneity:	Q=0.77 (df=1)	p=0.3809	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

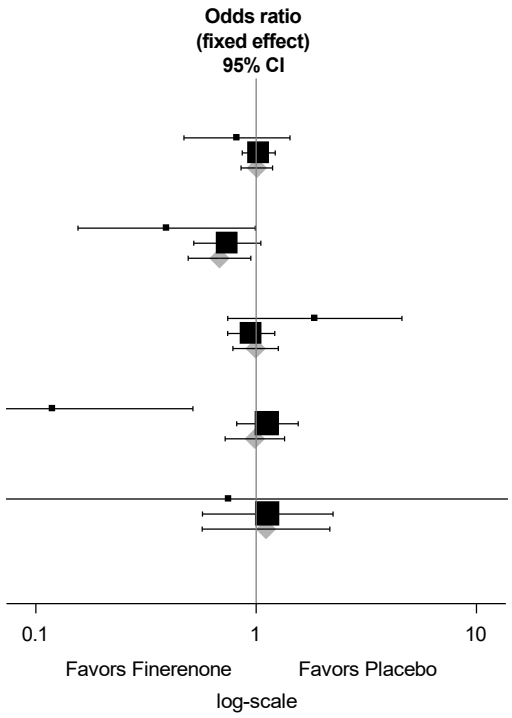
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	69 / 211	91 / 221	8.4	0.70 [0.47,1.03]	
FIGARO-DKD	861 / 2327	861 / 2304	91.6	0.98 [0.87,1.11]	
Total	930 / 2538	952 / 2525		0.96 [0.85,1.07]	Z=-0.79, p=0.4317
Heterogeneity:	Q=2.71 (df=1)	p=0.0997	I^2=63.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.5.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

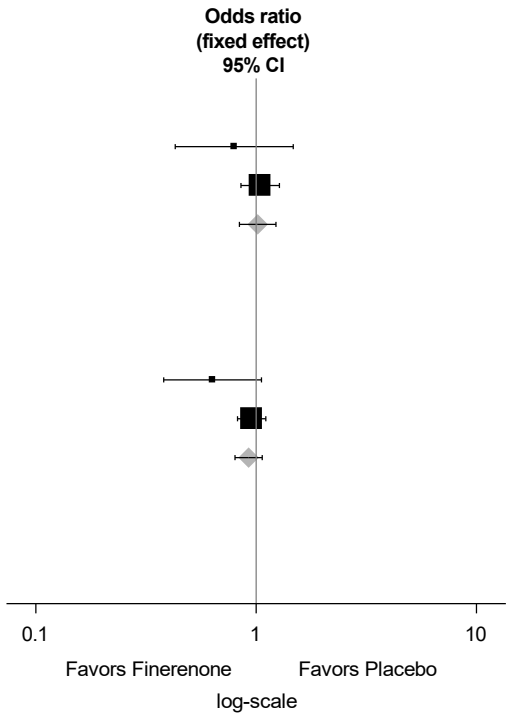
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 104	44 / 112	8.8	0.82 [0.47,1.42]	
FIGARO-DKD	411 / 1114	403 / 1111	91.2	1.03 [0.86,1.22]	
Total	447 / 1218	447 / 1223		1.01 [0.85,1.19]	Z=0.08, p=0.9375
Heterogeneity:	Q=0.59 (df=1)	p=0.4424	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 42	19 / 40	12.5	0.39 [0.16,0.99]	
FIGARO-DKD	87 / 292	101 / 277	87.5	0.74 [0.52,1.05]	
Total	98 / 334	120 / 317		0.68 [0.49,0.95]	Z=-2.30, p=0.0217
Heterogeneity:	Q=1.58 (df=1)	p=0.2094	I^2=36.5%		
Asia					
FIDELIO-DKD	18 / 39	13 / 41	6.8	1.85 [0.74,4.59]	
FIGARO-DKD	214 / 522	221 / 523	93.2	0.95 [0.74,1.21]	
Total	232 / 561	234 / 564		0.99 [0.78,1.26]	Z=-0.05, p=0.9610
Heterogeneity:	Q=1.91 (df=1)	p=0.1670	I^2=47.6%		
Latin America					
FIDELIO-DKD	3 / 21	14 / 24	4.6	0.12 [0.03,0.52]	
FIGARO-DKD	124 / 322	113 / 316	95.4	1.13 [0.82,1.55]	
Total	127 / 343	127 / 340		0.99 [0.72,1.35]	Z=-0.09, p=0.9309
Heterogeneity:	Q=8.62 (df=1)	p=0.0033	I^2=88.4%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	4.5	0.75 [0.03,17.51]	
FIGARO-DKD	25 / 77	23 / 77	95.5	1.13 [0.57,2.23]	
Total	26 / 82	24 / 81		1.11 [0.57,2.16]	Z=0.30, p=0.7624
Heterogeneity:	Q=0.06 (df=1)	p=0.8037	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.82 (df=4)	p=0.3067	I^2=16.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.5.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

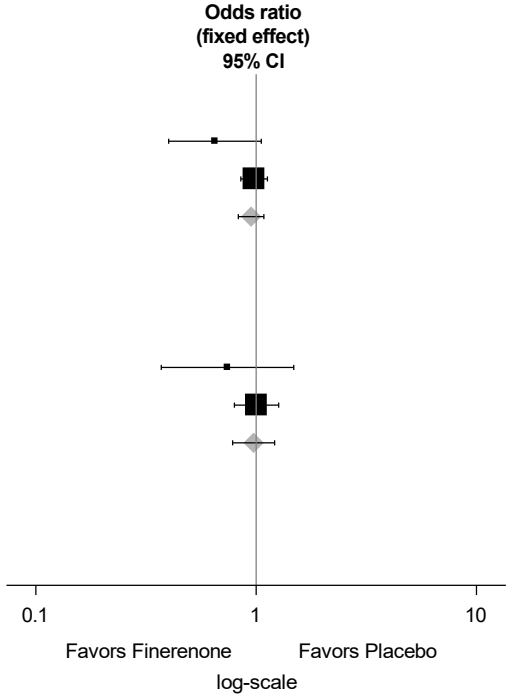
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	29 / 88	34 / 89	9.6	0.80 [0.43,1.47]	
FIGARO-DKD	312 / 811	301 / 803	90.4	1.04 [0.85,1.28]	
Total	341 / 899	335 / 892		1.02 [0.84,1.23]	Z=0.16, p=0.8715
Heterogeneity:	Q=0.67 (df=1)	p=0.4126	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 123	57 / 132	7.7	0.63 [0.38,1.06]	
FIGARO-DKD	549 / 1516	560 / 1501	92.3	0.95 [0.82,1.11]	
Total	589 / 1639	617 / 1633		0.92 [0.80,1.07]	Z=-1.09, p=0.2755
Heterogeneity:	Q=2.27 (df=1)	p=0.1323	I^2=55.9%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4351	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.5.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

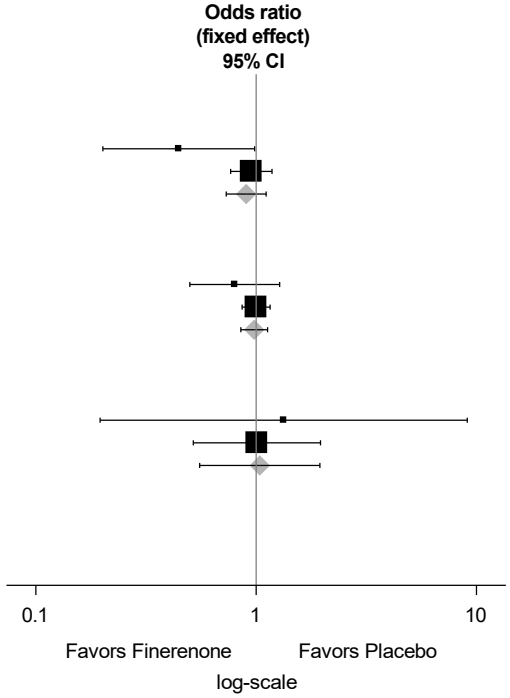
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	41 / 144	60 / 158	7.6	0.65 [0.40,1.05]	
FIGARO-DKD	636 / 1719	630 / 1680	92.4	0.98 [0.85,1.12]	
Total	677 / 1863	690 / 1838		0.95 [0.83,1.08]	Z=-0.78, p=0.4364
Heterogeneity:	Q=2.54 (df=1)	p=0.1113	I^2=60.6%		
> 4.5					
FIDELIO-DKD	28 / 67	31 / 63	10.0	0.74 [0.37,1.48]	
FIGARO-DKD	225 / 608	230 / 623	90.0	1.00 [0.80,1.27]	
Total	253 / 675	261 / 686		0.97 [0.78,1.21]	Z=-0.24, p=0.8110
Heterogeneity:	Q=0.66 (df=1)	p=0.4154	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8413	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.5.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

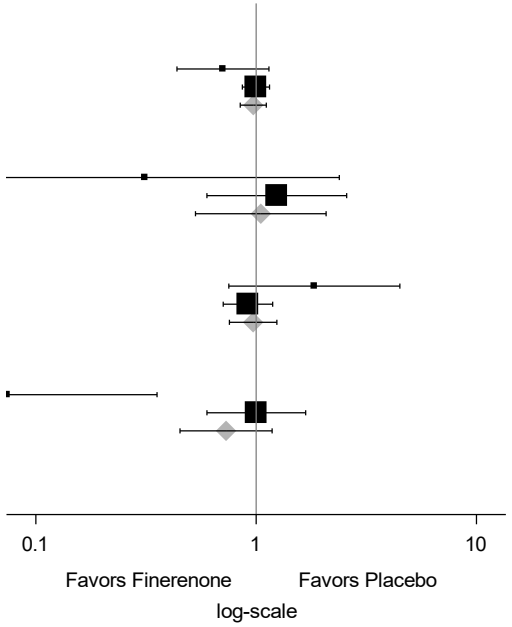
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 64	22 / 54	6.9	0.45 [0.20,0.98]	
FIGARO-DKD	260 / 693	271 / 700	93.1	0.95 [0.77,1.18]	
Total	275 / 757	293 / 754		0.90 [0.73,1.11]	Z=-0.98, p=0.3263
Heterogeneity:	Q=3.27 (df=1)	p=0.0706	I^2=69.4%		
130 - < 160					
FIDELIO-DKD	51 / 138	66 / 156	8.9	0.80 [0.50,1.28]	
FIGARO-DKD	575 / 1561	562 / 1525	91.1	1.00 [0.86,1.16]	
Total	626 / 1699	628 / 1681		0.98 [0.85,1.13]	Z=-0.29, p=0.7729
Heterogeneity:	Q=0.79 (df=1)	p=0.3736	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 9	3 / 11	10.7	1.33 [0.20,9.08]	
FIGARO-DKD	26 / 73	28 / 79	89.3	1.01 [0.52,1.96]	
Total	29 / 82	31 / 90		1.04 [0.55,1.95]	Z=0.12, p=0.9066
Heterogeneity:	Q=0.07 (df=1)	p=0.7869	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=2)	p=0.7805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.5.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

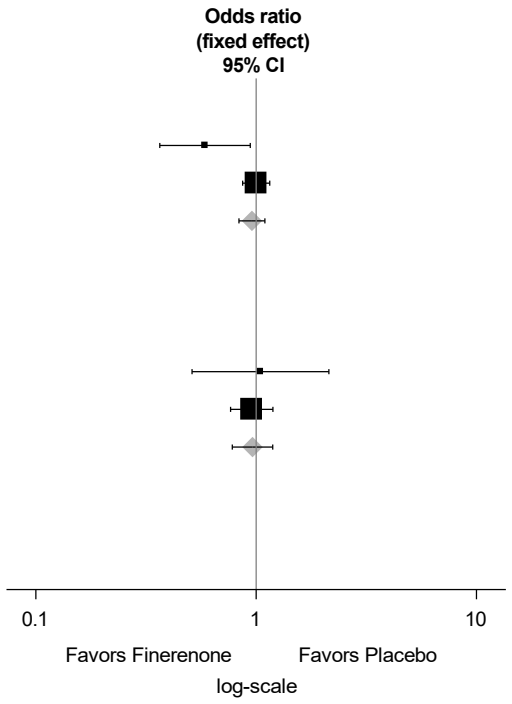
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 140	61 / 152	8.0	0.71 [0.44,1.14]	
FIGARO-DKD	610 / 1659	594 / 1613	92.0	1.00 [0.87,1.15]	
Total	655 / 1799	655 / 1765		0.97 [0.85,1.11]	Z=-0.44, p=0.6623
Heterogeneity:	Q=1.82 (df=1)	p=0.1775	I^2=45.0%		
Black					
FIDELIO-DKD	2 / 10	4 / 9	11.4	0.31 [0.04,2.38]	
FIGARO-DKD	21 / 70	19 / 74	88.6	1.24 [0.60,2.58]	
Total	23 / 80	23 / 83		1.05 [0.53,2.08]	Z=0.14, p=0.8898
Heterogeneity:	Q=1.57 (df=1)	p=0.2107	I^2=36.2%		
Asian					
FIDELIO-DKD	18 / 39	14 / 44	7.7	1.84 [0.75,4.49]	
FIGARO-DKD	187 / 464	206 / 486	92.3	0.92 [0.71,1.19]	
Total	205 / 503	220 / 530		0.97 [0.76,1.24]	Z=-0.25, p=0.8016
Heterogeneity:	Q=2.14 (df=1)	p=0.1437	I^2=53.2%		
Others					
FIDELIO-DKD	4 / 22	12 / 16	9.8	0.07 [0.02,0.35]	
FIGARO-DKD	43 / 134	42 / 131	90.2	1.00 [0.60,1.68]	
Total	47 / 156	54 / 147		0.73 [0.45,1.18]	Z=-1.28, p=0.1999
Heterogeneity:	Q=9.64 (df=1)	p=0.0019	I^2=89.6%		
Subgroup Heterogeneity:	Q=1.33 (df=3)	p=0.7211	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.5.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

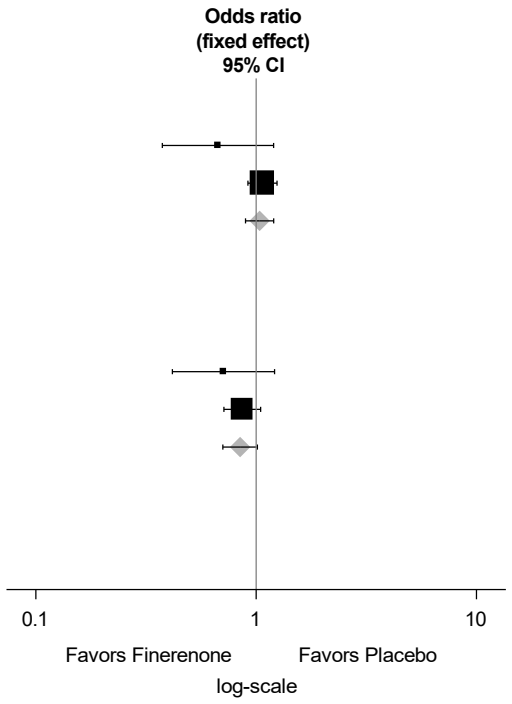
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	45 / 153	64 / 154	8.2	0.59 [0.37,0.94]	
FIGARO-DKD	613 / 1611	624 / 1640	91.8	1.00 [0.87,1.15]	
Total	658 / 1764	688 / 1794		0.96 [0.84,1.10]	Z=-0.64, p=0.5199
Heterogeneity:	Q=4.51 (df=1)	p=0.0338	I^2=77.8%		
Female					
FIDELIO-DKD	24 / 58	27 / 67	8.7	1.05 [0.51,2.14]	
FIGARO-DKD	248 / 716	237 / 664	91.3	0.95 [0.77,1.19]	
Total	272 / 774	264 / 731		0.96 [0.78,1.19]	Z=-0.36, p=0.7219
Heterogeneity:	Q=0.06 (df=1)	p=0.8116	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9619	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.5.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

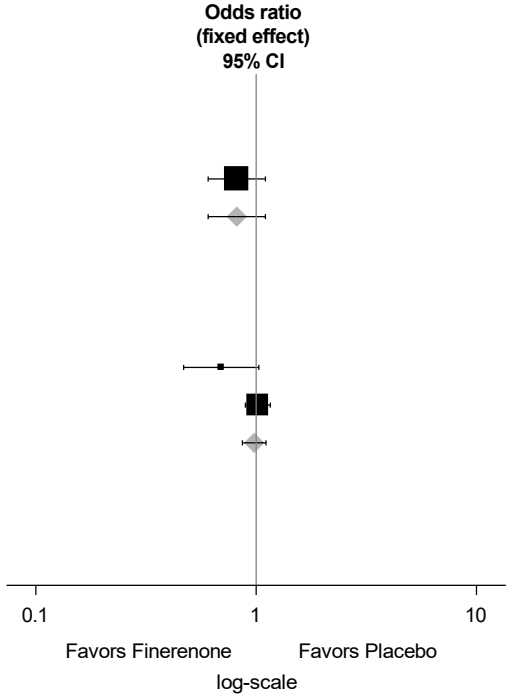
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 99	41 / 96	6.4	0.67 [0.37,1.20]	
FIGARO-DKD	540 / 1416	520 / 1421	93.6	1.07 [0.92,1.24]	
Total	573 / 1515	561 / 1517		1.04 [0.89,1.20]	Z=0.48, p=0.6328
Heterogeneity:	Q=2.30 (df=1)	p=0.1292	I^2=56.6%		
>= 65					
FIDELIO-DKD	36 / 112	50 / 125	11.4	0.71 [0.42,1.21]	
FIGARO-DKD	321 / 911	341 / 883	88.6	0.86 [0.71,1.05]	
Total	357 / 1023	391 / 1008		0.85 [0.71,1.01]	Z=-1.82, p=0.0684
Heterogeneity:	Q=0.46 (df=1)	p=0.4975	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.94 (df=1)	p=0.0864	I^2=66.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.5.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

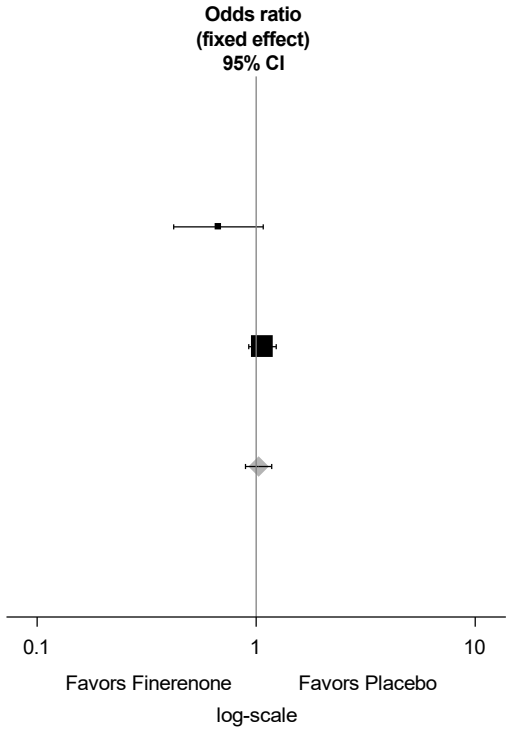
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	144 / 363	153 / 343	100.0	0.82 [0.61,1.10]	
Total	144 / 363	153 / 343		0.82 [0.61,1.10]	Z=-1.33, p=0.1844
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	69 / 211	91 / 221	9.9	0.69 [0.47,1.03]	
FIGARO-DKD	717 / 1964	708 / 1961	90.1	1.02 [0.89,1.16]	
Total	786 / 2175	799 / 2182		0.98 [0.87,1.11]	Z=-0.33, p=0.7436
Heterogeneity:	Q=3.28 (df=1)	p=0.0702	I^2=69.5%		
Subgroup Heterogeneity:	Q=1.22 (df=1)	p=0.2703	I^2=17.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

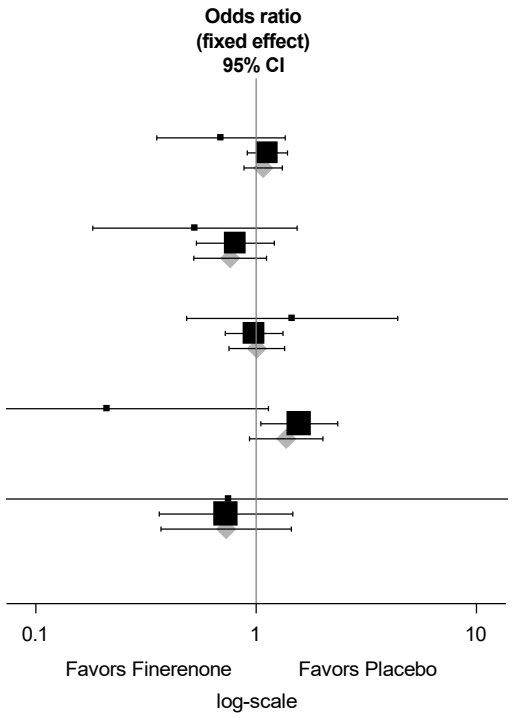
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 211	53 / 221	8.6	0.67 [0.42,1.08]	
FIGARO-DKD	479 / 2327	449 / 2304	91.4	1.07 [0.92,1.23]	
Total	516 / 2538	502 / 2525		1.03 [0.89,1.18]	Z=0.36, p=0.7158
Heterogeneity:	Q=3.39 (df=1)	p=0.0654	I^2=70.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.6.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

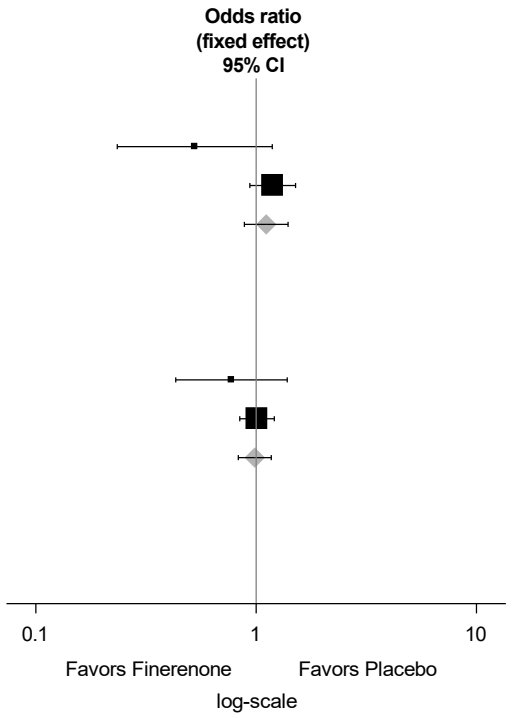
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 104	26 / 112	8.9	0.69 [0.35;1.35]	
FIGARO-DKD	227 / 1114	206 / 1111	91.1	1.12 [0.91;1.39]	
Total	245 / 1218	232 / 1223		1.08 [0.88;1.31]	Z=0.72, p=0.4734
Heterogeneity:	Q=1.83 (df=1)	p=0.1766	I^2=45.2%		
North America					
FIDELIO-DKD	7 / 42	11 / 40	12.7	0.53 [0.18;1.53]	
FIGARO-DKD	55 / 292	62 / 277	87.3	0.80 [0.54;1.21]	
Total	62 / 334	73 / 317		0.76 [0.52;1.11]	Z=-1.40, p=0.1608
Heterogeneity:	Q=0.53 (df=1)	p=0.4684	I^2=0.0%		
Asia					
FIDELIO-DKD	9 / 39	7 / 41	7.0	1.46 [0.48;4.39]	
FIGARO-DKD	105 / 522	107 / 523	93.0	0.98 [0.72;1.32]	
Total	114 / 561	114 / 564		1.01 [0.75;1.35]	Z=0.04, p=0.9643
Heterogeneity:	Q=0.46 (df=1)	p=0.4954	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	8 / 24	5.4	0.21 [0.04;1.14]	
FIGARO-DKD	72 / 322	49 / 316	94.6	1.57 [1.05;2.35]	
Total	74 / 343	57 / 340		1.37 [0.93;2.01]	Z=1.60, p=0.1088
Heterogeneity:	Q=5.18 (df=1)	p=0.0229	I^2=80.7%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	4.7	0.75 [0.03;17.51]	
FIGARO-DKD	20 / 77	25 / 77	95.3	0.73 [0.36;1.47]	
Total	21 / 82	26 / 81		0.73 [0.37;1.44]	Z=-0.90, p=0.3669
Heterogeneity:	Q=0.00 (df=1)	p=0.9868	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.71 (df=4)	p=0.2220	I^2=29.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.6.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

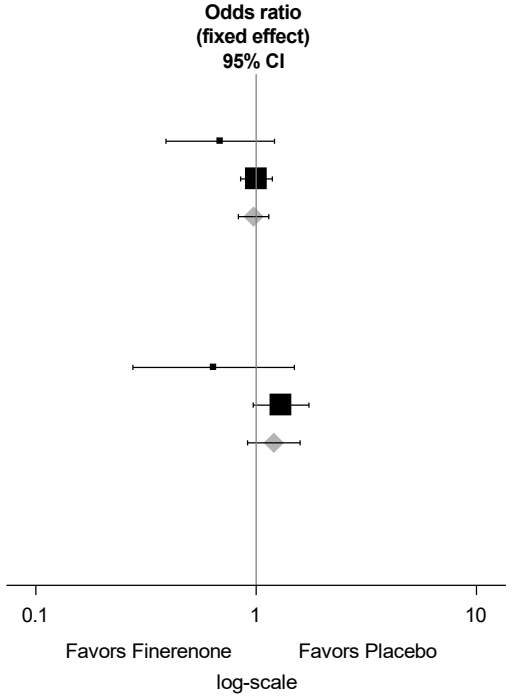
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	11 / 88	19 / 89	8.0	0.53 [0.23,1.18]	
FIGARO-DKD	184 / 811	159 / 803	92.0	1.19 [0.94,1.51]	
Total	195 / 899	178 / 892		1.11 [0.88,1.40]	Z=0.90, p=0.3679
Heterogeneity:	Q=3.57 (df=1)	p=0.0587	I^2=72.0%		
Absent					
FIDELIO-DKD	26 / 123	34 / 132	8.8	0.77 [0.43,1.38]	
FIGARO-DKD	295 / 1516	290 / 1501	91.2	1.01 [0.84,1.21]	
Total	321 / 1639	324 / 1633		0.99 [0.83,1.17]	Z=-0.17, p=0.8676
Heterogeneity:	Q=0.74 (df=1)	p=0.3912	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=1)	p=0.4127	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.6.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

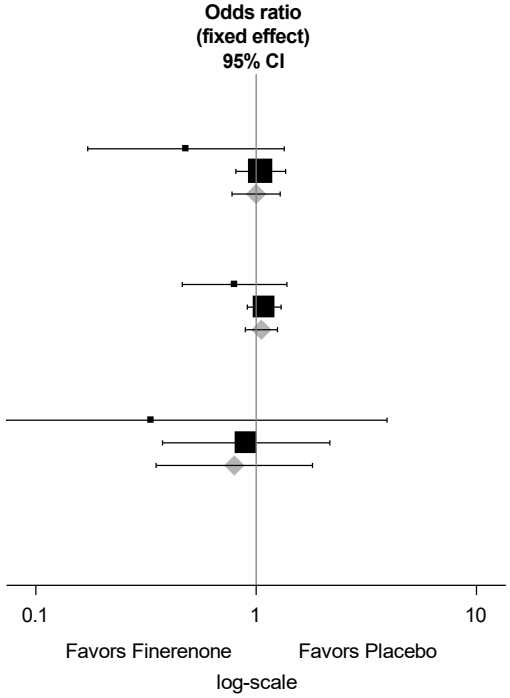
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	37 / 158	7.9	0.69 [0.39,1.21]	
FIGARO-DKD	357 / 1719	348 / 1680	92.1	1.00 [0.85,1.18]	
Total	382 / 1863	385 / 1838		0.97 [0.83,1.14]	Z=-0.33, p=0.7390
Heterogeneity:	Q=1.58 (df=1)	p=0.2090	I^2=36.6%		
> 4.5					
FIDELIO-DKD	12 / 67	16 / 63	10.6	0.64 [0.28,1.49]	
FIGARO-DKD	122 / 608	101 / 623	89.4	1.30 [0.97,1.74]	
Total	134 / 675	117 / 686		1.20 [0.91,1.58]	Z=1.32, p=0.1877
Heterogeneity:	Q=2.40 (df=1)	p=0.1215	I^2=58.3%		
Subgroup Heterogeneity:	Q=1.71 (df=1)	p=0.1912	I^2=41.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.6.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

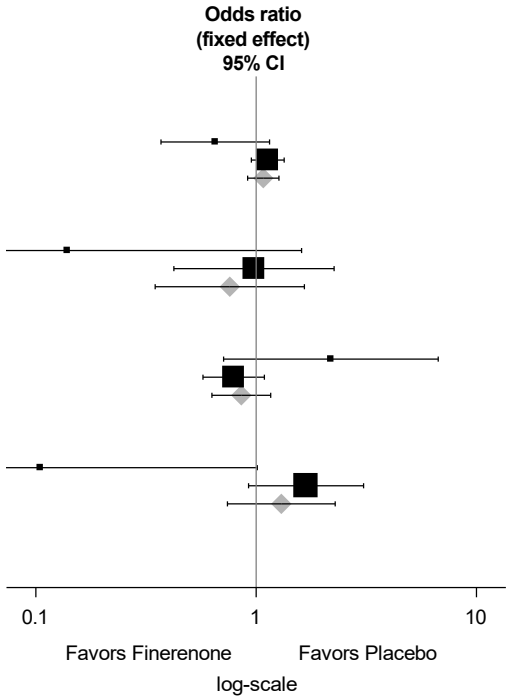
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 64	11 / 54	6.0	0.48 [0.17,1.34]	
FIGARO-DKD	145 / 693	141 / 700	94.0	1.05 [0.81,1.36]	
Total	152 / 757	152 / 754		1.00 [0.78,1.29]	Z=-0.01, p=0.9955
Heterogeneity:	Q=2.09 (df=1)	p=0.1481	I^2=52.2%		
130 - < 160					
FIDELIO-DKD	29 / 138	39 / 156	9.4	0.80 [0.46,1.38]	
FIGARO-DKD	323 / 1561	295 / 1525	90.6	1.09 [0.91,1.30]	
Total	352 / 1699	334 / 1681		1.06 [0.89,1.25]	Z=0.64, p=0.5223
Heterogeneity:	Q=1.12 (df=1)	p=0.2909	I^2=10.3%		
>= 160					
FIDELIO-DKD	1 / 9	3 / 11	11.2	0.33 [0.03,3.93]	
FIGARO-DKD	11 / 73	13 / 79	88.8	0.90 [0.38,2.16]	
Total	12 / 82	16 / 90		0.80 [0.35,1.80]	Z=-0.55, p=0.5835
Heterogeneity:	Q=0.56 (df=1)	p=0.4561	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.53 (df=2)	p=0.7689	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.6.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

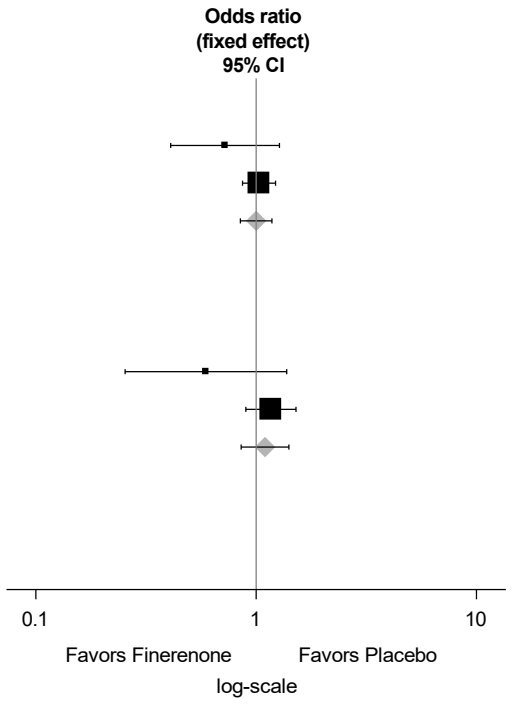
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	25 / 140	38 / 152	8.4	0.65 [0.37,1.15]	
FIGARO-DKD	349 / 1659	308 / 1613	91.6	1.13 [0.95,1.34]	
Total	374 / 1799	346 / 1765		1.08 [0.91,1.27]	Z=0.89, p=0.3730
Heterogeneity:	Q=3.29 (df=1)	p=0.0696	I^2=69.6%		
Black					
FIDELIO-DKD	1 / 10	4 / 9	10.5	0.14 [0.01,1.61]	
FIGARO-DKD	13 / 70	14 / 74	89.5	0.98 [0.42,2.26]	
Total	14 / 80	18 / 83		0.76 [0.35,1.66]	Z=-0.69, p=0.4881
Heterogeneity:	Q=2.20 (df=1)	p=0.1382	I^2=54.5%		
Asian					
FIDELIO-DKD	10 / 39	6 / 44	7.6	2.18 [0.71,6.70]	
FIGARO-DKD	83 / 464	105 / 486	92.4	0.79 [0.57,1.09]	
Total	93 / 503	111 / 530		0.86 [0.63,1.16]	Z=-0.99, p=0.3217
Heterogeneity:	Q=2.92 (df=1)	p=0.0877	I^2=65.7%		
Others					
FIDELIO-DKD	1 / 22	5 / 16	6.6	0.10 [0.01,1.01]	
FIGARO-DKD	34 / 134	22 / 131	93.4	1.68 [0.92,3.07]	
Total	35 / 156	27 / 147		1.30 [0.74,2.28]	Z=0.91, p=0.3603
Heterogeneity:	Q=5.45 (df=1)	p=0.0196	I^2=81.7%		
Subgroup Heterogeneity:	Q=2.93 (df=3)	p=0.4029	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.6.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

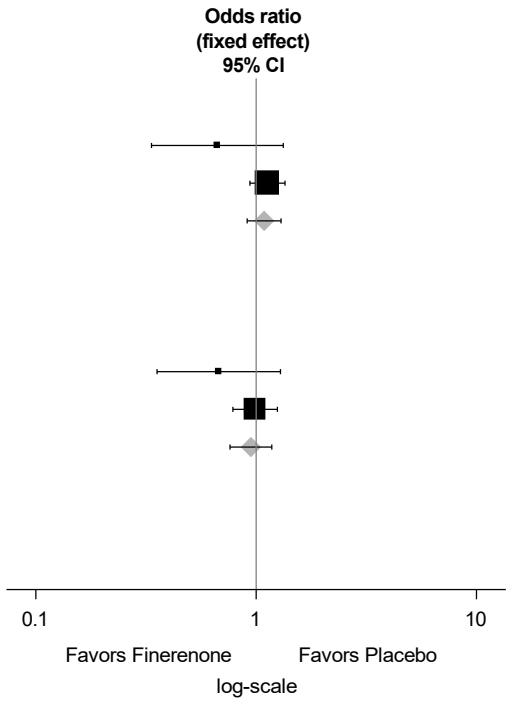
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 153	34 / 154	8.4	0.72 [0.41,1.28]	
FIGARO-DKD	323 / 1611	321 / 1640	91.6	1.03 [0.87,1.22]	
Total	349 / 1764	355 / 1794		1.00 [0.85,1.18]	Z=-0.00, p=0.9980
Heterogeneity:	Q=1.37 (df=1)	p=0.2415	I^2=27.1%		
Female					
FIDELIO-DKD	11 / 58	19 / 67	8.8	0.59 [0.25,1.38]	
FIGARO-DKD	156 / 716	128 / 664	91.2	1.17 [0.90,1.52]	
Total	167 / 774	147 / 731		1.10 [0.85,1.41]	Z=0.73, p=0.4669
Heterogeneity:	Q=2.27 (df=1)	p=0.1320	I^2=55.9%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5431	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.6.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

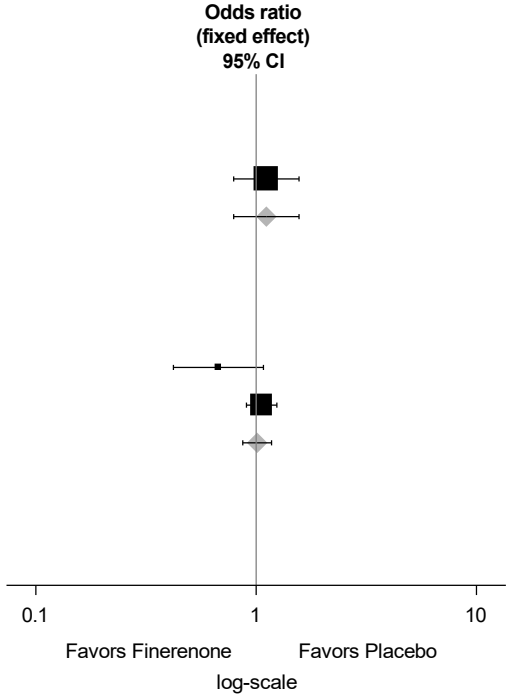
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 99	24 / 96	6.6	0.67 [0.33,1.33]	
FIGARO-DKD	300 / 1416	274 / 1421	93.4	1.13 [0.94,1.35]	
Total	318 / 1515	298 / 1517		1.09 [0.91,1.30]	Z=0.92, p=0.3580
Heterogeneity:	Q=2.07 (df=1)	p=0.1499	I^2=51.8%		
>= 65					
FIDELIO-DKD	19 / 112	29 / 125	11.5	0.68 [0.35,1.29]	
FIGARO-DKD	179 / 911	175 / 883	88.5	0.99 [0.78,1.25]	
Total	198 / 1023	204 / 1008		0.95 [0.76,1.18]	Z=-0.50, p=0.6204
Heterogeneity:	Q=1.18 (df=1)	p=0.2769	I^2=15.4%		
Subgroup Heterogeneity:	Q=0.93 (df=1)	p=0.3353	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.6.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

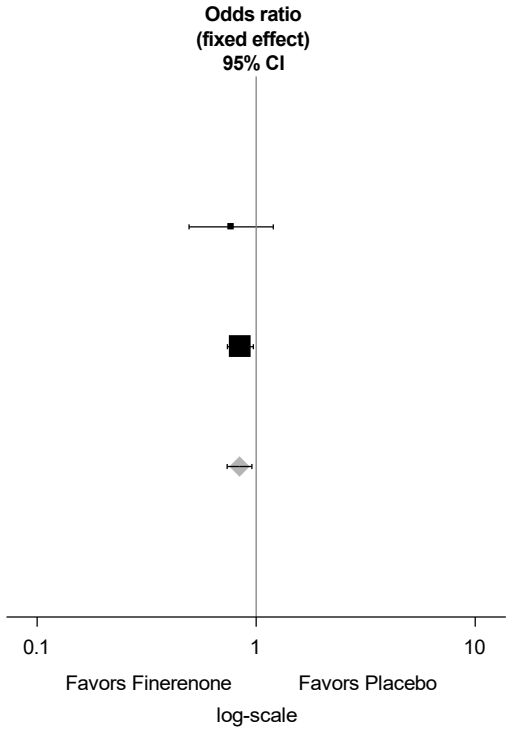
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	94 / 363	82 / 343	100.0	1.11 [0.79,1.57]	
Total	94 / 363	82 / 343		1.11 [0.79,1.57]	Z=0.61, p=0.5416
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	37 / 211	53 / 221	10.3	0.67 [0.42,1.08]	
FIGARO-DKD	385 / 1964	367 / 1961	89.7	1.06 [0.90,1.24]	
Total	422 / 2175	420 / 2182		1.01 [0.87,1.17]	Z=0.13, p=0.8929
Heterogeneity:	Q=3.18 (df=1)	p=0.0745	I^2=68.6%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6140	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

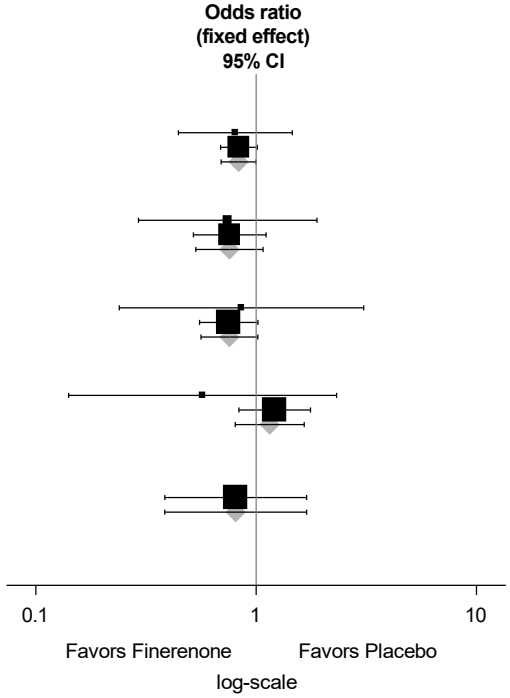
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 211	61 / 221	8.6	0.77 [0.49,1.20]	
FIGARO-DKD	514 / 2327	577 / 2304	91.4	0.85 [0.74,0.97]	
Total	562 / 2538	638 / 2525		0.84 [0.74,0.96]	Z=-2.64, p=0.0083
Heterogeneity:	Q=0.17 (df=1)	p=0.6825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.7.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

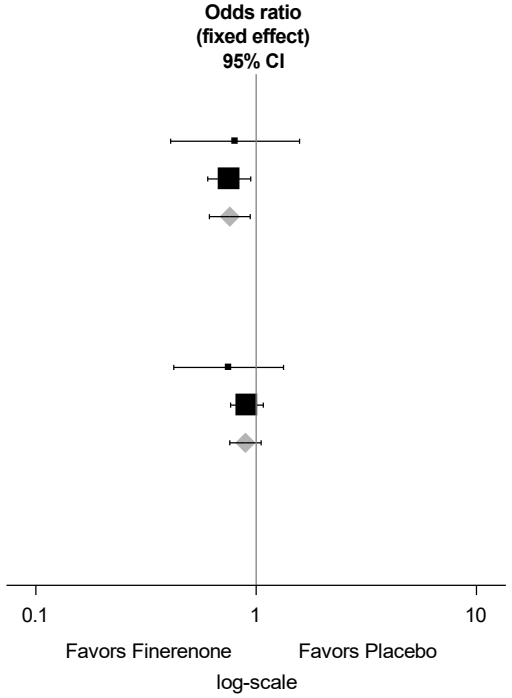
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 104	34 / 112	9.4	0.80 [0.44,1.46]	
FIGARO-DKD	262 / 1114	299 / 1111	90.6	0.84 [0.69,1.01]	
Total	289 / 1218	333 / 1223		0.83 [0.69,1.00]	Z=-1.97, p=0.0485
Heterogeneity:	Q=0.01 (df=1)	p=0.9066	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 42	14 / 40	14.2	0.74 [0.29,1.89]	
FIGARO-DKD	66 / 292	77 / 277	85.8	0.76 [0.52,1.11]	
Total	78 / 334	91 / 317		0.76 [0.53,1.08]	Z=-1.56, p=0.1197
Heterogeneity:	Q=0.00 (df=1)	p=0.9676	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 39	6 / 41	5.4	0.86 [0.24,3.08]	
FIGARO-DKD	92 / 522	116 / 523	94.6	0.75 [0.55,1.02]	
Total	97 / 561	122 / 564		0.76 [0.56,1.02]	Z=-1.85, p=0.0650
Heterogeneity:	Q=0.04 (df=1)	p=0.8421	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 21	7 / 24	6.7	0.57 [0.14,2.32]	
FIGARO-DKD	77 / 322	65 / 316	93.3	1.21 [0.83,1.76]	
Total	81 / 343	72 / 340		1.15 [0.80,1.65]	Z=0.77, p=0.4409
Heterogeneity:	Q=1.04 (df=1)	p=0.3084	I^2=3.6%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	17 / 77	20 / 77	100.0	0.81 [0.38,1.69]	
Total	17 / 82	20 / 81		0.81 [0.38,1.69]	Z=-0.57, p=0.5718
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.80 (df=4)	p=0.4337	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.7.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

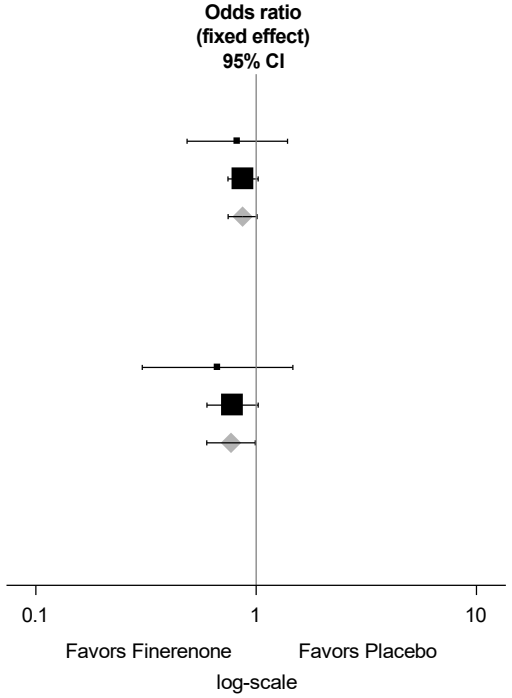
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	21 / 88	25 / 89	10.0	0.80 [0.41,1.57]	
FIGARO-DKD	185 / 811	226 / 803	90.0	0.75 [0.60,0.94]	
Total	206 / 899	251 / 892		0.76 [0.61,0.94]	Z=-2.53, p=0.0113
Heterogeneity:	Q=0.03 (df=1)	p=0.8652	I^2=0.0%		
Absent					
FIDELIO-DKD	27 / 123	36 / 132	8.2	0.75 [0.42,1.33]	
FIGARO-DKD	329 / 1516	351 / 1501	91.8	0.91 [0.77,1.08]	
Total	356 / 1639	387 / 1633		0.89 [0.76,1.05]	Z=-1.34, p=0.1797
Heterogeneity:	Q=0.39 (df=1)	p=0.5310	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.42 (df=1)	p=0.2334	I^2=29.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.7.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

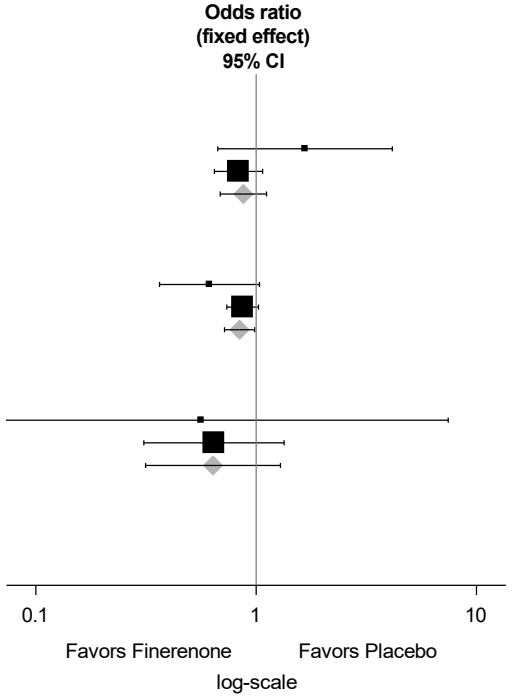
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	33 / 144	42 / 158	8.3	0.82 [0.49,1.39]	
FIGARO-DKD	389 / 1719	422 / 1680	91.7	0.87 [0.74,1.02]	
Total	422 / 1863	464 / 1838		0.87 [0.75,1.01]	Z=-1.84, p=0.0655
Heterogeneity:	Q=0.05 (df=1)	p=0.8301	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 67	19 / 63	10.4	0.67 [0.30,1.47]	
FIGARO-DKD	125 / 608	155 / 623	89.6	0.78 [0.60,1.02]	
Total	140 / 675	174 / 686		0.77 [0.60,0.99]	Z=-2.03, p=0.0420
Heterogeneity:	Q=0.14 (df=1)	p=0.7117	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4220	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.7.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

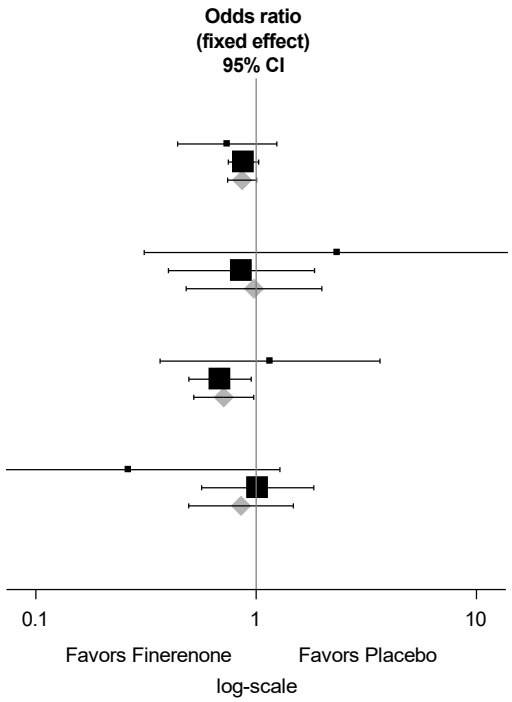
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	16 / 64	9 / 54	7.1	1.67 [0.67,4.15]	
FIGARO-DKD	145 / 693	169 / 700	92.9	0.83 [0.65,1.07]	
Total	161 / 757	178 / 754		0.87 [0.69,1.11]	Z=-1.08, p=0.2794
Heterogeneity:	Q=2.07 (df=1)	p=0.1498	I^2=51.8%		
130 - < 160					
FIDELIO-DKD	31 / 138	50 / 156	9.1	0.61 [0.36,1.04]	
FIGARO-DKD	353 / 1561	384 / 1525	90.9	0.87 [0.74,1.02]	
Total	384 / 1699	434 / 1681		0.84 [0.72,0.98]	Z=-2.15, p=0.0312
Heterogeneity:	Q=1.53 (df=1)	p=0.2157	I^2=34.8%		
>= 160					
FIDELIO-DKD	1 / 9	2 / 11	7.5	0.56 [0.04,7.44]	
FIGARO-DKD	16 / 73	24 / 79	92.5	0.64 [0.31,1.34]	
Total	17 / 82	26 / 90		0.64 [0.31,1.29]	Z=-1.26, p=0.2095
Heterogeneity:	Q=0.01 (df=1)	p=0.9220	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.70 (df=2)	p=0.7046	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.7.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

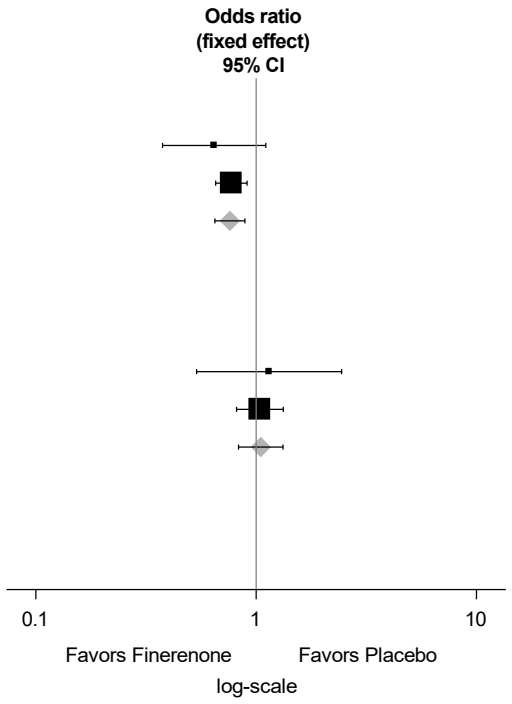
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	34 / 140	46 / 152	8.5	0.74 [0.44,1.24]	
FIGARO-DKD	393 / 1659	422 / 1613	91.5	0.88 [0.75,1.03]	
Total	427 / 1799	468 / 1765		0.86 [0.74,1.00]	Z=-1.90, p=0.0576
Heterogeneity:	Q=0.38 (df=1)	p=0.5389	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	2 / 9	12.5	2.33 [0.31,17.54]	
FIGARO-DKD	16 / 70	19 / 74	87.5	0.86 [0.40,1.84]	
Total	20 / 80	21 / 83		0.98 [0.48,1.99]	Z=-0.06, p=0.9504
Heterogeneity:	Q=0.83 (df=1)	p=0.3631	I^2=0.0%		
Asian					
FIDELIO-DKD	7 / 39	7 / 44	7.4	1.16 [0.37,3.65]	
FIGARO-DKD	76 / 464	108 / 486	92.6	0.69 [0.49,0.95]	
Total	83 / 503	115 / 530		0.71 [0.52,0.97]	Z=-2.12, p=0.0339
Heterogeneity:	Q=0.74 (df=1)	p=0.3912	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 22	6 / 16	12.1	0.26 [0.05,1.28]	
FIGARO-DKD	29 / 134	28 / 131	87.9	1.02 [0.57,1.83]	
Total	32 / 156	34 / 147		0.85 [0.49,1.47]	Z=-0.57, p=0.5709
Heterogeneity:	Q=2.46 (df=1)	p=0.1167	I^2=59.4%		
Subgroup Heterogeneity:	Q=1.37 (df=3)	p=0.7132	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.7.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

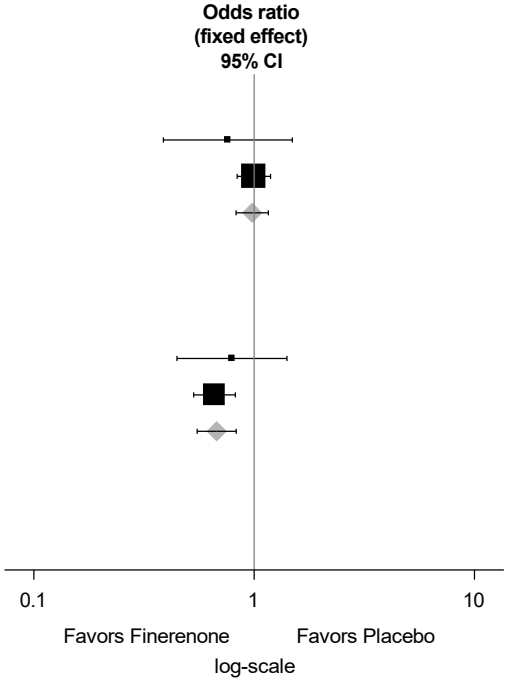
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 153	41 / 154	8.5	0.64 [0.38,1.11]	
FIGARO-DKD	333 / 1611	414 / 1640	91.5	0.77 [0.65,0.91]	
Total	362 / 1764	455 / 1794		0.76 [0.65,0.89]	Z=-3.43, p=0.0006
Heterogeneity:	Q=0.39 (df=1)	p=0.5318	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 58	20 / 67	9.4	1.14 [0.54,2.44]	
FIGARO-DKD	181 / 716	163 / 664	90.6	1.04 [0.81,1.33]	
Total	200 / 774	183 / 731		1.05 [0.83,1.32]	Z=0.41, p=0.6849
Heterogeneity:	Q=0.06 (df=1)	p=0.8128	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.08 (df=1)	p=0.0241	I^2=80.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.7.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

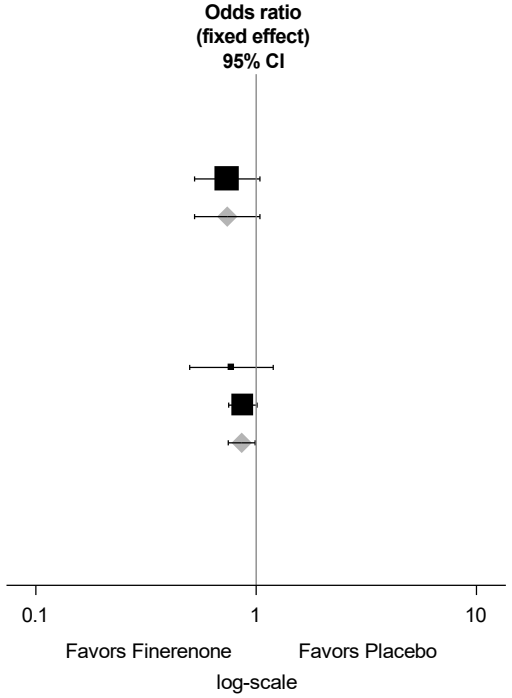
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	20 / 99	24 / 96	6.3	0.76 [0.39,1.49]	
FIGARO-DKD	328 / 1416	330 / 1421	93.7	1.00 [0.84,1.19]	
Total	348 / 1515	354 / 1517		0.98 [0.83,1.16]	Z=-0.24, p=0.8122
Heterogeneity:	Q=0.59 (df=1)	p=0.4441	I^2=0.0%		
>= 65					
FIDELIO-DKD	28 / 112	37 / 125	12.6	0.79 [0.45,1.41]	
FIGARO-DKD	186 / 911	247 / 883	87.4	0.66 [0.53,0.82]	
Total	214 / 1023	284 / 1008		0.68 [0.55,0.83]	Z=-3.77, p=0.0002
Heterogeneity:	Q=0.34 (df=1)	p=0.5609	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.56 (df=1)	p=0.0060	I^2=86.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.7.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

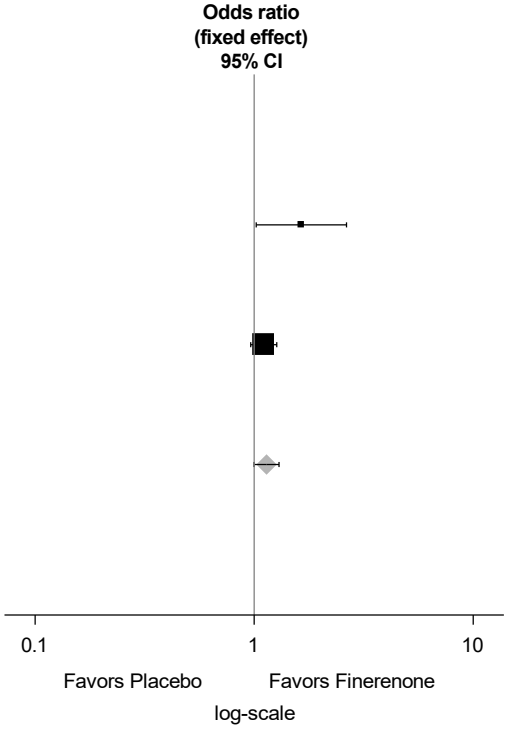
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	81 / 363	96 / 343	100.0	0.74 [0.53,1.04]	
Total	81 / 363	96 / 343		0.74 [0.53,1.04]	Z=-1.74, p=0.0826
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	48 / 211	61 / 221	10.3	0.77 [0.50,1.20]	
FIGARO-DKD	433 / 1964	481 / 1961	89.7	0.87 [0.75,1.01]	
Total	481 / 2175	542 / 2182		0.86 [0.75,0.99]	Z=-2.11, p=0.0345
Heterogeneity:	Q=0.26 (df=1)	p=0.6122	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4226	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

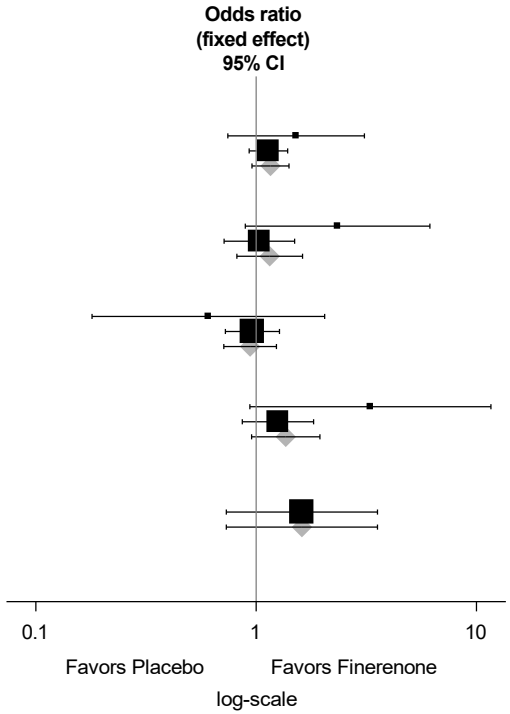
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 211	39 / 221	7.7	1.64 [1.02,2.64]	
FIGARO-DKD	560 / 2327	513 / 2304	92.3	1.11 [0.96,1.27]	
Total	614 / 2538	552 / 2525		1.14 [1.00,1.30]	Z=1.94, p=0.0524
Heterogeneity:	Q=2.46 (df=1)	p=0.1166	I^2=59.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.8.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

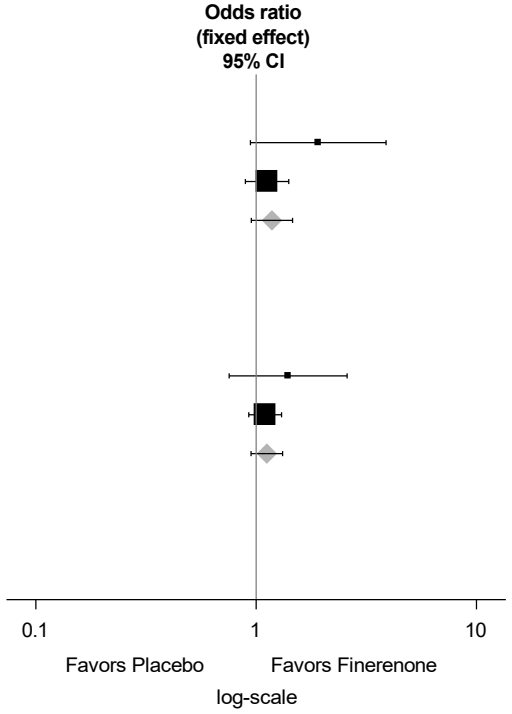
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 104	16 / 112	7.4	1.52 [0.74,3.10]	
FIGARO-DKD	256 / 1114	231 / 1111	92.6	1.14 [0.93,1.39]	
Total	277 / 1218	247 / 1223		1.16 [0.96,1.41]	Z=1.51, p=0.1300
Heterogeneity:	Q=0.59 (df=1)	p=0.4443	I^2=0.0%		
North America					
FIDELIO-DKD	17 / 42	9 / 40	12.7	2.34 [0.89,6.15]	
FIGARO-DKD	81 / 292	75 / 277	87.3	1.03 [0.72,1.49]	
Total	98 / 334	84 / 317		1.15 [0.82,1.62]	Z=0.81, p=0.4188
Heterogeneity:	Q=2.41 (df=1)	p=0.1206	I^2=58.5%		
Asia					
FIDELIO-DKD	5 / 39	8 / 41	5.1	0.61 [0.18,2.05]	
FIGARO-DKD	125 / 522	129 / 523	94.9	0.96 [0.72,1.28]	
Total	130 / 561	137 / 564		0.94 [0.71,1.24]	Z=-0.45, p=0.6518
Heterogeneity:	Q=0.52 (df=1)	p=0.4693	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 21	6 / 24	8.0	3.30 [0.94,11.63]	
FIGARO-DKD	79 / 322	65 / 316	92.0	1.26 [0.86,1.82]	
Total	90 / 343	71 / 340		1.36 [0.95,1.95]	Z=1.70, p=0.0897
Heterogeneity:	Q=2.08 (df=1)	p=0.1493	I^2=51.9%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	19 / 77	13 / 77	100.0	1.61 [0.73,3.55]	
Total	19 / 82	13 / 81		1.61 [0.73,3.55]	Z=1.19, p=0.2357
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.65 (df=4)	p=0.4550	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.8.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

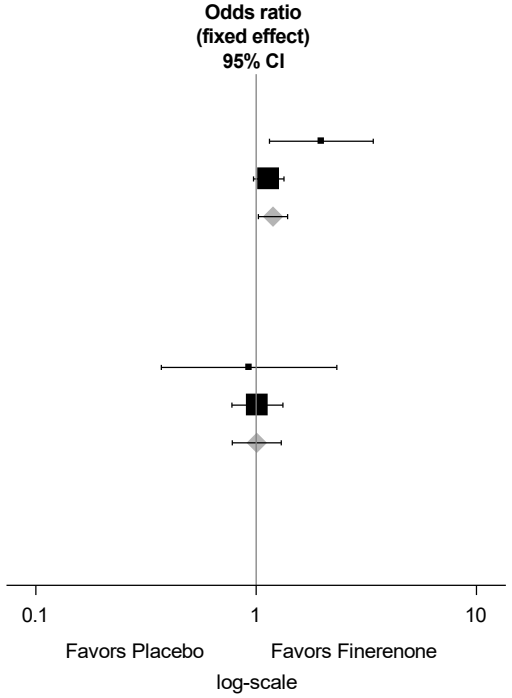
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 88	16 / 89	9.3	1.91 [0.94,3.89]	
FIGARO-DKD	208 / 811	189 / 803	90.7	1.12 [0.89,1.41]	
Total	234 / 899	205 / 892		1.18 [0.95,1.46]	Z=1.50, p=0.1343
Heterogeneity:	Q=1.99 (df=1)	p=0.1589	I^2=49.6%		
Absent					
FIDELIO-DKD	28 / 123	23 / 132	7.2	1.40 [0.75,2.59]	
FIGARO-DKD	352 / 1516	324 / 1501	92.8	1.10 [0.93,1.30]	
Total	380 / 1639	347 / 1633		1.12 [0.95,1.32]	Z=1.32, p=0.1862
Heterogeneity:	Q=0.54 (df=1)	p=0.4618	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.6995	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.8.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

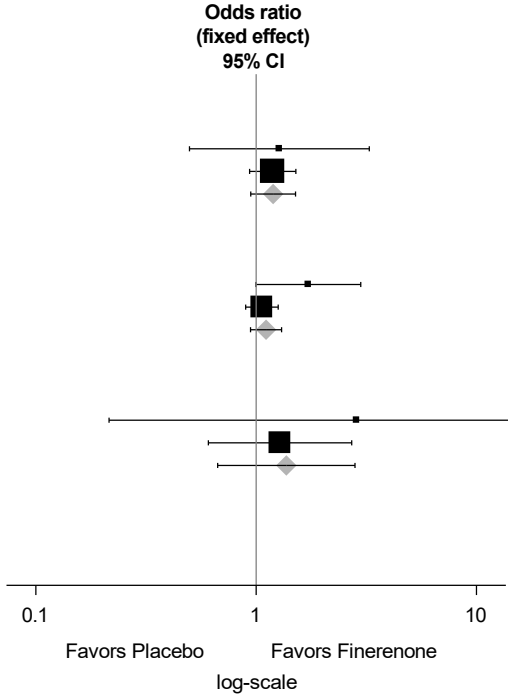
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	43 / 144	28 / 158	7.9	1.98 [1.15,3.40]	
FIGARO-DKD	421 / 1719	372 / 1680	92.1	1.14 [0.97,1.34]	
Total	464 / 1863	400 / 1838		1.19 [1.02,1.39]	Z=2.26, p=0.0238
Heterogeneity:	Q=3.64 (df=1)	p=0.0565	I^2=72.5%		
> 4.5					
FIDELIO-DKD	11 / 67	11 / 63	7.8	0.93 [0.37,2.32]	
FIGARO-DKD	139 / 608	141 / 623	92.2	1.01 [0.78,1.32]	
Total	150 / 675	152 / 686		1.01 [0.78,1.30]	Z=0.05, p=0.9617
Heterogeneity:	Q=0.03 (df=1)	p=0.8580	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.25 (df=1)	p=0.2642	I^2=19.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.8.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

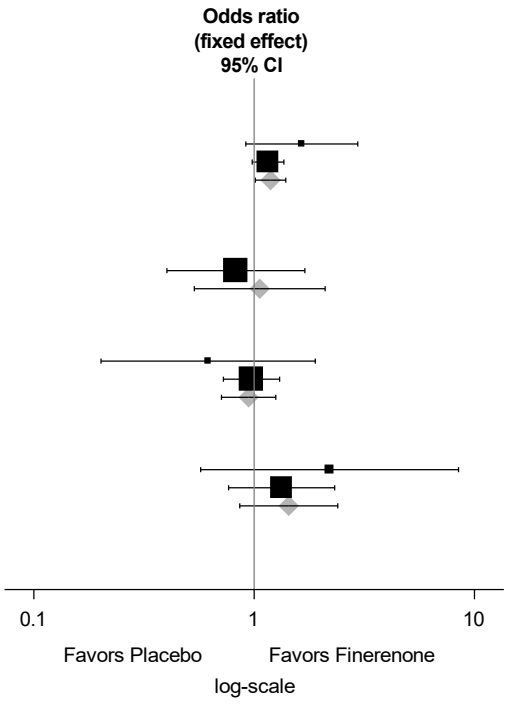
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 64	9 / 54	6.2	1.27 [0.50,3.26]	
FIGARO-DKD	187 / 693	166 / 700	93.8	1.19 [0.93,1.51]	
Total	200 / 757	175 / 754		1.19 [0.94,1.51]	Z=1.48, p=0.1377
Heterogeneity:	Q=0.02 (df=1)	p=0.8882	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	39 / 138	29 / 156	8.8	1.73 [1.00,2.98]	
FIGARO-DKD	354 / 1561	330 / 1525	91.2	1.06 [0.90,1.26]	
Total	393 / 1699	359 / 1681		1.11 [0.94,1.30]	Z=1.25, p=0.2119
Heterogeneity:	Q=2.75 (df=1)	p=0.0973	I^2=63.6%		
>= 160					
FIDELIO-DKD	2 / 9	1 / 11	7.7	2.86 [0.21,37.99]	
FIGARO-DKD	19 / 73	17 / 79	92.3	1.28 [0.61,2.71]	
Total	21 / 82	18 / 90		1.37 [0.67,2.81]	Z=0.86, p=0.3893
Heterogeneity:	Q=0.34 (df=1)	p=0.5602	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=2)	p=0.7736	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.8.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

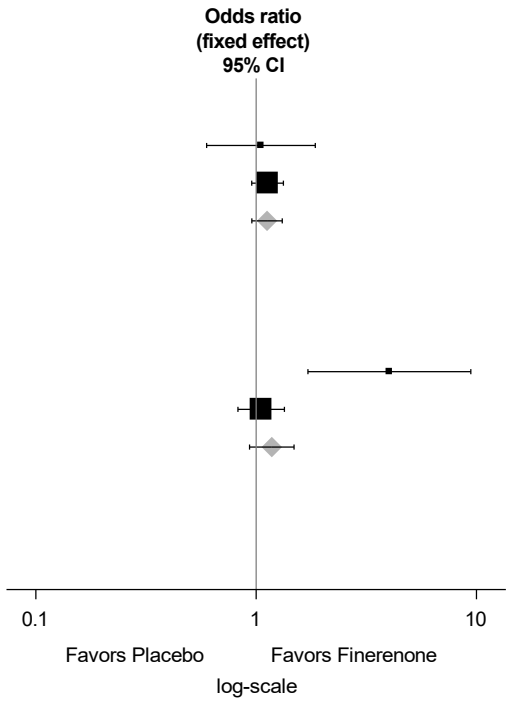
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	33 / 140	24 / 152	7.4	1.64 [0.92,2.95]	
FIGARO-DKD	388 / 1659	337 / 1613	92.6	1.16 [0.98,1.36]	
Total	421 / 1799	361 / 1765		1.19 [1.01,1.39]	Z=2.11, p=0.0348
Heterogeneity:	Q=1.29 (df=1)	p=0.2554	I^2=22.7%		
Black					
FIDELIO-DKD	4 / 10	0 / 9	0.0	511E9 [511E9,511E9]	
FIGARO-DKD	19 / 70	23 / 74	100.0	0.83 [0.40,1.70]	
Total	23 / 80	23 / 83		1.06 [0.54,2.10]	Z=0.17, p=0.8676
Heterogeneity:	Q=0.46 (df=1)	p=0.4981	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 39	10 / 44	6.4	0.62 [0.20,1.89]	
FIGARO-DKD	115 / 464	123 / 486	93.6	0.97 [0.73,1.30]	
Total	121 / 503	133 / 530		0.94 [0.71,1.25]	Z=-0.40, p=0.6895
Heterogeneity:	Q=0.59 (df=1)	p=0.4430	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 22	5 / 16	14.5	2.20 [0.57,8.47]	
FIGARO-DKD	38 / 134	30 / 131	85.5	1.33 [0.77,2.32]	
Total	49 / 156	35 / 147		1.44 [0.86,2.40]	Z=1.38, p=0.1665
Heterogeneity:	Q=0.45 (df=1)	p=0.5001	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.77 (df=3)	p=0.4285	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.8.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

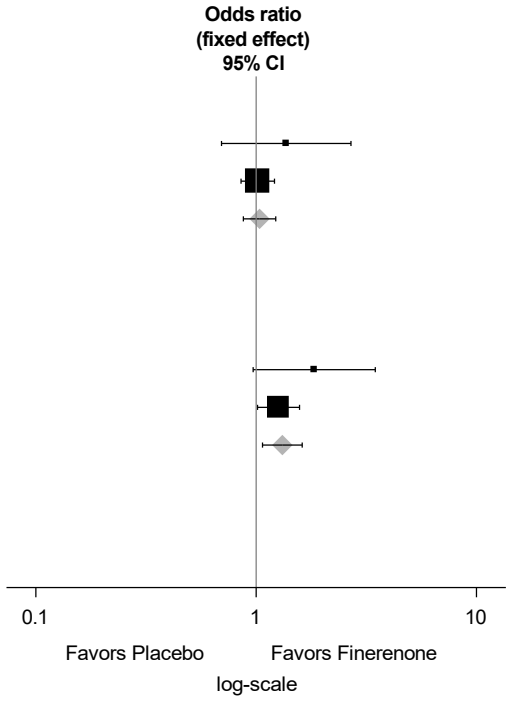
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	30 / 153	29 / 154	7.8	1.05 [0.60,1.86]	
FIGARO-DKD	375 / 1611	348 / 1640	92.2	1.13 [0.95,1.33]	
Total	405 / 1764	377 / 1794		1.12 [0.96,1.31]	Z=1.40, p=0.1608
Heterogeneity:	Q=0.05 (df=1)	p=0.8191	I^2=0.0%		
Female					
FIDELIO-DKD	24 / 58	10 / 67	7.5	4.02 [1.72,9.43]	
FIGARO-DKD	185 / 716	165 / 664	92.5	1.05 [0.83,1.34]	
Total	209 / 774	175 / 731		1.18 [0.93,1.49]	Z=1.38, p=0.1688
Heterogeneity:	Q=8.81 (df=1)	p=0.0030	I^2=88.6%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7297	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.8.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

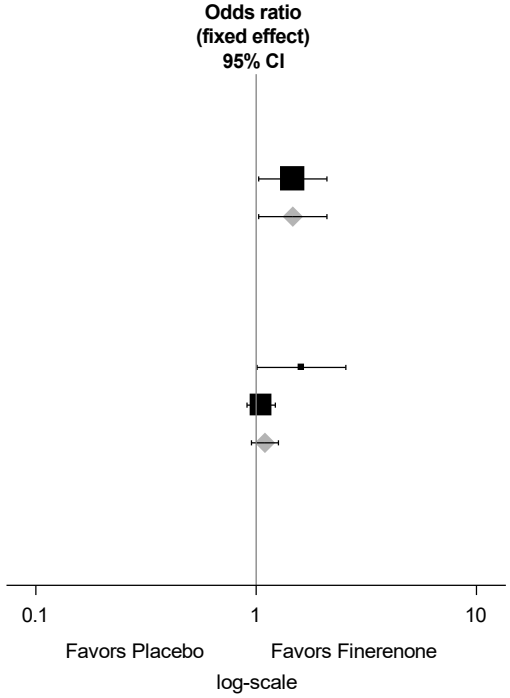
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	25 / 99	19 / 96	6.3	1.37 [0.70,2.69]	
FIGARO-DKD	328 / 1416	325 / 1421	93.7	1.02 [0.85,1.21]	
Total	353 / 1515	344 / 1517		1.04 [0.87,1.23]	Z=0.41, p=0.6826
Heterogeneity:	Q=0.70 (df=1)	p=0.4037	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 112	20 / 125	10.6	1.83 [0.97,3.47]	
FIGARO-DKD	232 / 911	188 / 883	89.4	1.26 [1.01,1.57]	
Total	261 / 1023	208 / 1008		1.31 [1.07,1.62]	Z=2.58, p=0.0098
Heterogeneity:	Q=1.17 (df=1)	p=0.2786	I^2=14.8%		
Subgroup Heterogeneity:	Q=3.04 (df=1)	p=0.0811	I^2=67.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.8.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

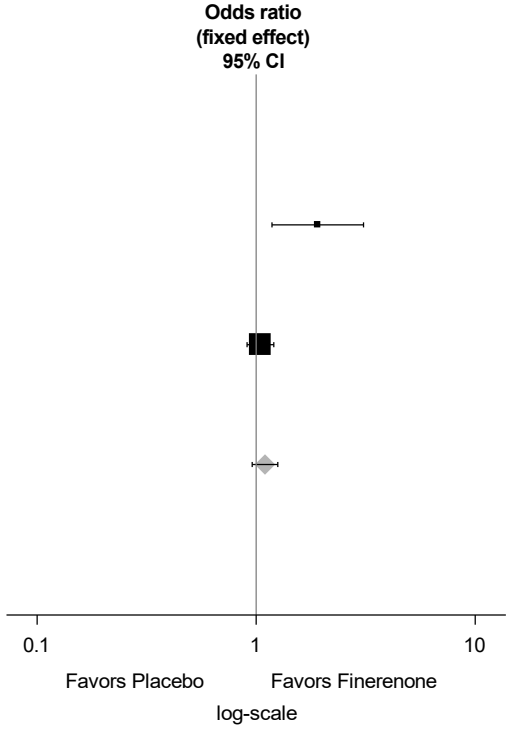
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	94 / 363	66 / 343	100.0	1.47 [1.03,2.10]	
Total	94 / 363	66 / 343		1.47 [1.03,2.10]	Z=2.10, p=0.0354
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 211	39 / 221	9.3	1.61 [1.01,2.55]	
FIGARO-DKD	466 / 1964	447 / 1961	90.7	1.05 [0.91,1.22]	
Total	520 / 2175	486 / 2182		1.10 [0.95,1.26]	Z=1.27, p=0.2025
Heterogeneity:	Q=2.87 (df=1)	p=0.0902	I^2=65.2%		
Subgroup Heterogeneity:	Q=2.22 (df=1)	p=0.1367	I^2=54.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

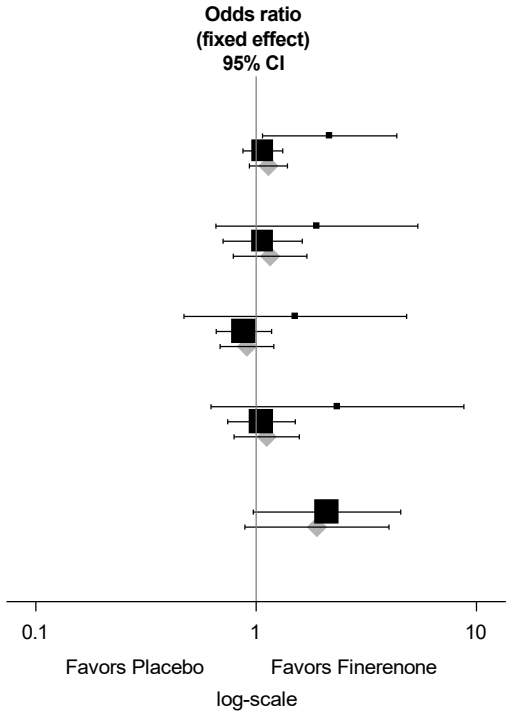
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 211	34 / 221	7.8	1.91 [1.18,3.09]	
FIGARO-DKD	510 / 2327	488 / 2304	92.2	1.05 [0.91,1.20]	
Total	564 / 2538	522 / 2525		1.10 [0.96,1.26]	Z=1.35, p=0.1766
Heterogeneity:	Q=5.55 (df=1)	p=0.0185	I^2=82.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.9.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

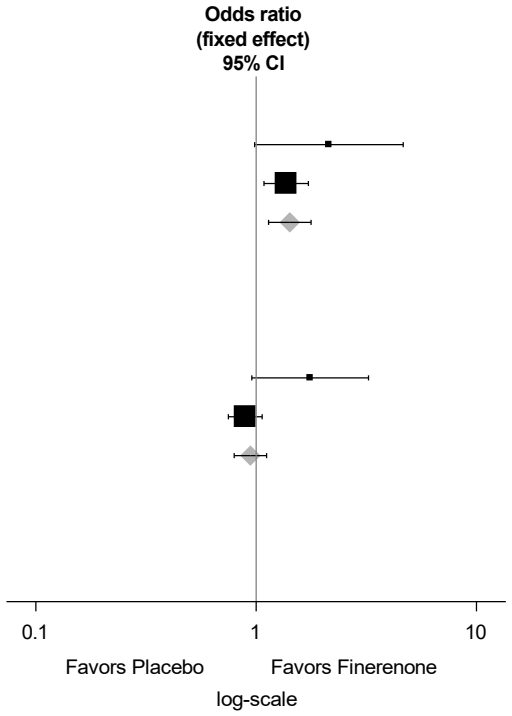
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 104	15 / 112	8.1	2.16 [1.07,4.35]	
FIGARO-DKD	229 / 1114	216 / 1111	91.9	1.07 [0.87,1.32]	
Total	255 / 1218	231 / 1223		1.14 [0.93,1.39]	Z=1.26, p=0.2067
Heterogeneity:	Q=3.50 (df=1)	p=0.0615	I^2=71.4%		
North America					
FIDELIO-DKD	12 / 42	7 / 40	13.3	1.89 [0.66,5.42]	
FIGARO-DKD	59 / 292	53 / 277	86.7	1.07 [0.71,1.62]	
Total	71 / 334	60 / 317		1.16 [0.79,1.70]	Z=0.74, p=0.4583
Heterogeneity:	Q=0.96 (df=1)	p=0.3273	I^2=0.0%		
Asia					
FIDELIO-DKD	8 / 39	6 / 41	5.8	1.51 [0.47,4.82]	
FIGARO-DKD	113 / 522	125 / 523	94.2	0.88 [0.66,1.17]	
Total	121 / 561	131 / 564		0.91 [0.69,1.20]	Z=-0.67, p=0.5003
Heterogeneity:	Q=0.77 (df=1)	p=0.3799	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	5 / 24	6.7	2.34 [0.62,8.77]	
FIGARO-DKD	86 / 322	81 / 316	93.3	1.06 [0.74,1.51]	
Total	94 / 343	86 / 340		1.12 [0.79,1.57]	Z=0.63, p=0.5262
Heterogeneity:	Q=1.29 (df=1)	p=0.2553	I^2=22.7%		
Others					
FIDELIO-DKD	0 / 5	1 / 4	0.0	0.00 [0.00,26E295]	
FIGARO-DKD	23 / 77	13 / 77	100.0	2.10 [0.97,4.53]	
Total	23 / 82	14 / 81		1.89 [0.89,4.01]	Z=1.65, p=0.0984
Heterogeneity:	Q=0.07 (df=1)	p=0.7886	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.94 (df=4)	p=0.4138	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.9.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

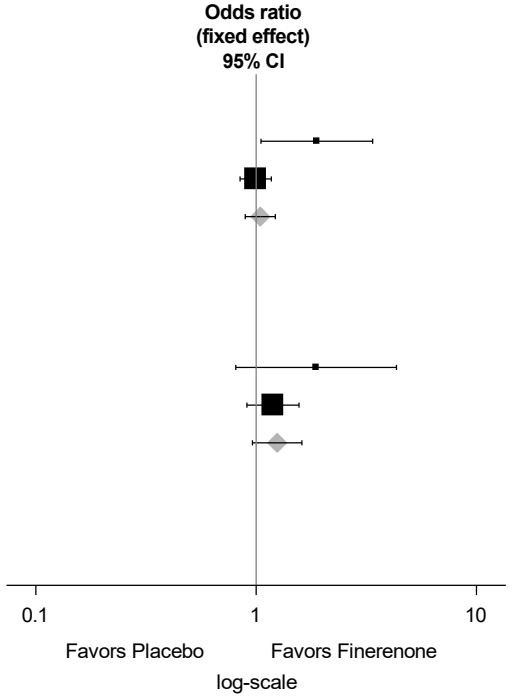
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	22 / 88	12 / 89	8.2	2.14 [0.98,4.65]	
FIGARO-DKD	212 / 811	165 / 803	91.8	1.37 [1.09,1.73]	
Total	234 / 899	177 / 892		1.42 [1.14,1.77]	Z=3.10, p=0.0019
Heterogeneity:	Q=1.17 (df=1)	p=0.2801	I^2=14.3%		
Absent					
FIDELIO-DKD	32 / 123	22 / 132	7.7	1.76 [0.96,3.24]	
FIGARO-DKD	298 / 1516	323 / 1501	92.3	0.89 [0.75,1.06]	
Total	330 / 1639	345 / 1633		0.94 [0.79,1.12]	Z=-0.70, p=0.4845
Heterogeneity:	Q=4.39 (df=1)	p=0.0362	I^2=77.2%		
Subgroup Heterogeneity:	Q=8.36 (df=1)	p=0.0038	I^2=88.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.9.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

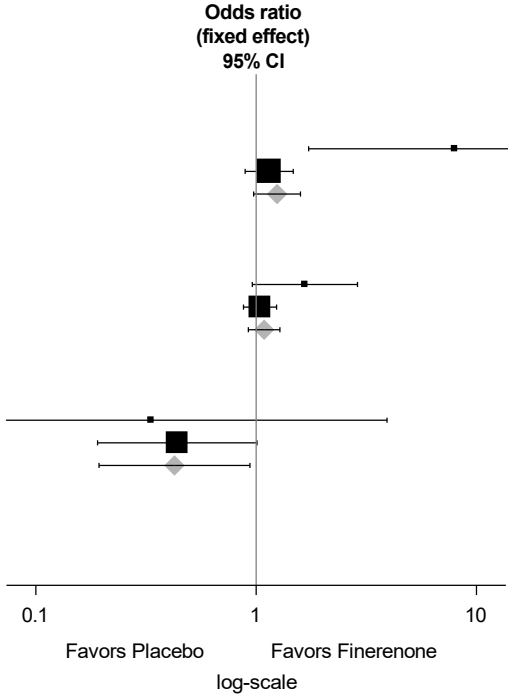
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	35 / 144	23 / 158	7.3	1.88 [1.05,3.38]	
FIGARO-DKD	370 / 1719	363 / 1680	92.7	1.00 [0.85,1.17]	
Total	405 / 1863	386 / 1838		1.04 [0.89,1.22]	Z=0.53, p=0.5943
Heterogeneity:	Q=4.27 (df=1)	p=0.0388	I^2=76.6%		
> 4.5					
FIDELIO-DKD	19 / 67	11 / 63	9.5	1.87 [0.81,4.33]	
FIGARO-DKD	140 / 608	125 / 623	90.5	1.19 [0.91,1.56]	
Total	159 / 675	136 / 686		1.25 [0.96,1.61]	Z=1.66, p=0.0962
Heterogeneity:	Q=1.00 (df=1)	p=0.3166	I^2=0.3%		
Subgroup Heterogeneity:	Q=1.31 (df=1)	p=0.2524	I^2=23.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.9.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

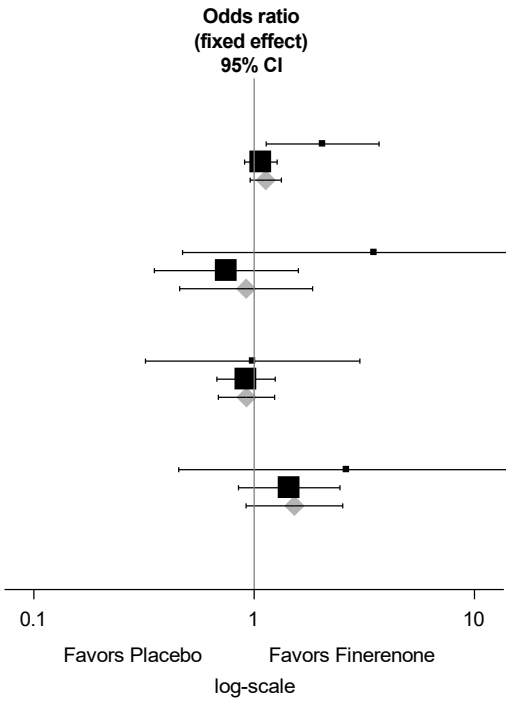
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 64	2 / 54	2.6	7.96 [1.73,36.62]	
FIGARO-DKD	165 / 693	150 / 700	97.4	1.15 [0.89,1.47]	
Total	180 / 757	152 / 754		1.24 [0.97,1.59]	Z=1.75, p=0.0802
Heterogeneity:	Q=6.09 (df=1)	p=0.0136	I^2=83.6%		
130 - < 160					
FIDELIO-DKD	38 / 138	29 / 156	9.0	1.66 [0.96,2.88]	
FIGARO-DKD	335 / 1561	317 / 1525	91.0	1.04 [0.88,1.24]	
Total	373 / 1699	346 / 1681		1.09 [0.92,1.28]	Z=0.99, p=0.3233
Heterogeneity:	Q=2.54 (df=1)	p=0.1108	I^2=60.7%		
>= 160					
FIDELIO-DKD	1 / 9	3 / 11	10.2	0.33 [0.03,3.93]	
FIGARO-DKD	10 / 73	21 / 79	89.8	0.44 [0.19,1.01]	
Total	11 / 82	24 / 90		0.43 [0.19,0.94]	Z=-2.12, p=0.0338
Heterogeneity:	Q=0.04 (df=1)	p=0.8366	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.56 (df=2)	p=0.0377	I^2=69.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.9.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

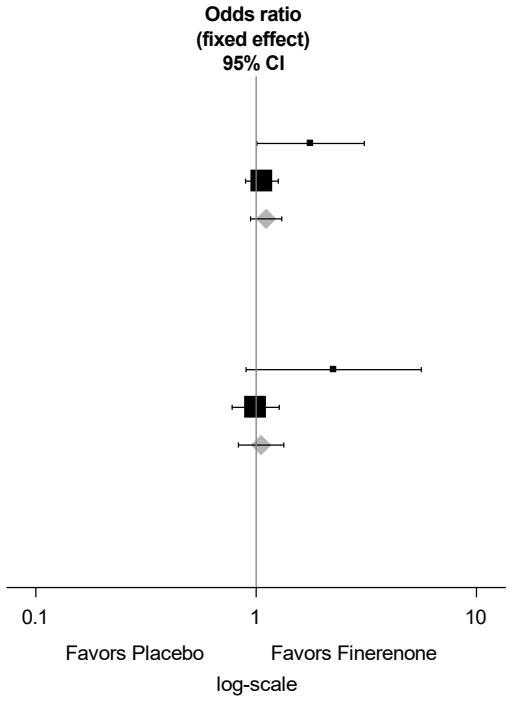
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	36 / 140	22 / 152	7.7	2.05 [1.13,3.69]	
FIGARO-DKD	348 / 1659	320 / 1613	92.3	1.07 [0.90,1.27]	
Total	384 / 1799	342 / 1765		1.13 [0.96,1.33]	Z=1.46, p=0.1456
Heterogeneity:	Q=4.25 (df=1)	p=0.0393	I^2=76.5%		
Black					
FIDELIO-DKD	5 / 10	2 / 9	12.4	3.50 [0.47,25.90]	
FIGARO-DKD	16 / 70	21 / 74	87.6	0.75 [0.35,1.59]	
Total	21 / 80	23 / 83		0.92 [0.46,1.84]	Z=-0.24, p=0.8123
Heterogeneity:	Q=2.00 (df=1)	p=0.1570	I^2=50.1%		
Asian					
FIDELIO-DKD	7 / 39	8 / 44	6.9	0.98 [0.32,3.02]	
FIGARO-DKD	101 / 464	113 / 486	93.1	0.92 [0.68,1.25]	
Total	108 / 503	121 / 530		0.92 [0.69,1.24]	Z=-0.54, p=0.5925
Heterogeneity:	Q=0.01 (df=1)	p=0.9068	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 22	2 / 16	8.4	2.62 [0.45,15.16]	
FIGARO-DKD	45 / 134	34 / 131	91.6	1.44 [0.85,2.45]	
Total	51 / 156	36 / 147		1.52 [0.92,2.52]	Z=1.63, p=0.1028
Heterogeneity:	Q=0.41 (df=1)	p=0.5217	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.31 (df=3)	p=0.3458	I^2=9.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.9.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

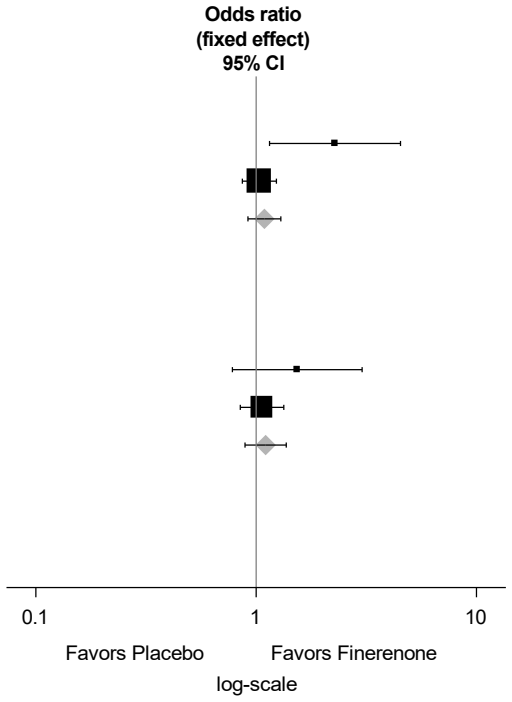
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	39 / 153	25 / 154	8.5	1.77 [1.01,3.10]	
FIGARO-DKD	336 / 1611	326 / 1640	91.5	1.06 [0.90,1.26]	
Total	375 / 1764	351 / 1794		1.11 [0.94,1.31]	Z=1.25, p=0.2104
Heterogeneity:	Q=2.87 (df=1)	p=0.0900	I^2=65.2%		
Female					
FIDELIO-DKD	15 / 58	9 / 67	6.7	2.25 [0.90,5.62]	
FIGARO-DKD	174 / 716	162 / 664	93.3	0.99 [0.78,1.27]	
Total	189 / 774	171 / 731		1.05 [0.83,1.34]	Z=0.43, p=0.6689
Heterogeneity:	Q=2.84 (df=1)	p=0.0919	I^2=64.8%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7210	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.9.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

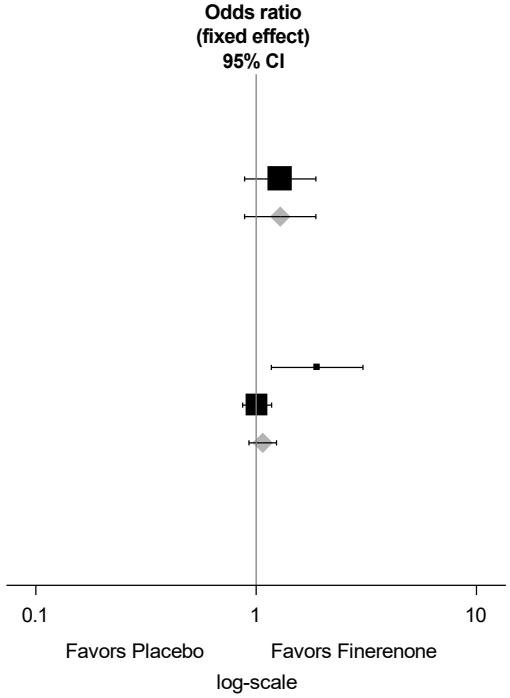
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	31 / 99	16 / 96	6.3	2.28 [1.15,4.52]	
FIGARO-DKD	314 / 1416	307 / 1421	93.7	1.03 [0.87,1.24]	
Total	345 / 1515	323 / 1517		1.09 [0.92,1.29]	Z=0.98, p=0.3270
Heterogeneity:	Q=4.80 (df=1)	p=0.0285	I^2=79.2%		
>= 65					
FIDELIO-DKD	23 / 112	18 / 125	10.1	1.54 [0.78,3.03]	
FIGARO-DKD	196 / 911	181 / 883	89.9	1.06 [0.85,1.33]	
Total	219 / 1023	199 / 1008		1.10 [0.89,1.37]	Z=0.90, p=0.3689
Heterogeneity:	Q=1.02 (df=1)	p=0.3130	I^2=1.8%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9272	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.9.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

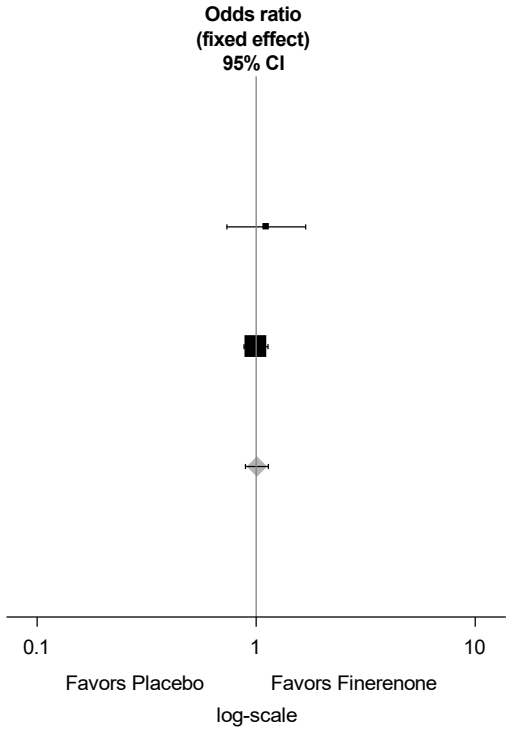
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	79 / 363	61 / 343	100.0	1.29 [0.89,1.87]	
Total	79 / 363	61 / 343		1.29 [0.89,1.87]	Z=1.32, p=0.1857
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 211	34 / 221	9.1	1.89 [1.17,3.05]	
FIGARO-DKD	431 / 1964	427 / 1961	90.9	1.01 [0.87,1.18]	
Total	485 / 2175	461 / 2182		1.07 [0.93,1.24]	Z=0.93, p=0.3510
Heterogeneity:	Q=6.00 (df=1)	p=0.0143	I^2=83.3%		
Subgroup Heterogeneity:	Q=0.81 (df=1)	p=0.3693	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.10: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

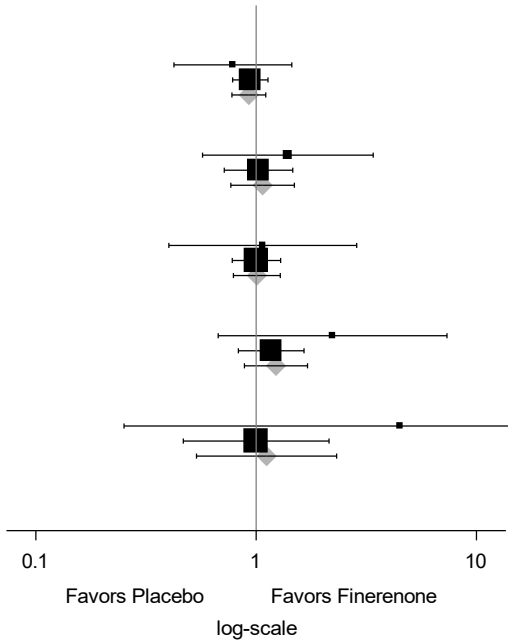
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 211	66 / 221	8.5	1.11 [0.74,1.68]	
FIGARO-DKD	698 / 2327	693 / 2304	91.5	1.00 [0.88,1.13]	
Total	766 / 2538	759 / 2525		1.01 [0.89,1.14]	Z=0.12, p=0.9006
Heterogeneity:	Q=0.24 (df=1)	p=0.6249	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.10.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

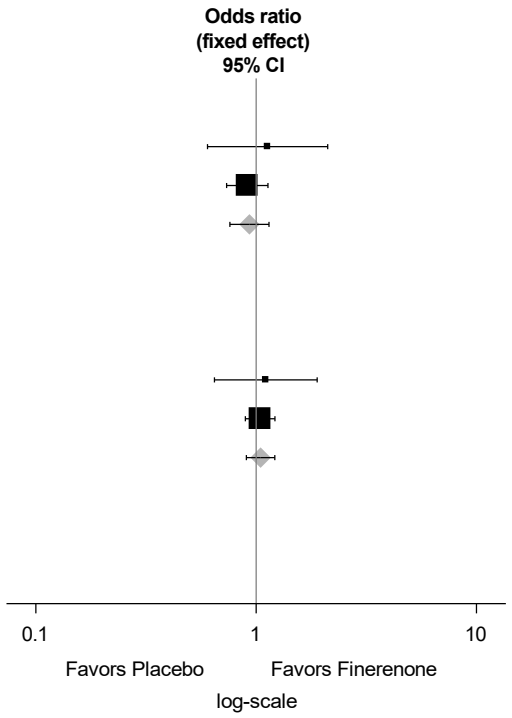
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	24 / 104	31 / 112	8.3	0.78 [0.42,1.45]	
FIGARO-DKD	307 / 1114	320 / 1111	91.7	0.94 [0.78,1.13]	
Total	331 / 1218	351 / 1223		0.93 [0.78,1.11]	Z=-0.85, p=0.3962
Heterogeneity:	Q=0.31 (df=1)	p=0.5791	I^2=0.0%		
North America					
FIDELIO-DKD	18 / 42	14 / 40	13.9	1.39 [0.57,3.40]	
FIGARO-DKD	89 / 292	83 / 277	86.1	1.02 [0.72,1.47]	
Total	107 / 334	97 / 317		1.07 [0.77,1.49]	Z=0.40, p=0.6915
Heterogeneity:	Q=0.39 (df=1)	p=0.5314	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 39	11 / 41	6.2	1.07 [0.40,2.86]	
FIGARO-DKD	187 / 522	187 / 523	93.8	1.00 [0.78,1.29]	
Total	198 / 561	198 / 564		1.01 [0.79,1.29]	Z=0.06, p=0.9548
Heterogeneity:	Q=0.02 (df=1)	p=0.8984	I^2=0.0%		
Latin America					
FIDELIO-DKD	12 / 21	9 / 24	7.6	2.22 [0.67,7.35]	
FIGARO-DKD	98 / 322	86 / 316	92.4	1.17 [0.83,1.65]	
Total	110 / 343	95 / 340		1.23 [0.88,1.71]	Z=1.23, p=0.2187
Heterogeneity:	Q=1.02 (df=1)	p=0.3122	I^2=2.1%		
Others					
FIDELIO-DKD	3 / 5	1 / 4	6.5	4.50 [0.25,80.57]	
FIGARO-DKD	17 / 77	17 / 77	93.5	1.00 [0.47,2.14]	
Total	20 / 82	18 / 81		1.11 [0.54,2.32]	Z=0.29, p=0.7715
Heterogeneity:	Q=0.98 (df=1)	p=0.3230	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.47 (df=4)	p=0.6502	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.10.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

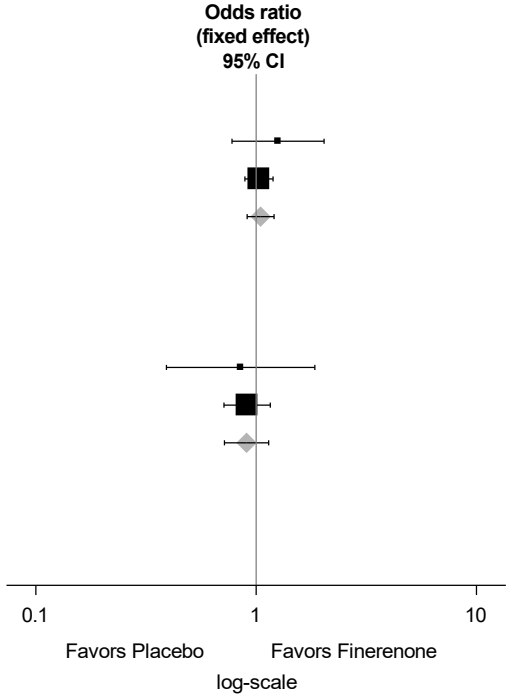
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	30 / 88	28 / 89	10.6	1.13 [0.60,2.11]	
FIGARO-DKD	224 / 811	237 / 803	89.4	0.91 [0.73,1.13]	
Total	254 / 899	265 / 892		0.93 [0.76,1.14]	Z=-0.68, p=0.4996
Heterogeneity:	Q=0.39 (df=1)	p=0.5311	I^2=0.0%		
Absent					
FIDELIO-DKD	38 / 123	38 / 132	7.7	1.11 [0.65,1.89]	
FIGARO-DKD	474 / 1516	456 / 1501	92.3	1.04 [0.89,1.22]	
Total	512 / 1639	494 / 1633		1.05 [0.90,1.21]	Z=0.61, p=0.5429
Heterogeneity:	Q=0.04 (df=1)	p=0.8359	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.82 (df=1)	p=0.3661	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.10.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

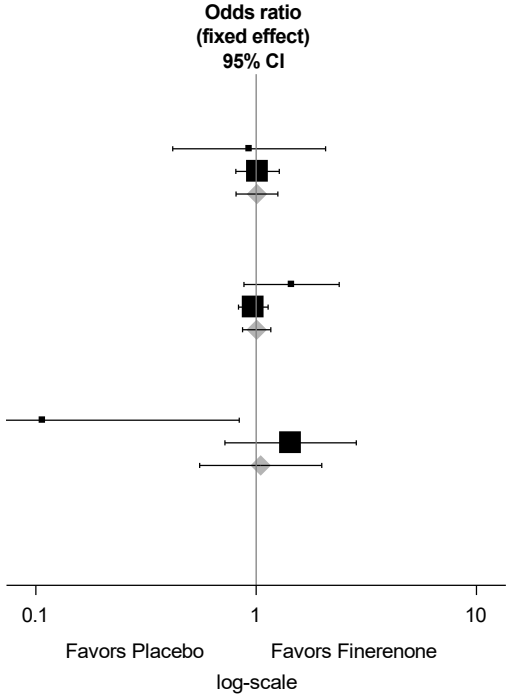
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	51 / 144	48 / 158	8.5	1.26 [0.78,2.03]	
FIGARO-DKD	517 / 1719	495 / 1680	91.5	1.03 [0.89,1.19]	
Total	568 / 1863	543 / 1838		1.05 [0.91,1.21]	Z=0.64, p=0.5190
Heterogeneity:	Q=0.60 (df=1)	p=0.4377	I^2=0.0%		
> 4.5					
FIDELIO-DKD	17 / 67	18 / 63	8.9	0.85 [0.39,1.85]	
FIGARO-DKD	181 / 608	198 / 623	91.1	0.91 [0.71,1.16]	
Total	198 / 675	216 / 686		0.90 [0.72,1.14]	Z=-0.85, p=0.3942
Heterogeneity:	Q=0.03 (df=1)	p=0.8696	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.13 (df=1)	p=0.2877	I^2=11.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.10.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

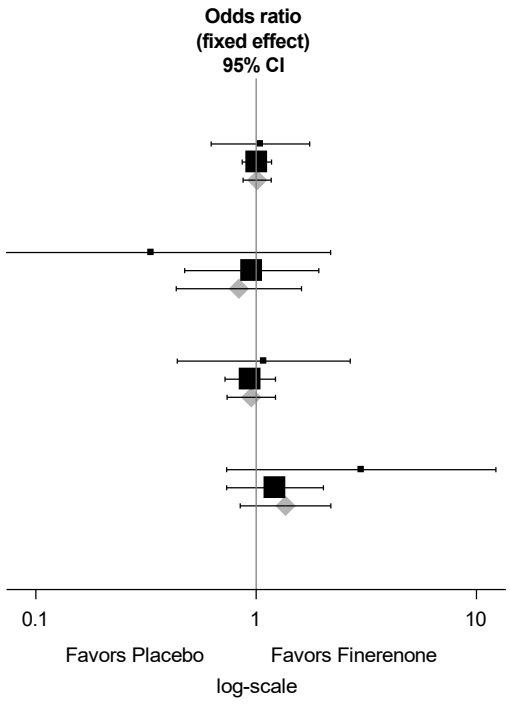
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	18 / 64	16 / 54	7.5	0.93 [0.42,2.07]	
FIGARO-DKD	216 / 693	216 / 700	92.5	1.01 [0.81,1.27]	
Total	234 / 757	232 / 754		1.01 [0.81,1.25]	Z=0.07, p=0.9427
Heterogeneity:	Q=0.04 (df=1)	p=0.8358	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	48 / 138	42 / 156	8.8	1.45 [0.88,2.38]	
FIGARO-DKD	456 / 1561	455 / 1525	91.2	0.97 [0.83,1.13]	
Total	504 / 1699	497 / 1681		1.01 [0.87,1.17]	Z=0.07, p=0.9434
Heterogeneity:	Q=2.26 (df=1)	p=0.1327	I^2=55.8%		
>= 160					
FIDELIO-DKD	2 / 9	8 / 11	10.0	0.11 [0.01,0.84]	
FIGARO-DKD	26 / 73	22 / 79	90.0	1.43 [0.72,2.85]	
Total	28 / 82	30 / 90		1.05 [0.55,1.98]	Z=0.15, p=0.8842
Heterogeneity:	Q=5.52 (df=1)	p=0.0188	I^2=81.9%		
Subgroup Heterogeneity:	Q=0.02 (df=2)	p=0.9921	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.10.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

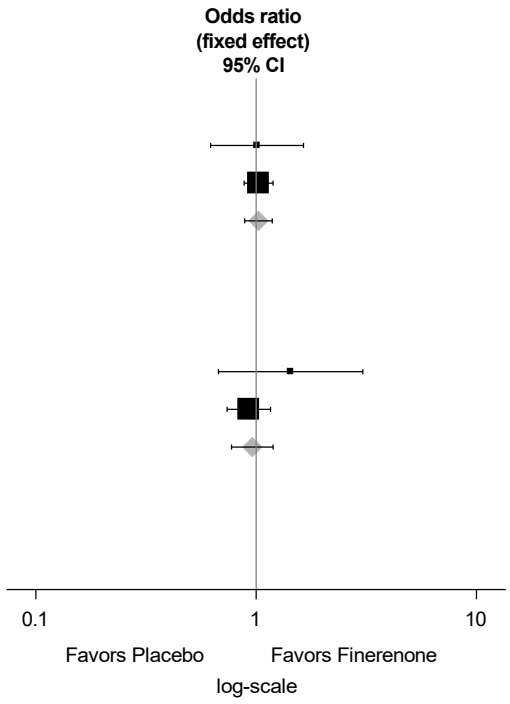
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	39 / 140	41 / 152	8.2	1.05 [0.62,1.75]	
FIGARO-DKD	458 / 1659	443 / 1613	91.8	1.01 [0.86,1.17]	
Total	497 / 1799	484 / 1765		1.01 [0.87,1.17]	Z=0.14, p=0.8920
Heterogeneity:	Q=0.02 (df=1)	p=0.8919	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 10	6 / 9	12.2	0.33 [0.05,2.18]	
FIGARO-DKD	22 / 70	24 / 74	87.8	0.95 [0.47,1.92]	
Total	26 / 80	30 / 83		0.83 [0.43,1.61]	Z=-0.54, p=0.5884
Heterogeneity:	Q=1.06 (df=1)	p=0.3031	I^2=5.7%		
Asian					
FIDELIO-DKD	14 / 39	15 / 44	7.8	1.08 [0.44,2.67]	
FIGARO-DKD	168 / 464	183 / 486	92.2	0.94 [0.72,1.22]	
Total	182 / 503	198 / 530		0.95 [0.74,1.22]	Z=-0.40, p=0.6926
Heterogeneity:	Q=0.09 (df=1)	p=0.7682	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 22	4 / 16	11.4	3.00 [0.73,12.25]	
FIGARO-DKD	50 / 134	43 / 131	88.6	1.22 [0.73,2.02]	
Total	61 / 156	47 / 147		1.36 [0.85,2.18]	Z=1.27, p=0.2041
Heterogeneity:	Q=1.40 (df=1)	p=0.2372	I^2=28.4%		
Subgroup Heterogeneity:	Q=2.06 (df=3)	p=0.5603	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.10.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

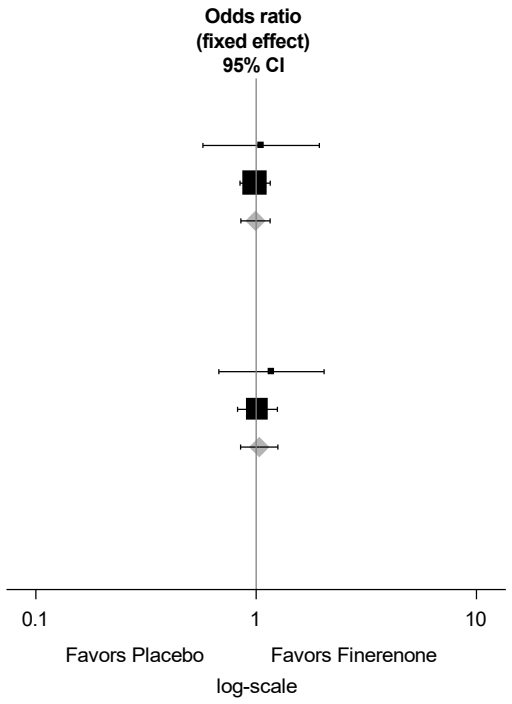
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	47 / 153	47 / 154	8.8	1.01 [0.62,1.64]	
FIGARO-DKD	477 / 1611	477 / 1640	91.2	1.03 [0.88,1.19]	
Total	524 / 1764	524 / 1794		1.02 [0.89,1.18]	Z=0.32, p=0.7457
Heterogeneity:	Q=0.00 (df=1)	p=0.9512	I^2=0.0%		
Female					
FIDELIO-DKD	21 / 58	19 / 67	8.3	1.43 [0.67,3.05]	
FIGARO-DKD	221 / 716	216 / 664	91.7	0.93 [0.74,1.16]	
Total	242 / 774	235 / 731		0.96 [0.77,1.19]	Z=-0.37, p=0.7150
Heterogeneity:	Q=1.18 (df=1)	p=0.2766	I^2=15.5%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6287	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.10.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

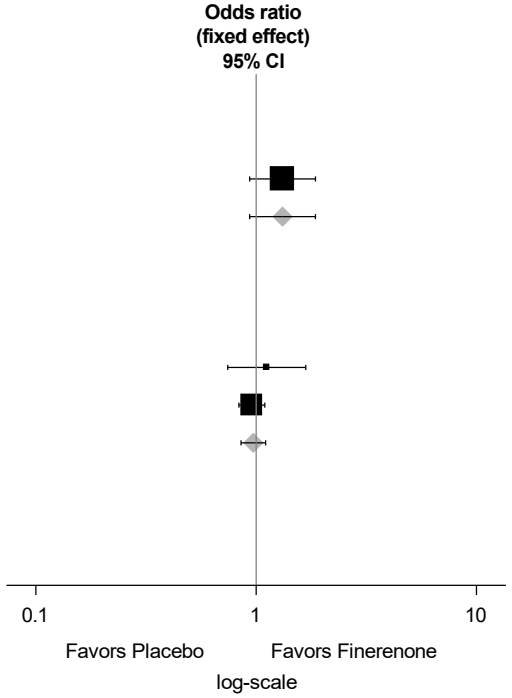
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	31 / 99	29 / 96	6.3	1.05 [0.57,1.94]	
FIGARO-DKD	450 / 1416	455 / 1421	93.7	0.99 [0.84,1.16]	
Total	481 / 1515	484 / 1517		0.99 [0.85,1.16]	Z=-0.09, p=0.9277
Heterogeneity:	Q=0.04 (df=1)	p=0.8445	I^2=0.0%		
>= 65					
FIDELIO-DKD	37 / 112	37 / 125	12.5	1.17 [0.68,2.03]	
FIGARO-DKD	248 / 911	238 / 883	87.5	1.01 [0.82,1.25]	
Total	285 / 1023	275 / 1008		1.03 [0.85,1.25]	Z=0.32, p=0.7477
Heterogeneity:	Q=0.24 (df=1)	p=0.6261	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7572	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.10.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

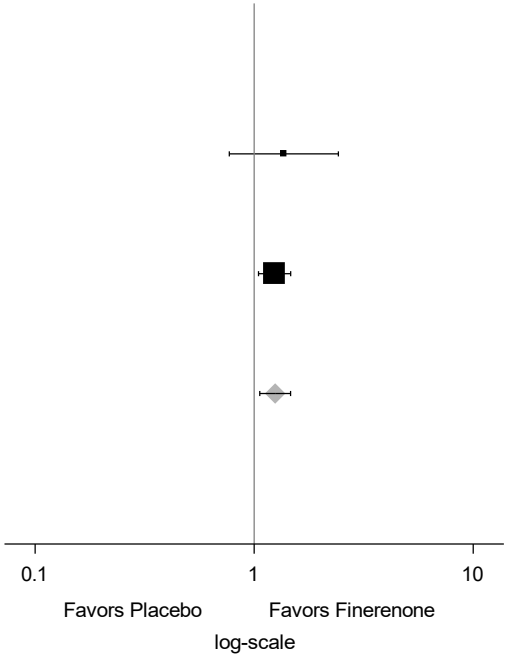
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	99 / 363	76 / 343	100.0	1.32 [0.93,1.86]	
Total	99 / 363	76 / 343		1.32 [0.93,1.86]	Z=1.57, p=0.1162
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	68 / 211	66 / 221	9.9	1.12 [0.74,1.68]	
FIGARO-DKD	599 / 1964	617 / 1961	90.1	0.96 [0.83,1.09]	
Total	667 / 2175	683 / 2182		0.97 [0.85,1.10]	Z=-0.45, p=0.6505
Heterogeneity:	Q=0.50 (df=1)	p=0.4780	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.66 (df=1)	p=0.1030	I^2=62.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.11: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

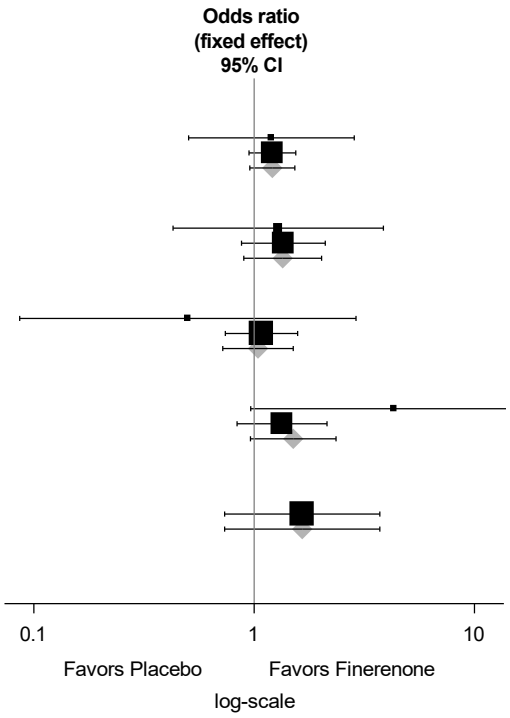
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 211	25 / 221	8.0	1.37 [0.77,2.42]	
FIGARO-DKD	346 / 2327	285 / 2304	92.0	1.24 [1.05,1.47]	
Total	377 / 2538	310 / 2525		1.25 [1.06,1.47]	Z=2.67, p=0.0076
Heterogeneity:	Q=0.10 (df=1)	p=0.7494	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.11.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

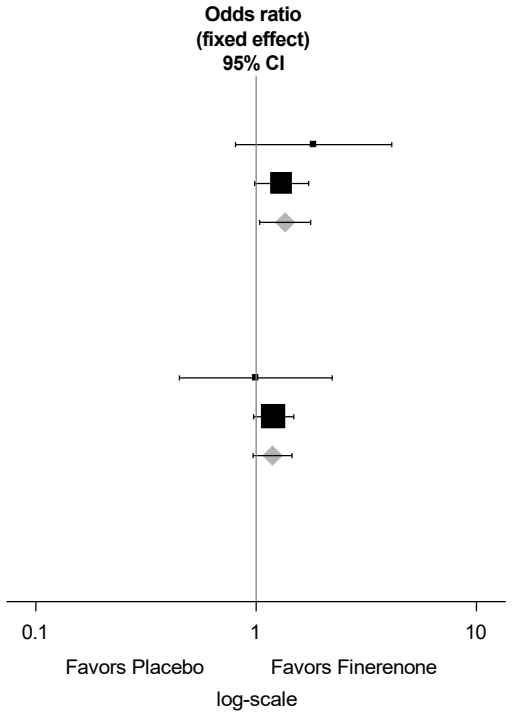
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 104	11 / 112	7.4	1.20 [0.50,2.85]	
FIGARO-DKD	162 / 1114	137 / 1111	92.6	1.21 [0.95,1.54]	
Total	174 / 1218	148 / 1223		1.21 [0.96,1.53]	Z=1.58, p=0.1139
Heterogeneity:	Q=0.00 (df=1)	p=0.9824	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	7 / 40	13.7	1.29 [0.43,3.86]	
FIGARO-DKD	57 / 292	42 / 277	86.3	1.36 [0.88,2.10]	
Total	66 / 334	49 / 317		1.35 [0.90,2.02]	Z=1.44, p=0.1509
Heterogeneity:	Q=0.01 (df=1)	p=0.9286	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	4 / 41	4.4	0.50 [0.09,2.90]	
FIGARO-DKD	63 / 522	59 / 523	95.6	1.08 [0.74,1.57]	
Total	65 / 561	63 / 564		1.04 [0.72,1.50]	Z=0.21, p=0.8314
Heterogeneity:	Q=0.70 (df=1)	p=0.4014	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 21	3 / 24	9.0	4.31 [0.96,19.24]	
FIGARO-DKD	46 / 322	35 / 316	91.0	1.34 [0.84,2.14]	
Total	54 / 343	38 / 340		1.50 [0.96,2.35]	Z=1.79, p=0.0736
Heterogeneity:	Q=2.14 (df=1)	p=0.1437	I^2=53.2%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	18 / 77	12 / 77	100.0	1.65 [0.73,3.72]	
Total	18 / 82	12 / 81		1.65 [0.73,3.72]	Z=1.21, p=0.2248
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.27 (df=4)	p=0.6865	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.11.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

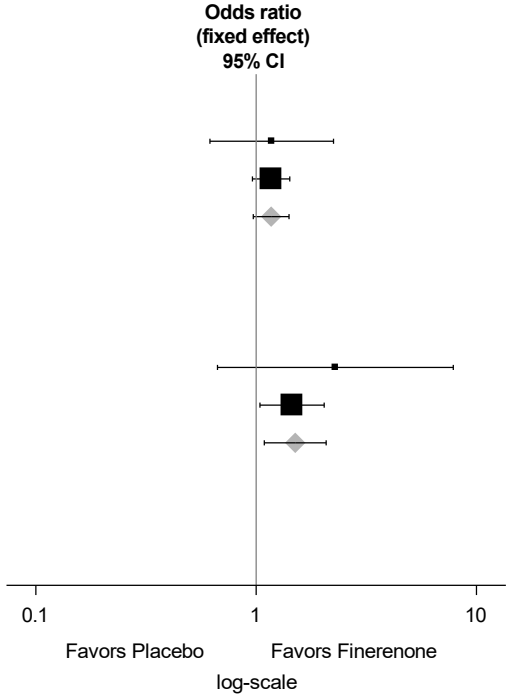
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	18 / 88	11 / 89	10.7	1.82 [0.81,4.13]	
FIGARO-DKD	127 / 811	100 / 803	89.3	1.31 [0.98,1.73]	
Total	145 / 899	111 / 892		1.35 [1.04,1.77]	Z=2.23, p=0.0260
Heterogeneity:	Q=0.58 (df=1)	p=0.4483	I^2=0.0%		
Absent					
FIDELIO-DKD	13 / 123	14 / 132	6.5	1.00 [0.45,2.21]	
FIGARO-DKD	219 / 1516	185 / 1501	93.5	1.20 [0.97,1.48]	
Total	232 / 1639	199 / 1633		1.19 [0.97,1.45]	Z=1.65, p=0.0988
Heterogeneity:	Q=0.20 (df=1)	p=0.6568	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=1)	p=0.4413	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.11.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

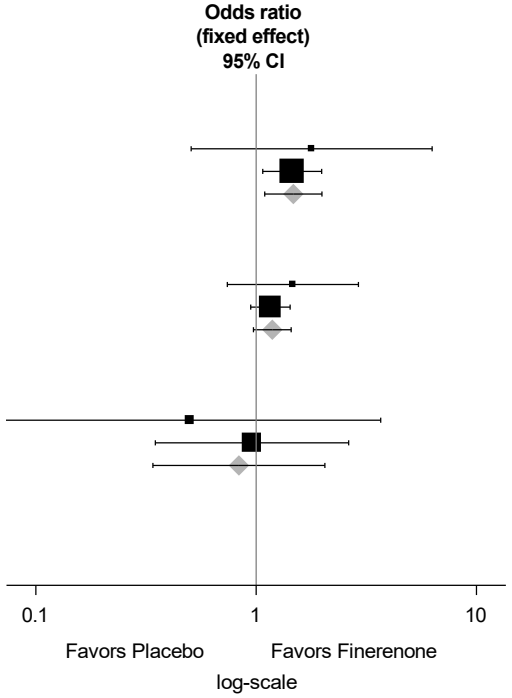
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 144	21 / 158	8.4	1.18 [0.62,2.24]	
FIGARO-DKD	254 / 1719	217 / 1680	91.6	1.17 [0.96,1.42]	
Total	276 / 1863	238 / 1838		1.17 [0.97,1.41]	Z=1.64, p=0.1003
Heterogeneity:	Q=0.00 (df=1)	p=0.9851	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 67	4 / 63	6.9	2.29 [0.67,7.85]	
FIGARO-DKD	92 / 608	68 / 623	93.1	1.46 [1.04,2.04]	
Total	101 / 675	72 / 686		1.50 [1.09,2.08]	Z=2.48, p=0.0133
Heterogeneity:	Q=0.48 (df=1)	p=0.4870	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.75 (df=1)	p=0.1865	I^2=42.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.11.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

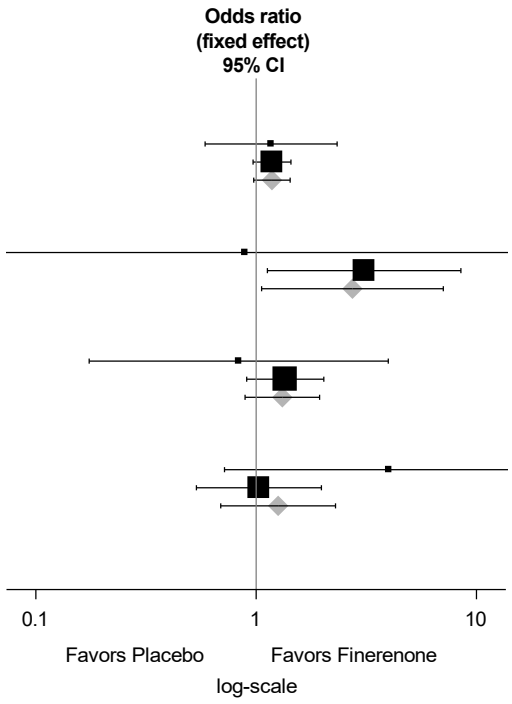
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 64	4 / 54	5.6	1.79 [0.51,6.29]	
FIGARO-DKD	111 / 693	81 / 700	94.4	1.46 [1.07,1.98]	
Total	119 / 757	85 / 754		1.47 [1.09,1.99]	Z=2.55, p=0.0109
Heterogeneity:	Q=0.09 (df=1)	p=0.7588	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	21 / 138	17 / 156	8.3	1.47 [0.74,2.91]	
FIGARO-DKD	227 / 1561	195 / 1525	91.7	1.16 [0.94,1.43]	
Total	248 / 1699	212 / 1681		1.18 [0.97,1.44]	Z=1.67, p=0.0940
Heterogeneity:	Q=0.41 (df=1)	p=0.5203	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 9	4 / 11	20.4	0.50 [0.07,3.67]	
FIGARO-DKD	8 / 73	9 / 79	79.6	0.96 [0.35,2.63]	
Total	10 / 82	13 / 90		0.83 [0.34,2.05]	Z=-0.39, p=0.6937
Heterogeneity:	Q=0.32 (df=1)	p=0.5691	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.24 (df=2)	p=0.3256	I^2=10.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.11.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

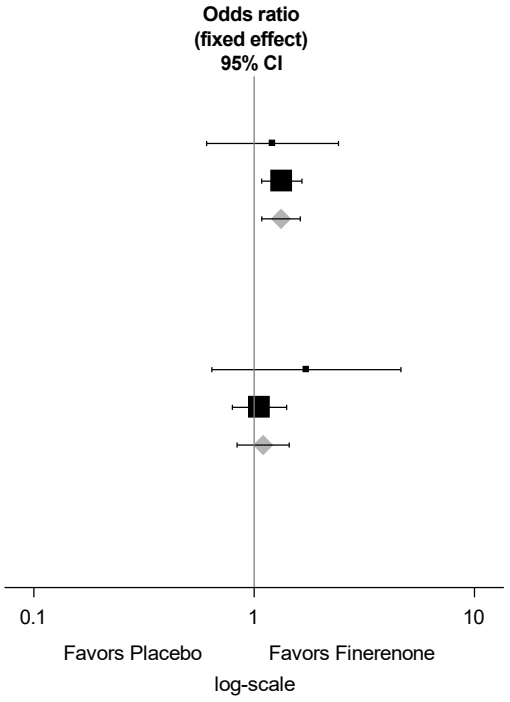
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	19 / 140	18 / 152	7.6	1.17 [0.59,2.33]	
FIGARO-DKD	249 / 1659	210 / 1613	92.4	1.18 [0.97,1.44]	
Total	268 / 1799	228 / 1765		1.18 [0.97,1.43]	Z=1.70, p=0.0898
Heterogeneity:	Q=0.00 (df=1)	p=0.9798	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	10.6	0.89 [0.05,16.66]	
FIGARO-DKD	15 / 70	6 / 74	89.4	3.09 [1.12,8.50]	
Total	16 / 80	7 / 83		2.74 [1.06,7.07]	Z=2.08, p=0.0378
Heterogeneity:	Q=0.62 (df=1)	p=0.4306	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	4 / 44	6.2	0.83 [0.17,3.98]	
FIGARO-DKD	60 / 464	48 / 486	93.8	1.36 [0.91,2.03]	
Total	63 / 503	52 / 530		1.31 [0.89,1.94]	Z=1.38, p=0.1691
Heterogeneity:	Q=0.35 (df=1)	p=0.5549	I^2=0.0%		
Others					
FIDELIO-DKD	8 / 22	2 / 16	12.6	4.00 [0.72,22.28]	
FIGARO-DKD	22 / 134	21 / 131	87.4	1.03 [0.54,1.98]	
Total	30 / 156	23 / 147		1.26 [0.69,2.29]	Z=0.75, p=0.4534
Heterogeneity:	Q=2.11 (df=1)	p=0.1467	I^2=52.5%		
Subgroup Heterogeneity:	Q=3.02 (df=3)	p=0.3879	I^2=0.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.11.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

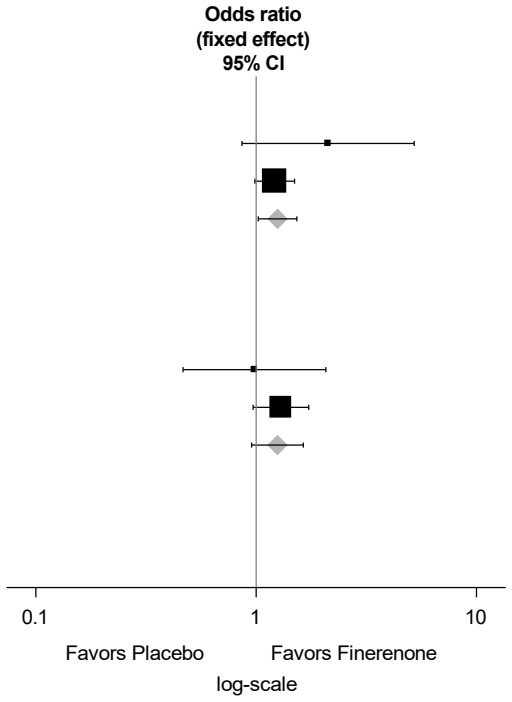
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	20 / 153	17 / 154	8.5	1.21 [0.61,2.41]	
FIGARO-DKD	224 / 1611	177 / 1640	91.5	1.33 [1.08,1.65]	
Total	244 / 1764	194 / 1794		1.32 [1.08,1.62]	Z=2.73, p=0.0063
Heterogeneity:	Q=0.07 (df=1)	p=0.7925	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 58	8 / 67	7.6	1.73 [0.64,4.64]	
FIGARO-DKD	122 / 716	108 / 664	92.4	1.06 [0.80,1.40]	
Total	133 / 774	116 / 731		1.10 [0.84,1.44]	Z=0.67, p=0.5007
Heterogeneity:	Q=0.87 (df=1)	p=0.3501	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.17 (df=1)	p=0.2794	I^2=14.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.11.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

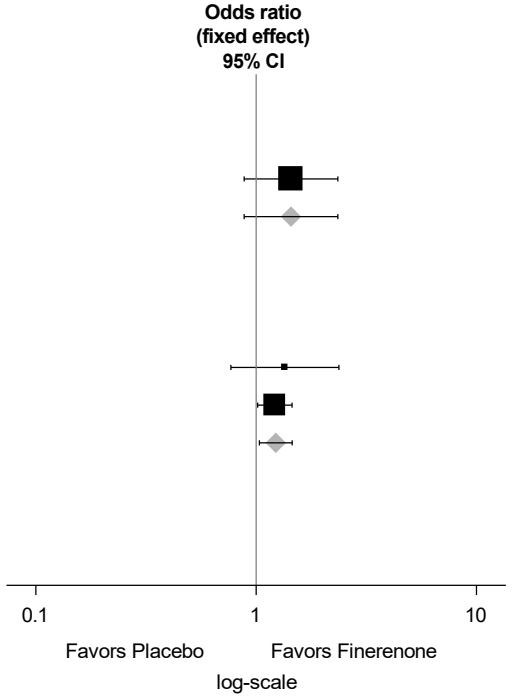
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	16 / 99	8 / 96	5.0	2.12 [0.86,5.22]	
FIGARO-DKD	228 / 1416	194 / 1421	95.0	1.21 [0.99,1.49]	
Total	244 / 1515	202 / 1517		1.25 [1.02,1.53]	Z=2.17, p=0.0300
Heterogeneity:	Q=1.40 (df=1)	p=0.2365	I^2=28.6%		
>= 65					
FIDELIO-DKD	15 / 112	17 / 125	13.2	0.98 [0.47,2.07]	
FIGARO-DKD	118 / 911	91 / 883	86.8	1.30 [0.97,1.73]	
Total	133 / 1023	108 / 1008		1.25 [0.95,1.64]	Z=1.61, p=0.1073
Heterogeneity:	Q=0.46 (df=1)	p=0.4990	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9942	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.11.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

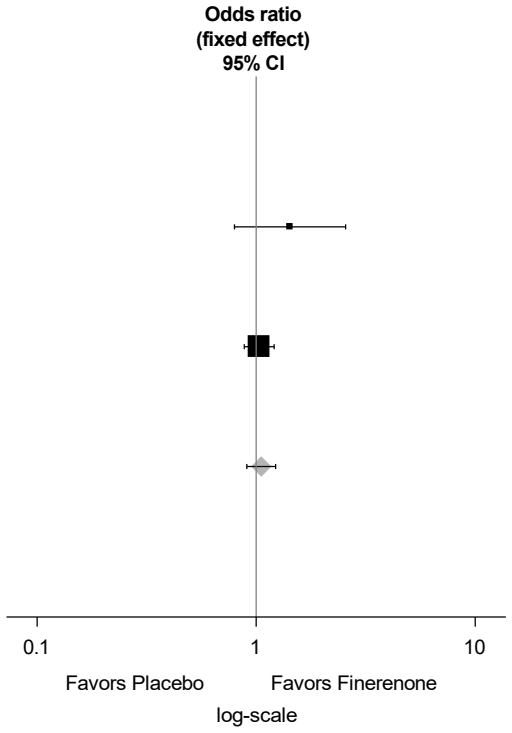
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	44 / 363	30 / 343	100.0	1.44 [0.88,2.35]	
Total	44 / 363	30 / 343		1.44 [0.88,2.35]	Z=1.46, p=0.1450
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	31 / 211	25 / 221	9.2	1.35 [0.77,2.37]	
FIGARO-DKD	302 / 1964	255 / 1961	90.8	1.22 [1.02,1.46]	
Total	333 / 2175	280 / 2182		1.23 [1.03,1.46]	Z=2.34, p=0.0190
Heterogeneity:	Q=0.12 (df=1)	p=0.7283	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5480	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.12: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 211	23 / 221	6.7	1.43 [0.80,2.56]	
FIGARO-DKD	380 / 2327	367 / 2304	93.3	1.03 [0.88,1.21]	
Total	410 / 2538	390 / 2525		1.05 [0.91,1.23]	Z=0.69, p=0.4916
Heterogeneity:	Q=1.10 (df=1)	p=0.2935	I^2=9.4%		

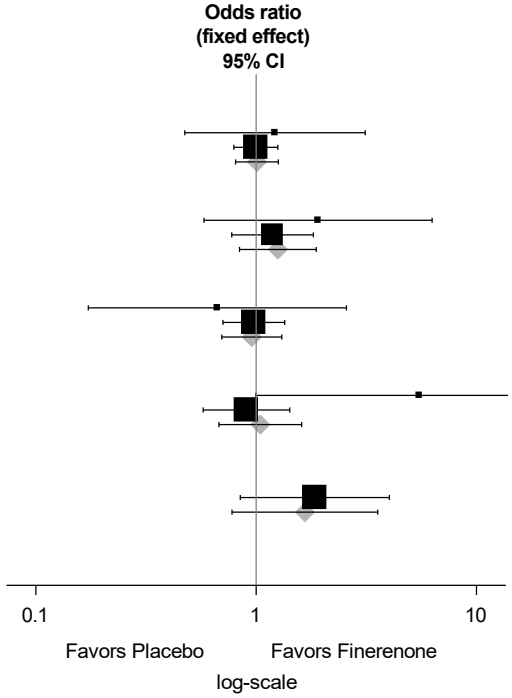


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B3.3.12.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region

Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 104	9 / 112	5.6	1.22 [0.47,3.13]	
FIGARO-DKD	172 / 1114	172 / 1111	94.4	1.00 [0.79,1.25]	
Total	182 / 1218	181 / 1223		1.01 [0.81,1.26]	Z=0.07, p=0.9437
Heterogeneity:	Q=0.16 (df=1)	p=0.6863	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	5 / 40	11.4	1.91 [0.58,6.29]	
FIGARO-DKD	57 / 292	47 / 277	88.6	1.19 [0.77,1.82]	
Total	66 / 334	52 / 317		1.26 [0.84,1.87]	Z=1.11, p=0.2671
Heterogeneity:	Q=0.54 (df=1)	p=0.4620	I^2=0.0%		
Asia					
FIDELIO-DKD	4 / 39	6 / 41	5.4	0.67 [0.17,2.57]	
FIGARO-DKD	88 / 522	90 / 523	94.6	0.98 [0.71,1.35]	
Total	92 / 561	96 / 564		0.96 [0.70,1.31]	Z=-0.29, p=0.7747
Heterogeneity:	Q=0.29 (df=1)	p=0.5907	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 21	2 / 24	6.6	5.50 [1.00,30.36]	
FIGARO-DKD	42 / 322	45 / 316	93.4	0.90 [0.57,1.42]	
Total	49 / 343	47 / 340		1.04 [0.68,1.61]	Z=0.20, p=0.8443
Heterogeneity:	Q=4.03 (df=1)	p=0.0448	I^2=75.2%		
Others					
FIDELIO-DKD	0 / 5	1 / 4	0.0	0.00 [0.00,26E295]	
FIGARO-DKD	21 / 77	13 / 77	100.0	1.85 [0.85,4.02]	
Total	21 / 82	14 / 81		1.66 [0.78,3.56]	Z=1.31, p=0.1903
Heterogeneity:	Q=0.07 (df=1)	p=0.7935	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.64 (df=4)	p=0.6199	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.

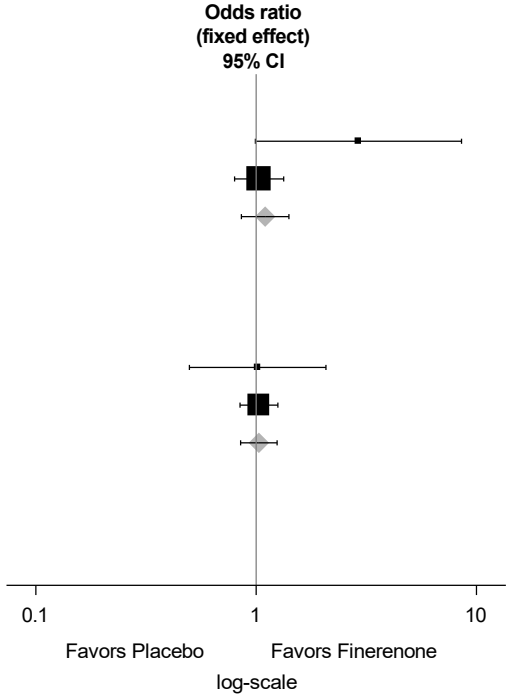
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.

Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.12.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

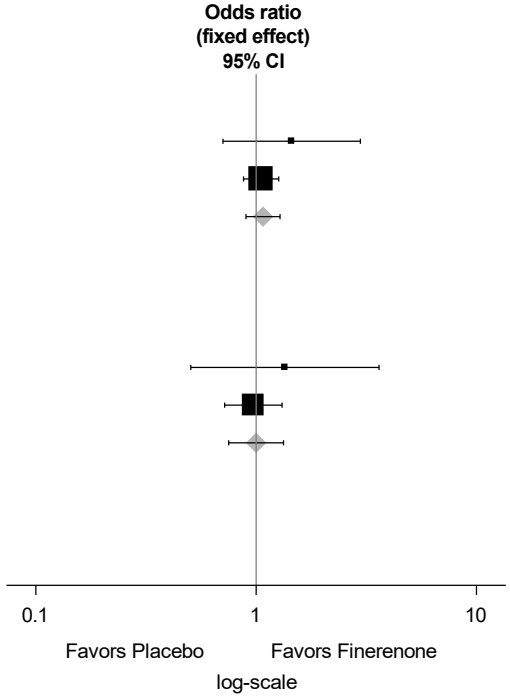
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 88	5 / 89	5.4	2.91 [0.99,8.55]	
FIGARO-DKD	144 / 811	139 / 803	94.6	1.03 [0.80,1.33]	
Total	157 / 899	144 / 892		1.10 [0.86,1.41]	Z=0.74, p=0.4590
Heterogeneity:	Q=3.38 (df=1)	p=0.0661	I^2=70.4%		
Absent					
FIDELIO-DKD	17 / 123	18 / 132	7.1	1.02 [0.50,2.07]	
FIGARO-DKD	236 / 1516	228 / 1501	92.9	1.03 [0.84,1.25]	
Total	253 / 1639	246 / 1633		1.03 [0.85,1.24]	Z=0.29, p=0.7731
Heterogeneity:	Q=0.00 (df=1)	p=0.9717	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.12.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

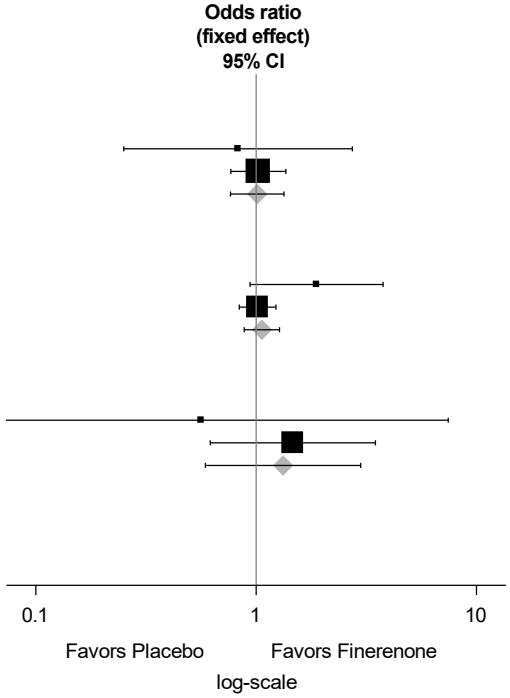
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 144	15 / 158	6.1	1.45 [0.71,2.97]	
FIGARO-DKD	280 / 1719	262 / 1680	93.9	1.05 [0.88,1.27]	
Total	299 / 1863	277 / 1838		1.07 [0.90,1.28]	Z=0.79, p=0.4310
Heterogeneity:	Q=0.71 (df=1)	p=0.3988	I^2=0.0%		
> 4.5					
FIDELIO-DKD	11 / 67	8 / 63	8.5	1.35 [0.50,3.61]	
FIGARO-DKD	100 / 608	105 / 623	91.5	0.97 [0.72,1.31]	
Total	111 / 675	113 / 686		1.00 [0.75,1.33]	Z=-0.01, p=0.9949
Heterogeneity:	Q=0.39 (df=1)	p=0.5298	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6739	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.12.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 64	6 / 54	5.5	0.83 [0.25,2.73]	
FIGARO-DKD	111 / 693	110 / 700	94.5	1.02 [0.77,1.36]	
Total	117 / 757	116 / 754		1.01 [0.76,1.34]	Z=0.08, p=0.9378
Heterogeneity:	Q=0.11 (df=1)	p=0.7353	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 138	15 / 156	7.0	1.88 [0.94,3.77]	
FIGARO-DKD	255 / 1561	246 / 1525	93.0	1.02 [0.84,1.23]	
Total	278 / 1699	261 / 1681		1.06 [0.88,1.28]	Z=0.63, p=0.5263
Heterogeneity:	Q=2.80 (df=1)	p=0.0941	I^2=64.3%		
>= 160					
FIDELIO-DKD	1 / 9	2 / 11	10.1	0.56 [0.04,7.44]	
FIGARO-DKD	14 / 73	11 / 79	89.9	1.47 [0.62,3.48]	
Total	15 / 82	13 / 90		1.32 [0.59,2.98]	Z=0.68, p=0.4975
Heterogeneity:	Q=0.48 (df=1)	p=0.4902	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.39 (df=2)	p=0.8211	I^2=0.0%		

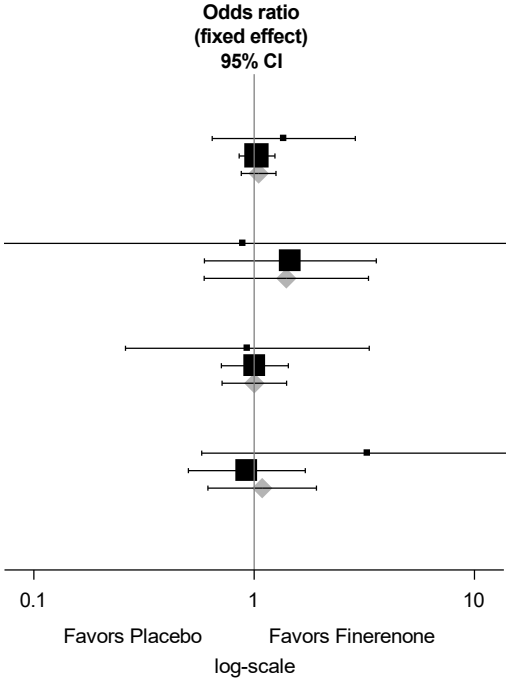


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B3.3.12.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race

Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 140	14 / 152	5.9	1.36 [0.64,2.88]	
FIGARO-DKD	269 / 1659	255 / 1613	94.1	1.03 [0.85,1.24]	
Total	286 / 1799	269 / 1765		1.05 [0.87,1.26]	Z=0.50, p=0.6140
Heterogeneity:	Q=0.50 (df=1)	p=0.4780	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	8.6	0.89 [0.05,16.66]	
FIGARO-DKD	13 / 70	10 / 74	91.4	1.46 [0.59,3.58]	
Total	14 / 80	11 / 83		1.40 [0.59,3.30]	Z=0.77, p=0.4430
Heterogeneity:	Q=0.10 (df=1)	p=0.7512	I^2=0.0%		
Asian					
FIDELIO-DKD	5 / 39	6 / 44	7.0	0.93 [0.26,3.33]	
FIGARO-DKD	73 / 464	76 / 486	93.0	1.01 [0.71,1.43]	
Total	78 / 503	82 / 530		1.00 [0.71,1.40]	Z=0.01, p=0.9922
Heterogeneity:	Q=0.01 (df=1)	p=0.9075	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 22	2 / 16	11.1	3.27 [0.58,18.46]	
FIGARO-DKD	25 / 134	26 / 131	88.9	0.93 [0.50,1.71]	
Total	32 / 156	28 / 147		1.09 [0.62,1.92]	Z=0.29, p=0.7724
Heterogeneity:	Q=1.81 (df=1)	p=0.1780	I^2=44.9%		
Subgroup Heterogeneity:	Q=0.52 (df=3)	p=0.9145	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.

Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.

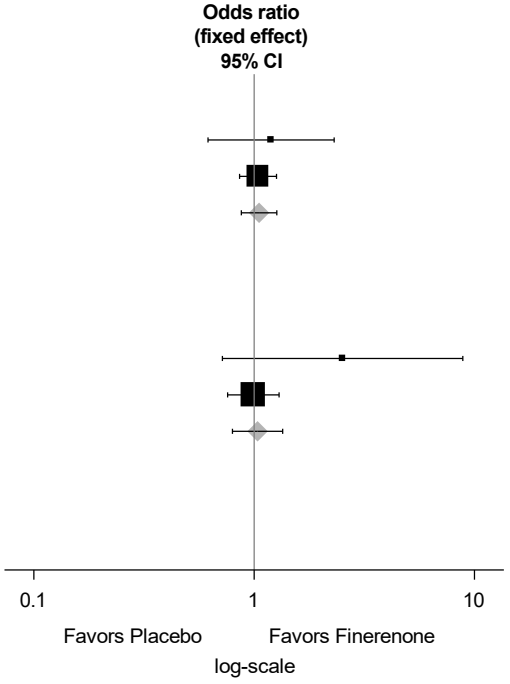
Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure B3.3.12.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

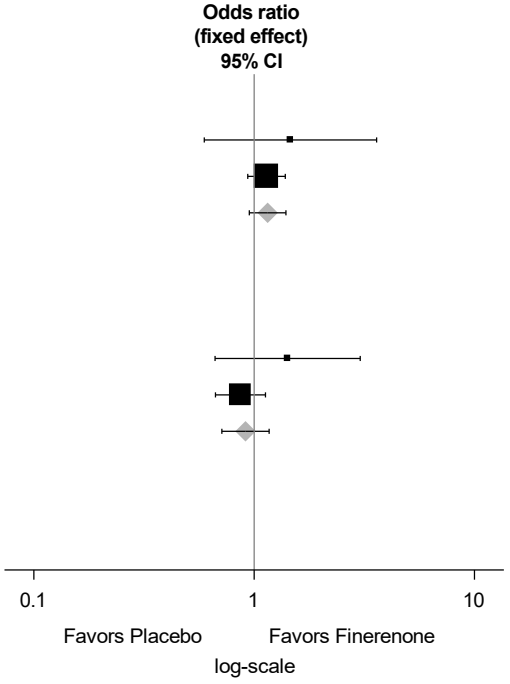
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	22 / 153	19 / 154	7.9	1.19 [0.62,2.31]	
FIGARO-DKD	244 / 1611	240 / 1640	92.1	1.04 [0.86,1.26]	
Total	266 / 1764	259 / 1794		1.05 [0.87,1.27]	Z=0.54, p=0.5883
Heterogeneity:	Q=0.15 (df=1)	p=0.6974	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 58	4 / 67	4.4	2.52 [0.72,8.85]	
FIGARO-DKD	136 / 716	127 / 664	95.6	0.99 [0.76,1.30]	
Total	144 / 774	131 / 731		1.04 [0.80,1.35]	Z=0.26, p=0.7914
Heterogeneity:	Q=2.03 (df=1)	p=0.1547	I^2=50.6%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9234	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.12.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

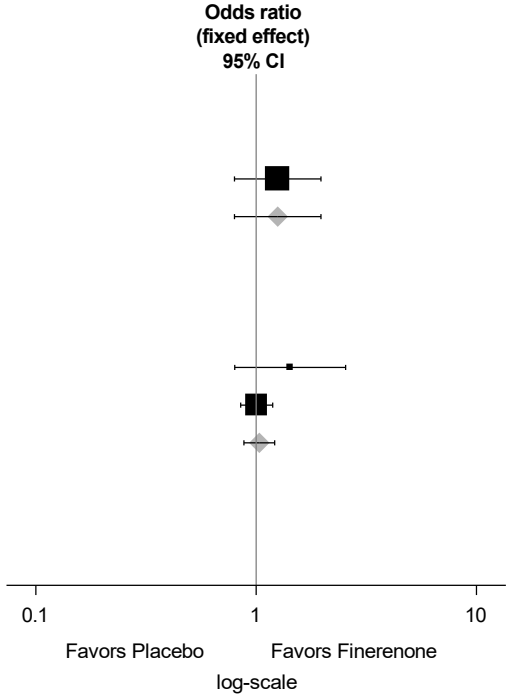
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	13 / 99	9 / 96	4.5	1.46 [0.59,3.60]	
FIGARO-DKD	254 / 1416	229 / 1421	95.5	1.14 [0.94,1.38]	
Total	267 / 1515	238 / 1517		1.15 [0.95,1.39]	Z=1.44, p=0.1502
Heterogeneity:	Q=0.28 (df=1)	p=0.5947	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 112	14 / 125	10.6	1.42 [0.66,3.03]	
FIGARO-DKD	126 / 911	138 / 883	89.4	0.87 [0.67,1.13]	
Total	143 / 1023	152 / 1008		0.91 [0.71,1.17]	Z=-0.72, p=0.4720
Heterogeneity:	Q=1.45 (df=1)	p=0.2284	I^2=31.1%		
Subgroup Heterogeneity:	Q=2.10 (df=1)	p=0.1471	I^2=52.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B3.3.12.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	49 / 363	38 / 343	100.0	1.25 [0.80,1.97]	
Total	49 / 363	38 / 343		1.25 [0.80,1.97]	Z=0.98, p=0.3289
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	30 / 211	23 / 221	7.7	1.43 [0.80,2.55]	
FIGARO-DKD	331 / 1964	329 / 1961	92.3	1.01 [0.85,1.19]	
Total	361 / 2175	352 / 2182		1.03 [0.88,1.21]	Z=0.40, p=0.6903
Heterogeneity:	Q=1.29 (df=1)	p=0.2553	I^2=22.7%		
Subgroup Heterogeneity:	Q=0.62 (df=1)	p=0.4316	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Any TEAE	2120(83.6%)	2115(83.8%)
Infections And Infestations	1061(41.8%)	1095(43.4%)
Nasopharyngitis	193(7.6%)	219(8.7%)
Urinary tract infection	157(6.2%)	146(5.8%)
Upper respiratory tract infection	144(5.7%)	150(5.9%)
Bronchitis	122(4.8%)	127(5.0%)
Influenza	100(3.9%)	113(4.5%)
Pneumonia	95(3.7%)	135(5.4%)
Cellulitis	62(2.4%)	56(2.2%)
Gastroenteritis	51(2.0%)	60(2.4%)
Respiratory tract infection	47(1.9%)	33(1.3%)
Conjunctivitis	34(1.3%)	45(1.8%)
Pharyngitis	31(1.2%)	32(1.3%)
Herpes zoster	30(1.2%)	33(1.3%)
Sinusitis	28(1.1%)	31(1.2%)
Periodontitis	25(1.0%)	16(0.6%)
Localised infection	22(0.9%)	16(0.6%)
Cystitis	21(0.8%)	19(0.8%)
Abscess limb	18(0.7%)	12(0.5%)
COVID-19	17(0.7%)	33(1.3%)
Viral infection	17(0.7%)	21(0.8%)
Otitis externa	17(0.7%)	12(0.5%)
Tooth abscess	17(0.7%)	8(0.3%)
Erysipelas	14(0.6%)	31(1.2%)
Osteomyelitis	14(0.6%)	20(0.8%)
Tonsillitis	14(0.6%)	17(0.7%)
Respiratory tract infection viral	13(0.5%)	22(0.9%)
Sepsis	13(0.5%)	12(0.5%)
Onychomycosis	13(0.5%)	11(0.4%)
Subcutaneous abscess	13(0.5%)	6(0.2%)
Wound infection	12(0.5%)	12(0.5%)
Ear infection	12(0.5%)	11(0.4%)
Lower respiratory tract infection	12(0.5%)	9(0.4%)
Otitis media	12(0.5%)	9(0.4%)
Helicobacter infection	12(0.5%)	6(0.2%)
Rhinitis	11(0.4%)	14(0.6%)
Tooth infection	11(0.4%)	13(0.5%)
Skin infection	11(0.4%)	12(0.5%)
Fungal skin infection	11(0.4%)	8(0.3%)
Pulpitis dental	11(0.4%)	4(0.2%)
Laryngitis	10(0.4%)	5(0.2%)
Diverticulitis	9(0.4%)	7(0.3%)
Postoperative wound infection	9(0.4%)	3(0.1%)
Acute sinusitis	8(0.3%)	6(0.2%)
Oral herpes	8(0.3%)	4(0.2%)
Tinea pedis	7(0.3%)	15(0.6%)
Urosepsis	7(0.3%)	11(0.4%)
Diabetic foot infection	7(0.3%)	6(0.2%)
Gastroenteritis viral	7(0.3%)	6(0.2%)
Pyelonephritis	7(0.3%)	2(0.1%)
COVID-19 pneumonia	6(0.2%)	9(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Folliculitis	6(0.2%)	5(0.2%)
Pyelonephritis chronic	6(0.2%)	5(0.2%)
Infected bite	6(0.2%)	4(0.2%)
Appendicitis	6(0.2%)	3(0.1%)
Orchitis	6(0.2%)	2(0.1%)
Dermatophytosis of nail	6(0.2%)	1(0.0%)
Gingivitis	5(0.2%)	13(0.5%)
Pyelonephritis acute	5(0.2%)	6(0.2%)
Infected skin ulcer	5(0.2%)	4(0.2%)
Chronic sinusitis	5(0.2%)	2(0.1%)
Tracheitis	5(0.2%)	2(0.1%)
Infected dermal cyst	5(0.2%)	1(0.0%)
Fungal infection	4(0.2%)	5(0.2%)
Labyrinthitis	4(0.2%)	5(0.2%)
Eye infection	4(0.2%)	4(0.2%)
Abscess	4(0.2%)	3(0.1%)
Asymptomatic bacteriuria	4(0.2%)	3(0.1%)
Pharyngotonsillitis	4(0.2%)	3(0.1%)
Tracheobronchitis	4(0.2%)	3(0.1%)
Septic shock	4(0.2%)	2(0.1%)
Tinea cruris	4(0.2%)	2(0.1%)
Oral fungal infection	4(0.2%)	1(0.0%)
Vaginal infection	4(0.2%)	1(0.0%)
Febrile infection	4(0.2%)	0
Paronychia	3(0.1%)	11(0.4%)
Acarodermatitis	3(0.1%)	9(0.4%)
Furuncle	3(0.1%)	8(0.3%)
Pneumonia bacterial	3(0.1%)	8(0.3%)
Gangrene	3(0.1%)	7(0.3%)
Hordeolum	3(0.1%)	5(0.2%)
Suspected COVID-19	3(0.1%)	3(0.1%)
Vulvovaginal mycotic infection	3(0.1%)	3(0.1%)
Gastrointestinal viral infection	3(0.1%)	2(0.1%)
Gingival abscess	3(0.1%)	2(0.1%)
Herpes simplex	3(0.1%)	2(0.1%)
Osteomyelitis chronic	3(0.1%)	2(0.1%)
Viral rhinitis	3(0.1%)	2(0.1%)
Bacterial infection	3(0.1%)	1(0.0%)
Enteritis infectious	3(0.1%)	1(0.0%)
Genital candidiasis	3(0.1%)	1(0.0%)
Genitourinary tract infection	3(0.1%)	1(0.0%)
Pustule	3(0.1%)	1(0.0%)
Bronchitis bacterial	3(0.1%)	0
Dengue fever	3(0.1%)	0
Herpes dermatitis	3(0.1%)	0
Viral upper respiratory tract infection	2(0.1%)	9(0.4%)
Infection	2(0.1%)	6(0.2%)
Soft tissue infection	2(0.1%)	6(0.2%)
Helicobacter gastritis	2(0.1%)	5(0.2%)
Vulvovaginal candidiasis	2(0.1%)	4(0.2%)
Anal abscess	2(0.1%)	3(0.1%)
Body tinea	2(0.1%)	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Conjunctivitis bacterial	2(0.1%)	3(0.1%)
Penile infection	2(0.1%)	3(0.1%)
Pneumonia viral	2(0.1%)	3(0.1%)
Pulmonary tuberculosis	2(0.1%)	3(0.1%)
Carbuncle	2(0.1%)	2(0.1%)
Hepatitis C	2(0.1%)	2(0.1%)
Epididymitis	2(0.1%)	1(0.0%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Mastoiditis	2(0.1%)	1(0.0%)
Otitis media chronic	2(0.1%)	1(0.0%)
Post procedural infection	2(0.1%)	1(0.0%)
Staphylococcal bacteraemia	2(0.1%)	1(0.0%)
Tinea infection	2(0.1%)	1(0.0%)
Candida infection	2(0.1%)	0
Enterocolitis viral	2(0.1%)	0
Gastrointestinal infection	2(0.1%)	0
Herpes virus infection	2(0.1%)	0
Infected cyst	2(0.1%)	0
Liver abscess	2(0.1%)	0
Scrotal abscess	2(0.1%)	0
Genital infection fungal	1(0.0%)	5(0.2%)
Oral candidiasis	1(0.0%)	5(0.2%)
Herpes ophthalmic	1(0.0%)	4(0.2%)
Urethritis	1(0.0%)	4(0.2%)
Genital infection	1(0.0%)	3(0.1%)
Groin infection	1(0.0%)	3(0.1%)
Oesophageal candidiasis	1(0.0%)	3(0.1%)
Urinary tract infection bacterial	1(0.0%)	3(0.1%)
Arthritis infective	1(0.0%)	2(0.1%)
Cholecystitis infective	1(0.0%)	2(0.1%)
Dacryocystitis	1(0.0%)	2(0.1%)
Infective exacerbation of bronchiectasis	1(0.0%)	2(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	2(0.1%)
Meningitis	1(0.0%)	2(0.1%)
Abscess oral	1(0.0%)	1(0.0%)
Alveolar osteitis	1(0.0%)	1(0.0%)
Asymptomatic COVID-19	1(0.0%)	1(0.0%)
Bacterial vaginosis	1(0.0%)	1(0.0%)
Chest wall abscess	1(0.0%)	1(0.0%)
Device related infection	1(0.0%)	1(0.0%)
Diabetic gangrene	1(0.0%)	1(0.0%)
Ear infection fungal	1(0.0%)	1(0.0%)
Genital herpes	1(0.0%)	1(0.0%)
Groin abscess	1(0.0%)	1(0.0%)
Nail infection	1(0.0%)	1(0.0%)
Necrotising fasciitis	1(0.0%)	1(0.0%)
Osteomyelitis acute	1(0.0%)	1(0.0%)
Otitis media acute	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Pharyngitis bacterial	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Pyoderma	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Sialoadenitis	1(0.0%)	1(0.0%)
Staphylococcal infection	1(0.0%)	1(0.0%)
Tinea versicolour	1(0.0%)	1(0.0%)
Urogenital infection fungal	1(0.0%)	1(0.0%)
Varicella zoster virus infection	1(0.0%)	1(0.0%)
Viral diarrhoea	1(0.0%)	1(0.0%)
Abdominal abscess	1(0.0%)	0
Abdominal infection	1(0.0%)	0
Abdominal wall abscess	1(0.0%)	0
Ascariasis	1(0.0%)	0
Bacterial disease carrier	1(0.0%)	0
Blister infected	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Burn infection	1(0.0%)	0
Cervicitis	1(0.0%)	0
Conjunctivitis viral	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Dacryocanaliculitis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Ear infection staphylococcal	1(0.0%)	0
Encephalitis viral	1(0.0%)	0
Endocarditis	1(0.0%)	0
Endophthalmitis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Erythema migrans	1(0.0%)	0
Escherichia bacteraemia	1(0.0%)	0
Eye infection viral	1(0.0%)	0
Eyelid infection	1(0.0%)	0
Fascioliasis	1(0.0%)	0
Fungal pharyngitis	1(0.0%)	0
Gastroenteritis rotavirus	1(0.0%)	0
Gastrointestinal candidiasis	1(0.0%)	0
HIV infection	1(0.0%)	0
Hand-foot-and-mouth disease	1(0.0%)	0
Hepatitis B	1(0.0%)	0
Hepatitis E	1(0.0%)	0
Herpangina	1(0.0%)	0
Impetigo	1(0.0%)	0
Injection site cellulitis	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Lower respiratory tract infection viral	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Mastitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Oral infection	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Otitis externa fungal	1(0.0%)	0
Otosalpingitis	1(0.0%)	0
Pharyngitis streptococcal	1(0.0%)	0
Pneumococcal infection	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia streptococcal	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Pulmonary mycosis	1(0.0%)	0
Purulent discharge	1(0.0%)	0
Pyuria	1(0.0%)	0
Q fever	1(0.0%)	0
Respiratory tract infection bacterial	1(0.0%)	0
Sinusitis bacterial	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0
Staphylococcal sepsis	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Tinea blanca	1(0.0%)	0
Tongue fungal infection	1(0.0%)	0
Tuberculosis	1(0.0%)	0
Urinary tract infection enterococcal	1(0.0%)	0
Viral sinusitis	1(0.0%)	0
Vulval abscess	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Atypical pneumonia	0	3(0.1%)
Chronic hepatitis C	0	3(0.1%)
Diarrhoea infectious	0	3(0.1%)
Tonsillitis bacterial	0	3(0.1%)
Bacteraemia	0	2(0.1%)
Bacteriuria	0	2(0.1%)
Balanitis candida	0	2(0.1%)
Bronchiolitis	0	2(0.1%)
Haematoma infection	0	2(0.1%)
Root canal infection	0	2(0.1%)
Salmonellosis	0	2(0.1%)
Vestibular neuronitis	0	2(0.1%)
Abdominal sepsis	0	1(0.0%)
Abscess jaw	0	1(0.0%)
Abscess of eyelid	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)
Adenoviral conjunctivitis	0	1(0.0%)
Anal fistula infection	0	1(0.0%)
Anorectal cellulitis	0	1(0.0%)
Arthritis bacterial	0	1(0.0%)
Arthropod-borne disease	0	1(0.0%)
Bacterial vulvovaginitis	0	1(0.0%)
Balanoposthitis infective	0	1(0.0%)
Bronchitis viral	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chikungunya virus infection	0	1(0.0%)
Chronic hepatitis B	0	1(0.0%)
Chronic tonsillitis	0	1(0.0%)
Clostridium colitis	0	1(0.0%)
Clostridium difficile infection	0	1(0.0%)
Dermatophytosis	0	1(0.0%)
Dysentery	0	1(0.0%)
Eczema impetiginous	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Eczema infected	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Epstein-Barr virus infection	0	1(0.0%)
Fungal balanitis	0	1(0.0%)
Gastroenteritis norovirus	0	1(0.0%)
Gastrointestinal fungal infection	0	1(0.0%)
Hepatitis A	0	1(0.0%)
Hepatitis viral	0	1(0.0%)
Herpes zoster infection neurological	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Herpes zoster oticus	0	1(0.0%)
Infected varicose vein	0	1(0.0%)
Injection site infection	0	1(0.0%)
Kidney infection	0	1(0.0%)
Large intestine infection	0	1(0.0%)
Leprosy	0	1(0.0%)
Lymphangitis	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Muscle abscess	0	1(0.0%)
Mycoplasma infection	0	1(0.0%)
Ophthalmic herpes simplex	0	1(0.0%)
Parotitis	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Perineal abscess	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Pseudomonas infection	0	1(0.0%)
Pulmonary sepsis	0	1(0.0%)
Pyelitis	0	1(0.0%)
Rash pustular	0	1(0.0%)
Retroperitoneal abscess	0	1(0.0%)
Rocky mountain spotted fever	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Skin candida	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Testicular abscess	0	1(0.0%)
Tinea manuum	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Trichomoniasis	0	1(0.0%)
Urinary tract candidiasis	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Viral pharyngitis	0	1(0.0%)
Vulvovaginitis trichomonal	0	1(0.0%)
Metabolism And Nutrition Disorders	760(30.0%)	687(27.2%)
Hyperkalaemia	167(6.6%)	90(3.6%)
Hyperuricaemia	118(4.7%)	77(3.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hypoglycaemia	108(4.3%)	108(4.3%)
Diabetes mellitus	71(2.8%)	90(3.6%)
Diabetes mellitus inadequate control	70(2.8%)	58(2.3%)
Hyperglycaemia	66(2.6%)	57(2.3%)
Type 2 diabetes mellitus	58(2.3%)	57(2.3%)
Hypertriglyceridaemia	49(1.9%)	35(1.4%)
Vitamin D deficiency	48(1.9%)	43(1.7%)
Gout	45(1.8%)	36(1.4%)
Dyslipidaemia	41(1.6%)	32(1.3%)
Diabetic metabolic decompensation	35(1.4%)	25(1.0%)
Hyperlipidaemia	33(1.3%)	31(1.2%)
Hypokalaemia	27(1.1%)	54(2.1%)
Hyponatraemia	27(1.1%)	10(0.4%)
Dehydration	17(0.7%)	16(0.6%)
Iron deficiency	16(0.6%)	11(0.4%)
Decreased appetite	14(0.6%)	21(0.8%)
Hypomagnesaemia	14(0.6%)	13(0.5%)
Vitamin B12 deficiency	12(0.5%)	7(0.3%)
Hypercholesterolaemia	11(0.4%)	6(0.2%)
Obesity	9(0.4%)	11(0.4%)
Hypoproteinaemia	9(0.4%)	9(0.4%)
Metabolic acidosis	8(0.3%)	4(0.2%)
Folate deficiency	5(0.2%)	9(0.4%)
Hypocalcaemia	5(0.2%)	9(0.4%)
Hypercalcaemia	4(0.2%)	5(0.2%)
Diabetic ketoacidosis	4(0.2%)	2(0.1%)
Metabolic disorder	3(0.1%)	10(0.4%)
Hypoalbuminaemia	3(0.1%)	4(0.2%)
Hyperphosphataemia	3(0.1%)	2(0.1%)
Fluid overload	3(0.1%)	1(0.0%)
Hypochloraemia	2(0.1%)	2(0.1%)
Abnormal loss of weight	2(0.1%)	1(0.0%)
Lipid metabolism disorder	2(0.1%)	1(0.0%)
Malnutrition	2(0.1%)	1(0.0%)
Metabolic syndrome	2(0.1%)	0
Overweight	2(0.1%)	0
Electrolyte imbalance	1(0.0%)	3(0.1%)
Hyperhomocysteinaemia	1(0.0%)	2(0.1%)
Hypervolaemia	1(0.0%)	2(0.1%)
Increased appetite	1(0.0%)	2(0.1%)
Magnesium deficiency	1(0.0%)	2(0.1%)
Hypophosphataemia	1(0.0%)	1(0.0%)
Hypovolaemia	1(0.0%)	1(0.0%)
Alkalosis	1(0.0%)	0
Diabetic ketosis	1(0.0%)	0
Food aversion	1(0.0%)	0
Hypocholesterolaemia	1(0.0%)	0
Ketoacidosis	1(0.0%)	0
Lactic acidosis	1(0.0%)	0
Cachexia	0	3(0.1%)
Hypernatraemia	0	3(0.1%)
Diabetic complication	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hyperchloraemia	0	2(0.1%)
Abnormal weight gain	0	1(0.0%)
Fluid retention	0	1(0.0%)
Hyperlactacidaemia	0	1(0.0%)
Hypoglycaemia unawareness	0	1(0.0%)
Hypovitaminosis	0	1(0.0%)
Hypozincaemia	0	1(0.0%)
Lactose intolerance	0	1(0.0%)
Metabolic alkalosis	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Periarthritis calcarea	0	1(0.0%)
Polydipsia	0	1(0.0%)
Vitamin B complex deficiency	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	668(26.3%)	658(26.1%)
Arthralgia	188(7.4%)	165(6.5%)
Back pain	162(6.4%)	147(5.8%)
Pain in extremity	90(3.5%)	81(3.2%)
Muscle spasms	66(2.6%)	79(3.1%)
Osteoarthritis	61(2.4%)	67(2.7%)
Myalgia	45(1.8%)	50(2.0%)
Intervertebral disc protrusion	30(1.2%)	31(1.2%)
Spinal osteoarthritis	28(1.1%)	34(1.3%)
Neck pain	27(1.1%)	26(1.0%)
Rotator cuff syndrome	23(0.9%)	28(1.1%)
Arthritis	23(0.9%)	22(0.9%)
Periarthritis	22(0.9%)	16(0.6%)
Musculoskeletal chest pain	13(0.5%)	11(0.4%)
Bursitis	11(0.4%)	17(0.7%)
Joint swelling	11(0.4%)	11(0.4%)
Flank pain	11(0.4%)	8(0.3%)
Lumbar spinal stenosis	11(0.4%)	6(0.2%)
Trigger finger	10(0.4%)	10(0.4%)
Muscular weakness	10(0.4%)	6(0.2%)
Osteoporosis	9(0.4%)	8(0.3%)
Tenosynovitis	9(0.4%)	6(0.2%)
Gouty arthritis	8(0.3%)	4(0.2%)
Spinal stenosis	8(0.3%)	4(0.2%)
Spinal pain	8(0.3%)	2(0.1%)
Plantar fasciitis	7(0.3%)	15(0.6%)
Tendon disorder	7(0.3%)	8(0.3%)
Musculoskeletal stiffness	7(0.3%)	6(0.2%)
Synovial cyst	7(0.3%)	5(0.2%)
Tendonitis	6(0.2%)	7(0.3%)
Neuropathic arthropathy	6(0.2%)	6(0.2%)
Osteochondrosis	6(0.2%)	6(0.2%)
Intervertebral disc degeneration	6(0.2%)	5(0.2%)
Osteopenia	6(0.2%)	4(0.2%)
Intervertebral disc disorder	5(0.2%)	7(0.3%)
Rheumatoid arthritis	5(0.2%)	3(0.1%)
Foot deformity	5(0.2%)	1(0.0%)
Musculoskeletal pain	4(0.2%)	10(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Exostosis	4(0.2%)	6(0.2%)
Synovitis	4(0.2%)	1(0.0%)
Chondropathy	3(0.1%)	1(0.0%)
Tenosynovitis stenosans	3(0.1%)	1(0.0%)
Muscle atrophy	3(0.1%)	0
Rhabdomyolysis	3(0.1%)	0
Dupuytren's contracture	2(0.1%)	5(0.2%)
Myositis	2(0.1%)	5(0.2%)
Limb discomfort	2(0.1%)	3(0.1%)
Osteitis	2(0.1%)	3(0.1%)
Scoliosis	2(0.1%)	3(0.1%)
Spondylolisthesis	2(0.1%)	3(0.1%)
Joint effusion	2(0.1%)	2(0.1%)
Polymyalgia rheumatica	2(0.1%)	2(0.1%)
Muscle contracture	2(0.1%)	1(0.0%)
Muscle twitching	2(0.1%)	1(0.0%)
Myopathy	2(0.1%)	1(0.0%)
Sacroiliitis	2(0.1%)	0
Costochondritis	1(0.0%)	5(0.2%)
Polyarthritis	1(0.0%)	3(0.1%)
Diastasis recti abdominis	1(0.0%)	2(0.1%)
Fibromyalgia	1(0.0%)	2(0.1%)
Metatarsalgia	1(0.0%)	2(0.1%)
Coccydynia	1(0.0%)	1(0.0%)
Degenerative bone disease	1(0.0%)	1(0.0%)
Fasciitis	1(0.0%)	1(0.0%)
Haematoma muscle	1(0.0%)	1(0.0%)
Joint range of motion decreased	1(0.0%)	1(0.0%)
Muscle rigidity	1(0.0%)	1(0.0%)
Musculoskeletal disorder	1(0.0%)	1(0.0%)
Spinal ligament ossification	1(0.0%)	1(0.0%)
Spondylitis	1(0.0%)	1(0.0%)
Vertebral foraminal stenosis	1(0.0%)	1(0.0%)
Enostosis	1(0.0%)	0
Enthesopathy	1(0.0%)	0
Exostosis of jaw	1(0.0%)	0
Femoroacetabular impingement	1(0.0%)	0
Fracture nonunion	1(0.0%)	0
Groin pain	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Joint stiffness	1(0.0%)	0
Knee deformity	1(0.0%)	0
Limb mass	1(0.0%)	0
Mobility decreased	1(0.0%)	0
Muscle disorder	1(0.0%)	0
Osteolysis	1(0.0%)	0
Osteonecrosis	1(0.0%)	0
Polymyositis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Soft tissue swelling	1(0.0%)	0
Spinal deformity	1(0.0%)	0
Spinal disorder	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Spinal synovial cyst	1(0.0%)	0
Temporomandibular joint syndrome	1(0.0%)	0
Tendon discomfort	1(0.0%)	0
Tendon pain	1(0.0%)	0
Muscle fatigue	0	4(0.2%)
Arthropathy	0	3(0.1%)
Bone pain	0	3(0.1%)
Cervical spinal stenosis	0	2(0.1%)
Chondromalacia	0	2(0.1%)
Haemarthrosis	0	2(0.1%)
Musculoskeletal discomfort	0	2(0.1%)
Pain in jaw	0	2(0.1%)
Patellofemoral pain syndrome	0	2(0.1%)
Psoriatic arthropathy	0	2(0.1%)
Spondyloarthropathy	0	2(0.1%)
Ankylosing spondylitis	0	1(0.0%)
Arthritis reactive	0	1(0.0%)
Back disorder	0	1(0.0%)
Bone formation increased	0	1(0.0%)
Chest wall cyst	0	1(0.0%)
Chest wall haematoma	0	1(0.0%)
Chondrocalcinosis	0	1(0.0%)
Chondrocalcinosis pyrophosphate	0	1(0.0%)
Joint contracture	0	1(0.0%)
Kyphoscoliosis	0	1(0.0%)
Loose body in joint	0	1(0.0%)
Muscle tightness	0	1(0.0%)
Neck mass	0	1(0.0%)
Osteoarthropathy	0	1(0.0%)
Osteochondritis	0	1(0.0%)
Osteoporotic fracture	0	1(0.0%)
Osteosclerosis	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Plantar fascial fibromatosis	0	1(0.0%)
Sjogren's syndrome	0	1(0.0%)
Soft tissue disorder	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Tendon calcification	0	1(0.0%)
Undifferentiated connective tissue disease	0	1(0.0%)
Gastrointestinal Disorders	654(25.8%)	593(23.5%)
Diarrhoea	155(6.1%)	133(5.3%)
Constipation	105(4.1%)	100(4.0%)
Nausea	59(2.3%)	44(1.7%)
Abdominal pain	50(2.0%)	48(1.9%)
Abdominal pain upper	45(1.8%)	32(1.3%)
Gastritis	43(1.7%)	36(1.4%)
Dyspepsia	43(1.7%)	27(1.1%)
Gastrooesophageal reflux disease	40(1.6%)	53(2.1%)
Vomiting	40(1.6%)	43(1.7%)
Chronic gastritis	35(1.4%)	29(1.1%)
Haemorrhoids	28(1.1%)	23(0.9%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Large intestine polyp	25(1.0%)	42(1.7%)
Toothache	23(0.9%)	24(1.0%)
Gastritis erosive	15(0.6%)	16(0.6%)
Abdominal discomfort	15(0.6%)	9(0.4%)
Diverticulum intestinal	14(0.6%)	12(0.5%)
Abdominal distension	13(0.5%)	15(0.6%)
Dental caries	13(0.5%)	12(0.5%)
Gastric ulcer	11(0.4%)	10(0.4%)
Duodenal ulcer	11(0.4%)	4(0.2%)
Hiatus hernia	10(0.4%)	13(0.5%)
Inguinal hernia	10(0.4%)	11(0.4%)
Pancreatitis acute	10(0.4%)	2(0.1%)
Flatulence	9(0.4%)	13(0.5%)
Umbilical hernia	9(0.4%)	7(0.3%)
Pancreatitis chronic	8(0.3%)	10(0.4%)
Dysphagia	7(0.3%)	6(0.2%)
Gastrointestinal haemorrhage	7(0.3%)	6(0.2%)
Gastric polyps	6(0.2%)	6(0.2%)
Abdominal pain lower	6(0.2%)	4(0.2%)
Rectal polyp	6(0.2%)	4(0.2%)
Oesophagitis	5(0.2%)	11(0.4%)
Colitis	5(0.2%)	6(0.2%)
Gastrointestinal disorder	5(0.2%)	5(0.2%)
Duodenitis	5(0.2%)	4(0.2%)
Melaena	5(0.2%)	4(0.2%)
Irritable bowel syndrome	5(0.2%)	3(0.1%)
Periodontal disease	5(0.2%)	3(0.1%)
Haematochezia	4(0.2%)	9(0.4%)
Food poisoning	4(0.2%)	4(0.2%)
Pancreatitis	4(0.2%)	2(0.1%)
Varices oesophageal	4(0.2%)	1(0.0%)
Gastrointestinal motility disorder	4(0.2%)	0
Ascites	3(0.1%)	4(0.2%)
Diverticulum	3(0.1%)	4(0.2%)
Dry mouth	3(0.1%)	4(0.2%)
Enteritis	3(0.1%)	4(0.2%)
Haemorrhoidal haemorrhage	3(0.1%)	3(0.1%)
Abdominal hernia	3(0.1%)	2(0.1%)
Enterocolitis	3(0.1%)	1(0.0%)
Gastritis haemorrhagic	3(0.1%)	1(0.0%)
Peptic ulcer	3(0.1%)	1(0.0%)
Gastric disorder	3(0.1%)	0
Gingival bleeding	3(0.1%)	0
Stomatitis	2(0.1%)	4(0.2%)
Upper gastrointestinal haemorrhage	2(0.1%)	4(0.2%)
Gastrointestinal angiodysplasia	2(0.1%)	3(0.1%)
Rectal haemorrhage	2(0.1%)	2(0.1%)
Abnormal faeces	2(0.1%)	1(0.0%)
Faeces soft	2(0.1%)	1(0.0%)
Gastric haemorrhage	2(0.1%)	1(0.0%)
Haematemesis	2(0.1%)	1(0.0%)
Loose tooth	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Mouth ulceration	2(0.1%)	1(0.0%)
Pancreatic cyst	2(0.1%)	1(0.0%)
Pancreatic steatosis	2(0.1%)	1(0.0%)
Portal hypertensive gastropathy	2(0.1%)	1(0.0%)
Tooth loss	2(0.1%)	1(0.0%)
Angular cheilitis	2(0.1%)	0
Aphthous ulcer	2(0.1%)	0
Colitis ischaemic	2(0.1%)	0
Duodenogastric reflux	2(0.1%)	0
Intestinal haemorrhage	2(0.1%)	0
Tongue ulceration	2(0.1%)	0
Small intestinal obstruction	1(0.0%)	4(0.2%)
Erosive duodenitis	1(0.0%)	3(0.1%)
Eructation	1(0.0%)	3(0.1%)
Tooth disorder	1(0.0%)	3(0.1%)
Anal fissure	1(0.0%)	2(0.1%)
Gastric ulcer haemorrhage	1(0.0%)	2(0.1%)
Ileus	1(0.0%)	2(0.1%)
Intestinal metaplasia	1(0.0%)	2(0.1%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Functional gastrointestinal disorder	1(0.0%)	1(0.0%)
Gastrointestinal hypermotility	1(0.0%)	1(0.0%)
Gingival swelling	1(0.0%)	1(0.0%)
Intestinal polyp	1(0.0%)	1(0.0%)
Lower gastrointestinal haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Mesenteric panniculitis	1(0.0%)	1(0.0%)
Noninfective gingivitis	1(0.0%)	1(0.0%)
Oesophageal polyp	1(0.0%)	1(0.0%)
Oesophageal ulcer	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Parotid gland enlargement	1(0.0%)	1(0.0%)
Proctitis	1(0.0%)	1(0.0%)
Subileus	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Acid peptic disease	1(0.0%)	0
Anal polyp	1(0.0%)	0
Bile acid malabsorption	1(0.0%)	0
Change of bowel habit	1(0.0%)	0
Coeliac artery stenosis	1(0.0%)	0
Duodenal polyp	1(0.0%)	0
Dysbiosis	1(0.0%)	0
Dyschezia	1(0.0%)	0
Epulis	1(0.0%)	0
Faeces discoloured	1(0.0%)	0
Faeces hard	1(0.0%)	0
Gastric mucosa erythema	1(0.0%)	0
Gastric mucosal lesion	1(0.0%)	0
Gastrointestinal oedema	1(0.0%)	0
Gastrointestinal polyp	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Large intestinal ulcer	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Lip disorder	1(0.0%)	0
Lip pain	1(0.0%)	0
Lip swelling	1(0.0%)	0
Lumbar hernia	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Oesophageal mass	1(0.0%)	0
Oesophageal obstruction	1(0.0%)	0
Oesophageal pain	1(0.0%)	0
Oral discomfort	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Stress ulcer	1(0.0%)	0
Submaxillary gland enlargement	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Tooth ankylosis	1(0.0%)	0
Tooth development disorder	1(0.0%)	0
Tooth impacted	1(0.0%)	0
Ulcerative duodenitis	1(0.0%)	0
Volvulus	1(0.0%)	0
Intestinal obstruction	0	5(0.2%)
Frequent bowel movements	0	4(0.2%)
Impaired gastric emptying	0	4(0.2%)
Anal incontinence	0	3(0.1%)
Abdominal adhesions	0	2(0.1%)
Anal fistula	0	2(0.1%)
Barrett's oesophagus	0	2(0.1%)
Breath odour	0	2(0.1%)
Coeliac disease	0	2(0.1%)
Colitis ulcerative	0	2(0.1%)
Diaphragmatic hernia	0	2(0.1%)
Gastrointestinal inflammation	0	2(0.1%)
Gingival pain	0	2(0.1%)
Glossodynia	0	2(0.1%)
Intestinal mass	0	2(0.1%)
Lip oedema	0	2(0.1%)
Oral pain	0	2(0.1%)
Reflux gastritis	0	2(0.1%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal haemorrhage	0	1(0.0%)
Anal inflammation	0	1(0.0%)
Anal rash	0	1(0.0%)
Anal skin tags	0	1(0.0%)
Bowel movement irregularity	0	1(0.0%)
Brunner's gland hyperplasia	0	1(0.0%)
Cheilitis	0	1(0.0%)
Crohn's disease	0	1(0.0%)
Diabetic gastroparesis	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Ectopic gastric mucosa	0	1(0.0%)
Enterovesical fistula	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Erosive oesophagitis	0	1(0.0%)
Faecaloma	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastrointestinal scarring	0	1(0.0%)
Gingival hypertrophy	0	1(0.0%)
Glycogenic acanthosis	0	1(0.0%)
Hypoaesthesia oral	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Internal hernia	0	1(0.0%)
Lymphangiectasia intestinal	0	1(0.0%)
Odynophagia	0	1(0.0%)
Oesophageal disorder	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Omental infarction	0	1(0.0%)
Oral mucosa erosion	0	1(0.0%)
Palatal disorder	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Peritoneal adhesions	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Rectal ulcer haemorrhage	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland calculus	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Small intestine ulcer	0	1(0.0%)
Steatorrhoea	0	1(0.0%)
Investigations	555(21.9%)	554(22.0%)
Glomerular filtration rate decreased	115(4.5%)	99(3.9%)
C-reactive protein increased	83(3.3%)	79(3.1%)
Blood creatine phosphokinase increased	77(3.0%)	101(4.0%)
Blood pressure increased	38(1.5%)	44(1.7%)
Blood potassium increased	36(1.4%)	17(0.7%)
Glycosylated haemoglobin increased	35(1.4%)	34(1.3%)
Blood creatinine increased	32(1.3%)	36(1.4%)
Weight decreased	32(1.3%)	27(1.1%)
Gamma-glutamyltransferase increased	28(1.1%)	35(1.4%)
Blood triglycerides increased	18(0.7%)	9(0.4%)
Blood glucose increased	15(0.6%)	20(0.8%)
Alanine aminotransferase increased	15(0.6%)	17(0.7%)
Aspartate aminotransferase increased	14(0.6%)	12(0.5%)
Blood uric acid increased	14(0.6%)	8(0.3%)
Weight increased	12(0.5%)	16(0.6%)
Hepatic enzyme increased	9(0.4%)	8(0.3%)
Liver function test increased	9(0.4%)	8(0.3%)
Haemoglobin decreased	6(0.2%)	13(0.5%)
Cardiac murmur	6(0.2%)	7(0.3%)
Blood potassium decreased	6(0.2%)	6(0.2%)
Blood lactate dehydrogenase increased	5(0.2%)	4(0.2%)
White blood cell count increased	5(0.2%)	4(0.2%)
Transaminases increased	5(0.2%)	3(0.1%)
Helicobacter test positive	4(0.2%)	8(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Blood alkaline phosphatase increased	4(0.2%)	5(0.2%)
Blood pressure decreased	4(0.2%)	4(0.2%)
Polymerase chain reaction positive	4(0.2%)	2(0.1%)
Vitamin D decreased	4(0.2%)	0
Heart rate increased	3(0.1%)	4(0.2%)
Electrocardiogram T wave inversion	3(0.1%)	3(0.1%)
Haemoglobin increased	3(0.1%)	3(0.1%)
Colonoscopy	3(0.1%)	2(0.1%)
Ejection fraction decreased	3(0.1%)	1(0.0%)
Blood sodium decreased	3(0.1%)	0
Blood urine present	3(0.1%)	0
Carcinoembryonic antigen increased	3(0.1%)	0
Electrocardiogram T wave amplitude decreased	3(0.1%)	0
Troponin T increased	3(0.1%)	0
Prostatic specific antigen increased	2(0.1%)	11(0.4%)
Electrocardiogram ST segment depression	2(0.1%)	5(0.2%)
Occult blood positive	2(0.1%)	4(0.2%)
Angiocardiogram	2(0.1%)	3(0.1%)
Blood urea increased	2(0.1%)	3(0.1%)
Liver function test abnormal	2(0.1%)	3(0.1%)
Urine albumin/creatinine ratio increased	2(0.1%)	3(0.1%)
Blood magnesium decreased	2(0.1%)	2(0.1%)
High density lipoprotein decreased	2(0.1%)	2(0.1%)
N-terminal prohormone brain natriuretic peptide increased	2(0.1%)	2(0.1%)
Protein urine present	2(0.1%)	2(0.1%)
SARS-CoV-2 test positive	2(0.1%)	2(0.1%)
Biopsy liver	2(0.1%)	1(0.0%)
Electrocardiogram T wave abnormal	2(0.1%)	1(0.0%)
Blood glucose decreased	2(0.1%)	0
Bone density decreased	2(0.1%)	0
Electrocardiogram change	2(0.1%)	0
Escherichia test positive	2(0.1%)	0
Lipids increased	2(0.1%)	0
Electrocardiogram abnormal	1(0.0%)	4(0.2%)
Intraocular pressure increased	1(0.0%)	4(0.2%)
QRS axis abnormal	1(0.0%)	4(0.2%)
Blood bicarbonate decreased	1(0.0%)	3(0.1%)
Blood cholesterol increased	1(0.0%)	3(0.1%)
Troponin increased	1(0.0%)	3(0.1%)
Blood calcium increased	1(0.0%)	2(0.1%)
Electrocardiogram QT prolonged	1(0.0%)	2(0.1%)
Haematocrit increased	1(0.0%)	2(0.1%)
Platelet count decreased	1(0.0%)	2(0.1%)
Vitamin B12 decreased	1(0.0%)	2(0.1%)
Arthroscopy	1(0.0%)	1(0.0%)
Biopsy kidney	1(0.0%)	1(0.0%)
Blood folate decreased	1(0.0%)	1(0.0%)
Blood phosphorus increased	1(0.0%)	1(0.0%)
Blood sodium increased	1(0.0%)	1(0.0%)
Blood testosterone decreased	1(0.0%)	1(0.0%)
Chest X-ray abnormal	1(0.0%)	1(0.0%)
ECG signs of myocardial ischaemia	1(0.0%)	1(0.0%)

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Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Electrocardiogram Q wave abnormal	1(0.0%)	1(0.0%)
Electrocardiogram ST segment elevation	1(0.0%)	1(0.0%)
Fibrin D dimer increased	1(0.0%)	1(0.0%)
Inflammatory marker increased	1(0.0%)	1(0.0%)
Low density lipoprotein decreased	1(0.0%)	1(0.0%)
Red blood cell count decreased	1(0.0%)	1(0.0%)
Respiratory syncytial virus test positive	1(0.0%)	1(0.0%)
White blood cells urine positive	1(0.0%)	1(0.0%)
Amylase increased	1(0.0%)	0
Angiogram	1(0.0%)	0
Angiogram retina	1(0.0%)	0
Arteriogram carotid abnormal	1(0.0%)	0
Aspiration joint	1(0.0%)	0
Blood bilirubin increased	1(0.0%)	0
Blood chloride decreased	1(0.0%)	0
Blood cholesterol decreased	1(0.0%)	0
Blood lactic acid increased	1(0.0%)	0
Blood pressure abnormal	1(0.0%)	0
Blood pressure diastolic increased	1(0.0%)	0
Blood thyroid stimulating hormone increased	1(0.0%)	0
Brain natriuretic peptide increased	1(0.0%)	0
Brucella test positive	1(0.0%)	0
Cardiac imaging procedure abnormal	1(0.0%)	0
Catheterisation cardiac	1(0.0%)	0
Colonoscopy abnormal	1(0.0%)	0
Computerised tomogram	1(0.0%)	0
Electrocardiogram PR prolongation	1(0.0%)	0
Electrocardiogram QRS complex abnormal	1(0.0%)	0
Endoscopy upper gastrointestinal tract	1(0.0%)	0
False positive investigation result	1(0.0%)	0
Haematocrit decreased	1(0.0%)	0
Hepatic enzyme abnormal	1(0.0%)	0
Hepatitis B core antibody positive	1(0.0%)	0
Hepatitis B surface antibody positive	1(0.0%)	0
Imaging procedure abnormal	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Investigation	1(0.0%)	0
Lipase increased	1(0.0%)	0
Low density lipoprotein increased	1(0.0%)	0
Neurone-specific enolase increased	1(0.0%)	0
Proteus test positive	1(0.0%)	0
Pulse absent	1(0.0%)	0
Renal function test abnormal	1(0.0%)	0
Rheumatoid factor increased	1(0.0%)	0
Sleep study	1(0.0%)	0
Transaminases abnormal	1(0.0%)	0
Urine alcohol test positive	1(0.0%)	0
Vascular resistance systemic increased	1(0.0%)	0
Influenza A virus test positive	0	5(0.2%)
Biopsy prostate	0	3(0.1%)
Platelet count increased	0	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Urinary occult blood positive	0	3(0.1%)
Blood creatine phosphokinase MB increased	0	2(0.1%)
Body temperature increased	0	2(0.1%)
Carotid bruit	0	2(0.1%)
Electrocardiogram ST segment abnormal	0	2(0.1%)
Heart rate decreased	0	2(0.1%)
Neutrophil count increased	0	2(0.1%)
Transferrin saturation decreased	0	2(0.1%)
Alpha 1 foetoprotein increased	0	1(0.0%)
Angiogram cerebral	0	1(0.0%)
Aspiration pleural cavity	0	1(0.0%)
Biopsy	0	1(0.0%)
Biopsy thyroid gland	0	1(0.0%)
Blood chromium decreased	0	1(0.0%)
Blood creatine phosphokinase abnormal	0	1(0.0%)
Blood iron decreased	0	1(0.0%)
Blood magnesium increased	0	1(0.0%)
Blood thyroid stimulating hormone decreased	0	1(0.0%)
Carbohydrate antigen 19-9 increased	0	1(0.0%)
Electrocardiogram QRS complex prolonged	0	1(0.0%)
Electrocardiogram QT interval abnormal	0	1(0.0%)
Endobronchial ultrasound	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Eosinophil count increased	0	1(0.0%)
Gastric pH decreased	0	1(0.0%)
Gastrin-releasing peptide precursor increased	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Glomerular filtration rate increased	0	1(0.0%)
Haematocrit abnormal	0	1(0.0%)
Haemoglobin abnormal	0	1(0.0%)
Hepatitis C virus test positive	0	1(0.0%)
Influenza B virus test positive	0	1(0.0%)
Laboratory test abnormal	0	1(0.0%)
Left ventricular end-diastolic pressure increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Muscle enzyme increased	0	1(0.0%)
Mycobacterium tuberculosis complex test positive	0	1(0.0%)
Myocardial necrosis marker increased	0	1(0.0%)
Oxygen consumption increased	0	1(0.0%)
Oxygen saturation decreased	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Pulmonary function test decreased	0	1(0.0%)
Pulmonary imaging procedure abnormal	0	1(0.0%)
Red blood cell count increased	0	1(0.0%)
Red blood cell sedimentation rate increased	0	1(0.0%)
Reticulocyte count increased	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
Scan myocardial perfusion abnormal	0	1(0.0%)
Staphylococcus test positive	0	1(0.0%)
Stool analysis abnormal	0	1(0.0%)
Troponin I increased	0	1(0.0%)
Ultrasound kidney abnormal	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Ultrasound liver abnormal	0	1(0.0%)
Urine protein/creatinine ratio increased	0	1(0.0%)
White blood cell count decreased	0	1(0.0%)
Nervous System Disorders	511(20.1%)	466(18.5%)
Dizziness	109(4.3%)	83(3.3%)
Headache	88(3.5%)	80(3.2%)
Diabetic neuropathy	62(2.4%)	66(2.6%)
Hypoaesthesia	23(0.9%)	27(1.1%)
Syncope	22(0.9%)	26(1.0%)
Sciatica	20(0.8%)	29(1.1%)
Neuropathy peripheral	20(0.8%)	16(0.6%)
Carpal tunnel syndrome	18(0.7%)	15(0.6%)
Paraesthesia	18(0.7%)	15(0.6%)
Carotid artery stenosis	16(0.6%)	17(0.7%)
Carotid arteriosclerosis	15(0.6%)	21(0.8%)
Lacunar infarction	11(0.4%)	4(0.2%)
Cerebral ischaemia	10(0.4%)	5(0.2%)
Dizziness postural	10(0.4%)	3(0.1%)
Facial paralysis	8(0.3%)	4(0.2%)
Presyncope	8(0.3%)	3(0.1%)
Neuralgia	7(0.3%)	7(0.3%)
Tremor	7(0.3%)	6(0.2%)
Cognitive disorder	7(0.3%)	5(0.2%)
Memory impairment	7(0.3%)	1(0.0%)
Parkinson's disease	6(0.2%)	9(0.4%)
Hemiparesis	6(0.2%)	4(0.2%)
Somnolence	6(0.2%)	4(0.2%)
Vascular encephalopathy	5(0.2%)	1(0.0%)
Balance disorder	4(0.2%)	6(0.2%)
Dementia	4(0.2%)	5(0.2%)
Polyneuropathy	4(0.2%)	5(0.2%)
Cerebral infarction	4(0.2%)	4(0.2%)
Lumbar radiculopathy	4(0.2%)	4(0.2%)
Cerebrovascular disorder	4(0.2%)	3(0.1%)
Tension headache	4(0.2%)	2(0.1%)
Poor quality sleep	4(0.2%)	1(0.0%)
Transient ischaemic attack	3(0.1%)	6(0.2%)
Cerebral arteriosclerosis	3(0.1%)	5(0.2%)
Cervicobrachial syndrome	3(0.1%)	4(0.2%)
Post herpetic neuralgia	3(0.1%)	3(0.1%)
Amnesia	3(0.1%)	2(0.1%)
Carotid artery occlusion	3(0.1%)	2(0.1%)
Dysaesthesia	3(0.1%)	2(0.1%)
Radiculopathy	3(0.1%)	2(0.1%)
Subarachnoid haemorrhage	3(0.1%)	2(0.1%)
Epilepsy	3(0.1%)	1(0.0%)
Lumbosacral radiculopathy	3(0.1%)	0
Metabolic encephalopathy	3(0.1%)	0
Orthostatic intolerance	3(0.1%)	0
Vertebral artery occlusion	3(0.1%)	0
Cervical radiculopathy	2(0.1%)	6(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Dementia Alzheimer's type	2(0.1%)	4(0.2%)
Loss of consciousness	2(0.1%)	4(0.2%)
Burning sensation	2(0.1%)	3(0.1%)
Dysarthria	2(0.1%)	3(0.1%)
Cerebral artery stenosis	2(0.1%)	2(0.1%)
Cerebral atrophy	2(0.1%)	2(0.1%)
Cerebral microangiopathy	2(0.1%)	2(0.1%)
Phantom limb syndrome	2(0.1%)	2(0.1%)
Carotid artery disease	2(0.1%)	1(0.0%)
Cerebrovascular accident	2(0.1%)	1(0.0%)
Demyelination	2(0.1%)	1(0.0%)
Dysgeusia	2(0.1%)	1(0.0%)
Essential tremor	2(0.1%)	1(0.0%)
Head discomfort	2(0.1%)	1(0.0%)
Hemianaesthesia	2(0.1%)	1(0.0%)
Intercostal neuralgia	2(0.1%)	1(0.0%)
Myelopathy	2(0.1%)	1(0.0%)
Peripheral sensorimotor neuropathy	2(0.1%)	1(0.0%)
Restless legs syndrome	2(0.1%)	1(0.0%)
Cerebral circulatory failure	2(0.1%)	0
Coordination abnormal	2(0.1%)	0
Cubital tunnel syndrome	2(0.1%)	0
Leukoencephalopathy	2(0.1%)	0
Nerve compression	2(0.1%)	0
Normal pressure hydrocephalus	2(0.1%)	0
Seizure	2(0.1%)	0
Transient global amnesia	2(0.1%)	0
Vocal cord paresis	2(0.1%)	0
Encephalopathy	1(0.0%)	3(0.1%)
Parkinsonism	1(0.0%)	3(0.1%)
Sensory disturbance	1(0.0%)	3(0.1%)
Facial paresis	1(0.0%)	2(0.1%)
Hemiparaesthesia	1(0.0%)	2(0.1%)
IIIrd nerve paralysis	1(0.0%)	2(0.1%)
Lethargy	1(0.0%)	2(0.1%)
Monoparesis	1(0.0%)	2(0.1%)
Ataxia	1(0.0%)	1(0.0%)
Brain oedema	1(0.0%)	1(0.0%)
Cerebral calcification	1(0.0%)	1(0.0%)
Cerebral small vessel ischaemic disease	1(0.0%)	1(0.0%)
Decreased vibratory sense	1(0.0%)	1(0.0%)
Meralgia paraesthetica	1(0.0%)	1(0.0%)
Paraparesis	1(0.0%)	1(0.0%)
Vascular dementia	1(0.0%)	1(0.0%)
Vertebral artery stenosis	1(0.0%)	1(0.0%)
Allodynia	1(0.0%)	0
Altered state of consciousness	1(0.0%)	0
Amputation stump pain	1(0.0%)	0
Brachial plexopathy	1(0.0%)	0
Brain injury	1(0.0%)	0
Central nervous system lesion	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cerebellar stroke	1(0.0%)	0
Cerebral artery occlusion	1(0.0%)	0
Cerebrovascular insufficiency	1(0.0%)	0
Complex regional pain syndrome	1(0.0%)	0
Demyelinating polyneuropathy	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Facial nerve disorder	1(0.0%)	0
Hemianopia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0
IVth nerve paralysis	1(0.0%)	0
Intracranial aneurysm	1(0.0%)	0
Intracranial hypotension	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0
Lacunar stroke	1(0.0%)	0
Migraine without aura	1(0.0%)	0
Mononeuropathy	1(0.0%)	0
Motor dysfunction	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Neurodegenerative disorder	1(0.0%)	0
Peripheral sensory neuropathy	1(0.0%)	0
Sinus headache	1(0.0%)	0
Sleep deficit	1(0.0%)	0
Spinal claudication	1(0.0%)	0
Spinal cord compression	1(0.0%)	0
Trigeminal neuralgia	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
VIth nerve paralysis	1(0.0%)	0
Vertebrobasilar dolichoectasia	1(0.0%)	0
Migraine	0	8(0.3%)
Anosmia	0	2(0.1%)
Hypoglycaemic coma	0	2(0.1%)
Radicular pain	0	2(0.1%)
Vertigo CNS origin	0	2(0.1%)
Visual field defect	0	2(0.1%)
Ageusia	0	1(0.0%)
Anaesthesia	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Carotid artery aneurysm	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebellar atrophy	0	1(0.0%)
Cerebral haemorrhage	0	1(0.0%)
Cerebral vascular occlusion	0	1(0.0%)
Cervicogenic headache	0	1(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.0%)
Clonus	0	1(0.0%)
Coma	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hyporeflexia	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
IVth nerve paresis	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Ischaemic neuropathy	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Multiple sclerosis	0	1(0.0%)
Muscle contractions involuntary	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Myoclonus	0	1(0.0%)
Neuralgic amyotrophy	0	1(0.0%)
Neuromyopathy	0	1(0.0%)
Parosmia	0	1(0.0%)
Sacral radiculopathy	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Toxic neuropathy	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Ulnar nerve palsy	0	1(0.0%)
Ulnar tunnel syndrome	0	1(0.0%)
VIth nerve paresis	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	404(15.9%)	430(17.0%)
Cough	105(4.1%)	113(4.5%)
Dyspnoea	49(1.9%)	76(3.0%)
Chronic obstructive pulmonary disease	39(1.5%)	38(1.5%)
Oropharyngeal pain	27(1.1%)	27(1.1%)
Sleep apnoea syndrome	26(1.0%)	26(1.0%)
Dyspnoea exertional	22(0.9%)	17(0.7%)
Asthma	19(0.7%)	22(0.9%)
Rhinitis allergic	18(0.7%)	16(0.6%)
Pulmonary mass	16(0.6%)	13(0.5%)
Epistaxis	15(0.6%)	17(0.7%)
Bronchitis chronic	15(0.6%)	5(0.2%)
Respiratory disorder	14(0.6%)	6(0.2%)
Acute respiratory failure	11(0.4%)	7(0.3%)
Pleural effusion	9(0.4%)	18(0.7%)
Rhinorrhoea	9(0.4%)	11(0.4%)
Upper respiratory tract inflammation	8(0.3%)	3(0.1%)
Pulmonary embolism	7(0.3%)	8(0.3%)
Respiratory failure	6(0.2%)	12(0.5%)
Catarrh	6(0.2%)	5(0.2%)
Productive cough	5(0.2%)	15(0.6%)
Emphysema	5(0.2%)	4(0.2%)
Atelectasis	5(0.2%)	3(0.1%)
Pulmonary hypertension	4(0.2%)	9(0.4%)
Hypoxia	4(0.2%)	6(0.2%)
Nasal congestion	4(0.2%)	6(0.2%)
Pulmonary fibrosis	4(0.2%)	5(0.2%)
Haemoptysis	4(0.2%)	4(0.2%)
Pulmonary oedema	3(0.1%)	6(0.2%)
Acute pulmonary oedema	3(0.1%)	5(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Interstitial lung disease	3(0.1%)	5(0.2%)
Restrictive pulmonary disease	3(0.1%)	1(0.0%)
Upper-airway cough syndrome	3(0.1%)	1(0.0%)
Obstructive airways disorder	3(0.1%)	0
Pleurisy	3(0.1%)	0
Sinus congestion	3(0.1%)	0
Bronchospasm	2(0.1%)	3(0.1%)
Pulmonary congestion	2(0.1%)	3(0.1%)
Aphonia	2(0.1%)	2(0.1%)
Cystic lung disease	2(0.1%)	2(0.1%)
Lung disorder	2(0.1%)	2(0.1%)
Bronchiectasis	2(0.1%)	1(0.0%)
Dyspnoea paroxysmal nocturnal	2(0.1%)	1(0.0%)
Orthopnoea	2(0.1%)	1(0.0%)
Pneumonia aspiration	2(0.1%)	1(0.0%)
Choking sensation	2(0.1%)	0
Hyperventilation	2(0.1%)	0
Lung infiltration	2(0.1%)	0
Nasal obstruction	2(0.1%)	0
Cough variant asthma	1(0.0%)	4(0.2%)
Dysphonia	1(0.0%)	3(0.1%)
Hiccups	1(0.0%)	3(0.1%)
Wheezing	1(0.0%)	3(0.1%)
Pneumonitis	1(0.0%)	2(0.1%)
Chronic respiratory failure	1(0.0%)	1(0.0%)
Increased bronchial secretion	1(0.0%)	1(0.0%)
Nasal septum deviation	1(0.0%)	1(0.0%)
Paranasal cyst	1(0.0%)	1(0.0%)
Pulmonary arterial hypertension	1(0.0%)	1(0.0%)
Respiratory acidosis	1(0.0%)	1(0.0%)
Rhonchi	1(0.0%)	1(0.0%)
Sneezing	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Hypercapnia	1(0.0%)	0
Idiopathic pulmonary fibrosis	1(0.0%)	0
Laryngeal cyst	1(0.0%)	0
Laryngeal polyp	1(0.0%)	0
Laryngitis allergic	1(0.0%)	0
Lung consolidation	1(0.0%)	0
Lung hyperinflation	1(0.0%)	0
Nasal dryness	1(0.0%)	0
Nasal mucosal erosion	1(0.0%)	0
Nasal polyps	1(0.0%)	0
Nasal turbinate hypertrophy	1(0.0%)	0
Oropharyngeal discomfort	1(0.0%)	0
Paranasal sinus inflammation	1(0.0%)	0
Pharyngeal erythema	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pleuritic pain	1(0.0%)	0
Pneumothorax	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Respiratory distress	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Respiratory tract inflammation	1(0.0%)	0
Rhinitis hypertrophic	1(0.0%)	0
Small airways disease	1(0.0%)	0
Stridor	1(0.0%)	0
Tonsillar cyst	1(0.0%)	0
Tracheal squamous cell metaplasia	1(0.0%)	0
Tracheal stenosis	1(0.0%)	0
Vocal cord inflammation	1(0.0%)	0
Dyspnoea at rest	0	2(0.1%)
Hydrothorax	0	2(0.1%)
Reflux laryngitis	0	2(0.1%)
Sinus disorder	0	2(0.1%)
Sinus pain	0	2(0.1%)
Upper respiratory tract congestion	0	2(0.1%)
Acute respiratory distress syndrome	0	1(0.0%)
Allergic respiratory disease	0	1(0.0%)
Apnoea	0	1(0.0%)
Bronchial secretion retention	0	1(0.0%)
Chronic respiratory disease	0	1(0.0%)
Diaphragmatic abnormal relaxation	0	1(0.0%)
Dry throat	0	1(0.0%)
Laryngeal mass	0	1(0.0%)
Lung cyst	0	1(0.0%)
Lung hypoinflation	0	1(0.0%)
Nocturnal dyspnoea	0	1(0.0%)
Paranasal sinus hypersecretion	0	1(0.0%)
Paranasal sinus mucosal hypertrophy	0	1(0.0%)
Pharyngeal inflammation	0	1(0.0%)
Pickwickian syndrome	0	1(0.0%)
Rales	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Sinus polyp	0	1(0.0%)
Snoring	0	1(0.0%)
Sputum increased	0	1(0.0%)
Vascular Disorders	399(15.7%)	443(17.6%)
Hypertension	159(6.3%)	226(9.0%)
Hypotension	82(3.2%)	38(1.5%)
Peripheral arterial occlusive disease	32(1.3%)	46(1.8%)
Arteriosclerosis	13(0.5%)	8(0.3%)
Peripheral venous disease	12(0.5%)	12(0.5%)
Intermittent claudication	12(0.5%)	9(0.4%)
Hypertensive crisis	11(0.4%)	15(0.6%)
Orthostatic hypotension	11(0.4%)	12(0.5%)
Aortic stenosis	11(0.4%)	11(0.4%)
Deep vein thrombosis	11(0.4%)	8(0.3%)
Aortic arteriosclerosis	10(0.4%)	18(0.7%)
Varicose vein	10(0.4%)	9(0.4%)
Peripheral artery stenosis	8(0.3%)	9(0.4%)
Peripheral artery occlusion	7(0.3%)	3(0.1%)
Peripheral ischaemia	7(0.3%)	1(0.0%)
Blood pressure inadequately controlled	5(0.2%)	11(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Peripheral vascular disorder	5(0.2%)	9(0.4%)
Haematoma	4(0.2%)	7(0.3%)
Phlebitis	4(0.2%)	3(0.1%)
Hypertensive emergency	4(0.2%)	2(0.1%)
Lymphoedema	4(0.2%)	1(0.0%)
Aortic aneurysm	3(0.1%)	6(0.2%)
Diabetic vascular disorder	3(0.1%)	6(0.2%)
Hot flush	3(0.1%)	3(0.1%)
Hypertensive urgency	3(0.1%)	3(0.1%)
Peripheral coldness	2(0.1%)	3(0.1%)
Peripheral artery thrombosis	2(0.1%)	2(0.1%)
Thrombophlebitis	2(0.1%)	2(0.1%)
Giant cell arteritis	2(0.1%)	1(0.0%)
Iliac artery stenosis	2(0.1%)	1(0.0%)
Macroangiopathy	2(0.1%)	1(0.0%)
Arterial disorder	2(0.1%)	0
Labile hypertension	2(0.1%)	0
Peripheral embolism	2(0.1%)	0
Phlebitis superficial	2(0.1%)	0
Thrombophlebitis superficial	2(0.1%)	0
Aortic dilatation	1(0.0%)	3(0.1%)
Circulatory collapse	1(0.0%)	3(0.1%)
Essential hypertension	1(0.0%)	3(0.1%)
Dry gangrene	1(0.0%)	1(0.0%)
Extremity necrosis	1(0.0%)	1(0.0%)
Poor peripheral circulation	1(0.0%)	1(0.0%)
Subclavian steal syndrome	1(0.0%)	1(0.0%)
Aortic dissection	1(0.0%)	0
Aortitis	1(0.0%)	0
Arterial occlusive disease	1(0.0%)	0
Brachiocephalic arteriosclerosis	1(0.0%)	0
Collateral circulation	1(0.0%)	0
Diastolic hypotension	1(0.0%)	0
Embolism venous	1(0.0%)	0
Haematocoele	1(0.0%)	0
Internal haemorrhage	1(0.0%)	0
Lymphorrhoea	1(0.0%)	0
Neovascularisation	1(0.0%)	0
Phlebosclerosis	1(0.0%)	0
Raynaud's phenomenon	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Thrombosis	1(0.0%)	0
Vasodilatation	1(0.0%)	0
Vein rupture	1(0.0%)	0
White coat hypertension	1(0.0%)	0
Flushing	0	3(0.1%)
Peripheral artery aneurysm	0	3(0.1%)
Accelerated hypertension	0	2(0.1%)
Diabetic macroangiopathy	0	2(0.1%)
Hypovolaemic shock	0	2(0.1%)
Microangiopathy	0	2(0.1%)
Systolic hypertension	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Venous thrombosis limb	0	2(0.1%)
Angiopathy	0	1(0.0%)
Angiosclerosis	0	1(0.0%)
Aortic aneurysm rupture	0	1(0.0%)
Aortic disorder	0	1(0.0%)
Leriche syndrome	0	1(0.0%)
Phlebolith	0	1(0.0%)
Post thrombotic syndrome	0	1(0.0%)
Shock	0	1(0.0%)
Supra-aortic trunk stenosis	0	1(0.0%)
Injury, Poisoning And Procedural Complications	398(15.7%)	364(14.4%)
Limb injury	54(2.1%)	62(2.5%)
Contusion	41(1.6%)	40(1.6%)
Ligament sprain	32(1.3%)	23(0.9%)
Fall	28(1.1%)	39(1.5%)
Skin abrasion	16(0.6%)	13(0.5%)
Rib fracture	15(0.6%)	13(0.5%)
Head injury	14(0.6%)	11(0.4%)
Thermal burn	13(0.5%)	14(0.6%)
Foot fracture	13(0.5%)	11(0.4%)
Meniscus injury	13(0.5%)	6(0.2%)
Procedural pain	11(0.4%)	8(0.3%)
Muscle strain	10(0.4%)	15(0.6%)
Joint injury	10(0.4%)	9(0.4%)
Ankle fracture	10(0.4%)	8(0.3%)
Post-traumatic pain	9(0.4%)	7(0.3%)
Bone contusion	8(0.3%)	6(0.2%)
Arthropod bite	8(0.3%)	5(0.2%)
Heat illness	8(0.3%)	4(0.2%)
Epicondylitis	7(0.3%)	7(0.3%)
Upper limb fracture	7(0.3%)	3(0.1%)
Tibia fracture	7(0.3%)	1(0.0%)
Tendon rupture	6(0.2%)	7(0.3%)
Lumbar vertebral fracture	6(0.2%)	6(0.2%)
Skin wound	6(0.2%)	5(0.2%)
Hand fracture	6(0.2%)	2(0.1%)
Skin laceration	5(0.2%)	10(0.4%)
Accident	5(0.2%)	5(0.2%)
Animal bite	5(0.2%)	4(0.2%)
Face injury	5(0.2%)	4(0.2%)
Radius fracture	5(0.2%)	4(0.2%)
Lower limb fracture	5(0.2%)	3(0.1%)
Chest injury	5(0.2%)	1(0.0%)
Foreign body in eye	5(0.2%)	1(0.0%)
Femur fracture	4(0.2%)	4(0.2%)
Tooth fracture	4(0.2%)	2(0.1%)
Arthropod sting	4(0.2%)	1(0.0%)
Burns second degree	4(0.2%)	1(0.0%)
Muscle injury	4(0.2%)	0
Scratch	4(0.2%)	0
Humerus fracture	3(0.1%)	6(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Fibula fracture	3(0.1%)	4(0.2%)
Road traffic accident	3(0.1%)	4(0.2%)
Joint dislocation	3(0.1%)	3(0.1%)
Fractured coccyx	3(0.1%)	2(0.1%)
Injury	3(0.1%)	1(0.0%)
Ligament injury	3(0.1%)	1(0.0%)
Ligament rupture	3(0.1%)	1(0.0%)
Traumatic haematoma	3(0.1%)	1(0.0%)
Hip fracture	3(0.1%)	0
Facial bones fracture	2(0.1%)	5(0.2%)
Craniocerebral injury	2(0.1%)	4(0.2%)
Subdural haematoma	2(0.1%)	4(0.2%)
Clavicle fracture	2(0.1%)	2(0.1%)
Eye injury	2(0.1%)	1(0.0%)
Heat stroke	2(0.1%)	1(0.0%)
Limb crushing injury	2(0.1%)	1(0.0%)
Multiple fractures	2(0.1%)	1(0.0%)
Nail avulsion	2(0.1%)	1(0.0%)
Nerve injury	2(0.1%)	1(0.0%)
Soft tissue injury	2(0.1%)	1(0.0%)
Toxicity to various agents	2(0.1%)	1(0.0%)
Back injury	2(0.1%)	0
Foreign body	2(0.1%)	0
Foreign body in throat	2(0.1%)	0
Inflammation of wound	2(0.1%)	0
Poisoning	2(0.1%)	0
Vascular injury	2(0.1%)	0
Wound	2(0.1%)	0
Spinal compression fracture	1(0.0%)	4(0.2%)
Subcutaneous haematoma	1(0.0%)	4(0.2%)
Eye contusion	1(0.0%)	3(0.1%)
Cartilage injury	1(0.0%)	2(0.1%)
Muscle rupture	1(0.0%)	2(0.1%)
Post procedural complication	1(0.0%)	2(0.1%)
Spinal column injury	1(0.0%)	2(0.1%)
Subdural haemorrhage	1(0.0%)	2(0.1%)
Abdominal injury	1(0.0%)	1(0.0%)
Fracture	1(0.0%)	1(0.0%)
Injury corneal	1(0.0%)	1(0.0%)
Lip injury	1(0.0%)	1(0.0%)
Mallet finger	1(0.0%)	1(0.0%)
Mouth injury	1(0.0%)	1(0.0%)
Nasal injury	1(0.0%)	1(0.0%)
Postoperative wound complication	1(0.0%)	1(0.0%)
Reactive gastropathy	1(0.0%)	1(0.0%)
Stomal hernia	1(0.0%)	1(0.0%)
Tongue injury	1(0.0%)	1(0.0%)
Traumatic fracture	1(0.0%)	1(0.0%)
Wound dehiscence	1(0.0%)	1(0.0%)
Alcohol poisoning	1(0.0%)	0
Arterial bypass occlusion	1(0.0%)	0
Arterial bypass stenosis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Burns third degree	1(0.0%)	0
Buttock injury	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Chillblains	1(0.0%)	0
Concussion	1(0.0%)	0
Corneal abrasion	1(0.0%)	0
Device placement issue	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Limb traumatic amputation	1(0.0%)	0
Multiple injuries	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Patella fracture	1(0.0%)	0
Post procedural discomfort	1(0.0%)	0
Post procedural hypotension	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Scar	1(0.0%)	0
Sciatic nerve injury	1(0.0%)	0
Seroma	1(0.0%)	0
Skin injury	1(0.0%)	0
Splenic rupture	1(0.0%)	0
Tendon injury	1(0.0%)	0
Traumatic arthritis	1(0.0%)	0
Traumatic haemorrhage	1(0.0%)	0
Ulna fracture	1(0.0%)	0
Vaccination complication	1(0.0%)	0
Vascular access site haematoma	1(0.0%)	0
Vascular access site thrombosis	1(0.0%)	0
Vascular pseudoaneurysm	1(0.0%)	0
Wound complication	1(0.0%)	0
Wound contamination	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Wrist fracture	0	7(0.3%)
Traumatic ulcer	0	5(0.2%)
Thoracic vertebral fracture	0	4(0.2%)
Burns first degree	0	3(0.1%)
Hyphaema	0	3(0.1%)
Sunburn	0	3(0.1%)
Anaemia postoperative	0	2(0.1%)
Brain contusion	0	2(0.1%)
Nail injury	0	2(0.1%)
Procedural nausea	0	2(0.1%)
Accidental overdose	0	1(0.0%)
Auricular haematoma	0	1(0.0%)
Bone fissure	0	1(0.0%)
Burn oral cavity	0	1(0.0%)
Cataract operation complication	0	1(0.0%)
Cervical vertebral fracture	0	1(0.0%)
Chemical burns of eye	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cystitis radiation	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Ear canal injury	0	1(0.0%)
Exposure to SARS-CoV-2	0	1(0.0%)
Exposure to communicable disease	0	1(0.0%)
Extra-axial haemorrhage	0	1(0.0%)
Eyelid injury	0	1(0.0%)
Incision site pain	0	1(0.0%)
Muscle contusion	0	1(0.0%)
Neck injury	0	1(0.0%)
Overdose	0	1(0.0%)
Peripheral nerve injury	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Post procedural constipation	0	1(0.0%)
Post procedural fever	0	1(0.0%)
Post procedural hypothyroidism	0	1(0.0%)
Post-traumatic neck syndrome	0	1(0.0%)
Postoperative ileus	0	1(0.0%)
Procedural hypertension	0	1(0.0%)
Procedural vomiting	0	1(0.0%)
Radiation associated pain	0	1(0.0%)
Radiation skin injury	0	1(0.0%)
Retinal injury	0	1(0.0%)
Skull fracture	0	1(0.0%)
Spinal fracture	0	1(0.0%)
Superficial injury of eye	0	1(0.0%)
Synovial rupture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Trunk injury	0	1(0.0%)
Ulnar nerve injury	0	1(0.0%)
Urethral injury	0	1(0.0%)
Vascular graft occlusion	0	1(0.0%)
Wound haemorrhage	0	1(0.0%)
General Disorders And Administration Site Conditions	368(14.5%)	423(16.8%)
Oedema peripheral	121(4.8%)	184(7.3%)
Chest pain	58(2.3%)	62(2.5%)
Fatigue	38(1.5%)	41(1.6%)
Pyrexia	38(1.5%)	39(1.5%)
Asthenia	34(1.3%)	30(1.2%)
Peripheral swelling	18(0.7%)	24(1.0%)
Influenza like illness	18(0.7%)	13(0.5%)
Oedema	14(0.6%)	24(1.0%)
Chest discomfort	14(0.6%)	11(0.4%)
Malaise	10(0.4%)	10(0.4%)
Pain	8(0.3%)	8(0.3%)
Death	6(0.2%)	2(0.1%)
Inflammation	4(0.2%)	8(0.3%)
Gait disturbance	4(0.2%)	5(0.2%)
Generalised oedema	4(0.2%)	5(0.2%)
General physical health deterioration	4(0.2%)	4(0.2%)
Chills	4(0.2%)	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cyst	4(0.2%)	3(0.1%)
Impaired healing	4(0.2%)	1(0.0%)
Hyperthermia	4(0.2%)	0
Non-cardiac chest pain	3(0.1%)	3(0.1%)
Exercise tolerance decreased	3(0.1%)	0
Hernia	3(0.1%)	0
Mass	2(0.1%)	3(0.1%)
Polyp	2(0.1%)	3(0.1%)
Multiple organ dysfunction syndrome	2(0.1%)	2(0.1%)
Nodule	2(0.1%)	1(0.0%)
Oedema due to renal disease	2(0.1%)	0
Drug intolerance	1(0.0%)	3(0.1%)
Illness	1(0.0%)	3(0.1%)
Thirst	1(0.0%)	3(0.1%)
Gravitational oedema	1(0.0%)	2(0.1%)
Swelling face	1(0.0%)	2(0.1%)
Granuloma	1(0.0%)	1(0.0%)
Axillary pain	1(0.0%)	0
Catheter site pain	1(0.0%)	0
Feeling abnormal	1(0.0%)	0
Feeling cold	1(0.0%)	0
Hanging	1(0.0%)	0
Injection site atrophy	1(0.0%)	0
Medical device pain	1(0.0%)	0
Physical deconditioning	1(0.0%)	0
Pseudocyst	1(0.0%)	0
Puncture site swelling	1(0.0%)	0
Soft tissue inflammation	1(0.0%)	0
Suprapubic pain	1(0.0%)	0
Vascular stent stenosis	1(0.0%)	0
Face oedema	0	2(0.1%)
Secretion discharge	0	2(0.1%)
Catheter site erythema	0	1(0.0%)
Facial pain	0	1(0.0%)
Haemorrhagic cyst	0	1(0.0%)
Hunger	0	1(0.0%)
Induration	0	1(0.0%)
Localised oedema	0	1(0.0%)
Medical device site pain	0	1(0.0%)
Pacemaker generated arrhythmia	0	1(0.0%)
Puncture site pain	0	1(0.0%)
Sensation of foreign body	0	1(0.0%)
Sudden death	0	1(0.0%)
Swelling	0	1(0.0%)
Temperature intolerance	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	362(14.3%)	358(14.2%)
Skin ulcer	56(2.2%)	64(2.5%)
Pruritus	44(1.7%)	44(1.7%)
Diabetic foot	38(1.5%)	33(1.3%)
Rash	37(1.5%)	34(1.3%)
Eczema	36(1.4%)	34(1.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Urticaria	17(0.7%)	12(0.5%)
Dermatitis	14(0.6%)	18(0.7%)
Dermatitis allergic	14(0.6%)	6(0.2%)
Hyperkeratosis	12(0.5%)	5(0.2%)
Dry skin	10(0.4%)	15(0.6%)
Erythema	9(0.4%)	12(0.5%)
Blister	9(0.4%)	9(0.4%)
Hyperhidrosis	9(0.4%)	5(0.2%)
Dermatitis contact	8(0.3%)	10(0.4%)
Skin lesion	8(0.3%)	7(0.3%)
Psoriasis	7(0.3%)	8(0.3%)
Decubitus ulcer	6(0.2%)	3(0.1%)
Skin disorder	6(0.2%)	0
Dermatitis atopic	5(0.2%)	4(0.2%)
Eczema asteatotic	5(0.2%)	1(0.0%)
Alopecia	4(0.2%)	8(0.3%)
Ingrowing nail	4(0.2%)	8(0.3%)
Stasis dermatitis	4(0.2%)	5(0.2%)
Seborrhoeic dermatitis	4(0.2%)	4(0.2%)
Hidradenitis	4(0.2%)	2(0.1%)
Angioedema	4(0.2%)	1(0.0%)
Neurodermatitis	4(0.2%)	0
Actinic keratosis	3(0.1%)	8(0.3%)
Dermal cyst	3(0.1%)	7(0.3%)
Skin discolouration	3(0.1%)	5(0.2%)
Skin exfoliation	3(0.1%)	3(0.1%)
Dyshidrotic eczema	3(0.1%)	0
Hand dermatitis	2(0.1%)	4(0.2%)
Ecchymosis	2(0.1%)	2(0.1%)
Eczema nummular	2(0.1%)	2(0.1%)
Miliaria	2(0.1%)	2(0.1%)
Palmoplantar keratoderma	2(0.1%)	2(0.1%)
Xeroderma	2(0.1%)	2(0.1%)
Asteatosis	2(0.1%)	1(0.0%)
Drug eruption	2(0.1%)	1(0.0%)
Nail dystrophy	2(0.1%)	1(0.0%)
Rosacea	2(0.1%)	1(0.0%)
Diabetic bullosis	2(0.1%)	0
Exfoliative rash	2(0.1%)	0
Onycholysis	2(0.1%)	0
Pigmentation disorder	2(0.1%)	0
Prurigo	2(0.1%)	0
Skin reaction	2(0.1%)	0
Rash pruritic	1(0.0%)	4(0.2%)
Skin fissures	1(0.0%)	2(0.1%)
Alopecia areata	1(0.0%)	1(0.0%)
Dermatitis bullous	1(0.0%)	1(0.0%)
Dermatitis psoriasiform	1(0.0%)	1(0.0%)
Haemorrhage subcutaneous	1(0.0%)	1(0.0%)
Itching scar	1(0.0%)	1(0.0%)
Night sweats	1(0.0%)	1(0.0%)
Papule	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Rash macular	1(0.0%)	1(0.0%)
Scab	1(0.0%)	1(0.0%)
Skin hypertrophy	1(0.0%)	1(0.0%)
Skin irritation	1(0.0%)	1(0.0%)
Skin necrosis	1(0.0%)	1(0.0%)
Angiodermatitis	1(0.0%)	0
Angiokeratoma	1(0.0%)	0
Autoimmune dermatitis	1(0.0%)	0
Brow ptosis	1(0.0%)	0
Cold sweat	1(0.0%)	0
Diffuse alopecia	1(0.0%)	0
Erythema ab igne	1(0.0%)	0
Fixed eruption	1(0.0%)	0
Intertrigo	1(0.0%)	0
Nail fold inflammation	1(0.0%)	0
Nail hypertrophy	1(0.0%)	0
Neuropathic ulcer	1(0.0%)	0
Pemphigoid	1(0.0%)	0
Purpura	1(0.0%)	0
Pustular psoriasis	1(0.0%)	0
Rash papular	1(0.0%)	0
Rhinophyma	1(0.0%)	0
Scar pain	1(0.0%)	0
Sebaceous adenitis	1(0.0%)	0
Seborrhoea	1(0.0%)	0
Senile xerosis	1(0.0%)	0
Skin burning sensation	1(0.0%)	0
Skin erosion	1(0.0%)	0
Solar lentigo	1(0.0%)	0
Toxic skin eruption	1(0.0%)	0
Urticaria chronic	1(0.0%)	0
Urticarial dermatitis	1(0.0%)	0
Diabetic ulcer	0	4(0.2%)
Lipohypertrophy	0	4(0.2%)
Nail discolouration	0	2(0.1%)
Rash maculo-papular	0	2(0.1%)
Skin induration	0	2(0.1%)
Skin mass	0	2(0.1%)
Vitiligo	0	2(0.1%)
Acne	0	1(0.0%)
Dandruff	0	1(0.0%)
Erythema annulare	0	1(0.0%)
Excessive skin	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Ischaemic skin ulcer	0	1(0.0%)
Lichen sclerosus	0	1(0.0%)
Lipodystrophy acquired	0	1(0.0%)
Nail bed bleeding	0	1(0.0%)
Nail bed inflammation	0	1(0.0%)
Nail disorder	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Onychoclasis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Palmoplantar pustulosis	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Pityriasis rosea	0	1(0.0%)
Pruritus allergic	0	1(0.0%)
Rash erythematous	0	1(0.0%)
Skin depigmentation	0	1(0.0%)
Skin hyperpigmentation	0	1(0.0%)
Eye Disorders	308(12.1%)	320(12.7%)
Cataract	103(4.1%)	96(3.8%)
Diabetic retinopathy	74(2.9%)	81(3.2%)
Vitreous haemorrhage	33(1.3%)	19(0.8%)
Dry eye	16(0.6%)	12(0.5%)
Retinal haemorrhage	15(0.6%)	16(0.6%)
Macular oedema	15(0.6%)	15(0.6%)
Glaucoma	14(0.6%)	12(0.5%)
Vision blurred	13(0.5%)	9(0.4%)
Retinal detachment	10(0.4%)	2(0.1%)
Blepharitis	8(0.3%)	9(0.4%)
Diabetic retinal oedema	7(0.3%)	7(0.3%)
Visual impairment	6(0.2%)	14(0.6%)
Conjunctivitis allergic	5(0.2%)	8(0.3%)
Macular fibrosis	5(0.2%)	5(0.2%)
Retinopathy	5(0.2%)	4(0.2%)
Retinopathy hypertensive	4(0.2%)	6(0.2%)
Eye pain	4(0.2%)	3(0.1%)
Macular degeneration	4(0.2%)	3(0.1%)
Visual acuity reduced	4(0.2%)	3(0.1%)
Vitreous floaters	4(0.2%)	2(0.1%)
Asthenopia	4(0.2%)	1(0.0%)
Blindness unilateral	4(0.2%)	1(0.0%)
Lacrimation increased	3(0.1%)	3(0.1%)
Ocular hypertension	3(0.1%)	3(0.1%)
Conjunctival haemorrhage	3(0.1%)	2(0.1%)
Ulcerative keratitis	3(0.1%)	2(0.1%)
Eye haemorrhage	3(0.1%)	1(0.0%)
Tractional retinal detachment	3(0.1%)	1(0.0%)
Posterior capsule opacification	2(0.1%)	5(0.2%)
Diplopia	2(0.1%)	3(0.1%)
Retinopathy proliferative	2(0.1%)	2(0.1%)
Vitreous opacities	2(0.1%)	2(0.1%)
Chalazion	2(0.1%)	1(0.0%)
Maculopathy	2(0.1%)	1(0.0%)
Ocular hyperaemia	2(0.1%)	1(0.0%)
Optic atrophy	2(0.1%)	1(0.0%)
Retinal tear	2(0.1%)	1(0.0%)
Vitreoretinal traction syndrome	2(0.1%)	1(0.0%)
Astigmatism	2(0.1%)	0
Blindness	2(0.1%)	0
Conjunctival hyperaemia	2(0.1%)	0
Diabetic eye disease	2(0.1%)	0
Entropion	2(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Pterygium	2(0.1%)	0
Sudden visual loss	2(0.1%)	0
Eye pruritus	1(0.0%)	6(0.2%)
Age-related macular degeneration	1(0.0%)	3(0.1%)
Keratitis	1(0.0%)	3(0.1%)
Vitreous detachment	1(0.0%)	3(0.1%)
Eyelid oedema	1(0.0%)	2(0.1%)
Retinal degeneration	1(0.0%)	2(0.1%)
Cataract diabetic	1(0.0%)	1(0.0%)
Choroidal neovascularisation	1(0.0%)	1(0.0%)
Dermatochalasis	1(0.0%)	1(0.0%)
Eczema eyelids	1(0.0%)	1(0.0%)
Eye allergy	1(0.0%)	1(0.0%)
Eye inflammation	1(0.0%)	1(0.0%)
Eye irritation	1(0.0%)	1(0.0%)
Macular cyst	1(0.0%)	1(0.0%)
Myopia	1(0.0%)	1(0.0%)
Ocular discomfort	1(0.0%)	1(0.0%)
Periorbital swelling	1(0.0%)	1(0.0%)
Punctate keratitis	1(0.0%)	1(0.0%)
Refraction disorder	1(0.0%)	1(0.0%)
Retinal aneurysm	1(0.0%)	1(0.0%)
Retinal oedema	1(0.0%)	1(0.0%)
Retinal vascular disorder	1(0.0%)	1(0.0%)
Retinal vein thrombosis	1(0.0%)	1(0.0%)
Swelling of eyelid	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Blepharochalasis	1(0.0%)	0
Corneal oedema	1(0.0%)	0
Deformity of orbit	1(0.0%)	0
Exposure keratitis	1(0.0%)	0
Extraocular muscle paresis	1(0.0%)	0
Eye discharge	1(0.0%)	0
Eye disorder	1(0.0%)	0
Eye ulcer	1(0.0%)	0
Hypermetropia	1(0.0%)	0
Iritis	1(0.0%)	0
Lens dislocation	1(0.0%)	0
Noninfective retinitis	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0
Ocular myasthenia	1(0.0%)	0
Orbit atrophy	1(0.0%)	0
Papilloedema	1(0.0%)	0
Pathologic myopia	1(0.0%)	0
Photophobia	1(0.0%)	0
Photopsia	1(0.0%)	0
Pupils unequal	1(0.0%)	0
Retinal artery spasm	1(0.0%)	0
Retinal neovascularisation	1(0.0%)	0
Rhegmatogenous retinal detachment	1(0.0%)	0
Uveitis	0	4(0.2%)
Cataract cortical	0	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Corneal erosion	0	3(0.1%)
Dacryostenosis acquired	0	3(0.1%)
Eyelid ptosis	0	3(0.1%)
Retinal vein occlusion	0	3(0.1%)
Xerophthalmia	0	3(0.1%)
Arteriosclerotic retinopathy	0	2(0.1%)
Cataract nuclear	0	2(0.1%)
Eye swelling	0	2(0.1%)
Eyelid cyst	0	2(0.1%)
Non-proliferative retinopathy	0	2(0.1%)
Blepharitis allergic	0	1(0.0%)
Cataract subcapsular	0	1(0.0%)
Cholesterolosis bulbi	0	1(0.0%)
Corneal infiltrates	0	1(0.0%)
Corneal leukoma	0	1(0.0%)
Cystoid macular oedema	0	1(0.0%)
Dry age-related macular degeneration	0	1(0.0%)
Ectropion	0	1(0.0%)
Episcleritis	0	1(0.0%)
Foreign body sensation in eyes	0	1(0.0%)
Halo vision	0	1(0.0%)
Hyalosis asteroid	0	1(0.0%)
Keratoconus	0	1(0.0%)
Lacrimal disorder	0	1(0.0%)
Lacrimal passage granuloma	0	1(0.0%)
Lenticular opacities	0	1(0.0%)
Open angle glaucoma	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Optic ischaemic neuropathy	0	1(0.0%)
Periorbital oedema	0	1(0.0%)
Presbyopia	0	1(0.0%)
Retinal artery occlusion	0	1(0.0%)
Retinal pigmentation	0	1(0.0%)
Retinoschisis	0	1(0.0%)
Scleritis	0	1(0.0%)
Vitreous prolapse	0	1(0.0%)
Cardiac Disorders	284(11.2%)	321(12.7%)
Cardiac failure	24(0.9%)	42(1.7%)
Coronary artery disease	22(0.9%)	28(1.1%)
Palpitations	22(0.9%)	14(0.6%)
Angina pectoris	21(0.8%)	31(1.2%)
Atrial fibrillation	21(0.8%)	14(0.6%)
Myocardial ischaemia	20(0.8%)	25(1.0%)
Cardiac failure chronic	17(0.7%)	20(0.8%)
Left ventricular hypertrophy	16(0.6%)	11(0.4%)
Ventricular extrasystoles	15(0.6%)	14(0.6%)
Mitral valve incompetence	13(0.5%)	17(0.7%)
Bundle branch block right	12(0.5%)	9(0.4%)
Arteriosclerosis coronary artery	12(0.5%)	8(0.3%)
Bundle branch block left	11(0.4%)	14(0.6%)
Atrioventricular block first degree	11(0.4%)	11(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Sinus bradycardia	11(0.4%)	6(0.2%)
Bradycardia	8(0.3%)	18(0.7%)
Cardiac failure congestive	8(0.3%)	14(0.6%)
Tricuspid valve incompetence	8(0.3%)	11(0.4%)
Atrioventricular block second degree	8(0.3%)	2(0.1%)
Tachycardia	7(0.3%)	12(0.5%)
Aortic valve incompetence	7(0.3%)	3(0.1%)
Supraventricular extrasystoles	6(0.2%)	6(0.2%)
Aortic valve stenosis	5(0.2%)	14(0.6%)
Sinus tachycardia	5(0.2%)	10(0.4%)
Coronary artery stenosis	5(0.2%)	8(0.3%)
Atrial flutter	5(0.2%)	3(0.1%)
Left atrial enlargement	5(0.2%)	2(0.1%)
Left ventricular dysfunction	5(0.2%)	2(0.1%)
Angina unstable	4(0.2%)	6(0.2%)
Ventricular tachycardia	4(0.2%)	5(0.2%)
Left ventricular failure	4(0.2%)	3(0.1%)
Ischaemic cardiomyopathy	4(0.2%)	2(0.1%)
Arrhythmia	3(0.1%)	9(0.4%)
Supraventricular tachycardia	3(0.1%)	6(0.2%)
Diastolic dysfunction	3(0.1%)	4(0.2%)
Sinus arrhythmia	3(0.1%)	4(0.2%)
Cardiomegaly	3(0.1%)	3(0.1%)
Extrasystoles	3(0.1%)	3(0.1%)
Pericardial effusion	3(0.1%)	3(0.1%)
Left atrial dilatation	2(0.1%)	4(0.2%)
Aortic valve calcification	2(0.1%)	3(0.1%)
Acute coronary syndrome	2(0.1%)	2(0.1%)
Hypertensive heart disease	2(0.1%)	2(0.1%)
Aortic valve disease mixed	2(0.1%)	1(0.0%)
Cardiac failure acute	2(0.1%)	1(0.0%)
Cardiomyopathy	2(0.1%)	1(0.0%)
Pulmonary valve incompetence	2(0.1%)	1(0.0%)
Ventricular hypokinesia	2(0.1%)	1(0.0%)
Defect conduction intraventricular	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Ventricular hypertrophy	2(0.1%)	0
Aortic valve sclerosis	1(0.0%)	4(0.2%)
Conduction disorder	1(0.0%)	3(0.1%)
Atrioventricular block	1(0.0%)	2(0.1%)
Congestive cardiomyopathy	1(0.0%)	2(0.1%)
Mitral valve sclerosis	1(0.0%)	2(0.1%)
Cardiac valve disease	1(0.0%)	1(0.0%)
Left ventricular dilatation	1(0.0%)	1(0.0%)
Mitral valve calcification	1(0.0%)	1(0.0%)
Myocardial fibrosis	1(0.0%)	1(0.0%)
Atrial thrombosis	1(0.0%)	0
Cardiac disorder	1(0.0%)	0
Cardiac hypertrophy	1(0.0%)	0
Cardiovascular insufficiency	1(0.0%)	0
Chronic left ventricular failure	1(0.0%)	0
Coronary artery occlusion	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Degenerative multivalvular disease	1(0.0%)	0
Diabetic cardiomyopathy	1(0.0%)	0
Dilatation atrial	1(0.0%)	0
Mitral valve disease	1(0.0%)	0
Mitral valve stenosis	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0
Rheumatic heart disease	1(0.0%)	0
Sigmoid-shaped ventricular septum	1(0.0%)	0
Sinus node dysfunction	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Atrioventricular block complete	0	3(0.1%)
Cardiogenic shock	0	3(0.1%)
Acute myocardial infarction	0	2(0.1%)
Cor pulmonale chronic	0	2(0.1%)
Coronary artery insufficiency	0	2(0.1%)
Ventricular arrhythmia	0	2(0.1%)
Acute left ventricular failure	0	1(0.0%)
Aortic valve disease	0	1(0.0%)
Atrial tachycardia	0	1(0.0%)
Bifascicular block	0	1(0.0%)
Bradyarrhythmia	0	1(0.0%)
Cardiac aneurysm	0	1(0.0%)
Cardiac arrest	0	1(0.0%)
Cardiac asthma	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac septal hypertrophy	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cardiovascular disorder	0	1(0.0%)
Heart valve incompetence	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Long QT syndrome	0	1(0.0%)
Mitral valve prolapse	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Nodal rhythm	0	1(0.0%)
Prinzmetal angina	0	1(0.0%)
Right atrial enlargement	0	1(0.0%)
Right ventricular dilatation	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Systolic dysfunction	0	1(0.0%)
Ventricular dysfunction	0	1(0.0%)
Renal And Urinary Disorders	271(10.7%)	336(13.3%)
Acute kidney injury	39(1.5%)	38(1.5%)
Renal impairment	39(1.5%)	32(1.3%)
Nephrolithiasis	33(1.3%)	35(1.4%)
Renal cyst	27(1.1%)	36(1.4%)
Haematuria	20(0.8%)	37(1.5%)
Dysuria	14(0.6%)	27(1.1%)
Urinary incontinence	13(0.5%)	11(0.4%)
Diabetic nephropathy	11(0.4%)	30(1.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Urinary retention	10(0.4%)	17(0.7%)
Pollakiuria	9(0.4%)	17(0.7%)
Nocturia	9(0.4%)	15(0.6%)
Chronic kidney disease	7(0.3%)	17(0.7%)
Ureterolithiasis	7(0.3%)	4(0.2%)
Hydronephrosis	6(0.2%)	8(0.3%)
Polyuria	6(0.2%)	5(0.2%)
Proteinuria	5(0.2%)	10(0.4%)
Renal colic	5(0.2%)	10(0.4%)
Renal failure	5(0.2%)	8(0.3%)
Urethral stenosis	5(0.2%)	4(0.2%)
Nephropathy	4(0.2%)	5(0.2%)
Albuminuria	3(0.1%)	6(0.2%)
Calculus urinary	3(0.1%)	5(0.2%)
Neurogenic bladder	3(0.1%)	2(0.1%)
Nephrotic syndrome	2(0.1%)	8(0.3%)
Calculus bladder	2(0.1%)	4(0.2%)
Micturition urgency	2(0.1%)	4(0.2%)
Lower urinary tract symptoms	2(0.1%)	3(0.1%)
Bladder spasm	2(0.1%)	2(0.1%)
Renal atrophy	2(0.1%)	1(0.0%)
Urinary hesitation	2(0.1%)	1(0.0%)
Urinary tract obstruction	2(0.1%)	1(0.0%)
Subacute kidney injury	2(0.1%)	0
Hypertonic bladder	1(0.0%)	10(0.4%)
Nephrosclerosis	1(0.0%)	3(0.1%)
Bladder diverticulum	1(0.0%)	2(0.1%)
Renal disorder	1(0.0%)	2(0.1%)
Urine odour abnormal	1(0.0%)	2(0.1%)
Acquired cystic kidney disease	1(0.0%)	1(0.0%)
End stage renal disease	1(0.0%)	1(0.0%)
Haemorrhage urinary tract	1(0.0%)	1(0.0%)
Hydroureter	1(0.0%)	1(0.0%)
Micturition disorder	1(0.0%)	1(0.0%)
Oliguria	1(0.0%)	1(0.0%)
Renal artery stenosis	1(0.0%)	1(0.0%)
Strangury	1(0.0%)	1(0.0%)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Urinary tract disorder	1(0.0%)	1(0.0%)
Bladder dilatation	1(0.0%)	0
Bladder dysfunction	1(0.0%)	0
Bladder hyperaemia	1(0.0%)	0
Bladder irritation	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Bladder pain	1(0.0%)	0
Focal segmental glomerulosclerosis	1(0.0%)	0
Hypocitraturia	1(0.0%)	0
Hyponatriuria	1(0.0%)	0
Incontinence	1(0.0%)	0
Microalbuminuria	1(0.0%)	0
Nephrocalcinosis	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Nephroptosis	1(0.0%)	0
Perinephritis	1(0.0%)	0
Renal cyst haemorrhage	1(0.0%)	0
Renal infarct	1(0.0%)	0
Renal injury	1(0.0%)	0
Renal tubular necrosis	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0
Renal mass	0	4(0.2%)
Tubulointerstitial nephritis	0	3(0.1%)
Azotaemia	0	2(0.1%)
Bladder hypertrophy	0	2(0.1%)
Glomerulonephritis chronic	0	2(0.1%)
Glomerulonephritis membranous	0	2(0.1%)
Renal pain	0	2(0.1%)
Stress urinary incontinence	0	2(0.1%)
Anuria	0	1(0.0%)
Chromaturia	0	1(0.0%)
Hypertensive nephropathy	0	1(0.0%)
Hyperuricosuria	0	1(0.0%)
Intercapillary glomerulosclerosis	0	1(0.0%)
Kidney enlargement	0	1(0.0%)
Nephritic syndrome	0	1(0.0%)
Nephritis	0	1(0.0%)
Nephroangiosclerosis	0	1(0.0%)
Post micturition dribble	0	1(0.0%)
Prerenal failure	0	1(0.0%)
Pyelocaliectasis	0	1(0.0%)
Renal hypertrophy	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Urethral meatus stenosis	0	1(0.0%)
Urine abnormality	0	1(0.0%)
Blood And Lymphatic System Disorders	205(8.1%)	200(7.9%)
Anaemia	135(5.3%)	119(4.7%)
Iron deficiency anaemia	22(0.9%)	20(0.8%)
Thrombocytopenia	14(0.6%)	11(0.4%)
Leukocytosis	7(0.3%)	8(0.3%)
Polycythaemia	6(0.2%)	3(0.1%)
Leukopenia	5(0.2%)	3(0.1%)
Lymphadenopathy	4(0.2%)	10(0.4%)
Splenomegaly	4(0.2%)	7(0.3%)
Blood loss anaemia	4(0.2%)	5(0.2%)
Nephrogenic anaemia	4(0.2%)	5(0.2%)
Microcytic anaemia	3(0.1%)	4(0.2%)
Normocytic anaemia	3(0.1%)	3(0.1%)
Normochromic normocytic anaemia	2(0.1%)	3(0.1%)
Lymphadenopathy mediastinal	2(0.1%)	2(0.1%)
Macrocytosis	1(0.0%)	1(0.0%)
Anaemia vitamin B12 deficiency	1(0.0%)	0
Bone marrow failure	1(0.0%)	0
Coagulopathy	1(0.0%)	0
Hypochromic anaemia	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Immune thrombocytopenia	1(0.0%)	0
Lymph node calcification	1(0.0%)	0
Lymphocytosis	1(0.0%)	0
Neutrophilia	1(0.0%)	0
Pseudolymphoma	1(0.0%)	0
Abdominal lymphadenopathy	0	3(0.1%)
Lymphadenitis	0	2(0.1%)
Thrombocytosis	0	2(0.1%)
Antiphospholipid syndrome	0	1(0.0%)
Eosinophilia	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)
Haemorrhagic diathesis	0	1(0.0%)
Hypercoagulation	0	1(0.0%)
Neutropenia	0	1(0.0%)
Pancytopenia	0	1(0.0%)
Splenic calcification	0	1(0.0%)
Splenic lesion	0	1(0.0%)
Splenic vein thrombosis	0	1(0.0%)
White blood cell disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	172(6.8%)	186(7.4%)
Prostate cancer	14(0.6%)	17(0.7%)
Colon cancer	9(0.4%)	5(0.2%)
Basal cell carcinoma	8(0.3%)	13(0.5%)
Skin papilloma	7(0.3%)	10(0.4%)
Lipoma	7(0.3%)	6(0.2%)
Bladder cancer	6(0.2%)	1(0.0%)
Renal neoplasm	6(0.2%)	1(0.0%)
Uterine leiomyoma	5(0.2%)	1(0.0%)
Seborrhoeic keratosis	4(0.2%)	7(0.3%)
Adrenal adenoma	4(0.2%)	5(0.2%)
Hepatocellular carcinoma	4(0.2%)	2(0.1%)
Lung neoplasm malignant	3(0.1%)	5(0.2%)
Hepatic cancer	3(0.1%)	2(0.1%)
Neoplasm	3(0.1%)	2(0.1%)
Transitional cell carcinoma	3(0.1%)	1(0.0%)
Bladder cancer recurrent	3(0.1%)	0
Colon adenoma	2(0.1%)	6(0.2%)
Melanocytic naevus	2(0.1%)	6(0.2%)
Pancreatic carcinoma	2(0.1%)	5(0.2%)
Squamous cell carcinoma of skin	2(0.1%)	3(0.1%)
Adrenal neoplasm	2(0.1%)	2(0.1%)
Gastric cancer	2(0.1%)	2(0.1%)
Meningioma	2(0.1%)	2(0.1%)
Acrochordon	2(0.1%)	1(0.0%)
Large intestine benign neoplasm	2(0.1%)	1(0.0%)
Lung adenocarcinoma	2(0.1%)	1(0.0%)
Neoplasm skin	2(0.1%)	1(0.0%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)
Plasma cell myeloma	2(0.1%)	1(0.0%)
Prostate cancer recurrent	2(0.1%)	1(0.0%)
Prostatic adenoma	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Squamous cell carcinoma	2(0.1%)	1(0.0%)
Benign breast neoplasm	2(0.1%)	0
Chronic lymphocytic leukaemia	2(0.1%)	0
Endometrial cancer	2(0.1%)	0
Renal cancer	1(0.0%)	4(0.2%)
Adenocarcinoma of colon	1(0.0%)	3(0.1%)
Breast cancer	1(0.0%)	3(0.1%)
Hypergammaglobulinaemia benign monoclonal	1(0.0%)	3(0.1%)
Lung neoplasm	1(0.0%)	3(0.1%)
Adenoma benign	1(0.0%)	2(0.1%)
B-cell lymphoma	1(0.0%)	2(0.1%)
Bowen's disease	1(0.0%)	2(0.1%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Haemangioma of liver	1(0.0%)	2(0.1%)
Monoclonal gammopathy	1(0.0%)	2(0.1%)
Oesophageal carcinoma	1(0.0%)	2(0.1%)
Papillary thyroid cancer	1(0.0%)	2(0.1%)
Squamous cell carcinoma of lung	1(0.0%)	2(0.1%)
Adenocarcinoma	1(0.0%)	1(0.0%)
Benign hepatic neoplasm	1(0.0%)	1(0.0%)
Benign neoplasm of thyroid gland	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Colorectal cancer	1(0.0%)	1(0.0%)
Gastrointestinal carcinoma	1(0.0%)	1(0.0%)
Metastases to lung	1(0.0%)	1(0.0%)
Metastases to lymph nodes	1(0.0%)	1(0.0%)
Metastatic malignant melanoma	1(0.0%)	1(0.0%)
Papillary renal cell carcinoma	1(0.0%)	1(0.0%)
Pituitary tumour benign	1(0.0%)	1(0.0%)
Rectal adenocarcinoma	1(0.0%)	1(0.0%)
Rectal adenoma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)
Tonsil cancer	1(0.0%)	1(0.0%)
Anogenital warts	1(0.0%)	0
Benign bone neoplasm	1(0.0%)	0
Benign mediastinal neoplasm	1(0.0%)	0
Benign neoplasm	1(0.0%)	0
Benign neoplasm of skin	1(0.0%)	0
Benign ovarian tumour	1(0.0%)	0
Benign renal neoplasm	1(0.0%)	0
Cerebral haemangioma	1(0.0%)	0
Choroid neoplasm	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Fibroadenoma of breast	1(0.0%)	0
Fibroma	1(0.0%)	0
Gastric adenoma	1(0.0%)	0
Gastrointestinal stromal tumour	1(0.0%)	0
Gastrointestinal submucosal tumour	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Intraductal papillary mucinous neoplasm	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Langerhans' cell histiocytosis	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Lymphoma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Neoplasm malignant	1(0.0%)	0
Nervous system neoplasm benign	1(0.0%)	0
Neuroendocrine tumour	1(0.0%)	0
Ocular neoplasm	1(0.0%)	0
Oral neoplasm	1(0.0%)	0
Pancreatic neuroendocrine tumour	1(0.0%)	0
Pharyngeal neoplasm	1(0.0%)	0
Rectal cancer metastatic	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Retroperitoneal neoplasm	1(0.0%)	0
Sarcoma	1(0.0%)	0
Schwannoma	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour ulceration	1(0.0%)	0
Cholesteatoma	0	3(0.1%)
Eye naevus	0	3(0.1%)
Benign lung neoplasm	0	2(0.1%)
Enchondromatosis	0	2(0.1%)
Malignant melanoma	0	2(0.1%)
Pancreatic neoplasm	0	2(0.1%)
Papillary cystadenoma lymphomatosum	0	2(0.1%)
Skin cancer	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Anal cancer	0	1(0.0%)
Benign neoplasm of eyelid	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Endometrial adenocarcinoma	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Haemangioma	0	1(0.0%)
Haemangioma of bone	0	1(0.0%)
Intraductal papilloma of breast	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Laryngeal squamous cell carcinoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Lip squamous cell carcinoma	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Mesenteric neoplasm	0	1(0.0%)
Metastases to bone	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Neoplasm prostate	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oral papilloma	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Papilloma	0	1(0.0%)
Paraproteinaemia	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Pyogenic granuloma	0	1(0.0%)
Renal hamartoma	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Seminoma	0	1(0.0%)
Testis cancer	0	1(0.0%)
Thyroid neoplasm	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Reproductive System And Breast Disorders	163(6.4%)	158(6.3%)
Benign prostatic hyperplasia	74(2.9%)	74(2.9%)
Erectile dysfunction	25(1.0%)	22(0.9%)
Prostatitis	7(0.3%)	8(0.3%)
Prostatomegaly	5(0.2%)	7(0.3%)
Balanoposthitis	5(0.2%)	6(0.2%)
Pruritus genital	4(0.2%)	1(0.0%)
Prostatic calcification	3(0.1%)	4(0.2%)
Breast pain	3(0.1%)	2(0.1%)
Sexual dysfunction	3(0.1%)	2(0.1%)
Vulvovaginal pruritus	3(0.1%)	1(0.0%)
Atrophic vulvovaginitis	3(0.1%)	0
Ovarian cyst	2(0.1%)	4(0.2%)
Prostatism	2(0.1%)	2(0.1%)
Pelvic pain	2(0.1%)	1(0.0%)
Testicular pain	1(0.0%)	2(0.1%)
Uterine polyp	1(0.0%)	2(0.1%)
Vaginal haemorrhage	1(0.0%)	2(0.1%)
Breast disorder	1(0.0%)	1(0.0%)
Breast mass	1(0.0%)	1(0.0%)
Cervical polyp	1(0.0%)	1(0.0%)
Genital lesion	1(0.0%)	1(0.0%)
Menopausal symptoms	1(0.0%)	1(0.0%)
Metrorrhagia	1(0.0%)	1(0.0%)
Penile pain	1(0.0%)	1(0.0%)
Perineal pain	1(0.0%)	1(0.0%)
Prostatic disorder	1(0.0%)	1(0.0%)
Prostatic mass	1(0.0%)	1(0.0%)
Vaginal disorder	1(0.0%)	1(0.0%)
Breast calcifications	1(0.0%)	0
Breast dysplasia	1(0.0%)	0
Breast tenderness	1(0.0%)	0
Dysmenorrhoea	1(0.0%)	0
Endometriosis	1(0.0%)	0
Fallopian tube cyst	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Menstruation irregular	1(0.0%)	0
Ovarian mass	1(0.0%)	0
Pelvic adhesions	1(0.0%)	0
Penile erythema	1(0.0%)	0
Peyronie's disease	1(0.0%)	0
Postmenopausal haemorrhage	1(0.0%)	0
Scrotal disorder	1(0.0%)	0
Uterine haemorrhage	1(0.0%)	0
Vulvovaginal dryness	1(0.0%)	0
Gynaecomastia	0	4(0.2%)
Varicocele	0	3(0.1%)
Breast hyperplasia	0	2(0.1%)
Menorrhagia	0	2(0.1%)
Calculus prostatic	0	1(0.0%)
Cervical dysplasia	0	1(0.0%)
Ejaculation disorder	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Galactorrhoea	0	1(0.0%)
Genital atrophy	0	1(0.0%)
Genital discomfort	0	1(0.0%)
Haematospermia	0	1(0.0%)
Nipple pain	0	1(0.0%)
Ovarian failure	0	1(0.0%)
Pelvic cyst	0	1(0.0%)
Prostatic cyst	0	1(0.0%)
Scrotal pain	0	1(0.0%)
Scrotal swelling	0	1(0.0%)
Testicular swelling	0	1(0.0%)
Uterine inflammation	0	1(0.0%)
Vulval eczema	0	1(0.0%)
Vulvovaginal pain	0	1(0.0%)
Hepatobiliary Disorders	155(6.1%)	141(5.6%)
Hepatic steatosis	57(2.2%)	47(1.9%)
Cholelithiasis	34(1.3%)	31(1.2%)
Hepatic function abnormal	17(0.7%)	12(0.5%)
Gallbladder polyp	12(0.5%)	8(0.3%)
Hepatic cirrhosis	10(0.4%)	8(0.3%)
Cholecystitis	6(0.2%)	4(0.2%)
Hepatomegaly	6(0.2%)	4(0.2%)
Bile duct stone	4(0.2%)	4(0.2%)
Cholecystitis chronic	3(0.1%)	8(0.3%)
Biliary colic	3(0.1%)	3(0.1%)
Cholecystitis acute	2(0.1%)	5(0.2%)
Cholestasis	2(0.1%)	4(0.2%)
Hepatic cyst	2(0.1%)	3(0.1%)
Nonalcoholic fatty liver disease	2(0.1%)	3(0.1%)
Cholangitis	2(0.1%)	2(0.1%)
Hepatic lesion	2(0.1%)	2(0.1%)
Hepatosplenomegaly	2(0.1%)	2(0.1%)
Hepatic calcification	2(0.1%)	1(0.0%)
Liver disorder	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Biliary dyskinesia	2(0.1%)	0
Hepatic mass	1(0.0%)	3(0.1%)
Hepatocellular injury	1(0.0%)	3(0.1%)
Jaundice cholestatic	1(0.0%)	2(0.1%)
Steatohepatitis	1(0.0%)	2(0.1%)
Biliary tract disorder	1(0.0%)	1(0.0%)
Hepatic failure	1(0.0%)	1(0.0%)
Non-alcoholic steatohepatitis	1(0.0%)	1(0.0%)
Biliary dilatation	1(0.0%)	0
Cholangiectasis acquired	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Drug-induced liver injury	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatitis acute	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Hepatotoxicity	1(0.0%)	0
Hyperplastic cholecystopathy	1(0.0%)	0
Hypertransaminasaemia	1(0.0%)	0
Ocular icterus	1(0.0%)	0
Cholangitis acute	0	2(0.1%)
Alcoholic liver disease	0	1(0.0%)
Biliary fistula	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Gallbladder cholesterolosis	0	1(0.0%)
Hepatitis toxic	0	1(0.0%)
Hepatobiliary disease	0	1(0.0%)
Hydrocholecystis	0	1(0.0%)
Jaundice	0	1(0.0%)
Liver injury	0	1(0.0%)
Porcelain gallbladder	0	1(0.0%)
Portal hypertension	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Surgical And Medical Procedures	154(6.1%)	124(4.9%)
Cataract operation	25(1.0%)	24(1.0%)
Tooth extraction	14(0.6%)	9(0.4%)
Knee arthroplasty	5(0.2%)	5(0.2%)
Dental implantation	5(0.2%)	3(0.1%)
Leg amputation	4(0.2%)	4(0.2%)
Intraocular lens implant	4(0.2%)	2(0.1%)
Skin lesion removal	4(0.2%)	2(0.1%)
Toe amputation	3(0.1%)	5(0.2%)
Vitrectomy	3(0.1%)	3(0.1%)
Hip arthroplasty	3(0.1%)	2(0.1%)
Gastric bypass	3(0.1%)	1(0.0%)
Retinal laser coagulation	3(0.1%)	1(0.0%)
Roux loop conversion	3(0.1%)	0
Tendon sheath incision	3(0.1%)	0
Cholecystectomy	2(0.1%)	6(0.2%)
Polypectomy	2(0.1%)	4(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Carpal tunnel decompression	2(0.1%)	3(0.1%)
Foot amputation	2(0.1%)	2(0.1%)
Skin neoplasm excision	2(0.1%)	2(0.1%)
Hysterectomy	2(0.1%)	1(0.0%)
Intervertebral disc operation	2(0.1%)	1(0.0%)
Cardioversion	2(0.1%)	0
Circumcision	2(0.1%)	0
Diabetes mellitus management	2(0.1%)	0
Eye operation	2(0.1%)	0
Removal of internal fixation	2(0.1%)	0
Shoulder operation	2(0.1%)	0
Spinal decompression	2(0.1%)	0
Large intestinal polypectomy	1(0.0%)	5(0.2%)
Eye laser surgery	1(0.0%)	4(0.2%)
Lens extraction	1(0.0%)	4(0.2%)
Abscess drainage	1(0.0%)	3(0.1%)
Dupuytren's contracture operation	1(0.0%)	2(0.1%)
Cardiac ablation	1(0.0%)	1(0.0%)
Coronary arterial stent insertion	1(0.0%)	1(0.0%)
Drug delivery device placement	1(0.0%)	1(0.0%)
Percutaneous coronary intervention	1(0.0%)	1(0.0%)
Umbilical hernia repair	1(0.0%)	1(0.0%)
Uterine polypectomy	1(0.0%)	1(0.0%)
Abdominal hernia repair	1(0.0%)	0
Acrochordon excision	1(0.0%)	0
Ankle operation	1(0.0%)	0
Atrial appendage closure	1(0.0%)	0
Benign tumour excision	1(0.0%)	0
Blepharoplasty	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Central venous catheterisation	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Colectomy	1(0.0%)	0
Coronary revascularisation	1(0.0%)	0
Dental care	1(0.0%)	0
Drug therapy	1(0.0%)	0
Endodontic procedure	1(0.0%)	0
Eyelid operation	1(0.0%)	0
Fasciotomy	1(0.0%)	0
Finger amputation	1(0.0%)	0
Gastric polypectomy	1(0.0%)	0
Glaucoma surgery	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Joint injection	1(0.0%)	0
Large intestine operation	1(0.0%)	0
Laser therapy	1(0.0%)	0
Lithotripsy	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Meniscus operation	1(0.0%)	0
Metabolic surgery	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Mole excision	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Nail operation	1(0.0%)	0
Neurolysis	1(0.0%)	0
Ocular stem cell transplant	1(0.0%)	0
Ostectomy	1(0.0%)	0
Peripheral artery bypass	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0
Platelet rich plasma therapy	1(0.0%)	0
Proctocolectomy	1(0.0%)	0
Ptosis repair	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Scar excision	1(0.0%)	0
Sequestrectomy	1(0.0%)	0
Small intestinal polypectomy	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Spinal operation	1(0.0%)	0
Tooth repair	1(0.0%)	0
Transurethral bladder resection	1(0.0%)	0
Tumour excision	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Vasectomy	1(0.0%)	0
Limb operation	0	3(0.1%)
Lipoma excision	0	3(0.1%)
Cardiac pacemaker insertion	0	2(0.1%)
Intra-ocular injection	0	2(0.1%)
Stent placement	0	2(0.1%)
Varicose vein operation	0	2(0.1%)
Amputation	0	1(0.0%)
Aortic surgery	0	1(0.0%)
Aortic valve replacement	0	1(0.0%)
Bone operation	0	1(0.0%)
Bunion operation	0	1(0.0%)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cardiac rehabilitation therapy	0	1(0.0%)
Coronary angioplasty	0	1(0.0%)
Coronary artery bypass	0	1(0.0%)
Cyst removal	0	1(0.0%)
Dental operation	0	1(0.0%)
Gastrectomy	0	1(0.0%)
Haemodialysis	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Hydrocele operation	0	1(0.0%)
Implantable defibrillator insertion	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Insertion of ambulatory peritoneal catheter	0	1(0.0%)
Intensive care	0	1(0.0%)
Intestinal polypectomy	0	1(0.0%)
Iridotomy	0	1(0.0%)
Keratomileusis	0	1(0.0%)
Knee operation	0	1(0.0%)
Ligament operation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Lung lobectomy	0	1(0.0%)
Mitral valve repair	0	1(0.0%)
Nasal operation	0	1(0.0%)
Parathyroidectomy	0	1(0.0%)
Peripheral nerve operation	0	1(0.0%)
Retinal operation	0	1(0.0%)
Retinopexy	0	1(0.0%)
Sinus operation	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Thyroidectomy	0	1(0.0%)
Toe operation	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Psychiatric Disorders	143(5.6%)	140(5.5%)
Insomnia	50(2.0%)	45(1.8%)
Depression	40(1.6%)	43(1.7%)
Anxiety	19(0.7%)	26(1.0%)
Sleep disorder	12(0.5%)	7(0.3%)
Depressed mood	4(0.2%)	6(0.2%)
Confusional state	4(0.2%)	2(0.1%)
Nervousness	3(0.1%)	3(0.1%)
Mixed anxiety and depressive disorder	3(0.1%)	0
Stress	3(0.1%)	0
Major depression	2(0.1%)	1(0.0%)
Nicotine dependence	2(0.1%)	1(0.0%)
Mental status changes	2(0.1%)	0
Restlessness	1(0.0%)	3(0.1%)
Anxiety disorder	1(0.0%)	2(0.1%)
Libido decreased	1(0.0%)	2(0.1%)
Abulia	1(0.0%)	1(0.0%)
Delirium	1(0.0%)	1(0.0%)
Drug use disorder	1(0.0%)	1(0.0%)
Nightmare	1(0.0%)	1(0.0%)
Affective disorder	1(0.0%)	0
Aggression	1(0.0%)	0
Attention deficit hyperactivity disorder	1(0.0%)	0
Autism spectrum disorder	1(0.0%)	0
Bipolar disorder	1(0.0%)	0
Irritability	1(0.0%)	0
Middle insomnia	1(0.0%)	0
Panic attack	1(0.0%)	0
Schizophreniform disorder	1(0.0%)	0
Tension	1(0.0%)	0
Adjustment disorder with depressed mood	0	3(0.1%)
Abnormal dreams	0	1(0.0%)
Adjustment disorder	0	1(0.0%)
Alcohol abuse	0	1(0.0%)
Apathy	0	1(0.0%)
Behaviour disorder	0	1(0.0%)
Disorientation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Drug abuse	0	1(0.0%)
Generalised anxiety disorder	0	1(0.0%)
Grief reaction	0	1(0.0%)
Hallucination	0	1(0.0%)
Impulse-control disorder	0	1(0.0%)
Mental disorder due to a general medical condition	0	1(0.0%)
Panic disorder	0	1(0.0%)
Polydipsia psychogenic	0	1(0.0%)
Psychotic disorder	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Tearfulness	0	1(0.0%)
Ear And Labyrinth Disorders	115(4.5%)	102(4.0%)
Vertigo	47(1.9%)	44(1.7%)
Tinnitus	13(0.5%)	13(0.5%)
Ear pain	9(0.4%)	9(0.4%)
Vertigo positional	9(0.4%)	5(0.2%)
Hypoacusis	7(0.3%)	4(0.2%)
Deafness	5(0.2%)	6(0.2%)
Sudden hearing loss	5(0.2%)	6(0.2%)
Deafness neurosensory	3(0.1%)	5(0.2%)
Ear pruritus	3(0.1%)	2(0.1%)
Ear discomfort	3(0.1%)	1(0.0%)
Cerumen impaction	2(0.1%)	6(0.2%)
Excessive cerumen production	2(0.1%)	3(0.1%)
Meniere's disease	2(0.1%)	0
Auditory disorder	1(0.0%)	1(0.0%)
Deafness unilateral	1(0.0%)	1(0.0%)
Presbyacusis	1(0.0%)	1(0.0%)
Auricular pseudocyst	1(0.0%)	0
Middle ear inflammation	1(0.0%)	0
Motion sickness	1(0.0%)	0
Otolithiasis	1(0.0%)	0
Tympanic membrane perforation	1(0.0%)	0
Deafness bilateral	0	4(0.2%)
Vestibular disorder	0	3(0.1%)
Ear disorder	0	1(0.0%)
Ear swelling	0	1(0.0%)
External ear inflammation	0	1(0.0%)
Mixed deafness	0	1(0.0%)
Endocrine Disorders	51(2.0%)	54(2.1%)
Hypothyroidism	20(0.8%)	14(0.6%)
Thyroid mass	10(0.4%)	9(0.4%)
Goitre	7(0.3%)	5(0.2%)
Hyperthyroidism	4(0.2%)	4(0.2%)
Hyperparathyroidism secondary	3(0.1%)	5(0.2%)
Adrenal mass	2(0.1%)	1(0.0%)
Autoimmune thyroiditis	2(0.1%)	1(0.0%)
Basedow's disease	1(0.0%)	1(0.0%)
Hyperparathyroidism	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Thyroid cyst	1(0.0%)	1(0.0%)
Autoimmune thyroid disorder	1(0.0%)	0
Empty sella syndrome	1(0.0%)	0
Hyperprolactinaemia	1(0.0%)	0
Primary adrenal insufficiency	1(0.0%)	0
Primary hypothyroidism	1(0.0%)	0
Adrenal cyst	0	3(0.1%)
Hypogonadism	0	3(0.1%)
Adrenal disorder	0	2(0.1%)
Adrenal insufficiency	0	1(0.0%)
Hyperparathyroidism primary	0	1(0.0%)
Hyperplasia adrenal	0	1(0.0%)
Hypoparathyroidism	0	1(0.0%)
Primary hyperaldosteronism	0	1(0.0%)
Testicular failure	0	1(0.0%)
Immune System Disorders	30(1.2%)	22(0.9%)
Seasonal allergy	9(0.4%)	6(0.2%)
Hypersensitivity	7(0.3%)	8(0.3%)
Drug hypersensitivity	6(0.2%)	3(0.1%)
Anaphylactic reaction	2(0.1%)	2(0.1%)
Allergy to arthropod bite	2(0.1%)	0
Anaphylactic shock	1(0.0%)	2(0.1%)
Sarcoidosis	1(0.0%)	2(0.1%)
Allergy to animal	1(0.0%)	0
Amyloidosis	1(0.0%)	0
Food allergy	0	1(0.0%)
Congenital, Familial And Genetic Disorders	15(0.6%)	19(0.8%)
Phimosis	4(0.2%)	5(0.2%)
Hydrocele	2(0.1%)	2(0.1%)
Adenomatous polyposis coli	2(0.1%)	1(0.0%)
Hypertrophic cardiomyopathy	2(0.1%)	0
Congenital cystic kidney disease	1(0.0%)	1(0.0%)
Thalassaemia	1(0.0%)	1(0.0%)
Accessory spleen	1(0.0%)	0
Arnold-Chiari malformation	1(0.0%)	0
Arteriovenous malformation	1(0.0%)	0
Thalassaemia alpha	1(0.0%)	0
Anomaly of middle ear congenital	0	1(0.0%)
Atrial septal defect	0	1(0.0%)
Cone dystrophy	0	1(0.0%)
Congenital renal cyst	0	1(0.0%)
Ectrodactyly	0	1(0.0%)
Familial tremor	0	1(0.0%)
Haemophilia	0	1(0.0%)
Kidney duplex	0	1(0.0%)
Rathke's cleft cyst	0	1(0.0%)
Tornwaldt cyst	0	1(0.0%)
Product Issues	2(0.1%)	5(0.2%)
Device loosening	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Device expulsion	1(0.0%)	0
Device breakage	0	2(0.1%)
Device dislocation	0	1(0.0%)
Device malfunction	0	1(0.0%)
Social Circumstances	0	1(0.0%)
Menopause	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Any TEAE	731(28.8%)	771(30.6%)
Infections And Infestations	218(8.6%)	251(9.9%)
Pneumonia	45(1.8%)	70(2.8%)
Cellulitis	22(0.9%)	18(0.7%)
Urinary tract infection	22(0.9%)	14(0.6%)
Osteomyelitis	9(0.4%)	13(0.5%)
Sepsis	8(0.3%)	10(0.4%)
Localised infection	8(0.3%)	3(0.1%)
Urosepsis	7(0.3%)	10(0.4%)
Abscess limb	7(0.3%)	4(0.2%)
COVID-19	6(0.2%)	16(0.6%)
Bronchitis	6(0.2%)	7(0.3%)
Gastroenteritis	6(0.2%)	7(0.3%)
Diabetic foot infection	6(0.2%)	4(0.2%)
Erysipelas	5(0.2%)	12(0.5%)
COVID-19 pneumonia	5(0.2%)	9(0.4%)
Appendicitis	5(0.2%)	2(0.1%)
Diverticulitis	4(0.2%)	4(0.2%)
Infected skin ulcer	4(0.2%)	1(0.0%)
Postoperative wound infection	4(0.2%)	1(0.0%)
Pyelonephritis	4(0.2%)	1(0.0%)
Pyelonephritis acute	3(0.1%)	3(0.1%)
Cystitis	3(0.1%)	2(0.1%)
Septic shock	3(0.1%)	1(0.0%)
Subcutaneous abscess	3(0.1%)	0
Gangrene	2(0.1%)	5(0.2%)
Upper respiratory tract infection	2(0.1%)	4(0.2%)
Pneumonia bacterial	2(0.1%)	3(0.1%)
Wound infection	2(0.1%)	3(0.1%)
Lower respiratory tract infection	2(0.1%)	2(0.1%)
Osteomyelitis chronic	2(0.1%)	2(0.1%)
Herpes zoster	2(0.1%)	1(0.0%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Respiratory tract infection	2(0.1%)	1(0.0%)
Bacterial infection	2(0.1%)	0
Bronchitis bacterial	2(0.1%)	0
Febrile infection	2(0.1%)	0
Anal abscess	1(0.0%)	3(0.1%)
Cholecystitis infective	1(0.0%)	2(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	2(0.1%)
Influenza	1(0.0%)	2(0.1%)
Diabetic gangrene	1(0.0%)	1(0.0%)
Necrotising fasciitis	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Chronic sinusitis	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Dengue fever	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Endocarditis	1(0.0%)	0
Endophthalmitis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Escherichia bacteraemia	1(0.0%)	0
Gastroenteritis rotavirus	1(0.0%)	0
Gastroenteritis viral	1(0.0%)	0
HIV infection	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Mastoiditis	1(0.0%)	0
Meningitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0
Otitis externa	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Peritonitis	1(0.0%)	0
Pharyngitis	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia streptococcal	1(0.0%)	0
Pneumonia viral	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Pyelonephritis chronic	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0
Staphylococcal sepsis	1(0.0%)	0
Infection	0	4(0.2%)
Soft tissue infection	0	3(0.1%)
Abscess	0	2(0.1%)
Infective exacerbation of bronchiectasis	0	2(0.1%)
Skin infection	0	2(0.1%)
Vestibular neuronitis	0	2(0.1%)
Abdominal sepsis	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)
Anorectal cellulitis	0	1(0.0%)
Arthritis bacterial	0	1(0.0%)
Atypical pneumonia	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Device related infection	0	1(0.0%)
Epididymitis	0	1(0.0%)
Furuncle	0	1(0.0%)
Hepatitis viral	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Infected bite	0	1(0.0%)
Labyrinthitis	0	1(0.0%)
Large intestine infection	0	1(0.0%)
Paronychia	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Pulmonary sepsis	0	1(0.0%)
Pulmonary tuberculosis	0	1(0.0%)
Pyelitis	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Staphylococcal bacteraemia	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Tracheobronchitis	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Metabolism And Nutrition Disorders	119(4.7%)	100(4.0%)
Type 2 diabetes mellitus	30(1.2%)	23(0.9%)
Diabetes mellitus inadequate control	21(0.8%)	13(0.5%)
Diabetic metabolic decompensation	16(0.6%)	11(0.4%)
Diabetes mellitus	15(0.6%)	21(0.8%)
Hyperkalaemia	11(0.4%)	2(0.1%)
Hyperglycaemia	9(0.4%)	6(0.2%)
Hypoglycaemia	8(0.3%)	12(0.5%)
Dehydration	4(0.2%)	4(0.2%)
Hyponatraemia	4(0.2%)	2(0.1%)
Obesity	3(0.1%)	2(0.1%)
Diabetic ketoacidosis	2(0.1%)	2(0.1%)
Gout	1(0.0%)	1(0.0%)
Electrolyte imbalance	1(0.0%)	0
Fluid overload	1(0.0%)	0
Hypercalcaemia	1(0.0%)	0
Hypomagnesaemia	1(0.0%)	0
Metabolic syndrome	1(0.0%)	0
Cachexia	0	2(0.1%)
Diabetic complication	0	2(0.1%)
Hypokalaemia	0	2(0.1%)
Metabolic acidosis	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	89(3.5%)	97(3.8%)
Prostate cancer	9(0.4%)	15(0.6%)
Colon cancer	9(0.4%)	5(0.2%)
Bladder cancer	6(0.2%)	0
Lung neoplasm malignant	3(0.1%)	5(0.2%)
Hepatic cancer	3(0.1%)	2(0.1%)
Hepatocellular carcinoma	3(0.1%)	1(0.0%)
Renal neoplasm	3(0.1%)	1(0.0%)
Pancreatic carcinoma	2(0.1%)	4(0.2%)
Gastric cancer	2(0.1%)	2(0.1%)
Lung adenocarcinoma	2(0.1%)	1(0.0%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Plasma cell myeloma	2(0.1%)	1(0.0%)
Transitional cell carcinoma	2(0.1%)	1(0.0%)
Bladder cancer recurrent	2(0.1%)	0
Basal cell carcinoma	1(0.0%)	4(0.2%)
Adenocarcinoma of colon	1(0.0%)	3(0.1%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Oesophageal carcinoma	1(0.0%)	2(0.1%)
Renal cancer	1(0.0%)	2(0.1%)
Squamous cell carcinoma of lung	1(0.0%)	2(0.1%)
Adenocarcinoma	1(0.0%)	1(0.0%)
B-cell lymphoma	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Colorectal cancer	1(0.0%)	1(0.0%)
Gastrointestinal carcinoma	1(0.0%)	1(0.0%)
Metastases to lung	1(0.0%)	1(0.0%)
Metastases to lymph nodes	1(0.0%)	1(0.0%)
Neoplasm	1(0.0%)	1(0.0%)
Papillary renal cell carcinoma	1(0.0%)	1(0.0%)
Rectal adenocarcinoma	1(0.0%)	1(0.0%)
Squamous cell carcinoma of skin	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)
Tonsil cancer	1(0.0%)	1(0.0%)
Choroid neoplasm	1(0.0%)	0
Chronic lymphocytic leukaemia	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Colon adenoma	1(0.0%)	0
Endometrial cancer	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Gastrointestinal stromal tumour	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0
Lipoma	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Prostatic adenoma	1(0.0%)	0
Rectal cancer metastatic	1(0.0%)	0
Rectal neoplasm	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Retroperitoneal neoplasm	1(0.0%)	0
Sarcoma	1(0.0%)	0
Skin papilloma	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour ulceration	1(0.0%)	0
Uterine leiomyoma	1(0.0%)	0
Breast cancer	0	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Lung neoplasm	0	2(0.1%)
Malignant melanoma	0	2(0.1%)
Pancreatic neoplasm	0	2(0.1%)
Papillary thyroid cancer	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal neoplasm	0	1(0.0%)
Anal cancer	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)
Bowen's disease	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Hypergammaglobulinaemia benign monoclonal	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Laryngeal squamous cell carcinoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastases to bone	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Papillary cystadenoma lymphomatosum	0	1(0.0%)
Papilloma	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Seminoma	0	1(0.0%)
Testis cancer	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Nervous System Disorders	69(2.7%)	50(2.0%)
Diabetic neuropathy	8(0.3%)	4(0.2%)
Dizziness	5(0.2%)	5(0.2%)
Syncope	5(0.2%)	5(0.2%)
Carotid artery stenosis	3(0.1%)	3(0.1%)
Subarachnoid haemorrhage	3(0.1%)	2(0.1%)
Facial paralysis	3(0.1%)	1(0.0%)
Cerebral ischaemia	3(0.1%)	0
Balance disorder	2(0.1%)	0
Epilepsy	2(0.1%)	0
Myelopathy	2(0.1%)	0
Presyncope	2(0.1%)	0
Hemiparesis	1(0.0%)	2(0.1%)
Cerebrovascular disorder	1(0.0%)	1(0.0%)
Lacunar infarction	1(0.0%)	1(0.0%)
Sensory disturbance	1(0.0%)	1(0.0%)
Transient ischaemic attack	1(0.0%)	1(0.0%)
Altered state of consciousness	1(0.0%)	0
Amputation stump pain	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Brain oedema	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral infarction	1(0.0%)	0
Cervicobrachial syndrome	1(0.0%)	0
Dementia Alzheimer's type	1(0.0%)	0
Dizziness postural	1(0.0%)	0
Dysarthria	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0
IIIrd nerve paralysis	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0
Memory impairment	1(0.0%)	0
Metabolic encephalopathy	1(0.0%)	0
Mononeuropathy	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Normal pressure hydrocephalus	1(0.0%)	0
Radiculopathy	1(0.0%)	0
Sciatica	1(0.0%)	0
Seizure	1(0.0%)	0
Spinal cord compression	1(0.0%)	0
Tension headache	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
Vascular encephalopathy	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Cervical radiculopathy	0	3(0.1%)
Encephalopathy	0	2(0.1%)
Facial paresis	0	2(0.1%)
Ataxia	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebral haemorrhage	0	1(0.0%)
Cerebral vascular occlusion	0	1(0.0%)
Cerebrovascular accident	0	1(0.0%)
Coma	0	1(0.0%)
Dementia	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Loss of consciousness	0	1(0.0%)
Lumbar radiculopathy	0	1(0.0%)
Meralgia paraesthetica	0	1(0.0%)
Migraine	0	1(0.0%)
Neuralgia	0	1(0.0%)
Parkinson's disease	0	1(0.0%)
Somnolence	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Vertigo CNS origin	0	1(0.0%)
Injury, Poisoning And Procedural Complications	65(2.6%)	52(2.1%)
Ankle fracture	5(0.2%)	4(0.2%)
Rib fracture	5(0.2%)	2(0.1%)
Femur fracture	4(0.2%)	4(0.2%)
Meniscus injury	4(0.2%)	0
Tendon rupture	3(0.1%)	1(0.0%)
Hip fracture	3(0.1%)	0
Subdural haematoma	2(0.1%)	3(0.1%)
Limb injury	2(0.1%)	2(0.1%)
Lumbar vertebral fracture	2(0.1%)	2(0.1%)
Head injury	2(0.1%)	1(0.0%)
Multiple fractures	2(0.1%)	1(0.0%)
Tibia fracture	2(0.1%)	1(0.0%)
Chest injury	2(0.1%)	0
Injury	2(0.1%)	0
Vascular injury	2(0.1%)	0
Craniocerebral injury	1(0.0%)	3(0.1%)
Radius fracture	1(0.0%)	3(0.1%)
Foot fracture	1(0.0%)	2(0.1%)
Subdural haemorrhage	1(0.0%)	2(0.1%)
Contusion	1(0.0%)	1(0.0%)
Lower limb fracture	1(0.0%)	1(0.0%)
Thermal burn	1(0.0%)	1(0.0%)
Toxicity to various agents	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0
Animal bite	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Cartilage injury	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Facial bones fracture	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Injury corneal	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Joint dislocation	1(0.0%)	0
Joint injury	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Poisoning	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Road traffic accident	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Skin abrasion	1(0.0%)	0
Ulna fracture	1(0.0%)	0
Upper limb fracture	1(0.0%)	0
Wound contamination	1(0.0%)	0
Fall	0	2(0.1%)
Heat illness	0	2(0.1%)
Humerus fracture	0	2(0.1%)
Anaemia postoperative	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Brain contusion	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Eye contusion	0	1(0.0%)
Fibula fracture	0	1(0.0%)
Hand fracture	0	1(0.0%)
Overdose	0	1(0.0%)
Skin laceration	0	1(0.0%)
Skin wound	0	1(0.0%)
Skull fracture	0	1(0.0%)
Spinal compression fracture	0	1(0.0%)
Spinal fracture	0	1(0.0%)
Stomal hernia	0	1(0.0%)
Thoracic vertebral fracture	0	1(0.0%)
Traumatic fracture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Traumatic ulcer	0	1(0.0%)
Gastrointestinal Disorders	64(2.5%)	69(2.7%)
Pancreatitis acute	10(0.4%)	2(0.1%)
Large intestine polyp	7(0.3%)	5(0.2%)
Gastrointestinal haemorrhage	5(0.2%)	4(0.2%)
Abdominal pain	4(0.2%)	3(0.1%)
Vomiting	3(0.1%)	1(0.0%)
Haemorrhoids	3(0.1%)	0
Pancreatitis	3(0.1%)	0
Abdominal pain upper	2(0.1%)	2(0.1%)
Chronic gastritis	2(0.1%)	2(0.1%)
Diarrhoea	2(0.1%)	2(0.1%)
Pancreatitis chronic	2(0.1%)	2(0.1%)
Duodenal ulcer	2(0.1%)	1(0.0%)
Gastritis haemorrhagic	2(0.1%)	1(0.0%)
Inguinal hernia	1(0.0%)	7(0.3%)
Small intestinal obstruction	1(0.0%)	4(0.2%)
Upper gastrointestinal haemorrhage	1(0.0%)	3(0.1%)
Gastric ulcer haemorrhage	1(0.0%)	2(0.1%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Melaena	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Umbilical hernia	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Colitis ischaemic	1(0.0%)	0
Duodenal polyp	1(0.0%)	0
Food poisoning	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric haemorrhage	1(0.0%)	0
Gastric mucosal lesion	1(0.0%)	0
Gastric polyps	1(0.0%)	0
Gastrointestinal oedema	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Mouth haemorrhage	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Subileus	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Varices oesophageal	1(0.0%)	0
Volvulus	1(0.0%)	0
Intestinal obstruction	0	4(0.2%)
Ascites	0	3(0.1%)
Gastritis erosive	0	2(0.1%)
Gastrooesophageal reflux disease	0	2(0.1%)
Abdominal adhesions	0	1(0.0%)
Abdominal hernia	0	1(0.0%)
Abdominal pain lower	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal haemorrhage	0	1(0.0%)
Barrett's oesophagus	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Dyspepsia	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastritis	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Haematochezia	0	1(0.0%)
Ileus	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Impaired gastric emptying	0	1(0.0%)
Internal hernia	0	1(0.0%)
Nausea	0	1(0.0%)
Oesophagitis	0	1(0.0%)
Omental infarction	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Rectal haemorrhage	0	1(0.0%)
Reflux gastritis	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Renal And Urinary Disorders	59(2.3%)	66(2.6%)
Acute kidney injury	17(0.7%)	14(0.6%)
Nephrolithiasis	9(0.4%)	5(0.2%)
Diabetic nephropathy	7(0.3%)	22(0.9%)
Haematuria	3(0.1%)	4(0.2%)
Urinary retention	3(0.1%)	3(0.1%)
Ureterolithiasis	3(0.1%)	2(0.1%)
Nephropathy	2(0.1%)	2(0.1%)
Hydronephrosis	2(0.1%)	1(0.0%)
Renal impairment	2(0.1%)	1(0.0%)
Urethral stenosis	2(0.1%)	0
Urinary incontinence	2(0.1%)	0
Renal failure	1(0.0%)	2(0.1%)
Calculus bladder	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
End stage renal disease	1(0.0%)	1(0.0%)
Renal colic	1(0.0%)	1(0.0%)
Urinary tract obstruction	1(0.0%)	1(0.0%)
Albuminuria	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Subacute kidney injury	1(0.0%)	0
Urinary hesitation	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0
Calculus urinary	0	2(0.1%)
Chronic kidney disease	0	2(0.1%)
Nephrotic syndrome	0	2(0.1%)
Proteinuria	0	2(0.1%)
Azotaemia	0	1(0.0%)
Dysuria	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Glomerulonephritis membranous	0	1(0.0%)
Stress urinary incontinence	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Surgical And Medical Procedures	59(2.3%)	46(1.8%)
Knee arthroplasty	4(0.2%)	4(0.2%)
Cataract operation	4(0.2%)	2(0.1%)
Leg amputation	3(0.1%)	4(0.2%)
Hip arthroplasty	3(0.1%)	2(0.1%)
Toe amputation	3(0.1%)	2(0.1%)
Vitrectomy	3(0.1%)	2(0.1%)
Gastric bypass	3(0.1%)	1(0.0%)
Roux loop conversion	3(0.1%)	0
Cholecystectomy	2(0.1%)	5(0.2%)
Hysterectomy	2(0.1%)	1(0.0%)
Intervertebral disc operation	2(0.1%)	1(0.0%)
Diabetes mellitus management	2(0.1%)	0
Removal of internal fixation	2(0.1%)	0
Spinal decompression	2(0.1%)	0
Polypectomy	1(0.0%)	3(0.1%)
Foot amputation	1(0.0%)	1(0.0%)
Atrial appendage closure	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Cardiac ablation	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Colectomy	1(0.0%)	0
Drug therapy	1(0.0%)	0
Eye operation	1(0.0%)	0
Eyelid operation	1(0.0%)	0
Finger amputation	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Intraocular lens implant	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Metabolic surgery	1(0.0%)	0
Neurolysis	1(0.0%)	0
Ocular stem cell transplant	1(0.0%)	0
Percutaneous coronary intervention	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Peripheral artery bypass	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0
Proctocolectomy	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Scar excision	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Spinal operation	1(0.0%)	0
Transurethral bladder resection	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Abscess drainage	0	3(0.1%)
Aortic surgery	0	1(0.0%)
Aortic valve replacement	0	1(0.0%)
Bone operation	0	1(0.0%)
Cardiac rehabilitation therapy	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Gastrectomy	0	1(0.0%)
Implantable defibrillator insertion	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Intensive care	0	1(0.0%)
Large intestinal polypectomy	0	1(0.0%)
Limb operation	0	1(0.0%)
Lipoma excision	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Parathyroidectomy	0	1(0.0%)
Thyroidectomy	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Umbilical hernia repair	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Uterine polypectomy	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	46(1.8%)	52(2.1%)
Osteoarthritis	13(0.5%)	4(0.2%)
Intervertebral disc protrusion	7(0.3%)	8(0.3%)
Back pain	4(0.2%)	3(0.1%)
Spinal osteoarthritis	4(0.2%)	2(0.1%)
Lumbar spinal stenosis	3(0.1%)	1(0.0%)
Spinal stenosis	2(0.1%)	2(0.1%)
Rotator cuff syndrome	1(0.0%)	4(0.2%)
Periarthritis	1(0.0%)	2(0.1%)
Vertebral foraminal stenosis	1(0.0%)	1(0.0%)
Arthralgia	1(0.0%)	0
Dupuytren's contracture	1(0.0%)	0
Fasciitis	1(0.0%)	0
Groin pain	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Muscle spasms	1(0.0%)	0
Myositis	1(0.0%)	0
Osteitis	1(0.0%)	0
Osteonecrosis	1(0.0%)	0
Osteoporosis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Rhabdomyolysis	1(0.0%)	0
Spondylolisthesis	1(0.0%)	0
Tendon discomfort	1(0.0%)	0
Tenosynovitis stenosans	1(0.0%)	0
Arthritis	0	3(0.1%)
Costochondritis	0	3(0.1%)
Pain in extremity	0	3(0.1%)
Bursitis	0	2(0.1%)
Ankylosing spondylitis	0	1(0.0%)
Arthritis reactive	0	1(0.0%)
Arthropathy	0	1(0.0%)
Cervical spinal stenosis	0	1(0.0%)
Chondromalacia	0	1(0.0%)
Diastasis recti abdominis	0	1(0.0%)
Haemarthrosis	0	1(0.0%)
Intervertebral disc degeneration	0	1(0.0%)
Muscular weakness	0	1(0.0%)
Musculoskeletal discomfort	0	1(0.0%)
Neuropathic arthropathy	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Plantar fascial fibromatosis	0	1(0.0%)
Polymyalgia rheumatica	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Spondyloarthropathy	0	1(0.0%)
Synovial cyst	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	45(1.8%)	58(2.3%)
Chronic obstructive pulmonary disease	13(0.5%)	13(0.5%)
Acute respiratory failure	8(0.3%)	5(0.2%)
Pulmonary embolism	6(0.2%)	6(0.2%)
Asthma	3(0.1%)	2(0.1%)
Respiratory failure	2(0.1%)	7(0.3%)
Epistaxis	2(0.1%)	2(0.1%)
Sleep apnoea syndrome	2(0.1%)	2(0.1%)
Dyspnoea exertional	2(0.1%)	1(0.0%)
Pulmonary mass	2(0.1%)	0
Dyspnoea	1(0.0%)	6(0.2%)
Acute pulmonary oedema	1(0.0%)	3(0.1%)
Pulmonary oedema	1(0.0%)	3(0.1%)
Hypoxia	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Lung disorder	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pneumonia aspiration	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Pleural effusion	0	6(0.2%)
Bronchospasm	0	2(0.1%)
Interstitial lung disease	0	2(0.1%)
Bronchiectasis	0	1(0.0%)
Bronchitis chronic	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Chronic respiratory failure	0	1(0.0%)
Haemoptysis	0	1(0.0%)
Hiccups	0	1(0.0%)
Nasal septum deviation	0	1(0.0%)
Pulmonary congestion	0	1(0.0%)
Respiratory acidosis	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Eye Disorders	45(1.8%)	36(1.4%)
Vitreous haemorrhage	14(0.6%)	7(0.3%)
Cataract	10(0.4%)	9(0.4%)
Diabetic retinopathy	9(0.4%)	10(0.4%)
Retinal detachment	4(0.2%)	1(0.0%)
Glaucoma	3(0.1%)	3(0.1%)
Macular fibrosis	2(0.1%)	2(0.1%)
Macular oedema	1(0.0%)	2(0.1%)
Retinal haemorrhage	1(0.0%)	2(0.1%)
Cataract diabetic	1(0.0%)	1(0.0%)
Eye haemorrhage	1(0.0%)	1(0.0%)
Diabetic eye disease	1(0.0%)	0
Diplopia	1(0.0%)	0
Extraocular muscle paresis	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0
Ulcerative keratitis	1(0.0%)	0
Vision blurred	1(0.0%)	0
Cataract nuclear	0	2(0.1%)
Dermatochalasis	0	1(0.0%)
Eyelid cyst	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Retinal artery occlusion	0	1(0.0%)
Retinopathy proliferative	0	1(0.0%)
Vascular Disorders	40(1.6%)	42(1.7%)
Hypertension	9(0.4%)	11(0.4%)
Deep vein thrombosis	3(0.1%)	2(0.1%)
Hypotension	2(0.1%)	3(0.1%)
Hypertensive emergency	2(0.1%)	2(0.1%)
Peripheral artery occlusion	2(0.1%)	1(0.0%)
Aortic aneurysm	2(0.1%)	0
Peripheral arterial occlusive disease	1(0.0%)	6(0.2%)
Aortic stenosis	1(0.0%)	2(0.1%)
Peripheral vascular disorder	1(0.0%)	2(0.1%)
Dry gangrene	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Peripheral artery thrombosis	1(0.0%)	1(0.0%)
Peripheral ischaemia	1(0.0%)	1(0.0%)
Aortic dissection	1(0.0%)	0
Aortitis	1(0.0%)	0
Circulatory collapse	1(0.0%)	0
Diabetic vascular disorder	1(0.0%)	0
Extremity necrosis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Haematoma	1(0.0%)	0
Intermittent claudication	1(0.0%)	0
Orthostatic hypotension	1(0.0%)	0
Peripheral artery stenosis	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Phlebitis	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Thrombosis	1(0.0%)	0
Hypertensive crisis	0	4(0.2%)
Essential hypertension	0	2(0.1%)
Hypertensive urgency	0	2(0.1%)
Hypovolaemic shock	0	1(0.0%)
Peripheral artery aneurysm	0	1(0.0%)
Shock	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
General Disorders And Administration Site Conditions	34(1.3%)	36(1.4%)
Chest pain	10(0.4%)	8(0.3%)
Death	6(0.2%)	2(0.1%)
Pyrexia	4(0.2%)	5(0.2%)
Oedema peripheral	3(0.1%)	8(0.3%)
Asthenia	2(0.1%)	1(0.0%)
Multiple organ dysfunction syndrome	2(0.1%)	1(0.0%)
Oedema	2(0.1%)	1(0.0%)
Peripheral swelling	2(0.1%)	1(0.0%)
General physical health deterioration	1(0.0%)	3(0.1%)
Fatigue	1(0.0%)	0
Gait disturbance	1(0.0%)	0
Hanging	1(0.0%)	0
Impaired healing	1(0.0%)	0
Polyp	1(0.0%)	0
Generalised oedema	0	2(0.1%)
Haemorrhagic cyst	0	1(0.0%)
Malaise	0	1(0.0%)
Non-cardiac chest pain	0	1(0.0%)
Sudden death	0	1(0.0%)
Cardiac Disorders	34(1.3%)	33(1.3%)
Coronary artery disease	4(0.2%)	6(0.2%)
Cardiac failure	3(0.1%)	4(0.2%)
Arteriosclerosis coronary artery	3(0.1%)	0
Aortic valve stenosis	2(0.1%)	2(0.1%)
Angina unstable	2(0.1%)	1(0.0%)
Myocardial ischaemia	2(0.1%)	1(0.0%)
Aortic valve disease mixed	2(0.1%)	0
Cardiac failure acute	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Bradycardia	1(0.0%)	2(0.1%)
Coronary artery stenosis	1(0.0%)	2(0.1%)
Acute coronary syndrome	1(0.0%)	1(0.0%)
Atrial fibrillation	1(0.0%)	1(0.0%)
Atrial flutter	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cardiac failure chronic	1(0.0%)	1(0.0%)
Palpitations	1(0.0%)	1(0.0%)
Angina pectoris	1(0.0%)	0
Arrhythmia	1(0.0%)	0
Atrioventricular block second degree	1(0.0%)	0
Cardiomyopathy	1(0.0%)	0
Extrasystoles	1(0.0%)	0
Mitral valve disease	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0
Sinus node dysfunction	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Acute myocardial infarction	0	2(0.1%)
Atrioventricular block complete	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac failure congestive	0	1(0.0%)
Cardiac valve disease	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Tachycardia	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	28(1.1%)	34(1.3%)
Diabetic foot	15(0.6%)	18(0.7%)
Skin ulcer	6(0.2%)	11(0.4%)
Angioedema	2(0.1%)	1(0.0%)
Rash	1(0.0%)	1(0.0%)
Angiokeratoma	1(0.0%)	0
Blister	1(0.0%)	0
Dermatitis	1(0.0%)	0
Hidradenitis	1(0.0%)	0
Neuropathic ulcer	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Actinic keratosis	0	1(0.0%)
Decubitus ulcer	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Hepatobiliary Disorders	25(1.0%)	18(0.7%)
Cholelithiasis	5(0.2%)	3(0.1%)
Cholecystitis	5(0.2%)	1(0.0%)
Bile duct stone	3(0.1%)	1(0.0%)
Cholecystitis acute	2(0.1%)	4(0.2%)
Cholangitis	2(0.1%)	2(0.1%)
Biliary dyskinesia	2(0.1%)	0
Jaundice cholestatic	1(0.0%)	2(0.1%)
Hepatic cirrhosis	1(0.0%)	1(0.0%)
Biliary colic	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cholecystitis chronic	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatic lesion	1(0.0%)	0
Hepatitis acute	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Liver disorder	1(0.0%)	0
Biliary fistula	0	1(0.0%)
Cholangitis acute	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Gallbladder polyp	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Jaundice	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Investigations	18(0.7%)	28(1.1%)
Colonoscopy	3(0.1%)	1(0.0%)
Blood potassium increased	2(0.1%)	0
Blood glucose increased	1(0.0%)	4(0.2%)
Blood creatinine increased	1(0.0%)	2(0.1%)
Blood pressure increased	1(0.0%)	2(0.1%)
Glomerular filtration rate decreased	1(0.0%)	1(0.0%)
Glycosylated haemoglobin increased	1(0.0%)	1(0.0%)
Weight decreased	1(0.0%)	1(0.0%)
Angiocardiogram	1(0.0%)	0
Angiogram	1(0.0%)	0
Blood potassium decreased	1(0.0%)	0
Computerised tomogram	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Investigation	1(0.0%)	0
Sleep study	1(0.0%)	0
Influenza A virus test positive	0	2(0.1%)
Angiogram cerebral	0	1(0.0%)
Arthroscopy	0	1(0.0%)
Biopsy kidney	0	1(0.0%)
Biopsy liver	0	1(0.0%)
Biopsy prostate	0	1(0.0%)
Blood creatine phosphokinase MB increased	0	1(0.0%)
Electrocardiogram abnormal	0	1(0.0%)
Endobronchial ultrasound	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Liver function test increased	0	1(0.0%)
Protein urine present	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
SARS-CoV-2 test positive	0	1(0.0%)
Reproductive System And Breast Disorders	14(0.6%)	16(0.6%)
Benign prostatic hyperplasia	8(0.3%)	9(0.4%)
Prostatitis	1(0.0%)	2(0.1%)
Prostatomegaly	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Ovarian cyst	1(0.0%)	1(0.0%)
Breast mass	1(0.0%)	0
Prostatic disorder	1(0.0%)	0
Prostatism	1(0.0%)	0
Erectile dysfunction	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Blood And Lymphatic System Disorders	14(0.6%)	7(0.3%)
Anaemia	9(0.4%)	3(0.1%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Iron deficiency anaemia	1(0.0%)	1(0.0%)
Coagulopathy	1(0.0%)	0
Lymphadenopathy	1(0.0%)	0
Febrile neutropenia	0	1(0.0%)
Neutropenia	0	1(0.0%)
Ear And Labyrinth Disorders	8(0.3%)	5(0.2%)
Vertigo	4(0.2%)	1(0.0%)
Sudden hearing loss	2(0.1%)	2(0.1%)
Tympanic membrane perforation	1(0.0%)	0
Vertigo positional	1(0.0%)	0
Deafness	0	1(0.0%)
Vestibular disorder	0	1(0.0%)
Psychiatric Disorders	5(0.2%)	3(0.1%)
Depression	2(0.1%)	1(0.0%)
Mental status changes	2(0.1%)	0
Confusional state	1(0.0%)	0
Major depression	1(0.0%)	0
Drug abuse	0	1(0.0%)
Suicide threat	0	1(0.0%)
Congenital, Familial And Genetic Disorders	3(0.1%)	1(0.0%)
Adenomatous polyposis coli	1(0.0%)	0
Arnold-Chiari malformation	1(0.0%)	0
Phimosis	1(0.0%)	0
Anomaly of middle ear congenital	0	1(0.0%)
Endocrine Disorders	2(0.1%)	0
Goitre	2(0.1%)	0
Immune System Disorders	1(0.0%)	1(0.0%)
Anaphylactic shock	1(0.0%)	1(0.0%)
Anaphylactic reaction	0	1(0.0%)
Product Issues	0	2(0.1%)
Device loosening	0	1(0.0%)
Device malfunction	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Any TEAE	384(15.1%)	448(17.8%)
Infections And Infestations	104(4.1%)	123(4.9%)
Pneumonia	16(0.6%)	28(1.1%)
Cellulitis	7(0.3%)	9(0.4%)
Localised infection	7(0.3%)	3(0.1%)
Sepsis	6(0.2%)	10(0.4%)
Osteomyelitis	5(0.2%)	7(0.3%)
COVID-19	4(0.2%)	11(0.4%)
Urosepsis	4(0.2%)	7(0.3%)
Urinary tract infection	4(0.2%)	3(0.1%)
Influenza	3(0.1%)	3(0.1%)
Septic shock	3(0.1%)	2(0.1%)
Abscess limb	3(0.1%)	1(0.0%)
Bronchitis	3(0.1%)	1(0.0%)
Infected skin ulcer	3(0.1%)	0
Postoperative wound infection	3(0.1%)	0
COVID-19 pneumonia	2(0.1%)	6(0.2%)
Erysipelas	2(0.1%)	4(0.2%)
Herpes zoster	2(0.1%)	2(0.1%)
Pyelonephritis acute	2(0.1%)	2(0.1%)
Intervertebral discitis	2(0.1%)	1(0.0%)
Gastroenteritis	1(0.0%)	3(0.1%)
Diabetic foot infection	1(0.0%)	2(0.1%)
Lower respiratory tract infection	1(0.0%)	2(0.1%)
Wound infection	1(0.0%)	2(0.1%)
Appendicitis	1(0.0%)	1(0.0%)
Diverticulitis	1(0.0%)	1(0.0%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	1(0.0%)
Meningitis	1(0.0%)	1(0.0%)
Osteomyelitis chronic	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Pneumonia viral	1(0.0%)	1(0.0%)
Pyelonephritis	1(0.0%)	1(0.0%)
Staphylococcal bacteraemia	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Bacterial infection	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Cholecystitis infective	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Cystitis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Encephalitis viral	1(0.0%)	0
Endocarditis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Genital candidiasis	1(0.0%)	0
HIV infection	1(0.0%)	0
Liver abscess	1(0.0%)	0
Necrotising fasciitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Otitis externa bacterial	1(0.0%)	0
Pharyngitis	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia bacterial	1(0.0%)	0
Pneumonia influenzal	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Respiratory tract infection	1(0.0%)	0
Subcutaneous abscess	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Gangrene	0	4(0.2%)
Infection	0	3(0.1%)
Skin infection	0	3(0.1%)
Anal abscess	0	2(0.1%)
Soft tissue infection	0	2(0.1%)
Arthritis bacterial	0	1(0.0%)
Atypical pneumonia	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Conjunctivitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Gastroenteritis norovirus	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Paronychia	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Pulmonary sepsis	0	1(0.0%)
Pulmonary tuberculosis	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Urinary tract infection bacterial	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	55(2.2%)	53(2.1%)
Prostate cancer	5(0.2%)	6(0.2%)
Colon cancer	5(0.2%)	2(0.1%)
Renal neoplasm	5(0.2%)	1(0.0%)
Hepatic cancer	3(0.1%)	2(0.1%)
Transitional cell carcinoma	3(0.1%)	0
Pancreatic carcinoma	2(0.1%)	4(0.2%)
Pancreatic carcinoma metastatic	2(0.1%)	1(0.0%)
Bladder cancer	2(0.1%)	0
Endometrial cancer	2(0.1%)	0
Lung neoplasm malignant	1(0.0%)	3(0.1%)
Adenocarcinoma of colon	1(0.0%)	2(0.1%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.1%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Oesophageal carcinoma	1(0.0%)	1(0.0%)
Plasma cell myeloma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Thyroid cancer	1(0.0%)	1(0.0%)
Adenocarcinoma	1(0.0%)	0
Bladder cancer recurrent	1(0.0%)	0
Chronic lymphocytic leukaemia	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Colon adenoma	1(0.0%)	0
Hepatocellular carcinoma	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastases to liver	1(0.0%)	0
Metastases to lymph nodes	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Neoplasm malignant	1(0.0%)	0
Prostate cancer recurrent	1(0.0%)	0
Rectal adenocarcinoma	1(0.0%)	0
Sarcoma	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Tonsil cancer	1(0.0%)	0
B-cell lymphoma	0	2(0.1%)
Breast cancer	0	2(0.1%)
Lung neoplasm	0	2(0.1%)
Adenocarcinoma pancreas	0	1(0.0%)
Basal cell carcinoma	0	1(0.0%)
Bowen's disease	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Epithelioid mesothelioma	0	1(0.0%)
Gastrointestinal carcinoma	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Malignant melanoma	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastases to bone	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Pancreatic neoplasm	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Papilloma	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Prostate cancer metastatic	0	1(0.0%)
Renal cancer	0	1(0.0%)
Seminoma	0	1(0.0%)
Squamous cell carcinoma of skin	0	1(0.0%)
Metabolism And Nutrition Disorders	50(2.0%)	44(1.7%)
Hypoglycaemia	11(0.4%)	10(0.4%)
Hyperkalaemia	9(0.4%)	3(0.1%)
Diabetes mellitus	5(0.2%)	6(0.2%)
Dehydration	4(0.2%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hyponatraemia	4(0.2%)	1(0.0%)
Hyperglycaemia	3(0.1%)	4(0.2%)
Type 2 diabetes mellitus	3(0.1%)	4(0.2%)
Hypertriglyceridaemia	2(0.1%)	1(0.0%)
Vitamin D deficiency	2(0.1%)	1(0.0%)
Diabetes mellitus inadequate control	1(0.0%)	7(0.3%)
Gout	1(0.0%)	3(0.1%)
Diabetic ketoacidosis	1(0.0%)	1(0.0%)
Hypoproteinaemia	1(0.0%)	1(0.0%)
Metabolic acidosis	1(0.0%)	1(0.0%)
Obesity	1(0.0%)	1(0.0%)
Diabetic metabolic decompensation	1(0.0%)	0
Lactic acidosis	1(0.0%)	0
Cachexia	0	2(0.1%)
Decreased appetite	0	1(0.0%)
Diabetic complication	0	1(0.0%)
Electrolyte imbalance	0	1(0.0%)
Hypokalaemia	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	39(1.5%)	39(1.5%)
Acute respiratory failure	7(0.3%)	7(0.3%)
Chronic obstructive pulmonary disease	7(0.3%)	6(0.2%)
Dyspnoea	5(0.2%)	4(0.2%)
Pulmonary embolism	5(0.2%)	3(0.1%)
Acute pulmonary oedema	3(0.1%)	3(0.1%)
Respiratory failure	2(0.1%)	5(0.2%)
Sleep apnoea syndrome	2(0.1%)	3(0.1%)
Asthma	2(0.1%)	1(0.0%)
Hypoxia	2(0.1%)	1(0.0%)
Pulmonary hypertension	2(0.1%)	0
Pulmonary oedema	1(0.0%)	3(0.1%)
Pneumonia aspiration	1(0.0%)	1(0.0%)
Asphyxia	1(0.0%)	0
Hypercapnia	1(0.0%)	0
Obstructive airways disorder	1(0.0%)	0
Pneumothorax	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Pulmonary mass	1(0.0%)	0
Respiratory acidosis	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Restrictive pulmonary disease	1(0.0%)	0
Pleural effusion	0	3(0.1%)
Apnoea	0	1(0.0%)
Bronchiectasis	0	1(0.0%)
Bronchospasm	0	1(0.0%)
Cough	0	1(0.0%)
Interstitial lung disease	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Vascular Disorders	36(1.4%)	39(1.5%)
Hypertension	8(0.3%)	13(0.5%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hypotension	4(0.2%)	0
Hypertensive emergency	3(0.1%)	2(0.1%)
Peripheral arterial occlusive disease	2(0.1%)	6(0.2%)
Peripheral artery stenosis	2(0.1%)	2(0.1%)
Aortic stenosis	2(0.1%)	1(0.0%)
Peripheral artery occlusion	2(0.1%)	1(0.0%)
Peripheral ischaemia	2(0.1%)	1(0.0%)
Deep vein thrombosis	2(0.1%)	0
Giant cell arteritis	1(0.0%)	1(0.0%)
Hypertensive urgency	1(0.0%)	1(0.0%)
Aortic dissection	1(0.0%)	0
Aortitis	1(0.0%)	0
Diabetic vascular disorder	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Extremity necrosis	1(0.0%)	0
Haematoma	1(0.0%)	0
Intermittent claudication	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Hypertensive crisis	0	3(0.1%)
Hypovolaemic shock	0	2(0.1%)
Aortic aneurysm	0	1(0.0%)
Aortic aneurysm rupture	0	1(0.0%)
Arteriosclerosis	0	1(0.0%)
Peripheral artery aneurysm	0	1(0.0%)
Peripheral vascular disorder	0	1(0.0%)
Peripheral venous disease	0	1(0.0%)
Shock	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
Nervous System Disorders	28(1.1%)	41(1.6%)
Syncope	2(0.1%)	3(0.1%)
Diabetic neuropathy	2(0.1%)	2(0.1%)
Dizziness	2(0.1%)	2(0.1%)
Hemiparesis	2(0.1%)	2(0.1%)
Subarachnoid haemorrhage	2(0.1%)	1(0.0%)
Carotid artery stenosis	1(0.0%)	4(0.2%)
Cerebrovascular accident	1(0.0%)	1(0.0%)
Cerebrovascular disorder	1(0.0%)	1(0.0%)
Epilepsy	1(0.0%)	1(0.0%)
Loss of consciousness	1(0.0%)	1(0.0%)
Paraparesis	1(0.0%)	1(0.0%)
Altered state of consciousness	1(0.0%)	0
Brain injury	1(0.0%)	0
Brain oedema	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral ischaemia	1(0.0%)	0
Dizziness postural	1(0.0%)	0
Facial paralysis	1(0.0%)	0
Headache	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
Hypoglycaemic unconsciousness	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
IVth nerve paralysis	1(0.0%)	0
Myelopathy	1(0.0%)	0
Presyncope	1(0.0%)	0
Sciatica	1(0.0%)	0
Seizure	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Carpal tunnel syndrome	0	2(0.1%)
Cervical radiculopathy	0	2(0.1%)
Encephalopathy	0	2(0.1%)
Brain stem haemorrhage	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cognitive disorder	0	1(0.0%)
Coma	0	1(0.0%)
Dementia	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Facial paresis	0	1(0.0%)
Generalised tonic-clonic seizure	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Parkinson's disease	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Transient ischaemic attack	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Vertebral artery stenosis	0	1(0.0%)
Vertigo CNS origin	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Cardiac Disorders	27(1.1%)	38(1.5%)
Coronary artery disease	5(0.2%)	7(0.3%)
Cardiac failure	3(0.1%)	6(0.2%)
Aortic valve stenosis	2(0.1%)	4(0.2%)
Cardiac failure congestive	2(0.1%)	2(0.1%)
Angina unstable	2(0.1%)	1(0.0%)
Cardiac failure acute	2(0.1%)	1(0.0%)
Acute coronary syndrome	2(0.1%)	0
Angina pectoris	2(0.1%)	0
Ventricular fibrillation	2(0.1%)	0
Ischaemic cardiomyopathy	1(0.0%)	2(0.1%)
Aortic valve disease mixed	1(0.0%)	1(0.0%)
Aortic valve incompetence	1(0.0%)	0
Atrioventricular block	1(0.0%)	0
Cardiac disorder	1(0.0%)	0
Cardiovascular insufficiency	1(0.0%)	0
Mitral valve calcification	1(0.0%)	0
Mitral valve disease	1(0.0%)	0
Mitral valve incompetence	1(0.0%)	0
Myocardial ischaemia	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Pericarditis	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Bradycardia	0	2(0.1%)
Cardiogenic shock	0	2(0.1%)
Atrial fibrillation	0	1(0.0%)
Atrial flutter	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Atrioventricular block second degree	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac arrest	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac failure chronic	0	1(0.0%)
Cardiomegaly	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Conduction disorder	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Mitral valve prolapse	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Renal And Urinary Disorders	27(1.1%)	37(1.5%)
Acute kidney injury	11(0.4%)	11(0.4%)
Nephrolithiasis	4(0.2%)	2(0.1%)
Renal impairment	3(0.1%)	1(0.0%)
Renal failure	2(0.1%)	3(0.1%)
Urinary retention	2(0.1%)	0
Hydronephrosis	1(0.0%)	2(0.1%)
End stage renal disease	1(0.0%)	1(0.0%)
Urinary tract obstruction	1(0.0%)	1(0.0%)
Oliguria	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Urinary incontinence	1(0.0%)	0
Diabetic nephropathy	0	4(0.2%)
Chronic kidney disease	0	3(0.1%)
Haematuria	0	3(0.1%)
Nephropathy	0	2(0.1%)
Calculus urinary	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Hypertonic bladder	0	1(0.0%)
Nephrotic syndrome	0	1(0.0%)
Proteinuria	0	1(0.0%)
Ureterolithiasis	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	26(1.0%)	29(1.1%)
Osteoarthritis	5(0.2%)	5(0.2%)
Back pain	5(0.2%)	2(0.1%)
Arthralgia	2(0.1%)	3(0.1%)
Pain in extremity	2(0.1%)	1(0.0%)
Spinal osteoarthritis	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Intervertebral disc protrusion	1(0.0%)	3(0.1%)
Intervertebral disc degeneration	1(0.0%)	1(0.0%)
Muscle spasms	1(0.0%)	1(0.0%)
Groin pain	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Lumbar spinal stenosis	1(0.0%)	0
Musculoskeletal pain	1(0.0%)	0
Myositis	1(0.0%)	0
Osteitis	1(0.0%)	0
Osteochondrosis	1(0.0%)	0
Osteoporosis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Rotator cuff syndrome	1(0.0%)	0
Spinal synovial cyst	1(0.0%)	0
Neuropathic arthropathy	0	3(0.1%)
Bursitis	0	2(0.1%)
Cervical spinal stenosis	0	2(0.1%)
Myalgia	0	2(0.1%)
Arthritis	0	1(0.0%)
Costochondritis	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Polymyalgia rheumatica	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Gastrointestinal Disorders	23(0.9%)	33(1.3%)
Gastrointestinal haemorrhage	3(0.1%)	2(0.1%)
Pancreatitis acute	3(0.1%)	1(0.0%)
Abdominal pain	1(0.0%)	1(0.0%)
Abdominal pain upper	1(0.0%)	1(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Mechanical ileus	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Chronic gastritis	1(0.0%)	0
Duodenal polyp	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric ulcer haemorrhage	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Pancreatitis	1(0.0%)	0
Pancreatitis chronic	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Toothache	1(0.0%)	0
Volvulus	1(0.0%)	0
Vomiting	1(0.0%)	0
Intestinal obstruction	0	4(0.2%)
Small intestinal obstruction	0	3(0.1%)
Upper gastrointestinal haemorrhage	0	3(0.1%)
Ascites	0	2(0.1%)
Inguinal hernia	0	2(0.1%)
Large intestine polyp	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Nausea	0	2(0.1%)
Abdominal adhesions	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Constipation	0	1(0.0%)
Diarrhoea	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Dyspepsia	0	1(0.0%)
Enteritis	0	1(0.0%)
Gastritis	0	1(0.0%)
Haematochezia	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Omental infarction	0	1(0.0%)
Rectal haemorrhage	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
General Disorders And Administration Site Conditions	22(0.9%)	19(0.8%)
Death	6(0.2%)	2(0.1%)
Chest pain	4(0.2%)	5(0.2%)
Oedema peripheral	3(0.1%)	0
Multiple organ dysfunction syndrome	2(0.1%)	2(0.1%)
General physical health deterioration	2(0.1%)	1(0.0%)
Peripheral swelling	2(0.1%)	1(0.0%)
Oedema	1(0.0%)	1(0.0%)
Hanging	1(0.0%)	0
Malaise	1(0.0%)	0
Pyrexia	0	2(0.1%)
Asthenia	0	1(0.0%)
Fatigue	0	1(0.0%)
Generalised oedema	0	1(0.0%)
Non-cardiac chest pain	0	1(0.0%)
Sudden death	0	1(0.0%)
Injury, Poisoning And Procedural Complications	21(0.8%)	18(0.7%)
Rib fracture	3(0.1%)	1(0.0%)
Hip fracture	2(0.1%)	0
Procedural pain	2(0.1%)	0
Foot fracture	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0
Ankle fracture	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Chest injury	1(0.0%)	0
Contusion	1(0.0%)	0
Fall	1(0.0%)	0
Femoral neck fracture	1(0.0%)	0
Femur fracture	1(0.0%)	0
Lower limb fracture	1(0.0%)	0
Poisoning	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Road traffic accident	1(0.0%)	0
Thermal burn	1(0.0%)	0
Toxicity to various agents	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Traumatic haematoma	1(0.0%)	0
Upper limb fracture	1(0.0%)	0
Craniocerebral injury	0	2(0.1%)
Lumbar vertebral fracture	0	2(0.1%)
Subdural haematoma	0	2(0.1%)
Brain contusion	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Eye contusion	0	1(0.0%)
Heat illness	0	1(0.0%)
Hyphaema	0	1(0.0%)
Limb injury	0	1(0.0%)
Multiple fractures	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Radius fracture	0	1(0.0%)
Skull fracture	0	1(0.0%)
Spinal fracture	0	1(0.0%)
Subdural haemorrhage	0	1(0.0%)
Thoracic vertebral fracture	0	1(0.0%)
Traumatic fracture	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Investigations	19(0.7%)	21(0.8%)
Glomerular filtration rate decreased	5(0.2%)	7(0.3%)
Blood creatinine increased	2(0.1%)	2(0.1%)
Weight decreased	2(0.1%)	2(0.1%)
Blood creatine phosphokinase increased	1(0.0%)	3(0.1%)
Blood pressure increased	1(0.0%)	2(0.1%)
Blood potassium increased	1(0.0%)	0
Blood sodium decreased	1(0.0%)	0
C-reactive protein increased	1(0.0%)	0
Glycosylated haemoglobin increased	1(0.0%)	0
Haemoglobin decreased	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Sleep study	1(0.0%)	0
Biopsy prostate	0	1(0.0%)
Blood triglycerides increased	0	1(0.0%)
Influenza A virus test positive	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
White blood cell count increased	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	18(0.7%)	23(0.9%)
Diabetic foot	9(0.4%)	8(0.3%)
Skin ulcer	2(0.1%)	7(0.3%)
Angioedema	2(0.1%)	0
Hidradenitis	1(0.0%)	1(0.0%)
Blister	1(0.0%)	0
Dermatitis allergic	1(0.0%)	0
Diabetic bullosis	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Actinic keratosis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Ingrowing nail	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Pruritus	0	1(0.0%)
Psoriasis	0	1(0.0%)
Rash	0	1(0.0%)
Rash pruritic	0	1(0.0%)
Eye Disorders	17(0.7%)	19(0.8%)
Diabetic retinopathy	7(0.3%)	6(0.2%)
Cataract	4(0.2%)	1(0.0%)
Vitreous haemorrhage	2(0.1%)	5(0.2%)
Retinal detachment	2(0.1%)	1(0.0%)
Sudden visual loss	2(0.1%)	0
Visual impairment	1(0.0%)	2(0.1%)
Glaucoma	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Blindness	1(0.0%)	0
Diabetic eye disease	1(0.0%)	0
Eye haemorrhage	1(0.0%)	0
Blindness unilateral	0	1(0.0%)
Dermatochalasis	0	1(0.0%)
Diabetic retinal oedema	0	1(0.0%)
Diplopia	0	1(0.0%)
Retinal vein occlusion	0	1(0.0%)
Retinopathy proliferative	0	1(0.0%)
Surgical And Medical Procedures	16(0.6%)	22(0.9%)
Leg amputation	2(0.1%)	3(0.1%)
Gastric bypass	2(0.1%)	1(0.0%)
Toe amputation	1(0.0%)	5(0.2%)
Cataract operation	1(0.0%)	2(0.1%)
Foot amputation	1(0.0%)	1(0.0%)
Intervertebral disc operation	1(0.0%)	1(0.0%)
Finger amputation	1(0.0%)	0
Hip arthroplasty	1(0.0%)	0
Hysterectomy	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Neurolysis	1(0.0%)	0
Roux loop conversion	1(0.0%)	0
Vitrectomy	1(0.0%)	0
Knee arthroplasty	0	2(0.1%)
Abscess drainage	0	1(0.0%)
Cardiac pacemaker insertion	0	1(0.0%)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cholecystectomy	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Intensive care	0	1(0.0%)
Lens extraction	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Transurethral prostatectomy	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Hepatobiliary Disorders	8(0.3%)	12(0.5%)
Cholelithiasis	2(0.1%)	1(0.0%)
Cholecystitis acute	1(0.0%)	3(0.1%)
Cholangitis	1(0.0%)	1(0.0%)
Cholecystitis	1(0.0%)	1(0.0%)
Biliary colic	1(0.0%)	0
Biliary dyskinesia	1(0.0%)	0
Cholecystitis chronic	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Liver disorder	1(0.0%)	0
Jaundice cholestatic	0	2(0.1%)
Cirrhosis alcoholic	0	1(0.0%)
Hepatic cirrhosis	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Hepatic lesion	0	1(0.0%)
Hepatic mass	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Blood And Lymphatic System Disorders	8(0.3%)	9(0.4%)
Anaemia	5(0.2%)	6(0.2%)
Blood loss anaemia	2(0.1%)	0
Coagulopathy	1(0.0%)	0
Iron deficiency anaemia	0	2(0.1%)
Febrile neutropenia	0	1(0.0%)
Psychiatric Disorders	4(0.2%)	7(0.3%)
Depression	1(0.0%)	3(0.1%)
Anxiety	1(0.0%)	0
Major depression	1(0.0%)	0
Mental status changes	1(0.0%)	0
Depressed mood	0	1(0.0%)
Drug abuse	0	1(0.0%)
Hallucination	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Reproductive System And Breast Disorders	2(0.1%)	6(0.2%)
Benign prostatic hyperplasia	1(0.0%)	3(0.1%)
Uterine haemorrhage	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Female genital tract fistula	0	1(0.0%)
Ovarian cyst	0	1(0.0%)
Prostatitis	0	1(0.0%)
Ear And Labyrinth Disorders	2(0.1%)	1(0.0%)
Tympanic membrane perforation	1(0.0%)	0
Vertigo	1(0.0%)	0
Vestibular disorder	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Immune System Disorders	1(0.0%)	2(0.1%)
Anaphylactic shock	1(0.0%)	2(0.1%)
Product Issues	0	2(0.1%)
Device loosening	0	1(0.0%)
Device malfunction	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Any TEAE	95(3.7%)	105(4.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	14(0.6%)	23(0.9%)
Colon cancer	2(0.1%)	2(0.1%)
Transitional cell carcinoma	2(0.1%)	0
Plasma cell myeloma	1(0.0%)	1(0.0%)
Clear cell renal cell carcinoma	1(0.0%)	0
Diffuse large B-cell lymphoma	1(0.0%)	0
Gastric cancer	1(0.0%)	0
Lymphoma	1(0.0%)	0
Meningioma	1(0.0%)	0
Pancreatic carcinoma metastatic	1(0.0%)	0
Prostate cancer	1(0.0%)	0
Renal neoplasm	1(0.0%)	0
Small cell lung cancer	1(0.0%)	0
Breast cancer	0	2(0.1%)
Pancreatic carcinoma	0	2(0.1%)
Pancreatic neoplasm	0	2(0.1%)
Adenocarcinoma of colon	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Cholangiocarcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Endometrial adenocarcinoma	0	1(0.0%)
Hepatic cancer	0	1(0.0%)
Hepatocellular carcinoma	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Lung neoplasm	0	1(0.0%)
Lung neoplasm malignant	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Tonsil cancer	0	1(0.0%)
Metabolism And Nutrition Disorders	14(0.6%)	8(0.3%)
Hyperkalaemia	11(0.4%)	6(0.2%)
Hyponatraemia	3(0.1%)	0
Cachexia	0	1(0.0%)
Hypokalaemia	0	1(0.0%)
Investigations	14(0.6%)	7(0.3%)
Glomerular filtration rate decreased	7(0.3%)	3(0.1%)
Blood potassium increased	5(0.2%)	1(0.0%)
Blood creatinine increased	1(0.0%)	1(0.0%)
Liver function test increased	1(0.0%)	0
Blood pressure increased	0	1(0.0%)
Hepatic enzyme increased	0	1(0.0%)
Nervous System Disorders	9(0.4%)	16(0.6%)
Dementia	2(0.1%)	3(0.1%)
Dizziness	1(0.0%)	2(0.1%)
Subarachnoid haemorrhage	1(0.0%)	2(0.1%)
Syncope	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cognitive disorder	1(0.0%)	1(0.0%)
Somnolence	1(0.0%)	1(0.0%)
Hemiparesis	1(0.0%)	0
Presyncope	1(0.0%)	0
Cerebral atrophy	0	1(0.0%)
Dementia Alzheimer's type	0	1(0.0%)
Dizziness postural	0	1(0.0%)
Loss of consciousness	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Paraesthesia	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Gastrointestinal Disorders	9(0.4%)	14(0.6%)
Diarrhoea	4(0.2%)	4(0.2%)
Constipation	1(0.0%)	3(0.1%)
Vomiting	1(0.0%)	1(0.0%)
Abdominal pain	1(0.0%)	0
Chronic gastritis	1(0.0%)	0
Dyspepsia	1(0.0%)	0
Gastrointestinal motility disorder	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Ascites	0	2(0.1%)
Nausea	0	2(0.1%)
Gastrooesophageal reflux disease	0	1(0.0%)
Oesophageal varices haemorrhage	0	1(0.0%)
Oesophagitis	0	1(0.0%)
General Disorders And Administration Site Conditions	5(0.2%)	7(0.3%)
Asthenia	1(0.0%)	1(0.0%)
Malaise	1(0.0%)	1(0.0%)
Chest pain	1(0.0%)	0
General physical health deterioration	1(0.0%)	0
Peripheral swelling	1(0.0%)	0
Fatigue	0	1(0.0%)
Multiple organ dysfunction syndrome	0	1(0.0%)
Oedema peripheral	0	1(0.0%)
Pain	0	1(0.0%)
Pyrexia	0	1(0.0%)
Renal And Urinary Disorders	5(0.2%)	6(0.2%)
Acute kidney injury	3(0.1%)	2(0.1%)
Subacute kidney injury	1(0.0%)	0
Urinary retention	1(0.0%)	0
Tubulointerstitial nephritis	0	2(0.1%)
Glomerulonephritis membranous	0	1(0.0%)
Proteinuria	0	1(0.0%)
Renal failure	0	1(0.0%)
Renal pain	0	1(0.0%)
Cardiac Disorders	4(0.2%)	7(0.3%)
Palpitations	1(0.0%)	1(0.0%)
Atrioventricular block	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Cardiac failure acute	1(0.0%)	0
Cardiac failure congestive	1(0.0%)	0
Cardiac failure	0	2(0.1%)
Aortic valve stenosis	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Myocardial ischaemia	0	1(0.0%)
Tachycardia	0	1(0.0%)
Infections And Infestations	4(0.2%)	4(0.2%)
Dengue fever	1(0.0%)	0
HIV infection	1(0.0%)	0
Helicobacter infection	1(0.0%)	0
Necrotising fasciitis	1(0.0%)	0
COVID-19	0	1(0.0%)
Diabetic foot infection	0	1(0.0%)
Pneumonia	0	1(0.0%)
Upper respiratory tract infection	0	1(0.0%)
Psychiatric Disorders	4(0.2%)	3(0.1%)
Anxiety	1(0.0%)	0
Bipolar disorder	1(0.0%)	0
Depression	1(0.0%)	0
Mental status changes	1(0.0%)	0
Behaviour disorder	0	1(0.0%)
Depressed mood	0	1(0.0%)
Nervousness	0	1(0.0%)
Vascular Disorders	4(0.2%)	2(0.1%)
Hypertension	2(0.1%)	0
Deep vein thrombosis	1(0.0%)	0
Hypotension	1(0.0%)	0
Flushing	0	1(0.0%)
Peripheral arterial occlusive disease	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	4(0.2%)	0
Dyspnoea	1(0.0%)	0
Dyspnoea exertional	1(0.0%)	0
Lung disorder	1(0.0%)	0
Productive cough	1(0.0%)	0
Skin And Subcutaneous Tissue Disorders	2(0.1%)	8(0.3%)
Rash	1(0.0%)	3(0.1%)
Dermatitis allergic	1(0.0%)	1(0.0%)
Dermatitis psoriasiform	0	1(0.0%)
Hyperhidrosis	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Pruritus	0	1(0.0%)
Hepatobiliary Disorders	2(0.1%)	5(0.2%)
Hepatic cirrhosis	2(0.1%)	1(0.0%)
Chronic hepatitis	1(0.0%)	0
Hepatic function abnormal	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table B2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2536)	Placebo (N=2523)
Hepatic mass	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver injury	0	1(0.0%)
Injury, Poisoning And Procedural Complications	2(0.1%)	3(0.1%)
Craniocerebral injury	1(0.0%)	1(0.0%)
Subdural haemorrhage	1(0.0%)	0
Brain contusion	0	1(0.0%)
Lumbar vertebral fracture	0	1(0.0%)
Skull fracture	0	1(0.0%)
Subdural haematoma	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	2(0.1%)	3(0.1%)
Muscle spasms	1(0.0%)	0
Myalgia	1(0.0%)	0
Fibromyalgia	0	1(0.0%)
Intervertebral disc protrusion	0	1(0.0%)
Joint swelling	0	1(0.0%)
Reproductive System And Breast Disorders	1(0.0%)	1(0.0%)
Erectile dysfunction	1(0.0%)	1(0.0%)
Immune System Disorders	1(0.0%)	0
Hypersensitivity	1(0.0%)	0
Eye Disorders	0	2(0.1%)
Optic ischaemic neuropathy	0	1(0.0%)
Periorbital swelling	0	1(0.0%)
Blood And Lymphatic System Disorders	0	1(0.0%)
Blood loss anaemia	0	1(0.0%)
Ear And Labyrinth Disorders	0	1(0.0%)
Vertigo	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

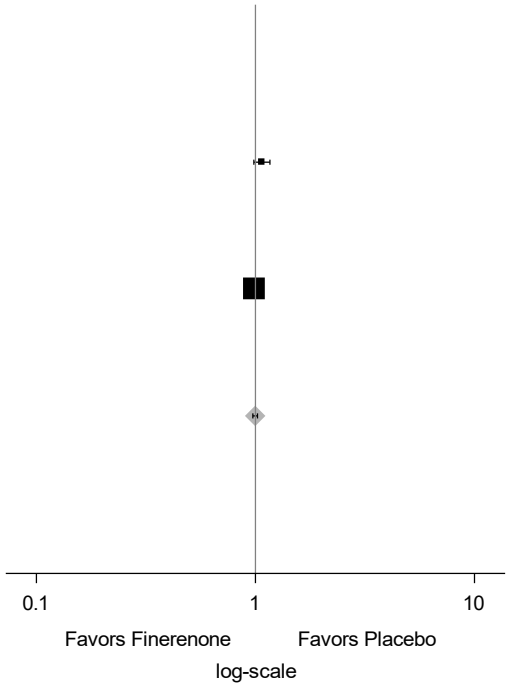
Table B2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

	Finerenone (N=2536)	Placebo (N=2523)	Total (N= 5059
Treatment duration (months)			
n	2536	2523	5059
Mean	35.4	35.1	35.2
SD	14.27	14.31	14.29
Median	35.7	35.3	35.4
Q1-Q3	27.5 - 46.2	26.8 - 46.1	27.1 - 46.2
Range	0.03 - 61.01	0.20 - 61.37	0.03 - 61.37

Abbreviations: eGFR=estimated glomerular filtration rate, N=number of subjects, n=number of subjects with non-missing values in category, Q1=first quartile, Q3=third quartile, SD=standard deviation.
Note: Treatment duration is defined as the time from start of study drug to permanent stop of study drug (in months).

Figure B2.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

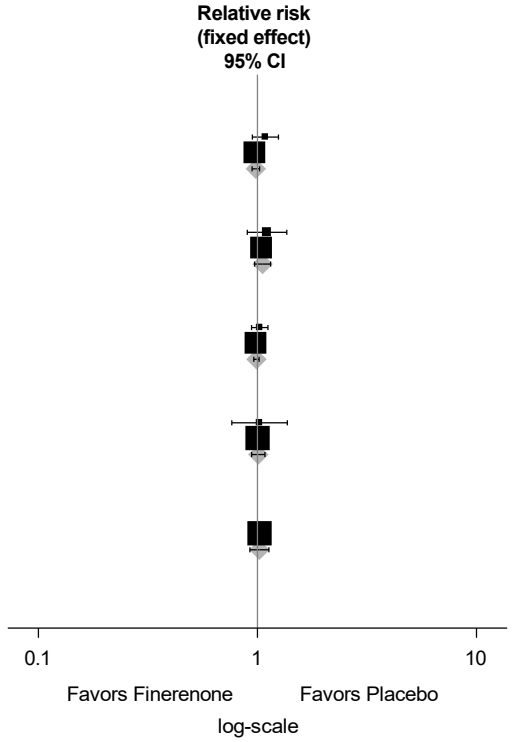
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 210	178 / 221	8.3	1.07 [0.98,1.16]	
FIGARO-DKD	1939 / 2326	1937 / 2302	91.7	0.99 [0.97,1.02]	
Total	2120 / 2536	2115 / 2523		1.00 [0.97,1.02]	Z=-0.24, p=0.8105
Heterogeneity:	Q=2.94 (df=1)	p=0.0865	I^2=66.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

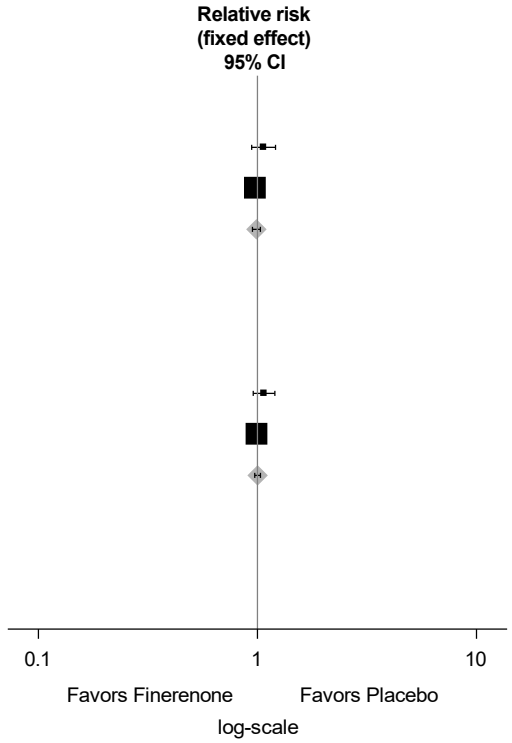
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	85 / 103	85 / 112	8.2	1.09 [0.95,1.25]	
FIGARO-DKD	885 / 1114	905 / 1110	91.8	0.97 [0.94,1.02]	
Total	970 / 1217	990 / 1222		0.98 [0.95,1.02]	Z=-0.85, p=0.3940
Heterogeneity:	Q=2.26 (df=1)	p=0.1328	I^2=55.7%		
North America					
FIDELIO-DKD	36 / 42	31 / 40	16.5	1.11 [0.90,1.36]	
FIGARO-DKD	227 / 292	206 / 277	83.5	1.05 [0.95,1.15]	
Total	263 / 334	237 / 317		1.06 [0.97,1.15]	Z=1.25, p=0.2106
Heterogeneity:	Q=0.24 (df=1)	p=0.6267	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 39	39 / 41	10.3	1.02 [0.94,1.12]	
FIGARO-DKD	490 / 522	498 / 523	89.7	0.99 [0.96,1.01]	
Total	528 / 561	537 / 564		0.99 [0.96,1.02]	Z=-0.74, p=0.4573
Heterogeneity:	Q=0.68 (df=1)	p=0.4081	I^2=0.0%		
Latin America					
FIDELIO-DKD	17 / 21	19 / 24	5.7	1.02 [0.76,1.37]	
FIGARO-DKD	266 / 322	259 / 316	94.3	1.01 [0.94,1.08]	
Total	283 / 343	278 / 340		1.01 [0.94,1.08]	Z=0.24, p=0.8077
Heterogeneity:	Q=0.01 (df=1)	p=0.9249	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 5	4 / 4	0.0	-	
FIGARO-DKD	71 / 76	69 / 76	100.0	1.03 [0.94,1.13]	
Total	76 / 81	73 / 80		1.02 [0.92,1.13]	Z=0.40, p=0.6889
Heterogeneity:	Q=0.03 (df=1)	p=0.8632	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.78 (df=4)	p=0.5949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

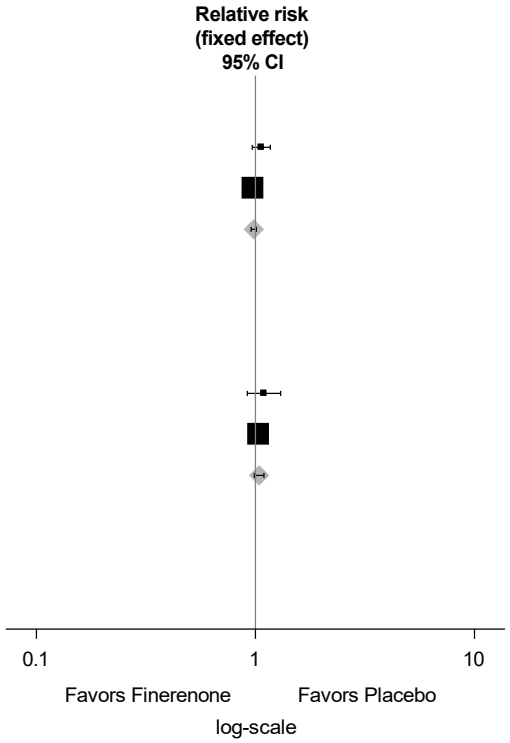
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	77 / 88	73 / 89	11.0	1.07 [0.94,1.21]	
FIGARO-DKD	667 / 811	674 / 803	89.0	0.98 [0.94,1.02]	
Total	744 / 899	747 / 892		0.99 [0.95,1.03]	Z=-0.52, p=0.6034
Heterogeneity:	Q=1.57 (df=1)	p=0.2097	I^2=36.5%		
Absent					
FIDELIO-DKD	104 / 122	105 / 132	6.9	1.07 [0.96,1.20]	
FIGARO-DKD	1272 / 1515	1263 / 1499	93.1	1.00 [0.97,1.03]	
Total	1376 / 1637	1368 / 1631		1.00 [0.97,1.03]	Z=0.10, p=0.9223
Heterogeneity:	Q=1.46 (df=1)	p=0.2266	I^2=31.6%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6322	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.1.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

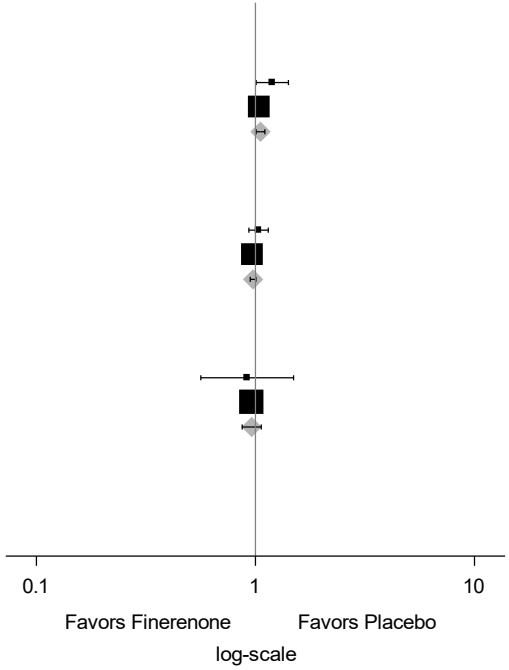
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	126 / 144	130 / 158	8.4	1.06 [0.97,1.17]	
FIGARO-DKD	1433 / 1719	1435 / 1679	91.6	0.98 [0.95,1.00]	
Total	1559 / 1863	1565 / 1837		0.98 [0.96,1.01]	Z=-1.26, p=0.2083
Heterogeneity:	Q=2.91 (df=1)	p=0.0882	I^2=65.6%		
> 4.5					
FIDELIO-DKD	55 / 66	48 / 63	8.2	1.09 [0.92,1.30]	
FIGARO-DKD	506 / 607	501 / 622	91.8	1.03 [0.98,1.09]	
Total	561 / 673	549 / 685		1.04 [0.99,1.09]	Z=1.52, p=0.1286
Heterogeneity:	Q=0.35 (df=1)	p=0.5536	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.76 (df=1)	p=0.0525	I^2=73.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.1.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

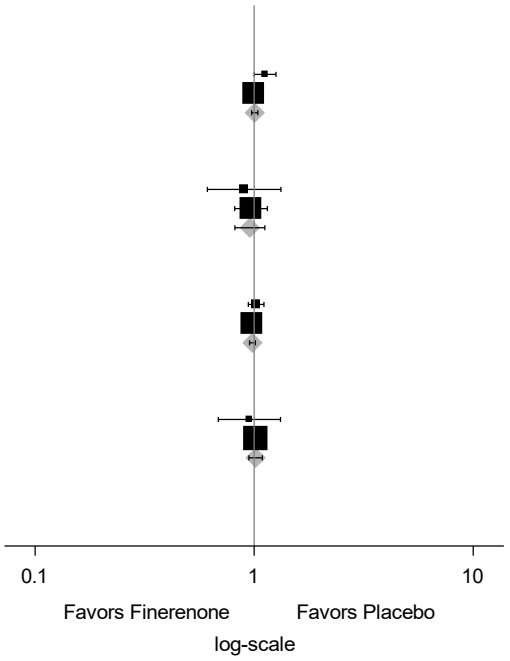
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	58 / 64	41 / 54	7.4	1.19 [1.01,1.41]	
FIGARO-DKD	586 / 693	567 / 699	92.6	1.04 [0.99,1.09]	
Total	644 / 757	608 / 753		1.05 [1.01,1.10]	Z=2.26, p=0.0240
Heterogeneity:	Q=2.27 (df=1)	p=0.1318	I^2=56.0%		
130 - < 160					
FIDELIO-DKD	117 / 138	128 / 156	8.5	1.03 [0.93,1.14]	
FIGARO-DKD	1288 / 1560	1297 / 1524	91.5	0.97 [0.94,1.00]	
Total	1405 / 1698	1425 / 1680		0.98 [0.95,1.00]	Z=-1.65, p=0.0980
Heterogeneity:	Q=1.35 (df=1)	p=0.2459	I^2=25.7%		
>= 160					
FIDELIO-DKD	6 / 8	9 / 11	4.2	0.92 [0.56,1.49]	
FIGARO-DKD	65 / 73	73 / 79	95.8	0.96 [0.87,1.07]	
Total	71 / 81	82 / 90		0.96 [0.87,1.06]	Z=-0.77, p=0.4427
Heterogeneity:	Q=0.04 (df=1)	p=0.8443	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.30 (df=2)	p=0.0157	I^2=75.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.1.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

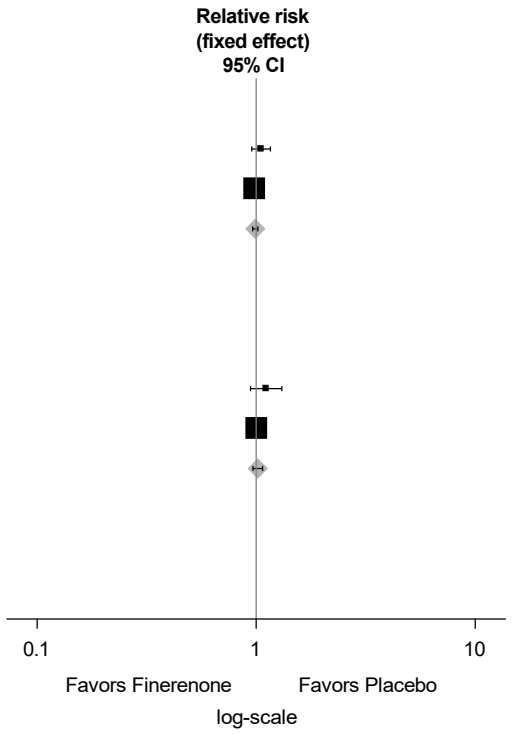
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	118 / 139	115 / 152	8.1	1.12 [1.00,1.26]	
FIGARO-DKD	1330 / 1658	1298 / 1612	91.9	1.00 [0.96,1.03]	
Total	1448 / 1797	1413 / 1764		1.01 [0.97,1.04]	Z=0.35, p=0.7271
Heterogeneity:	Q=3.83 (df=1)	p=0.0504	I^2=73.9%		
Black					
FIDELIO-DKD	8 / 10	8 / 9	16.5	0.90 [0.61,1.32]	
FIGARO-DKD	54 / 70	59 / 74	83.5	0.97 [0.81,1.15]	
Total	62 / 80	67 / 83		0.96 [0.82,1.12]	Z=-0.56, p=0.5746
Heterogeneity:	Q=0.11 (df=1)	p=0.7373	I^2=0.0%		
Asian					
FIDELIO-DKD	38 / 39	42 / 44	13.4	1.02 [0.94,1.11]	
FIGARO-DKD	431 / 464	461 / 485	86.6	0.98 [0.95,1.01]	
Total	469 / 503	503 / 529		0.98 [0.95,1.01]	Z=-1.14, p=0.2523
Heterogeneity:	Q=0.94 (df=1)	p=0.3327	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 22	13 / 16	4.7	0.95 [0.69,1.32]	
FIGARO-DKD	124 / 134	119 / 131	95.3	1.02 [0.95,1.10]	
Total	141 / 156	132 / 147		1.02 [0.95,1.09]	Z=0.43, p=0.6698
Heterogeneity:	Q=0.16 (df=1)	p=0.6874	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.67 (df=3)	p=0.6434	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.1.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

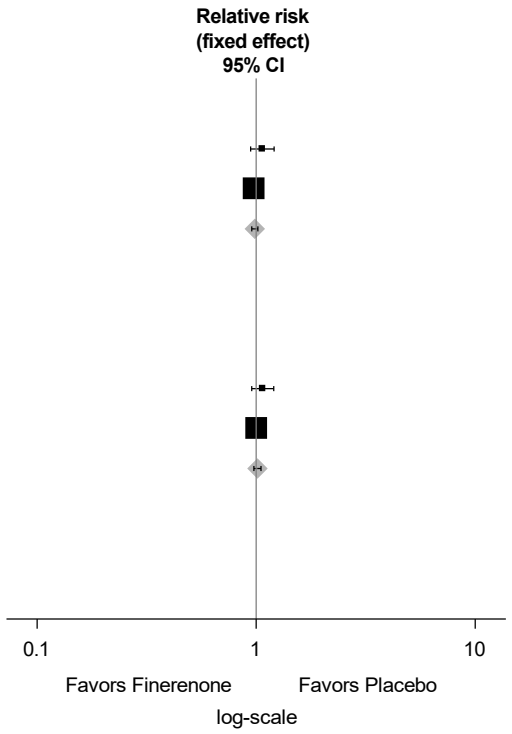
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	131 / 152	126 / 154	7.9	1.05 [0.96,1.16]	
FIGARO-DKD	1363 / 1610	1407 / 1638	92.1	0.99 [0.96,1.01]	
Total	1494 / 1762	1533 / 1792		0.99 [0.96,1.02]	Z=-0.67, p=0.5058
Heterogeneity:	Q=1.63 (df=1)	p=0.2014	I^2=38.7%		
Female					
FIDELIO-DKD	50 / 58	52 / 67	9.3	1.11 [0.94,1.31]	
FIGARO-DKD	576 / 716	530 / 664	90.7	1.01 [0.96,1.06]	
Total	626 / 774	582 / 731		1.02 [0.97,1.07]	Z=0.65, p=0.5145
Heterogeneity:	Q=1.21 (df=1)	p=0.2706	I^2=17.6%		
Subgroup Heterogeneity:	Q=0.79 (df=1)	p=0.3731	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

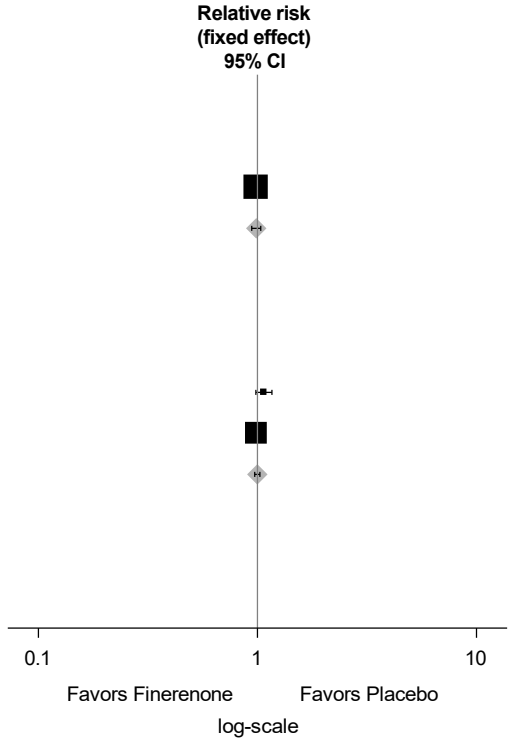
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	85 / 98	78 / 96	6.7	1.07 [0.94,1.21]	
FIGARO-DKD	1165 / 1416	1192 / 1420	93.3	0.98 [0.95,1.01]	
Total	1250 / 1514	1270 / 1516		0.99 [0.95,1.02]	Z=-0.87, p=0.3818
Heterogeneity:	Q=1.72 (df=1)	p=0.1902	I^2=41.7%		
>= 65					
FIDELIO-DKD	96 / 112	100 / 125	10.3	1.07 [0.95,1.20]	
FIGARO-DKD	774 / 910	745 / 882	89.7	1.01 [0.97,1.05]	
Total	870 / 1022	845 / 1007		1.01 [0.98,1.05]	Z=0.70, p=0.4842
Heterogeneity:	Q=0.99 (df=1)	p=0.3197	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.21 (df=1)	p=0.2711	I^2=17.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.1.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

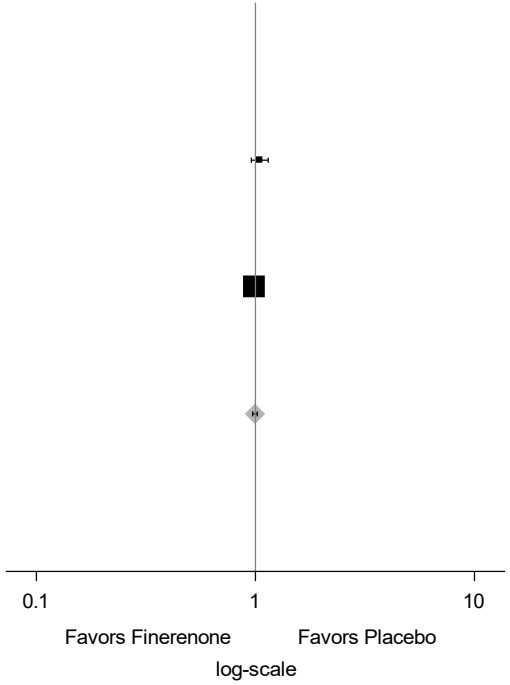
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	327 / 363	312 / 342	100.0	0.99 [0.94,1.04]	
Total	327 / 363	312 / 342		0.99 [0.94,1.04]	Z=-0.52, p=0.6012
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	181 / 210	178 / 221	10.4	1.07 [0.98,1.16]	
FIGARO-DKD	1612 / 1963	1625 / 1960	89.6	0.99 [0.96,1.02]	
Total	1793 / 2173	1803 / 2181		1.00 [0.97,1.03]	Z=-0.11, p=0.9129
Heterogeneity:	Q=2.89 (df=1)	p=0.0894	I^2=65.3%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

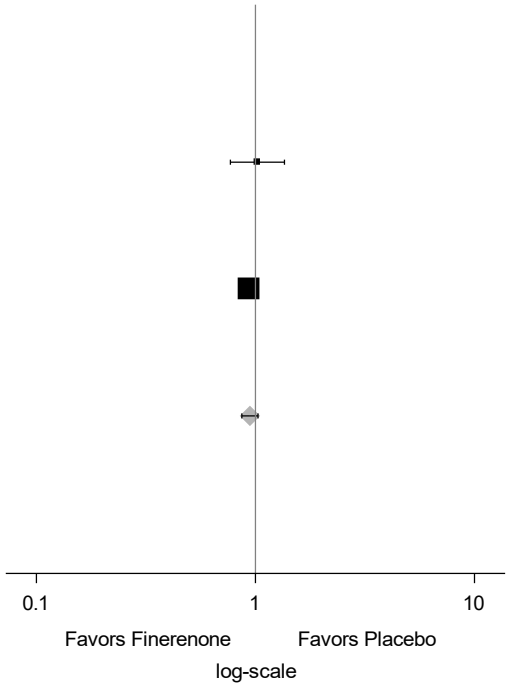
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	176 / 210	177 / 221	7.9	1.05 [0.96,1.14]	
FIGARO-DKD	1926 / 2326	1924 / 2302	92.1	0.99 [0.97,1.02]	
Total	2102 / 2536	2101 / 2523		0.99 [0.97,1.02]	Z=-0.40, p=0.6910
Heterogeneity:	Q=1.35 (df=1)	p=0.2454	I^2=25.9%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

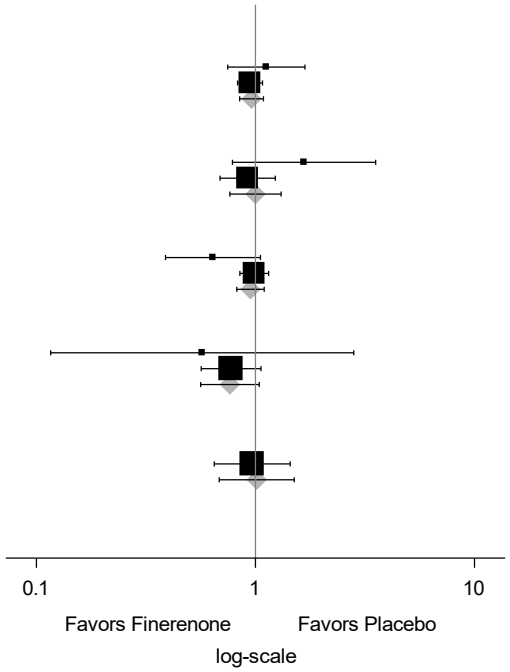
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 210	67 / 221	8.9	1.02 [0.77,1.36]	
FIGARO-DKD	666 / 2326	704 / 2302	91.1	0.94 [0.86,1.02]	
Total	731 / 2536	771 / 2523		0.94 [0.87,1.03]	Z=-1.34, p=0.1792
Heterogeneity:	Q=0.33 (df=1)	p=0.5686	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.3.1: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

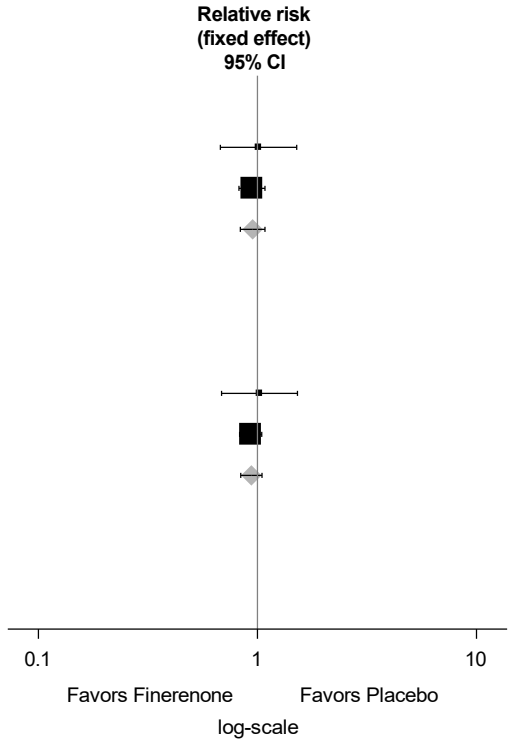
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	33 / 103	32 / 112	9.5	1.12 [0.75,1.68]	
FIGARO-DKD	310 / 1114	327 / 1110	90.5	0.94 [0.83,1.08]	
Total	343 / 1217	359 / 1222		0.96 [0.85,1.09]	Z=-0.64, p=0.5221
Heterogeneity:	Q=0.62 (df=1)	p=0.4308	I^2=0.0%		
North America					
FIDELIO-DKD	14 / 42	8 / 40	12.9	1.67 [0.78,3.54]	
FIGARO-DKD	68 / 292	70 / 277	87.1	0.92 [0.69,1.23]	
Total	82 / 334	78 / 317		1.00 [0.76,1.31]	Z=0.00, p=0.9987
Heterogeneity:	Q=2.07 (df=1)	p=0.1500	I^2=51.7%		
Asia					
FIDELIO-DKD	14 / 39	23 / 41	8.4	0.64 [0.39,1.05]	
FIGARO-DKD	203 / 522	206 / 523	91.6	0.99 [0.85,1.15]	
Total	217 / 561	229 / 564		0.95 [0.82,1.10]	Z=-0.71, p=0.4777
Heterogeneity:	Q=2.66 (df=1)	p=0.1031	I^2=62.4%		
Latin America					
FIDELIO-DKD	2 / 21	4 / 24	3.7	0.57 [0.12,2.81]	
FIGARO-DKD	56 / 322	71 / 316	96.3	0.77 [0.57,1.06]	
Total	58 / 343	75 / 340		0.76 [0.56,1.04]	Z=-1.71, p=0.0878
Heterogeneity:	Q=0.13 (df=1)	p=0.7141	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 5	0 / 4	0.0	282E9 [282E9,282E9]	
FIGARO-DKD	29 / 76	30 / 76	100.0	0.97 [0.65,1.44]	
Total	31 / 81	30 / 80		1.01 [0.68,1.50]	Z=0.07, p=0.9478
Heterogeneity:	Q=0.05 (df=1)	p=0.8173	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.17 (df=4)	p=0.7049	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.3.2: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

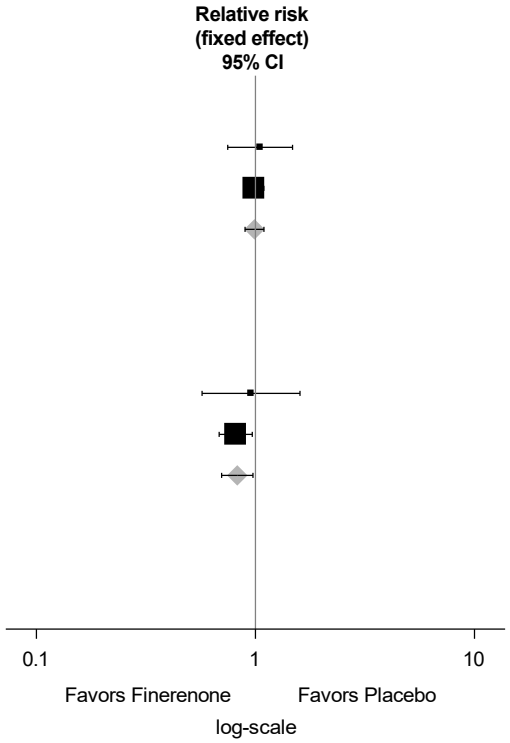
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	31 / 88	31 / 89	10.4	1.01 [0.68,1.51]	
FIGARO-DKD	266 / 811	279 / 803	89.6	0.94 [0.82,1.08]	
Total	297 / 899	310 / 892		0.95 [0.84,1.08]	Z=-0.76, p=0.4446
Heterogeneity:	Q=0.10 (df=1)	p=0.7500	I^2=0.0%		
Absent					
FIDELIO-DKD	34 / 122	36 / 132	7.8	1.02 [0.69,1.52]	
FIGARO-DKD	400 / 1515	425 / 1499	92.2	0.93 [0.83,1.05]	
Total	434 / 1637	461 / 1631		0.94 [0.84,1.05]	Z=-1.12, p=0.2617
Heterogeneity:	Q=0.19 (df=1)	p=0.6614	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8769	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.3.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

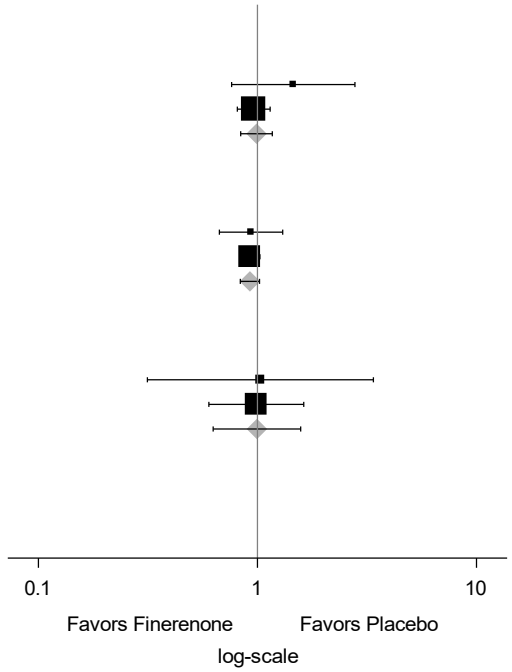
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	45 / 144	47 / 158	8.5	1.05 [0.75,1.48]	
FIGARO-DKD	505 / 1719	501 / 1679	91.5	0.98 [0.89,1.09]	
Total	550 / 1863	548 / 1837		0.99 [0.90,1.09]	Z=-0.20, p=0.8418
Heterogeneity:	Q=0.13 (df=1)	p=0.7210	I^2=0.0%		
> 4.5					
FIDELIO-DKD	20 / 66	20 / 63	10.3	0.95 [0.57,1.60]	
FIGARO-DKD	161 / 607	203 / 622	89.7	0.81 [0.68,0.97]	
Total	181 / 673	223 / 685		0.83 [0.70,0.97]	Z=-2.27, p=0.0230
Heterogeneity:	Q=0.34 (df=1)	p=0.5617	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.40 (df=1)	p=0.0652	I^2=70.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.3.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

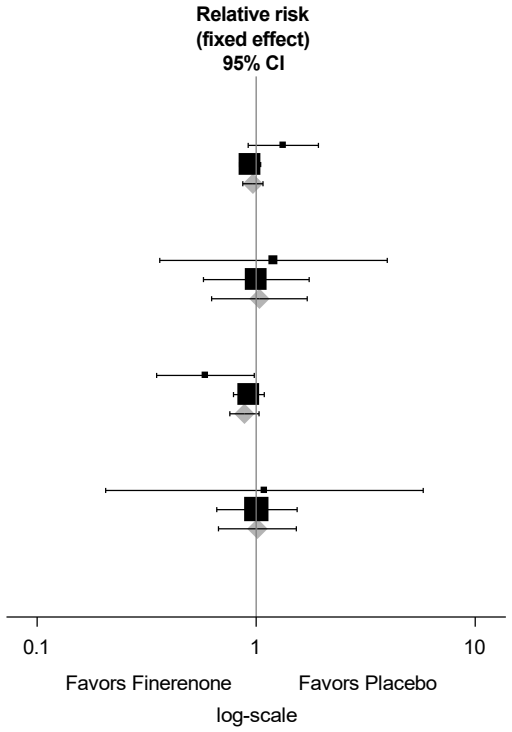
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	19 / 64	11 / 54	6.6	1.46 [0.76,2.79]	
FIGARO-DKD	184 / 693	193 / 699	93.4	0.96 [0.81,1.14]	
Total	203 / 757	204 / 753		0.99 [0.84,1.17]	Z=-0.12, p=0.9057
Heterogeneity:	Q=1.48 (df=1)	p=0.2244	I^2=32.3%		
130 - < 160					
FIDELIO-DKD	43 / 138	52 / 156	9.2	0.93 [0.67,1.30]	
FIGARO-DKD	461 / 1560	488 / 1524	90.8	0.92 [0.83,1.03]	
Total	504 / 1698	540 / 1680		0.92 [0.84,1.02]	Z=-1.54, p=0.1247
Heterogeneity:	Q=0.01 (df=1)	p=0.9426	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 8	4 / 11	15.0	1.03 [0.31,3.38]	
FIGARO-DKD	21 / 73	23 / 79	85.0	0.99 [0.60,1.63]	
Total	24 / 81	27 / 90		0.99 [0.63,1.58]	Z=-0.02, p=0.9809
Heterogeneity:	Q=0.00 (df=1)	p=0.9481	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=2)	p=0.7643	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.3.5: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

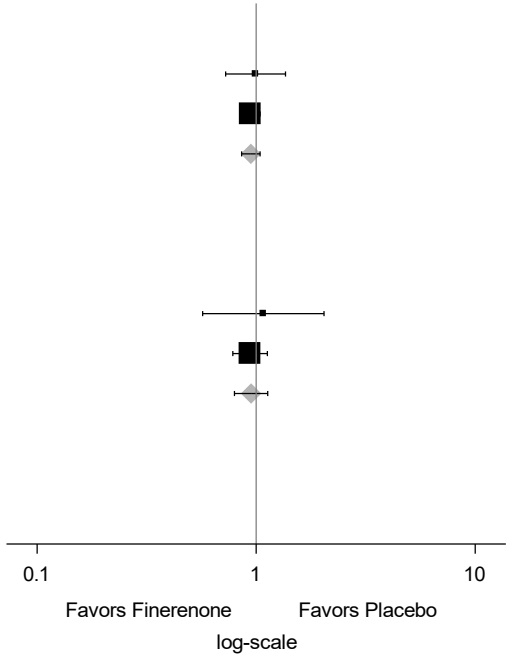
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 139	37 / 152	8.3	1.33 [0.92,1.92]	
FIGARO-DKD	444 / 1658	460 / 1612	91.7	0.94 [0.84,1.05]	
Total	489 / 1797	497 / 1764		0.97 [0.87,1.07]	Z=-0.64, p=0.5252
Heterogeneity:	Q=3.14 (df=1)	p=0.0762	I^2=68.2%		
Black					
FIDELIO-DKD	4 / 10	3 / 9	17.8	1.20 [0.36,3.97]	
FIGARO-DKD	18 / 70	19 / 74	82.2	1.00 [0.57,1.75]	
Total	22 / 80	22 / 83		1.03 [0.63,1.71]	Z=0.13, p=0.8942
Heterogeneity:	Q=0.07 (df=1)	p=0.7881	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 39	25 / 44	9.0	0.59 [0.35,0.98]	
FIGARO-DKD	171 / 464	193 / 485	91.0	0.93 [0.79,1.09]	
Total	184 / 503	218 / 529		0.88 [0.76,1.03]	Z=-1.57, p=0.1153
Heterogeneity:	Q=2.77 (df=1)	p=0.0960	I^2=63.9%		
Others					
FIDELIO-DKD	3 / 22	2 / 16	6.0	1.09 [0.21,5.79]	
FIGARO-DKD	33 / 134	32 / 131	94.0	1.01 [0.66,1.54]	
Total	36 / 156	34 / 147		1.01 [0.67,1.53]	Z=0.06, p=0.9507
Heterogeneity:	Q=0.01 (df=1)	p=0.9285	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.13 (df=3)	p=0.7701	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.3.6: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

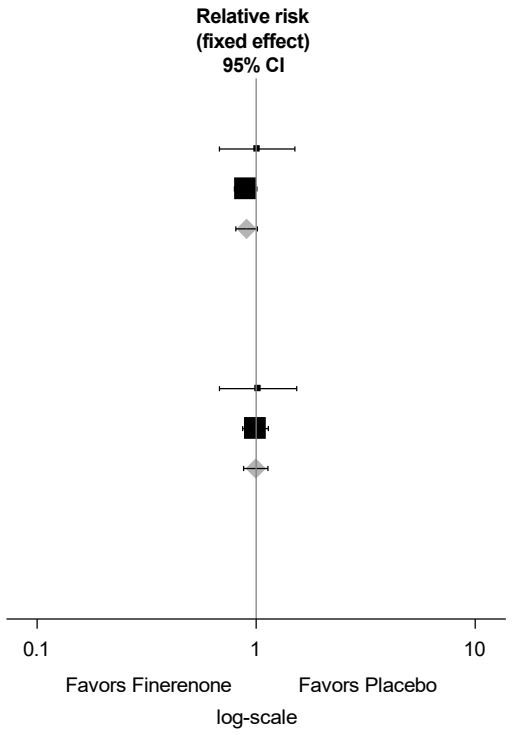
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 152	52 / 154	9.4	0.99 [0.73,1.36]	
FIGARO-DKD	491 / 1610	531 / 1638	90.6	0.94 [0.85,1.04]	
Total	542 / 1762	583 / 1792		0.95 [0.86,1.04]	Z=-1.13, p=0.2571
Heterogeneity:	Q=0.11 (df=1)	p=0.7456	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 58	15 / 67	7.5	1.08 [0.57,2.04]	
FIGARO-DKD	175 / 716	173 / 664	92.5	0.94 [0.78,1.12]	
Total	189 / 774	188 / 731		0.95 [0.80,1.13]	Z=-0.60, p=0.5485
Heterogeneity:	Q=0.17 (df=1)	p=0.6809	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9813	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.3.7: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

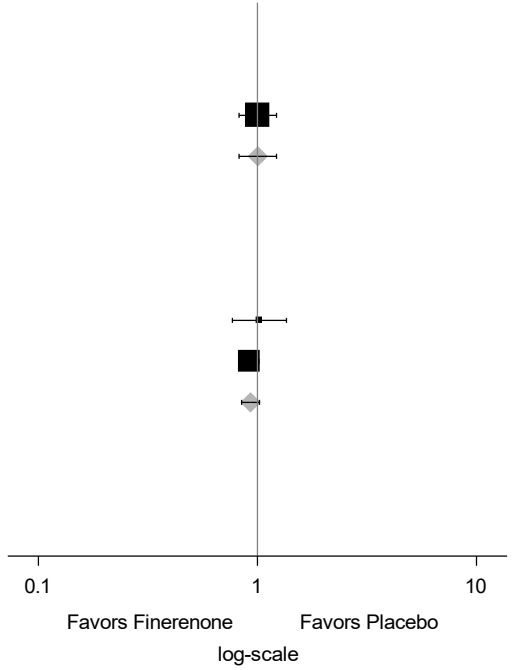
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 98	32 / 96	8.2	1.01 [0.68,1.50]	
FIGARO-DKD	375 / 1416	420 / 1420	91.8	0.90 [0.80,1.01]	
Total	408 / 1514	452 / 1516		0.90 [0.81,1.01]	Z=-1.74, p=0.0814
Heterogeneity:	Q=0.33 (df=1)	p=0.5676	I^2=0.0%		
>= 65					
FIDELIO-DKD	32 / 112	35 / 125	9.9	1.02 [0.68,1.53]	
FIGARO-DKD	291 / 910	284 / 882	90.1	0.99 [0.87,1.14]	
Total	323 / 1022	319 / 1007		1.00 [0.88,1.13]	Z=-0.06, p=0.9485
Heterogeneity:	Q=0.02 (df=1)	p=0.9011	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.22 (df=1)	p=0.2684	I^2=18.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.3.8: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

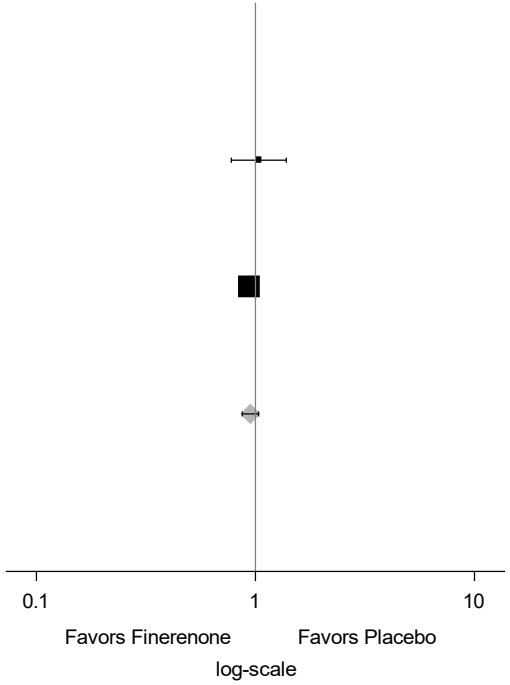
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	131 / 363	123 / 342	100.0	1.00 [0.82,1.22]	
Total	131 / 363	123 / 342		1.00 [0.82,1.22]	Z=0.03, p=0.9728
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	65 / 210	67 / 221	10.9	1.02 [0.77,1.36]	
FIGARO-DKD	535 / 1963	581 / 1960	89.1	0.92 [0.83,1.02]	
Total	600 / 2173	648 / 2181		0.93 [0.85,1.02]	Z=-1.52, p=0.1291
Heterogeneity:	Q=0.47 (df=1)	p=0.4952	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4942	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

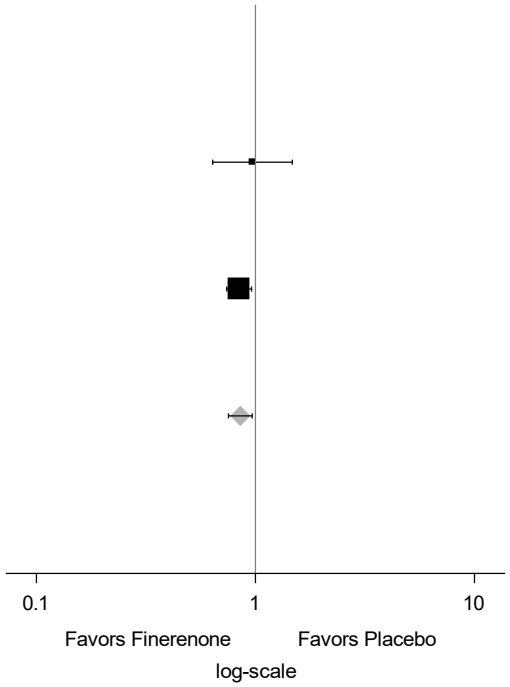
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 210	65 / 221	8.8	1.04 [0.78,1.38]	
FIGARO-DKD	661 / 2326	696 / 2302	91.2	0.94 [0.86,1.03]	
Total	725 / 2536	761 / 2523		0.95 [0.87,1.03]	Z=-1.23, p=0.2205
Heterogeneity:	Q=0.40 (df=1)	p=0.5274	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

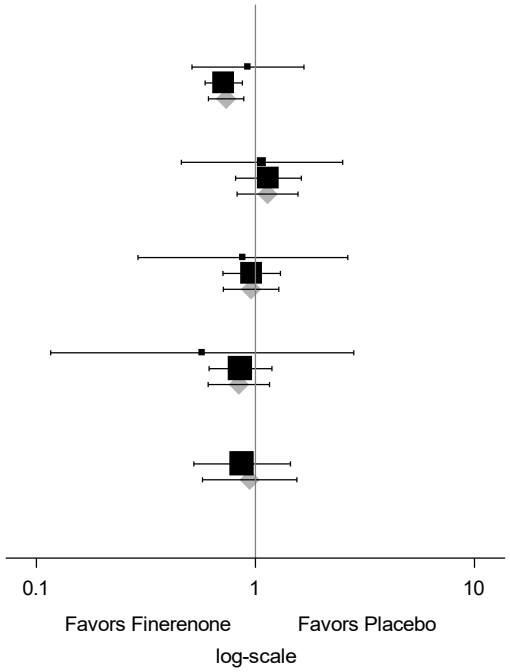
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 210	38 / 221	8.9	0.97 [0.64,1.47]	
FIGARO-DKD	349 / 2326	410 / 2302	91.1	0.84 [0.74,0.96]	
Total	384 / 2536	448 / 2523		0.85 [0.75,0.97]	Z=-2.50, p=0.0124
Heterogeneity:	Q=0.39 (df=1)	p=0.5306	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.5.1: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

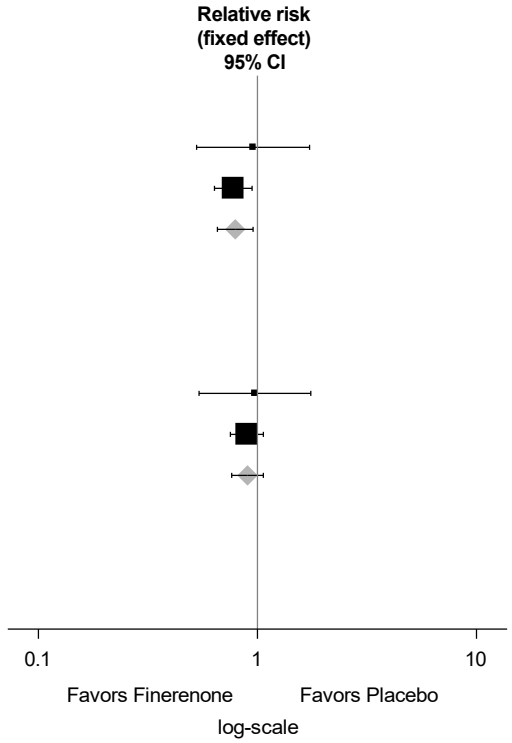
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	17 / 103	20 / 112	10.0	0.92 [0.51,1.67]	
FIGARO-DKD	146 / 1114	203 / 1110	90.0	0.72 [0.59,0.87]	
Total	163 / 1217	223 / 1222		0.73 [0.61,0.88]	Z=-3.25, p=0.0011
Heterogeneity:	Q=0.65 (df=1)	p=0.4214	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	8 / 40	14.2	1.07 [0.46,2.50]	
FIGARO-DKD	58 / 292	48 / 277	85.8	1.15 [0.81,1.62]	
Total	67 / 334	56 / 317		1.14 [0.82,1.56]	Z=0.78, p=0.4366
Heterogeneity:	Q=0.02 (df=1)	p=0.8851	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 39	6 / 41	7.0	0.88 [0.29,2.64]	
FIGARO-DKD	71 / 522	74 / 523	93.0	0.96 [0.71,1.30]	
Total	76 / 561	80 / 564		0.96 [0.71,1.28]	Z=-0.31, p=0.7571
Heterogeneity:	Q=0.03 (df=1)	p=0.8736	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	4 / 24	4.1	0.57 [0.12,2.81]	
FIGARO-DKD	54 / 322	62 / 316	95.9	0.85 [0.61,1.19]	
Total	56 / 343	66 / 340		0.84 [0.61,1.16]	Z=-1.06, p=0.2889
Heterogeneity:	Q=0.24 (df=1)	p=0.6276	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 5	0 / 4	0.0	282E9 [282E9,282E9]	
FIGARO-DKD	20 / 76	23 / 76	100.0	0.87 [0.52,1.45]	
Total	22 / 81	23 / 80		0.94 [0.57,1.55]	Z=-0.24, p=0.8103
Heterogeneity:	Q=0.09 (df=1)	p=0.7605	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.29 (df=4)	p=0.1783	I^2=36.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.5.2: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

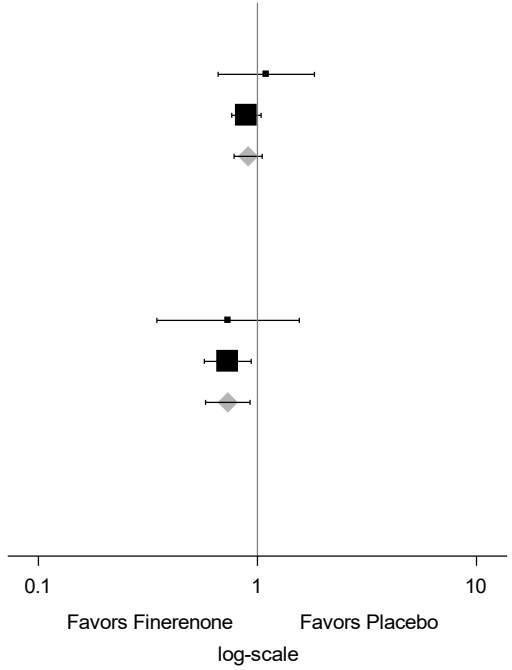
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 88	18 / 89	10.0	0.96 [0.53,1.73]	
FIGARO-DKD	141 / 811	180 / 803	90.0	0.78 [0.64,0.95]	
Total	158 / 899	198 / 892		0.79 [0.66,0.95]	Z=-2.44, p=0.0146
Heterogeneity:	Q=0.43 (df=1)	p=0.5143	I^2=0.0%		
Absent					
FIDELIO-DKD	18 / 122	20 / 132	8.0	0.97 [0.54,1.75]	
FIGARO-DKD	208 / 1515	230 / 1499	92.0	0.89 [0.75,1.06]	
Total	226 / 1637	250 / 1631		0.90 [0.76,1.06]	Z=-1.23, p=0.2186
Heterogeneity:	Q=0.07 (df=1)	p=0.7866	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.02 (df=1)	p=0.3125	I^2=2.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.5.3: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

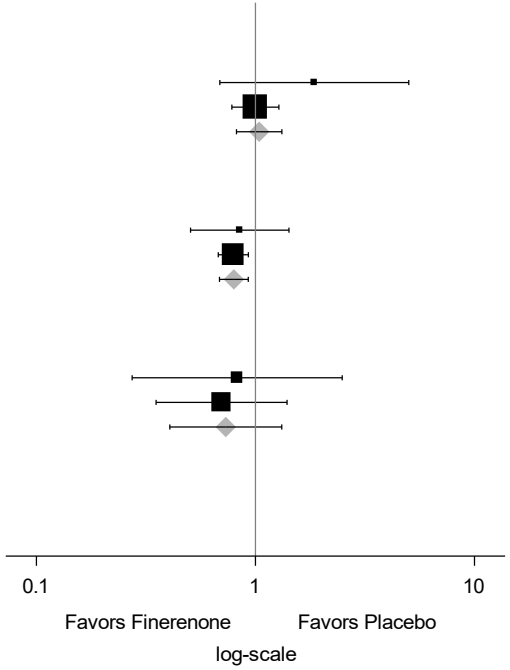
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	25 / 158	8.5	1.10 [0.66,1.82]	
FIGARO-DKD	259 / 1719	284 / 1679	91.5	0.89 [0.76,1.04]	
Total	284 / 1863	309 / 1837		0.91 [0.78,1.05]	Z=-1.30, p=0.1932
Heterogeneity:	Q=0.60 (df=1)	p=0.4401	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 66	13 / 63	9.8	0.73 [0.35,1.55]	
FIGARO-DKD	90 / 607	126 / 622	90.2	0.73 [0.57,0.94]	
Total	100 / 673	139 / 685		0.73 [0.58,0.93]	Z=-2.61, p=0.0090
Heterogeneity:	Q=0.00 (df=1)	p=0.9937	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.29 (df=1)	p=0.1301	I^2=56.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.5.4: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

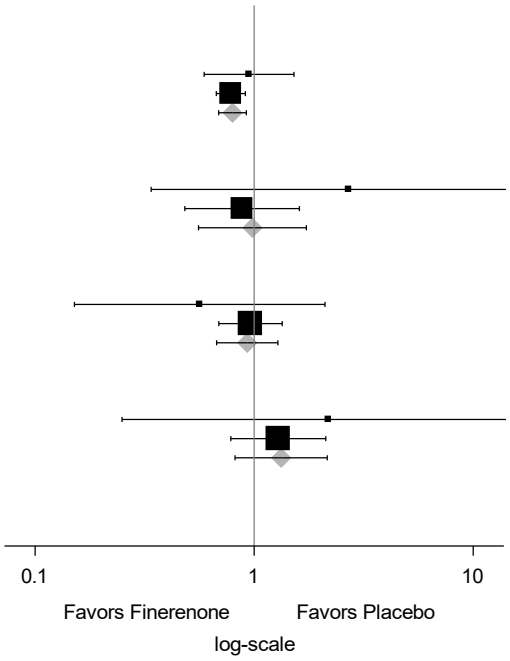
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	11 / 64	5 / 54	5.8	1.86 [0.69,5.01]	
FIGARO-DKD	106 / 693	107 / 699	94.2	1.00 [0.78,1.28]	
Total	117 / 757	112 / 753		1.04 [0.82,1.32]	Z=0.32, p=0.7482
Heterogeneity:	Q=1.41 (df=1)	p=0.2355	I^2=29.0%		
130 - < 160					
FIDELIO-DKD	21 / 138	28 / 156	8.5	0.85 [0.51,1.42]	
FIGARO-DKD	232 / 1560	286 / 1524	91.5	0.79 [0.68,0.93]	
Total	253 / 1698	314 / 1680		0.80 [0.69,0.93]	Z=-2.94, p=0.0033
Heterogeneity:	Q=0.06 (df=1)	p=0.8067	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 8	5 / 11	28.0	0.83 [0.27,2.49]	
FIGARO-DKD	11 / 73	17 / 79	72.0	0.70 [0.35,1.39]	
Total	14 / 81	22 / 90		0.73 [0.41,1.32]	Z=-1.04, p=0.2986
Heterogeneity:	Q=0.06 (df=1)	p=0.8049	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.68 (df=2)	p=0.1588	I^2=45.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.5.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

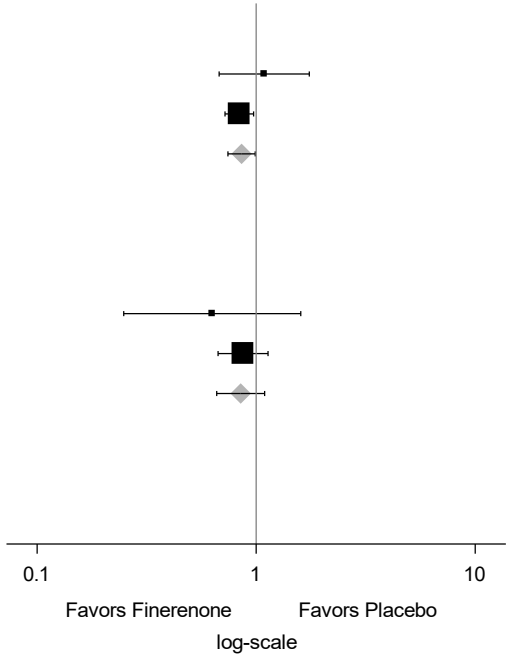
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	26 / 139	30 / 152	9.5	0.95 [0.59,1.52]	
FIGARO-DKD	247 / 1658	307 / 1612	90.5	0.78 [0.67,0.91]	
Total	273 / 1797	337 / 1764		0.80 [0.69,0.92]	Z=-3.07, p=0.0022
Heterogeneity:	Q=0.57 (df=1)	p=0.4485	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 10	1 / 9	7.8	2.70 [0.34,21.53]	
FIGARO-DKD	15 / 70	18 / 74	92.2	0.88 [0.48,1.61]	
Total	18 / 80	19 / 83		0.98 [0.56,1.73]	Z=-0.06, p=0.9497
Heterogeneity:	Q=1.04 (df=1)	p=0.3087	I^2=3.5%		
Asian					
FIDELIO-DKD	3 / 39	6 / 44	6.0	0.56 [0.15,2.11]	
FIGARO-DKD	58 / 464	63 / 485	94.0	0.96 [0.69,1.34]	
Total	61 / 503	69 / 529		0.93 [0.67,1.28]	Z=-0.44, p=0.6569
Heterogeneity:	Q=0.59 (df=1)	p=0.4409	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 22	1 / 16	5.0	2.18 [0.25,19.10]	
FIGARO-DKD	29 / 134	22 / 131	95.0	1.29 [0.78,2.12]	
Total	32 / 156	23 / 147		1.33 [0.82,2.16]	Z=1.15, p=0.2515
Heterogeneity:	Q=0.22 (df=1)	p=0.6428	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.57 (df=3)	p=0.2062	I^2=34.3%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.5.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

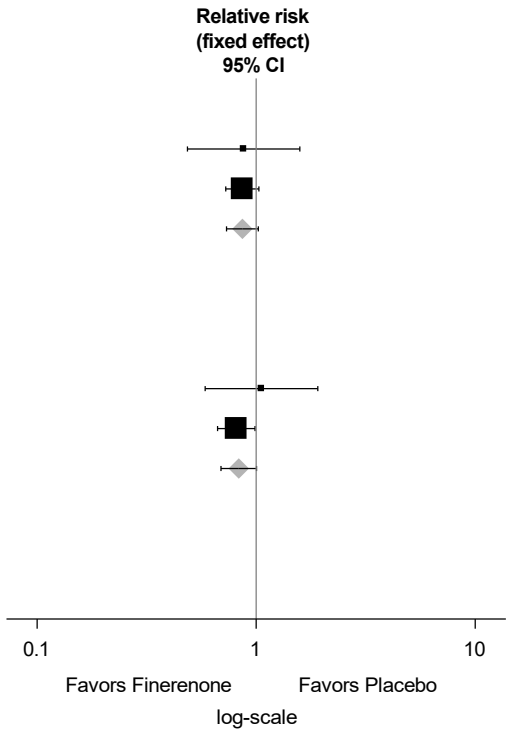
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 152	27 / 154	9.2	1.09 [0.68,1.75]	
FIGARO-DKD	256 / 1610	311 / 1638	90.8	0.84 [0.72,0.97]	
Total	285 / 1762	338 / 1792		0.86 [0.74,0.99]	Z=-2.10, p=0.0357
Heterogeneity:	Q=1.07 (df=1)	p=0.3018	I^2=6.2%		
Female					
FIDELIO-DKD	6 / 58	11 / 67	7.4	0.63 [0.25,1.60]	
FIGARO-DKD	93 / 716	99 / 664	92.6	0.87 [0.67,1.13]	
Total	99 / 774	110 / 731		0.85 [0.66,1.09]	Z=-1.27, p=0.2053
Heterogeneity:	Q=0.43 (df=1)	p=0.5113	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9492	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.5.7: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

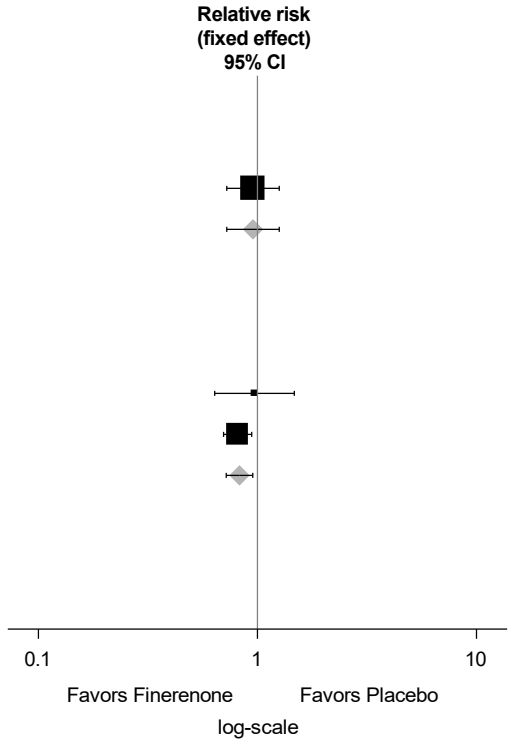
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	17 / 98	19 / 96	8.0	0.88 [0.49,1.58]	
FIGARO-DKD	200 / 1416	232 / 1420	92.0	0.86 [0.73,1.03]	
Total	217 / 1514	251 / 1516		0.87 [0.73,1.02]	Z=-1.69, p=0.0901
Heterogeneity:	Q=0.00 (df=1)	p=0.9651	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 112	19 / 125	10.0	1.06 [0.58,1.91]	
FIGARO-DKD	149 / 910	178 / 882	90.0	0.81 [0.67,0.99]	
Total	167 / 1022	197 / 1007		0.83 [0.69,1.00]	Z=-1.92, p=0.0549
Heterogeneity:	Q=0.69 (df=1)	p=0.4055	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7632	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.5.8: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

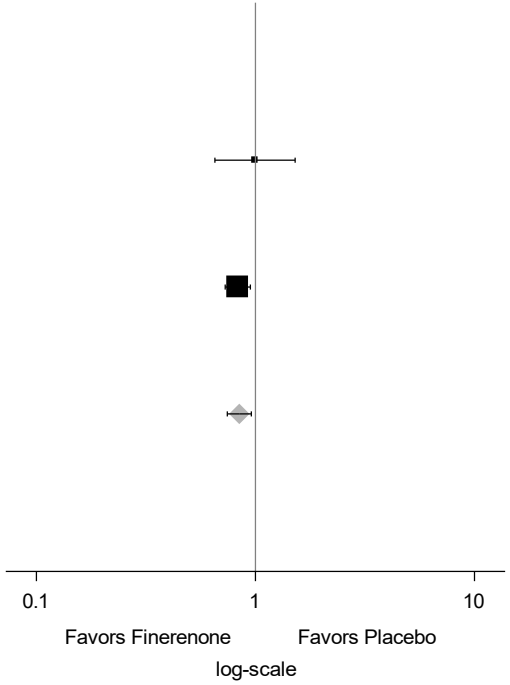
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	79 / 363	78 / 342	100.0	0.95 [0.72,1.26]	
Total	79 / 363	78 / 342		0.95 [0.72,1.26]	Z=-0.33, p=0.7392
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	35 / 210	38 / 221	11.1	0.97 [0.64,1.47]	
FIGARO-DKD	270 / 1963	332 / 1960	88.9	0.81 [0.70,0.94]	
Total	305 / 2173	370 / 2181		0.83 [0.72,0.95]	Z=-2.65, p=0.0080
Heterogeneity:	Q=0.61 (df=1)	p=0.4344	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=1)	p=0.3682	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

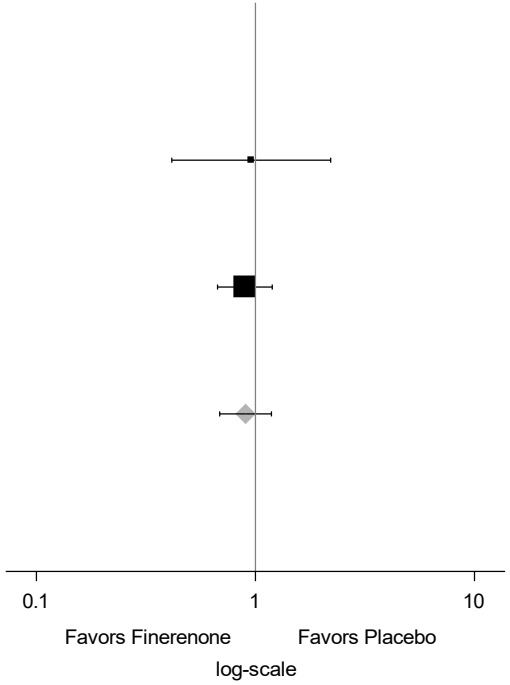
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 210	37 / 221	9.0	1.00 [0.65,1.52]	
FIGARO-DKD	339 / 2326	404 / 2302	91.0	0.83 [0.73,0.95]	
Total	374 / 2536	441 / 2523		0.84 [0.74,0.96]	Z=-2.63, p=0.0085
Heterogeneity:	Q=0.65 (df=1)	p=0.4216	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

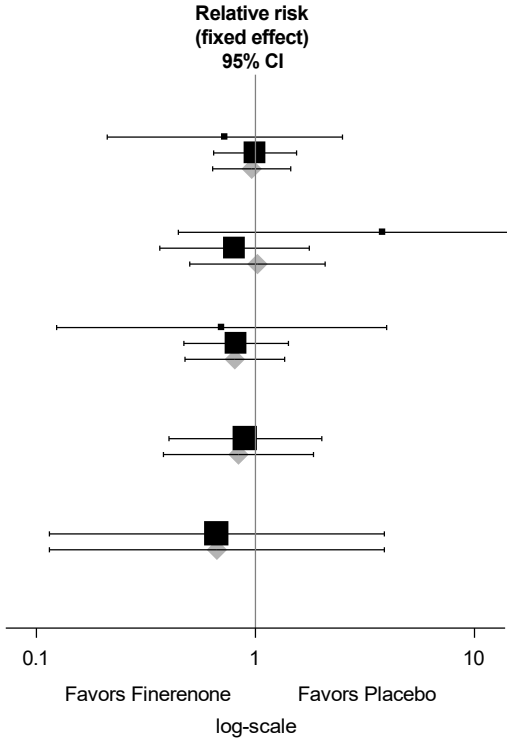
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	11 / 221	10.6	0.96 [0.41,2.21]	
FIGARO-DKD	85 / 2326	94 / 2302	89.4	0.89 [0.67,1.19]	
Total	95 / 2536	105 / 2523		0.90 [0.69,1.18]	Z=-0.75, p=0.4538
Heterogeneity:	Q=0.02 (df=1)	p=0.8823	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.7.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

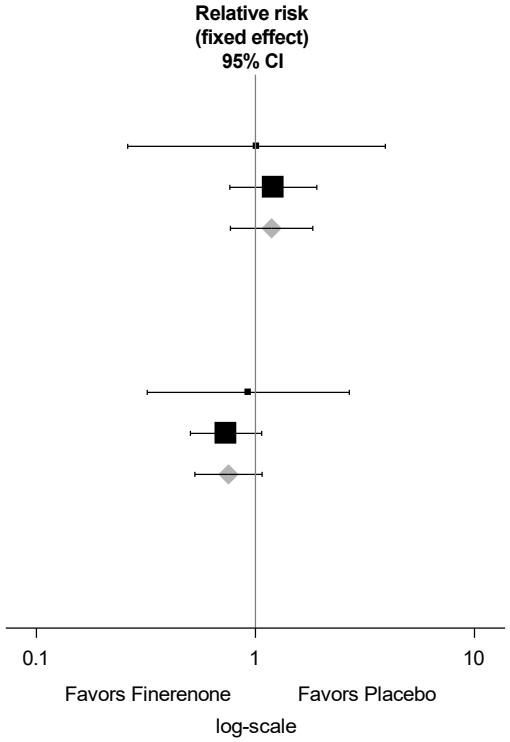
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	4 / 103	6 / 112	11.1	0.72 [0.21,2.50]	
FIGARO-DKD	39 / 1114	39 / 1110	88.9	1.00 [0.64,1.54]	
Total	43 / 1217	45 / 1222		0.96 [0.64,1.45]	Z=-0.19, p=0.8503
Heterogeneity:	Q=0.23 (df=1)	p=0.6344	I^2=0.0%		
North America					
FIDELIO-DKD	4 / 42	1 / 40	11.8	3.81 [0.44,32.64]	
FIGARO-DKD	11 / 292	13 / 277	88.2	0.80 [0.37,1.76]	
Total	15 / 334	14 / 317		1.02 [0.50,2.08]	Z=0.06, p=0.9542
Heterogeneity:	Q=1.80 (df=1)	p=0.1793	I^2=44.5%		
Asia					
FIDELIO-DKD	2 / 39	3 / 41	9.1	0.70 [0.12,3.97]	
FIGARO-DKD	22 / 522	27 / 523	90.9	0.82 [0.47,1.41]	
Total	24 / 561	30 / 564		0.80 [0.48,1.36]	Z=-0.81, p=0.4168
Heterogeneity:	Q=0.03 (df=1)	p=0.8695	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,83E295]	
FIGARO-DKD	11 / 322	12 / 316	100.0	0.90 [0.40,2.01]	
Total	11 / 343	13 / 340		0.84 [0.38,1.84]	Z=-0.44, p=0.6573
Heterogeneity:	Q=0.03 (df=1)	p=0.8591	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	3 / 76	100.0	0.67 [0.11,3.88]	
Total	2 / 81	3 / 80		0.67 [0.11,3.88]	Z=-0.45, p=0.6517
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=4)	p=0.9696	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.7.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

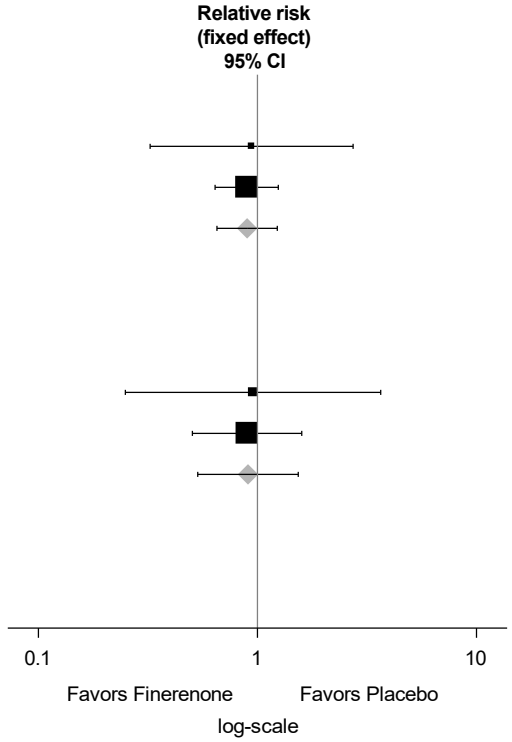
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	4 / 89	10.2	1.01 [0.26,3.92]	
FIGARO-DKD	39 / 811	32 / 803	89.8	1.21 [0.76,1.91]	
Total	43 / 899	36 / 892		1.19 [0.77,1.83]	Z=0.77, p=0.4418
Heterogeneity:	Q=0.06 (df=1)	p=0.8086	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 122	7 / 132	11.1	0.93 [0.32,2.68]	
FIGARO-DKD	46 / 1515	62 / 1499	88.9	0.73 [0.50,1.07]	
Total	52 / 1637	69 / 1631		0.75 [0.53,1.07]	Z=-1.57, p=0.1157
Heterogeneity:	Q=0.17 (df=1)	p=0.6842	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.53 (df=1)	p=0.1117	I^2=60.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.7.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

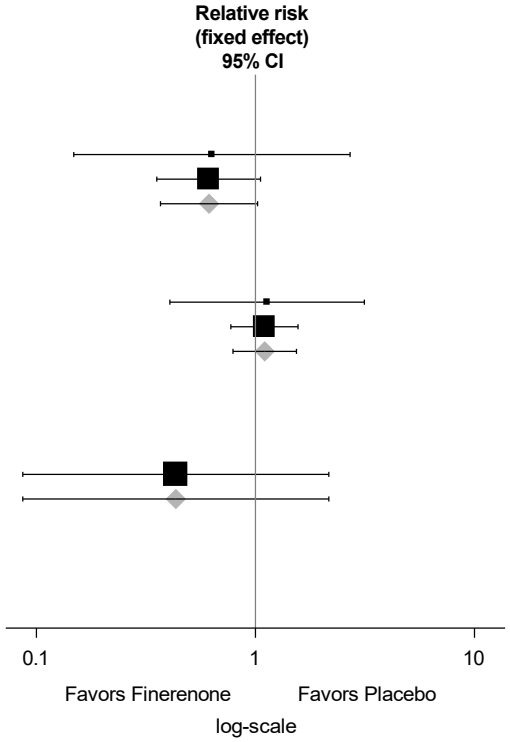
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	7 / 158	8.8	0.94 [0.32,2.73]	
FIGARO-DKD	64 / 1719	70 / 1679	91.2	0.89 [0.64,1.24]	
Total	70 / 1863	77 / 1837		0.90 [0.65,1.23]	Z=-0.67, p=0.5023
Heterogeneity:	Q=0.01 (df=1)	p=0.9276	I^2=0.0%		
> 4.5					
FIDELIO-DKD	4 / 66	4 / 63	15.5	0.95 [0.25,3.65]	
FIGARO-DKD	21 / 607	24 / 622	84.5	0.90 [0.50,1.59]	
Total	25 / 673	28 / 685		0.91 [0.53,1.54]	Z=-0.37, p=0.7123
Heterogeneity:	Q=0.01 (df=1)	p=0.9330	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9767	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.7.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

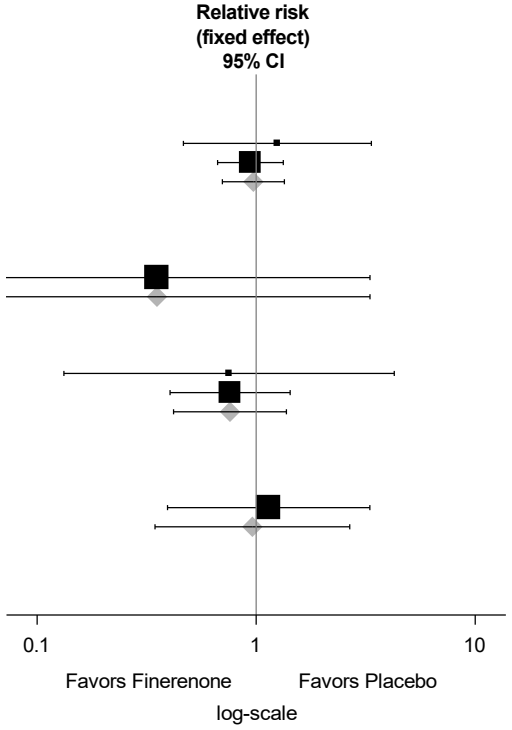
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	4 / 54	12.4	0.63 [0.15,2.70]	
FIGARO-DKD	20 / 693	33 / 699	87.6	0.61 [0.35,1.05]	
Total	23 / 757	37 / 753		0.61 [0.37,1.02]	Z=-1.87, p=0.0610
Heterogeneity:	Q=0.00 (df=1)	p=0.9652	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	7 / 138	7 / 156	10.7	1.13 [0.41,3.14]	
FIGARO-DKD	63 / 1560	56 / 1524	89.3	1.10 [0.77,1.56]	
Total	70 / 1698	63 / 1680		1.10 [0.79,1.54]	Z=0.57, p=0.5671
Heterogeneity:	Q=0.00 (df=1)	p=0.9593	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	5 / 79	100.0	0.43 [0.09,2.16]	
Total	2 / 81	5 / 90		0.43 [0.09,2.16]	Z=-1.02, p=0.3077
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.37 (df=2)	p=0.1125	I^2=54.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.7.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

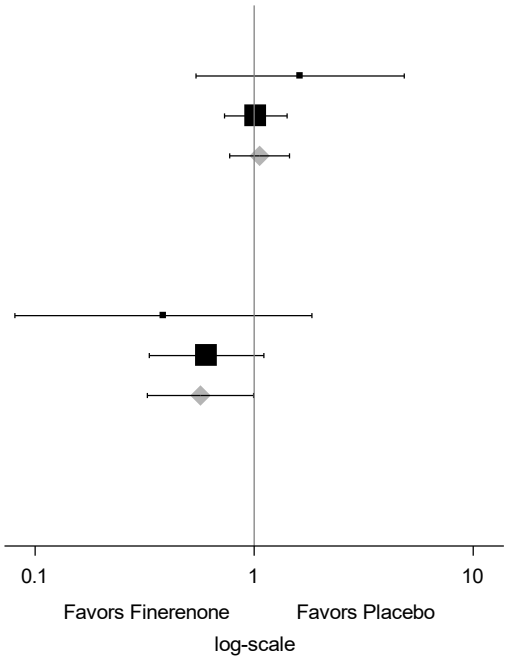
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 139	7 / 152	10.9	1.25 [0.47,3.36]	
FIGARO-DKD	61 / 1658	63 / 1612	89.1	0.94 [0.67,1.33]	
Total	69 / 1797	70 / 1764		0.97 [0.70,1.35]	Z=-0.18, p=0.8594
Heterogeneity:	Q=0.28 (df=1)	p=0.5957	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	3 / 74	100.0	0.35 [0.04,3.31]	
Total	1 / 80	3 / 83		0.35 [0.04,3.31]	Z=-0.91, p=0.3613
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 39	3 / 44	11.7	0.75 [0.13,4.27]	
FIGARO-DKD	16 / 464	22 / 485	88.3	0.76 [0.40,1.43]	
Total	18 / 503	25 / 529		0.76 [0.42,1.37]	Z=-0.91, p=0.3629
Heterogeneity:	Q=0.00 (df=1)	p=0.9910	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,55E295]	
FIGARO-DKD	7 / 134	6 / 131	100.0	1.14 [0.39,3.30]	
Total	7 / 156	7 / 147		0.96 [0.35,2.67]	Z=-0.08, p=0.9391
Heterogeneity:	Q=0.10 (df=1)	p=0.7521	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.21 (df=3)	p=0.7506	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.7.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

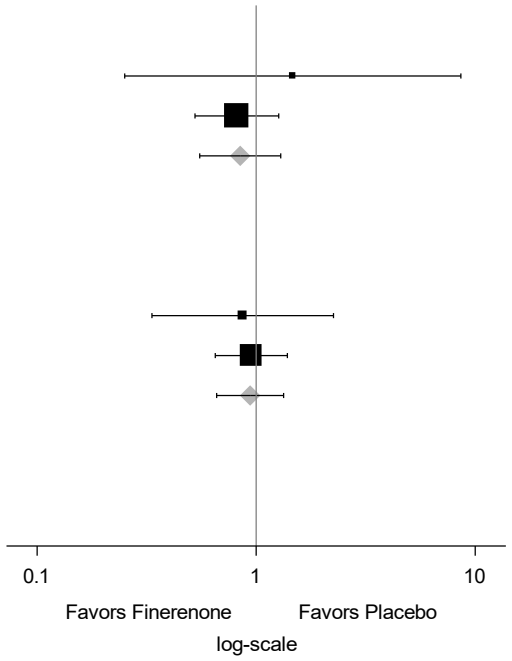
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	5 / 154	8.3	1.62 [0.54,4.84]	
FIGARO-DKD	68 / 1610	68 / 1638	91.7	1.02 [0.73,1.41]	
Total	76 / 1762	73 / 1792		1.06 [0.77,1.45]	Z=0.36, p=0.7215
Heterogeneity:	Q=0.64 (df=1)	p=0.4244	I^2=0.0%		
Female					
FIDELIO-DKD	2 / 58	6 / 67	12.9	0.39 [0.08,1.83]	
FIGARO-DKD	17 / 716	26 / 664	87.1	0.61 [0.33,1.11]	
Total	19 / 774	32 / 731		0.57 [0.33,0.99]	Z=-1.98, p=0.0474
Heterogeneity:	Q=0.28 (df=1)	p=0.5946	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.62 (df=1)	p=0.0572	I^2=72.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.7.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

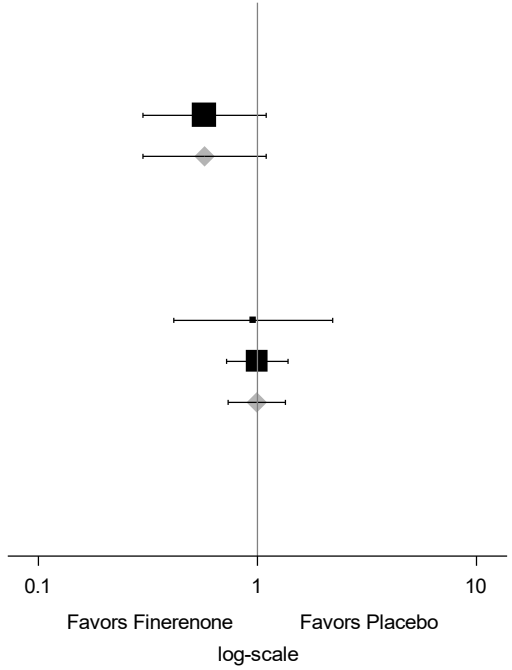
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 98	2 / 96	5.8	1.47 [0.25,8.60]	
FIGARO-DKD	35 / 1416	43 / 1420	94.2	0.82 [0.53,1.27]	
Total	38 / 1514	45 / 1516		0.85 [0.55,1.29]	Z=-0.77, p=0.4402
Heterogeneity:	Q=0.40 (df=1)	p=0.5269	I^2=0.0%		
>= 65					
FIDELIO-DKD	7 / 112	9 / 125	13.6	0.87 [0.33,2.25]	
FIGARO-DKD	50 / 910	51 / 882	86.4	0.95 [0.65,1.39]	
Total	57 / 1022	60 / 1007		0.94 [0.66,1.33]	Z=-0.35, p=0.7239
Heterogeneity:	Q=0.03 (df=1)	p=0.8629	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7114	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.7.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

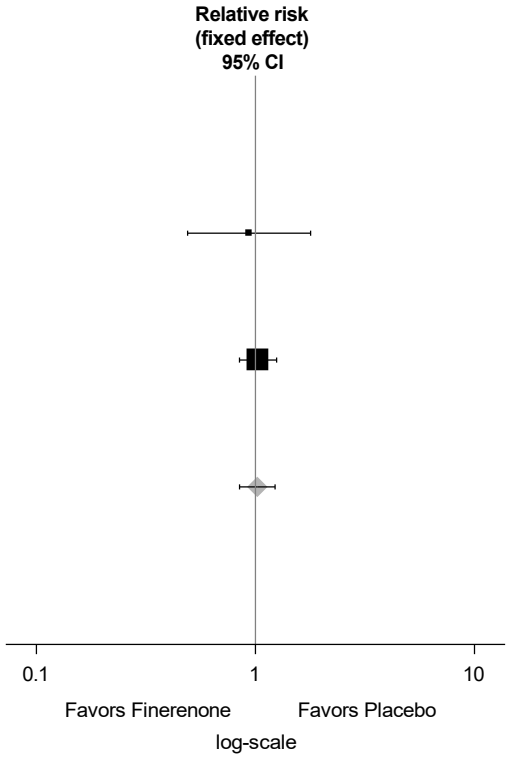
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	14 / 363	23 / 342	100.0	0.57 [0.30,1.10]	
Total	14 / 363	23 / 342		0.57 [0.30,1.10]	Z=-1.68, p=0.0925
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	10 / 210	11 / 221	13.0	0.96 [0.41,2.21]	
FIGARO-DKD	71 / 1963	71 / 1960	87.0	1.00 [0.72,1.38]	
Total	81 / 2173	82 / 2181		0.99 [0.73,1.34]	Z=-0.05, p=0.9632
Heterogeneity:	Q=0.01 (df=1)	p=0.9255	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.27 (df=1)	p=0.1320	I^2=55.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

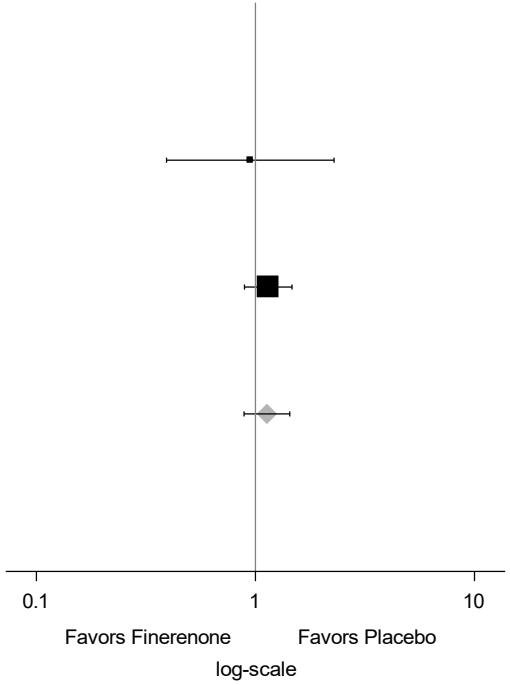
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	16 / 210	18 / 221	8.4	0.94 [0.49,1.79]	
FIGARO-DKD	189 / 2326	182 / 2302	91.6	1.03 [0.85,1.25]	
Total	205 / 2536	200 / 2523		1.02 [0.85,1.23]	Z=0.20, p=0.8380
Heterogeneity:	Q=0.07 (df=1)	p=0.7848	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

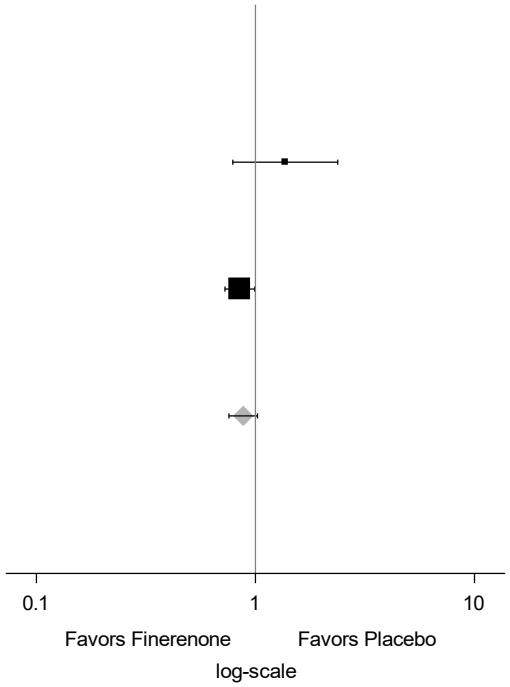
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	10 / 221	7.5	0.95 [0.39,2.28]	
FIGARO-DKD	126 / 2326	109 / 2302	92.5	1.14 [0.89,1.47]	
Total	135 / 2536	119 / 2523		1.13 [0.89,1.43]	Z=0.98, p=0.3256
Heterogeneity:	Q=0.16 (df=1)	p=0.6859	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.10: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

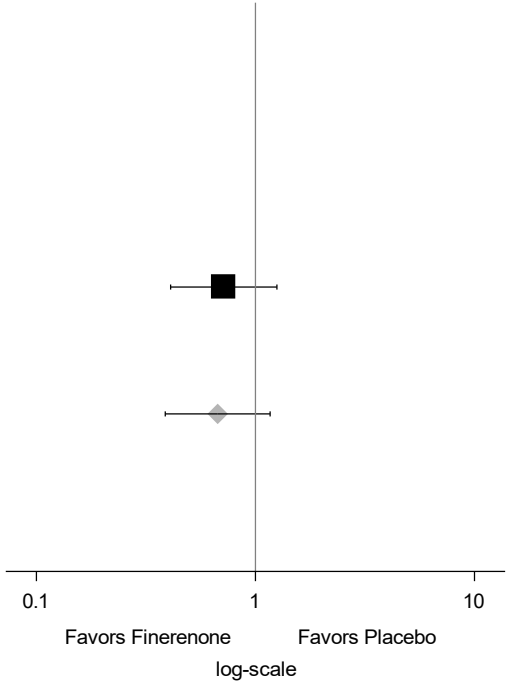
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 210	20 / 221	7.4	1.37 [0.79,2.37]	
FIGARO-DKD	258 / 2326	301 / 2302	92.6	0.85 [0.73,0.99]	
Total	284 / 2536	321 / 2523		0.88 [0.76,1.02]	Z=-1.68, p=0.0923
Heterogeneity:	Q=2.67 (df=1)	p=0.1022	I^2=62.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.11: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

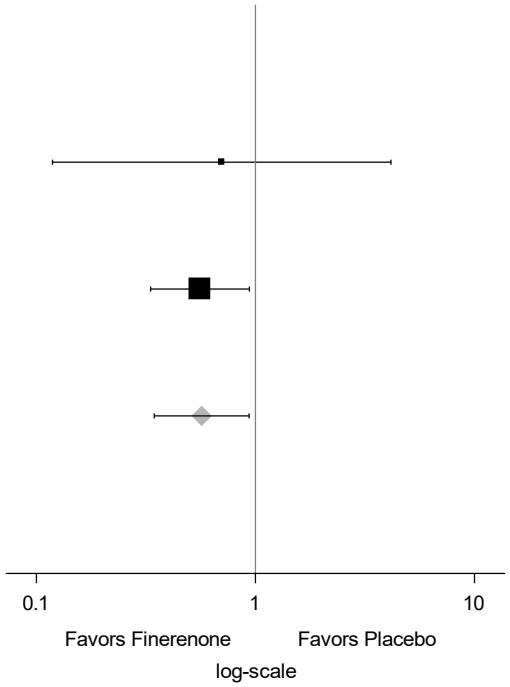
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	21 / 2326	29 / 2302	100.0	0.72 [0.41,1.25]	
Total	21 / 2536	31 / 2523		0.67 [0.39,1.17]	Z=-1.41, p=0.1579
Heterogeneity:	Q=0.05 (df=1)	p=0.8224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.12: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

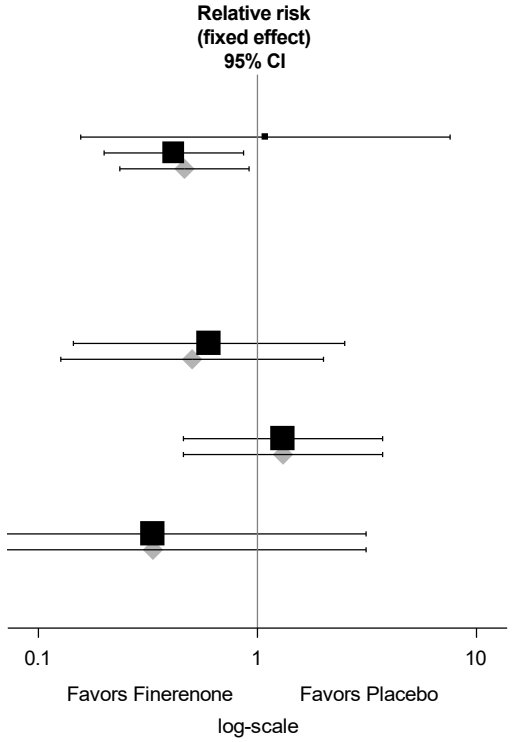
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.9	0.70 [0.12,4.16]	
FIGARO-DKD	22 / 2326	39 / 2302	92.1	0.56 [0.33,0.94]	
Total	24 / 2536	42 / 2523		0.57 [0.35,0.94]	Z=-2.22, p=0.0262
Heterogeneity:	Q=0.06 (df=1)	p=0.8091	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.12.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

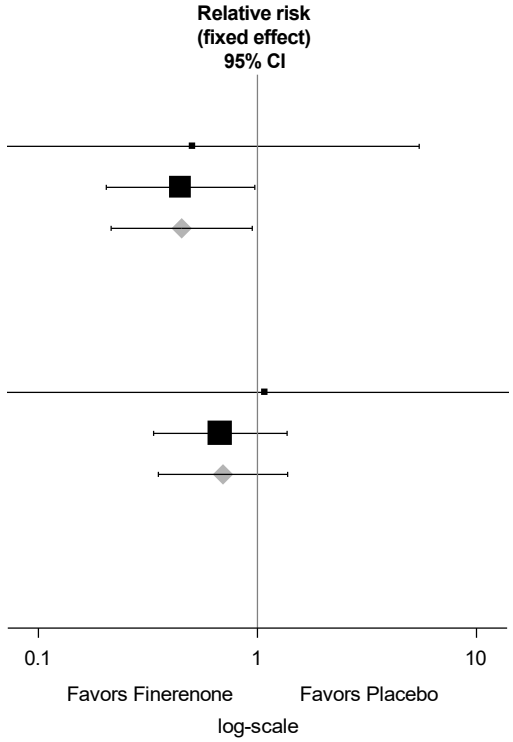
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	2 / 103	2 / 112	12.5	1.09 [0.16,7.58]	
FIGARO-DKD	10 / 1114	24 / 1110	87.5	0.42 [0.20,0.86]	
Total	12 / 1217	26 / 1222		0.46 [0.24,0.92]	Z=-2.21, p=0.0268
Heterogeneity:	Q=0.83 (df=1)	p=0.3630	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	-	-	
FIGARO-DKD	0 / 292	1 / 277	0.0	0.00 [0.00,12E296]	
Total	0 / 334	1 / 317		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	3 / 522	5 / 523	100.0	0.60 [0.14,2.50]	
Total	3 / 561	6 / 564		0.50 [0.13,2.00]	Z=-0.97, p=0.3298
Heterogeneity:	Q=0.06 (df=1)	p=0.8071	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	-	-	
FIGARO-DKD	8 / 322	6 / 316	100.0	1.31 [0.46,3.73]	
Total	8 / 343	6 / 340		1.31 [0.46,3.73]	Z=0.50, p=0.6148
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	-	-	
FIGARO-DKD	1 / 76	3 / 76	100.0	0.33 [0.04,3.13]	
Total	1 / 81	3 / 80		0.33 [0.04,3.13]	Z=-0.96, p=0.3366
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.00 (df=4)	p=0.5575	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.12.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

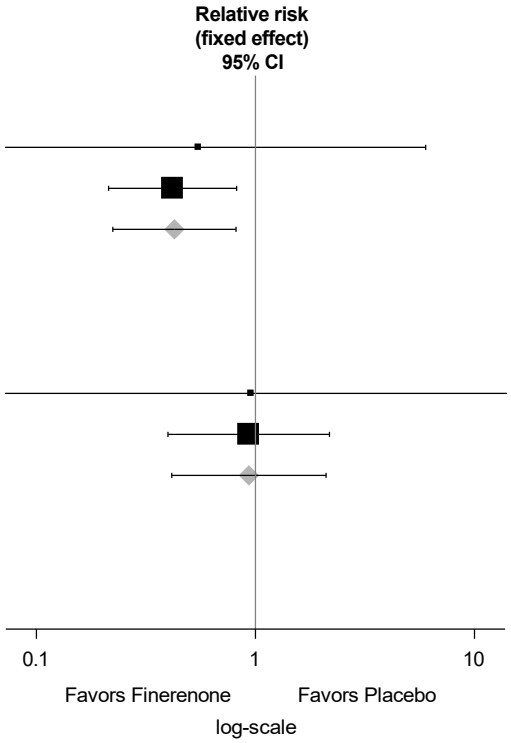
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	9.7	0.51 [0.05,5.48]	
FIGARO-DKD	9 / 811	20 / 803	90.3	0.45 [0.20,0.97]	
Total	10 / 899	22 / 892		0.45 [0.21,0.95]	Z=-2.10, p=0.0353
Heterogeneity:	Q=0.01 (df=1)	p=0.9212	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	1 / 132	6.1	1.08 [0.07,17.11]	
FIGARO-DKD	13 / 1515	19 / 1499	93.9	0.68 [0.34,1.37]	
Total	14 / 1637	20 / 1631		0.70 [0.35,1.37]	Z=-1.04, p=0.2962
Heterogeneity:	Q=0.10 (df=1)	p=0.7470	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.72 (df=1)	p=0.3975	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.12.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	2 / 158	7.3	0.55 [0.05,5.99]	
FIGARO-DKD	12 / 1719	28 / 1679	92.7	0.42 [0.21,0.82]	
Total	13 / 1863	30 / 1837		0.43 [0.22,0.82]	Z=-2.58, p=0.0099
Heterogeneity:	Q=0.05 (df=1)	p=0.8309	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	1 / 63	8.7	0.95 [0.06,14.93]	
FIGARO-DKD	10 / 607	11 / 622	91.3	0.93 [0.40,2.18]	
Total	11 / 673	12 / 685		0.93 [0.41,2.10]	Z=-0.17, p=0.8680
Heterogeneity:	Q=0.00 (df=1)	p=0.9868	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.19 (df=1)	p=0.1392	I^2=54.3%		

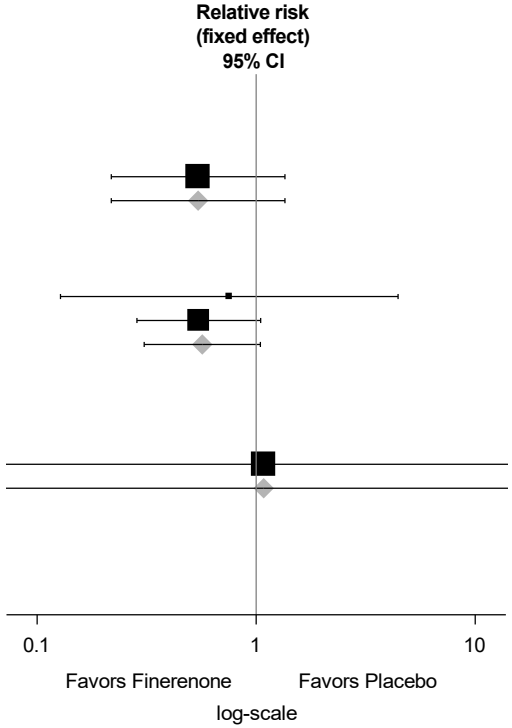


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.12.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

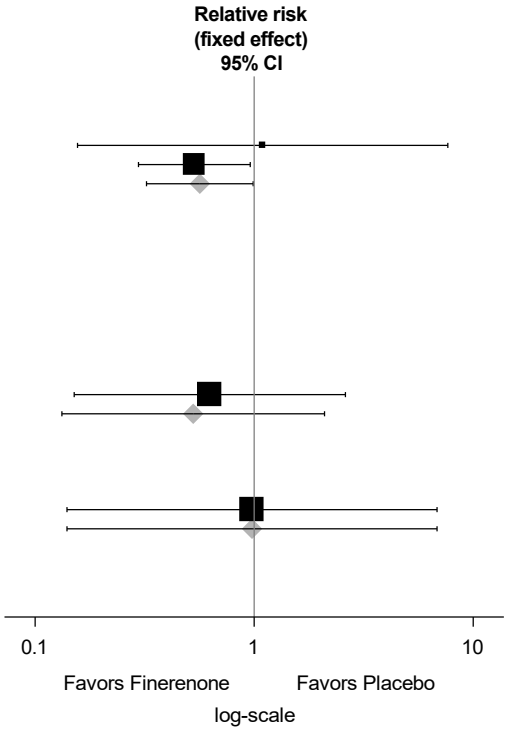
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	7 / 693	13 / 699	100.0	0.54 [0.22,1.35]	
Total	7 / 757	13 / 753		0.54 [0.22,1.35]	Z=-1.31, p=0.1900
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	3 / 156	11.8	0.75 [0.13,4.44]	
FIGARO-DKD	14 / 1560	25 / 1524	88.2	0.55 [0.29,1.05]	
Total	16 / 1698	28 / 1680		0.57 [0.31,1.05]	Z=-1.82, p=0.0690
Heterogeneity:	Q=0.11 (df=1)	p=0.7397	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	1 / 79	100.0	1.08 [0.07,16.99]	
Total	1 / 81	1 / 90		1.08 [0.07,16.99]	Z=0.06, p=0.9552
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=2)	p=0.8963	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.12.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

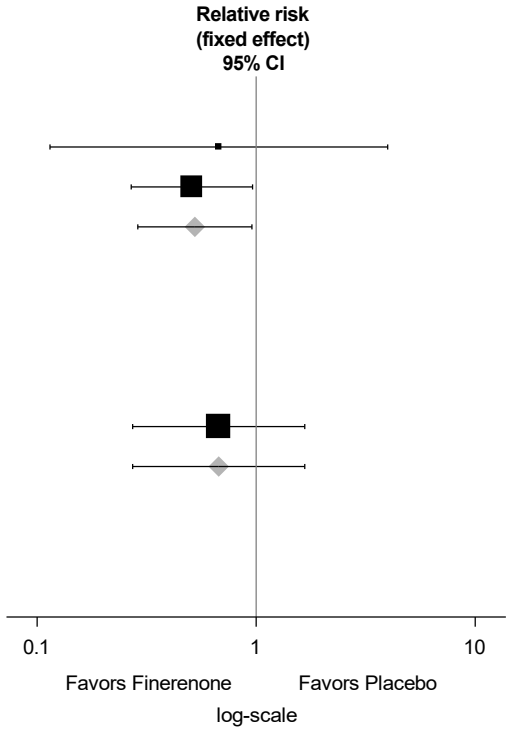
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	2 / 152	8.4	1.09 [0.16,7.66]	
FIGARO-DKD	17 / 1658	31 / 1612	91.6	0.53 [0.30,0.96]	
Total	19 / 1797	33 / 1764		0.56 [0.32,0.99]	Z=-2.00, p=0.0458
Heterogeneity:	Q=0.48 (df=1)	p=0.4886	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,94E295]	
Total	0 / 80	1 / 83		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	3 / 464	5 / 485	100.0	0.63 [0.15,2.61]	
Total	3 / 503	6 / 529		0.53 [0.13,2.09]	Z=-0.91, p=0.3628
Heterogeneity:	Q=0.06 (df=1)	p=0.8105	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	2 / 131	100.0	0.98 [0.14,6.84]	
Total	2 / 156	2 / 147		0.98 [0.14,6.84]	Z=-0.02, p=0.9818
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=3)	p=0.9593	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.12.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

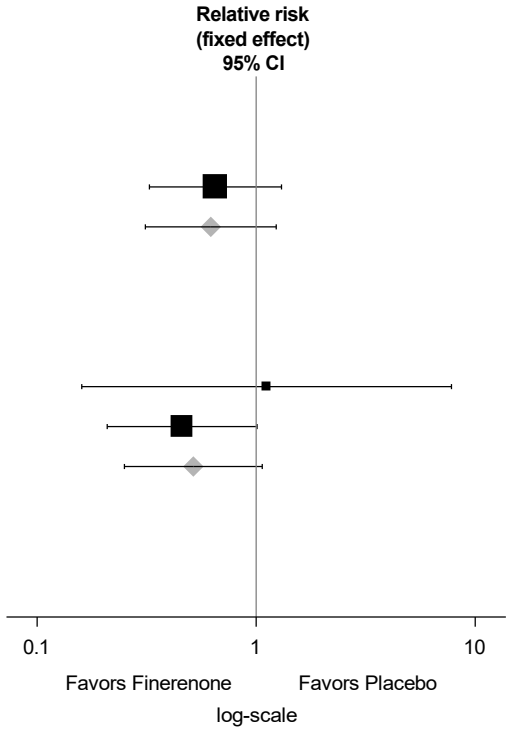
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	11.4	0.68 [0.11,3.99]	
FIGARO-DKD	14 / 1610	28 / 1638	88.6	0.51 [0.27,0.96]	
Total	16 / 1762	31 / 1792		0.52 [0.29,0.96]	Z=-2.11, p=0.0352
Heterogeneity:	Q=0.09 (df=1)	p=0.7683	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	8 / 716	11 / 664	100.0	0.67 [0.27,1.67]	
Total	8 / 774	11 / 731		0.67 [0.27,1.67]	Z=-0.85, p=0.3935
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6508	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.12.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

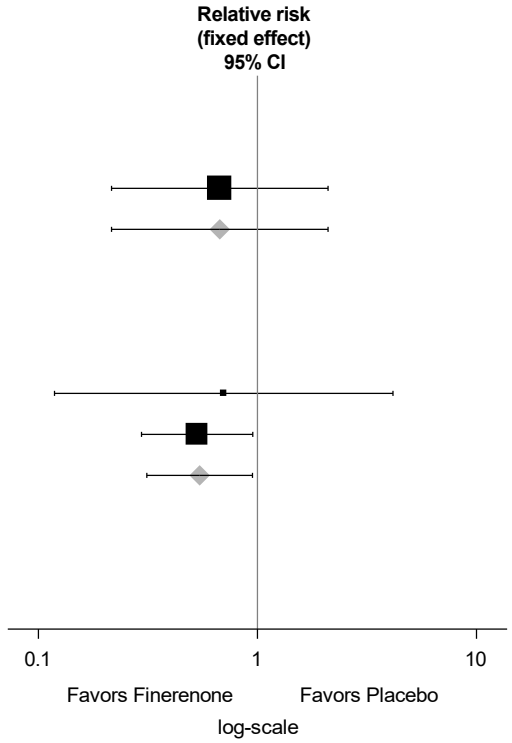
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	1 / 96	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	13 / 1416	20 / 1420	100.0	0.65 [0.33,1.31]	
Total	13 / 1514	21 / 1516		0.62 [0.31,1.23]	Z=-1.36, p=0.1740
Heterogeneity:	Q=0.02 (df=1)	p=0.8896	I^2=0.0%		
>= 65					
FIDELIO-DKD	2 / 112	2 / 125	14.1	1.12 [0.16,7.79]	
FIGARO-DKD	9 / 910	19 / 882	85.9	0.46 [0.21,1.01]	
Total	11 / 1022	21 / 1007		0.52 [0.25,1.07]	Z=-1.79, p=0.0739
Heterogeneity:	Q=0.69 (df=1)	p=0.4062	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7190	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.12.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

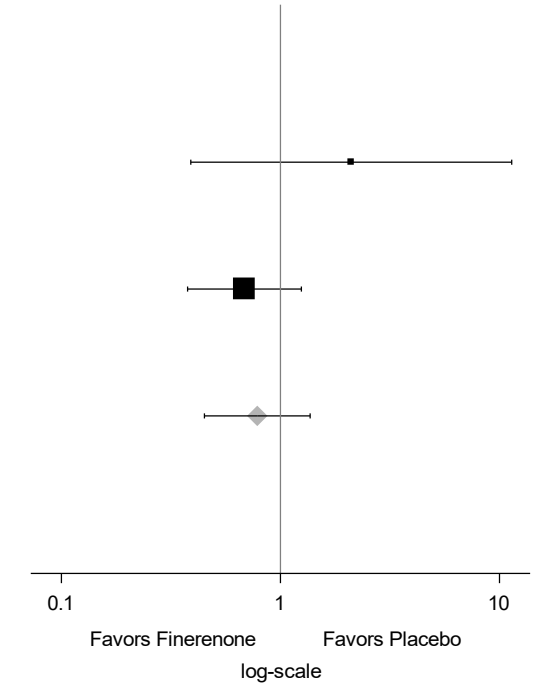
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	7 / 342	100.0	0.67 [0.22,2.10]	
Total	5 / 363	7 / 342		0.67 [0.22,2.10]	Z=-0.68, p=0.4952
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	3 / 221	9.8	0.70 [0.12,4.16]	
FIGARO-DKD	17 / 1963	32 / 1960	90.2	0.53 [0.30,0.95]	
Total	19 / 2173	35 / 2181		0.54 [0.31,0.95]	Z=-2.14, p=0.0320
Heterogeneity:	Q=0.09 (df=1)	p=0.7698	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7433	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.13: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

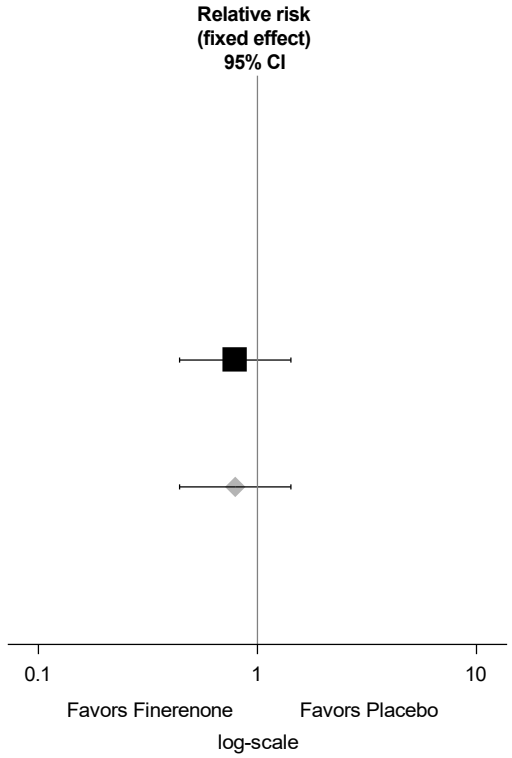
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	11.2	2.10 [0.39,11.37]	
FIGARO-DKD	18 / 2326	26 / 2302	88.8	0.69 [0.38,1.25]	
Total	22 / 2536	28 / 2523		0.78 [0.45,1.37]	Z=-0.86, p=0.3900
Heterogeneity:	Q=1.51 (df=1)	p=0.2189	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.14: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

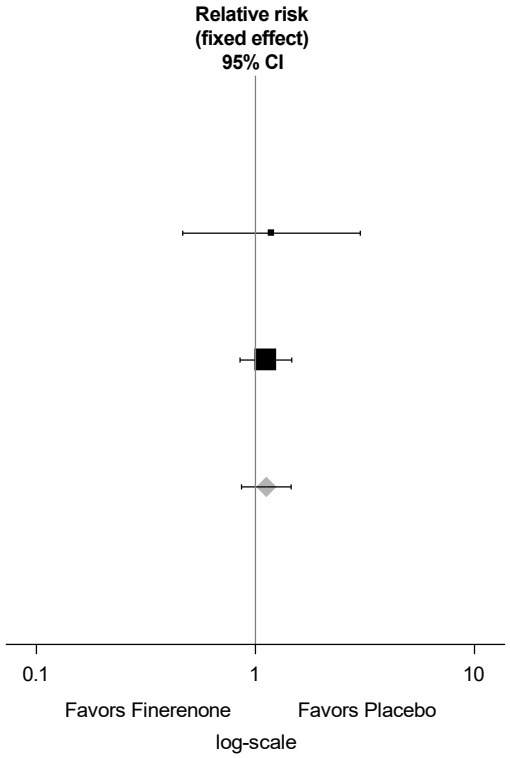
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	20 / 2326	25 / 2302	100.0	0.79 [0.44,1.42]	
Total	20 / 2536	25 / 2523		0.79 [0.44,1.42]	Z=-0.78, p=0.4341
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.15: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

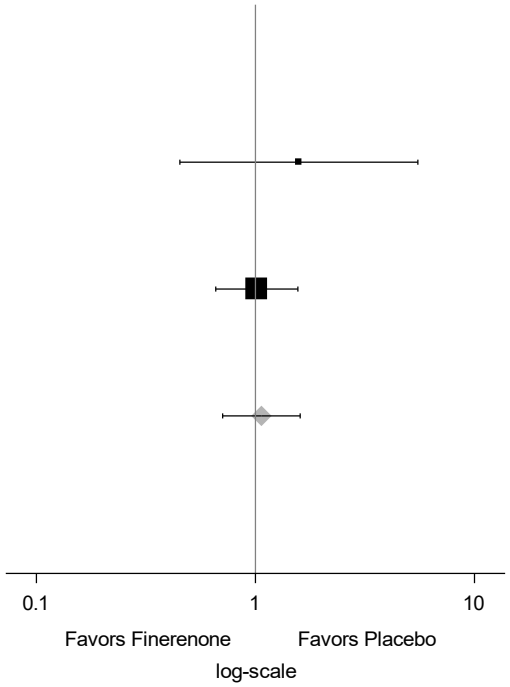
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	8 / 221	7.8	1.18 [0.47,3.01]	
FIGARO-DKD	106 / 2326	94 / 2302	92.2	1.12 [0.85,1.46]	
Total	115 / 2536	102 / 2523		1.12 [0.86,1.46]	Z=0.86, p=0.3900
Heterogeneity:	Q=0.01 (df=1)	p=0.9052	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.16: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

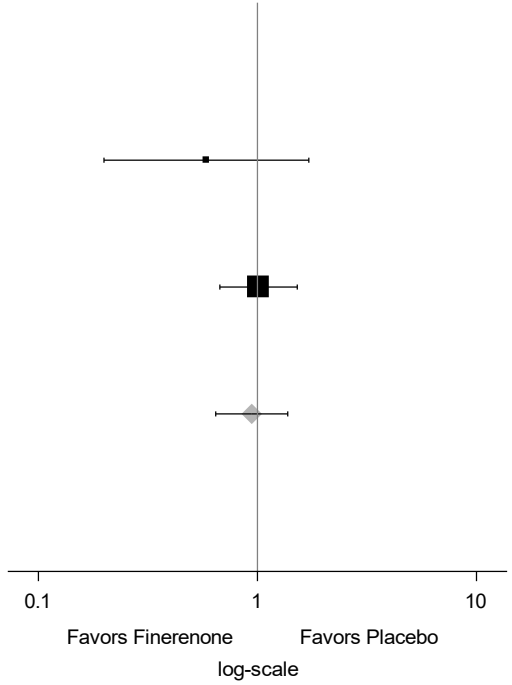
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	4 / 221	10.6	1.58 [0.45,5.52]	
FIGARO-DKD	41 / 2326	40 / 2302	89.4	1.01 [0.66,1.56]	
Total	47 / 2536	44 / 2523		1.06 [0.71,1.60]	Z=0.30, p=0.7633
Heterogeneity:	Q=0.43 (df=1)	p=0.5125	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.17: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

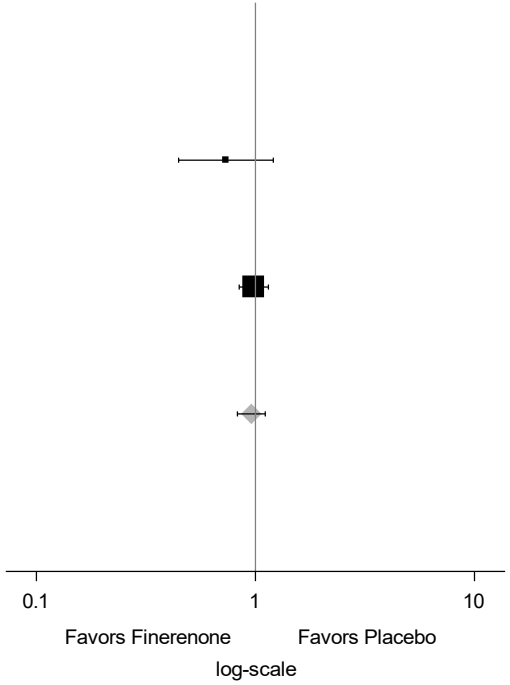
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	9 / 221	12.5	0.58 [0.20,1.72]	
FIGARO-DKD	46 / 2326	45 / 2302	87.5	1.01 [0.67,1.52]	
Total	51 / 2536	54 / 2523		0.94 [0.64,1.37]	Z=-0.31, p=0.7555
Heterogeneity:	Q=0.87 (df=1)	p=0.3504	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.18: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

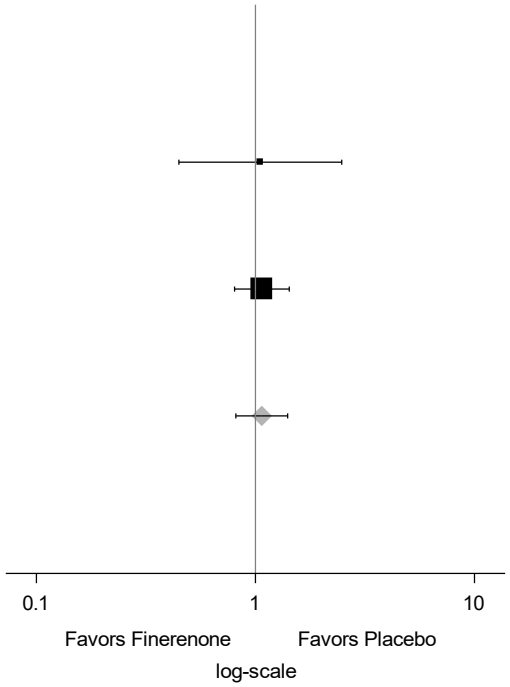
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 210	33 / 221	8.7	0.73 [0.45,1.21]	
FIGARO-DKD	285 / 2326	287 / 2302	91.3	0.98 [0.84,1.15]	
Total	308 / 2536	320 / 2523		0.96 [0.83,1.11]	Z=-0.58, p=0.5623
Heterogeneity:	Q=1.21 (df=1)	p=0.2709	I^2=17.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.19: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

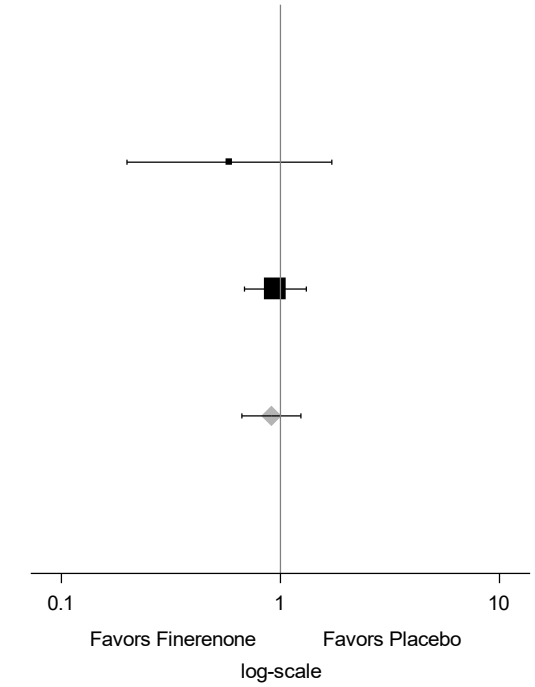
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	10 / 221	10.1	1.05 [0.45,2.48]	
FIGARO-DKD	93 / 2326	86 / 2302	89.9	1.07 [0.80,1.43]	
Total	103 / 2536	96 / 2523		1.07 [0.81,1.40]	Z=0.48, p=0.6341
Heterogeneity:	Q=0.00 (df=1)	p=0.9709	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.20: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

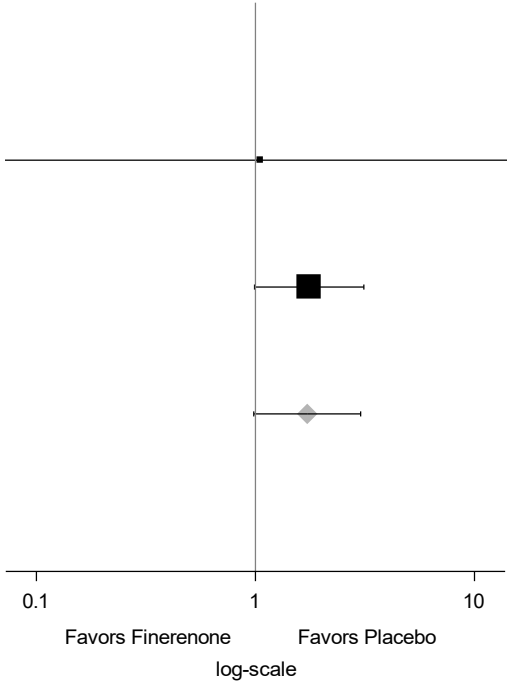
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	9 / 221	8.4	0.58 [0.20,1.72]	
FIGARO-DKD	69 / 2326	72 / 2302	91.6	0.95 [0.69,1.31]	
Total	74 / 2536	81 / 2523		0.91 [0.67,1.24]	Z=-0.60, p=0.5473
Heterogeneity:	Q=0.71 (df=1)	p=0.3992	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.21: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

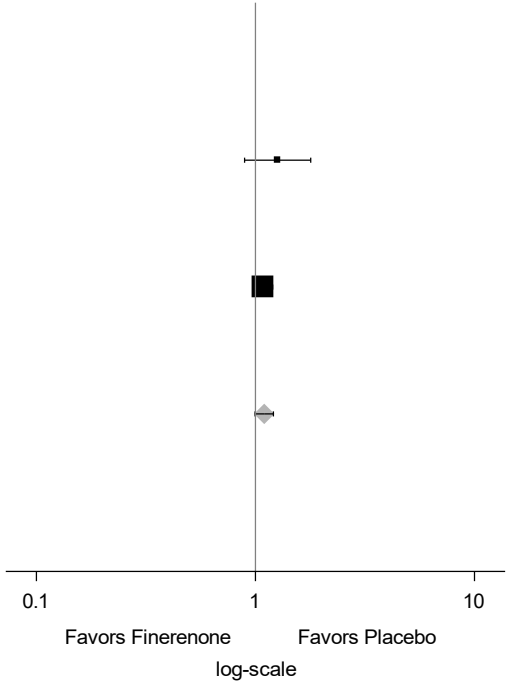
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	1 / 221	4.1	1.05 [0.07,16.72]	
FIGARO-DKD	32 / 2326	18 / 2302	95.9	1.76 [0.99,3.13]	
Total	33 / 2536	19 / 2523		1.72 [0.98,3.02]	Z=1.90, p=0.0576
Heterogeneity:	Q=0.13 (df=1)	p=0.7214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.22: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

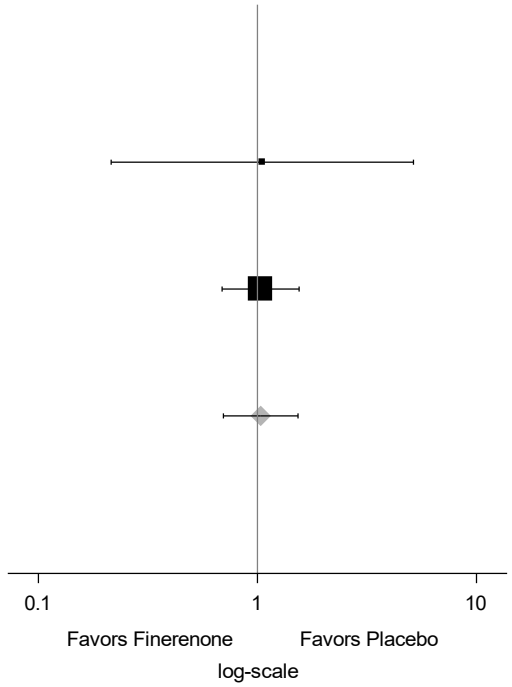
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 210	45 / 221	7.7	1.26 [0.89,1.79]	
FIGARO-DKD	600 / 2326	548 / 2302	92.3	1.08 [0.98,1.20]	
Total	654 / 2536	593 / 2523		1.10 [1.00,1.21]	Z=1.87, p=0.0612
Heterogeneity:	Q=0.69 (df=1)	p=0.4069	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.23: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

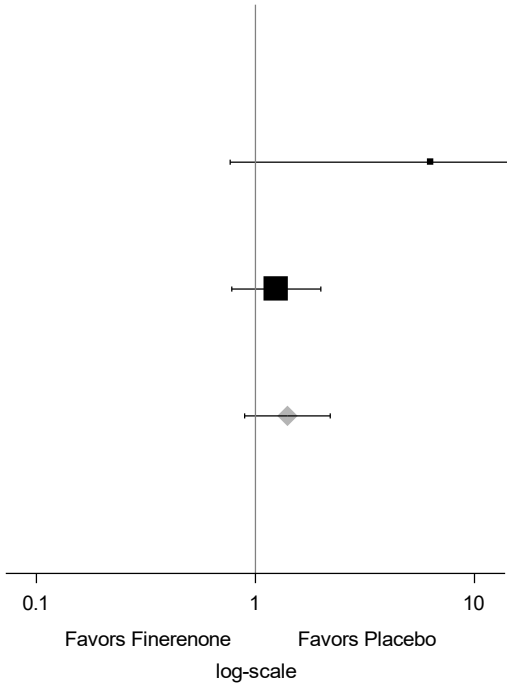
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	6.1	1.05 [0.21,5.16]	
FIGARO-DKD	47 / 2326	45 / 2302	93.9	1.03 [0.69,1.55]	
Total	50 / 2536	48 / 2523		1.03 [0.70,1.53]	Z=0.17, p=0.8643
Heterogeneity:	Q=0.00 (df=1)	p=0.9829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.24: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

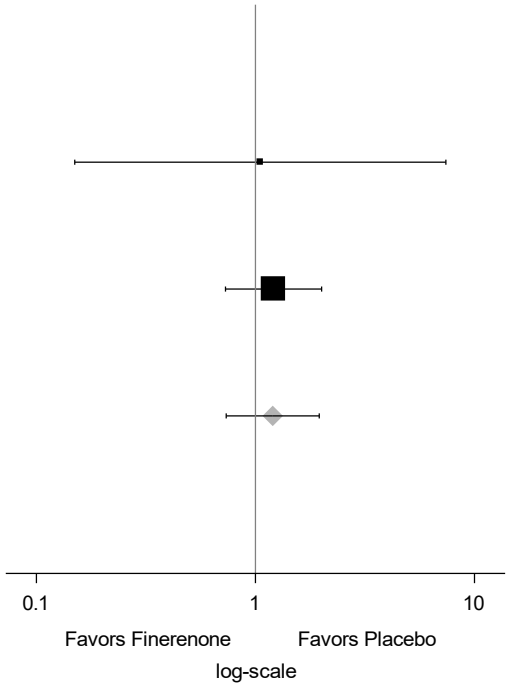
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	1 / 221	4.7	6.31 [0.77,52.01]	
FIGARO-DKD	39 / 2326	31 / 2302	95.3	1.25 [0.78,1.99]	
Total	45 / 2536	32 / 2523		1.40 [0.89,2.20]	Z=1.47, p=0.1429
Heterogeneity:	Q=2.20 (df=1)	p=0.1379	I^2=54.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.25: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

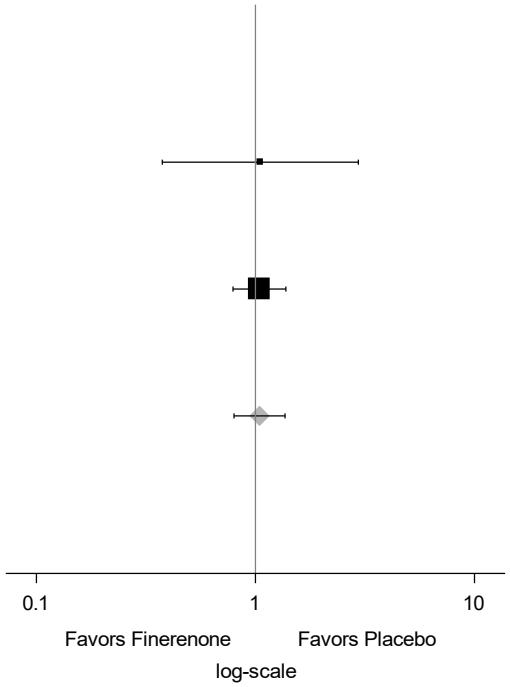
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	6.3	1.05 [0.15,7.40]	
FIGARO-DKD	33 / 2326	27 / 2302	93.7	1.21 [0.73,2.00]	
Total	35 / 2536	29 / 2523		1.20 [0.74,1.96]	Z=0.73, p=0.4668
Heterogeneity:	Q=0.02 (df=1)	p=0.8923	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.26: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

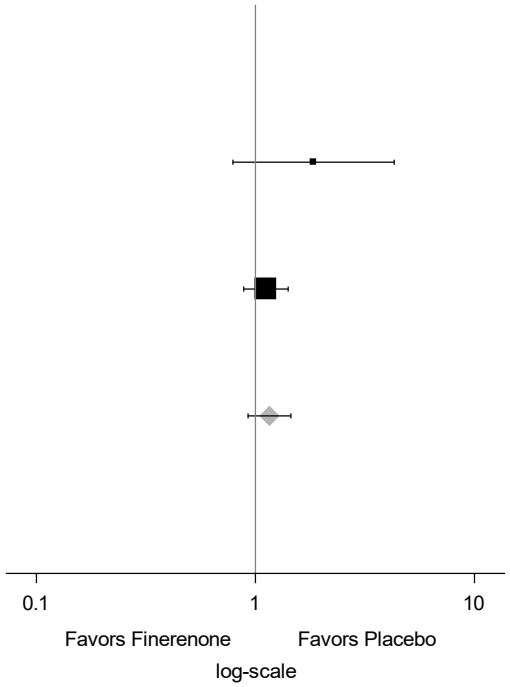
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	7 / 221	6.8	1.05 [0.38,2.95]	
FIGARO-DKD	98 / 2326	93 / 2302	93.2	1.04 [0.79,1.38]	
Total	105 / 2536	100 / 2523		1.04 [0.80,1.36]	Z=0.31, p=0.7555
Heterogeneity:	Q=0.00 (df=1)	p=0.9867	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.27: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

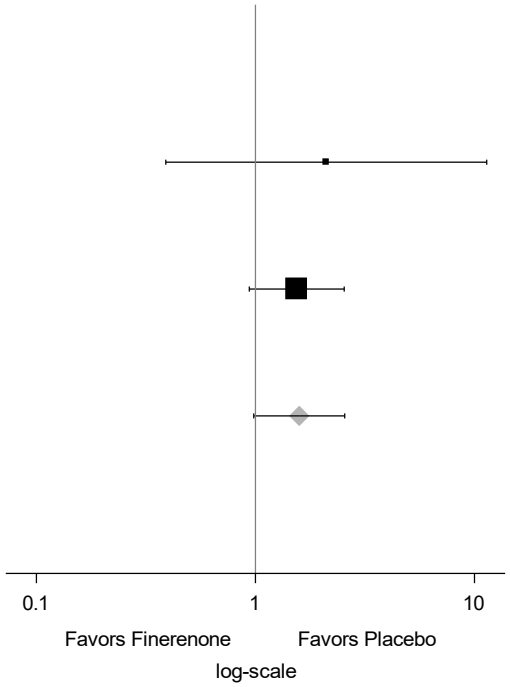
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	8 / 221	7.1	1.84 [0.79,4.30]	
FIGARO-DKD	141 / 2326	125 / 2302	92.9	1.12 [0.88,1.41]	
Total	155 / 2536	133 / 2523		1.16 [0.93,1.45]	Z=1.28, p=0.1998
Heterogeneity:	Q=1.24 (df=1)	p=0.2646	I^2=19.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.28: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

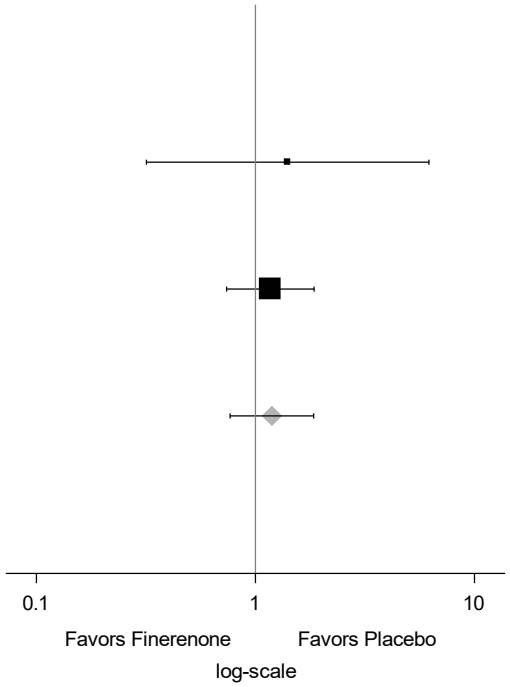
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	8.0	2.10 [0.39,11.37]	
FIGARO-DKD	39 / 2326	25 / 2302	92.0	1.54 [0.94,2.54]	
Total	43 / 2536	27 / 2523		1.58 [0.98,2.56]	Z=1.89, p=0.0592
Heterogeneity:	Q=0.12 (df=1)	p=0.7299	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.29: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

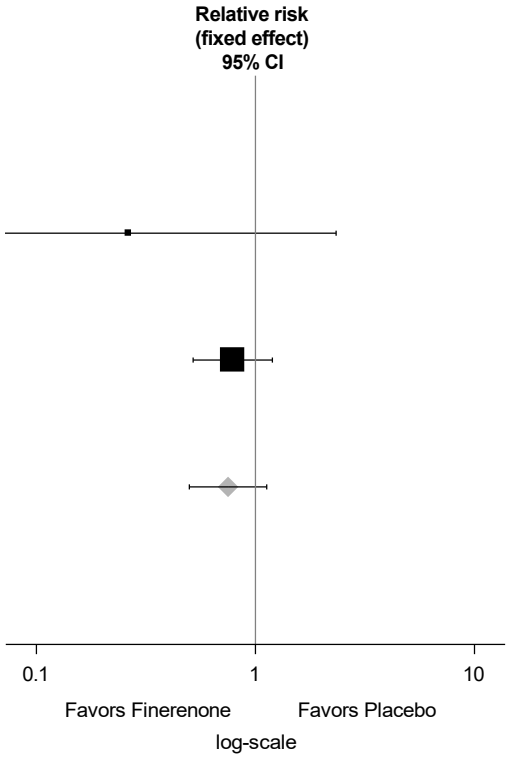
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.8	1.40 [0.32,6.19]	
FIGARO-DKD	39 / 2326	33 / 2302	91.2	1.17 [0.74,1.85]	
Total	43 / 2536	36 / 2523		1.19 [0.77,1.84]	Z=0.77, p=0.4408
Heterogeneity:	Q=0.05 (df=1)	p=0.8185	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.30: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

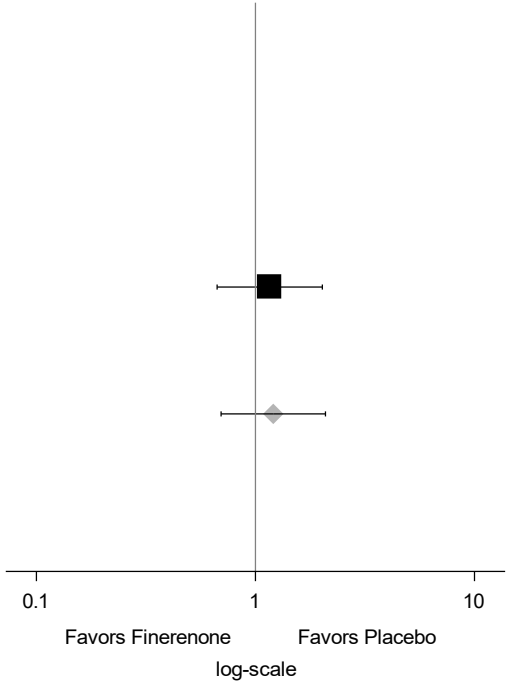
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	3.5	0.26 [0.03,2.33]	
FIGARO-DKD	39 / 2326	49 / 2302	96.5	0.79 [0.52,1.19]	
Total	40 / 2536	53 / 2523		0.75 [0.50,1.13]	Z=-1.39, p=0.1650
Heterogeneity:	Q=0.94 (df=1)	p=0.3328	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.31: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

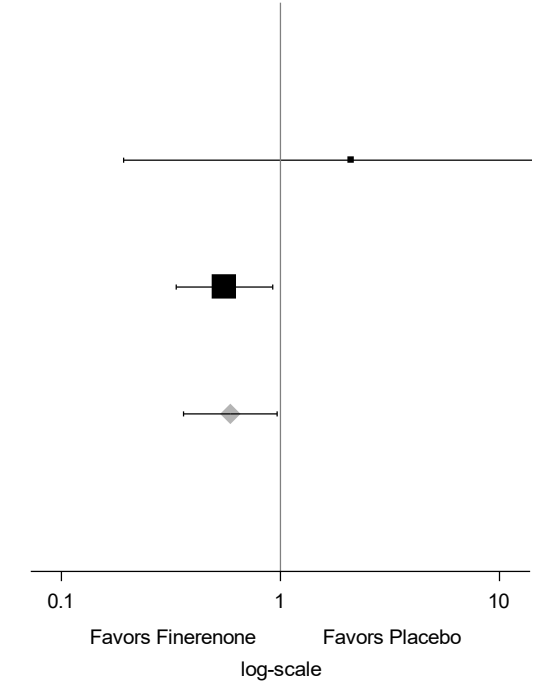
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	0 / 221	0.0	183E9 [183E9,183E9]	
FIGARO-DKD	27 / 2326	23 / 2302	100.0	1.16 [0.67,2.02]	
Total	28 / 2536	23 / 2523		1.21 [0.70,2.09]	Z=0.67, p=0.5036
Heterogeneity:	Q=0.02 (df=1)	p=0.8950	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.32: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

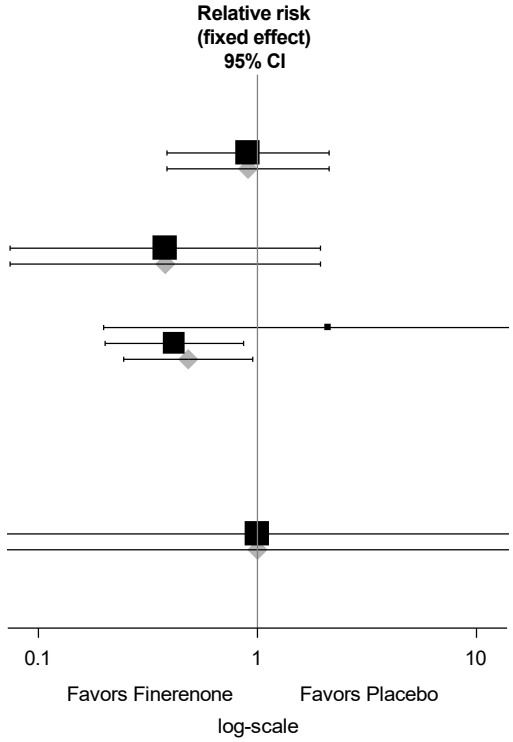
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.3	2.10 [0.19,23.04]	
FIGARO-DKD	23 / 2326	41 / 2302	95.7	0.56 [0.33,0.92]	
Total	25 / 2536	42 / 2523		0.59 [0.36,0.97]	Z=-2.10, p=0.0358
Heterogeneity:	Q=1.14 (df=1)	p=0.2856	I^2=12.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.32.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

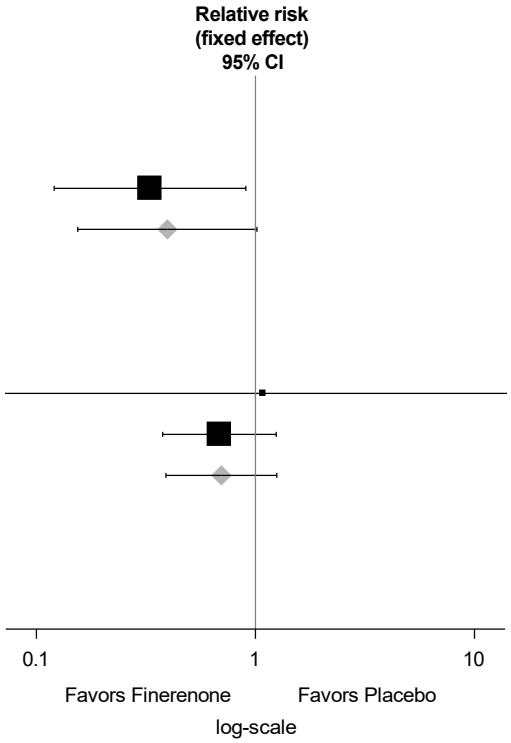
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	10 / 1114	11 / 1110	100.0	0.91 [0.39,2.12]	
Total	10 / 1217	11 / 1222		0.91 [0.39,2.12]	Z=-0.23, p=0.8201
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	2 / 292	5 / 277	100.0	0.38 [0.07,1.94]	
Total	2 / 334	5 / 317		0.38 [0.07,1.94]	Z=-1.16, p=0.2444
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	1 / 41	8.7	2.10 [0.20,22.27]	
FIGARO-DKD	10 / 522	24 / 523	91.3	0.42 [0.20,0.86]	
Total	12 / 561	25 / 564		0.48 [0.25,0.95]	Z=-2.10, p=0.0355
Heterogeneity:	Q=1.65 (df=1)	p=0.1995	I^2=39.3%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	0 / 316	0.0	-	
Total	0 / 343	0 / 340		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	1 / 76	100.0	1.00 [0.06,15.70]	
Total	1 / 81	1 / 80		1.00 [0.06,15.70]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.73 (df=4)	p=0.7862	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.32.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

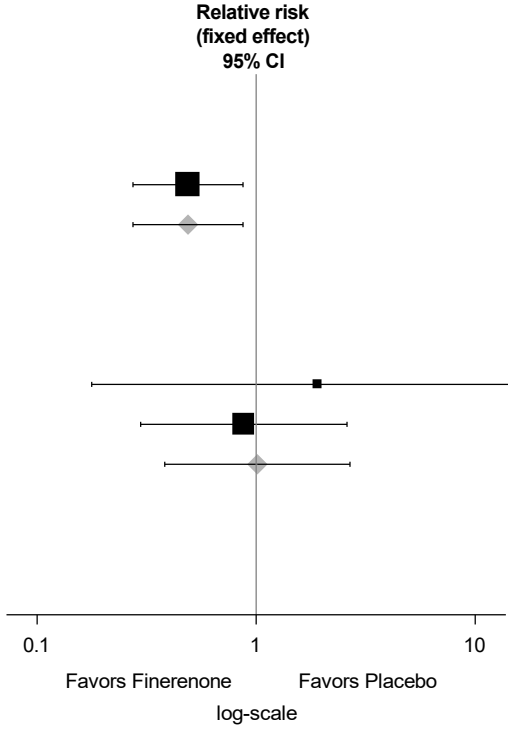
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	0 / 89	0.0	161E9 [161E9,161E9]	
FIGARO-DKD	5 / 811	15 / 803	100.0	0.33 [0.12,0.90]	
Total	6 / 899	15 / 892		0.40 [0.15,1.02]	Z=-1.93, p=0.0540
Heterogeneity:	Q=0.13 (df=1)	p=0.7227	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	1 / 132	4.5	1.08 [0.07,17.11]	
FIGARO-DKD	18 / 1515	26 / 1499	95.5	0.68 [0.38,1.24]	
Total	19 / 1637	27 / 1631		0.70 [0.39,1.25]	Z=-1.20, p=0.2283
Heterogeneity:	Q=0.10 (df=1)	p=0.7511	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.01 (df=1)	p=0.3151	I^2=0.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.32.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

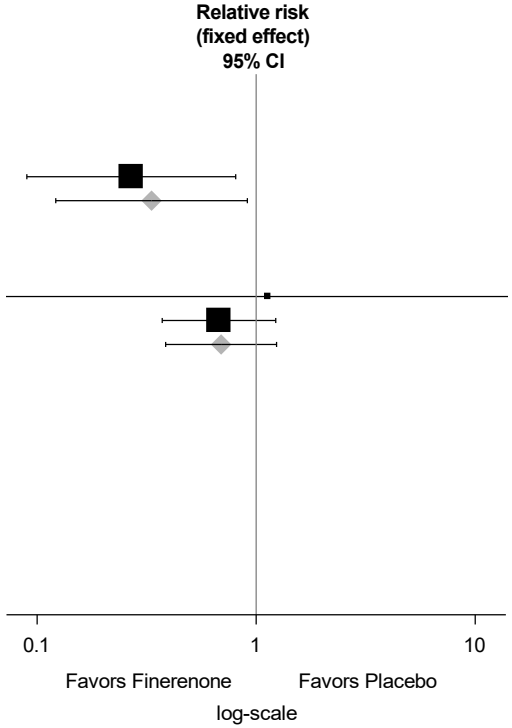
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	0 / 158	0.0	-	
FIGARO-DKD	17 / 1719	34 / 1679	100.0	0.49 [0.27,0.87]	
Total	17 / 1863	34 / 1837		0.49 [0.27,0.87]	Z=-2.43, p=0.0151
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
> 4.5					
FIDELIO-DKD	2 / 66	1 / 63	17.3	1.91 [0.18,20.53]	
FIGARO-DKD	6 / 607	7 / 622	82.7	0.88 [0.30,2.60]	
Total	8 / 673	8 / 685		1.01 [0.38,2.68]	Z=0.03, p=0.9798
Heterogeneity:	Q=0.34 (df=1)	p=0.5599	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.59 (df=1)	p=0.2069	I^2=37.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.32.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

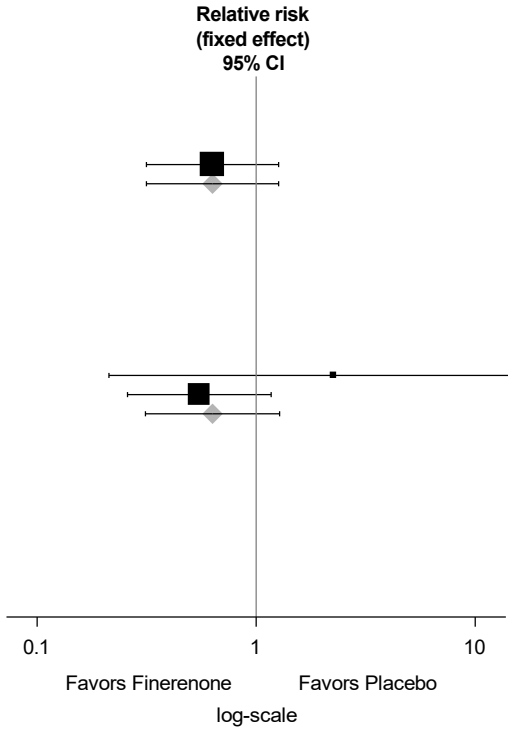
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	814E8 [814E8,814E8]	
FIGARO-DKD	4 / 693	15 / 699	100.0	0.27 [0.09,0.81]	
Total	5 / 757	15 / 753		0.33 [0.12,0.91]	Z=-2.14, p=0.0323
Heterogeneity:	Q=0.14 (df=1)	p=0.7035	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	1 / 156	4.5	1.13 [0.07,17.90]	
FIGARO-DKD	18 / 1560	26 / 1524	95.5	0.68 [0.37,1.23]	
Total	19 / 1698	27 / 1680		0.69 [0.39,1.24]	Z=-1.24, p=0.2152
Heterogeneity:	Q=0.13 (df=1)	p=0.7217	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	0 / 79	0.0	194E9 [194E9,194E9]	
Total	1 / 81	0 / 90		2.02E7 [2.02E7,2.02E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.52 (df=2)	p=0.4684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.32.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

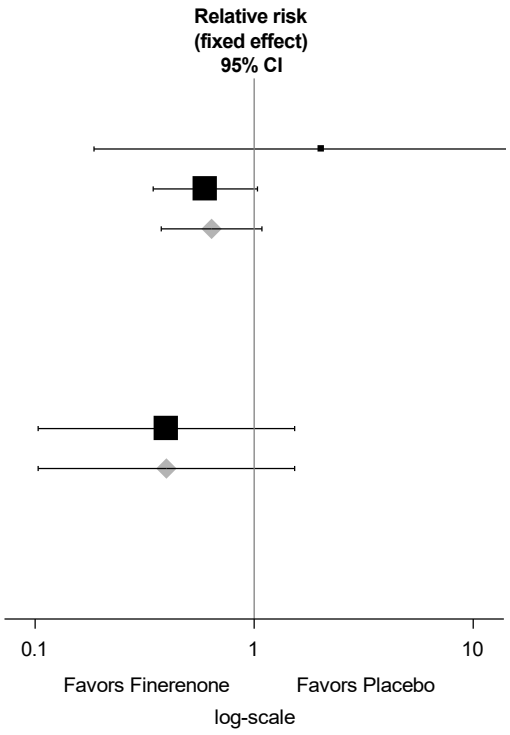
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	13 / 1658	20 / 1612	100.0	0.63 [0.32,1.27]	
Total	13 / 1797	20 / 1764		0.63 [0.32,1.27]	Z=-1.29, p=0.1955
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,94E295]	
Total	0 / 80	1 / 83		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	2 / 39	1 / 44	9.3	2.26 [0.21,23.93]	
FIGARO-DKD	10 / 464	19 / 485	90.7	0.55 [0.26,1.17]	
Total	12 / 503	20 / 529		0.63 [0.31,1.28]	Z=-1.28, p=0.2022
Heterogeneity:	Q=1.25 (df=1)	p=0.2644	I^2=19.7%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,17E296]	
Total	0 / 156	1 / 147		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.00 (df=3)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.32.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

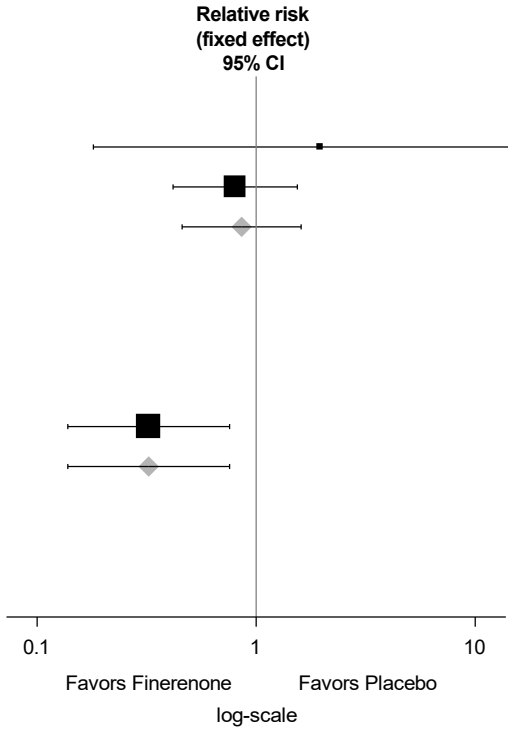
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	1 / 154	5.0	2.03 [0.19,22.11]	
FIGARO-DKD	20 / 1610	34 / 1638	95.0	0.60 [0.35,1.04]	
Total	22 / 1762	35 / 1792		0.64 [0.38,1.08]	Z=-1.66, p=0.0973
Heterogeneity:	Q=0.95 (df=1)	p=0.3295	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	3 / 716	7 / 664	100.0	0.40 [0.10,1.53]	
Total	3 / 774	7 / 731		0.40 [0.10,1.53]	Z=-1.34, p=0.1799
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.32.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

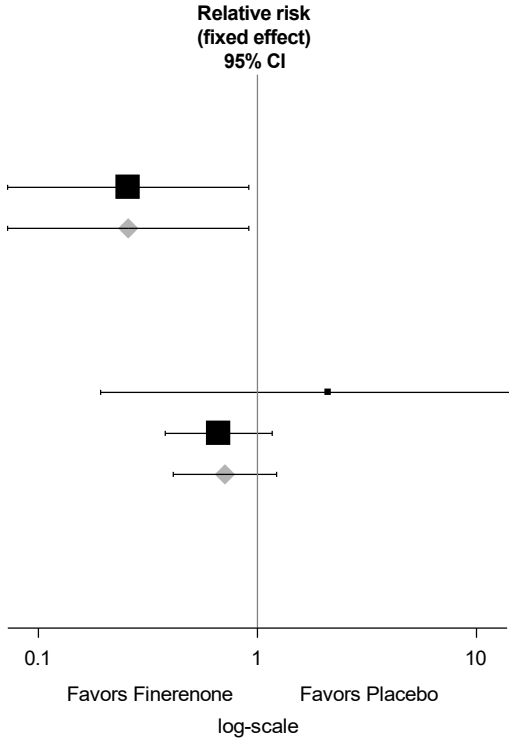
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	1 / 96	7.0	1.96 [0.18,21.25]	
FIGARO-DKD	16 / 1416	20 / 1420	93.0	0.80 [0.42,1.54]	
Total	18 / 1514	21 / 1516		0.86 [0.46,1.60]	Z=-0.48, p=0.6317
Heterogeneity:	Q=0.50 (df=1)	p=0.4789	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	0 / 125	0.0	-	
FIGARO-DKD	7 / 910	21 / 882	100.0	0.32 [0.14,0.76]	
Total	7 / 1022	21 / 1007		0.32 [0.14,0.76]	Z=-2.60, p=0.0092
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.29 (df=1)	p=0.0697	I^2=69.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.32.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

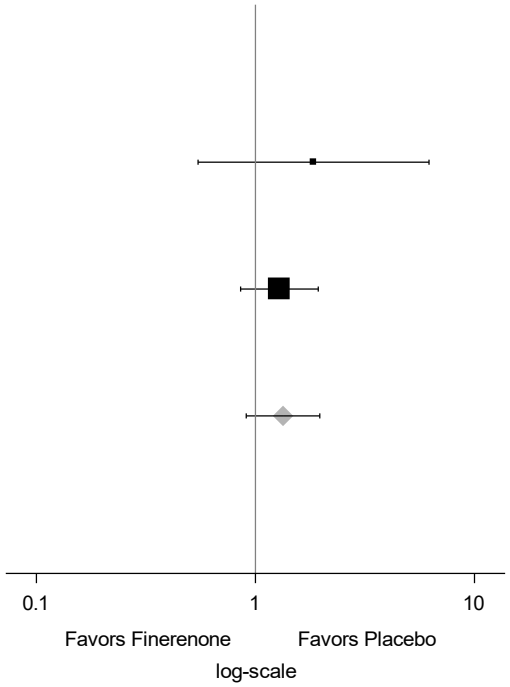
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	3 / 363	11 / 342	100.0	0.26 [0.07,0.91]	
Total	3 / 363	11 / 342		0.26 [0.07,0.91]	Z=-2.10, p=0.0357
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	1 / 221	5.2	2.10 [0.19,23.04]	
FIGARO-DKD	20 / 1963	30 / 1960	94.8	0.67 [0.38,1.17]	
Total	22 / 2173	31 / 2181		0.71 [0.41,1.22]	Z=-1.23, p=0.2173
Heterogeneity:	Q=0.84 (df=1)	p=0.3586	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1485	I^2=52.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.33: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

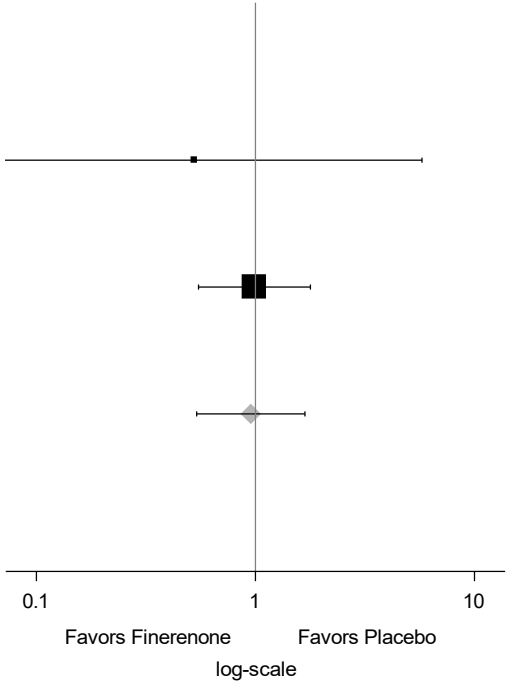
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	4 / 221	10.2	1.84 [0.55,6.20]	
FIGARO-DKD	52 / 2326	40 / 2302	89.8	1.29 [0.86,1.94]	
Total	59 / 2536	44 / 2523		1.34 [0.91,1.97]	Z=1.47, p=0.1417
Heterogeneity:	Q=0.30 (df=1)	p=0.5830	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.34: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Toothache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

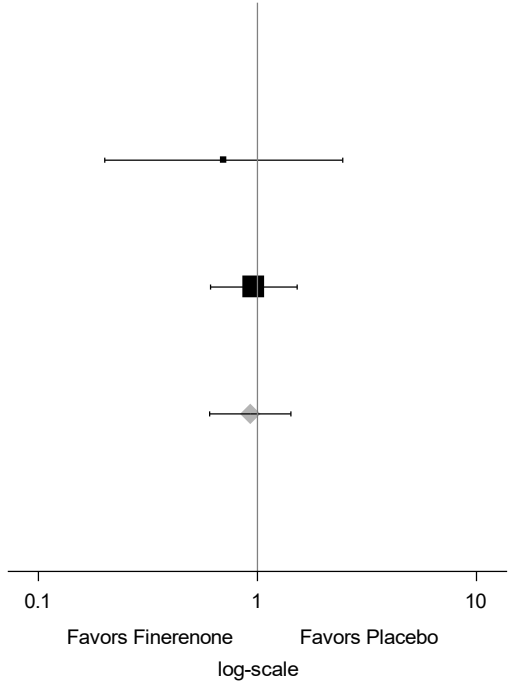
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	2 / 221	5.7	0.53 [0.05,5.76]	
FIGARO-DKD	22 / 2326	22 / 2302	94.3	0.99 [0.55,1.78]	
Total	23 / 2536	24 / 2523		0.95 [0.54,1.68]	Z=-0.17, p=0.8662
Heterogeneity:	Q=0.25 (df=1)	p=0.6153	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.35: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

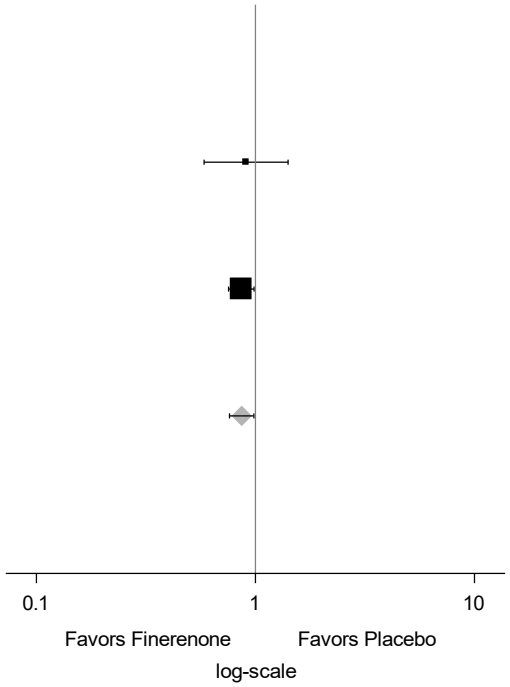
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	6 / 221	11.7	0.70 [0.20,2.45]	
FIGARO-DKD	36 / 2326	37 / 2302	88.3	0.96 [0.61,1.52]	
Total	40 / 2536	43 / 2523		0.93 [0.61,1.42]	Z=-0.35, p=0.7287
Heterogeneity:	Q=0.22 (df=1)	p=0.6411	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.36: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

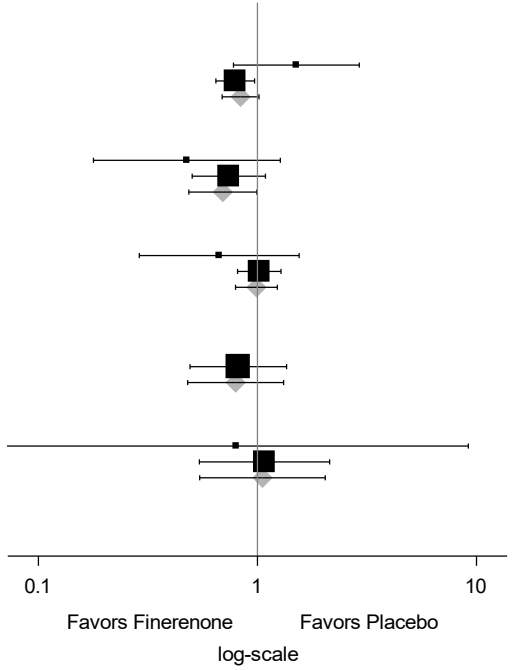
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 210	36 / 221	8.5	0.91 [0.58,1.41]	
FIGARO-DKD	337 / 2326	387 / 2302	91.5	0.86 [0.75,0.99]	
Total	368 / 2536	423 / 2523		0.87 [0.76,0.98]	Z=-2.21, p=0.0274
Heterogeneity:	Q=0.05 (df=1)	p=0.8310	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.36.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 103	13 / 112	8.6	1.51 [0.78,2.92]	
FIGARO-DKD	143 / 1114	180 / 1110	91.4	0.79 [0.65,0.97]	
Total	161 / 1217	193 / 1222		0.84 [0.69,1.02]	Z=-1.80, p=0.0725
Heterogeneity:	Q=3.32 (df=1)	p=0.0685	I^2=69.9%		
North America					
FIDELIO-DKD	5 / 42	10 / 40	13.3	0.48 [0.18,1.27]	
FIGARO-DKD	39 / 292	50 / 277	86.7	0.74 [0.50,1.09]	
Total	44 / 334	60 / 317		0.69 [0.49,0.99]	Z=-2.00, p=0.0458
Heterogeneity:	Q=0.67 (df=1)	p=0.4128	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 39	11 / 41	6.9	0.67 [0.29,1.55]	
FIGARO-DKD	116 / 522	114 / 523	93.1	1.02 [0.81,1.28]	
Total	123 / 561	125 / 564		0.99 [0.79,1.23]	Z=-0.10, p=0.9226
Heterogeneity:	Q=0.90 (df=1)	p=0.3429	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,83E295]	
FIGARO-DKD	25 / 322	30 / 316	100.0	0.82 [0.49,1.36]	
Total	25 / 343	31 / 340		0.80 [0.48,1.32]	Z=-0.89, p=0.3727
Heterogeneity:	Q=0.01 (df=1)	p=0.9134	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	7.3	0.80 [0.07,9.18]	
FIGARO-DKD	14 / 76	13 / 76	92.7	1.08 [0.54,2.14]	
Total	15 / 81	14 / 80		1.05 [0.54,2.04]	Z=0.16, p=0.8757
Heterogeneity:	Q=0.05 (df=1)	p=0.8182	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.43 (df=4)	p=0.4889	I^2=0.0%		

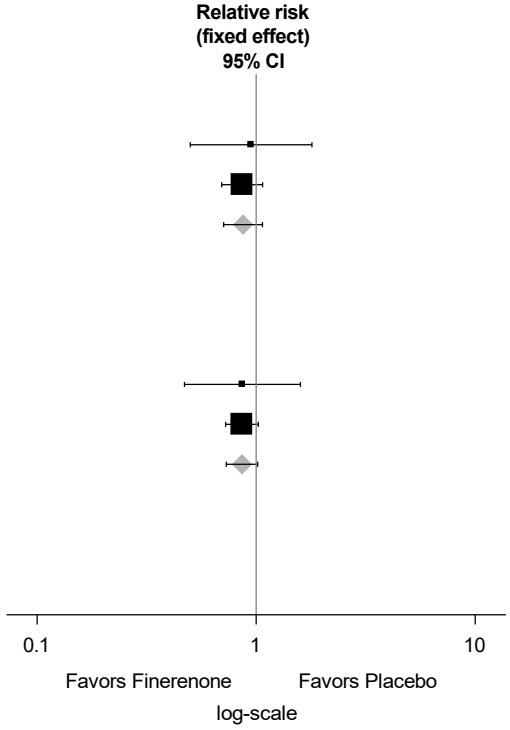


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.36.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

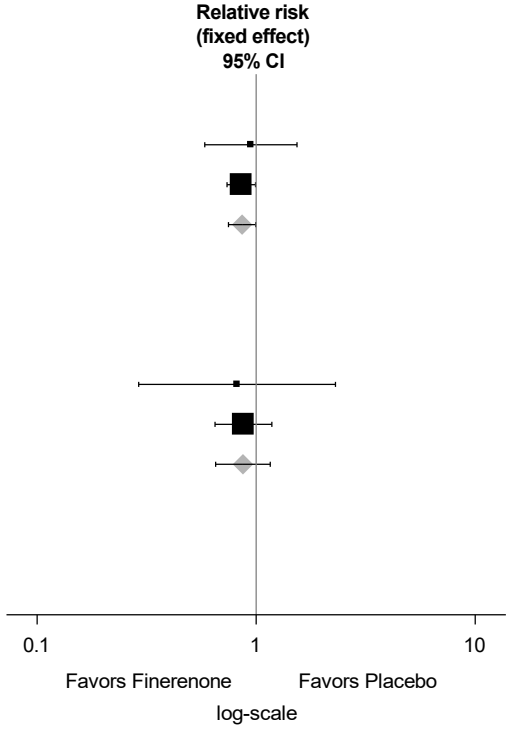
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 88	16 / 89	10.1	0.95 [0.50,1.80]	
FIGARO-DKD	129 / 811	148 / 803	89.9	0.86 [0.70,1.07]	
Total	144 / 899	164 / 892		0.87 [0.71,1.07]	Z=-1.33, p=0.1850
Heterogeneity:	Q=0.07 (df=1)	p=0.7847	I^2=0.0%		
Absent					
FIDELIO-DKD	16 / 122	20 / 132	7.3	0.87 [0.47,1.59]	
FIGARO-DKD	208 / 1515	239 / 1499	92.7	0.86 [0.73,1.02]	
Total	224 / 1637	259 / 1631		0.86 [0.73,1.02]	Z=-1.77, p=0.0767
Heterogeneity:	Q=0.00 (df=1)	p=0.9872	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9324	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.36.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

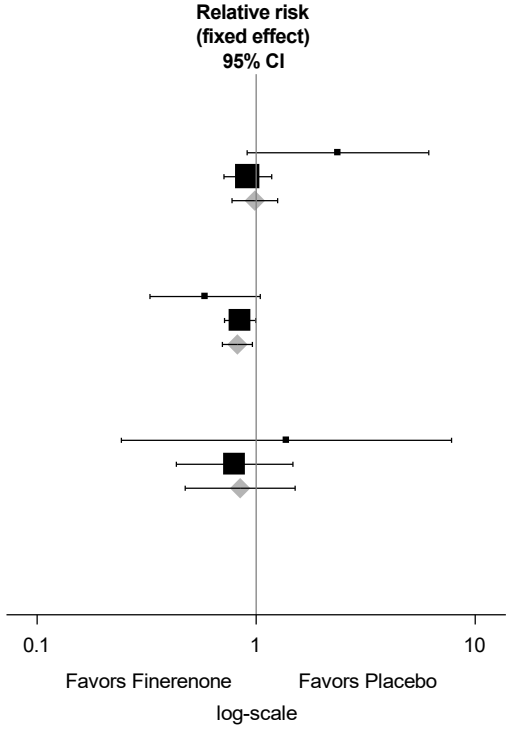
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	29 / 158	8.7	0.95 [0.58,1.54]	
FIGARO-DKD	267 / 1719	305 / 1679	91.3	0.86 [0.74,0.99]	
Total	292 / 1863	334 / 1837		0.86 [0.75,1.00]	Z=-2.02, p=0.0430
Heterogeneity:	Q=0.15 (df=1)	p=0.6966	I^2=0.0%		
> 4.5					
FIDELIO-DKD	6 / 66	7 / 63	7.7	0.82 [0.29,2.30]	
FIGARO-DKD	70 / 607	82 / 622	92.3	0.87 [0.65,1.18]	
Total	76 / 673	89 / 685		0.87 [0.65,1.16]	Z=-0.95, p=0.3426
Heterogeneity:	Q=0.01 (df=1)	p=0.9031	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9567	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.36.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

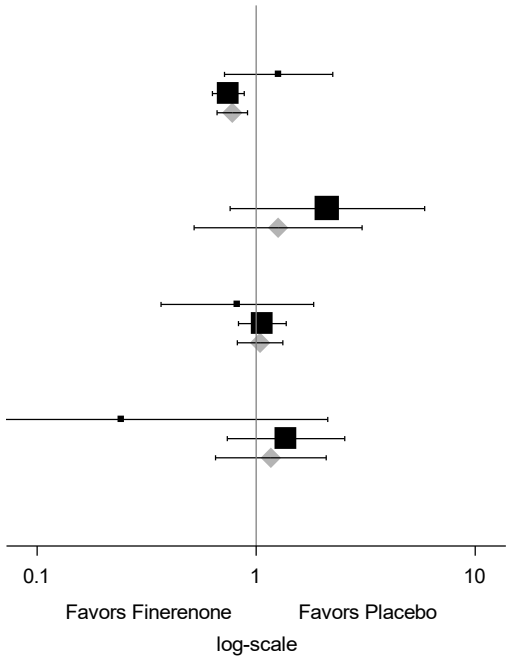
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 64	5 / 54	6.5	2.36 [0.91,6.14]	
FIGARO-DKD	99 / 693	109 / 699	93.5	0.92 [0.71,1.18]	
Total	113 / 757	114 / 753		0.99 [0.78,1.25]	Z=-0.12, p=0.9077
Heterogeneity:	Q=3.55 (df=1)	p=0.0596	I^2=71.8%		
130 - < 160					
FIDELIO-DKD	15 / 138	29 / 156	7.4	0.58 [0.33,1.04]	
FIGARO-DKD	224 / 1560	259 / 1524	92.6	0.84 [0.72,1.00]	
Total	239 / 1698	288 / 1680		0.82 [0.70,0.96]	Z=-2.45, p=0.0141
Heterogeneity:	Q=1.43 (df=1)	p=0.2311	I^2=30.3%		
>= 160					
FIDELIO-DKD	2 / 8	2 / 11	11.1	1.37 [0.24,7.80]	
FIGARO-DKD	14 / 73	19 / 79	88.9	0.80 [0.43,1.47]	
Total	16 / 81	21 / 90		0.85 [0.47,1.51]	Z=-0.57, p=0.5682
Heterogeneity:	Q=0.34 (df=1)	p=0.5617	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.57 (df=2)	p=0.4552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.36.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

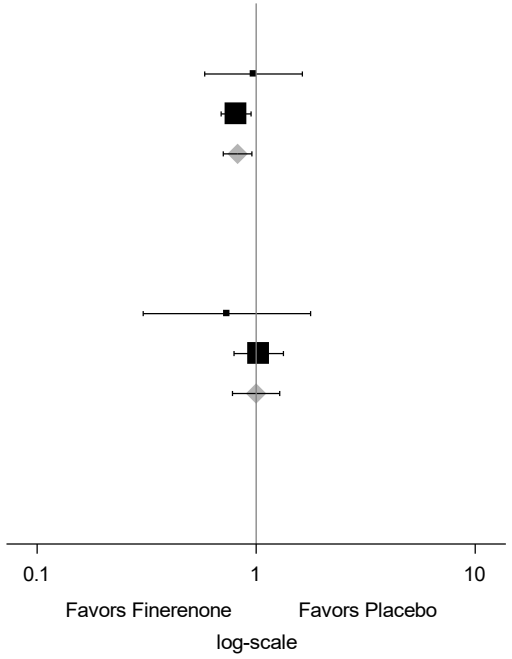
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 139	19 / 152	7.9	1.27 [0.72,2.24]	
FIGARO-DKD	208 / 1658	271 / 1612	92.1	0.75 [0.63,0.88]	
Total	230 / 1797	290 / 1764		0.78 [0.66,0.91]	Z=-3.07, p=0.0021
Heterogeneity:	Q=3.05 (df=1)	p=0.0806	I^2=67.2%		
Black					
FIDELIO-DKD	0 / 10	3 / 9	0.0	0.00 [0.00,28E295]	
FIGARO-DKD	10 / 70	5 / 74	100.0	2.11 [0.76,5.88]	
Total	10 / 80	8 / 83		1.26 [0.52,3.04]	Z=0.51, p=0.6087
Heterogeneity:	Q=0.99 (df=1)	p=0.3207	I^2=0.0%		
Asian					
FIDELIO-DKD	8 / 39	11 / 44	8.9	0.82 [0.37,1.83]	
FIGARO-DKD	98 / 464	96 / 485	91.1	1.07 [0.83,1.37]	
Total	106 / 503	107 / 529		1.04 [0.82,1.32]	Z=0.34, p=0.7369
Heterogeneity:	Q=0.38 (df=1)	p=0.5402	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	3 / 16	7.5	0.24 [0.03,2.12]	
FIGARO-DKD	21 / 134	15 / 131	92.5	1.37 [0.74,2.54]	
Total	22 / 156	18 / 147		1.17 [0.65,2.09]	Z=0.52, p=0.6027
Heterogeneity:	Q=2.27 (df=1)	p=0.1318	I^2=56.0%		
Subgroup Heterogeneity:	Q=5.71 (df=3)	p=0.1267	I^2=47.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.36.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

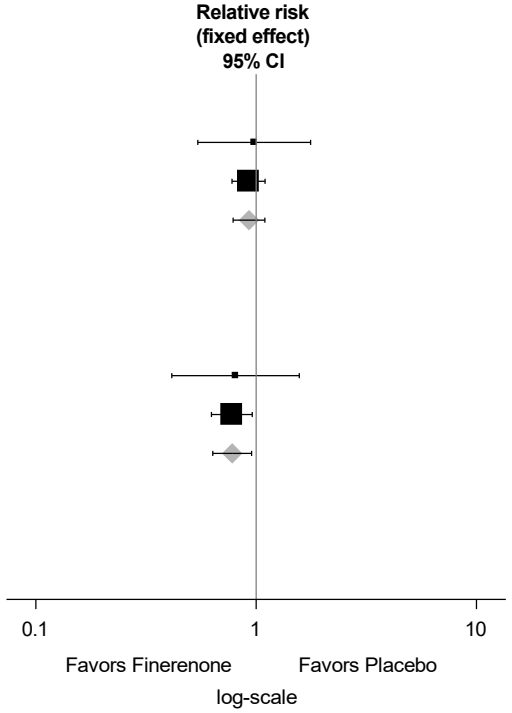
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 152	25 / 154	8.6	0.97 [0.58,1.63]	
FIGARO-DKD	234 / 1610	294 / 1638	91.4	0.81 [0.69,0.95]	
Total	258 / 1762	319 / 1792		0.82 [0.71,0.96]	Z=-2.55, p=0.0109
Heterogeneity:	Q=0.45 (df=1)	p=0.5035	I^2=0.0%		
Female					
FIDELIO-DKD	7 / 58	11 / 67	8.0	0.74 [0.30,1.77]	
FIGARO-DKD	103 / 716	93 / 664	92.0	1.03 [0.79,1.33]	
Total	110 / 774	104 / 731		1.00 [0.78,1.28]	Z=-0.01, p=0.9944
Heterogeneity:	Q=0.51 (df=1)	p=0.4749	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.72 (df=1)	p=0.1892	I^2=42.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.36.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

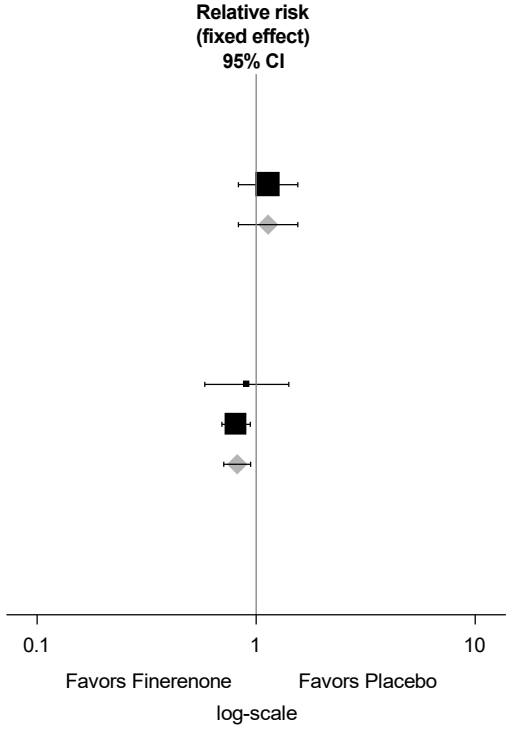
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 98	18 / 96	7.9	0.98 [0.54,1.77]	
FIGARO-DKD	209 / 1416	227 / 1420	92.1	0.92 [0.78,1.10]	
Total	227 / 1514	245 / 1516		0.93 [0.79,1.10]	Z=-0.89, p=0.3748
Heterogeneity:	Q=0.04 (df=1)	p=0.8503	I^2=0.0%		
>= 65					
FIDELIO-DKD	13 / 112	18 / 125	9.3	0.81 [0.41,1.57]	
FIGARO-DKD	128 / 910	160 / 882	90.7	0.78 [0.63,0.96]	
Total	141 / 1022	178 / 1007		0.78 [0.64,0.95]	Z=-2.42, p=0.0155
Heterogeneity:	Q=0.01 (df=1)	p=0.9135	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.72 (df=1)	p=0.1891	I^2=42.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.36.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

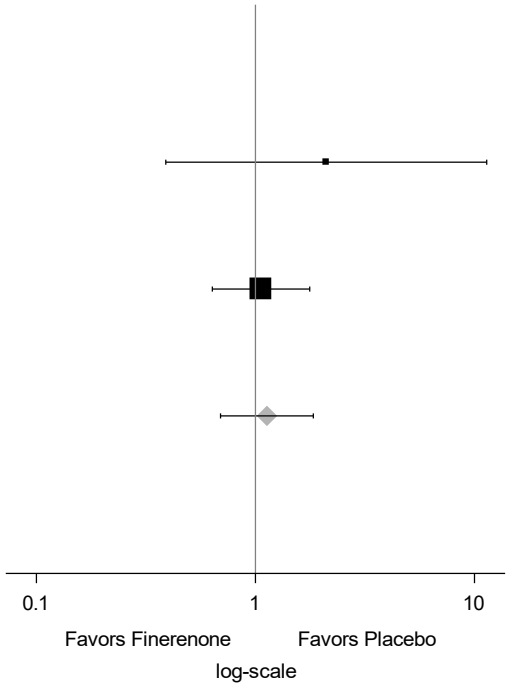
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	71 / 363	59 / 342	100.0	1.13 [0.83,1.55]	
Total	71 / 363	59 / 342		1.13 [0.83,1.55]	Z=0.79, p=0.4304
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	31 / 210	36 / 221	10.2	0.91 [0.58,1.41]	
FIGARO-DKD	266 / 1963	328 / 1960	89.8	0.81 [0.70,0.94]	
Total	297 / 2173	364 / 2181		0.82 [0.71,0.94]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.22 (df=1)	p=0.6359	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.46 (df=1)	p=0.0629	I^2=71.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.37: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

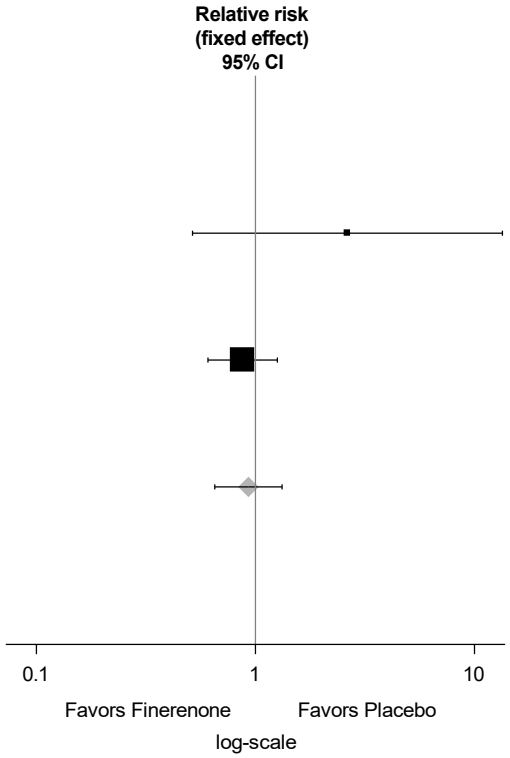
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	8.4	2.10 [0.39,11.37]	
FIGARO-DKD	30 / 2326	28 / 2302	91.6	1.06 [0.64,1.77]	
Total	34 / 2536	30 / 2523		1.13 [0.69,1.84]	Z=0.48, p=0.6279
Heterogeneity:	Q=0.58 (df=1)	p=0.4458	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.38: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

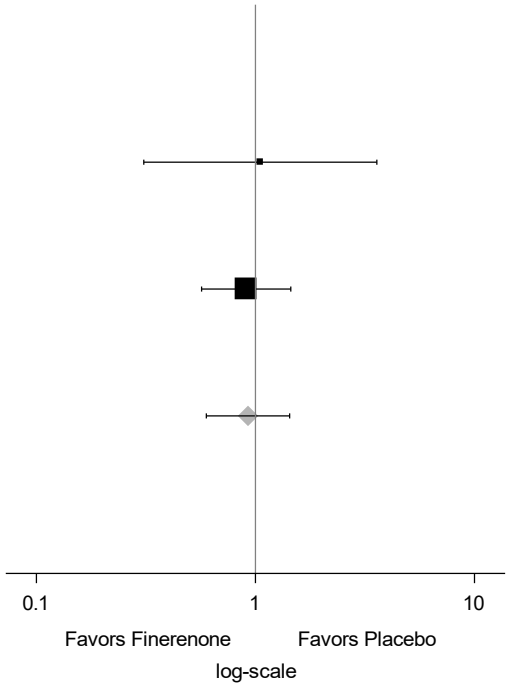
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	4.8	2.63 [0.52,13.41]	
FIGARO-DKD	53 / 2326	60 / 2302	95.2	0.87 [0.61,1.26]	
Total	58 / 2536	62 / 2523		0.93 [0.65,1.32]	Z=-0.41, p=0.6820
Heterogeneity:	Q=1.68 (df=1)	p=0.1956	I^2=40.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.39: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

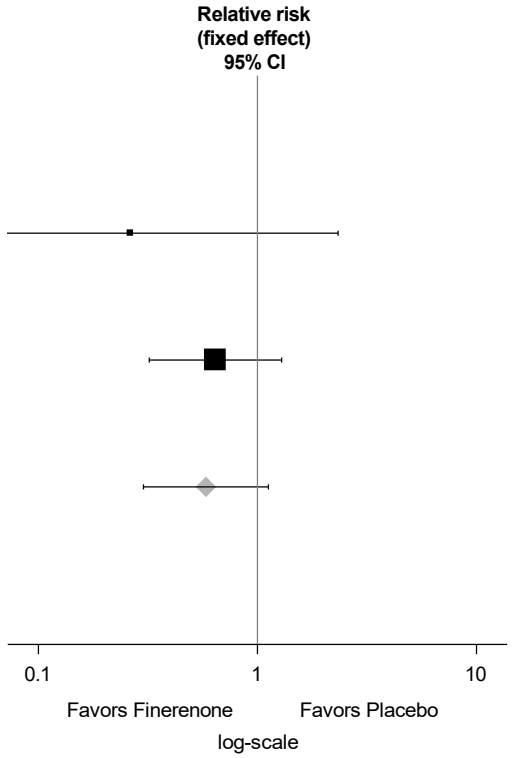
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	5 / 221	12.8	1.05 [0.31,3.58]	
FIGARO-DKD	33 / 2326	36 / 2302	87.2	0.91 [0.57,1.45]	
Total	38 / 2536	41 / 2523		0.92 [0.60,1.43]	Z=-0.35, p=0.7254
Heterogeneity:	Q=0.05 (df=1)	p=0.8245	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.40: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

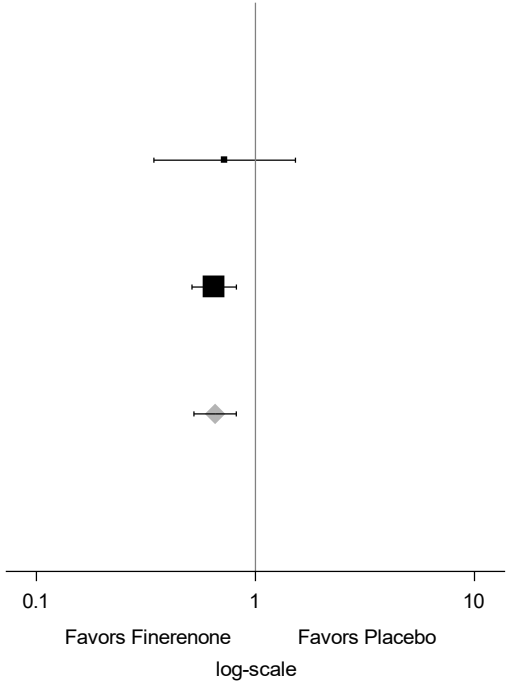
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	9.2	0.26 [0.03,2.33]	
FIGARO-DKD	13 / 2326	20 / 2302	90.8	0.64 [0.32,1.29]	
Total	14 / 2536	24 / 2523		0.58 [0.30,1.12]	Z=-1.62, p=0.1060
Heterogeneity:	Q=0.59 (df=1)	p=0.4433	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.41: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

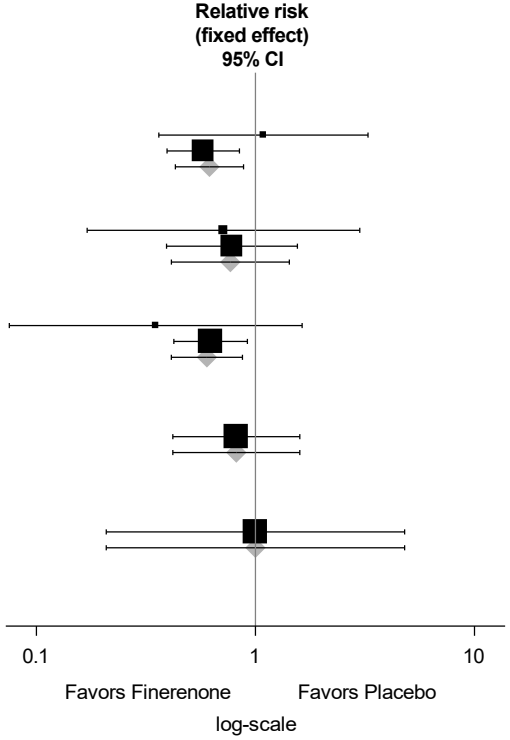
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	16 / 221	9.0	0.72 [0.34,1.52]	
FIGARO-DKD	110 / 2326	168 / 2302	91.0	0.65 [0.51,0.82]	
Total	121 / 2536	184 / 2523		0.65 [0.52,0.82]	Z=-3.73, p=0.0002
Heterogeneity:	Q=0.08 (df=1)	p=0.7818	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.41.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

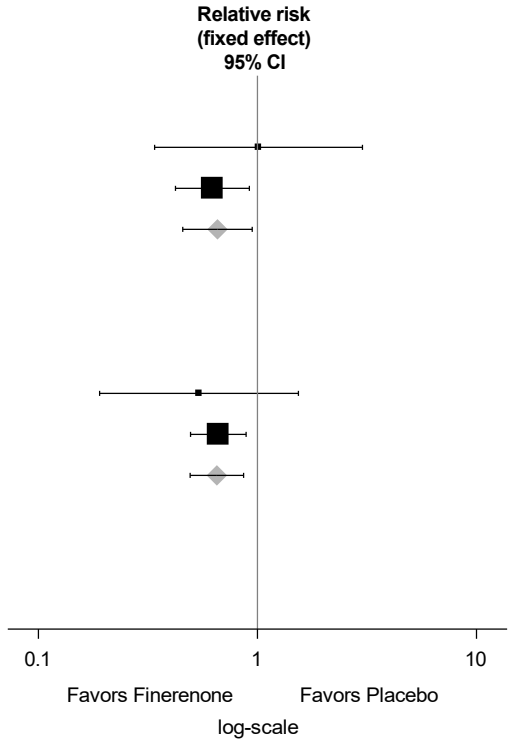
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 103	6 / 112	10.7	1.09 [0.36,3.27]	
FIGARO-DKD	40 / 1114	69 / 1110	89.3	0.58 [0.39,0.85]	
Total	46 / 1217	75 / 1222		0.62 [0.43,0.88]	Z=-2.64, p=0.0082
Heterogeneity:	Q=1.14 (df=1)	p=0.2865	I^2=12.0%		
North America					
FIDELIO-DKD	3 / 42	4 / 40	18.7	0.71 [0.17,2.99]	
FIGARO-DKD	14 / 292	17 / 277	81.3	0.78 [0.39,1.55]	
Total	17 / 334	21 / 317		0.77 [0.41,1.43]	Z=-0.83, p=0.4044
Heterogeneity:	Q=0.01 (df=1)	p=0.9120	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	6 / 41	5.9	0.35 [0.08,1.63]	
FIGARO-DKD	38 / 522	61 / 523	94.1	0.62 [0.42,0.92]	
Total	40 / 561	67 / 564		0.60 [0.41,0.87]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.51 (df=1)	p=0.4756	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	15 / 322	18 / 316	100.0	0.82 [0.42,1.59]	
Total	15 / 343	18 / 340		0.82 [0.42,1.59]	Z=-0.59, p=0.5547
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	3 / 76	100.0	1.00 [0.21,4.80]	
Total	3 / 81	3 / 80		1.00 [0.21,4.80]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=4)	p=0.8652	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.41.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

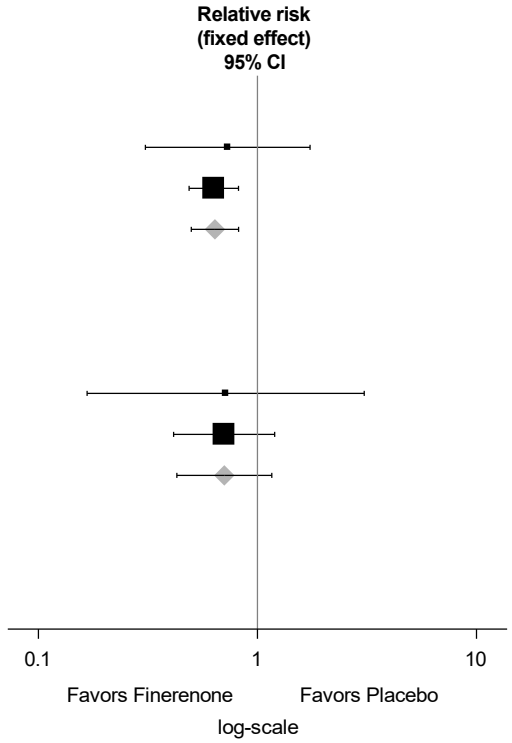
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	6 / 88	6 / 89	11.2	1.01 [0.34,3.02]	
FIGARO-DKD	39 / 811	62 / 803	88.8	0.62 [0.42,0.92]	
Total	45 / 899	68 / 892		0.66 [0.46,0.95]	Z=-2.26, p=0.0240
Heterogeneity:	Q=0.67 (df=1)	p=0.4125	I^2=0.0%		
Absent					
FIDELIO-DKD	5 / 122	10 / 132	7.2	0.54 [0.19,1.54]	
FIGARO-DKD	71 / 1515	106 / 1499	92.8	0.66 [0.49,0.89]	
Total	76 / 1637	116 / 1631		0.65 [0.49,0.86]	Z=-2.97, p=0.0029
Heterogeneity:	Q=0.13 (df=1)	p=0.7138	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9788	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.41.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	8 / 144	12 / 158	8.2	0.73 [0.31,1.74]	
FIGARO-DKD	88 / 1719	136 / 1679	91.8	0.63 [0.49,0.82]	
Total	96 / 1863	148 / 1837		0.64 [0.50,0.82]	Z=-3.52, p=0.0004
Heterogeneity:	Q=0.10 (df=1)	p=0.7512	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 66	4 / 63	11.7	0.72 [0.17,3.07]	
FIGARO-DKD	22 / 607	32 / 622	88.3	0.70 [0.41,1.20]	
Total	25 / 673	36 / 685		0.71 [0.43,1.16]	Z=-1.37, p=0.1712
Heterogeneity:	Q=0.00 (df=1)	p=0.9838	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7289	I^2=0.0%		

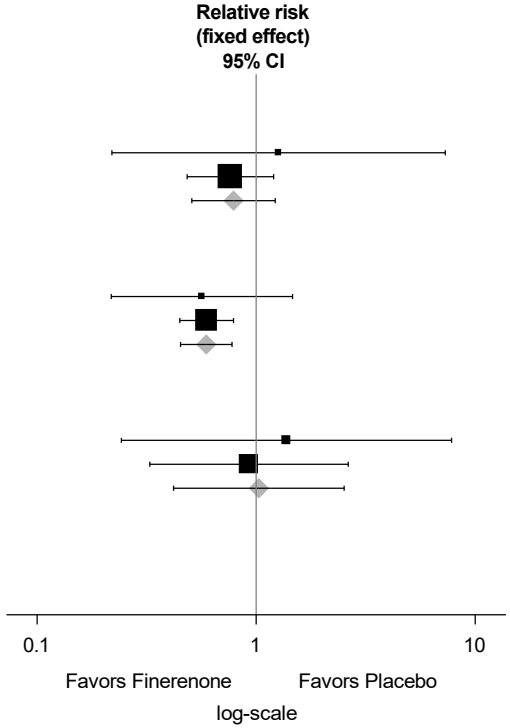


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.41.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

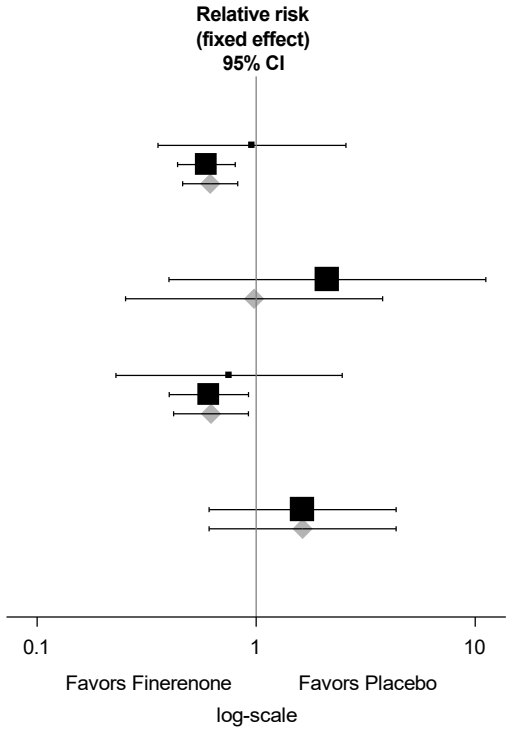
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	2 / 54	6.3	1.27 [0.22,7.30]	
FIGARO-DKD	31 / 693	41 / 699	93.7	0.76 [0.48,1.20]	
Total	34 / 757	43 / 753		0.79 [0.51,1.22]	Z=-1.06, p=0.2870
Heterogeneity:	Q=0.30 (df=1)	p=0.5834	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	6 / 138	12 / 156	8.1	0.57 [0.22,1.47]	
FIGARO-DKD	73 / 1560	120 / 1524	91.9	0.59 [0.45,0.79]	
Total	79 / 1698	132 / 1680		0.59 [0.45,0.78]	Z=-3.80, p=0.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9212	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 8	2 / 11	26.5	1.37 [0.24,7.80]	
FIGARO-DKD	6 / 73	7 / 79	73.5	0.93 [0.33,2.63]	
Total	8 / 81	9 / 90		1.03 [0.42,2.52]	Z=0.06, p=0.9511
Heterogeneity:	Q=0.15 (df=1)	p=0.7032	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.19 (df=2)	p=0.3343	I^2=8.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.41.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

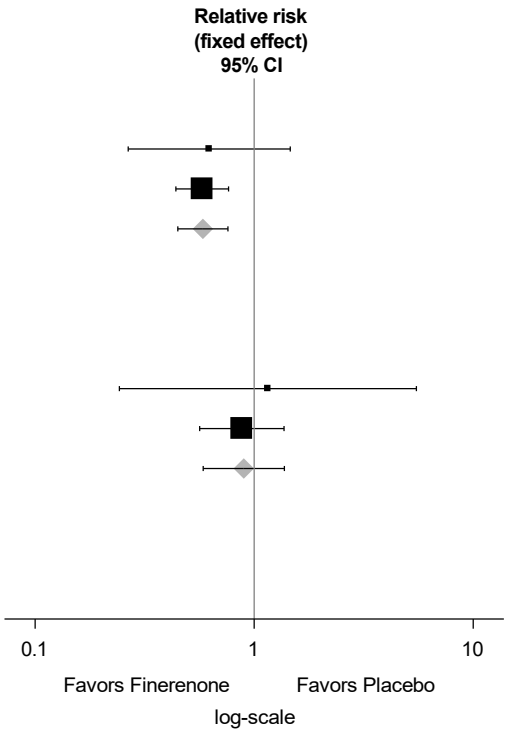
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	7 / 139	8 / 152	8.6	0.96 [0.36,2.57]	
FIGARO-DKD	64 / 1658	105 / 1612	91.4	0.59 [0.44,0.80]	
Total	71 / 1797	113 / 1764		0.62 [0.46,0.82]	Z=-3.27, p=0.0011
Heterogeneity:	Q=0.83 (df=1)	p=0.3635	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	2 / 9	0.0	0.00 [0.00,42E295]	
FIGARO-DKD	4 / 70	2 / 74	100.0	2.11 [0.40,11.18]	
Total	4 / 80	4 / 83		0.98 [0.25,3.78]	Z=-0.03, p=0.9747
Heterogeneity:	Q=0.82 (df=1)	p=0.3645	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 39	6 / 44	10.9	0.75 [0.23,2.47]	
FIGARO-DKD	32 / 464	55 / 485	89.1	0.61 [0.40,0.92]	
Total	36 / 503	61 / 529		0.62 [0.42,0.92]	Z=-2.37, p=0.0180
Heterogeneity:	Q=0.11 (df=1)	p=0.7410	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	10 / 134	6 / 131	100.0	1.63 [0.61,4.35]	
Total	10 / 156	6 / 147		1.63 [0.61,4.35]	Z=0.97, p=0.3304
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.87 (df=3)	p=0.2758	I^2=22.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.41.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

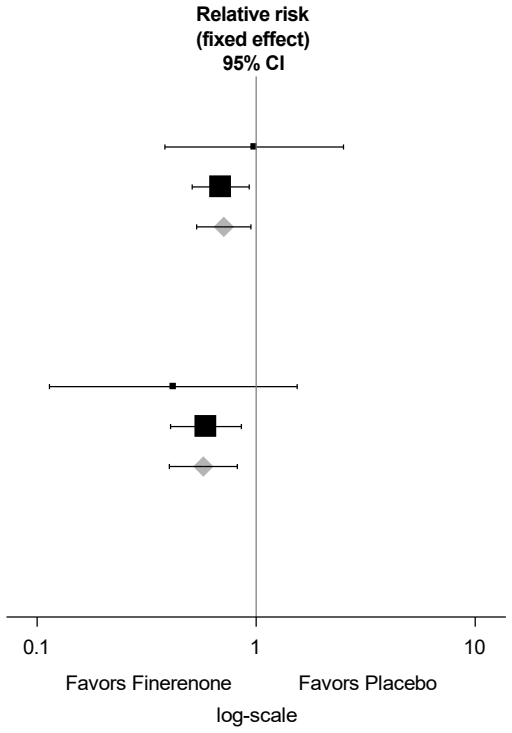
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	13 / 154	9.6	0.62 [0.27,1.46]	
FIGARO-DKD	74 / 1610	130 / 1638	90.4	0.58 [0.44,0.76]	
Total	82 / 1762	143 / 1792		0.58 [0.45,0.76]	Z=-4.01, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8717	I^2=0.0%		
Female					
FIDELIO-DKD	3 / 58	3 / 67	7.5	1.16 [0.24,5.50]	
FIGARO-DKD	36 / 716	38 / 664	92.5	0.88 [0.56,1.37]	
Total	39 / 774	41 / 731		0.90 [0.59,1.37]	Z=-0.50, p=0.6162
Heterogeneity:	Q=0.11 (df=1)	p=0.7410	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.83 (df=1)	p=0.0928	I^2=64.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.41.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

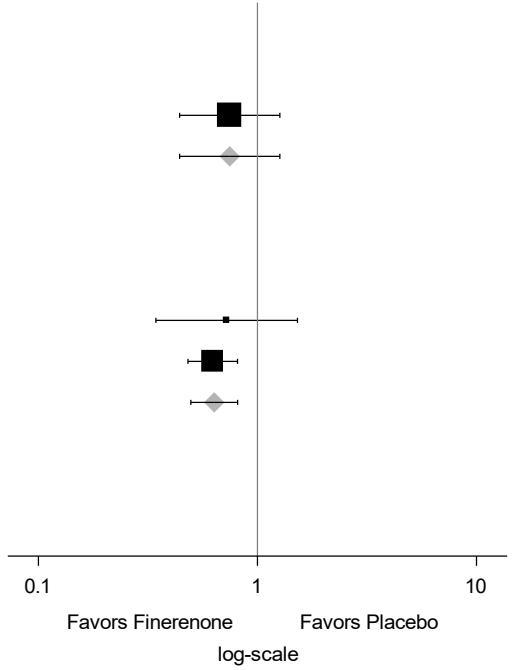
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	8 / 96	9.3	0.98 [0.38,2.50]	
FIGARO-DKD	68 / 1416	99 / 1420	90.7	0.69 [0.51,0.93]	
Total	76 / 1514	107 / 1516		0.71 [0.53,0.95]	Z=-2.34, p=0.0192
Heterogeneity:	Q=0.49 (df=1)	p=0.4836	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	8 / 125	7.6	0.42 [0.11,1.54]	
FIGARO-DKD	42 / 910	69 / 882	92.4	0.59 [0.41,0.86]	
Total	45 / 1022	77 / 1007		0.57 [0.40,0.82]	Z=-3.05, p=0.0023
Heterogeneity:	Q=0.25 (df=1)	p=0.6192	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.85 (df=1)	p=0.3570	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.41.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

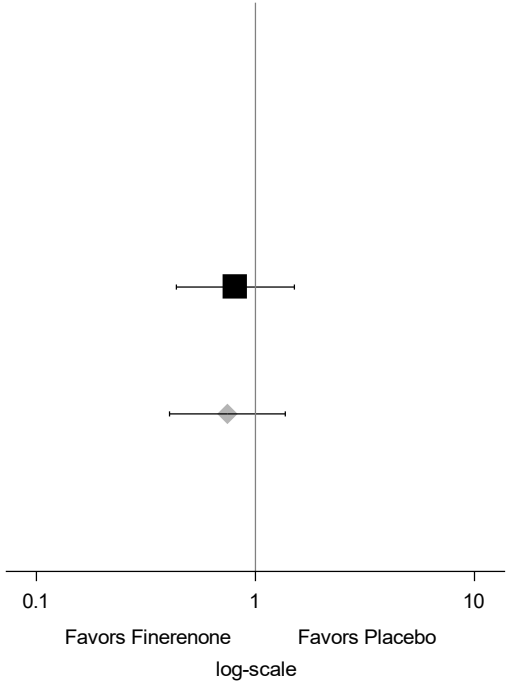
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	23 / 363	29 / 342	100.0	0.75 [0.44,1.27]	
Total	23 / 363	29 / 342		0.75 [0.44,1.27]	Z=-1.08, p=0.2784
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	11 / 210	16 / 221	10.9	0.72 [0.34,1.52]	
FIGARO-DKD	87 / 1963	139 / 1960	89.1	0.62 [0.48,0.81]	
Total	98 / 2173	155 / 2181		0.63 [0.50,0.81]	Z=-3.62, p=0.0003
Heterogeneity:	Q=0.13 (df=1)	p=0.7158	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5828	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.42: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

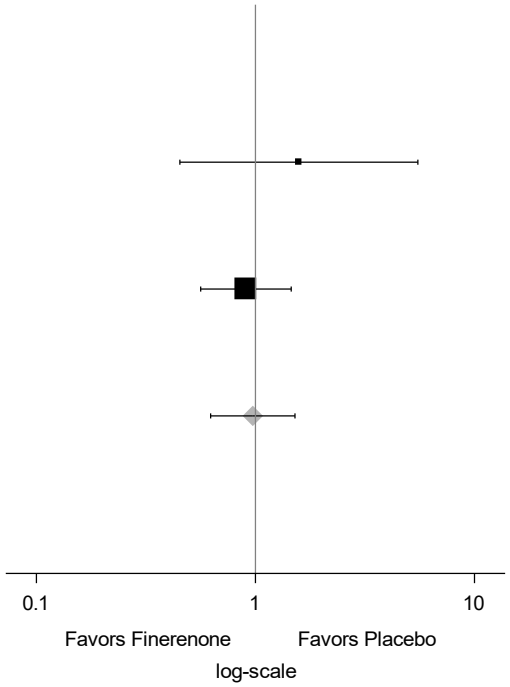
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	18 / 2326	22 / 2302	100.0	0.81 [0.44,1.51]	
Total	18 / 2536	24 / 2523		0.74 [0.41,1.37]	Z=-0.95, p=0.3424
Heterogeneity:	Q=0.07 (df=1)	p=0.7912	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.43: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

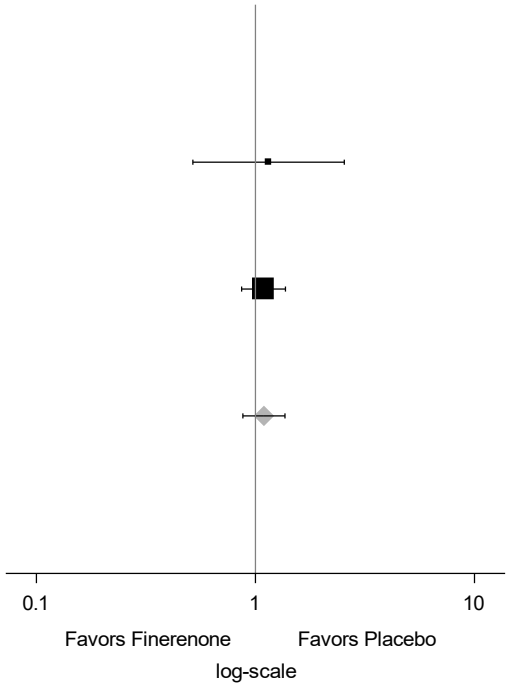
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	4 / 221	12.6	1.58 [0.45,5.52]	
FIGARO-DKD	32 / 2326	35 / 2302	87.4	0.90 [0.56,1.46]	
Total	38 / 2536	39 / 2523		0.97 [0.62,1.52]	Z=-0.12, p=0.9021
Heterogeneity:	Q=0.66 (df=1)	p=0.4151	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.44: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

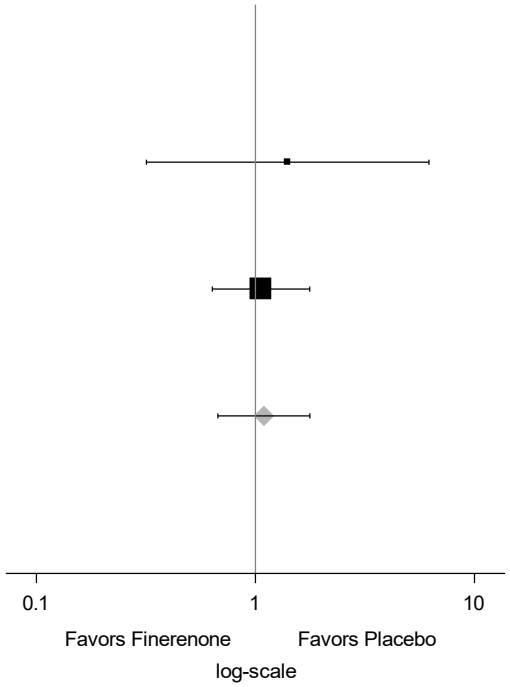
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	11 / 221	7.7	1.15 [0.52,2.54]	
FIGARO-DKD	143 / 2326	130 / 2302	92.3	1.09 [0.86,1.37]	
Total	155 / 2536	141 / 2523		1.09 [0.88,1.36]	Z=0.79, p=0.4304
Heterogeneity:	Q=0.02 (df=1)	p=0.9000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.45: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

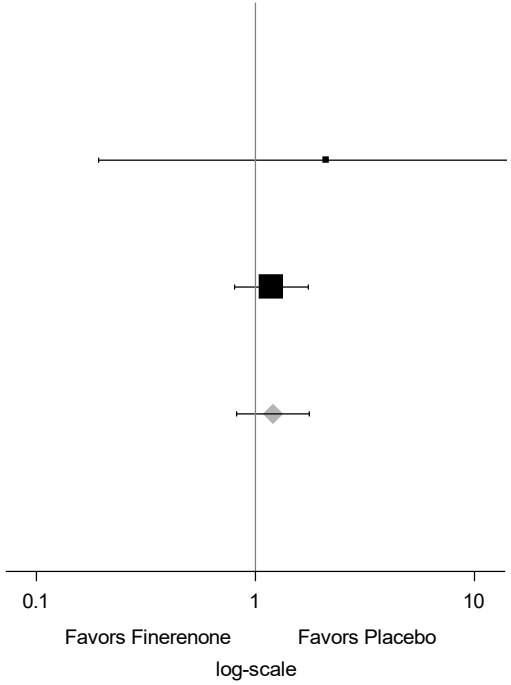
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	10.6	1.40 [0.32,6.19]	
FIGARO-DKD	30 / 2326	28 / 2302	89.4	1.06 [0.64,1.77]	
Total	34 / 2536	31 / 2523		1.09 [0.67,1.77]	Z=0.36, p=0.7192
Heterogeneity:	Q=0.12 (df=1)	p=0.7267	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.46: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

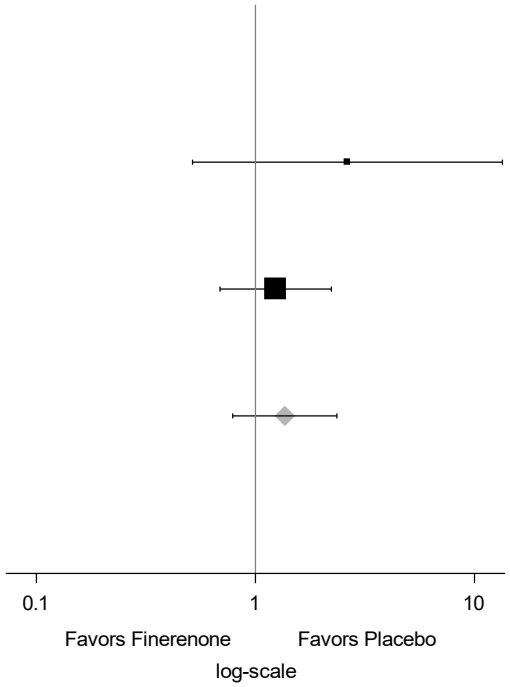
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	2.6	2.10 [0.19,23.04]	
FIGARO-DKD	55 / 2326	46 / 2302	97.4	1.18 [0.80,1.74]	
Total	57 / 2536	47 / 2523		1.20 [0.82,1.76]	Z=0.94, p=0.3450
Heterogeneity:	Q=0.22 (df=1)	p=0.6415	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.47: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

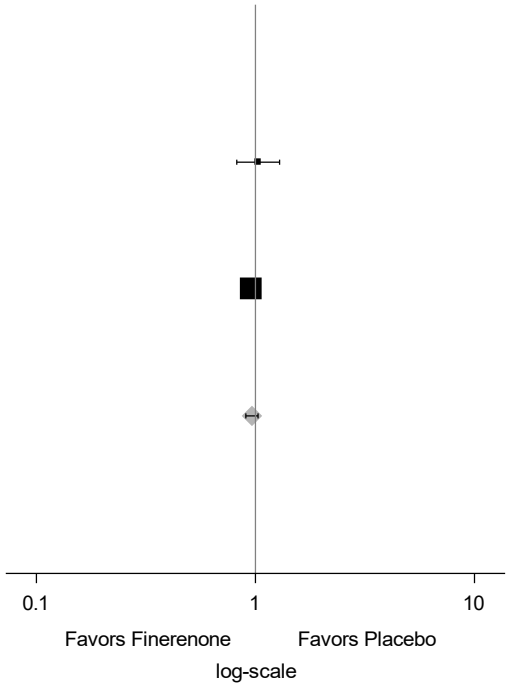
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	11.4	2.63 [0.52,13.41]	
FIGARO-DKD	25 / 2326	20 / 2302	88.6	1.24 [0.69,2.22]	
Total	30 / 2536	22 / 2523		1.36 [0.79,2.35]	Z=1.11, p=0.2691
Heterogeneity:	Q=0.73 (df=1)	p=0.3925	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.48: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

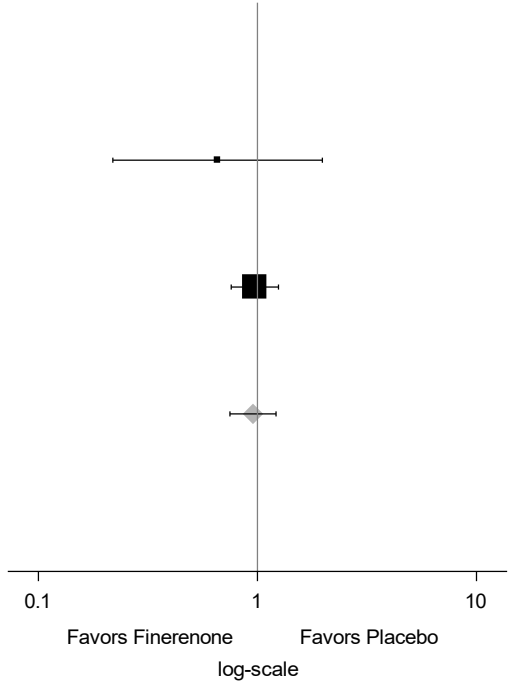
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	88 / 210	90 / 221	8.1	1.03 [0.82,1.29]	
FIGARO-DKD	973 / 2326	1005 / 2302	91.9	0.96 [0.90,1.02]	
Total	1061 / 2536	1095 / 2523		0.96 [0.90,1.03]	Z=-1.13, p=0.2571
Heterogeneity:	Q=0.35 (df=1)	p=0.5516	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.49: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

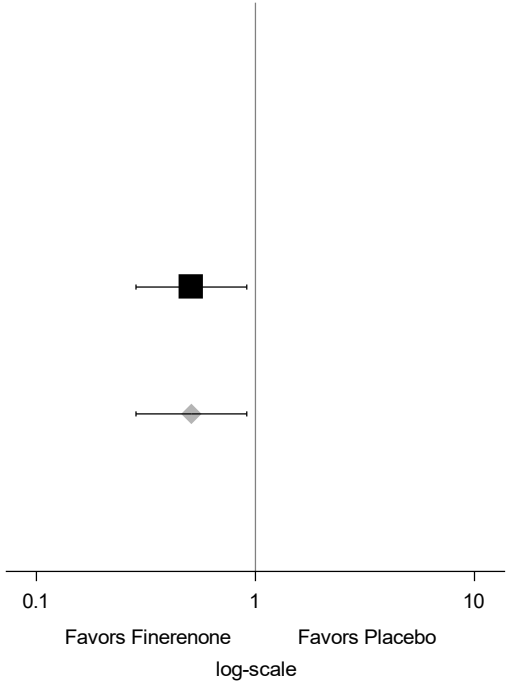
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	8 / 221	4.8	0.66 [0.22,1.98]	
FIGARO-DKD	117 / 2326	119 / 2302	95.2	0.97 [0.76,1.25]	
Total	122 / 2536	127 / 2523		0.95 [0.75,1.22]	Z=-0.38, p=0.7041
Heterogeneity:	Q=0.46 (df=1)	p=0.4966	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.50: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

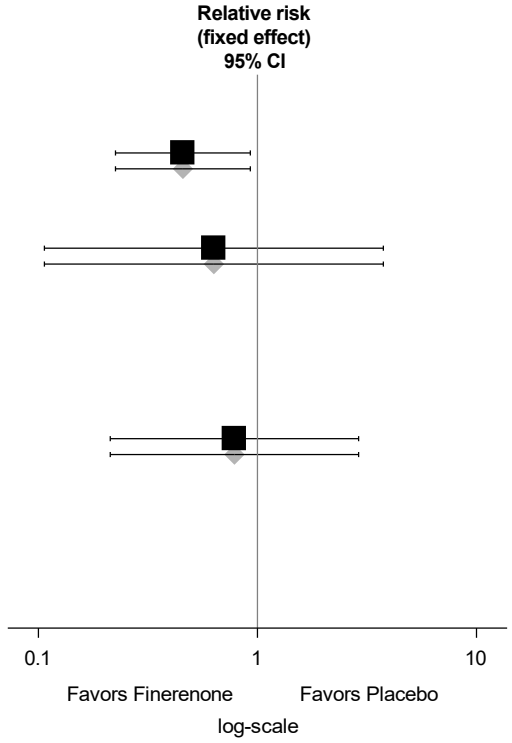
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	17 / 2326	33 / 2302	100.0	0.51 [0.28,0.91]	
Total	17 / 2536	33 / 2523		0.51 [0.28,0.91]	Z=-2.27, p=0.0234
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.50.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

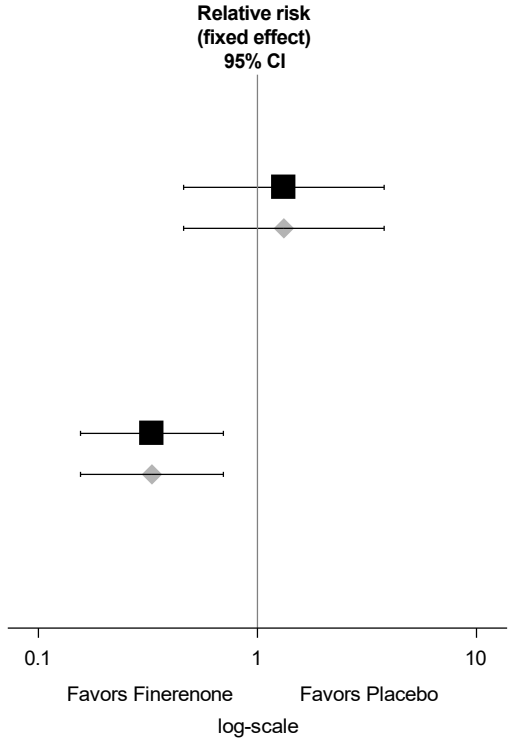
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	11 / 1114	24 / 1110	100.0	0.46 [0.22,0.93]	
Total	11 / 1217	24 / 1222		0.46 [0.22,0.93]	Z=-2.17, p=0.0302
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	2 / 292	3 / 277	100.0	0.63 [0.11,3.76]	
Total	2 / 334	3 / 317		0.63 [0.11,3.76]	Z=-0.50, p=0.6142
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	0 / 522	0 / 523	0.0	-	
Total	0 / 561	0 / 564		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	4 / 322	5 / 316	100.0	0.79 [0.21,2.90]	
Total	4 / 343	5 / 340		0.79 [0.21,2.90]	Z=-0.36, p=0.7164
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	1 / 76	0.0	0.00 [0.00,97E295]	
Total	0 / 81	1 / 80		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.56 (df=4)	p=0.9679	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.50.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

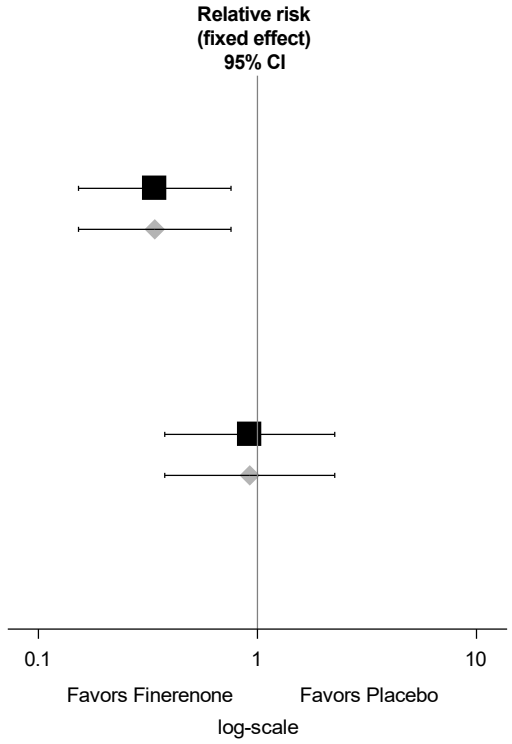
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	8 / 811	6 / 803	100.0	1.32 [0.46,3.79]	
Total	8 / 899	6 / 892		1.32 [0.46,3.79]	Z=0.52, p=0.6055
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	0 / 132	0.0	-	
FIGARO-DKD	9 / 1515	27 / 1499	100.0	0.33 [0.16,0.70]	
Total	9 / 1637	27 / 1631		0.33 [0.16,0.70]	Z=-2.89, p=0.0038
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.41 (df=1)	p=0.0357	I^2=77.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.50.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

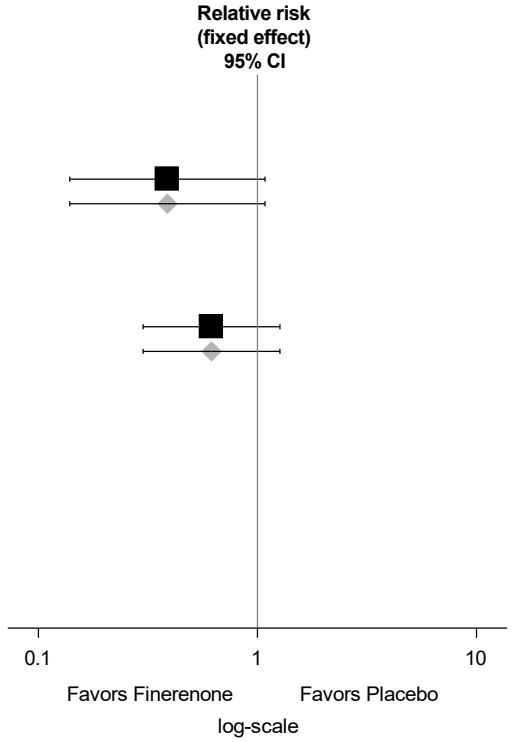
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	0 / 158	0.0	-	
FIGARO-DKD	8 / 1719	23 / 1679	100.0	0.34 [0.15,0.76]	
Total	8 / 1863	23 / 1837		0.34 [0.15,0.76]	Z=-2.64, p=0.0083
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	9 / 607	10 / 622	100.0	0.92 [0.38,2.25]	
Total	9 / 673	10 / 685		0.92 [0.38,2.25]	Z=-0.18, p=0.8591
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.66 (df=1)	p=0.1030	I^2=62.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.50.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

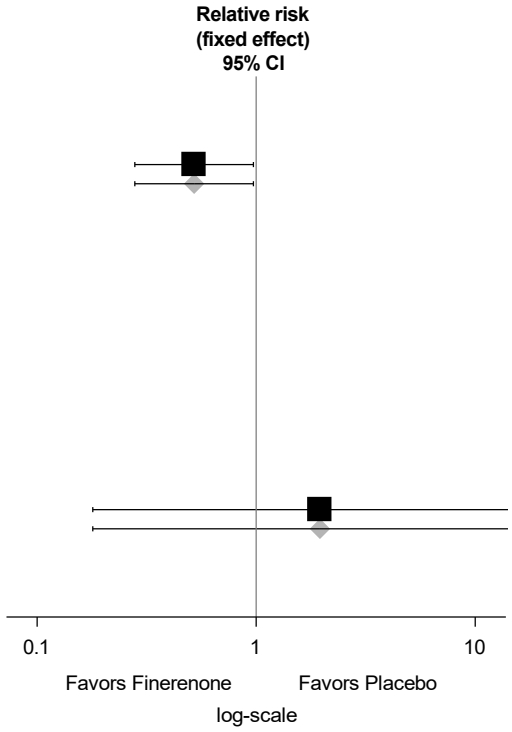
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	5 / 693	13 / 699	100.0	0.39 [0.14,1.08]	
Total	5 / 757	13 / 753		0.39 [0.14,1.08]	Z=-1.81, p=0.0705
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	0 / 156	0.0	-	
FIGARO-DKD	12 / 1560	19 / 1524	100.0	0.62 [0.30,1.27]	
Total	12 / 1698	19 / 1680		0.62 [0.30,1.27]	Z=-1.32, p=0.1882
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,1E297]	
Total	0 / 81	1 / 90		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.53 (df=2)	p=0.7684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.50.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

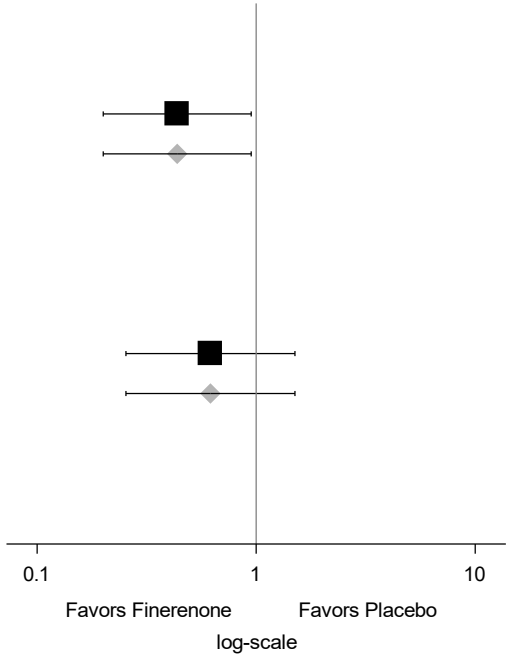
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	15 / 1658	28 / 1612	100.0	0.52 [0.28,0.97]	
Total	15 / 1797	28 / 1764		0.52 [0.28,0.97]	Z=-2.05, p=0.0403
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	2 / 74	0.0	0.00 [0.00,12E296]	
Total	0 / 80	2 / 83		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	0 / 464	2 / 485	0.0	0.00 [0.00,11E296]	
Total	0 / 503	2 / 529		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	1 / 131	100.0	1.96 [0.18,21.30]	
Total	2 / 156	1 / 147		1.96 [0.18,21.30]	Z=0.55, p=0.5822
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.10 (df=3)	p=0.7763	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.50.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

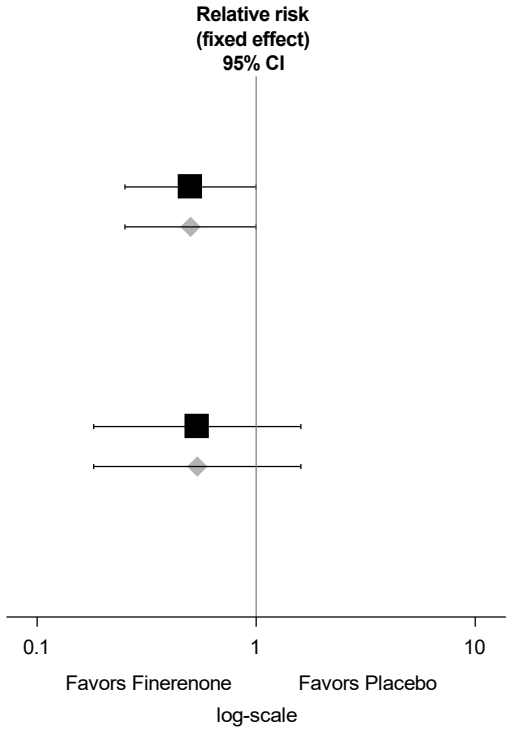
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	0 / 154	0.0	-	
FIGARO-DKD	9 / 1610	21 / 1638	100.0	0.44 [0.20,0.95]	
Total	9 / 1762	21 / 1792		0.44 [0.20,0.95]	Z=-2.09, p=0.0365
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	8 / 716	12 / 664	100.0	0.62 [0.25,1.50]	
Total	8 / 774	12 / 731		0.62 [0.25,1.50]	Z=-1.06, p=0.2887
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5622	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.50.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

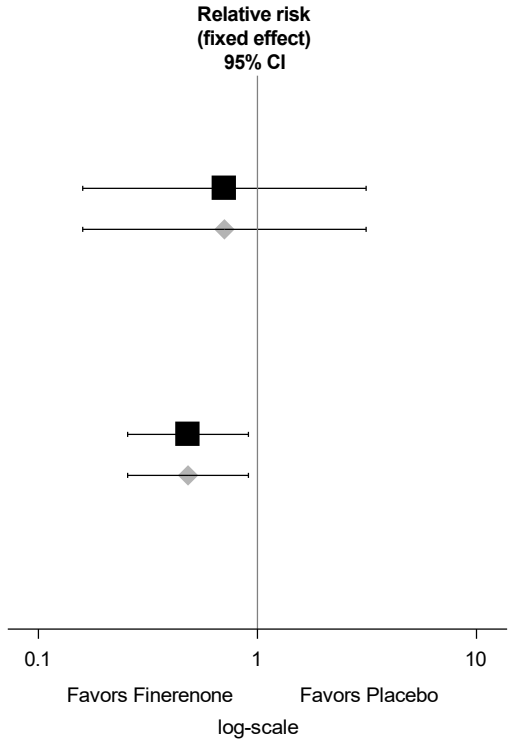
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	12 / 1416	24 / 1420	100.0	0.50 [0.25,1.00]	
Total	12 / 1514	24 / 1516		0.50 [0.25,1.00]	Z=-1.96, p=0.0496
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	0 / 125	0.0	-	
FIGARO-DKD	5 / 910	9 / 882	100.0	0.54 [0.18,1.60]	
Total	5 / 1022	9 / 1007		0.54 [0.18,1.60]	Z=-1.11, p=0.2653
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9137	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.50.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

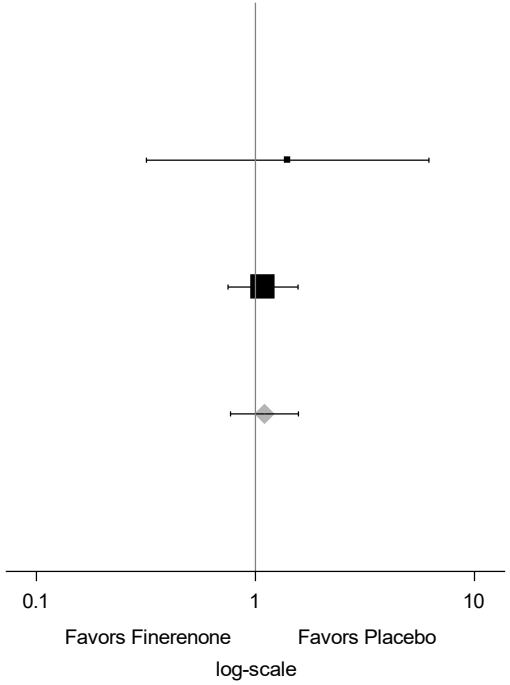
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	3 / 363	4 / 342	100.0	0.71 [0.16,3.13]	
Total	3 / 363	4 / 342		0.71 [0.16,3.13]	Z=-0.46, p=0.6477
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	14 / 1963	29 / 1960	100.0	0.48 [0.26,0.91]	
Total	14 / 2173	29 / 2181		0.48 [0.26,0.91]	Z=-2.25, p=0.0242
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6434	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.51: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

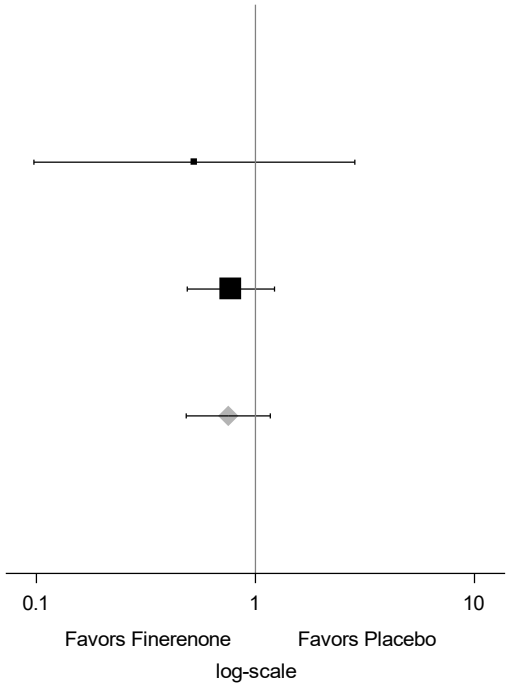
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	5.8	1.40 [0.32,6.19]	
FIGARO-DKD	58 / 2326	53 / 2302	94.2	1.08 [0.75,1.56]	
Total	62 / 2536	56 / 2523		1.10 [0.77,1.57]	Z=0.52, p=0.6023
Heterogeneity:	Q=0.11 (df=1)	p=0.7401	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.52: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

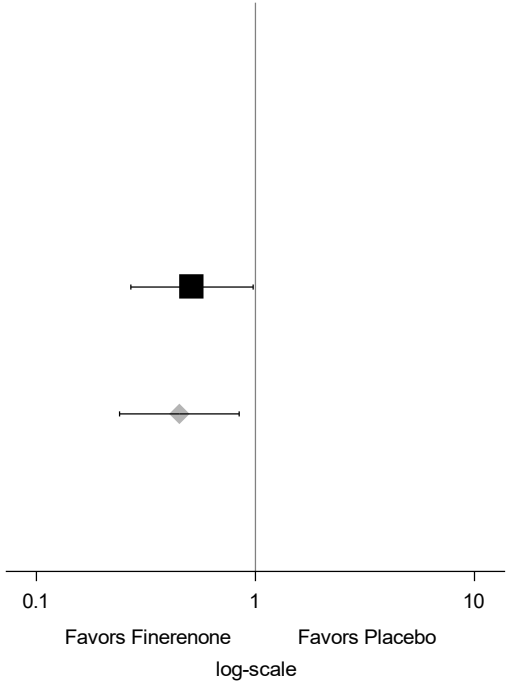
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	6.9	0.53 [0.10,2.84]	
FIGARO-DKD	32 / 2326	41 / 2302	93.1	0.77 [0.49,1.22]	
Total	34 / 2536	45 / 2523		0.75 [0.48,1.17]	Z=-1.27, p=0.2047
Heterogeneity:	Q=0.19 (df=1)	p=0.6669	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.53: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

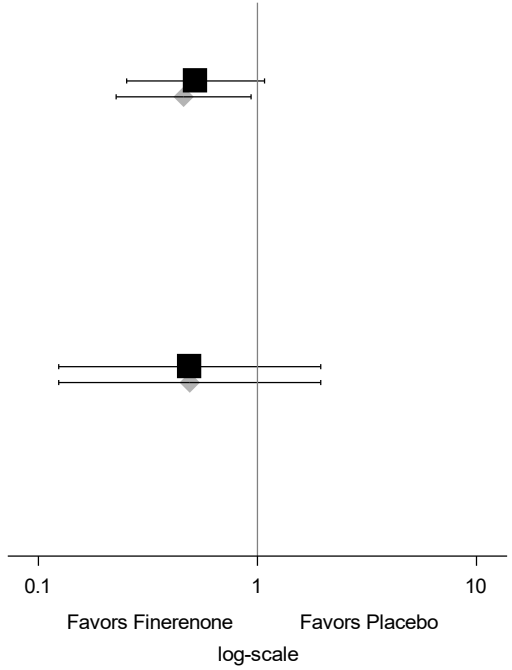
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	4 / 221	0.0	0.00 [0.00,19E296]	
FIGARO-DKD	14 / 2326	27 / 2302	100.0	0.51 [0.27,0.98]	
Total	14 / 2536	31 / 2523		0.45 [0.24,0.84]	Z=-2.49, p=0.0126
Heterogeneity:	Q=0.16 (df=1)	p=0.6857	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.53.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

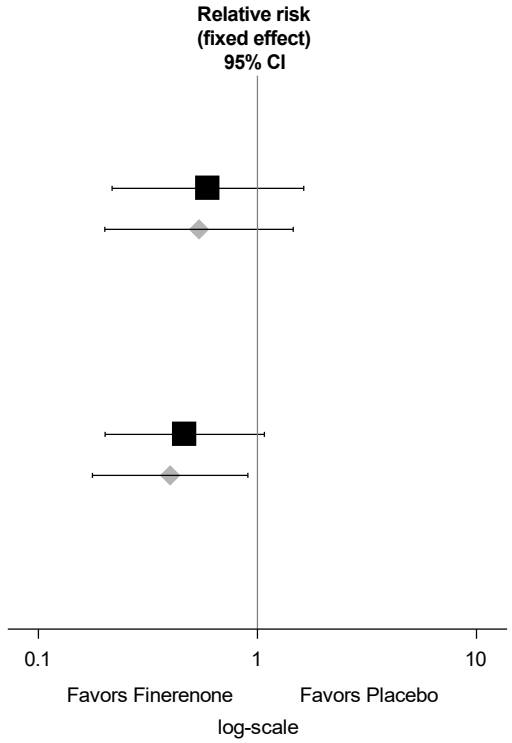
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	3 / 112	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	11 / 1114	21 / 1110	100.0	0.52 [0.25,1.08]	
Total	11 / 1217	24 / 1222		0.46 [0.23,0.94]	Z=-2.15, p=0.0319
Heterogeneity:	Q=0.12 (df=1)	p=0.7331	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	0 / 292	0 / 277	0.0	-	
Total	0 / 334	0 / 317		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	0 / 522	0 / 523	0.0	-	
Total	0 / 561	1 / 564		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	3 / 322	6 / 316	100.0	0.49 [0.12,1.94]	
Total	3 / 343	6 / 340		0.49 [0.12,1.94]	Z=-1.01, p=0.3109
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	0 / 76	0.0	-	
Total	0 / 81	0 / 80		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.01 (df=4)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.53.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

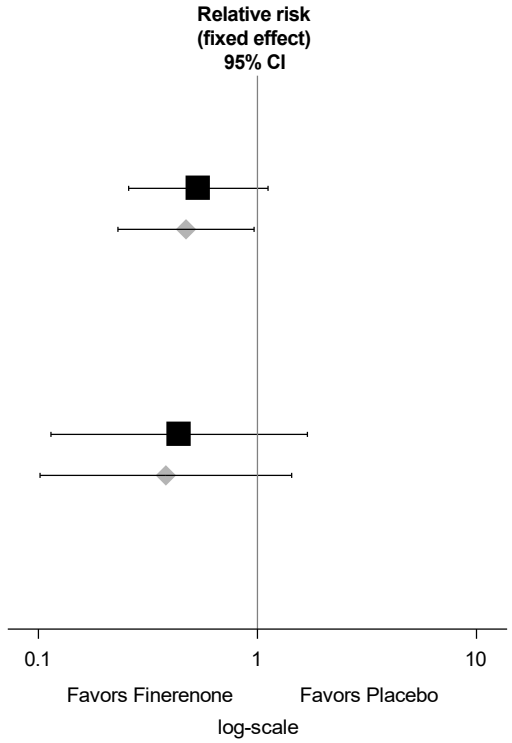
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	1 / 89	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	6 / 811	10 / 803	100.0	0.59 [0.22,1.63]	
Total	6 / 899	11 / 892		0.54 [0.20,1.46]	Z=-1.22, p=0.2240
Heterogeneity:	Q=0.03 (df=1)	p=0.8553	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	3 / 132	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	8 / 1515	17 / 1499	100.0	0.47 [0.20,1.08]	
Total	8 / 1637	20 / 1631		0.40 [0.18,0.90]	Z=-2.20, p=0.0277
Heterogeneity:	Q=0.13 (df=1)	p=0.7194	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.53.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

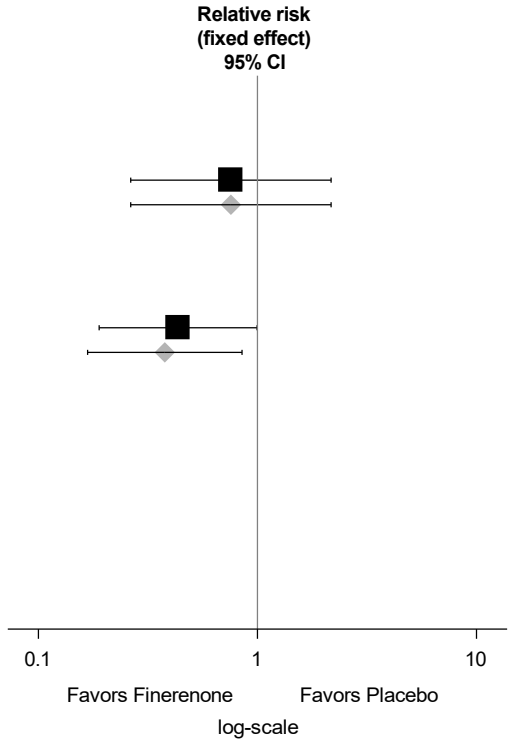
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	3 / 158	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	11 / 1719	20 / 1679	100.0	0.54 [0.26,1.12]	
Total	11 / 1863	23 / 1837		0.47 [0.23,0.97]	Z=-2.06, p=0.0397
Heterogeneity:	Q=0.12 (df=1)	p=0.7285	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	1 / 63	0.0	0.00 [0.00,8E296]	
FIGARO-DKD	3 / 607	7 / 622	100.0	0.44 [0.11,1.69]	
Total	3 / 673	8 / 685		0.38 [0.10,1.43]	Z=-1.43, p=0.1536
Heterogeneity:	Q=0.04 (df=1)	p=0.8386	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.53.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

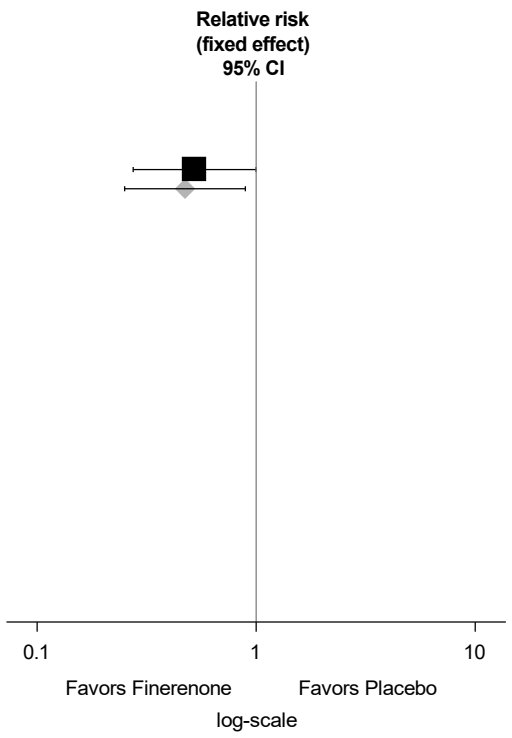
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	8 / 699	100.0	0.76 [0.26,2.17]	
Total	6 / 757	8 / 753		0.76 [0.26,2.17]	Z=-0.52, p=0.6036
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	3 / 156	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	8 / 1560	18 / 1524	100.0	0.43 [0.19,1.00]	
Total	8 / 1698	21 / 1680		0.38 [0.17,0.85]	Z=-2.35, p=0.0187
Heterogeneity:	Q=0.11 (df=1)	p=0.7416	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	1 / 11	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,1E297]	
Total	0 / 81	2 / 90		0.00 [0.00,18E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.05 (df=2)	p=0.5919	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.53.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

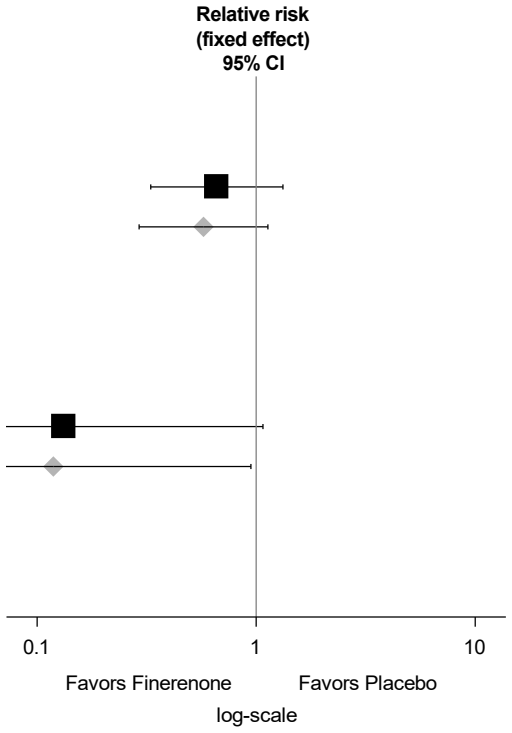
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	3 / 152	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	14 / 1658	26 / 1612	100.0	0.52 [0.27,1.00]	
Total	14 / 1797	29 / 1764		0.47 [0.25,0.89]	Z=-2.31, p=0.0208
Heterogeneity:	Q=0.09 (df=1)	p=0.7594	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	0 / 80	0 / 83		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	0 / 464	0 / 485	0.0	-	
Total	0 / 503	1 / 529		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,17E296]	
Total	0 / 156	1 / 147		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.00 (df=3)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.53.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

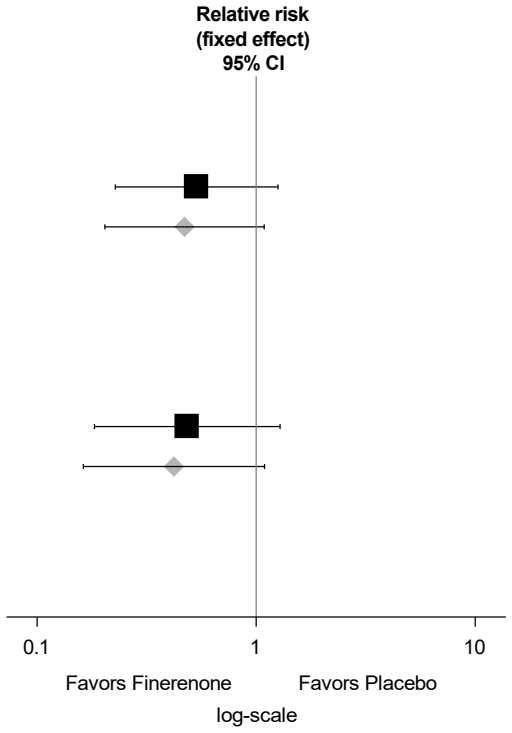
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	3 / 154	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	13 / 1610	20 / 1638	100.0	0.66 [0.33,1.32]	
Total	13 / 1762	23 / 1792		0.57 [0.29,1.13]	Z=-1.60, p=0.1089
Heterogeneity:	Q=0.16 (df=1)	p=0.6928	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	1 / 67	0.0	0.00 [0.00,23E296]	
FIGARO-DKD	1 / 716	7 / 664	100.0	0.13 [0.02,1.07]	
Total	1 / 774	8 / 731		0.12 [0.01,0.95]	Z=-2.01, p=0.0442
Heterogeneity:	Q=0.01 (df=1)	p=0.9172	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.01 (df=1)	p=0.1566	I^2=50.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.53.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

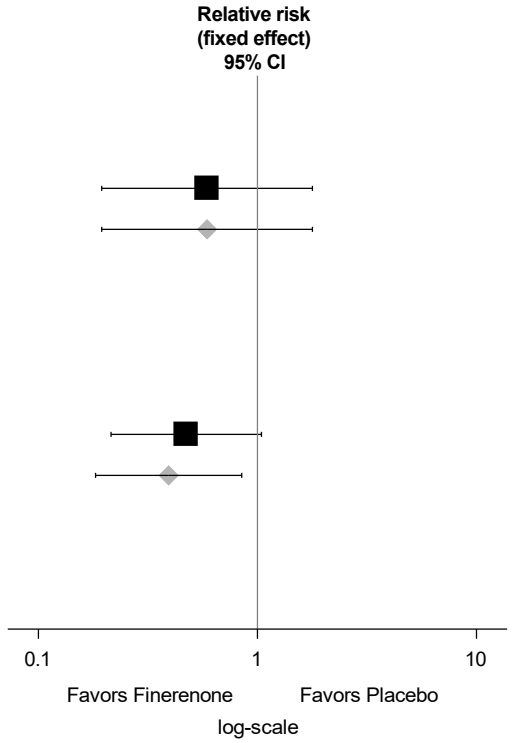
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	2 / 96	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	8 / 1416	15 / 1420	100.0	0.53 [0.23,1.26]	
Total	8 / 1514	17 / 1516		0.47 [0.20,1.09]	Z=-1.76, p=0.0779
Heterogeneity:	Q=0.09 (df=1)	p=0.7704	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	2 / 125	0.0	0.00 [0.00,22E296]	
FIGARO-DKD	6 / 910	12 / 882	100.0	0.48 [0.18,1.29]	
Total	6 / 1022	14 / 1007		0.42 [0.16,1.09]	Z=-1.78, p=0.0752
Heterogeneity:	Q=0.08 (df=1)	p=0.7782	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8632	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.53.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

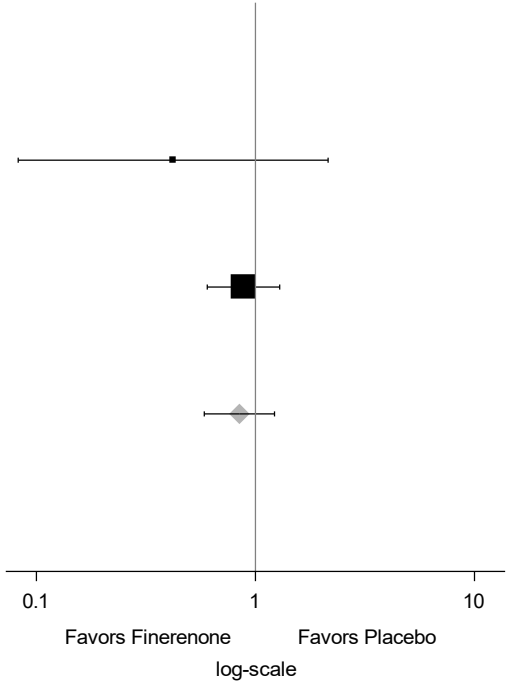
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	8 / 342	100.0	0.59 [0.19,1.78]	
Total	5 / 363	8 / 342		0.59 [0.19,1.78]	Z=-0.94, p=0.3487
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	0 / 210	4 / 221	0.0	0.00 [0.00,19E296]	
FIGARO-DKD	9 / 1963	19 / 1960	100.0	0.47 [0.21,1.04]	
Total	9 / 2173	23 / 2181		0.39 [0.18,0.85]	Z=-2.38, p=0.0172
Heterogeneity:	Q=0.21 (df=1)	p=0.6468	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5570	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.54: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

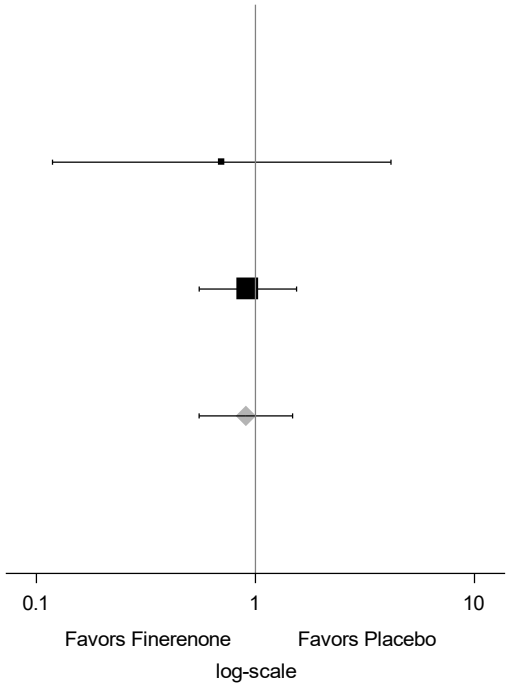
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	5.2	0.42 [0.08,2.15]	
FIGARO-DKD	49 / 2326	55 / 2302	94.8	0.88 [0.60,1.29]	
Total	51 / 2536	60 / 2523		0.84 [0.58,1.22]	Z=-0.90, p=0.3703
Heterogeneity:	Q=0.75 (df=1)	p=0.3862	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.55: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

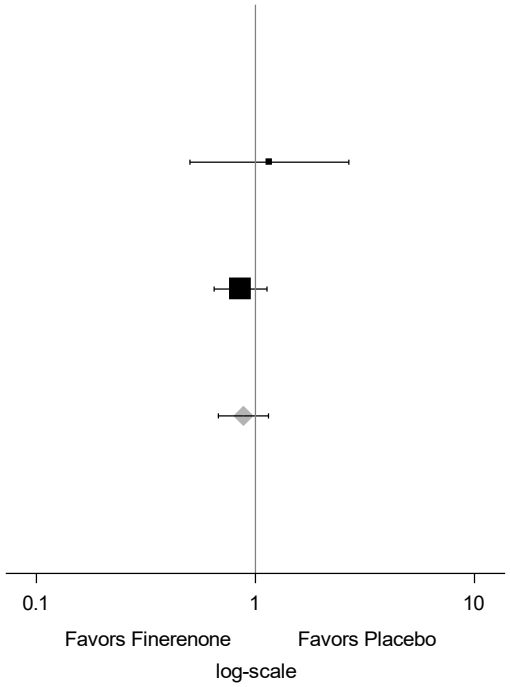
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.6	0.70 [0.12,4.16]	
FIGARO-DKD	28 / 2326	30 / 2302	92.4	0.92 [0.55,1.54]	
Total	30 / 2536	33 / 2523		0.90 [0.55,1.48]	Z=-0.40, p=0.6876
Heterogeneity:	Q=0.08 (df=1)	p=0.7709	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.56: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

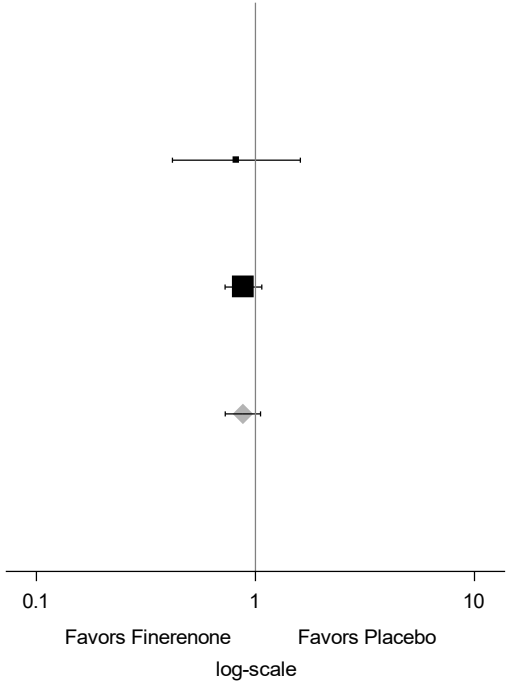
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	10 / 221	10.0	1.16 [0.50,2.67]	
FIGARO-DKD	89 / 2326	103 / 2302	90.0	0.86 [0.65,1.13]	
Total	100 / 2536	113 / 2523		0.88 [0.68,1.15]	Z=-0.94, p=0.3471
Heterogeneity:	Q=0.45 (df=1)	p=0.5001	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.57: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

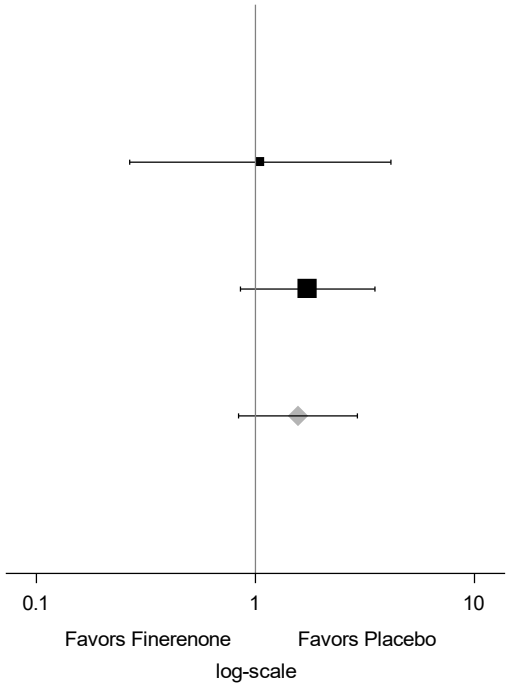
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	18 / 221	7.6	0.82 [0.42,1.60]	
FIGARO-DKD	179 / 2326	201 / 2302	92.4	0.88 [0.73,1.07]	
Total	193 / 2536	219 / 2523		0.88 [0.73,1.06]	Z=-1.39, p=0.1633
Heterogeneity:	Q=0.04 (df=1)	p=0.8358	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.58: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Periodontitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

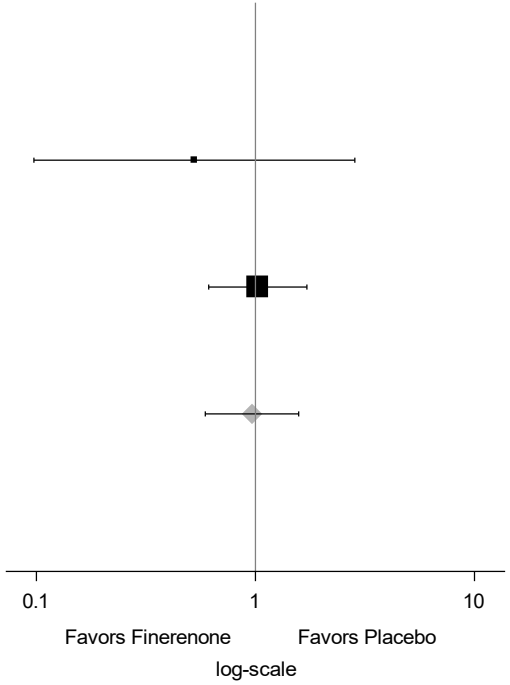
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	4 / 221	21.0	1.05 [0.27,4.15]	
FIGARO-DKD	21 / 2326	12 / 2302	79.0	1.73 [0.85,3.51]	
Total	25 / 2536	16 / 2523		1.56 [0.84,2.92]	Z=1.40, p=0.1607
Heterogeneity:	Q=0.40 (df=1)	p=0.5272	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.59: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

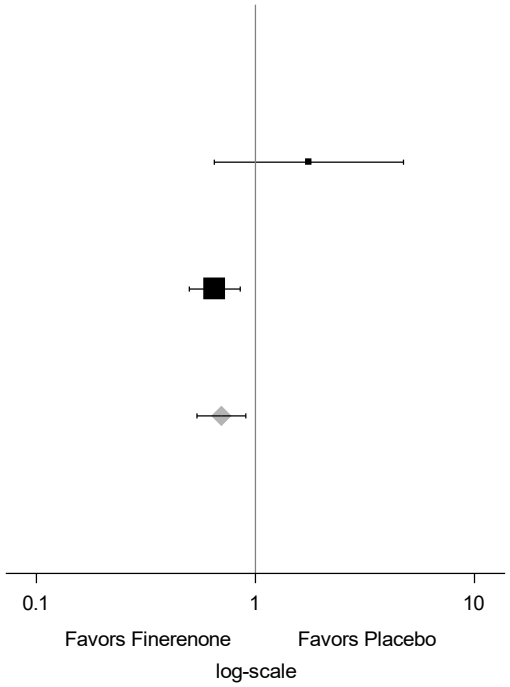
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	8.6	0.53 [0.10,2.84]	
FIGARO-DKD	29 / 2326	28 / 2302	91.4	1.03 [0.61,1.72]	
Total	31 / 2536	32 / 2523		0.96 [0.59,1.58]	Z=-0.15, p=0.8846
Heterogeneity:	Q=0.55 (df=1)	p=0.4587	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.60: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

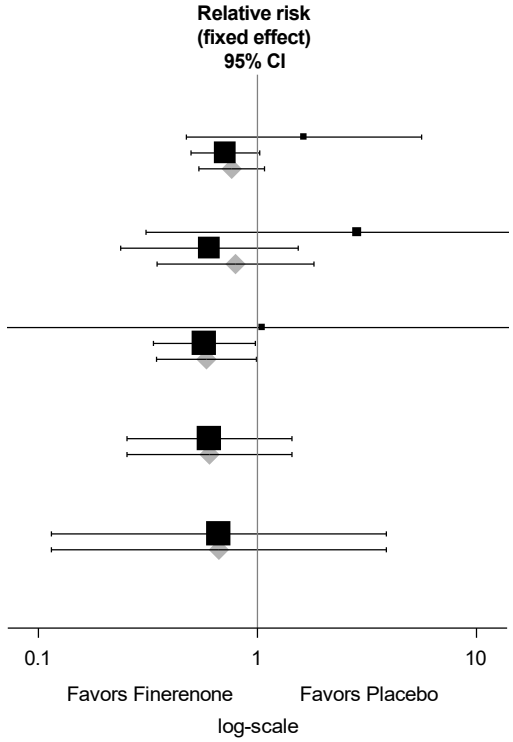
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	6 / 221	6.8	1.75 [0.65,4.74]	
FIGARO-DKD	85 / 2326	129 / 2302	93.2	0.65 [0.50,0.85]	
Total	95 / 2536	135 / 2523		0.70 [0.54,0.90]	Z=-2.74, p=0.0062
Heterogeneity:	Q=3.55 (df=1)	p=0.0597	I^2=71.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.60.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

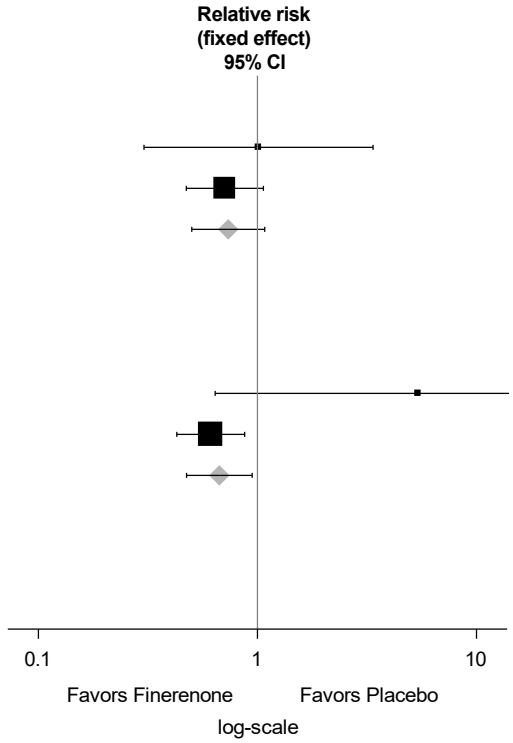
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 103	4 / 112	7.9	1.63 [0.47,5.62]	
FIGARO-DKD	48 / 1114	67 / 1110	92.1	0.71 [0.50,1.02]	
Total	54 / 1217	71 / 1222		0.76 [0.54,1.08]	Z=-1.54, p=0.1240
Heterogeneity:	Q=1.58 (df=1)	p=0.2087	I^2=36.7%		
North America					
FIDELIO-DKD	3 / 42	1 / 40	15.0	2.86 [0.31,26.34]	
FIGARO-DKD	7 / 292	11 / 277	85.0	0.60 [0.24,1.54]	
Total	10 / 334	12 / 317		0.79 [0.35,1.81]	Z=-0.55, p=0.5838
Heterogeneity:	Q=1.61 (df=1)	p=0.2048	I^2=37.8%		
Asia					
FIDELIO-DKD	1 / 39	1 / 41	3.7	1.05 [0.07,16.23]	
FIGARO-DKD	20 / 522	35 / 523	96.3	0.57 [0.34,0.98]	
Total	21 / 561	36 / 564		0.59 [0.35,0.99]	Z=-2.00, p=0.0454
Heterogeneity:	Q=0.18 (df=1)	p=0.6693	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	8 / 322	13 / 316	100.0	0.60 [0.25,1.44]	
Total	8 / 343	13 / 340		0.60 [0.25,1.44]	Z=-1.14, p=0.2542
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	3 / 76	100.0	0.67 [0.11,3.88]	
Total	2 / 81	3 / 80		0.67 [0.11,3.88]	Z=-0.45, p=0.6517
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=4)	p=0.9260	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.60.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

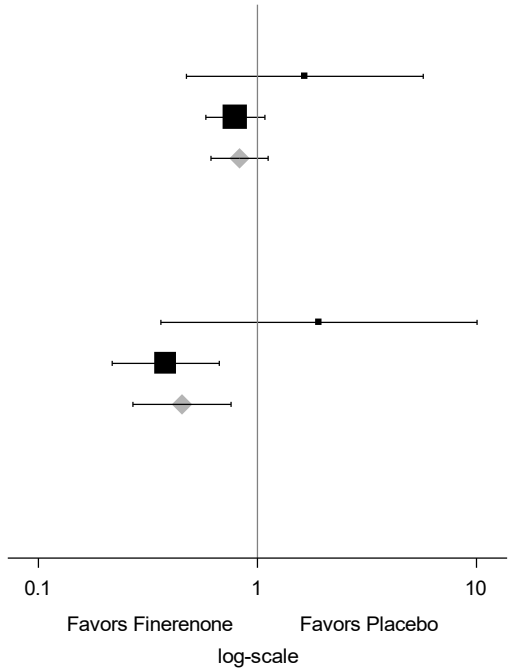
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	5 / 88	5 / 89	10.2	1.01 [0.30,3.37]	
FIGARO-DKD	38 / 811	53 / 803	89.8	0.71 [0.47,1.06]	
Total	43 / 899	58 / 892		0.74 [0.50,1.08]	Z=-1.57, p=0.1165
Heterogeneity:	Q=0.30 (df=1)	p=0.5850	I^2=0.0%		
Absent					
FIDELIO-DKD	5 / 122	1 / 132	2.7	5.41 [0.64,45.65]	
FIGARO-DKD	47 / 1515	76 / 1499	97.3	0.61 [0.43,0.87]	
Total	52 / 1637	77 / 1631		0.67 [0.47,0.95]	Z=-2.28, p=0.0229
Heterogeneity:	Q=3.93 (df=1)	p=0.0474	I^2=74.6%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7223	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.60.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

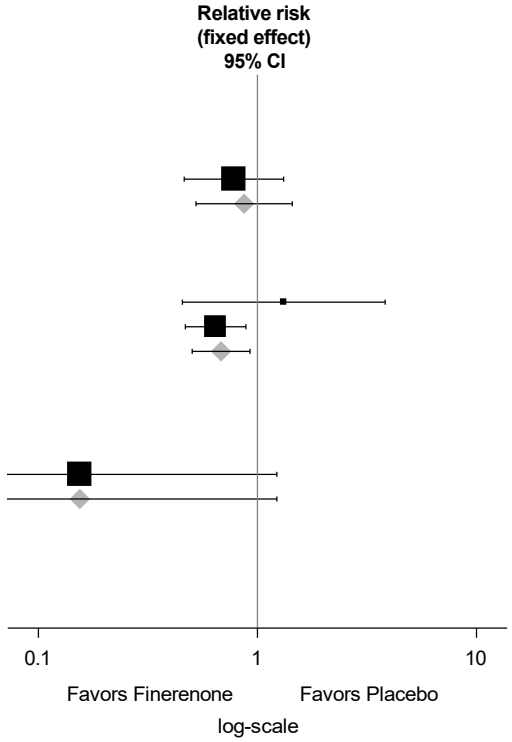
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	4 / 158	5.9	1.65 [0.47,5.71]	
FIGARO-DKD	69 / 1719	85 / 1679	94.1	0.79 [0.58,1.08]	
Total	75 / 1863	89 / 1837		0.83 [0.61,1.12]	Z=-1.23, p=0.2195
Heterogeneity:	Q=1.24 (df=1)	p=0.2645	I^2=19.7%		
> 4.5					
FIDELIO-DKD	4 / 66	2 / 63	10.3	1.91 [0.36,10.06]	
FIGARO-DKD	16 / 607	43 / 622	89.7	0.38 [0.22,0.67]	
Total	20 / 673	45 / 685		0.45 [0.27,0.76]	Z=-3.01, p=0.0026
Heterogeneity:	Q=3.24 (df=1)	p=0.0720	I^2=69.1%		
Subgroup Heterogeneity:	Q=3.95 (df=1)	p=0.0470	I^2=74.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.60.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

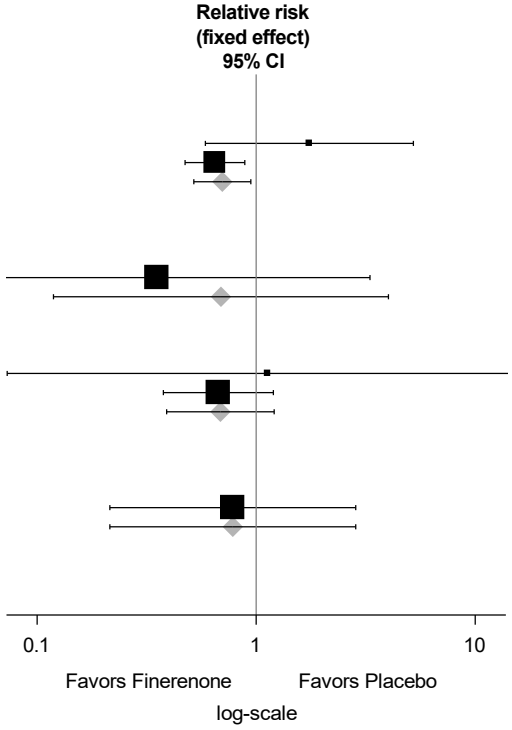
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	0 / 54	0.0	244E9 [244E9,244E9]	
FIGARO-DKD	24 / 693	31 / 699	100.0	0.78 [0.46,1.32]	
Total	27 / 757	31 / 753		0.87 [0.52,1.44]	Z=-0.54, p=0.5869
Heterogeneity:	Q=0.16 (df=1)	p=0.6879	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	7 / 138	6 / 156	8.2	1.32 [0.45,3.83]	
FIGARO-DKD	60 / 1560	91 / 1524	91.8	0.64 [0.47,0.89]	
Total	67 / 1698	97 / 1680		0.68 [0.50,0.92]	Z=-2.46, p=0.0137
Heterogeneity:	Q=1.59 (df=1)	p=0.2068	I^2=37.3%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	7 / 79	100.0	0.15 [0.02,1.23]	
Total	1 / 81	7 / 90		0.15 [0.02,1.23]	Z=-1.77, p=0.0773
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.76 (df=2)	p=0.2514	I^2=27.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.60.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

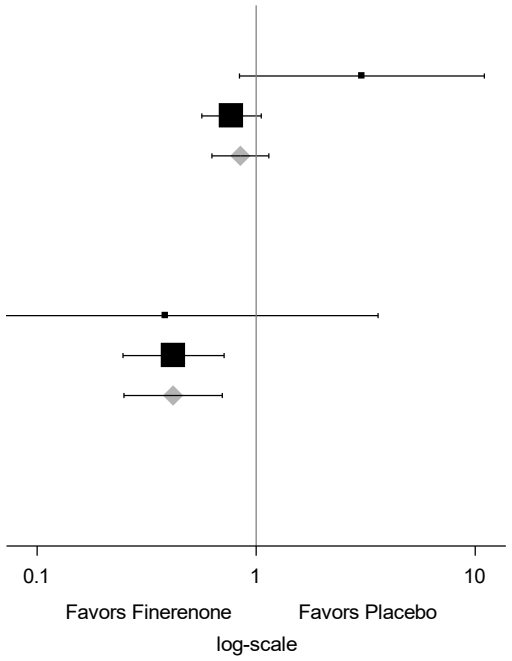
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 139	5 / 152	7.6	1.75 [0.59,5.22]	
FIGARO-DKD	62 / 1658	93 / 1612	92.4	0.65 [0.47,0.89]	
Total	70 / 1797	98 / 1764		0.70 [0.52,0.95]	Z=-2.33, p=0.0199
Heterogeneity:	Q=2.93 (df=1)	p=0.0871	I^2=65.8%		
Black					
FIDELIO-DKD	1 / 10	0 / 9	0.0	192E9 [192E9,192E9]	
FIGARO-DKD	1 / 70	3 / 74	100.0	0.35 [0.04,3.31]	
Total	2 / 80	3 / 83		0.69 [0.12,4.02]	Z=-0.41, p=0.6803
Heterogeneity:	Q=0.35 (df=1)	p=0.5560	I^2=0.0%		
Asian					
FIDELIO-DKD	1 / 39	1 / 44	4.3	1.13 [0.07,17.44]	
FIGARO-DKD	18 / 464	28 / 485	95.7	0.67 [0.38,1.20]	
Total	19 / 503	29 / 529		0.69 [0.39,1.21]	Z=-1.30, p=0.1923
Heterogeneity:	Q=0.13 (df=1)	p=0.7167	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	4 / 134	5 / 131	100.0	0.78 [0.21,2.85]	
Total	4 / 156	5 / 147		0.78 [0.21,2.85]	Z=-0.37, p=0.7094
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=3)	p=0.9984	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.60.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

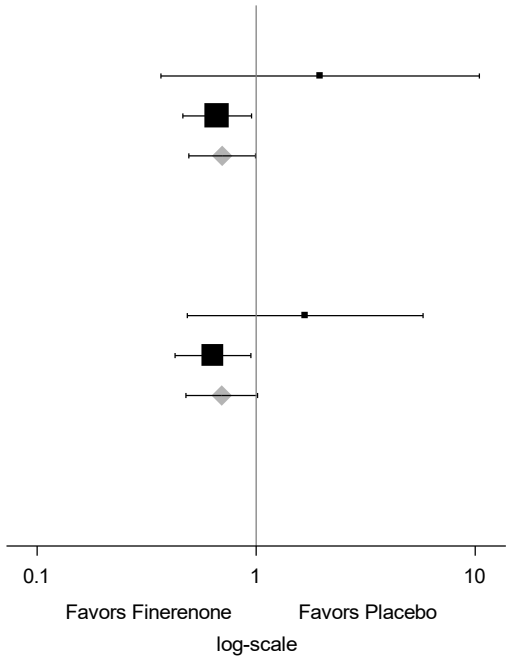
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 152	3 / 154	5.6	3.04 [0.84,11.01]	
FIGARO-DKD	66 / 1610	87 / 1638	94.4	0.77 [0.56,1.05]	
Total	75 / 1762	90 / 1792		0.85 [0.63,1.14]	Z=-1.09, p=0.2767
Heterogeneity:	Q=4.12 (df=1)	p=0.0423	I^2=75.8%		
Female					
FIDELIO-DKD	1 / 58	3 / 67	5.3	0.39 [0.04,3.60]	
FIGARO-DKD	19 / 716	42 / 664	94.7	0.42 [0.25,0.71]	
Total	20 / 774	45 / 731		0.42 [0.25,0.70]	Z=-3.31, p=0.0009
Heterogeneity:	Q=0.01 (df=1)	p=0.9417	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.38 (df=1)	p=0.0203	I^2=81.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.60.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

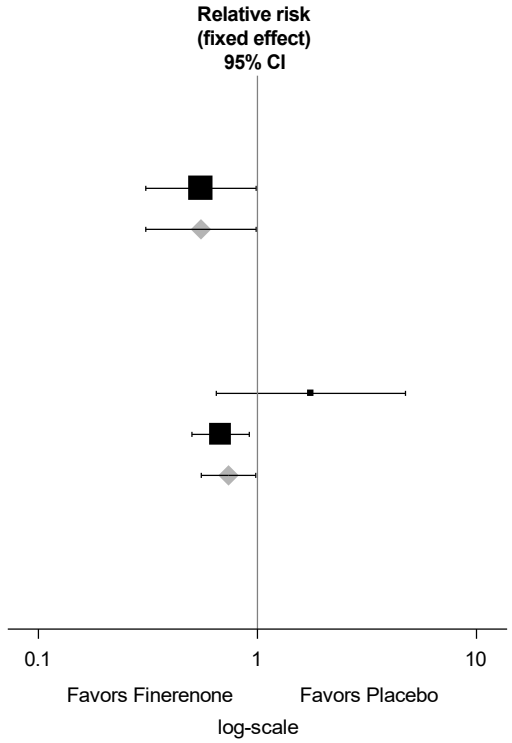
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	4 / 98	2 / 96	4.4	1.96 [0.37,10.45]	
FIGARO-DKD	47 / 1416	71 / 1420	95.6	0.66 [0.46,0.95]	
Total	51 / 1514	73 / 1516		0.70 [0.49,0.99]	Z=-2.00, p=0.0456
Heterogeneity:	Q=1.53 (df=1)	p=0.2154	I^2=34.8%		
>= 65					
FIDELIO-DKD	6 / 112	4 / 125	9.4	1.67 [0.48,5.78]	
FIGARO-DKD	38 / 910	58 / 882	90.6	0.64 [0.43,0.95]	
Total	44 / 1022	62 / 1007		0.70 [0.48,1.01]	Z=-1.89, p=0.0594
Heterogeneity:	Q=2.13 (df=1)	p=0.1444	I^2=53.1%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9859	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.60.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

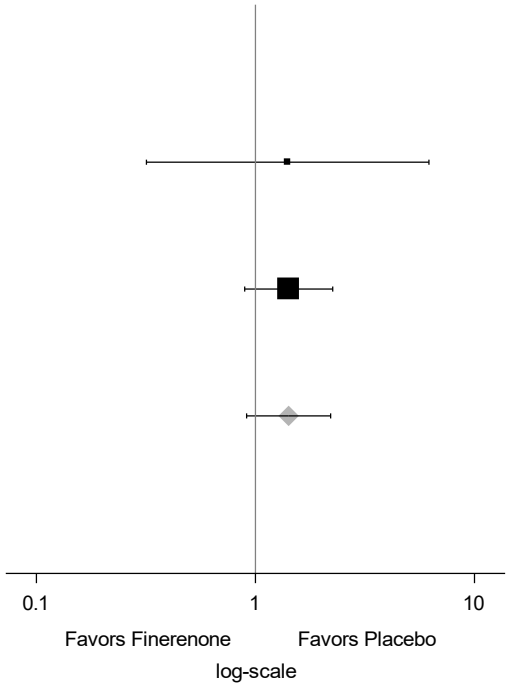
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	17 / 363	29 / 342	100.0	0.55 [0.31,0.99]	
Total	17 / 363	29 / 342		0.55 [0.31,0.99]	Z=-2.01, p=0.0449
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	10 / 210	6 / 221	8.4	1.75 [0.65,4.74]	
FIGARO-DKD	68 / 1963	100 / 1960	91.6	0.68 [0.50,0.92]	
Total	78 / 2173	106 / 2181		0.74 [0.55,0.98]	Z=-2.08, p=0.0373
Heterogeneity:	Q=3.21 (df=1)	p=0.0734	I^2=68.8%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.61: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

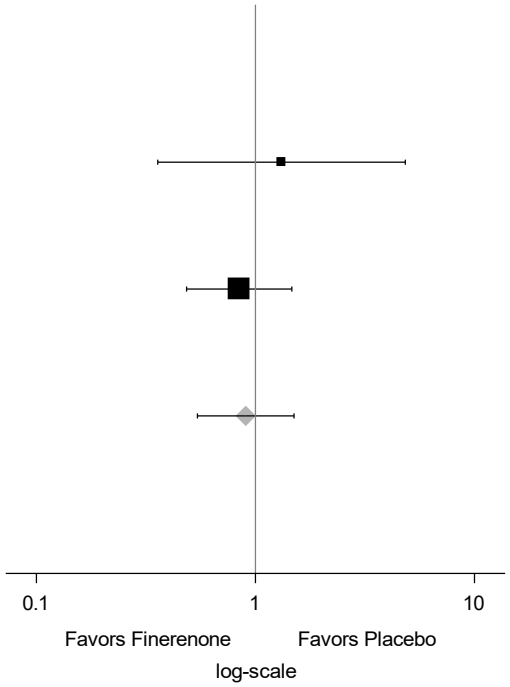
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.8	1.40 [0.32,6.19]	
FIGARO-DKD	43 / 2326	30 / 2302	91.2	1.42 [0.89,2.25]	
Total	47 / 2536	33 / 2523		1.42 [0.91,2.20]	Z=1.55, p=0.1218
Heterogeneity:	Q=0.00 (df=1)	p=0.9890	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.62: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

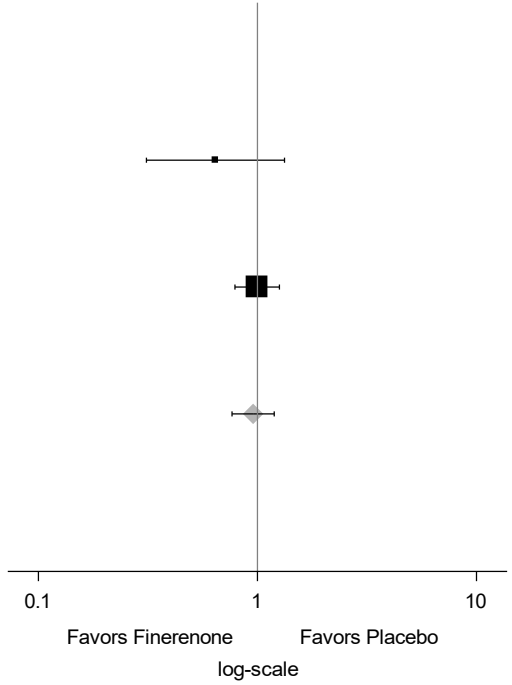
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	15.3	1.32 [0.36,4.83]	
FIGARO-DKD	23 / 2326	27 / 2302	84.7	0.84 [0.48,1.47]	
Total	28 / 2536	31 / 2523		0.90 [0.54,1.50]	Z=-0.39, p=0.6932
Heterogeneity:	Q=0.38 (df=1)	p=0.5374	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.63: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

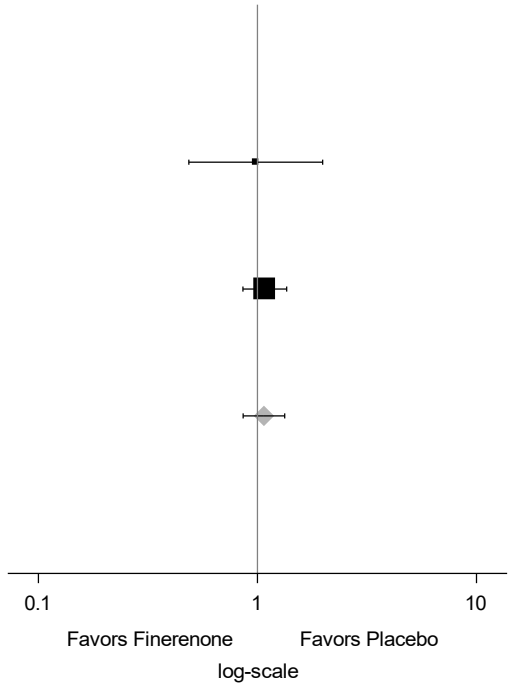
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	18 / 221	9.4	0.64 [0.31,1.33]	
FIGARO-DKD	133 / 2326	132 / 2302	90.6	1.00 [0.79,1.26]	
Total	144 / 2536	150 / 2523		0.96 [0.77,1.19]	Z=-0.40, p=0.6875
Heterogeneity:	Q=1.27 (df=1)	p=0.2596	I^2=21.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.64: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

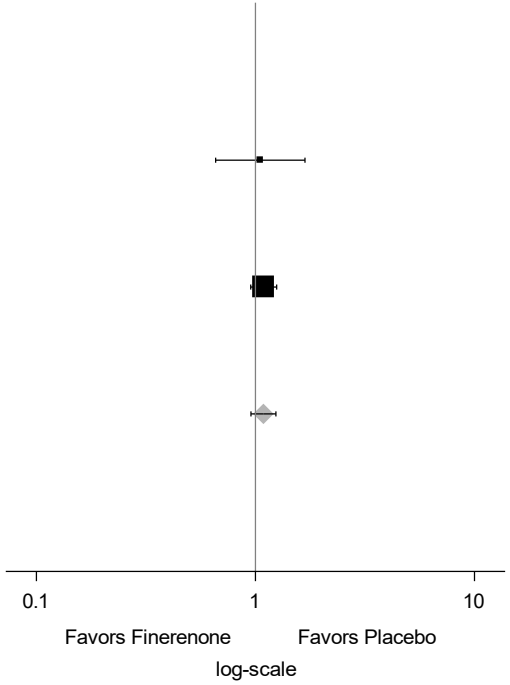
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	15 / 221	9.7	0.98 [0.49,1.98]	
FIGARO-DKD	143 / 2326	131 / 2302	90.3	1.08 [0.86,1.36]	
Total	157 / 2536	146 / 2523		1.07 [0.86,1.33]	Z=0.61, p=0.5414
Heterogeneity:	Q=0.06 (df=1)	p=0.8009	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.65: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

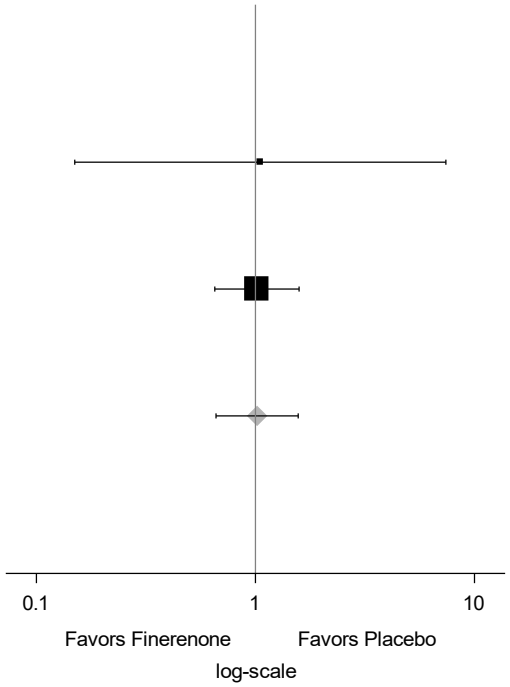
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	30 / 221	7.8	1.05 [0.66,1.68]	
FIGARO-DKD	368 / 2326	334 / 2302	92.2	1.09 [0.95,1.25]	
Total	398 / 2536	364 / 2523		1.09 [0.95,1.24]	Z=1.25, p=0.2100
Heterogeneity:	Q=0.02 (df=1)	p=0.8868	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.66: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

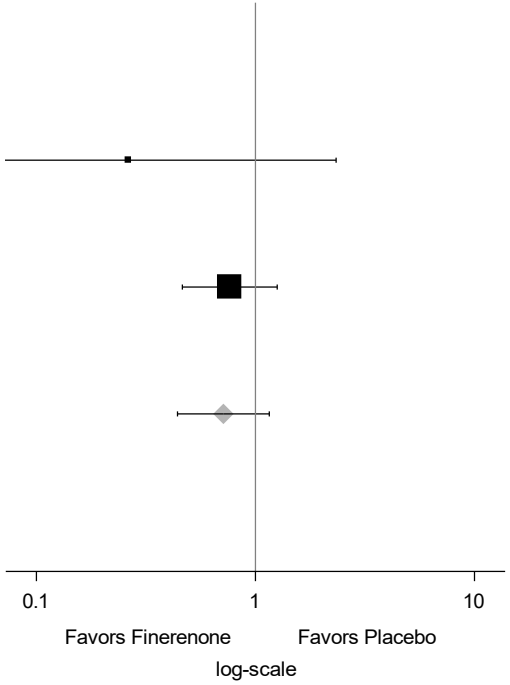
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	4.9	1.05 [0.15,7.40]	
FIGARO-DKD	39 / 2326	38 / 2302	95.1	1.02 [0.65,1.58]	
Total	41 / 2536	40 / 2523		1.02 [0.66,1.57]	Z=0.08, p=0.9373
Heterogeneity:	Q=0.00 (df=1)	p=0.9723	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.67: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

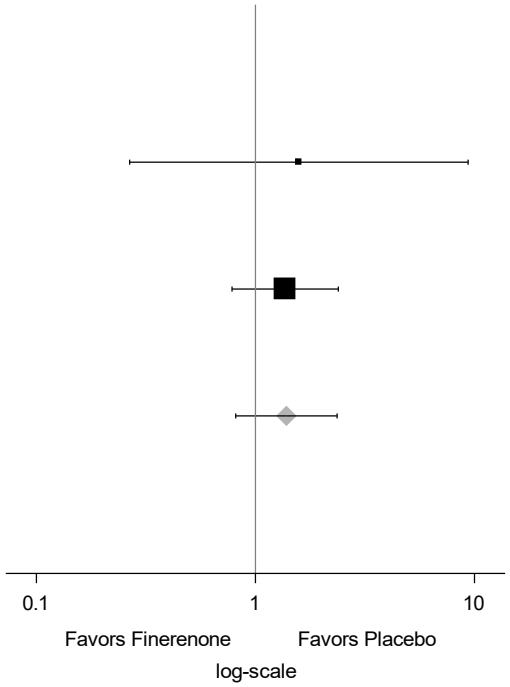
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	5.0	0.26 [0.03,2.33]	
FIGARO-DKD	27 / 2326	35 / 2302	95.0	0.76 [0.46,1.26]	
Total	28 / 2536	39 / 2523		0.71 [0.44,1.16]	Z=-1.37, p=0.1708
Heterogeneity:	Q=0.87 (df=1)	p=0.3502	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.68: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

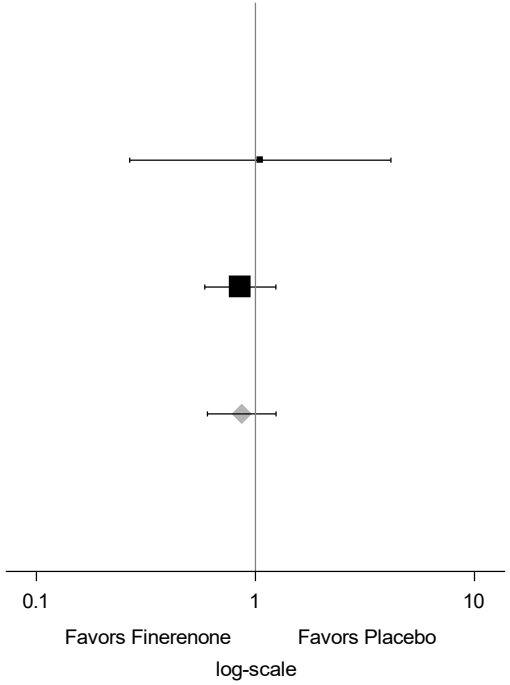
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	9.0	1.58 [0.27,9.35]	
FIGARO-DKD	29 / 2326	21 / 2302	91.0	1.37 [0.78,2.39]	
Total	32 / 2536	23 / 2523		1.38 [0.81,2.36]	Z=1.20, p=0.2313
Heterogeneity:	Q=0.02 (df=1)	p=0.8796	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.69: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

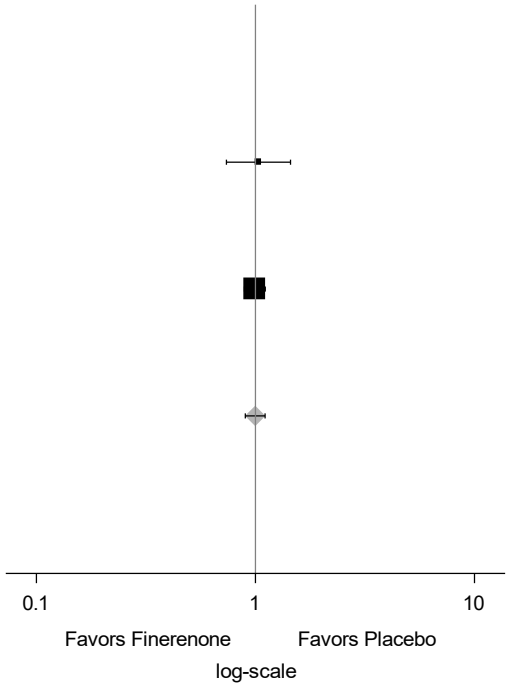
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	4 / 221	6.9	1.05 [0.27,4.15]	
FIGARO-DKD	50 / 2326	58 / 2302	93.1	0.85 [0.59,1.24]	
Total	54 / 2536	62 / 2523		0.87 [0.60,1.24]	Z=-0.78, p=0.4327
Heterogeneity:	Q=0.08 (df=1)	p=0.7725	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.70: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

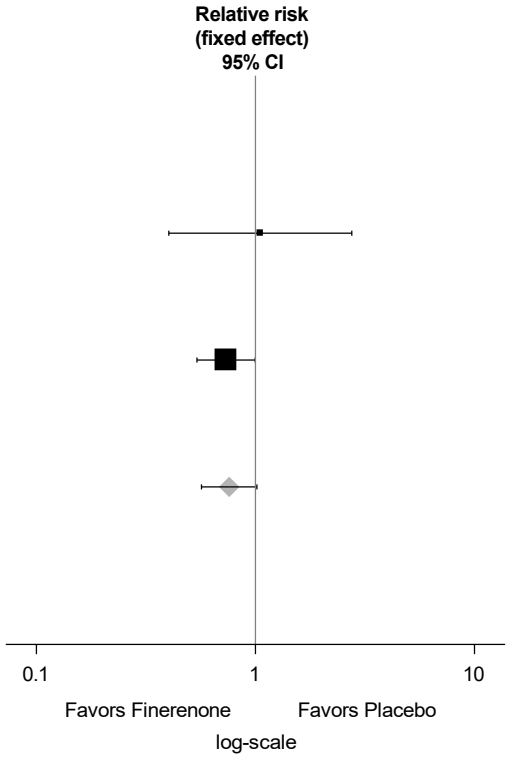
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 210	52 / 221	9.5	1.03 [0.74,1.45]	
FIGARO-DKD	504 / 2326	502 / 2302	90.5	0.99 [0.89,1.11]	
Total	555 / 2536	554 / 2523		1.00 [0.90,1.11]	Z=-0.05, p=0.9583
Heterogeneity:	Q=0.04 (df=1)	p=0.8333	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.71: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

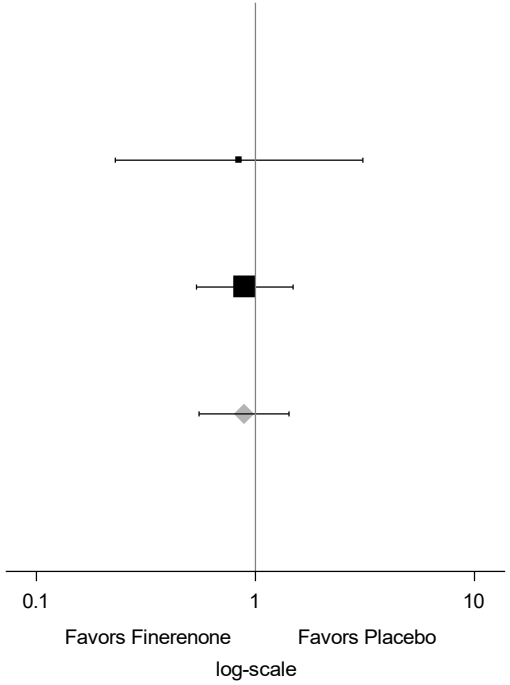
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	8 / 221	9.2	1.05 [0.40,2.75]	
FIGARO-DKD	69 / 2326	93 / 2302	90.8	0.73 [0.54,1.00]	
Total	77 / 2536	101 / 2523		0.76 [0.57,1.02]	Z=-1.86, p=0.0632
Heterogeneity:	Q=0.49 (df=1)	p=0.4845	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.72: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

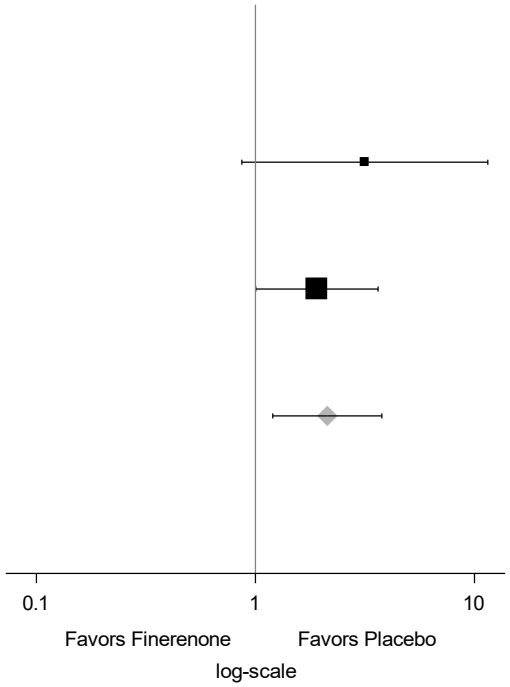
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	13.2	0.84 [0.23,3.09]	
FIGARO-DKD	28 / 2326	31 / 2302	86.8	0.89 [0.54,1.49]	
Total	32 / 2536	36 / 2523		0.89 [0.55,1.42]	Z=-0.50, p=0.6187
Heterogeneity:	Q=0.01 (df=1)	p=0.9330	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.73: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

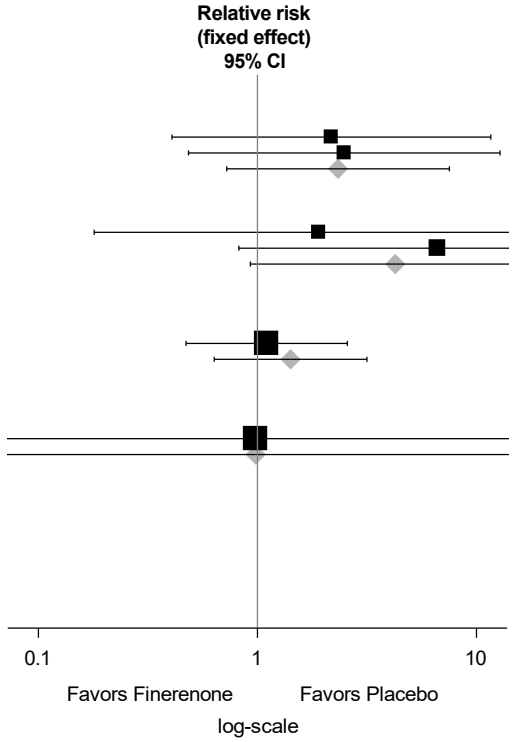
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	3 / 221	19.8	3.16 [0.87,11.50]	
FIGARO-DKD	27 / 2326	14 / 2302	80.2	1.91 [1.00,3.63]	
Total	36 / 2536	17 / 2523		2.13 [1.20,3.78]	Z=2.58, p=0.0098
Heterogeneity:	Q=0.47 (df=1)	p=0.4941	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.73.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

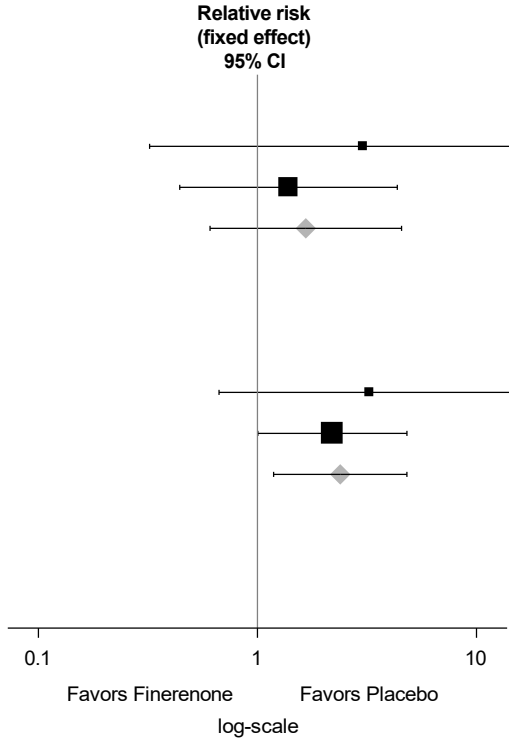
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	4 / 103	2 / 112	48.8	2.17 [0.41,11.62]	
FIGARO-DKD	5 / 1114	2 / 1110	51.2	2.49 [0.48,12.81]	
Total	9 / 1217	4 / 1222		2.33 [0.72,7.52]	Z=1.42, p=0.1559
Heterogeneity:	Q=0.01 (df=1)	p=0.9096	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	1 / 40	43.9	1.90 [0.18,20.19]	
FIGARO-DKD	7 / 292	1 / 277	56.1	6.64 [0.82,53.62]	
Total	9 / 334	2 / 317		4.26 [0.93,19.52]	Z=1.86, p=0.0623
Heterogeneity:	Q=0.62 (df=1)	p=0.4311	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	0 / 41	0.0	147E9 [147E9,147E9]	
FIGARO-DKD	11 / 522	10 / 523	100.0	1.10 [0.47,2.57]	
Total	14 / 561	10 / 564		1.42 [0.63,3.16]	Z=0.85, p=0.3950
Heterogeneity:	Q=0.34 (df=1)	p=0.5615	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	1 / 316	100.0	0.98 [0.06,15.62]	
Total	1 / 343	1 / 340		0.98 [0.06,15.62]	Z=-0.01, p=0.9894
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	0 / 76	0.0	206E9 [206E9,206E9]	
Total	3 / 81	0 / 80		6.4E7 [6.4E7,6.4E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.93 (df=4)	p=0.7493	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.73.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

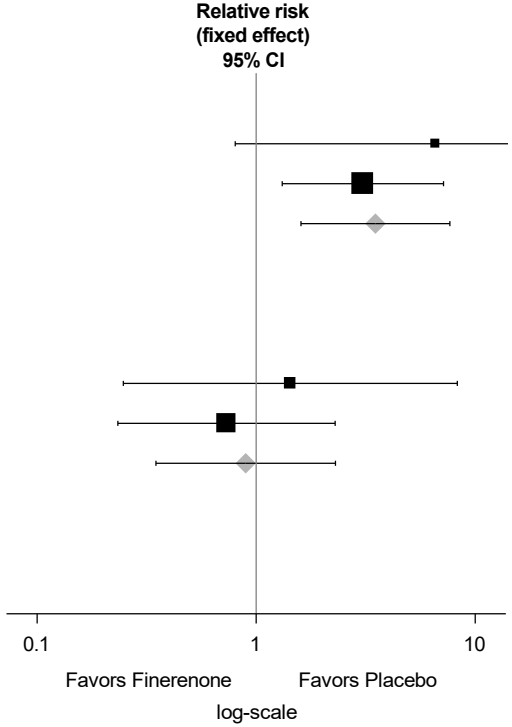
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	3 / 88	1 / 89	20.6	3.03 [0.32,28.61]	
FIGARO-DKD	7 / 811	5 / 803	79.4	1.39 [0.44,4.35]	
Total	10 / 899	6 / 892		1.66 [0.61,4.55]	Z=0.99, p=0.3225
Heterogeneity:	Q=0.37 (df=1)	p=0.5413	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 122	2 / 132	19.7	3.25 [0.67,15.78]	
FIGARO-DKD	20 / 1515	9 / 1499	80.3	2.20 [1.00,4.81]	
Total	26 / 1637	11 / 1631		2.39 [1.18,4.81]	Z=2.43, p=0.0149
Heterogeneity:	Q=0.19 (df=1)	p=0.6651	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=1)	p=0.5627	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.73.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

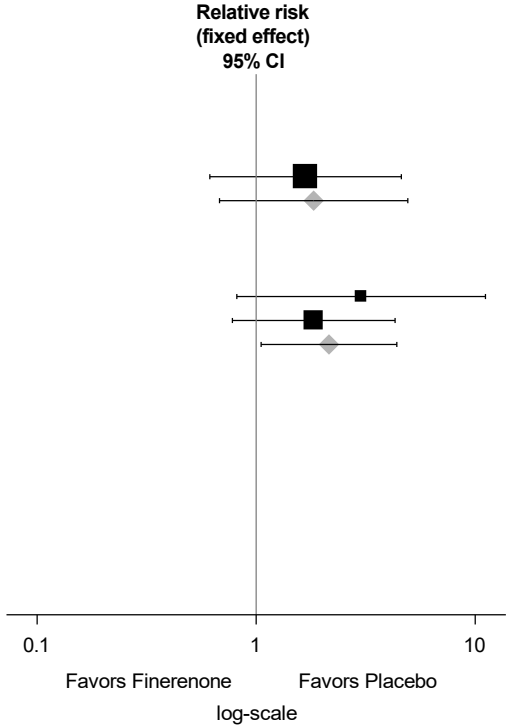
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	1 / 158	14.0	6.58 [0.80,54.03]	
FIGARO-DKD	22 / 1719	7 / 1679	86.0	3.07 [1.31,7.17]	
Total	28 / 1863	8 / 1837		3.50 [1.60,7.66]	Z=3.14, p=0.0017
Heterogeneity:	Q=0.44 (df=1)	p=0.5080	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 66	2 / 63	29.7	1.43 [0.25,8.29]	
FIGARO-DKD	5 / 607	7 / 622	70.3	0.73 [0.23,2.29]	
Total	8 / 673	9 / 685		0.90 [0.35,2.30]	Z=-0.23, p=0.8191
Heterogeneity:	Q=0.39 (df=1)	p=0.5300	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.75 (df=1)	p=0.0292	I^2=79.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.73.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

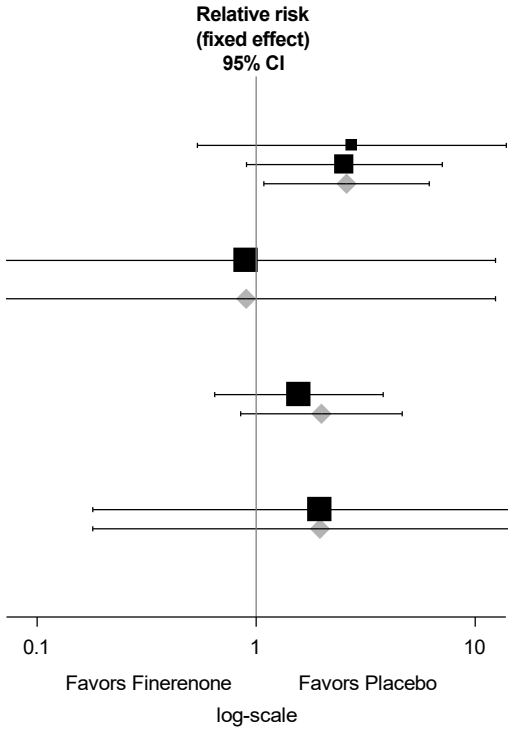
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	814E8 [814E8,814E8]	
FIGARO-DKD	10 / 693	6 / 699	100.0	1.68 [0.61,4.60]	
Total	11 / 757	6 / 753		1.83 [0.68,4.92]	Z=1.20, p=0.2314
Heterogeneity:	Q=0.03 (df=1)	p=0.8688	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	8 / 138	3 / 156	30.0	3.01 [0.82,11.14]	
FIGARO-DKD	15 / 1560	8 / 1524	70.0	1.83 [0.78,4.31]	
Total	23 / 1698	11 / 1680		2.15 [1.05,4.39]	Z=2.10, p=0.0355
Heterogeneity:	Q=0.39 (df=1)	p=0.5314	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	0 / 79	0.0	143E9 [143E9,143E9]	
Total	2 / 81	0 / 90		4.03E7 [4.03E7,4.03E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.07 (df=2)	p=0.9671	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.73.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

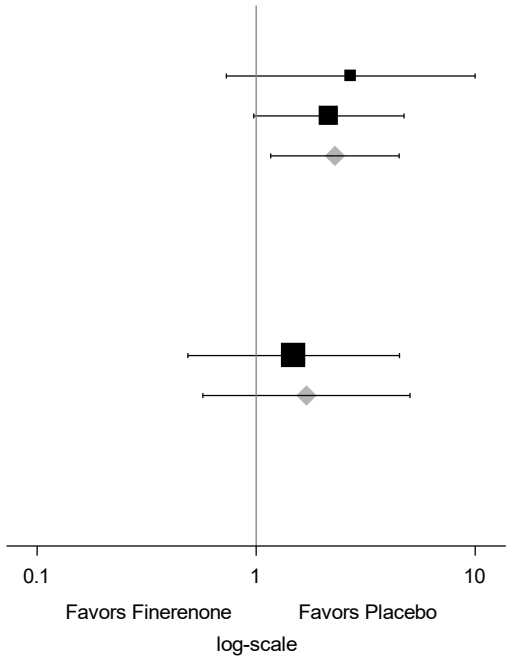
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	5 / 139	2 / 152	28.7	2.73 [0.54,13.86]	
FIGARO-DKD	13 / 1658	5 / 1612	71.3	2.53 [0.90,7.07]	
Total	18 / 1797	7 / 1764		2.59 [1.08,6.17]	Z=2.14, p=0.0322
Heterogeneity:	Q=0.01 (df=1)	p=0.9363	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	100.0	0.90 [0.07,12.38]	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	1 / 80	1 / 83		0.90 [0.07,12.38]	Z=-0.08, p=0.9372
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	0 / 44	0.0	147E9 [147E9,147E9]	
FIGARO-DKD	12 / 464	8 / 485	100.0	1.57 [0.65,3.80]	
Total	15 / 503	8 / 529		1.99 [0.85,4.64]	Z=1.58, p=0.1133
Heterogeneity:	Q=0.27 (df=1)	p=0.6008	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	1 / 131	100.0	1.96 [0.18,21.30]	
Total	2 / 156	1 / 147		1.96 [0.18,21.30]	Z=0.55, p=0.5822
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=3)	p=0.8880	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.73.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

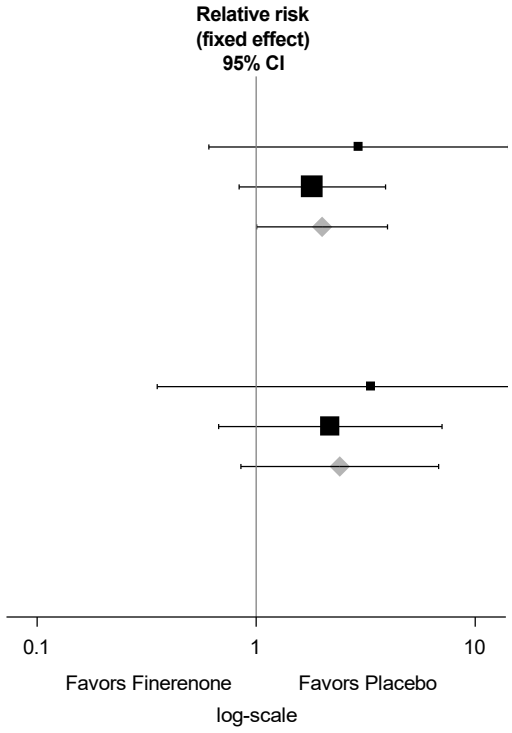
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	3 / 154	26.7	2.70 [0.73,9.99]	
FIGARO-DKD	19 / 1610	9 / 1638	73.3	2.15 [0.97,4.73]	
Total	27 / 1762	12 / 1792		2.29 [1.17,4.50]	Z=2.40, p=0.0162
Heterogeneity:	Q=0.09 (df=1)	p=0.7685	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	0 / 67	0.0	244E9 [244E9,244E9]	
FIGARO-DKD	8 / 716	5 / 664	100.0	1.48 [0.49,4.51]	
Total	9 / 774	5 / 731		1.70 [0.57,5.04]	Z=0.95, p=0.3416
Heterogeneity:	Q=0.06 (df=1)	p=0.8136	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6467	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.73.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

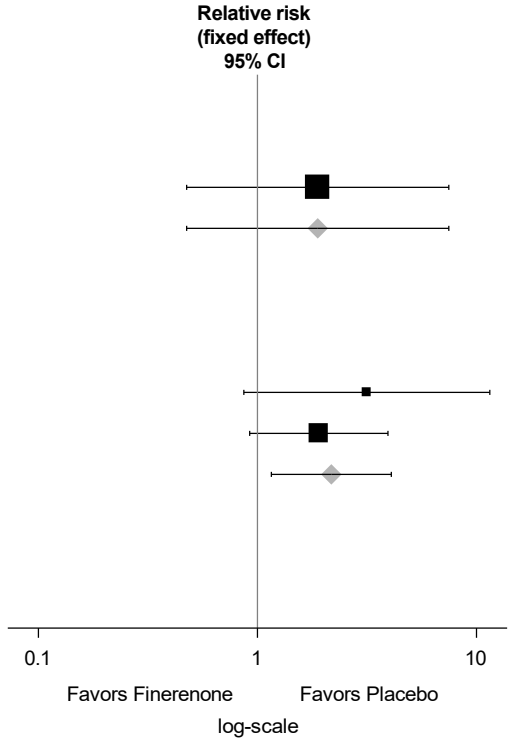
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	6 / 98	2 / 96	19.3	2.94 [0.61,14.20]	
FIGARO-DKD	18 / 1416	10 / 1420	80.7	1.81 [0.84,3.90]	
Total	24 / 1514	12 / 1516		2.00 [1.01,3.98]	Z=1.98, p=0.0482
Heterogeneity:	Q=0.30 (df=1)	p=0.5855	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	1 / 125	21.4	3.35 [0.35,31.73]	
FIGARO-DKD	9 / 910	4 / 882	78.6	2.18 [0.67,7.06]	
Total	12 / 1022	5 / 1007		2.41 [0.85,6.81]	Z=1.66, p=0.0975
Heterogeneity:	Q=0.11 (df=1)	p=0.7402	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7702	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.73.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

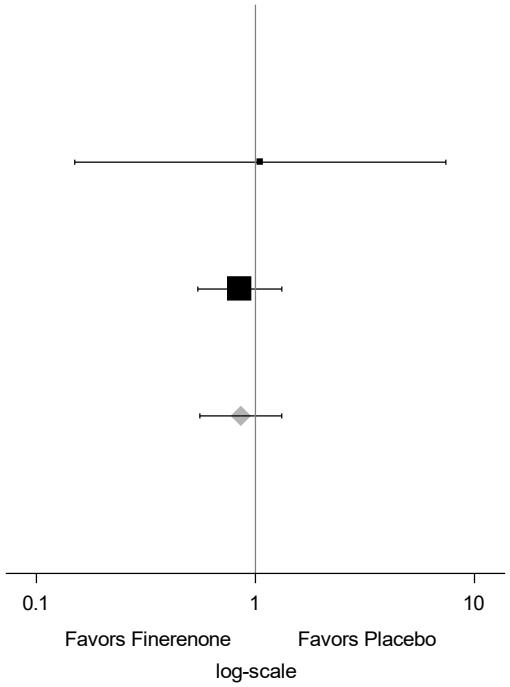
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	3 / 342	100.0	1.88 [0.47,7.48]	
Total	6 / 363	3 / 342		1.88 [0.47,7.48]	Z=0.90, p=0.3675
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	9 / 210	3 / 221	24.0	3.16 [0.87,11.50]	
FIGARO-DKD	21 / 1963	11 / 1960	76.0	1.91 [0.92,3.94]	
Total	30 / 2173	14 / 2181		2.17 [1.16,4.09]	Z=2.41, p=0.0158
Heterogeneity:	Q=0.45 (df=1)	p=0.5044	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8531	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.74: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

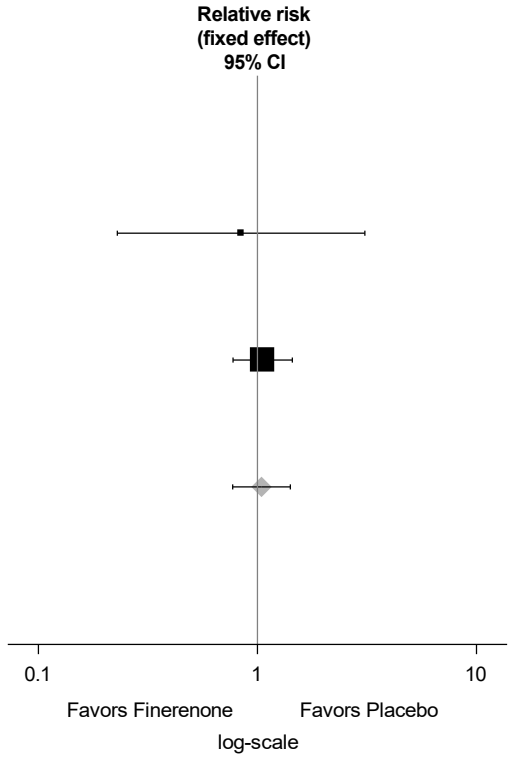
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	4.9	1.05 [0.15,7.40]	
FIGARO-DKD	36 / 2326	42 / 2302	95.1	0.85 [0.55,1.32]	
Total	38 / 2536	44 / 2523		0.86 [0.56,1.32]	Z=-0.70, p=0.4830
Heterogeneity:	Q=0.04 (df=1)	p=0.8327	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.75: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

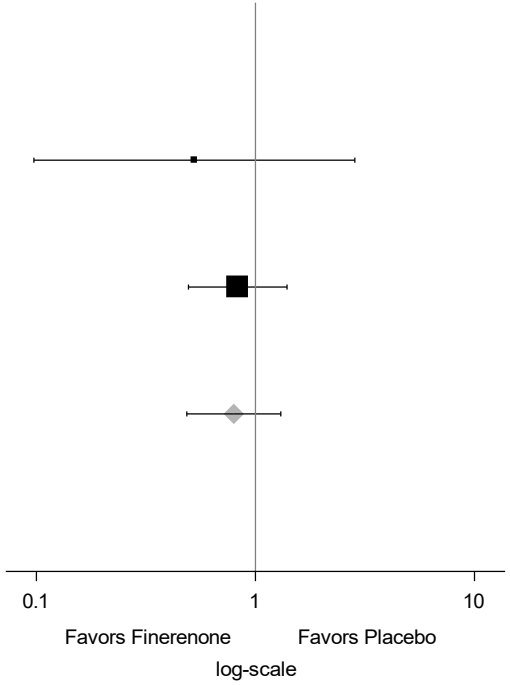
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	5.4	0.84 [0.23,3.09]	
FIGARO-DKD	79 / 2326	74 / 2302	94.6	1.06 [0.77,1.44]	
Total	83 / 2536	79 / 2523		1.04 [0.77,1.41]	Z=0.28, p=0.7830
Heterogeneity:	Q=0.11 (df=1)	p=0.7394	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.76: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

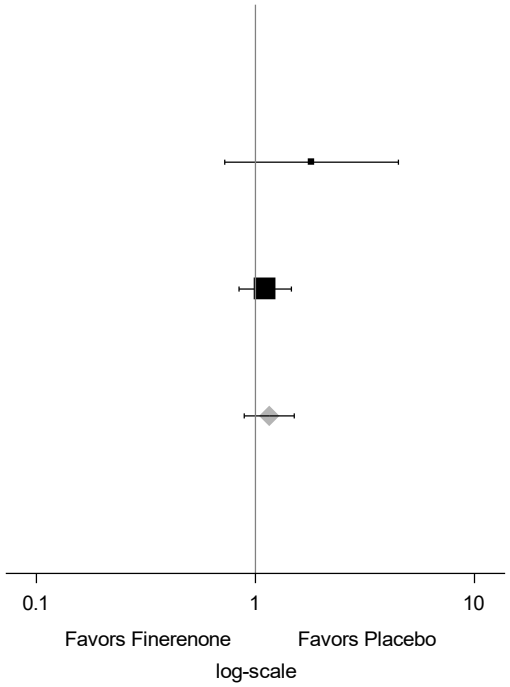
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	8.6	0.53 [0.10,2.84]	
FIGARO-DKD	26 / 2326	31 / 2302	91.4	0.83 [0.49,1.39]	
Total	28 / 2536	35 / 2523		0.80 [0.49,1.30]	Z=-0.90, p=0.3661
Heterogeneity:	Q=0.26 (df=1)	p=0.6126	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.77: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

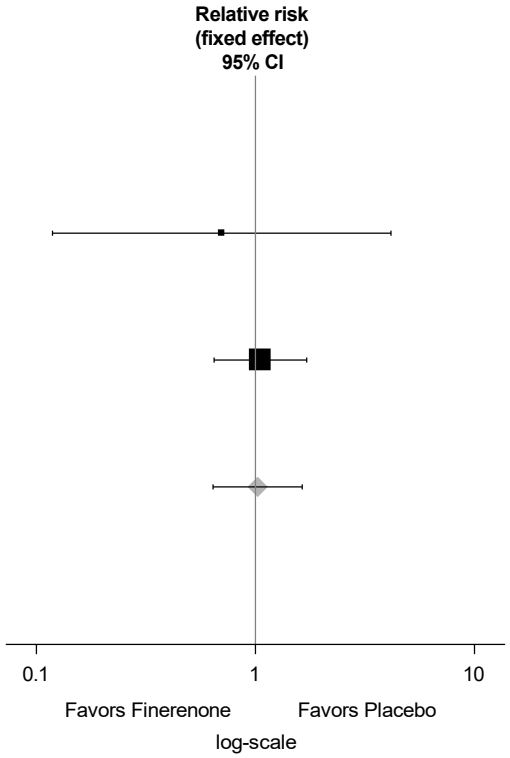
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	7 / 221	8.3	1.80 [0.72,4.49]	
FIGARO-DKD	103 / 2326	92 / 2302	91.7	1.11 [0.84,1.46]	
Total	115 / 2536	99 / 2523		1.16 [0.89,1.50]	Z=1.08, p=0.2799
Heterogeneity:	Q=1.00 (df=1)	p=0.3162	I^2=0.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.78: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

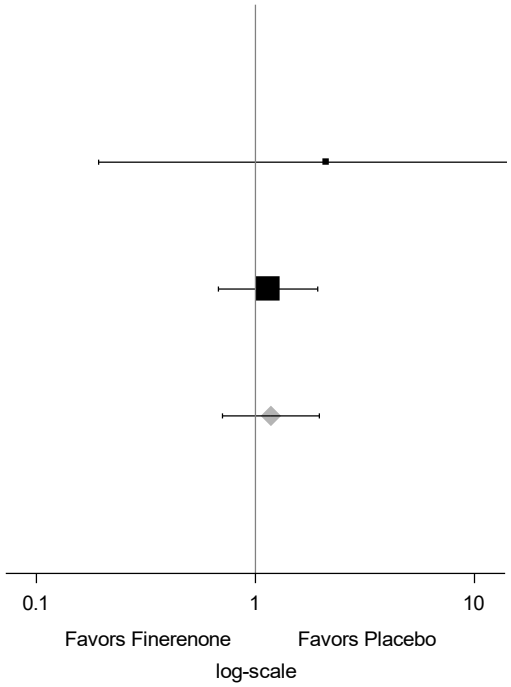
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.0	0.70 [0.12,4.16]	
FIGARO-DKD	33 / 2326	31 / 2302	93.0	1.05 [0.65,1.71]	
Total	35 / 2536	34 / 2523		1.02 [0.64,1.64]	Z=0.10, p=0.9230
Heterogeneity:	Q=0.19 (df=1)	p=0.6657	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.79: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

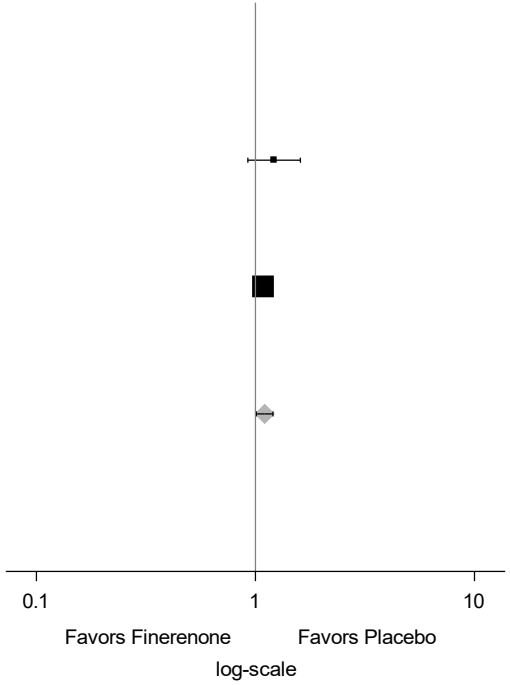
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.5	2.10 [0.19,23.04]	
FIGARO-DKD	30 / 2326	26 / 2302	95.5	1.14 [0.68,1.92]	
Total	32 / 2536	27 / 2523		1.18 [0.71,1.96]	Z=0.63, p=0.5316
Heterogeneity:	Q=0.24 (df=1)	p=0.6246	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.80: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

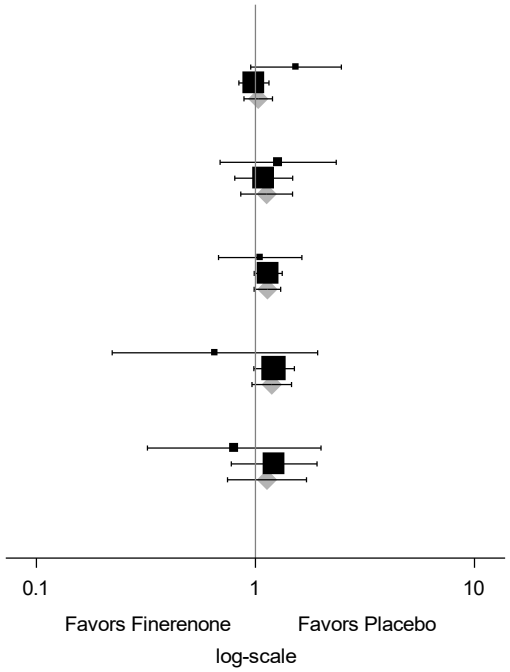
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	74 / 210	64 / 221	10.0	1.22 [0.92,1.60]	
FIGARO-DKD	686 / 2326	623 / 2302	90.0	1.09 [0.99,1.19]	
Total	760 / 2536	687 / 2523		1.10 [1.01,1.20]	Z=2.18, p=0.0292
Heterogeneity:	Q=0.55 (df=1)	p=0.4577	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.80.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

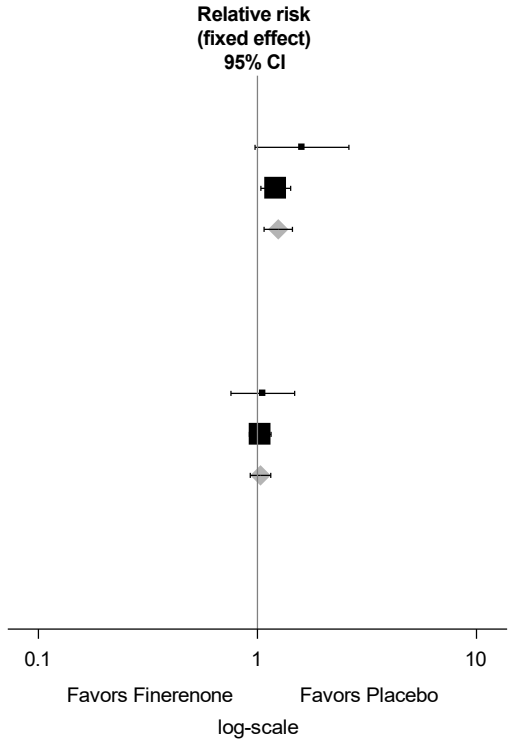
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	31 / 103	22 / 112	9.9	1.53 [0.95,2.47]	
FIGARO-DKD	239 / 1114	242 / 1110	90.1	0.98 [0.84,1.15]	
Total	270 / 1217	264 / 1222		1.03 [0.89,1.20]	Z=0.38, p=0.7033
Heterogeneity:	Q=2.99 (df=1)	p=0.0838	I^2=66.5%		
North America					
FIDELIO-DKD	16 / 42	12 / 40	19.9	1.27 [0.69,2.34]	
FIGARO-DKD	69 / 292	60 / 277	80.1	1.09 [0.80,1.48]	
Total	85 / 334	72 / 317		1.12 [0.86,1.48]	Z=0.85, p=0.3967
Heterogeneity:	Q=0.19 (df=1)	p=0.6626	I^2=0.0%		
Asia					
FIDELIO-DKD	20 / 39	20 / 41	10.2	1.05 [0.68,1.63]	
FIGARO-DKD	226 / 522	198 / 523	89.8	1.14 [0.99,1.33]	
Total	246 / 561	218 / 564		1.13 [0.99,1.30]	Z=1.76, p=0.0777
Heterogeneity:	Q=0.13 (df=1)	p=0.7212	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 21	7 / 24	3.7	0.65 [0.22,1.92]	
FIGARO-DKD	124 / 322	100 / 316	96.3	1.22 [0.98,1.51]	
Total	128 / 343	107 / 340		1.19 [0.96,1.46]	Z=1.62, p=0.1062
Heterogeneity:	Q=1.23 (df=1)	p=0.2677	I^2=18.6%		
Others					
FIDELIO-DKD	3 / 5	3 / 4	19.6	0.80 [0.32,1.99]	
FIGARO-DKD	28 / 76	23 / 76	80.4	1.22 [0.78,1.91]	
Total	31 / 81	26 / 80		1.13 [0.75,1.71]	Z=0.57, p=0.5666
Heterogeneity:	Q=0.66 (df=1)	p=0.4183	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.47 (df=4)	p=0.8328	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.80.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

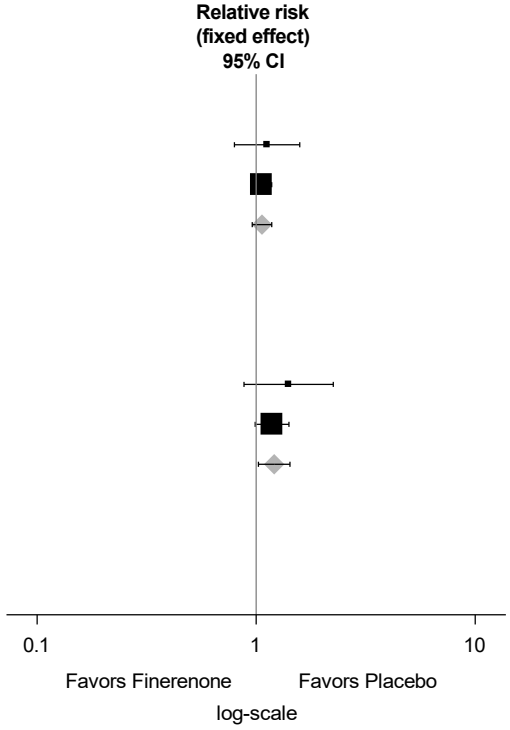
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	30 / 88	19 / 89	9.2	1.60 [0.98,2.62]	
FIGARO-DKD	251 / 811	205 / 803	90.8	1.21 [1.04,1.42]	
Total	281 / 899	224 / 892		1.24 [1.07,1.44]	Z=2.87, p=0.0040
Heterogeneity:	Q=1.09 (df=1)	p=0.2968	I^2=8.1%		
Absent					
FIDELIO-DKD	44 / 122	45 / 132	10.3	1.06 [0.76,1.48]	
FIGARO-DKD	435 / 1515	418 / 1499	89.7	1.03 [0.92,1.15]	
Total	479 / 1637	463 / 1631		1.03 [0.93,1.15]	Z=0.58, p=0.5596
Heterogeneity:	Q=0.02 (df=1)	p=0.8808	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.96 (df=1)	p=0.0467	I^2=74.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.80.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

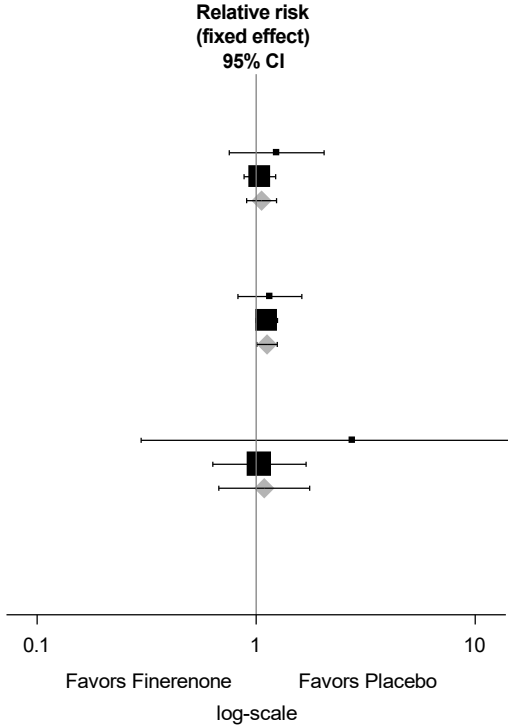
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 144	45 / 158	8.9	1.12 [0.80,1.58]	
FIGARO-DKD	498 / 1719	460 / 1679	91.1	1.06 [0.95,1.18]	
Total	544 / 1863	505 / 1837		1.06 [0.96,1.18]	Z=1.17, p=0.2430
Heterogeneity:	Q=0.10 (df=1)	p=0.7482	I^2=0.0%		
> 4.5					
FIDELIO-DKD	28 / 66	19 / 63	12.5	1.41 [0.88,2.25]	
FIGARO-DKD	188 / 607	163 / 622	87.5	1.18 [0.99,1.41]	
Total	216 / 673	182 / 685		1.21 [1.02,1.43]	Z=2.24, p=0.0250
Heterogeneity:	Q=0.46 (df=1)	p=0.4963	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.67 (df=1)	p=0.1967	I^2=40.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.80.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

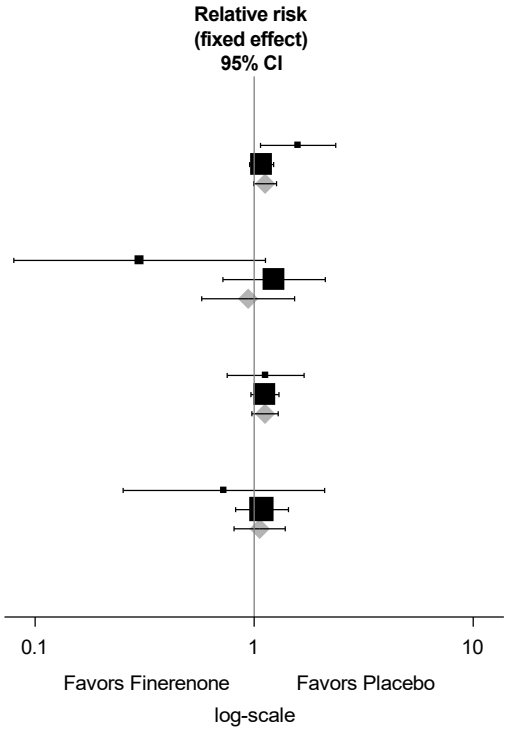
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	25 / 64	17 / 54	10.0	1.24 [0.75,2.04]	
FIGARO-DKD	202 / 693	196 / 699	90.0	1.04 [0.88,1.23]	
Total	227 / 757	213 / 753		1.06 [0.90,1.24]	Z=0.71, p=0.4782
Heterogeneity:	Q=0.44 (df=1)	p=0.5091	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	47 / 138	46 / 156	10.2	1.16 [0.83,1.62]	
FIGARO-DKD	462 / 1560	404 / 1524	89.8	1.12 [1.00,1.25]	
Total	509 / 1698	450 / 1680		1.12 [1.01,1.25]	Z=2.08, p=0.0371
Heterogeneity:	Q=0.03 (df=1)	p=0.8539	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 8	1 / 11	4.6	2.75 [0.30,25.35]	
FIGARO-DKD	22 / 73	23 / 79	95.4	1.04 [0.63,1.69]	
Total	24 / 81	24 / 90		1.09 [0.68,1.75]	Z=0.35, p=0.7279
Heterogeneity:	Q=0.71 (df=1)	p=0.3997	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=2)	p=0.8394	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.80.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

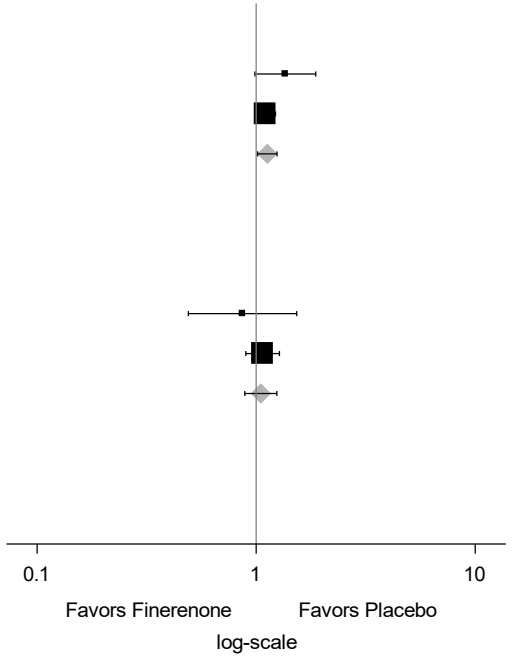
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 139	31 / 152	9.2	1.59 [1.07,2.36]	
FIGARO-DKD	395 / 1658	355 / 1612	90.8	1.08 [0.95,1.23]	
Total	440 / 1797	386 / 1764		1.12 [1.00,1.26]	Z=1.88, p=0.0599
Heterogeneity:	Q=3.28 (df=1)	p=0.0701	I^2=69.5%		
Black					
FIDELIO-DKD	2 / 10	6 / 9	14.2	0.30 [0.08,1.13]	
FIGARO-DKD	21 / 70	18 / 74	85.8	1.23 [0.72,2.11]	
Total	23 / 80	24 / 83		0.94 [0.58,1.53]	Z=-0.25, p=0.7995
Heterogeneity:	Q=3.85 (df=1)	p=0.0499	I^2=74.0%		
Asian					
FIDELIO-DKD	22 / 39	22 / 44	11.7	1.13 [0.75,1.69]	
FIGARO-DKD	210 / 464	196 / 485	88.3	1.12 [0.97,1.30]	
Total	232 / 503	218 / 529		1.12 [0.98,1.29]	Z=1.62, p=0.1060
Heterogeneity:	Q=0.00 (df=1)	p=0.9732	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 22	5 / 16	6.4	0.73 [0.25,2.10]	
FIGARO-DKD	60 / 134	54 / 131	93.6	1.09 [0.82,1.43]	
Total	65 / 156	59 / 147		1.06 [0.81,1.39]	Z=0.42, p=0.6750
Heterogeneity:	Q=0.52 (df=1)	p=0.4727	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.62 (df=3)	p=0.8920	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.80.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

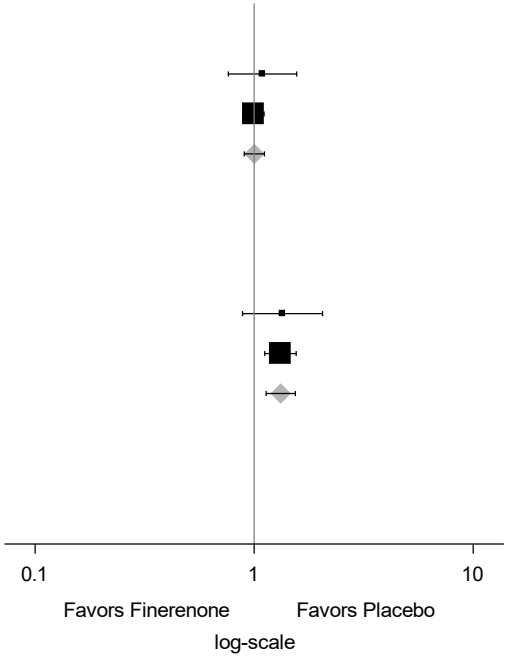
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	59 / 152	44 / 154	10.2	1.36 [0.99,1.87]	
FIGARO-DKD	491 / 1610	454 / 1638	89.8	1.10 [0.99,1.23]	
Total	550 / 1762	498 / 1792		1.12 [1.02,1.25]	Z=2.26, p=0.0238
Heterogeneity:	Q=1.50 (df=1)	p=0.2205	I^2=33.4%		
Female					
FIDELIO-DKD	15 / 58	20 / 67	8.8	0.87 [0.49,1.53]	
FIGARO-DKD	195 / 716	169 / 664	91.2	1.07 [0.90,1.28]	
Total	210 / 774	189 / 731		1.05 [0.89,1.24]	Z=0.57, p=0.5698
Heterogeneity:	Q=0.48 (df=1)	p=0.4879	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.80.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	39 / 98	35 / 96	8.7	1.09 [0.76,1.56]	
FIGARO-DKD	433 / 1416	437 / 1420	91.3	0.99 [0.89,1.11]	
Total	472 / 1514	472 / 1516		1.00 [0.90,1.11]	Z=0.03, p=0.9735
Heterogeneity:	Q=0.24 (df=1)	p=0.6241	I^2=0.0%		
>= 65					
FIDELIO-DKD	35 / 112	29 / 125	13.3	1.35 [0.88,2.05]	
FIGARO-DKD	253 / 910	186 / 882	86.7	1.32 [1.12,1.56]	
Total	288 / 1022	215 / 1007		1.32 [1.13,1.54]	Z=3.56, p=0.0004
Heterogeneity:	Q=0.01 (df=1)	p=0.9258	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.50 (df=1)	p=0.0036	I^2=88.2%		

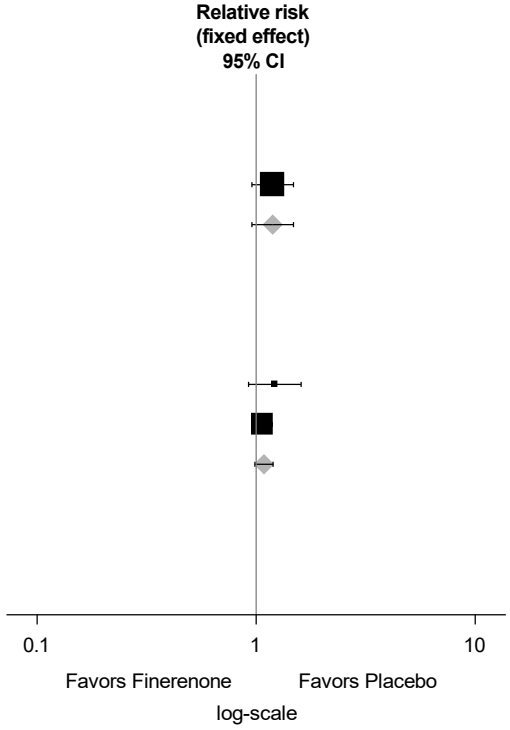


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.80.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

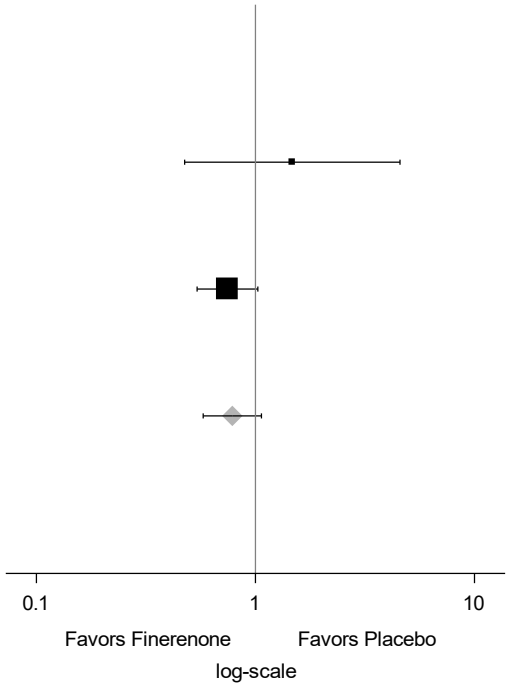
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	125 / 363	99 / 342	100.0	1.19 [0.96,1.48]	
Total	125 / 363	99 / 342		1.19 [0.96,1.48]	Z=1.56, p=0.1193
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	74 / 210	64 / 221	11.9	1.22 [0.92,1.60]	
FIGARO-DKD	561 / 1963	524 / 1960	88.1	1.07 [0.97,1.18]	
Total	635 / 2173	588 / 2181		1.09 [0.99,1.19]	Z=1.69, p=0.0904
Heterogeneity:	Q=0.75 (df=1)	p=0.3881	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4519	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.81: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

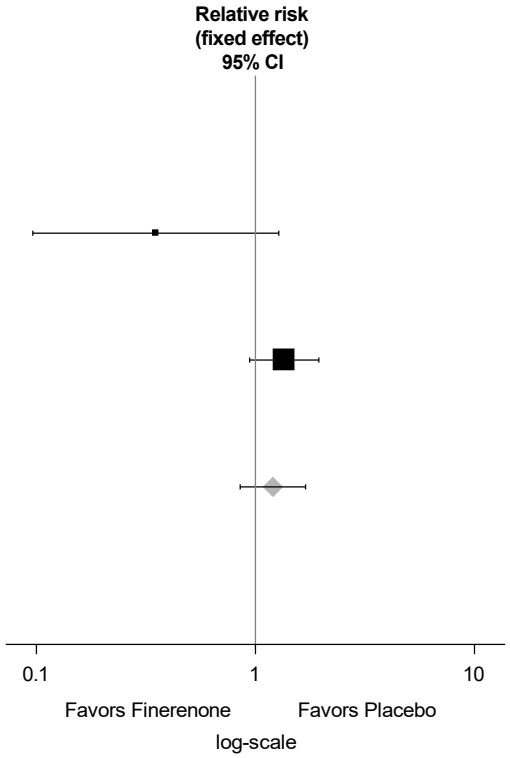
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	7.4	1.47 [0.47,4.57]	
FIGARO-DKD	64 / 2326	85 / 2302	92.6	0.75 [0.54,1.03]	
Total	71 / 2536	90 / 2523		0.78 [0.58,1.07]	Z=-1.56, p=0.1196
Heterogeneity:	Q=1.29 (df=1)	p=0.2560	I^2=22.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.82: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

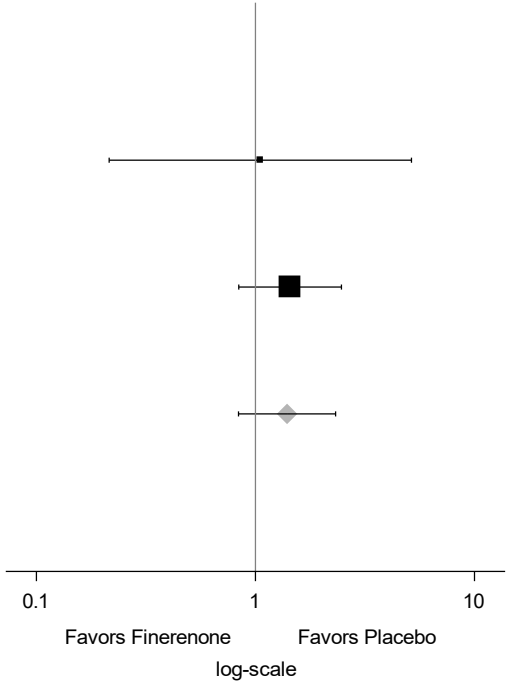
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	9 / 221	7.3	0.35 [0.10,1.28]	
FIGARO-DKD	67 / 2326	49 / 2302	92.7	1.35 [0.94,1.95]	
Total	70 / 2536	58 / 2523		1.20 [0.85,1.69]	Z=1.04, p=0.2962
Heterogeneity:	Q=3.89 (df=1)	p=0.0485	I^2=74.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.83: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

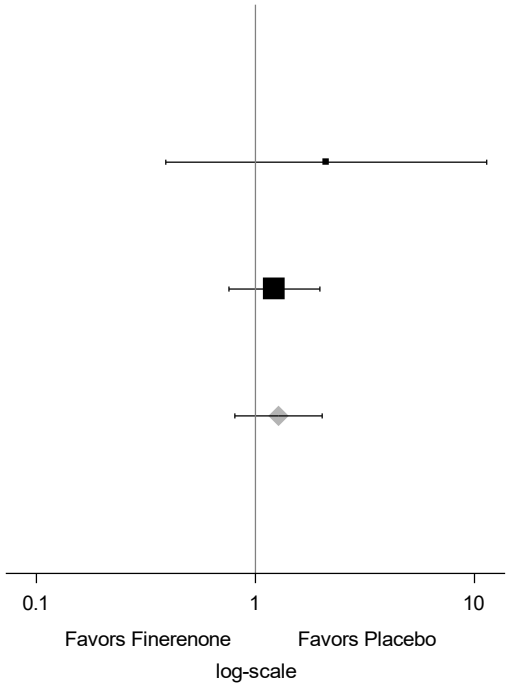
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	10.3	1.05 [0.21,5.16]	
FIGARO-DKD	32 / 2326	22 / 2302	89.7	1.44 [0.84,2.47]	
Total	35 / 2536	25 / 2523		1.39 [0.84,2.32]	Z=1.28, p=0.2020
Heterogeneity:	Q=0.13 (df=1)	p=0.7145	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.84: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

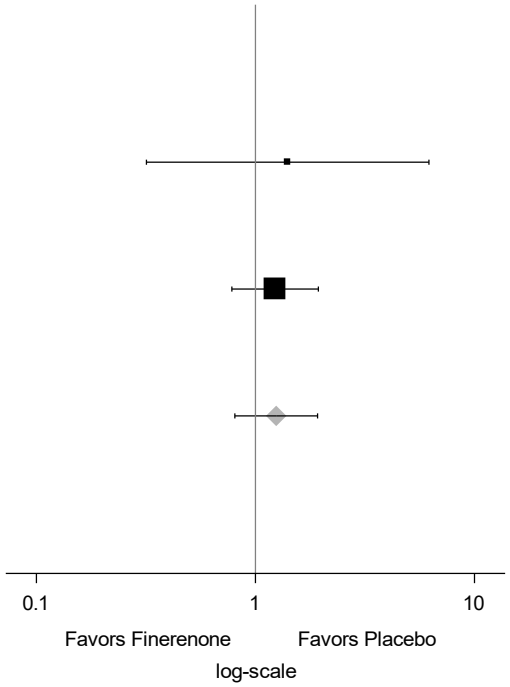
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	7.4	2.10 [0.39,11.37]	
FIGARO-DKD	37 / 2326	30 / 2302	92.6	1.22 [0.76,1.97]	
Total	41 / 2536	32 / 2523		1.27 [0.81,2.02]	Z=1.04, p=0.3005
Heterogeneity:	Q=0.37 (df=1)	p=0.5424	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.85: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

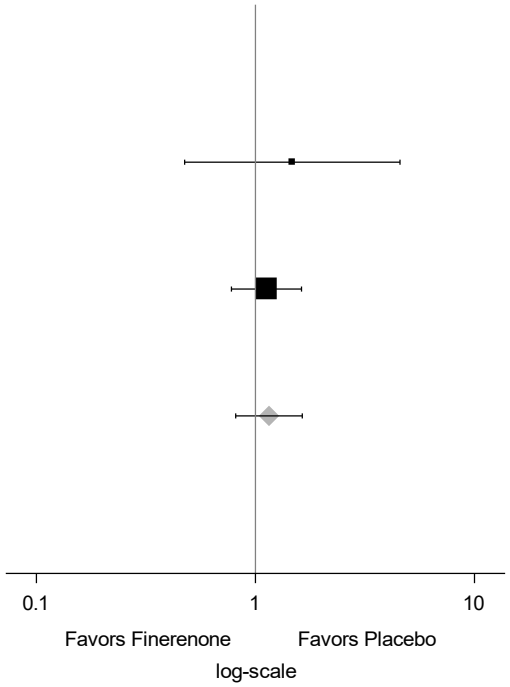
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.6	1.40 [0.32,6.19]	
FIGARO-DKD	41 / 2326	33 / 2302	91.4	1.23 [0.78,1.94]	
Total	45 / 2536	36 / 2523		1.24 [0.81,1.92]	Z=0.98, p=0.3255
Heterogeneity:	Q=0.03 (df=1)	p=0.8677	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.86: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

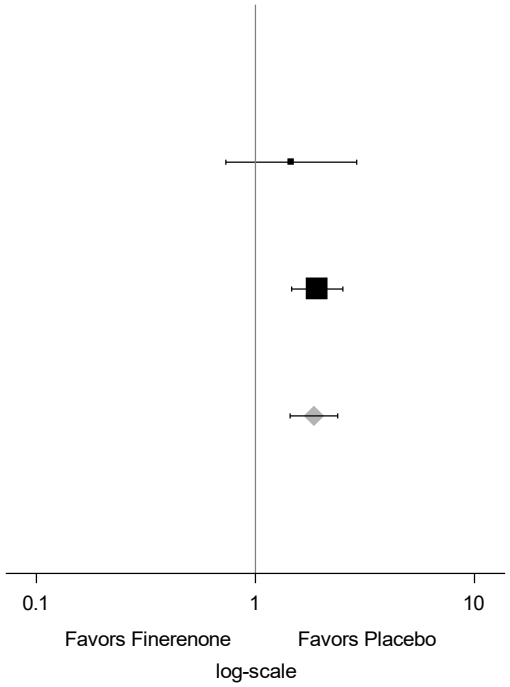
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	9.6	1.47 [0.47,4.57]	
FIGARO-DKD	59 / 2326	52 / 2302	90.4	1.12 [0.78,1.62]	
Total	66 / 2536	57 / 2523		1.15 [0.81,1.64]	Z=0.80, p=0.4256
Heterogeneity:	Q=0.20 (df=1)	p=0.6547	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.87: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

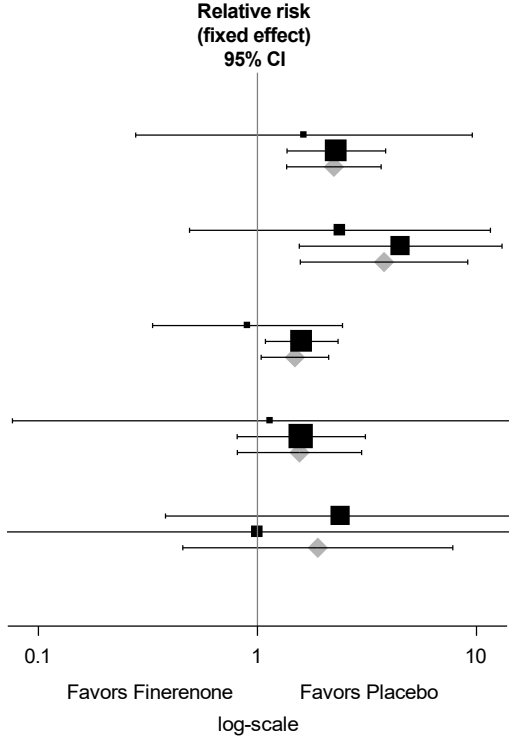
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 210	13 / 221	13.3	1.46 [0.73,2.90]	
FIGARO-DKD	149 / 2326	77 / 2302	86.7	1.92 [1.46,2.51]	
Total	167 / 2536	90 / 2523		1.85 [1.44,2.37]	Z=4.81, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4683	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.87.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

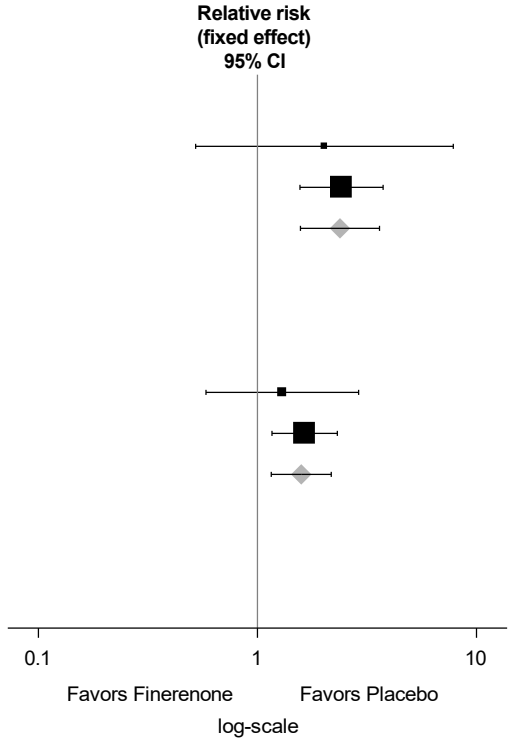
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	2 / 112	7.9	1.63 [0.28,9.57]	
FIGARO-DKD	46 / 1114	20 / 1110	92.1	2.29 [1.36,3.85]	
Total	49 / 1217	22 / 1222		2.23 [1.36,3.67]	Z=3.17, p=0.0015
Heterogeneity:	Q=0.13 (df=1)	p=0.7177	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 42	2 / 40	31.2	2.38 [0.49,11.58]	
FIGARO-DKD	19 / 292	4 / 277	68.8	4.51 [1.55,13.08]	
Total	24 / 334	6 / 317		3.78 [1.57,9.12]	Z=2.96, p=0.0030
Heterogeneity:	Q=0.43 (df=1)	p=0.5106	I^2=0.0%		
Asia					
FIDELIO-DKD	6 / 39	7 / 41	12.8	0.90 [0.33,2.45]	
FIGARO-DKD	62 / 522	39 / 523	87.2	1.59 [1.09,2.33]	
Total	68 / 561	46 / 564		1.48 [1.04,2.11]	Z=2.18, p=0.0296
Heterogeneity:	Q=1.09 (df=1)	p=0.2963	I^2=8.3%		
Latin America					
FIDELIO-DKD	1 / 21	1 / 24	5.8	1.14 [0.08,17.16]	
FIGARO-DKD	21 / 322	13 / 316	94.2	1.59 [0.81,3.11]	
Total	22 / 343	14 / 340		1.56 [0.81,2.99]	Z=1.33, p=0.1848
Heterogeneity:	Q=0.05 (df=1)	p=0.8183	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 5	1 / 4	69.1	2.40 [0.38,15.14]	
FIGARO-DKD	1 / 76	1 / 76	30.9	1.00 [0.06,15.70]	
Total	4 / 81	2 / 80		1.89 [0.46,7.80]	Z=0.88, p=0.3809
Heterogeneity:	Q=0.27 (df=1)	p=0.6035	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.81 (df=4)	p=0.3078	I^2=16.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.87.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

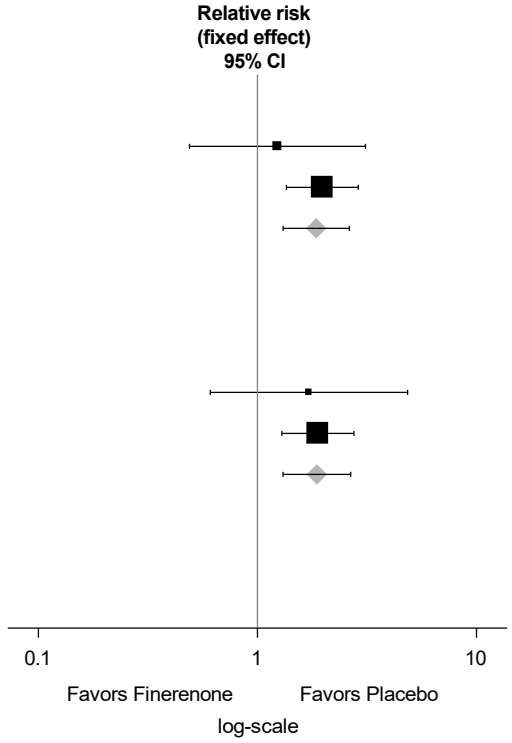
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	6 / 88	3 / 89	9.4	2.02 [0.52,7.84]	
FIGARO-DKD	66 / 811	27 / 803	90.6	2.42 [1.56,3.75]	
Total	72 / 899	30 / 892		2.38 [1.57,3.61]	Z=4.09, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.8048	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 122	10 / 132	15.5	1.30 [0.58,2.90]	
FIGARO-DKD	83 / 1515	50 / 1499	84.5	1.64 [1.16,2.32]	
Total	95 / 1637	60 / 1631		1.58 [1.16,2.17]	Z=2.86, p=0.0042
Heterogeneity:	Q=0.28 (df=1)	p=0.5975	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.34 (df=1)	p=0.1262	I^2=57.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.87.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	9 / 144	8 / 158	14.3	1.23 [0.49,3.11]	
FIGARO-DKD	79 / 1719	39 / 1679	85.7	1.98 [1.36,2.89]	
Total	88 / 1863	47 / 1837		1.85 [1.31,2.63]	Z=3.48, p=0.0005
Heterogeneity:	Q=0.86 (df=1)	p=0.3548	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 66	5 / 63	11.8	1.72 [0.61,4.85]	
FIGARO-DKD	70 / 607	38 / 622	88.2	1.89 [1.29,2.76]	
Total	79 / 673	43 / 685		1.87 [1.31,2.67]	Z=3.44, p=0.0006
Heterogeneity:	Q=0.03 (df=1)	p=0.8674	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9776	I^2=0.0%		

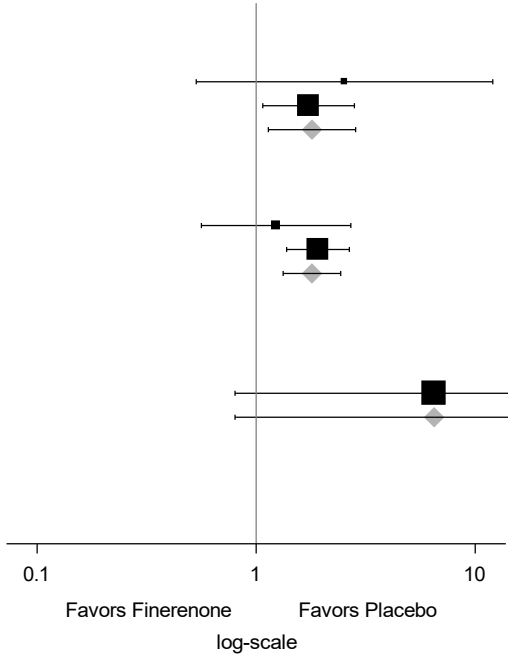


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.87.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

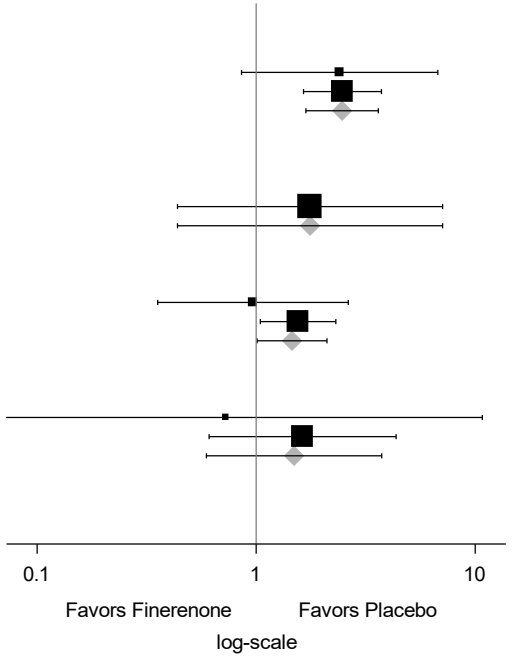
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 64	2 / 54	8.7	2.53 [0.53,12.03]	
FIGARO-DKD	43 / 693	25 / 699	91.3	1.73 [1.07,2.81]	
Total	49 / 757	27 / 753		1.80 [1.14,2.85]	Z=2.51, p=0.0122
Heterogeneity:	Q=0.21 (df=1)	p=0.6498	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 138	11 / 156	15.0	1.23 [0.56,2.70]	
FIGARO-DKD	100 / 1560	51 / 1524	85.0	1.92 [1.38,2.66]	
Total	112 / 1698	62 / 1680		1.80 [1.33,2.43]	Z=3.79, p=0.0001
Heterogeneity:	Q=1.03 (df=1)	p=0.3109	I^2=2.6%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	6 / 73	1 / 79	100.0	6.49 [0.80,52.65]	
Total	6 / 81	1 / 90		6.49 [0.80,52.65]	Z=1.75, p=0.0798
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=2)	p=0.4901	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.87.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

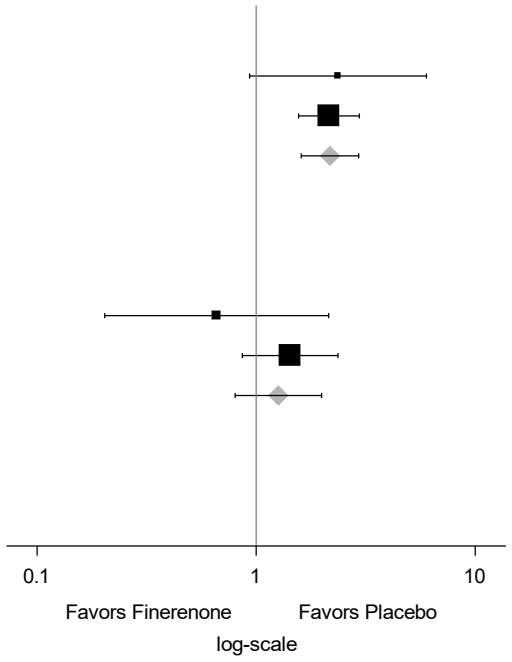
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	11 / 139	5 / 152	13.6	2.41 [0.86,6.75]	
FIGARO-DKD	79 / 1658	31 / 1612	86.4	2.48 [1.64,3.73]	
Total	90 / 1797	36 / 1764		2.47 [1.69,3.61]	Z=4.65, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9585	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	5 / 70	3 / 74	100.0	1.76 [0.44,7.10]	
Total	5 / 80	3 / 83		1.76 [0.44,7.10]	Z=0.80, p=0.4257
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 39	7 / 44	13.6	0.97 [0.36,2.63]	
FIGARO-DKD	55 / 464	37 / 485	86.4	1.55 [1.04,2.31]	
Total	61 / 503	44 / 529		1.46 [1.01,2.10]	Z=2.01, p=0.0444
Heterogeneity:	Q=0.74 (df=1)	p=0.3883	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	1 / 16	11.7	0.73 [0.05,10.78]	
FIGARO-DKD	10 / 134	6 / 131	88.3	1.63 [0.61,4.35]	
Total	11 / 156	7 / 147		1.49 [0.59,3.74]	Z=0.85, p=0.3967
Heterogeneity:	Q=0.30 (df=1)	p=0.5816	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.03 (df=3)	p=0.2578	I^2=25.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.87.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

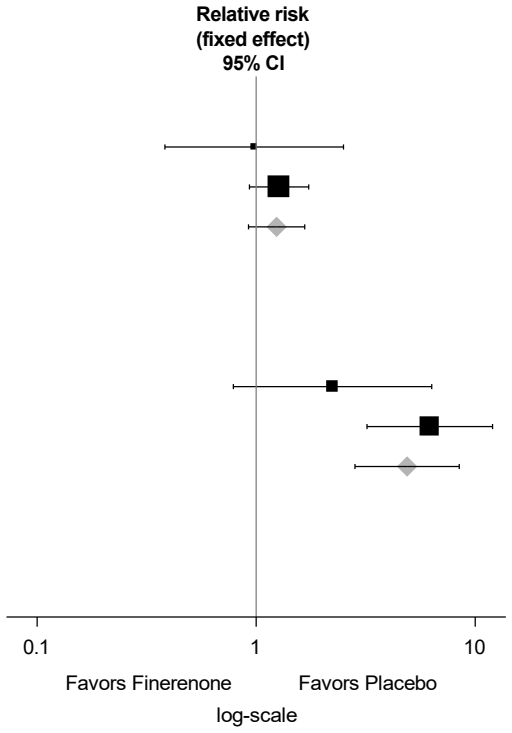
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	14 / 152	6 / 154	10.6	2.36 [0.93,5.99]	
FIGARO-DKD	112 / 1610	53 / 1638	89.4	2.15 [1.56,2.96]	
Total	126 / 1762	59 / 1792		2.17 [1.61,2.94]	Z=5.03, p=<.0001
Heterogeneity:	Q=0.04 (df=1)	p=0.8499	I^2=0.0%		
Female					
FIDELIO-DKD	4 / 58	7 / 67	15.4	0.66 [0.20,2.14]	
FIGARO-DKD	37 / 716	24 / 664	84.6	1.43 [0.86,2.36]	
Total	41 / 774	31 / 731		1.26 [0.80,1.99]	Z=1.01, p=0.3148
Heterogeneity:	Q=1.40 (df=1)	p=0.2366	I^2=28.6%		
Subgroup Heterogeneity:	Q=3.79 (df=1)	p=0.0515	I^2=73.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.87.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

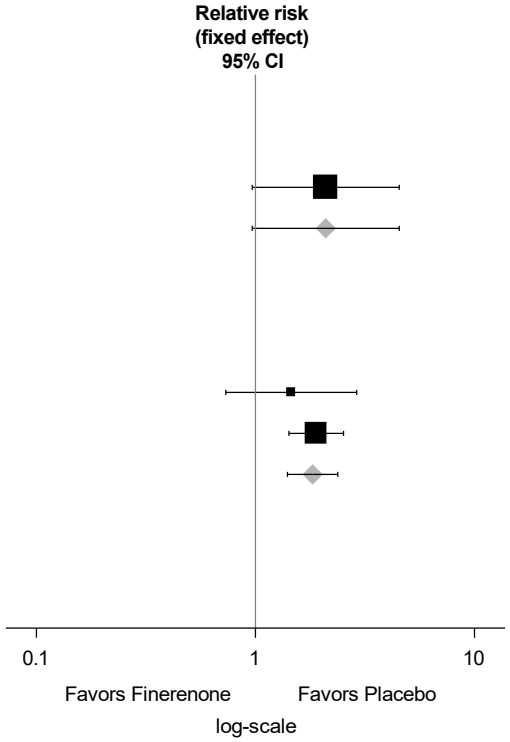
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	8 / 96	9.9	0.98 [0.38,2.50]	
FIGARO-DKD	85 / 1416	67 / 1420	90.1	1.27 [0.93,1.74]	
Total	93 / 1514	75 / 1516		1.24 [0.92,1.67]	Z=1.43, p=0.1540
Heterogeneity:	Q=0.27 (df=1)	p=0.6045	I^2=0.0%		
>= 65					
FIDELIO-DKD	10 / 112	5 / 125	28.6	2.23 [0.79,6.33]	
FIGARO-DKD	64 / 910	10 / 882	71.4	6.20 [3.21,12.00]	
Total	74 / 1022	15 / 1007		4.89 [2.83,8.45]	Z=5.68, p=<.0001
Heterogeneity:	Q=2.67 (df=1)	p=0.1022	I^2=62.6%		
Subgroup Heterogeneity:	Q=18.65 (df=1)	p=<.0001	I^2=94.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.87.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

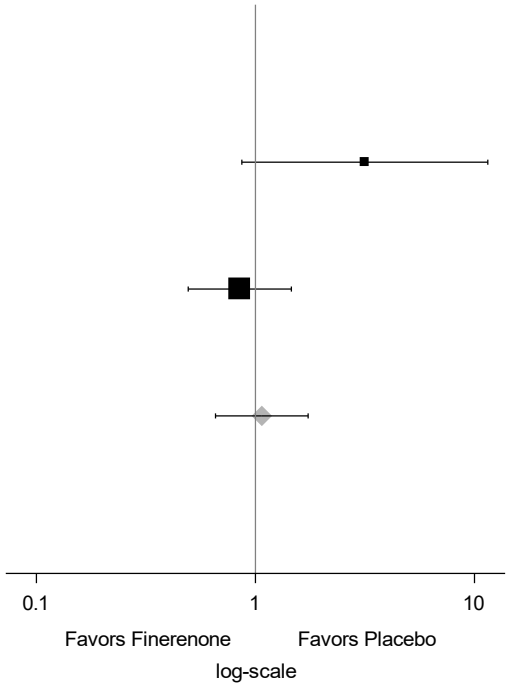
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	20 / 363	9 / 342	100.0	2.09 [0.97,4.53]	
Total	20 / 363	9 / 342		2.09 [0.97,4.53]	Z=1.87, p=0.0609
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	18 / 210	13 / 221	14.8	1.46 [0.73,2.90]	
FIGARO-DKD	129 / 1963	68 / 1960	85.2	1.89 [1.42,2.52]	
Total	147 / 2173	81 / 2181		1.82 [1.40,2.38]	Z=4.45, p=<.0001
Heterogeneity:	Q=0.48 (df=1)	p=0.4904	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7406	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.88: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

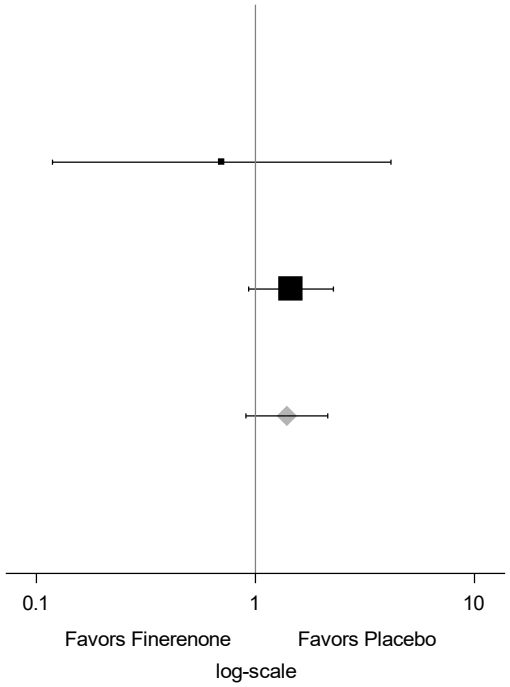
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	3 / 221	15.0	3.16 [0.87,11.50]	
FIGARO-DKD	24 / 2326	28 / 2302	85.0	0.85 [0.49,1.46]	
Total	33 / 2536	31 / 2523		1.07 [0.66,1.74]	Z=0.27, p=0.7878
Heterogeneity:	Q=3.39 (df=1)	p=0.0654	I^2=70.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.89: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

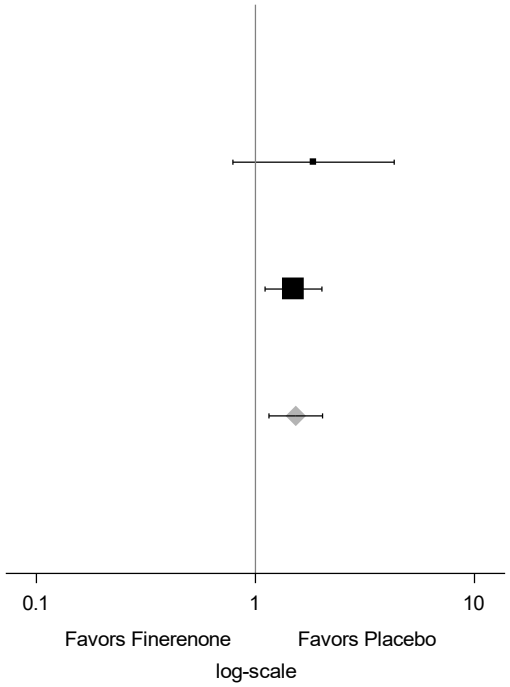
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	5.9	0.70 [0.12,4.16]	
FIGARO-DKD	47 / 2326	32 / 2302	94.1	1.45 [0.93,2.27]	
Total	49 / 2536	35 / 2523		1.39 [0.90,2.14]	Z=1.50, p=0.1328
Heterogeneity:	Q=0.61 (df=1)	p=0.4363	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.90: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

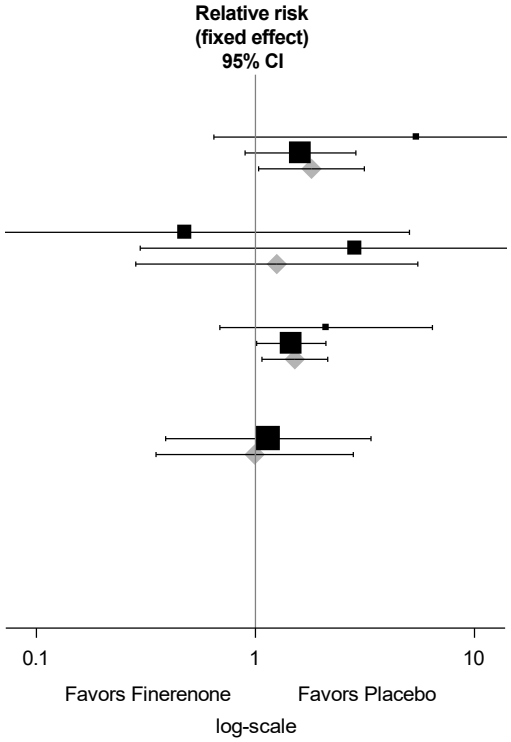
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	8 / 221	11.0	1.84 [0.79,4.30]	
FIGARO-DKD	104 / 2326	69 / 2302	89.0	1.49 [1.11,2.01]	
Total	118 / 2536	77 / 2523		1.53 [1.15,2.02]	Z=2.95, p=0.0032
Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.90.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

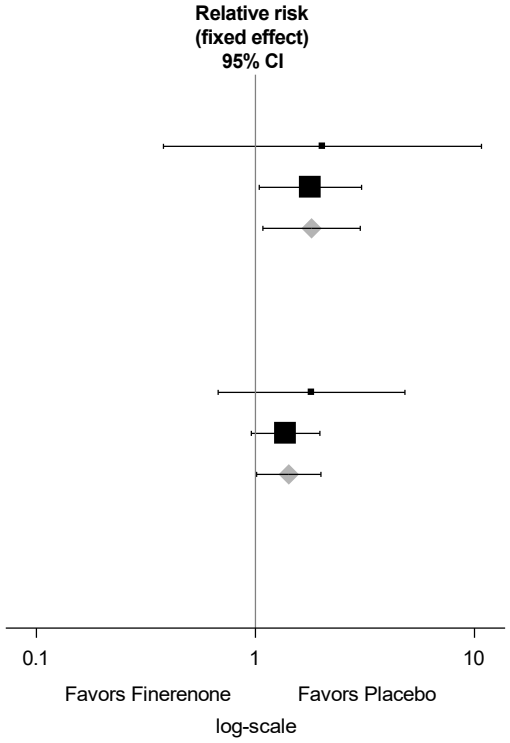
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	5 / 103	1 / 112	7.0	5.44 [0.65,45.76]	
FIGARO-DKD	29 / 1114	18 / 1110	93.0	1.61 [0.90,2.87]	
Total	34 / 1217	19 / 1222		1.80 [1.03,3.14]	Z=2.08, p=0.0378
Heterogeneity:	Q=1.18 (df=1)	p=0.2766	I^2=15.5%		
North America					
FIDELIO-DKD	1 / 42	2 / 40	47.8	0.48 [0.04,5.05]	
FIGARO-DKD	3 / 292	1 / 277	52.2	2.85 [0.30,27.20]	
Total	4 / 334	3 / 317		1.25 [0.28,5.51]	Z=0.30, p=0.7668
Heterogeneity:	Q=1.15 (df=1)	p=0.2831	I^2=13.2%		
Asia					
FIDELIO-DKD	8 / 39	4 / 41	9.6	2.10 [0.69,6.43]	
FIGARO-DKD	64 / 522	44 / 523	90.4	1.46 [1.01,2.10]	
Total	72 / 561	48 / 564		1.51 [1.07,2.14]	Z=2.35, p=0.0189
Heterogeneity:	Q=0.37 (df=1)	p=0.5409	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,83E295]	
FIGARO-DKD	7 / 322	6 / 316	100.0	1.14 [0.39,3.37]	
Total	7 / 343	7 / 340		0.99 [0.35,2.80]	Z=-0.02, p=0.9876
Heterogeneity:	Q=0.07 (df=1)	p=0.7944	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	0 / 76	0.0	186E9 [186E9,186E9]	
Total	1 / 81	0 / 80		2.15E7 [2.15E7,2.15E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.08 (df=4)	p=0.8977	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.90.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

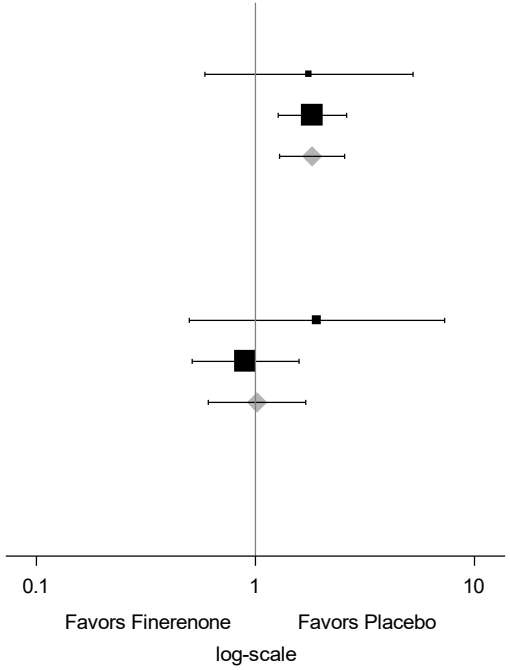
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	2 / 89	9.4	2.02 [0.38,10.76]	
FIGARO-DKD	36 / 811	20 / 803	90.6	1.78 [1.04,3.05]	
Total	40 / 899	22 / 892		1.80 [1.08,3.01]	Z=2.26, p=0.0239
Heterogeneity:	Q=0.02 (df=1)	p=0.8877	I^2=0.0%		
Absent					
FIDELIO-DKD	10 / 122	6 / 132	11.9	1.80 [0.68,4.81]	
FIGARO-DKD	68 / 1515	49 / 1499	88.1	1.37 [0.96,1.97]	
Total	78 / 1637	55 / 1631		1.42 [1.01,1.99]	Z=2.03, p=0.0423
Heterogeneity:	Q=0.26 (df=1)	p=0.6095	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=1)	p=0.4439	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.90.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	8 / 144	5 / 158	9.8	1.76 [0.59,5.24]	
FIGARO-DKD	82 / 1719	44 / 1679	90.2	1.82 [1.27,2.61]	
Total	90 / 1863	49 / 1837		1.81 [1.29,2.55]	Z=3.41, p=0.0006
Heterogeneity:	Q=0.00 (df=1)	p=0.9509	I^2=0.0%		
> 4.5					
FIDELIO-DKD	6 / 66	3 / 63	14.9	1.91 [0.50,7.31]	
FIGARO-DKD	22 / 607	25 / 622	85.1	0.90 [0.51,1.58]	
Total	28 / 673	28 / 685		1.02 [0.61,1.70]	Z=0.06, p=0.9503
Heterogeneity:	Q=1.02 (df=1)	p=0.3121	I^2=2.1%		
Subgroup Heterogeneity:	Q=3.40 (df=1)	p=0.0653	I^2=70.6%		

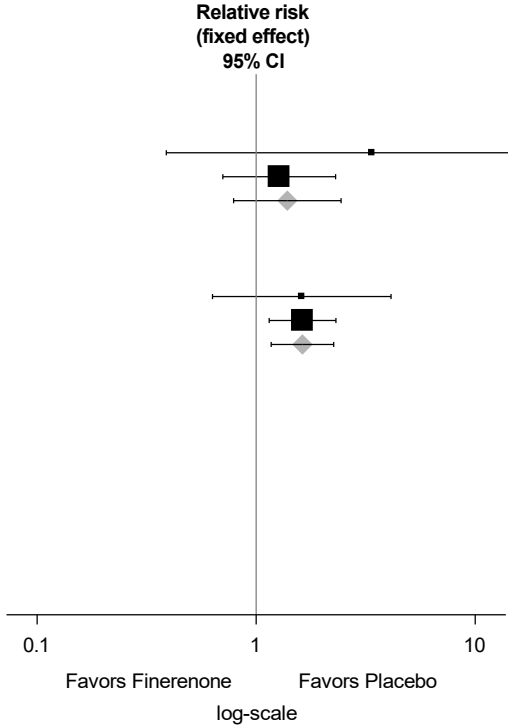


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.90.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

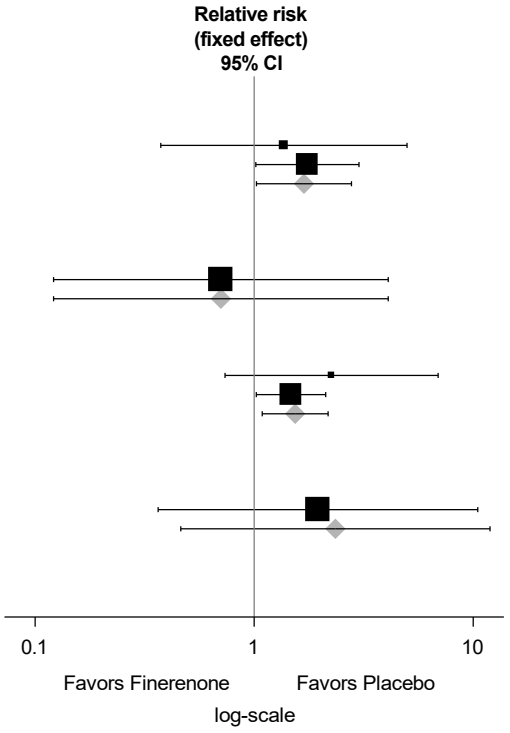
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 64	1 / 54	7.0	3.37 [0.39,29.30]	
FIGARO-DKD	24 / 693	19 / 699	93.0	1.27 [0.70,2.30]	
Total	28 / 757	20 / 753		1.39 [0.79,2.44]	Z=1.14, p=0.2557
Heterogeneity:	Q=0.73 (df=1)	p=0.3931	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	10 / 138	7 / 156	12.3	1.61 [0.63,4.13]	
FIGARO-DKD	80 / 1560	48 / 1524	87.7	1.63 [1.15,2.31]	
Total	90 / 1698	55 / 1680		1.63 [1.17,2.26]	Z=2.90, p=0.0037
Heterogeneity:	Q=0.00 (df=1)	p=0.9872	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	2 / 79	0.0	0.00 [0.00,14E296]	
Total	0 / 81	2 / 90		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.23 (df=2)	p=0.8927	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.90.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

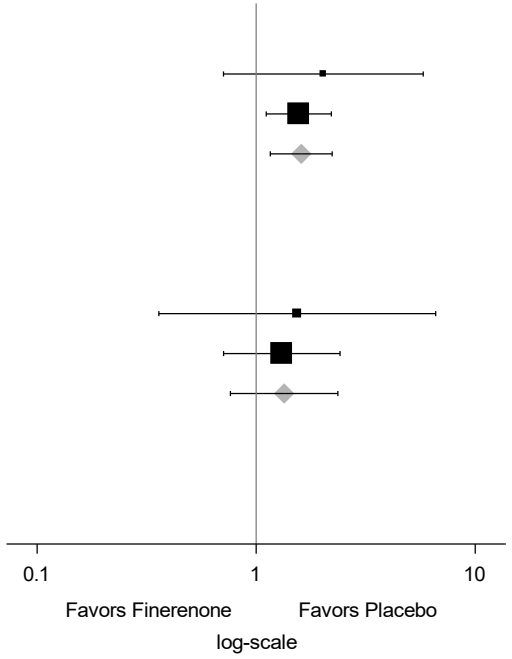
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	5 / 139	4 / 152	14.9	1.37 [0.37,4.99]	
FIGARO-DKD	36 / 1658	20 / 1612	85.1	1.75 [1.02,3.01]	
Total	41 / 1797	24 / 1764		1.69 [1.02,2.78]	Z=2.05, p=0.0399
Heterogeneity:	Q=0.12 (df=1)	p=0.7300	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	2 / 70	3 / 74	100.0	0.70 [0.12,4.09]	
Total	2 / 80	3 / 83		0.70 [0.12,4.09]	Z=-0.39, p=0.6966
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	8 / 39	4 / 44	9.6	2.26 [0.74,6.92]	
FIGARO-DKD	62 / 464	44 / 485	90.4	1.47 [1.02,2.12]	
Total	70 / 503	48 / 529		1.54 [1.09,2.18]	Z=2.44, p=0.0147
Heterogeneity:	Q=0.50 (df=1)	p=0.4778	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	0 / 16	0.0	871E8 [871E8,871E8]	
FIGARO-DKD	4 / 134	2 / 131	100.0	1.96 [0.36,10.49]	
Total	5 / 156	2 / 147		2.35 [0.46,11.94]	Z=1.03, p=0.3032
Heterogeneity:	Q=0.05 (df=1)	p=0.8306	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.13 (df=3)	p=0.7708	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.90.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

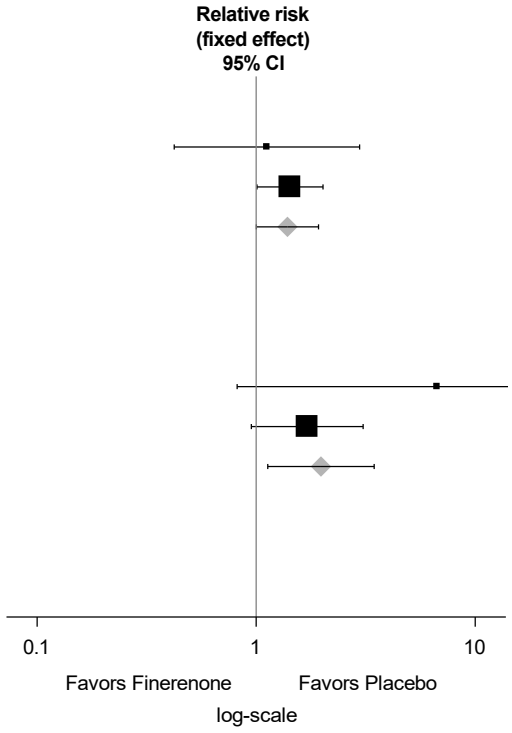
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	10 / 152	5 / 154	9.6	2.03 [0.71,5.79]	
FIGARO-DKD	80 / 1610	52 / 1638	90.4	1.57 [1.11,2.20]	
Total	90 / 1762	57 / 1792		1.61 [1.16,2.22]	Z=2.86, p=0.0043
Heterogeneity:	Q=0.21 (df=1)	p=0.6467	I^2=0.0%		
Female					
FIDELIO-DKD	4 / 58	3 / 67	15.0	1.54 [0.36,6.60]	
FIGARO-DKD	24 / 716	17 / 664	85.0	1.31 [0.71,2.42]	
Total	28 / 774	20 / 731		1.34 [0.76,2.36]	Z=1.02, p=0.3074
Heterogeneity:	Q=0.04 (df=1)	p=0.8401	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5890	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.90.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

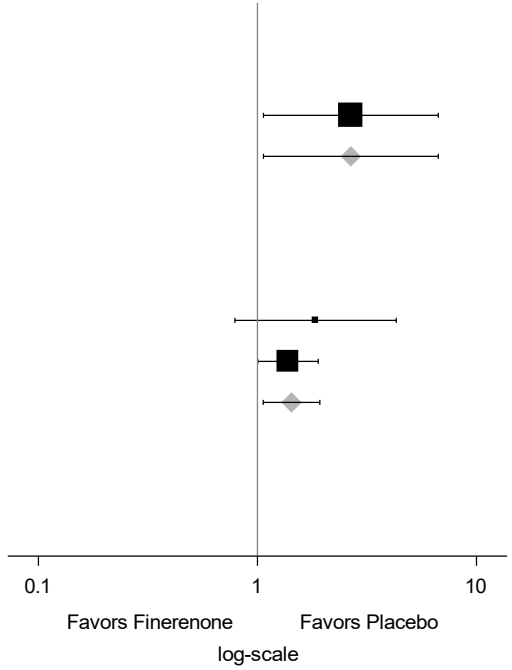
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	7 / 96	11.2	1.12 [0.42,2.97]	
FIGARO-DKD	74 / 1416	52 / 1420	88.8	1.43 [1.01,2.02]	
Total	82 / 1514	59 / 1516		1.39 [1.00,1.93]	Z=1.97, p=0.0486
Heterogeneity:	Q=0.21 (df=1)	p=0.6456	I^2=0.0%		
>= 65					
FIDELIO-DKD	6 / 112	1 / 125	7.3	6.70 [0.82,54.77]	
FIGARO-DKD	30 / 910	17 / 882	92.7	1.71 [0.95,3.08]	
Total	36 / 1022	18 / 1007		1.98 [1.13,3.46]	Z=2.39, p=0.0170
Heterogeneity:	Q=1.53 (df=1)	p=0.2165	I^2=34.5%		
Subgroup Heterogeneity:	Q=1.14 (df=1)	p=0.2863	I^2=12.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.90.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

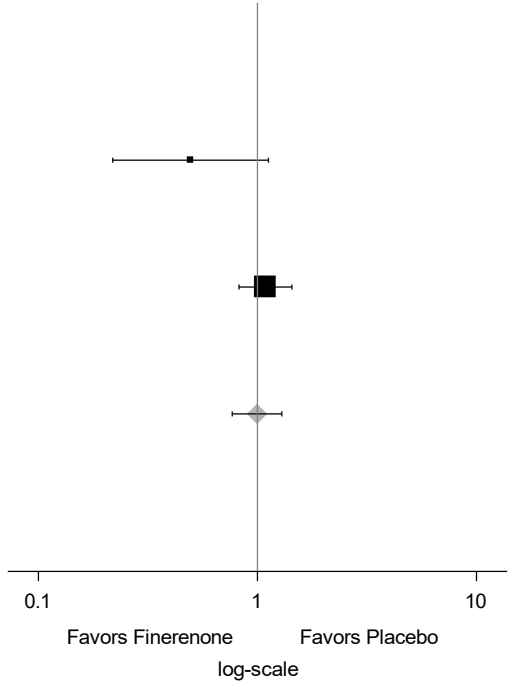
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	17 / 363	6 / 342	100.0	2.67 [1.06,6.69]	
Total	17 / 363	6 / 342		2.67 [1.06,6.69]	Z=2.09, p=0.0362
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	14 / 210	8 / 221	12.3	1.84 [0.79,4.30]	
FIGARO-DKD	87 / 1963	63 / 1960	87.7	1.38 [1.00,1.90]	
Total	101 / 2173	71 / 2181		1.43 [1.06,1.93]	Z=2.36, p=0.0184
Heterogeneity:	Q=0.39 (df=1)	p=0.5310	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2056	I^2=37.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.91: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

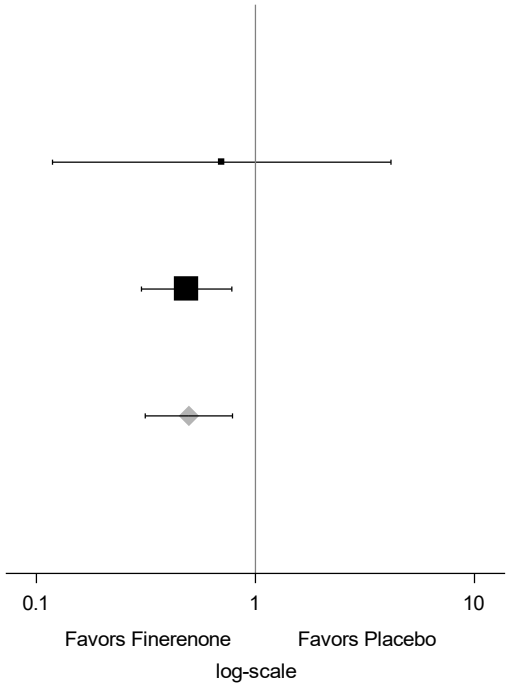
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	17 / 221	10.3	0.50 [0.22,1.12]	
FIGARO-DKD	100 / 2326	91 / 2302	89.7	1.09 [0.82,1.44]	
Total	108 / 2536	108 / 2523		1.00 [0.77,1.29]	Z=-0.03, p=0.9723
Heterogeneity:	Q=3.18 (df=1)	p=0.0745	I^2=68.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.92: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

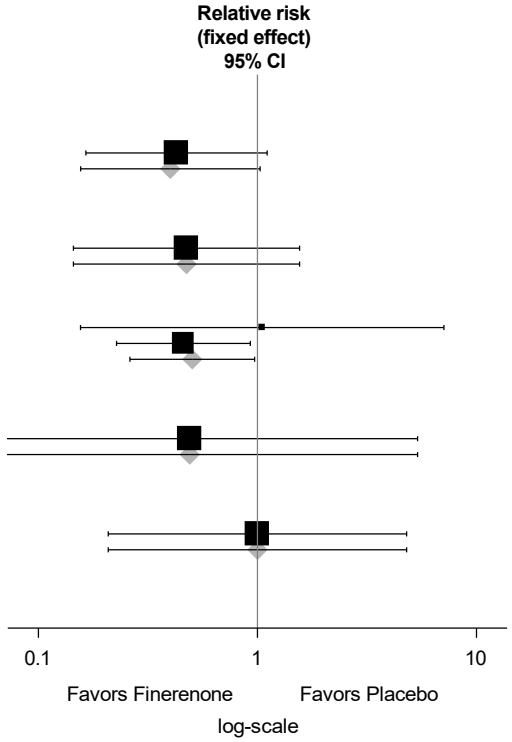
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	6.7	0.70 [0.12,4.16]	
FIGARO-DKD	25 / 2326	51 / 2302	93.3	0.49 [0.30,0.78]	
Total	27 / 2536	54 / 2523		0.50 [0.31,0.79]	Z=-2.99, p=0.0028
Heterogeneity:	Q=0.15 (df=1)	p=0.6946	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.92.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

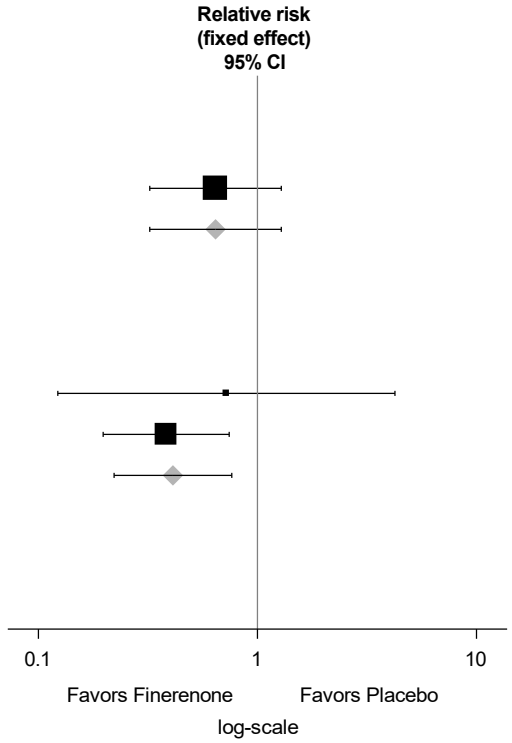
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	1 / 112	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	6 / 1114	14 / 1110	100.0	0.43 [0.16,1.11]	
Total	6 / 1217	15 / 1222		0.40 [0.16,1.03]	Z=-1.90, p=0.0571
Heterogeneity:	Q=0.02 (df=1)	p=0.8942	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	4 / 292	8 / 277	100.0	0.47 [0.14,1.56]	
Total	4 / 334	8 / 317		0.47 [0.14,1.56]	Z=-1.23, p=0.2188
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	2 / 41	11.9	1.05 [0.16,7.10]	
FIGARO-DKD	11 / 522	24 / 523	88.1	0.46 [0.23,0.93]	
Total	13 / 561	26 / 564		0.50 [0.26,0.97]	Z=-2.05, p=0.0404
Heterogeneity:	Q=0.64 (df=1)	p=0.4251	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	2 / 316	100.0	0.49 [0.04,5.38]	
Total	1 / 343	2 / 340		0.49 [0.04,5.38]	Z=-0.58, p=0.5602
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	3 / 76	100.0	1.00 [0.21,4.80]	
Total	3 / 81	3 / 80		1.00 [0.21,4.80]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.97 (df=4)	p=0.9140	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.92.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

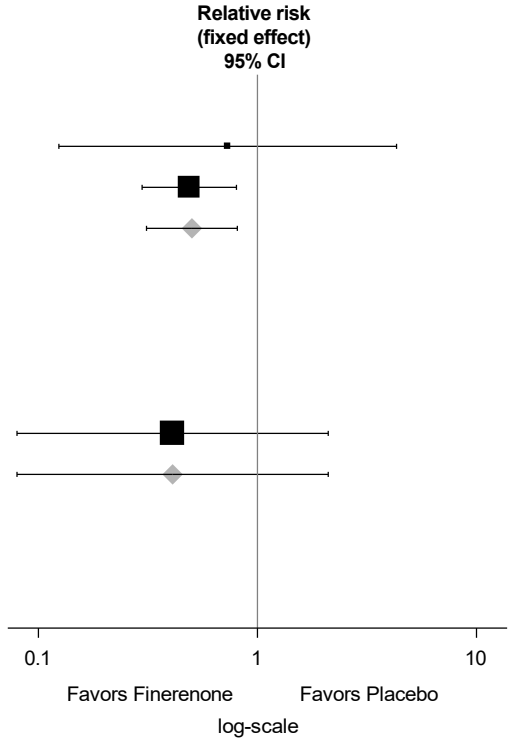
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	13 / 811	20 / 803	100.0	0.64 [0.32,1.28]	
Total	13 / 899	20 / 892		0.64 [0.32,1.28]	Z=-1.25, p=0.2116
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	2 / 122	3 / 132	12.3	0.72 [0.12,4.24]	
FIGARO-DKD	12 / 1515	31 / 1499	87.7	0.38 [0.20,0.74]	
Total	14 / 1637	34 / 1631		0.41 [0.22,0.76]	Z=-2.82, p=0.0049
Heterogeneity:	Q=0.43 (df=1)	p=0.5118	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.90 (df=1)	p=0.3441	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.92.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	3 / 158	7.2	0.73 [0.12,4.32]	
FIGARO-DKD	23 / 1719	46 / 1679	92.8	0.49 [0.30,0.80]	
Total	25 / 1863	49 / 1837		0.50 [0.31,0.81]	Z=-2.83, p=0.0047
Heterogeneity:	Q=0.18 (df=1)	p=0.6674	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	2 / 607	5 / 622	100.0	0.41 [0.08,2.10]	
Total	2 / 673	5 / 685		0.41 [0.08,2.10]	Z=-1.07, p=0.2853
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8154	I^2=0.0%		

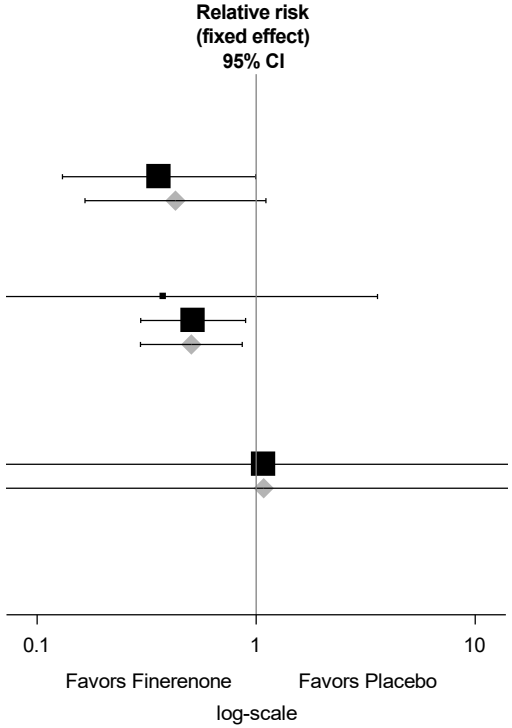


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.92.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

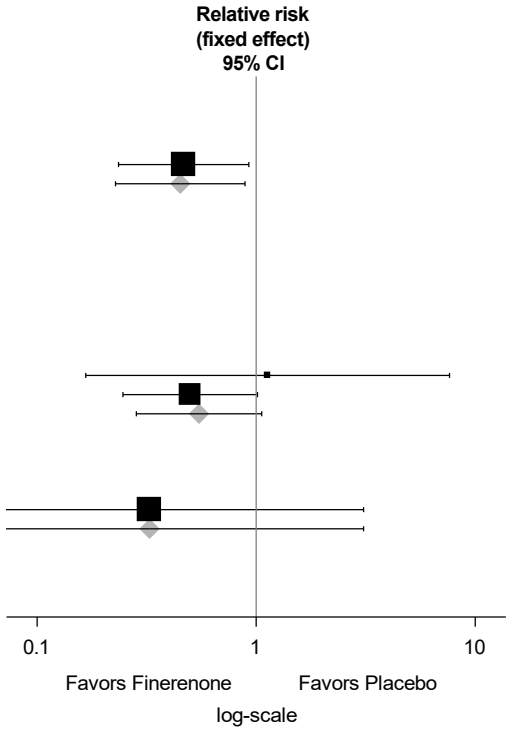
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	814E8 [814E8,814E8]	
FIGARO-DKD	5 / 693	14 / 699	100.0	0.36 [0.13,0.99]	
Total	6 / 757	14 / 753		0.43 [0.17,1.11]	Z=-1.75, p=0.0804
Heterogeneity:	Q=0.11 (df=1)	p=0.7392	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	3 / 156	5.7	0.38 [0.04,3.58]	
FIGARO-DKD	19 / 1560	36 / 1524	94.3	0.52 [0.30,0.89]	
Total	20 / 1698	39 / 1680		0.51 [0.30,0.86]	Z=-2.50, p=0.0125
Heterogeneity:	Q=0.07 (df=1)	p=0.7909	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	1 / 79	100.0	1.08 [0.07,16.99]	
Total	1 / 81	1 / 90		1.08 [0.07,16.99]	Z=0.06, p=0.9552
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=2)	p=0.8164	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.92.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

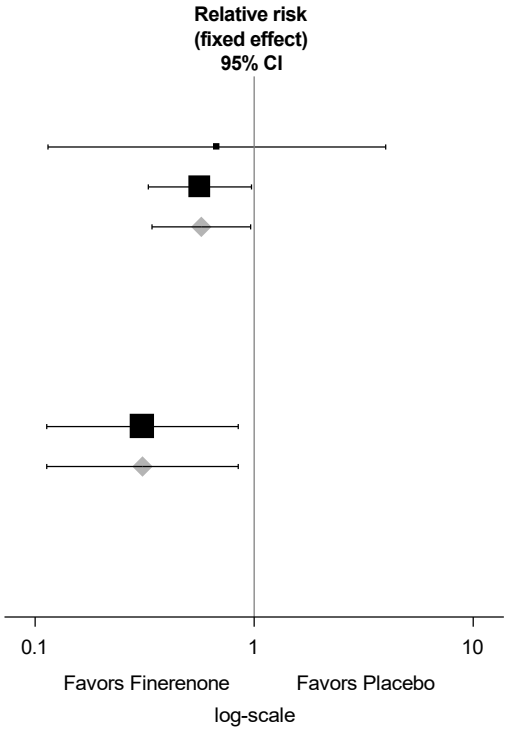
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	1 / 152	0.0	0.00 [0.00,19E296]	
FIGARO-DKD	12 / 1658	25 / 1612	100.0	0.47 [0.24,0.93]	
Total	12 / 1797	26 / 1764		0.45 [0.23,0.89]	Z=-2.30, p=0.0216
Heterogeneity:	Q=0.01 (df=1)	p=0.9181	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	0 / 74	0.0	202E9 [202E9,202E9]	
Total	1 / 80	0 / 83		2.15E7 [2.15E7,2.15E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	2 / 39	2 / 44	12.0	1.13 [0.17,7.63]	
FIGARO-DKD	11 / 464	23 / 485	88.0	0.50 [0.25,1.01]	
Total	13 / 503	25 / 529		0.55 [0.28,1.06]	Z=-1.79, p=0.0739
Heterogeneity:	Q=0.61 (df=1)	p=0.4338	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	1 / 134	3 / 131	100.0	0.33 [0.03,3.09]	
Total	1 / 156	3 / 147		0.33 [0.03,3.09]	Z=-0.98, p=0.3288
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=3)	p=0.9605	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.92.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

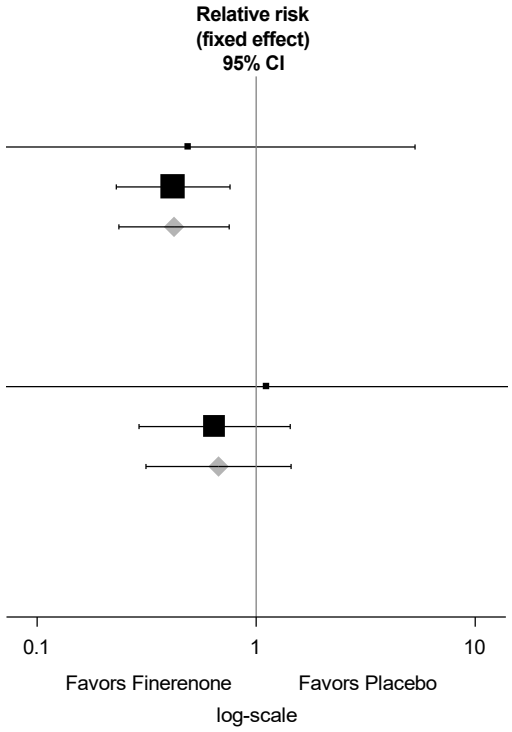
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	8.5	0.68 [0.11,3.99]	
FIGARO-DKD	20 / 1610	36 / 1638	91.5	0.57 [0.33,0.97]	
Total	22 / 1762	39 / 1792		0.57 [0.34,0.96]	Z=-2.10, p=0.0357
Heterogeneity:	Q=0.04 (df=1)	p=0.8508	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	5 / 716	15 / 664	100.0	0.31 [0.11,0.85]	
Total	5 / 774	15 / 731		0.31 [0.11,0.85]	Z=-2.29, p=0.0223
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.15 (df=1)	p=0.2844	I^2=12.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.92.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

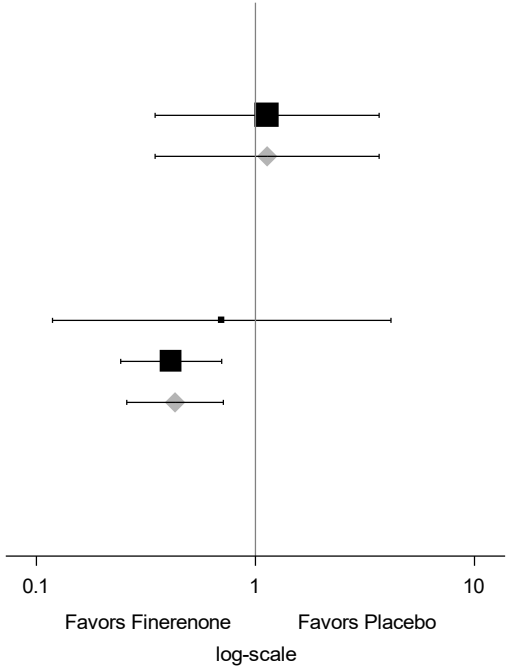
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	2 / 96	5.9	0.49 [0.05,5.31]	
FIGARO-DKD	15 / 1416	36 / 1420	94.1	0.42 [0.23,0.76]	
Total	16 / 1514	38 / 1516		0.42 [0.24,0.75]	Z=-2.92, p=0.0035
Heterogeneity:	Q=0.02 (df=1)	p=0.8992	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	1 / 125	7.7	1.12 [0.07,17.63]	
FIGARO-DKD	10 / 910	15 / 882	92.3	0.65 [0.29,1.43]	
Total	11 / 1022	16 / 1007		0.67 [0.31,1.44]	Z=-1.02, p=0.3091
Heterogeneity:	Q=0.14 (df=1)	p=0.7092	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3387	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.92.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

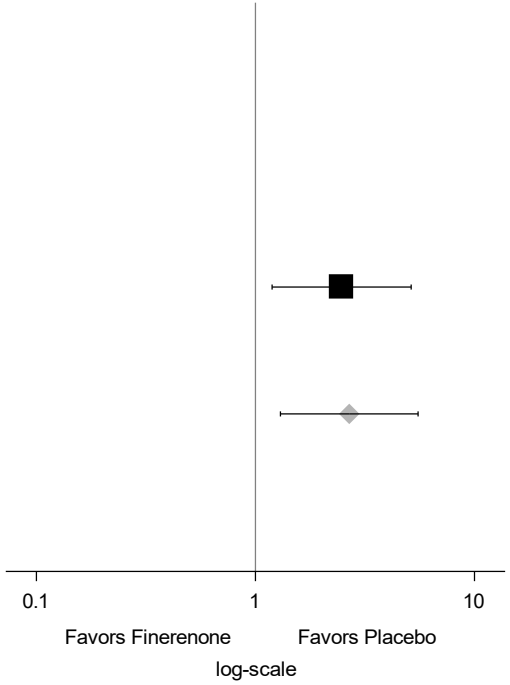
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	5 / 342	100.0	1.13 [0.35,3.67]	
Total	6 / 363	5 / 342		1.13 [0.35,3.67]	Z=0.20, p=0.8381
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	3 / 221	8.2	0.70 [0.12,4.16]	
FIGARO-DKD	19 / 1963	46 / 1960	91.8	0.41 [0.24,0.70]	
Total	21 / 2173	49 / 2181		0.43 [0.26,0.71]	Z=-3.26, p=0.0011
Heterogeneity:	Q=0.31 (df=1)	p=0.5748	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.19 (df=1)	p=0.1390	I^2=54.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.93: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

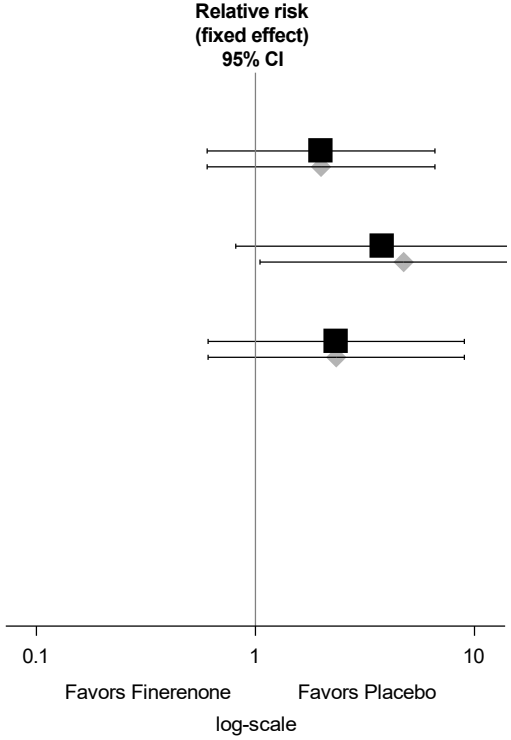
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	0 / 221	0.0	135E9 [135E9,135E9]	
FIGARO-DKD	25 / 2326	10 / 2302	100.0	2.47 [1.19,5.14]	
Total	27 / 2536	10 / 2523		2.68 [1.30,5.53]	Z=2.67, p=0.0076
Heterogeneity:	Q=0.05 (df=1)	p=0.8299	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.93.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

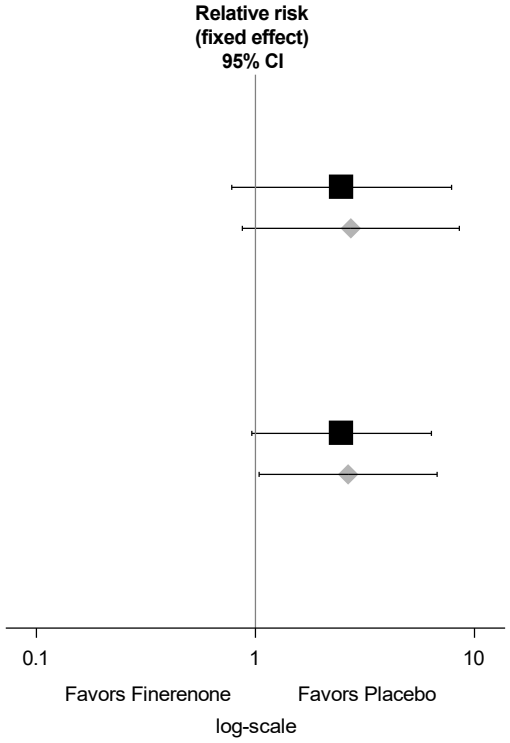
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	8 / 1114	4 / 1110	100.0	1.99 [0.60,6.60]	
Total	8 / 1217	4 / 1222		1.99 [0.60,6.60]	Z=1.13, p=0.2590
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	0 / 40	0.0	248E9 [248E9,248E9]	
FIGARO-DKD	8 / 292	2 / 277	100.0	3.79 [0.81,17.71]	
Total	10 / 334	2 / 317		4.75 [1.05,21.51]	Z=2.02, p=0.0432
Heterogeneity:	Q=0.08 (df=1)	p=0.7751	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	7 / 522	3 / 523	100.0	2.34 [0.61,8.99]	
Total	7 / 561	3 / 564		2.34 [0.61,8.99]	Z=1.24, p=0.2166
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	1 / 316	0.0	0.00 [0.00,15E296]	
Total	0 / 343	1 / 340		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	0 / 76	0.0	137E9 [137E9,137E9]	
Total	2 / 81	0 / 80		4.28E7 [4.28E7,4.28E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.82 (df=4)	p=0.9352	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.93.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

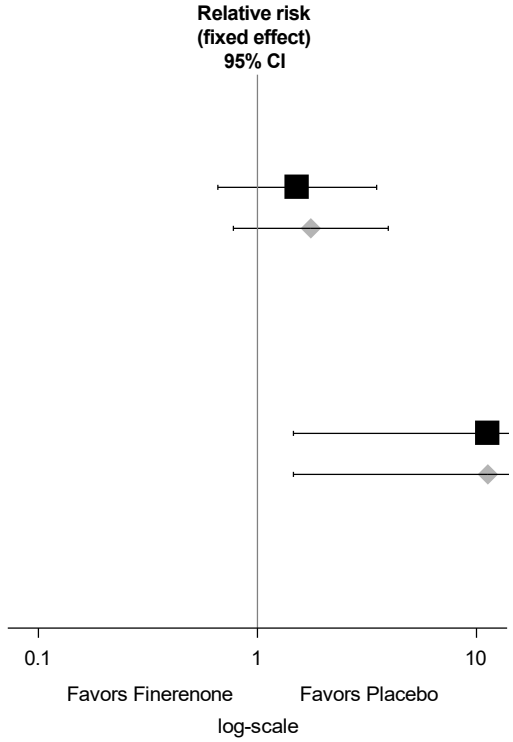
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	0 / 89	0.0	161E9 [161E9,161E9]	
FIGARO-DKD	10 / 811	4 / 803	100.0	2.48 [0.78,7.86]	
Total	11 / 899	4 / 892		2.73 [0.87,8.53]	Z=1.72, p=0.0848
Heterogeneity:	Q=0.03 (df=1)	p=0.8699	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	0 / 132	0.0	116E9 [116E9,116E9]	
FIGARO-DKD	15 / 1515	6 / 1499	100.0	2.47 [0.96,6.36]	
Total	16 / 1637	6 / 1631		2.65 [1.04,6.75]	Z=2.04, p=0.0413
Heterogeneity:	Q=0.02 (df=1)	p=0.8869	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9696	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.93.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	0 / 158	0.0	197E9 [197E9,197E9]	
FIGARO-DKD	14 / 1719	9 / 1679	100.0	1.52 [0.66,3.50]	
Total	16 / 1863	9 / 1837		1.75 [0.78,3.96]	Z=1.35, p=0.1767
Heterogeneity:	Q=0.11 (df=1)	p=0.7371	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	11 / 607	1 / 622	100.0	11.27 [1.46,87.04]	
Total	11 / 673	1 / 685		11.27 [1.46,87.04]	Z=2.32, p=0.0202
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=1)	p=0.0974	I^2=63.6%		

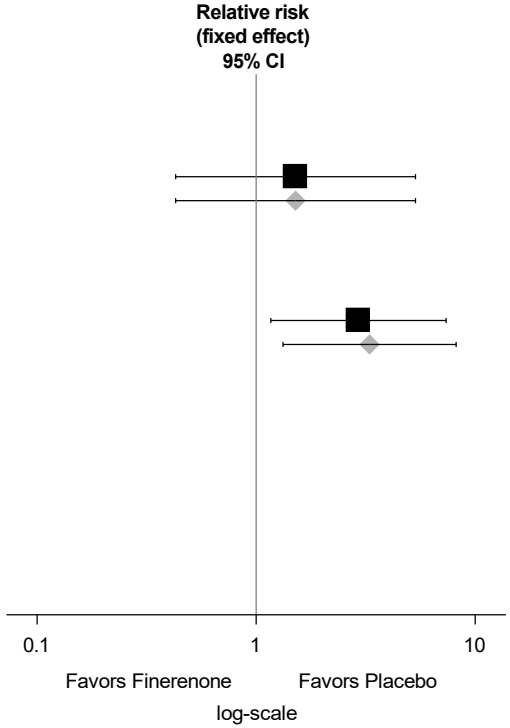


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.93.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

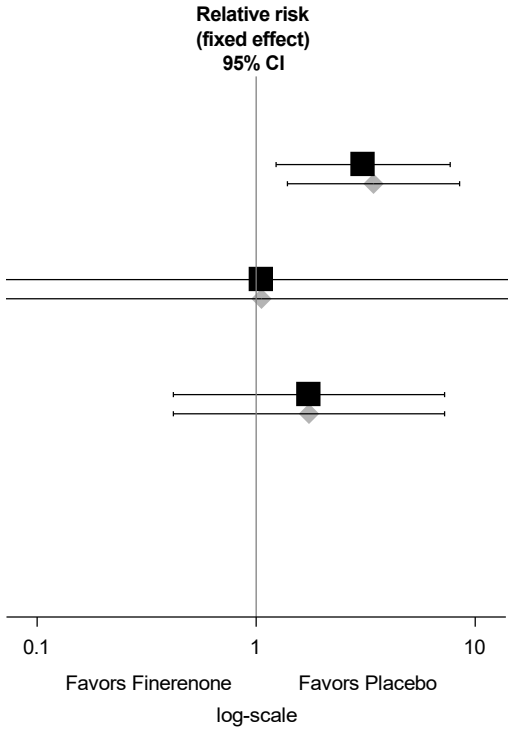
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	4 / 699	100.0	1.51 [0.43,5.34]	
Total	6 / 757	4 / 753		1.51 [0.43,5.34]	Z=0.64, p=0.5198
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	0 / 156	0.0	205E9 [205E9,205E9]	
FIGARO-DKD	18 / 1560	6 / 1524	100.0	2.93 [1.17,7.36]	
Total	20 / 1698	6 / 1680		3.29 [1.33,8.18]	Z=2.57, p=0.0102
Heterogeneity:	Q=0.06 (df=1)	p=0.8035	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	0 / 79	0.0	194E9 [194E9,194E9]	
Total	1 / 81	0 / 90		2.02E7 [2.02E7,2.02E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.96 (df=2)	p=0.6181	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.93.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

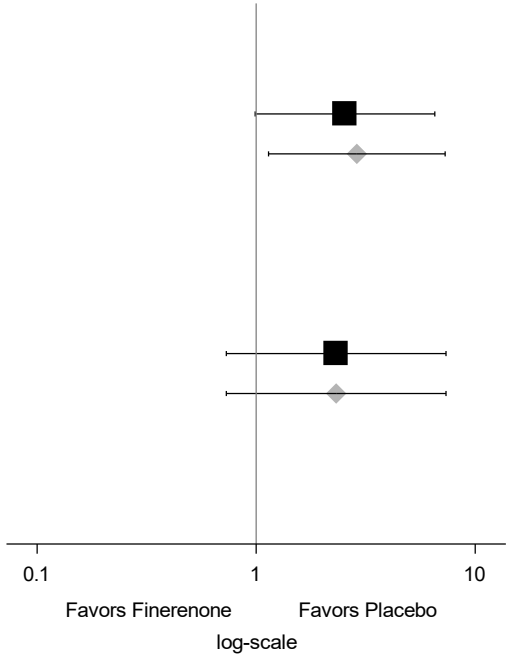
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	0 / 152	0.0	204E9 [204E9,204E9]	
FIGARO-DKD	19 / 1658	6 / 1612	100.0	3.08 [1.23,7.69]	
Total	21 / 1797	6 / 1764		3.43 [1.39,8.49]	Z=2.67, p=0.0075
Heterogeneity:	Q=0.05 (df=1)	p=0.8154	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	1 / 74	100.0	1.06 [0.07,16.58]	
Total	1 / 80	1 / 83		1.06 [0.07,16.58]	Z=0.04, p=0.9684
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	5 / 464	3 / 485	100.0	1.74 [0.42,7.25]	
Total	5 / 503	3 / 529		1.74 [0.42,7.25]	Z=0.76, p=0.4454
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	0 / 131	0.0	-	
Total	0 / 156	0 / 147		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.08 (df=3)	p=0.7831	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.93.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

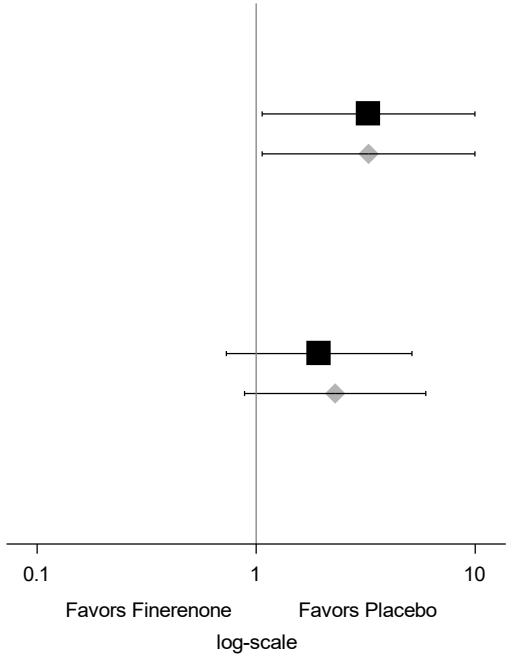
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	0 / 154	0.0	186E9 [186E9,186E9]	
FIGARO-DKD	15 / 1610	6 / 1638	100.0	2.54 [0.99,6.54]	
Total	17 / 1762	6 / 1792		2.88 [1.14,7.29]	Z=2.23, p=0.0255
Heterogeneity:	Q=0.07 (df=1)	p=0.7956	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	10 / 716	4 / 664	100.0	2.32 [0.73,7.36]	
Total	10 / 774	4 / 731		2.32 [0.73,7.36]	Z=1.43, p=0.1535
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7736	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.93.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

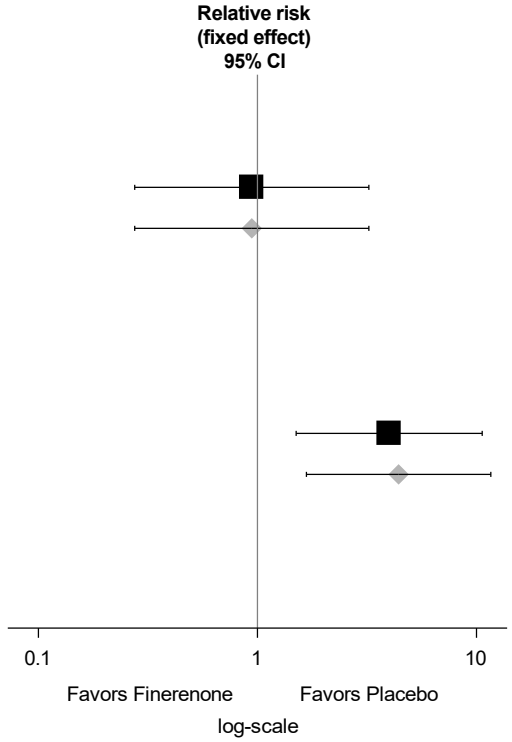
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	13 / 1416	4 / 1420	100.0	3.26 [1.07,9.97]	
Total	13 / 1514	4 / 1516		3.26 [1.07,9.97]	Z=2.07, p=0.0384
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	2 / 112	0 / 125	0.0	253E9 [253E9,253E9]	
FIGARO-DKD	12 / 910	6 / 882	100.0	1.94 [0.73,5.14]	
Total	14 / 1022	6 / 1007		2.29 [0.88,5.95]	Z=1.71, p=0.0876
Heterogeneity:	Q=0.11 (df=1)	p=0.7350	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6394	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.93.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

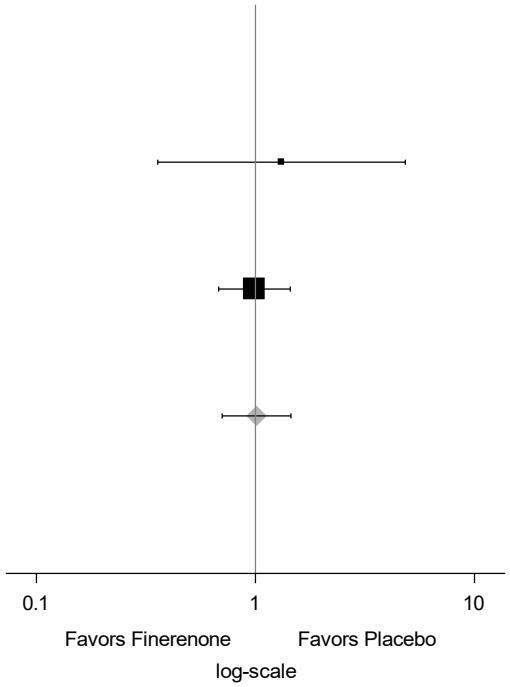
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	5 / 342	100.0	0.94 [0.28,3.23]	
Total	5 / 363	5 / 342		0.94 [0.28,3.23]	Z=-0.09, p=0.9244
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	0 / 221	0.0	135E9 [135E9,135E9]	
FIGARO-DKD	20 / 1963	5 / 1960	100.0	3.99 [1.50,10.62]	
Total	22 / 2173	5 / 2181		4.41 [1.67,11.63]	Z=3.00, p=0.0027
Heterogeneity:	Q=0.04 (df=1)	p=0.8425	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.73 (df=1)	p=0.0535	I^2=73.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.94: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

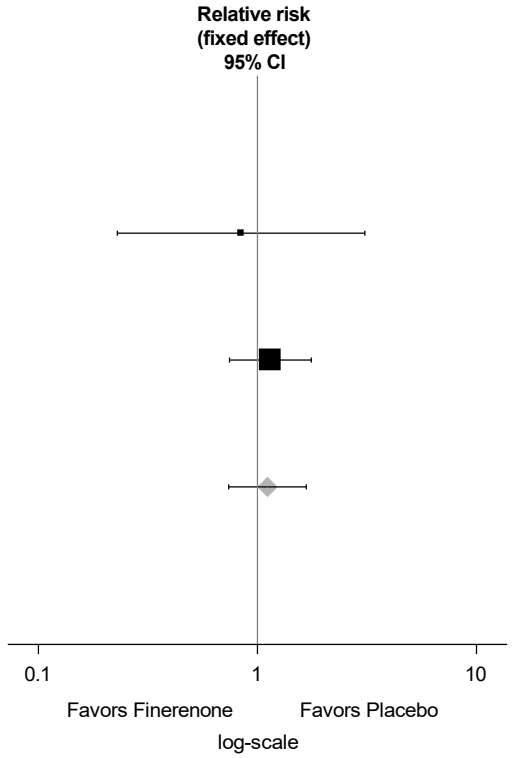
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	7.7	1.32 [0.36,4.83]	
FIGARO-DKD	53 / 2326	53 / 2302	92.3	0.99 [0.68,1.44]	
Total	58 / 2536	57 / 2523		1.01 [0.70,1.45]	Z=0.06, p=0.9490
Heterogeneity:	Q=0.17 (df=1)	p=0.6805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.95: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

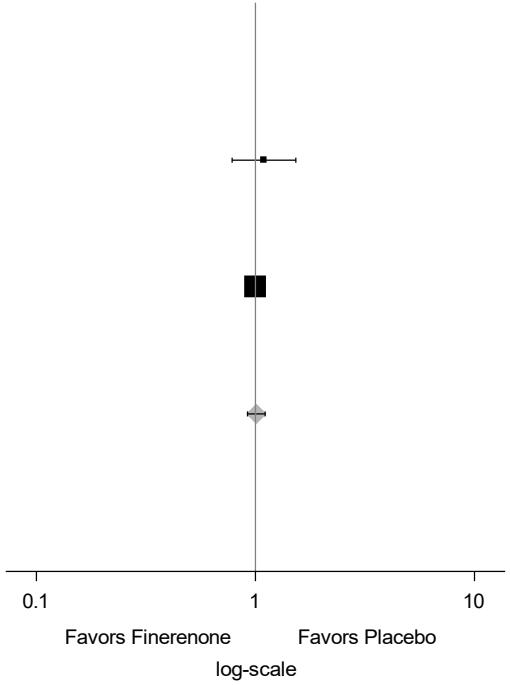
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	9.9	0.84 [0.23,3.09]	
FIGARO-DKD	44 / 2326	38 / 2302	90.1	1.15 [0.75,1.76]	
Total	48 / 2536	43 / 2523		1.11 [0.74,1.67]	Z=0.51, p=0.6117
Heterogeneity:	Q=0.19 (df=1)	p=0.6592	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.96: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

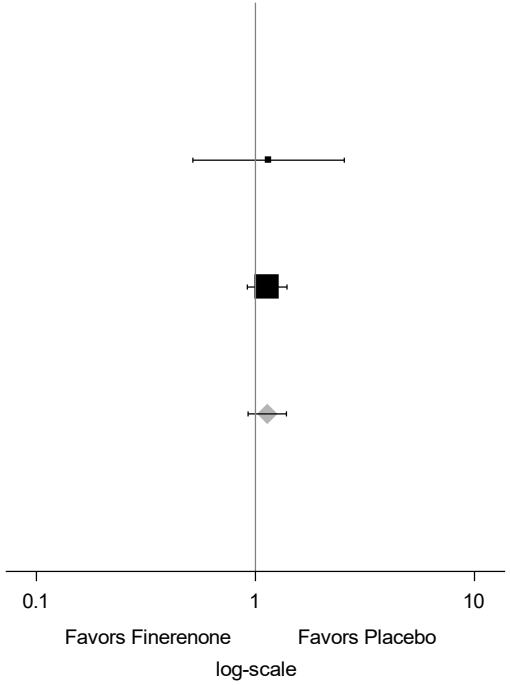
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 210	51 / 221	7.6	1.09 [0.78,1.53]	
FIGARO-DKD	615 / 2326	607 / 2302	92.4	1.00 [0.91,1.10]	
Total	668 / 2536	658 / 2523		1.01 [0.92,1.11]	Z=0.20, p=0.8430
Heterogeneity:	Q=0.24 (df=1)	p=0.6253	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.97: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

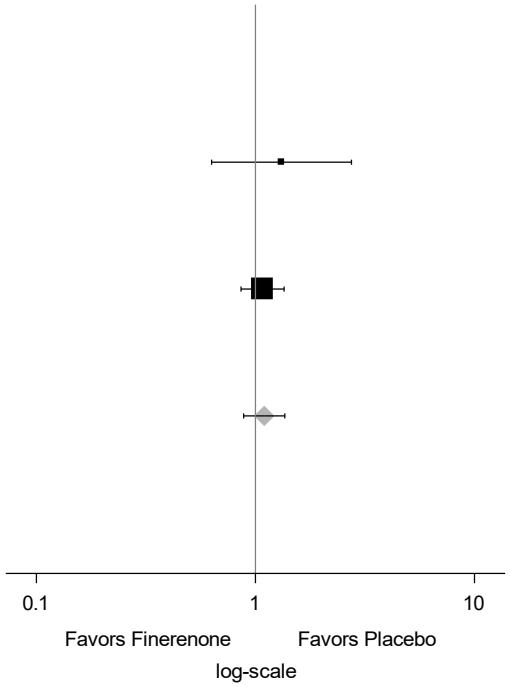
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	11 / 221	6.4	1.15 [0.52,2.54]	
FIGARO-DKD	176 / 2326	154 / 2302	93.6	1.13 [0.92,1.39]	
Total	188 / 2536	165 / 2523		1.13 [0.93,1.39]	Z=1.21, p=0.2277
Heterogeneity:	Q=0.00 (df=1)	p=0.9717	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.98: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

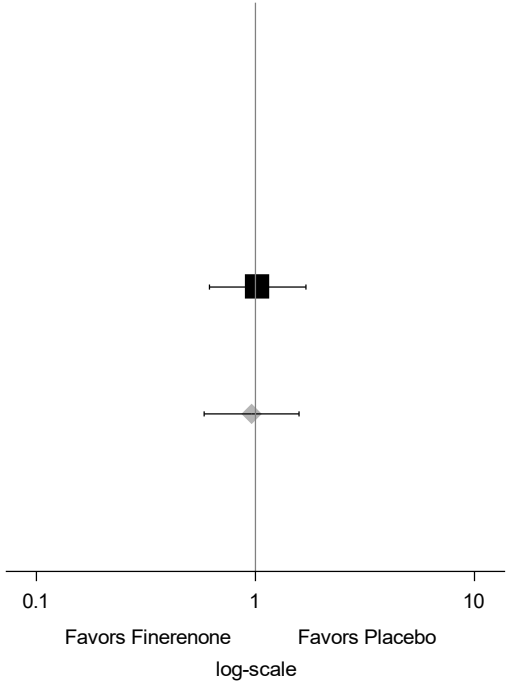
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	15 / 210	12 / 221	8.7	1.32 [0.63,2.74]	
FIGARO-DKD	147 / 2326	135 / 2302	91.3	1.08 [0.86,1.35]	
Total	162 / 2536	147 / 2523		1.10 [0.88,1.36]	Z=0.84, p=0.4036
Heterogeneity:	Q=0.26 (df=1)	p=0.6114	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.99: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

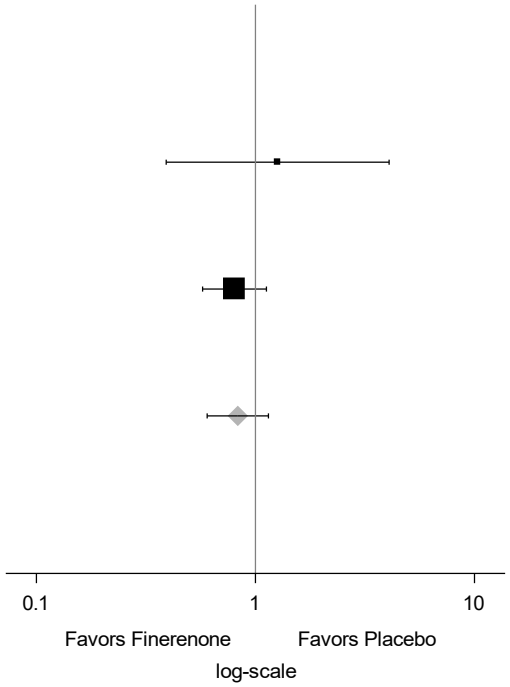
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	30 / 2326	29 / 2302	100.0	1.02 [0.62,1.70]	
Total	30 / 2536	31 / 2523		0.96 [0.58,1.58]	Z=-0.16, p=0.8731
Heterogeneity:	Q=0.06 (df=1)	p=0.8041	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.100: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

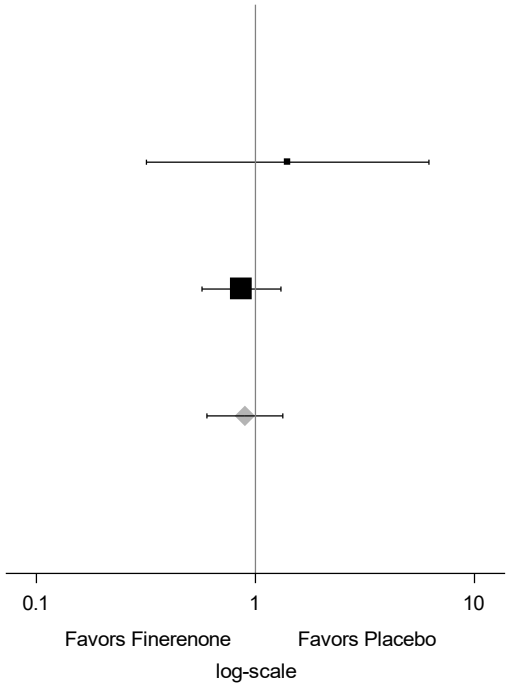
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	5 / 221	7.6	1.26 [0.39,4.08]	
FIGARO-DKD	60 / 2326	74 / 2302	92.4	0.80 [0.57,1.12]	
Total	66 / 2536	79 / 2523		0.83 [0.60,1.15]	Z=-1.13, p=0.2588
Heterogeneity:	Q=0.53 (df=1)	p=0.4659	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.101: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

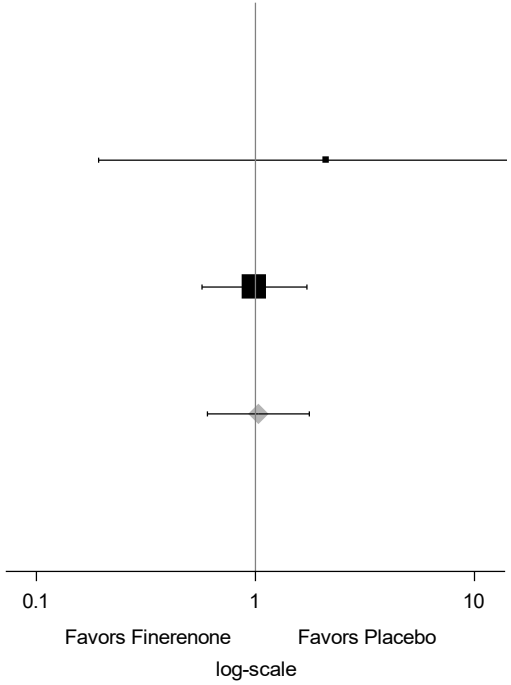
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	7.2	1.40 [0.32,6.19]	
FIGARO-DKD	41 / 2326	47 / 2302	92.8	0.86 [0.57,1.31]	
Total	45 / 2536	50 / 2523		0.89 [0.60,1.33]	Z=-0.55, p=0.5845
Heterogeneity:	Q=0.38 (df=1)	p=0.5370	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.102: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

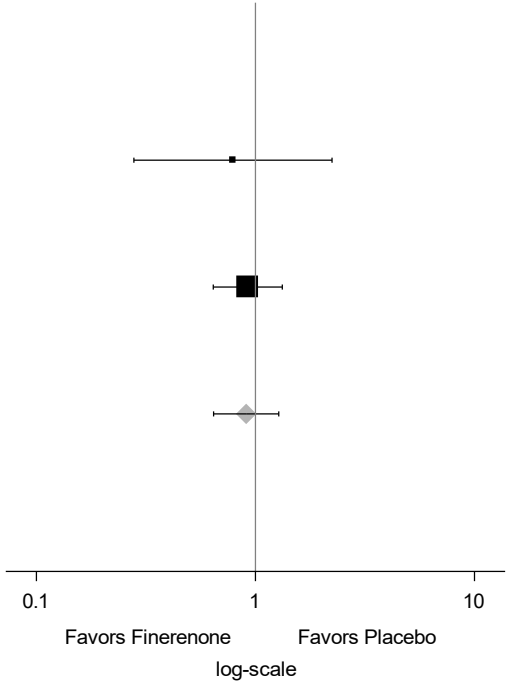
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.0	2.10 [0.19,23.04]	
FIGARO-DKD	25 / 2326	25 / 2302	95.0	0.99 [0.57,1.72]	
Total	27 / 2536	26 / 2523		1.03 [0.60,1.76]	Z=0.11, p=0.9106
Heterogeneity:	Q=0.36 (df=1)	p=0.5469	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.103: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

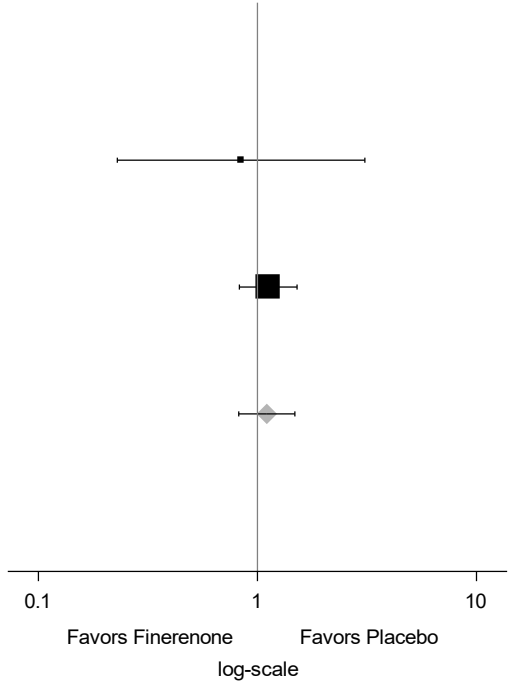
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	8 / 221	10.8	0.79 [0.28,2.24]	
FIGARO-DKD	55 / 2326	59 / 2302	89.2	0.92 [0.64,1.33]	
Total	61 / 2536	67 / 2523		0.91 [0.64,1.28]	Z=-0.56, p=0.5764
Heterogeneity:	Q=0.08 (df=1)	p=0.7815	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.104: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

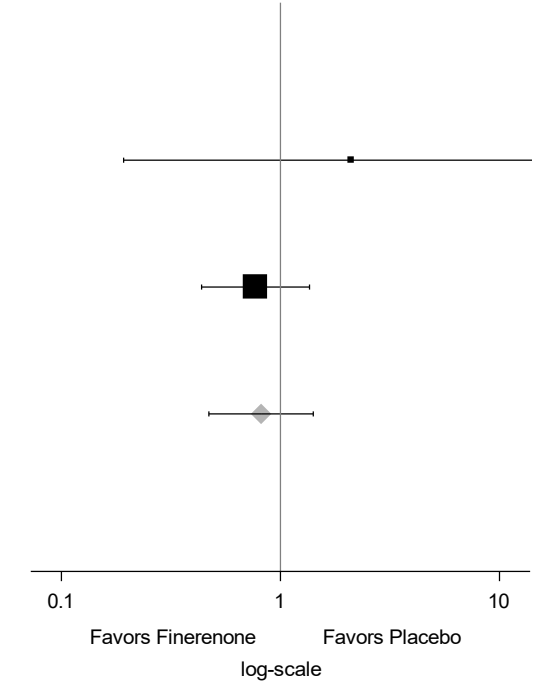
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	5.1	0.84 [0.23,3.09]	
FIGARO-DKD	86 / 2326	76 / 2302	94.9	1.12 [0.83,1.52]	
Total	90 / 2536	81 / 2523		1.10 [0.82,1.48]	Z=0.65, p=0.5132
Heterogeneity:	Q=0.18 (df=1)	p=0.6755	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.105: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Rotator cuff syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

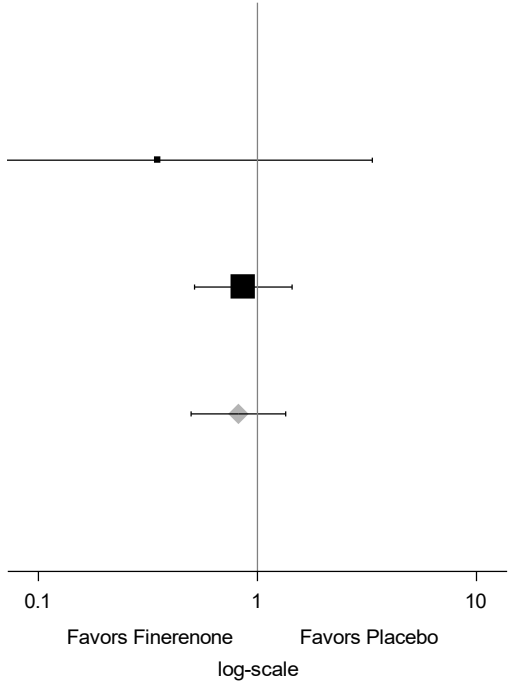
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.3	2.10 [0.19,23.04]	
FIGARO-DKD	21 / 2326	27 / 2302	94.7	0.77 [0.44,1.36]	
Total	23 / 2536	28 / 2523		0.82 [0.47,1.41]	Z=-0.73, p=0.4670
Heterogeneity:	Q=0.64 (df=1)	p=0.4227	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.106: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

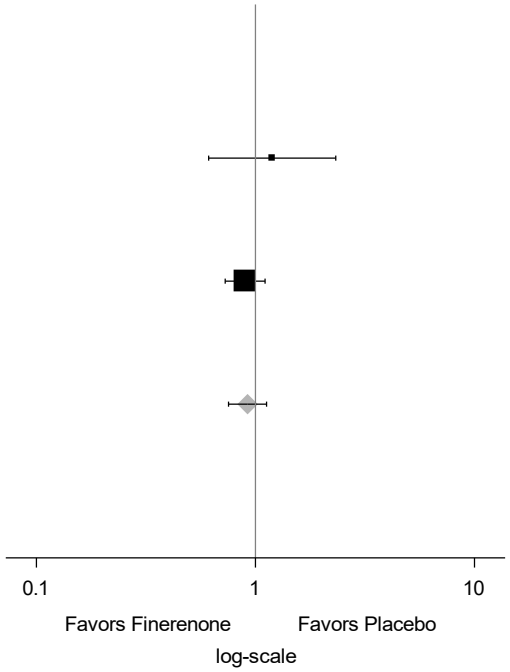
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	4.9	0.35 [0.04,3.35]	
FIGARO-DKD	27 / 2326	31 / 2302	95.1	0.86 [0.52,1.44]	
Total	28 / 2536	34 / 2523		0.82 [0.50,1.35]	Z=-0.79, p=0.4294
Heterogeneity:	Q=0.58 (df=1)	p=0.4458	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.107: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

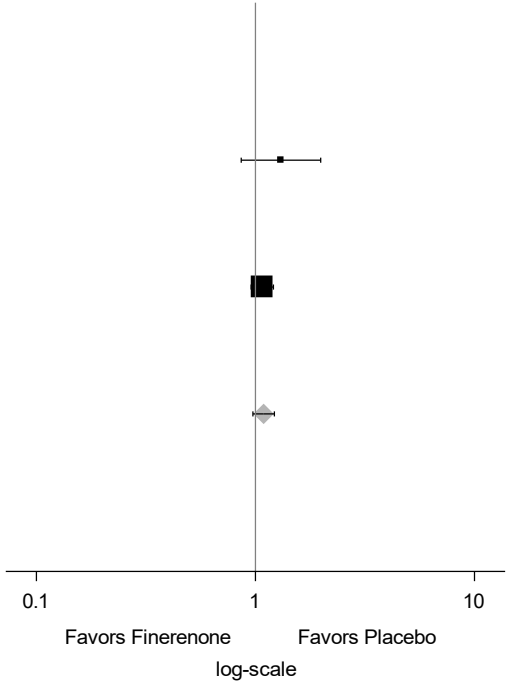
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 210	15 / 221	9.0	1.19 [0.61,2.33]	
FIGARO-DKD	155 / 2326	171 / 2302	91.0	0.90 [0.73,1.11]	
Total	172 / 2536	186 / 2523		0.92 [0.75,1.12]	Z=-0.81, p=0.4154
Heterogeneity:	Q=0.64 (df=1)	p=0.4253	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.108: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

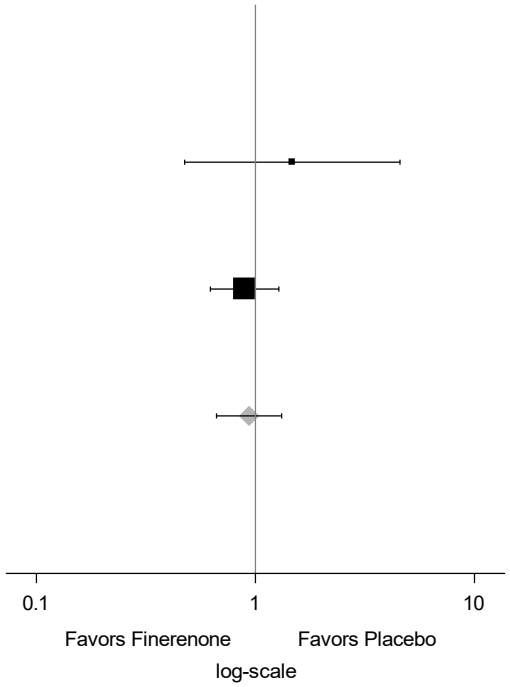
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 210	33 / 221	7.3	1.31 [0.86,1.99]	
FIGARO-DKD	470 / 2326	433 / 2302	92.7	1.07 [0.96,1.21]	
Total	511 / 2536	466 / 2523		1.09 [0.97,1.22]	Z=1.50, p=0.1347
Heterogeneity:	Q=0.79 (df=1)	p=0.3746	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.109: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

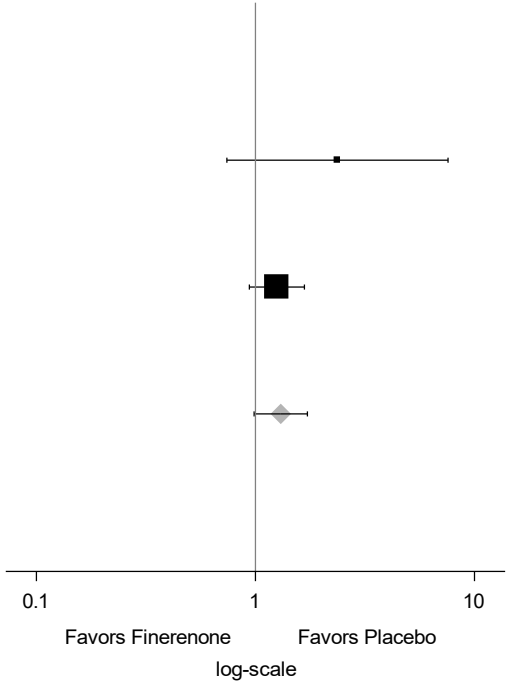
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	9.2	1.47 [0.47,4.57]	
FIGARO-DKD	55 / 2326	61 / 2302	90.8	0.89 [0.62,1.28]	
Total	62 / 2536	66 / 2523		0.94 [0.66,1.32]	Z=-0.38, p=0.7011
Heterogeneity:	Q=0.68 (df=1)	p=0.4080	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.110: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

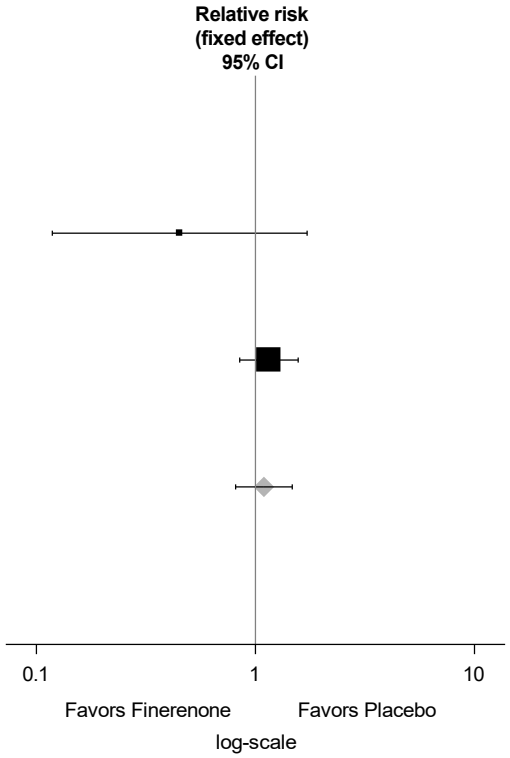
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	4 / 221	5.8	2.37 [0.74,7.57]	
FIGARO-DKD	100 / 2326	79 / 2302	94.2	1.25 [0.94,1.67]	
Total	109 / 2536	83 / 2523		1.30 [0.99,1.73]	Z=1.86, p=0.0628
Heterogeneity:	Q=1.09 (df=1)	p=0.2975	I^2=7.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.111: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

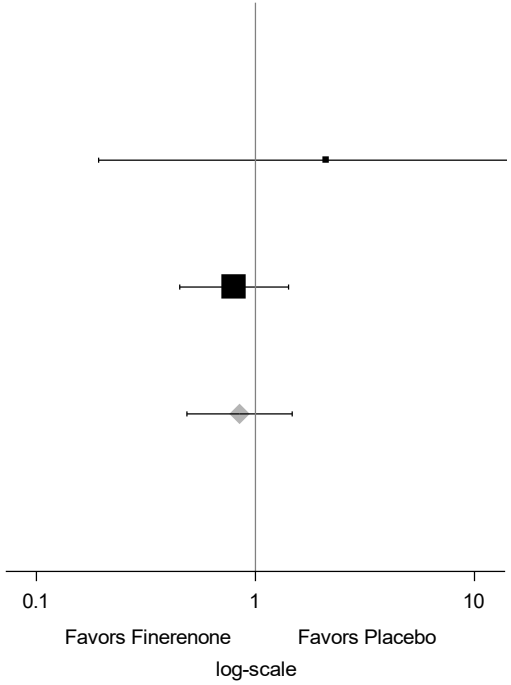
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	7 / 221	5.0	0.45 [0.12,1.72]	
FIGARO-DKD	85 / 2326	73 / 2302	95.0	1.15 [0.85,1.57]	
Total	88 / 2536	80 / 2523		1.09 [0.81,1.47]	Z=0.59, p=0.5572
Heterogeneity:	Q=1.79 (df=1)	p=0.1807	I^2=44.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.112: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

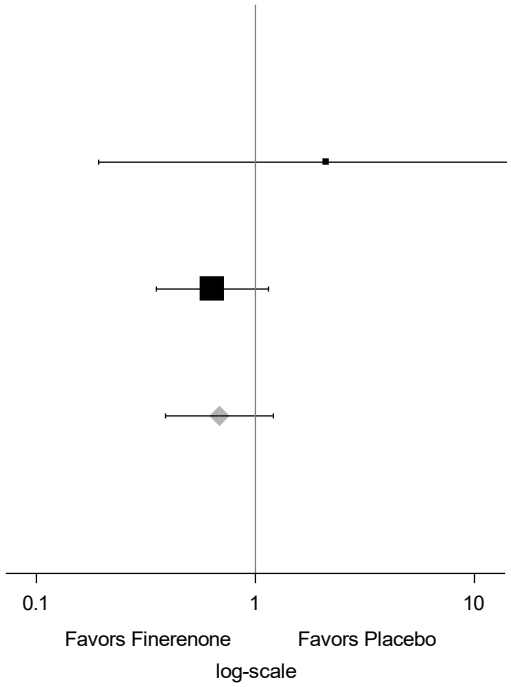
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.4	2.10 [0.19,23.04]	
FIGARO-DKD	21 / 2326	26 / 2302	94.6	0.80 [0.45,1.42]	
Total	23 / 2536	27 / 2523		0.85 [0.49,1.47]	Z=-0.59, p=0.5537
Heterogeneity:	Q=0.60 (df=1)	p=0.4405	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.113: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

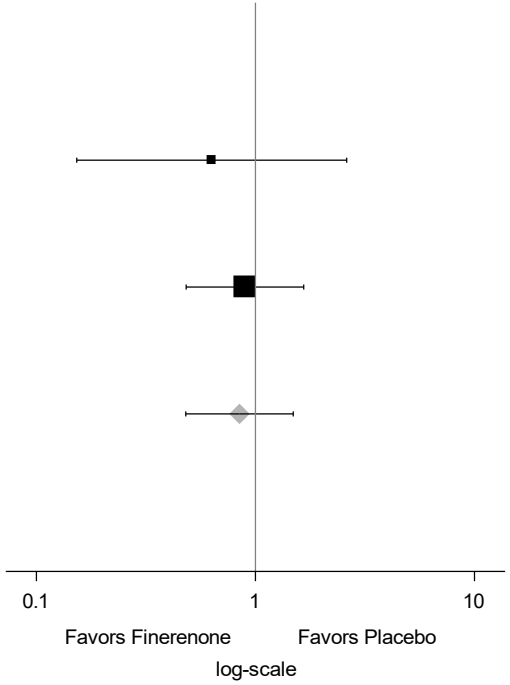
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.7	2.10 [0.19,23.04]	
FIGARO-DKD	18 / 2326	28 / 2302	94.3	0.64 [0.35,1.15]	
Total	20 / 2536	29 / 2523		0.68 [0.39,1.21]	Z=-1.31, p=0.1909
Heterogeneity:	Q=0.91 (df=1)	p=0.3413	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.114: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

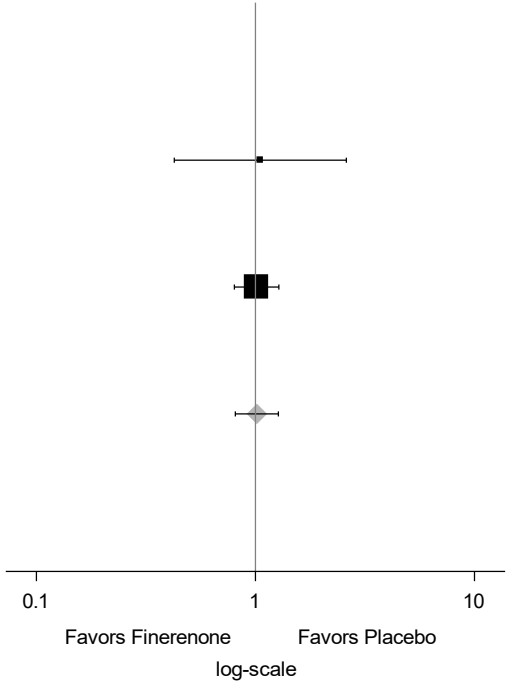
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	5 / 221	15.9	0.63 [0.15,2.61]	
FIGARO-DKD	19 / 2326	21 / 2302	84.1	0.90 [0.48,1.66]	
Total	22 / 2536	26 / 2523		0.85 [0.48,1.49]	Z=-0.58, p=0.5607
Heterogeneity:	Q=0.20 (df=1)	p=0.6582	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.115: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

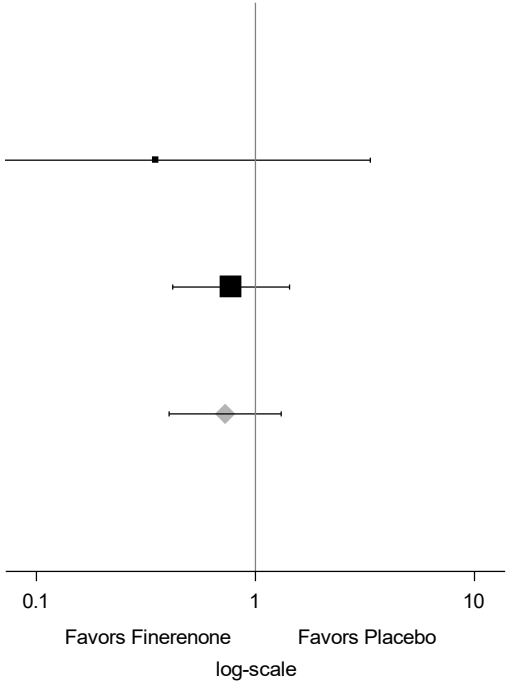
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	9 / 221	6.3	1.05 [0.43,2.60]	
FIGARO-DKD	134 / 2326	131 / 2302	93.7	1.01 [0.80,1.28]	
Total	143 / 2536	140 / 2523		1.01 [0.81,1.27]	Z=0.13, p=0.8987
Heterogeneity:	Q=0.01 (df=1)	p=0.9351	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.116: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

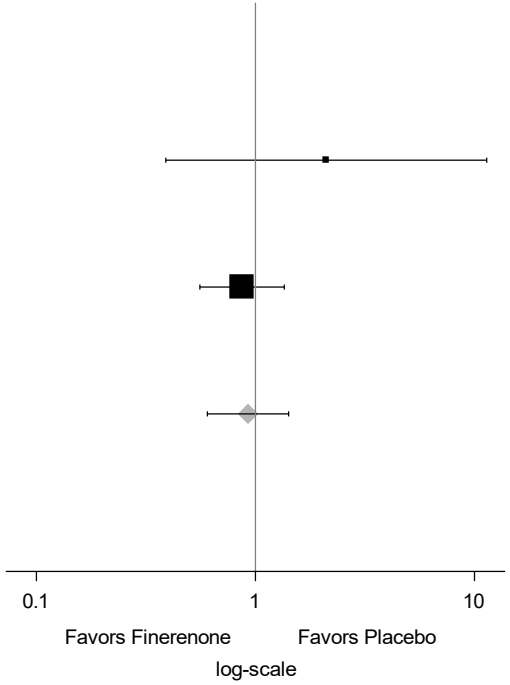
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	6.9	0.35 [0.04,3.35]	
FIGARO-DKD	18 / 2326	23 / 2302	93.1	0.77 [0.42,1.43]	
Total	19 / 2536	26 / 2523		0.73 [0.40,1.31]	Z=-1.06, p=0.2890
Heterogeneity:	Q=0.44 (df=1)	p=0.5062	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.117: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

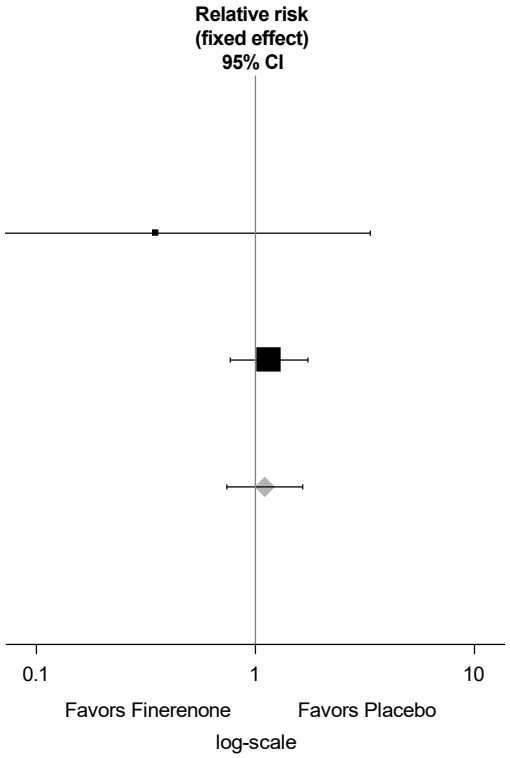
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	6.5	2.10 [0.39,11.37]	
FIGARO-DKD	36 / 2326	41 / 2302	93.5	0.87 [0.56,1.35]	
Total	40 / 2536	43 / 2523		0.92 [0.60,1.42]	Z=-0.36, p=0.7189
Heterogeneity:	Q=0.99 (df=1)	p=0.3201	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.118: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

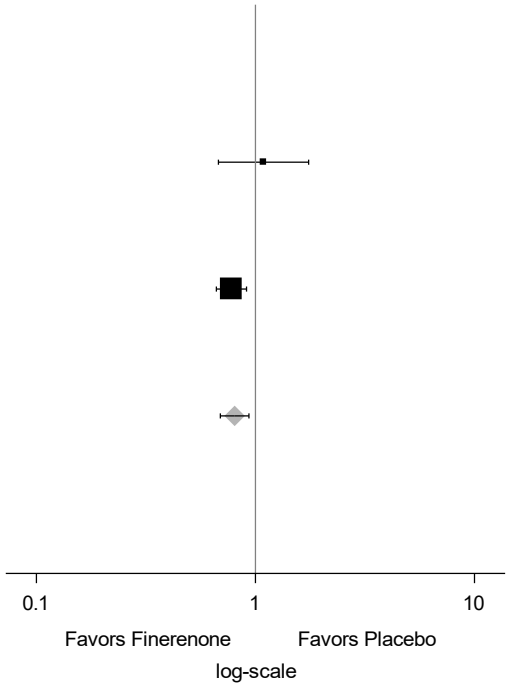
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	3.2	0.35 [0.04,3.35]	
FIGARO-DKD	49 / 2326	42 / 2302	96.8	1.15 [0.77,1.74]	
Total	50 / 2536	45 / 2523		1.10 [0.74,1.64]	Z=0.48, p=0.6300
Heterogeneity:	Q=1.04 (df=1)	p=0.3079	I^2=3.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.119: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

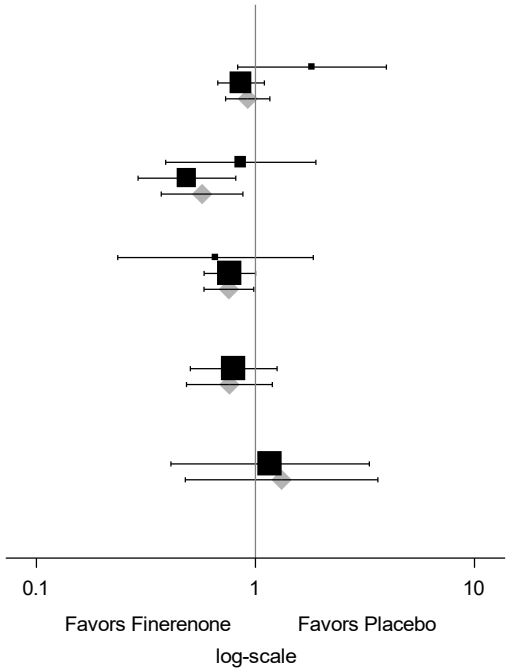
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	29 / 221	10.1	1.09 [0.68,1.75]	
FIGARO-DKD	241 / 2326	307 / 2302	89.9	0.78 [0.66,0.91]	
Total	271 / 2536	336 / 2523		0.80 [0.69,0.93]	Z=-2.85, p=0.0043
Heterogeneity:	Q=1.75 (df=1)	p=0.1860	I^2=42.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.119.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

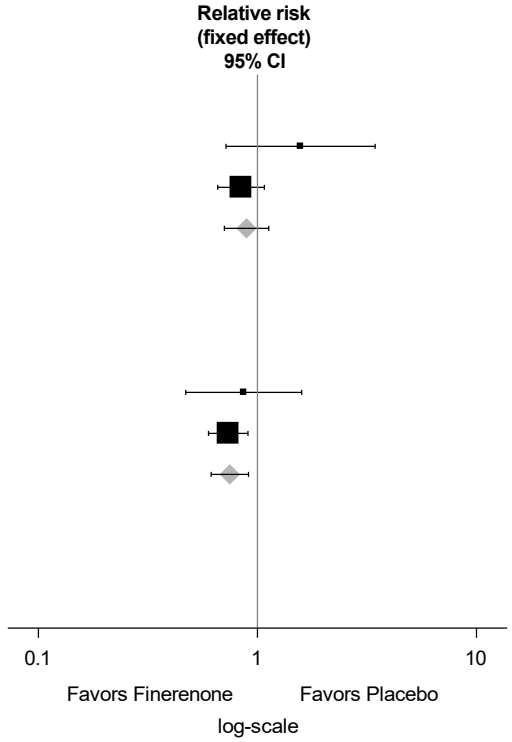
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 103	9 / 112	8.9	1.81 [0.83,3.96]	
FIGARO-DKD	107 / 1114	124 / 1110	91.1	0.86 [0.67,1.10]	
Total	122 / 1217	133 / 1222		0.92 [0.73,1.16]	Z=-0.68, p=0.4938
Heterogeneity:	Q=3.18 (df=1)	p=0.0744	I^2=68.6%		
North America					
FIDELIO-DKD	9 / 42	10 / 40	29.7	0.86 [0.39,1.89]	
FIGARO-DKD	20 / 292	39 / 277	70.3	0.49 [0.29,0.81]	
Total	29 / 334	49 / 317		0.57 [0.37,0.88]	Z=-2.56, p=0.0104
Heterogeneity:	Q=1.39 (df=1)	p=0.2382	I^2=28.1%		
Asia					
FIDELIO-DKD	5 / 39	8 / 41	6.5	0.66 [0.24,1.84]	
FIGARO-DKD	77 / 522	101 / 523	93.5	0.76 [0.58,1.00]	
Total	82 / 561	109 / 564		0.76 [0.58,0.98]	Z=-2.09, p=0.0363
Heterogeneity:	Q=0.08 (df=1)	p=0.7812	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	2 / 24	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	30 / 322	37 / 316	100.0	0.80 [0.50,1.26]	
Total	30 / 343	39 / 340		0.76 [0.48,1.19]	Z=-1.19, p=0.2342
Heterogeneity:	Q=0.04 (df=1)	p=0.8455	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 5	0 / 4	0.0	383E9 [383E9,383E9]	
FIGARO-DKD	7 / 76	6 / 76	100.0	1.17 [0.41,3.31]	
Total	8 / 81	6 / 80		1.32 [0.48,3.62]	Z=0.53, p=0.5945
Heterogeneity:	Q=0.05 (df=1)	p=0.8205	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.96 (df=4)	p=0.2910	I^2=19.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.119.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

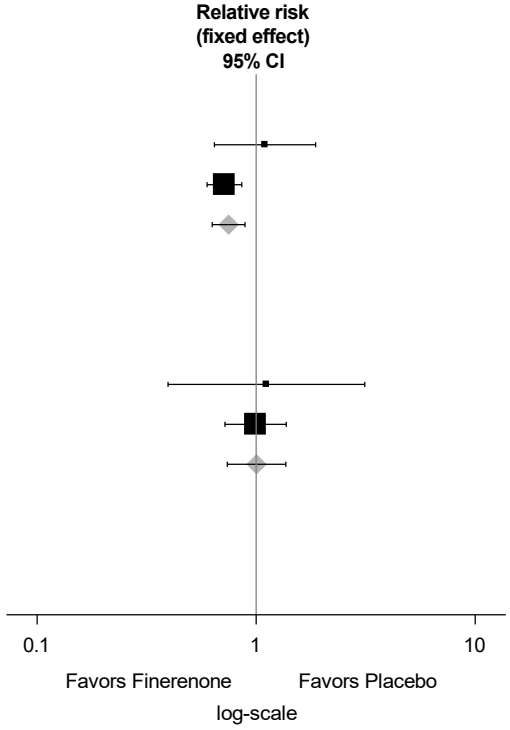
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	14 / 88	9 / 89	8.9	1.57 [0.72,3.45]	
FIGARO-DKD	102 / 811	120 / 803	91.1	0.84 [0.66,1.08]	
Total	116 / 899	129 / 892		0.89 [0.71,1.13]	Z=-0.96, p=0.3351
Heterogeneity:	Q=2.23 (df=1)	p=0.1355	I^2=55.1%		
Absent					
FIDELIO-DKD	16 / 122	20 / 132	10.4	0.87 [0.47,1.59]	
FIGARO-DKD	139 / 1515	187 / 1499	89.6	0.74 [0.60,0.91]	
Total	155 / 1637	207 / 1631		0.75 [0.61,0.91]	Z=-2.90, p=0.0038
Heterogeneity:	Q=0.25 (df=1)	p=0.6200	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=1)	p=0.2581	I^2=21.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.119.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

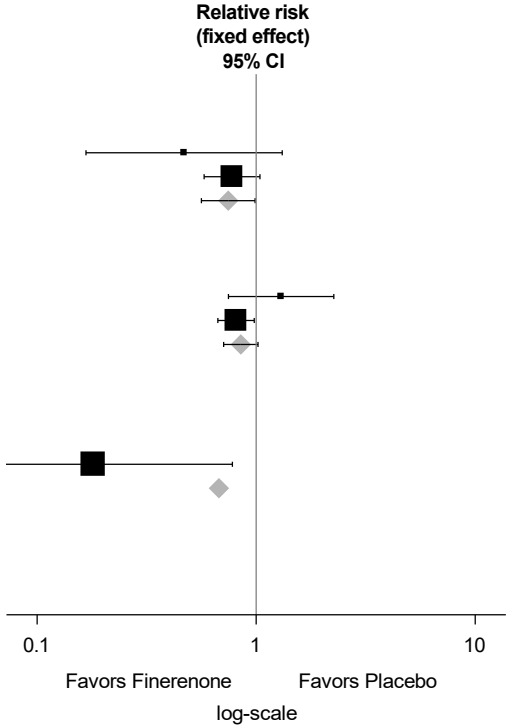
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 144	23 / 158	10.5	1.10 [0.64,1.87]	
FIGARO-DKD	176 / 1719	240 / 1679	89.5	0.72 [0.60,0.86]	
Total	199 / 1863	263 / 1837		0.75 [0.63,0.89]	Z=-3.29, p=0.0010
Heterogeneity:	Q=2.21 (df=1)	p=0.1372	I^2=54.7%		
> 4.5					
FIDELIO-DKD	7 / 66	6 / 63	8.9	1.11 [0.40,3.13]	
FIGARO-DKD	65 / 607	67 / 622	91.1	0.99 [0.72,1.37]	
Total	72 / 673	73 / 685		1.00 [0.74,1.37]	Z=0.03, p=0.9787
Heterogeneity:	Q=0.04 (df=1)	p=0.8373	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.67 (df=1)	p=0.1024	I^2=62.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.119.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

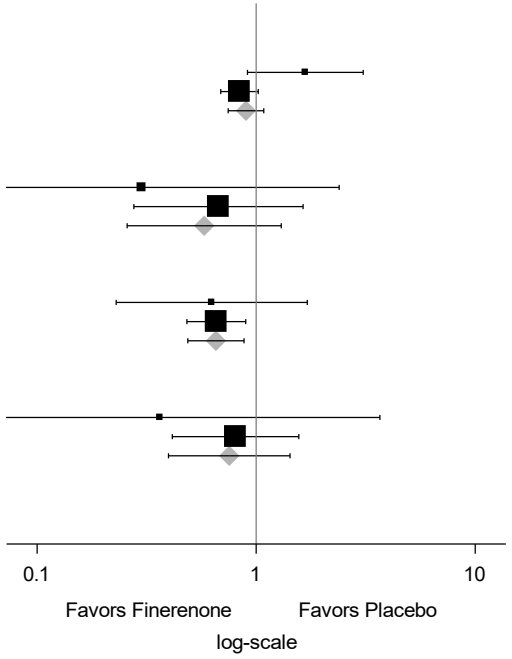
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 64	9 / 54	7.5	0.47 [0.17,1.31]	
FIGARO-DKD	70 / 693	91 / 699	92.5	0.78 [0.58,1.04]	
Total	75 / 757	100 / 753		0.75 [0.56,0.99]	Z=-2.04, p=0.0412
Heterogeneity:	Q=0.85 (df=1)	p=0.3570	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 138	20 / 156	10.7	1.30 [0.75,2.26]	
FIGARO-DKD	169 / 1560	204 / 1524	89.3	0.81 [0.67,0.98]	
Total	192 / 1698	224 / 1680		0.85 [0.71,1.02]	Z=-1.75, p=0.0801
Heterogeneity:	Q=2.51 (df=1)	p=0.1128	I^2=60.2%		
>= 160					
FIDELIO-DKD	2 / 8	0 / 11	0.0	479E9 [479E9,479E9]	
FIGARO-DKD	2 / 73	12 / 79	100.0	0.18 [0.04,0.78]	
Total	4 / 81	12 / 90		0.68 [0.68,0.68]	Z=. , p=.
Heterogeneity:	Q=3.13 (df=1)	p=0.0767	I^2=68.1%		
Subgroup Heterogeneity:	Q=0.60 (df=2)	p=0.7406	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.119.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

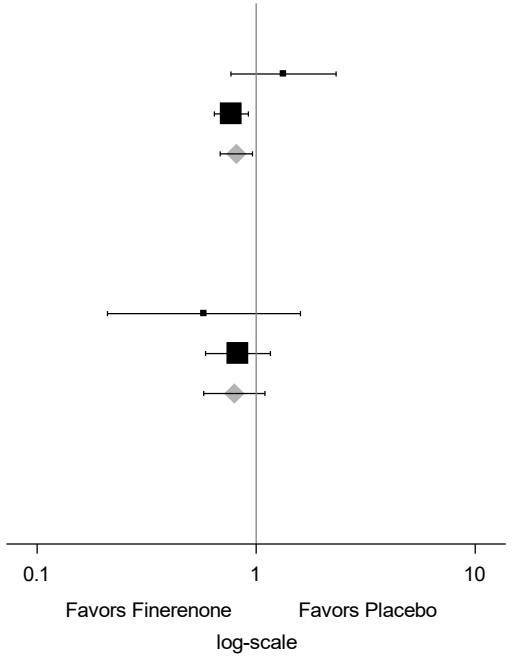
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	23 / 139	15 / 152	9.5	1.68 [0.91,3.08]	
FIGARO-DKD	164 / 1658	190 / 1612	90.5	0.84 [0.69,1.02]	
Total	187 / 1797	205 / 1764		0.90 [0.75,1.08]	Z=-1.12, p=0.2612
Heterogeneity:	Q=4.50 (df=1)	p=0.0339	I^2=77.8%		
Black					
FIDELIO-DKD	1 / 10	3 / 9	15.5	0.30 [0.04,2.39]	
FIGARO-DKD	7 / 70	11 / 74	84.5	0.67 [0.28,1.64]	
Total	8 / 80	14 / 83		0.58 [0.26,1.30]	Z=-1.32, p=0.1859
Heterogeneity:	Q=0.49 (df=1)	p=0.4819	I^2=0.0%		
Asian					
FIDELIO-DKD	5 / 39	9 / 44	8.6	0.63 [0.23,1.71]	
FIGARO-DKD	56 / 464	89 / 485	91.4	0.66 [0.48,0.90]	
Total	61 / 503	98 / 529		0.65 [0.49,0.88]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.01 (df=1)	p=0.9285	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	2 / 16	7.6	0.36 [0.04,3.67]	
FIGARO-DKD	14 / 134	17 / 131	92.4	0.81 [0.41,1.57]	
Total	15 / 156	19 / 147		0.75 [0.40,1.43]	Z=-0.87, p=0.3851
Heterogeneity:	Q=0.42 (df=1)	p=0.5172	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.87 (df=3)	p=0.2757	I^2=22.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.119.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

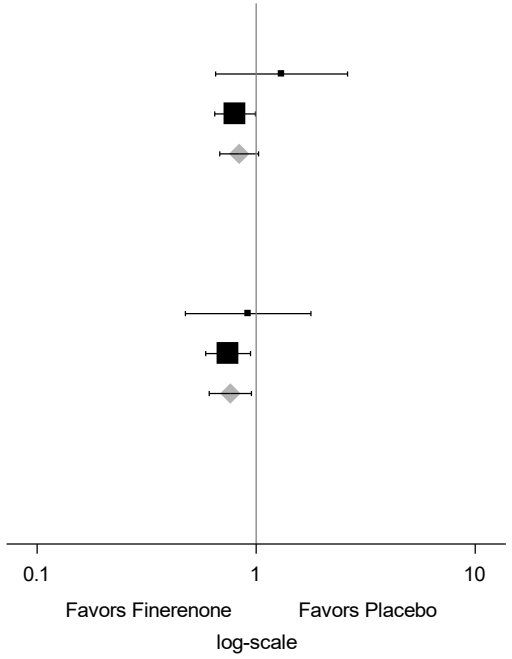
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 152	19 / 154	9.5	1.33 [0.77,2.32]	
FIGARO-DKD	184 / 1610	243 / 1638	90.5	0.77 [0.64,0.92]	
Total	209 / 1762	262 / 1792		0.81 [0.69,0.96]	Z=-2.41, p=0.0159
Heterogeneity:	Q=3.42 (df=1)	p=0.0643	I^2=70.8%		
Female					
FIDELIO-DKD	5 / 58	10 / 67	10.2	0.58 [0.21,1.59]	
FIGARO-DKD	57 / 716	64 / 664	89.8	0.83 [0.59,1.16]	
Total	62 / 774	74 / 731		0.79 [0.58,1.10]	Z=-1.40, p=0.1624
Heterogeneity:	Q=0.43 (df=1)	p=0.5123	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9101	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.119.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

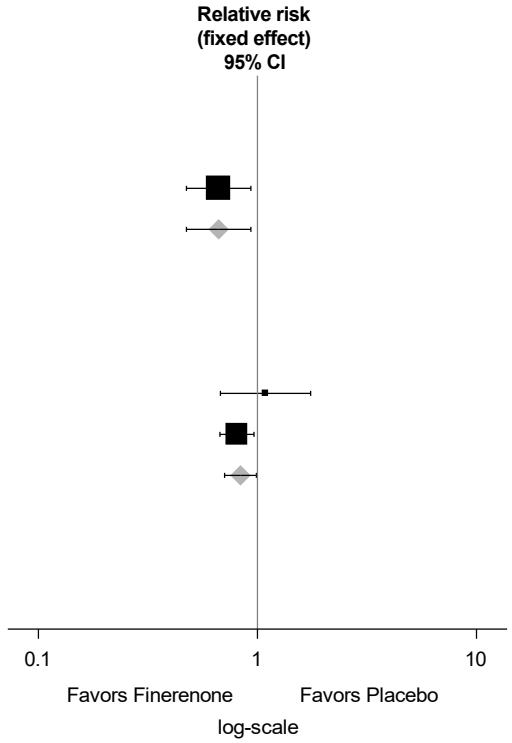
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	16 / 98	12 / 96	8.7	1.31 [0.65,2.61]	
FIGARO-DKD	135 / 1416	169 / 1420	91.3	0.80 [0.65,0.99]	
Total	151 / 1514	181 / 1516		0.84 [0.68,1.03]	Z=-1.72, p=0.0857
Heterogeneity:	Q=1.74 (df=1)	p=0.1868	I^2=42.6%		
>= 65					
FIDELIO-DKD	14 / 112	17 / 125	11.3	0.92 [0.48,1.78]	
FIGARO-DKD	106 / 910	138 / 882	88.7	0.74 [0.59,0.94]	
Total	120 / 1022	155 / 1007		0.76 [0.61,0.95]	Z=-2.40, p=0.0165
Heterogeneity:	Q=0.35 (df=1)	p=0.5555	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.119.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

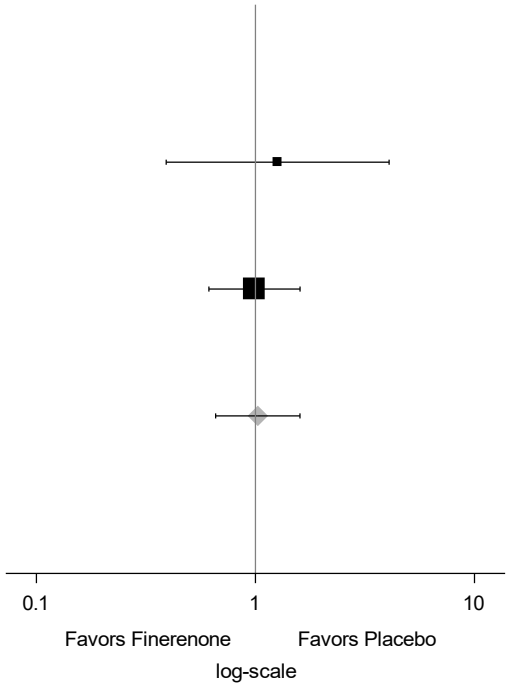
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	48 / 363	68 / 342	100.0	0.67 [0.47,0.93]	
Total	48 / 363	68 / 342		0.67 [0.47,0.93]	Z=-2.36, p=0.0183
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	30 / 210	29 / 221	12.5	1.09 [0.68,1.75]	
FIGARO-DKD	193 / 1963	239 / 1960	87.5	0.81 [0.67,0.96]	
Total	223 / 2173	268 / 2181		0.84 [0.71,0.99]	Z=-2.09, p=0.0370
Heterogeneity:	Q=1.35 (df=1)	p=0.2456	I^2=25.8%		
Subgroup Heterogeneity:	Q=1.42 (df=1)	p=0.2332	I^2=29.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.120: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

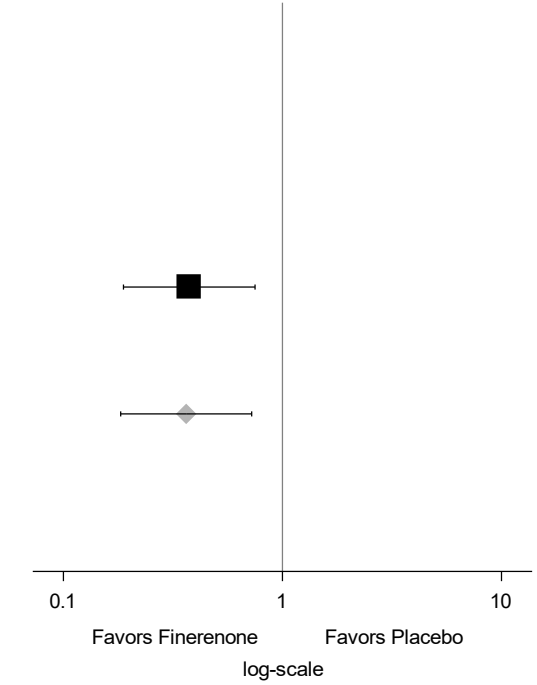
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	5 / 221	14.3	1.26 [0.39,4.08]	
FIGARO-DKD	33 / 2326	33 / 2302	85.7	0.99 [0.61,1.60]	
Total	39 / 2536	38 / 2523		1.03 [0.66,1.60]	Z=0.11, p=0.9129
Heterogeneity:	Q=0.14 (df=1)	p=0.7059	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.121: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

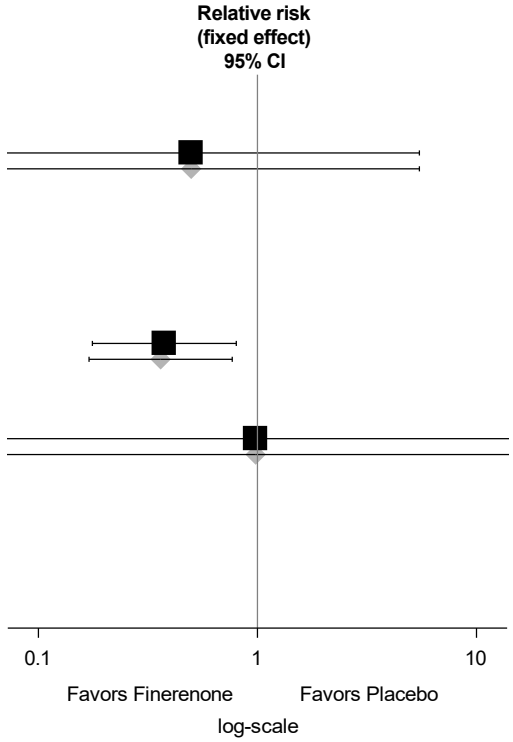
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	11 / 2326	29 / 2302	100.0	0.38 [0.19,0.75]	
Total	11 / 2536	30 / 2523		0.36 [0.18,0.72]	Z=-2.88, p=0.0040
Heterogeneity:	Q=0.01 (df=1)	p=0.9271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.121.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

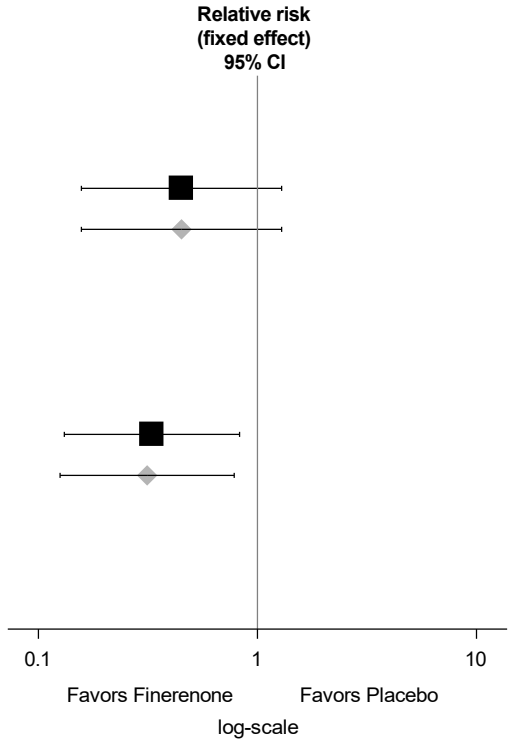
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	1 / 1114	2 / 1110	100.0	0.50 [0.05,5.49]	
Total	1 / 1217	2 / 1222		0.50 [0.05,5.49]	Z=-0.57, p=0.5692
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	0 / 292	1 / 277	0.0	0.00 [0.00,12E296]	
Total	0 / 334	1 / 317		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	9 / 522	24 / 523	100.0	0.38 [0.18,0.80]	
Total	9 / 561	25 / 564		0.36 [0.17,0.77]	Z=-2.65, p=0.0080
Heterogeneity:	Q=0.01 (df=1)	p=0.9198	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	1 / 316	100.0	0.98 [0.06,15.62]	
Total	1 / 343	1 / 340		0.98 [0.06,15.62]	Z=-0.01, p=0.9894
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	1 / 76	0.0	0.00 [0.00,97E295]	
Total	0 / 81	1 / 80		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.50 (df=4)	p=0.9730	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.121.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	5 / 811	11 / 803	100.0	0.45 [0.16,1.29]	
Total	5 / 899	11 / 892		0.45 [0.16,1.29]	Z=-1.49, p=0.1371
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	1 / 132	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	6 / 1515	18 / 1499	100.0	0.33 [0.13,0.83]	
Total	6 / 1637	19 / 1631		0.31 [0.13,0.78]	Z=-2.48, p=0.0130
Heterogeneity:	Q=0.01 (df=1)	p=0.9146	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6117	I^2=0.0%		

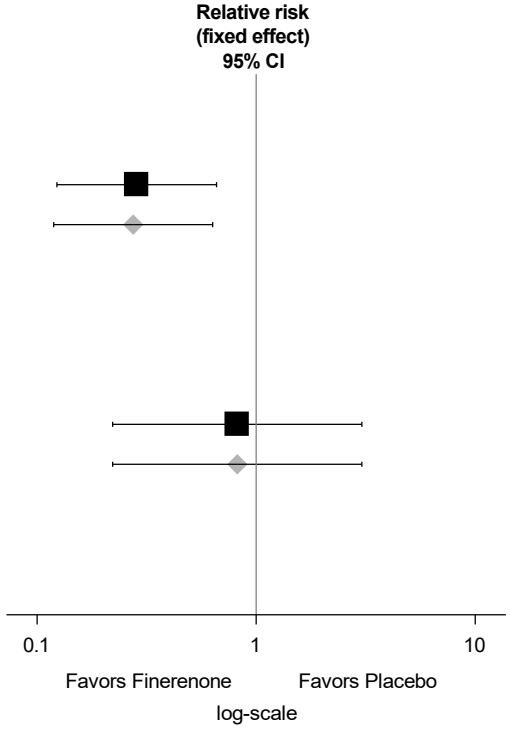


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.121.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetic nephropathy (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

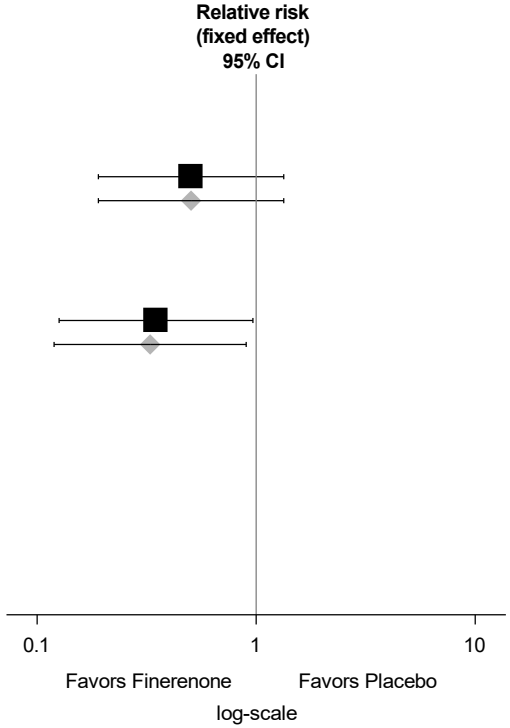
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	1 / 158	0.0	0.00 [0.00,2E297]	
FIGARO-DKD	7 / 1719	24 / 1679	100.0	0.28 [0.12,0.66]	
Total	7 / 1863	25 / 1837		0.27 [0.12,0.63]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.01 (df=1)	p=0.9309	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	4 / 607	5 / 622	100.0	0.82 [0.22,3.04]	
Total	4 / 673	5 / 685		0.82 [0.22,3.04]	Z=-0.30, p=0.7662
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.90 (df=1)	p=0.1676	I^2=47.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.121.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

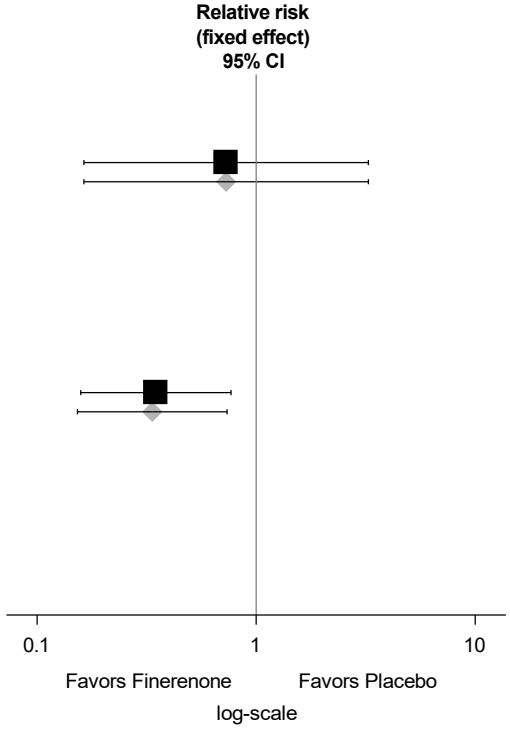
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	12 / 699	100.0	0.50 [0.19,1.34]	
Total	6 / 757	12 / 753		0.50 [0.19,1.34]	Z=-1.38, p=0.1685
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	1 / 156	0.0	0.00 [0.00,2E297]	
FIGARO-DKD	5 / 1560	14 / 1524	100.0	0.35 [0.13,0.97]	
Total	5 / 1698	15 / 1680		0.33 [0.12,0.90]	Z=-2.16, p=0.0305
Heterogeneity:	Q=0.01 (df=1)	p=0.9053	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	3 / 79	0.0	0.00 [0.00,91E295]	
Total	0 / 81	3 / 90		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.36 (df=2)	p=0.8348	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.121.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

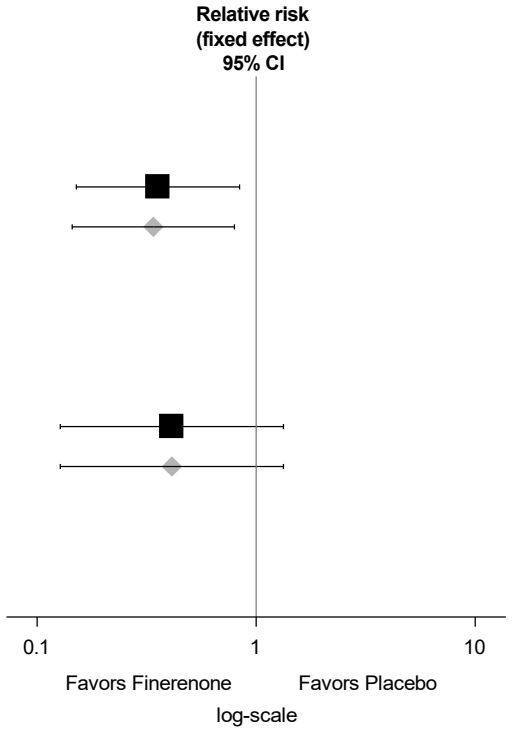
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	3 / 1658	4 / 1612	100.0	0.73 [0.16,3.25]	
Total	3 / 1797	4 / 1764		0.73 [0.16,3.25]	Z=-0.41, p=0.6789
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	0 / 80	0 / 83		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	8 / 464	24 / 485	100.0	0.35 [0.16,0.77]	
Total	8 / 503	25 / 529		0.34 [0.15,0.74]	Z=-2.72, p=0.0065
Heterogeneity:	Q=0.01 (df=1)	p=0.9250	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,17E296]	
Total	0 / 156	1 / 147		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.81 (df=3)	p=0.8468	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.121.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

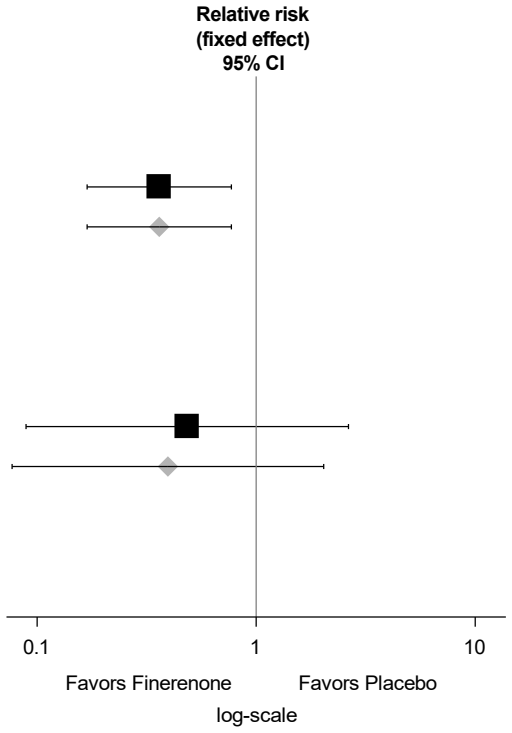
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	1 / 154	0.0	0.00 [0.00,2E297]	
FIGARO-DKD	7 / 1610	20 / 1638	100.0	0.36 [0.15,0.84]	
Total	7 / 1762	21 / 1792		0.34 [0.14,0.80]	Z=-2.49, p=0.0129
Heterogeneity:	Q=0.01 (df=1)	p=0.9113	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	4 / 716	9 / 664	100.0	0.41 [0.13,1.33]	
Total	4 / 774	9 / 731		0.41 [0.13,1.33]	Z=-1.48, p=0.1386
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7921	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.121.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

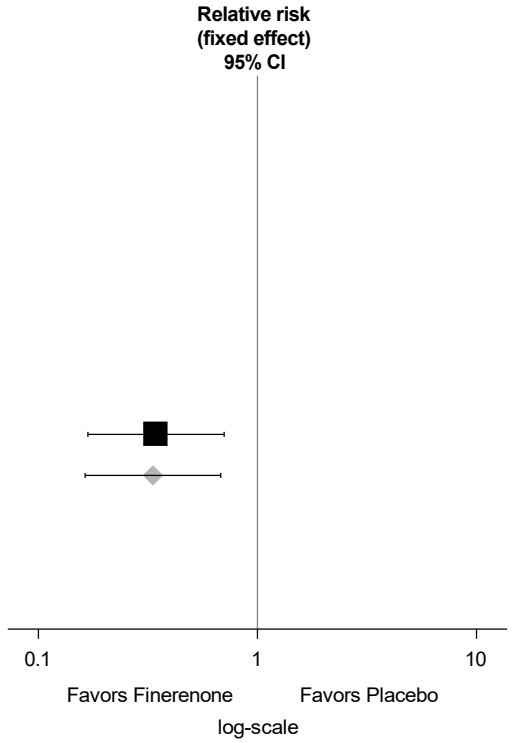
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	9 / 1416	25 / 1420	100.0	0.36 [0.17,0.77]	
Total	9 / 1514	25 / 1516		0.36 [0.17,0.77]	Z=-2.63, p=0.0085
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	1 / 125	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	2 / 910	4 / 882	100.0	0.48 [0.09,2.64]	
Total	2 / 1022	5 / 1007		0.40 [0.08,2.03]	Z=-1.11, p=0.2668
Heterogeneity:	Q=0.06 (df=1)	p=0.8138	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.121.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

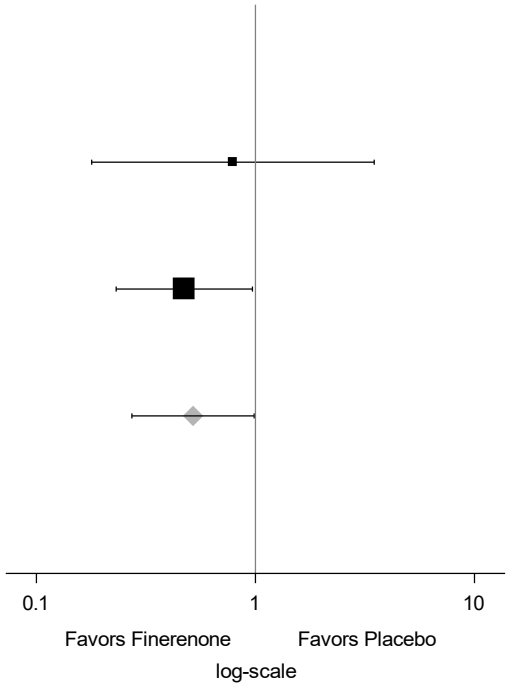
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	1 / 363	0 / 342	0.0	106E9 [106E9,106E9]	
Total	1 / 363	0 / 342		106E9 [106E9,106E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Very High					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	10 / 1963	29 / 1960	100.0	0.34 [0.17,0.70]	
Total	10 / 2173	30 / 2181		0.33 [0.16,0.68]	Z=-3.02, p=0.0025
Heterogeneity:	Q=0.01 (df=1)	p=0.9293	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.122: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

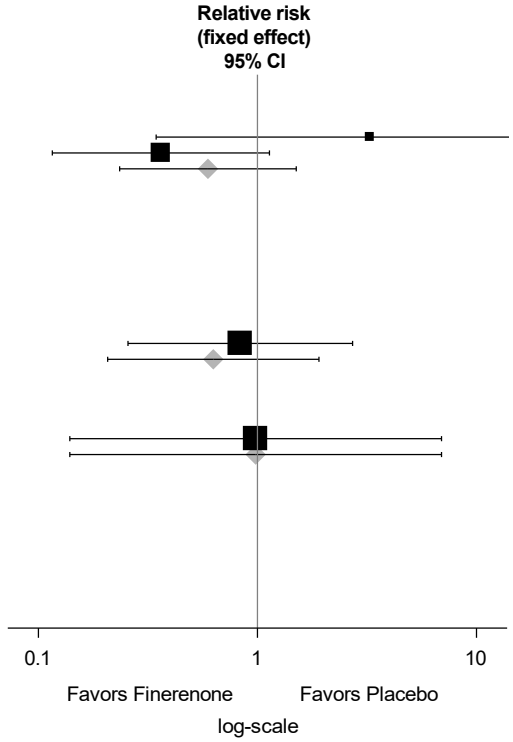
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	18.9	0.79 [0.18,3.48]	
FIGARO-DKD	11 / 2326	23 / 2302	81.1	0.47 [0.23,0.97]	
Total	14 / 2536	27 / 2523		0.52 [0.27,0.99]	Z=-2.00, p=0.0455
Heterogeneity:	Q=0.37 (df=1)	p=0.5431	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.122.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

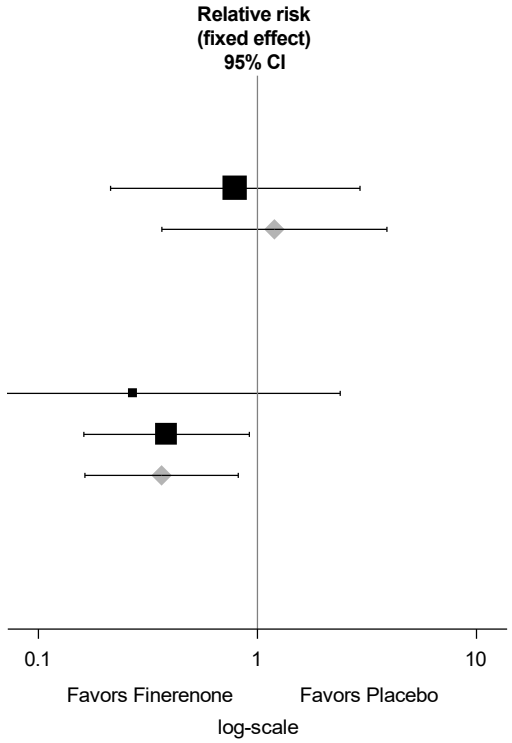
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	1 / 112	20.5	3.26 [0.34,30.87]	
FIGARO-DKD	4 / 1114	11 / 1110	79.5	0.36 [0.12,1.13]	
Total	7 / 1217	12 / 1222		0.59 [0.23,1.50]	Z=-1.10, p=0.2719
Heterogeneity:	Q=2.93 (df=1)	p=0.0871	I^2=65.8%		
North America					
FIDELIO-DKD	0 / 42	1 / 40	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	0 / 292	4 / 277	0.0	0.00 [0.00,88E295]	
Total	0 / 334	5 / 317		0.00 [0.00,81E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	2 / 41	0.0	0.00 [0.00,71E295]	
FIGARO-DKD	5 / 522	6 / 523	100.0	0.83 [0.26,2.72]	
Total	5 / 561	8 / 564		0.63 [0.21,1.91]	Z=-0.82, p=0.4128
Heterogeneity:	Q=0.22 (df=1)	p=0.6377	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	2 / 322	2 / 316	100.0	0.98 [0.14,6.92]	
Total	2 / 343	2 / 340		0.98 [0.14,6.92]	Z=-0.02, p=0.9849
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	0 / 76	0.0	-	
Total	0 / 81	0 / 80		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.21 (df=4)	p=0.9949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.122.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

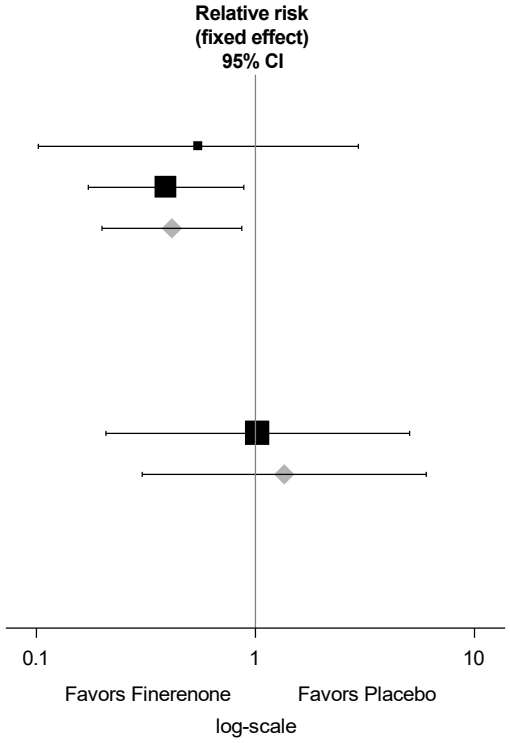
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	2 / 88	0 / 89	0.0	118E9 [118E9,118E9]	
FIGARO-DKD	4 / 811	5 / 803	100.0	0.79 [0.21,2.94]	
Total	6 / 899	5 / 892		1.20 [0.37,3.90]	Z=0.30, p=0.7678
Heterogeneity:	Q=0.38 (df=1)	p=0.5387	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	4 / 132	13.8	0.27 [0.03,2.39]	
FIGARO-DKD	7 / 1515	18 / 1499	86.2	0.38 [0.16,0.92]	
Total	8 / 1637	22 / 1631		0.36 [0.16,0.82]	Z=-2.45, p=0.0143
Heterogeneity:	Q=0.09 (df=1)	p=0.7682	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.64 (df=1)	p=0.1044	I^2=62.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.122.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

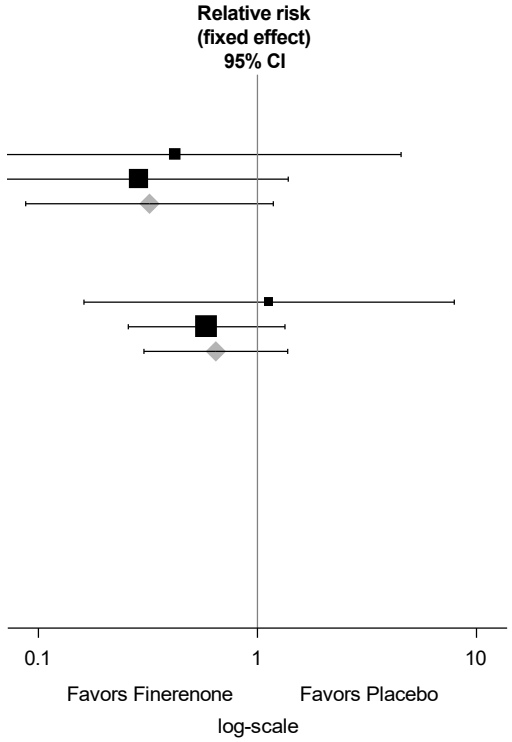
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	4 / 158	19.1	0.55 [0.10,2.95]	
FIGARO-DKD	8 / 1719	20 / 1679	80.9	0.39 [0.17,0.88]	
Total	10 / 1863	24 / 1837		0.42 [0.20,0.87]	Z=-2.34, p=0.0191
Heterogeneity:	Q=0.13 (df=1)	p=0.7219	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	0 / 63	0.0	214E9 [214E9,214E9]	
FIGARO-DKD	3 / 607	3 / 622	100.0	1.02 [0.21,5.06]	
Total	4 / 673	3 / 685		1.35 [0.30,6.02]	Z=0.40, p=0.6911
Heterogeneity:	Q=0.12 (df=1)	p=0.7326	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.94 (df=1)	p=0.1642	I^2=48.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.122.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

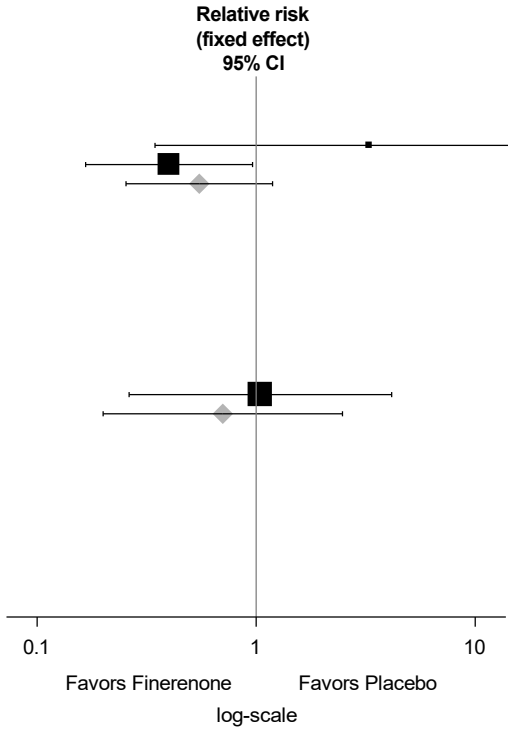
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	2 / 54	30.4	0.42 [0.04,4.53]	
FIGARO-DKD	2 / 693	7 / 699	69.6	0.29 [0.06,1.38]	
Total	3 / 757	9 / 753		0.32 [0.09,1.18]	Z=-1.71, p=0.0874
Heterogeneity:	Q=0.07 (df=1)	p=0.7927	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	2 / 156	15.2	1.13 [0.16,7.92]	
FIGARO-DKD	9 / 1560	15 / 1524	84.8	0.59 [0.26,1.34]	
Total	11 / 1698	17 / 1680		0.65 [0.30,1.37]	Z=-1.14, p=0.2562
Heterogeneity:	Q=0.37 (df=1)	p=0.5424	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,1E297]	
Total	0 / 81	1 / 90		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.82 (df=2)	p=0.6622	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.122.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

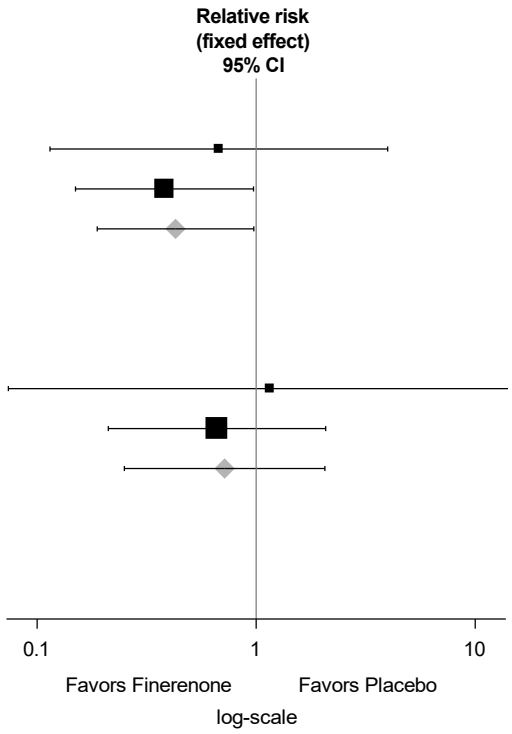
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	3 / 139	1 / 152	13.2	3.28 [0.35,31.17]	
FIGARO-DKD	7 / 1658	17 / 1612	86.8	0.40 [0.17,0.96]	
Total	10 / 1797	18 / 1764		0.55 [0.25,1.19]	Z=-1.52, p=0.1282
Heterogeneity:	Q=2.92 (df=1)	p=0.0875	I^2=65.8%		
Black					
FIDELIO-DKD	0 / 10	1 / 9	0.0	0.00 [0.00,84E295]	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,94E295]	
Total	0 / 80	2 / 83		0.00 [0.00,15E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	2 / 44	0.0	0.00 [0.00,76E295]	
FIGARO-DKD	4 / 464	4 / 485	100.0	1.05 [0.26,4.15]	
Total	4 / 503	6 / 529		0.70 [0.20,2.48]	Z=-0.55, p=0.5846
Heterogeneity:	Q=0.31 (df=1)	p=0.5747	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,17E296]	
Total	0 / 156	1 / 147		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.11 (df=3)	p=0.9909	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.122.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

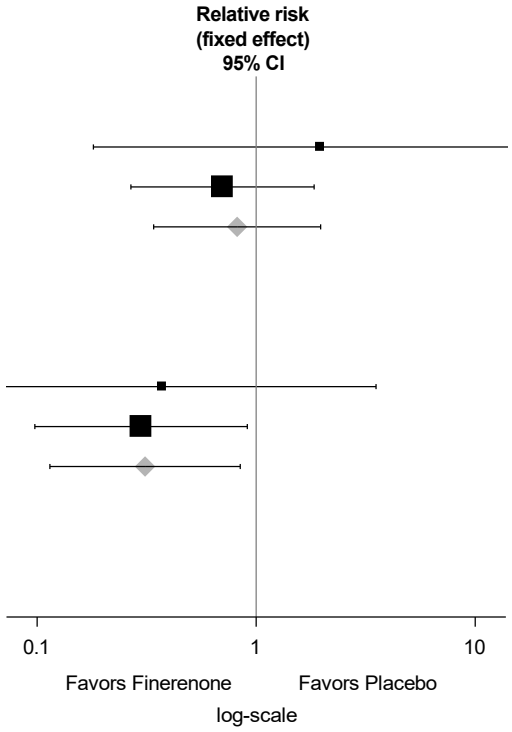
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	21.7	0.68 [0.11,3.99]	
FIGARO-DKD	6 / 1610	16 / 1638	78.3	0.38 [0.15,0.97]	
Total	8 / 1762	19 / 1792		0.43 [0.19,0.98]	Z=-2.02, p=0.0435
Heterogeneity:	Q=0.31 (df=1)	p=0.5767	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	1 / 67	14.7	1.16 [0.07,18.06]	
FIGARO-DKD	5 / 716	7 / 664	85.3	0.66 [0.21,2.08]	
Total	6 / 774	8 / 731		0.72 [0.25,2.06]	Z=-0.62, p=0.5374
Heterogeneity:	Q=0.13 (df=1)	p=0.7143	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4495	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.122.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

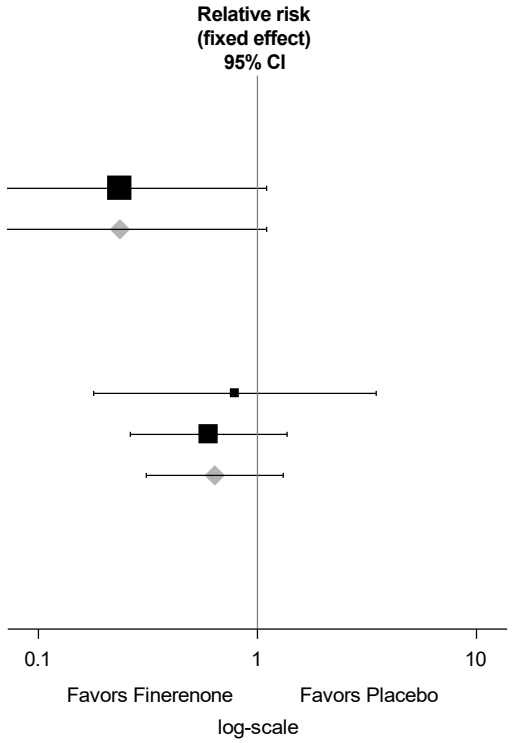
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	1 / 96	14.0	1.96 [0.18,21.25]	
FIGARO-DKD	7 / 1416	10 / 1420	86.0	0.70 [0.27,1.84]	
Total	9 / 1514	11 / 1516		0.82 [0.34,1.97]	Z=-0.45, p=0.6549
Heterogeneity:	Q=0.61 (df=1)	p=0.4338	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	3 / 125	19.8	0.37 [0.04,3.53]	
FIGARO-DKD	4 / 910	13 / 882	80.2	0.30 [0.10,0.91]	
Total	5 / 1022	16 / 1007		0.31 [0.11,0.85]	Z=-2.29, p=0.0221
Heterogeneity:	Q=0.03 (df=1)	p=0.8629	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.03 (df=1)	p=0.1540	I^2=50.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.122.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

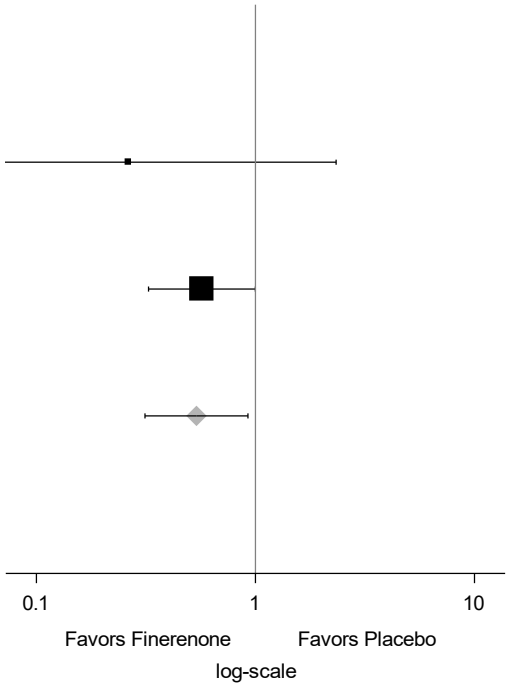
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	2 / 363	8 / 342	100.0	0.24 [0.05,1.10]	
Total	2 / 363	8 / 342		0.24 [0.05,1.10]	Z=-1.84, p=0.0662
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	3 / 210	4 / 221	23.5	0.79 [0.18,3.48]	
FIGARO-DKD	9 / 1963	15 / 1960	76.5	0.60 [0.26,1.37]	
Total	12 / 2173	19 / 2181		0.64 [0.31,1.31]	Z=-1.22, p=0.2218
Heterogeneity:	Q=0.10 (df=1)	p=0.7503	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.32 (df=1)	p=0.2509	I^2=24.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.123: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

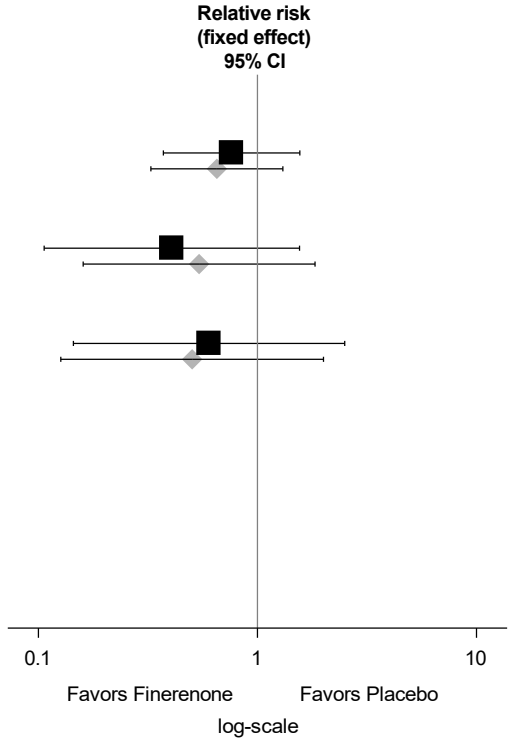
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	6.2	0.26 [0.03,2.33]	
FIGARO-DKD	19 / 2326	33 / 2302	93.8	0.57 [0.33,1.00]	
Total	20 / 2536	37 / 2523		0.54 [0.31,0.92]	Z=-2.25, p=0.0247
Heterogeneity:	Q=0.45 (df=1)	p=0.5010	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.123.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

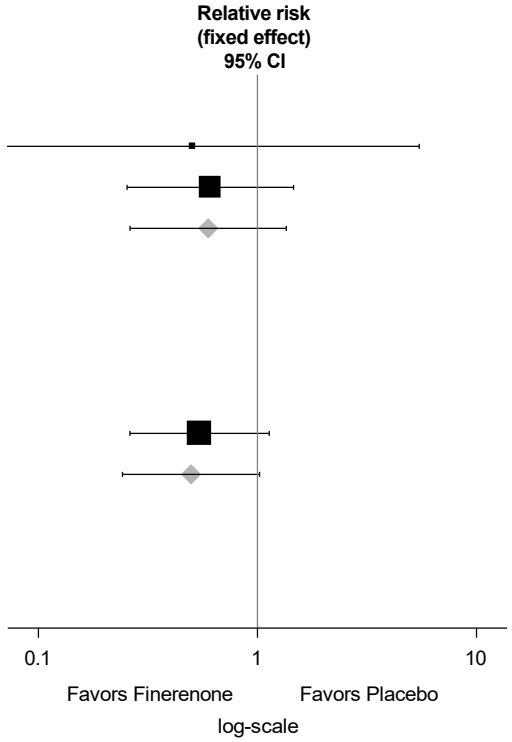
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	3 / 112	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	13 / 1114	17 / 1110	100.0	0.76 [0.37,1.56]	
Total	13 / 1217	20 / 1222		0.65 [0.33,1.31]	Z=-1.21, p=0.2282
Heterogeneity:	Q=0.18 (df=1)	p=0.6726	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 42	0 / 40	0.0	124E9 [124E9,124E9]	
FIGARO-DKD	3 / 292	7 / 277	100.0	0.41 [0.11,1.56]	
Total	4 / 334	7 / 317		0.54 [0.16,1.83]	Z=-0.99, p=0.3240
Heterogeneity:	Q=0.18 (df=1)	p=0.6755	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	3 / 522	5 / 523	100.0	0.60 [0.14,2.50]	
Total	3 / 561	6 / 564		0.50 [0.13,2.00]	Z=-0.97, p=0.3298
Heterogeneity:	Q=0.06 (df=1)	p=0.8071	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	2 / 316	0.0	0.00 [0.00,2E297]	
Total	0 / 343	2 / 340		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	2 / 76	0.0	0.00 [0.00,13E296]	
Total	0 / 81	2 / 80		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.15 (df=4)	p=0.9975	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.123.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

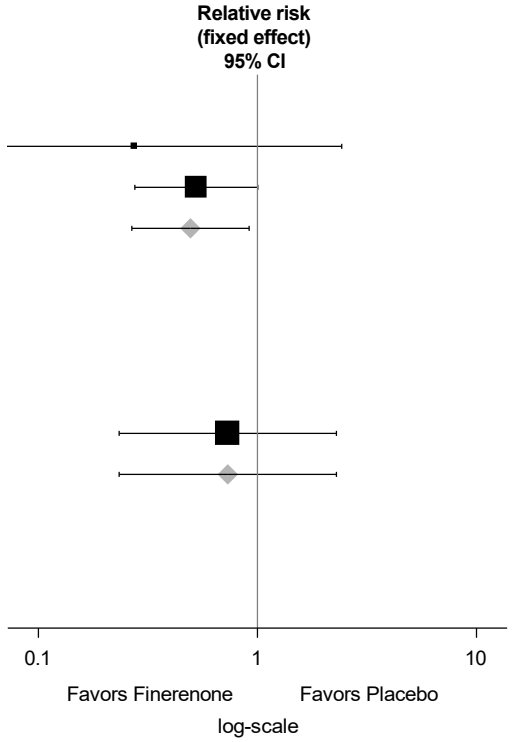
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	11.9	0.51 [0.05,5.48]	
FIGARO-DKD	8 / 811	13 / 803	88.1	0.61 [0.25,1.46]	
Total	9 / 899	15 / 892		0.60 [0.26,1.35]	Z=-1.24, p=0.2162
Heterogeneity:	Q=0.02 (df=1)	p=0.8855	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	2 / 132	0.0	0.00 [0.00,84E295]	
FIGARO-DKD	11 / 1515	20 / 1499	100.0	0.54 [0.26,1.13]	
Total	11 / 1637	22 / 1631		0.50 [0.24,1.02]	Z=-1.90, p=0.0575
Heterogeneity:	Q=0.06 (df=1)	p=0.8101	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7467	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.123.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

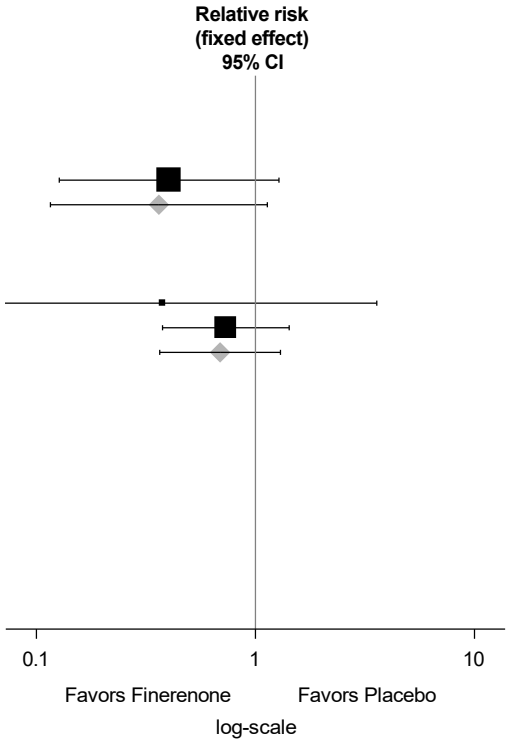
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	4 / 158	8.1	0.27 [0.03,2.43]	
FIGARO-DKD	14 / 1719	26 / 1679	91.9	0.53 [0.28,1.00]	
Total	15 / 1863	30 / 1837		0.49 [0.27,0.92]	Z=-2.24, p=0.0252
Heterogeneity:	Q=0.32 (df=1)	p=0.5742	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	5 / 607	7 / 622	100.0	0.73 [0.23,2.29]	
Total	5 / 673	7 / 685		0.73 [0.23,2.29]	Z=-0.54, p=0.5923
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5537	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.123.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

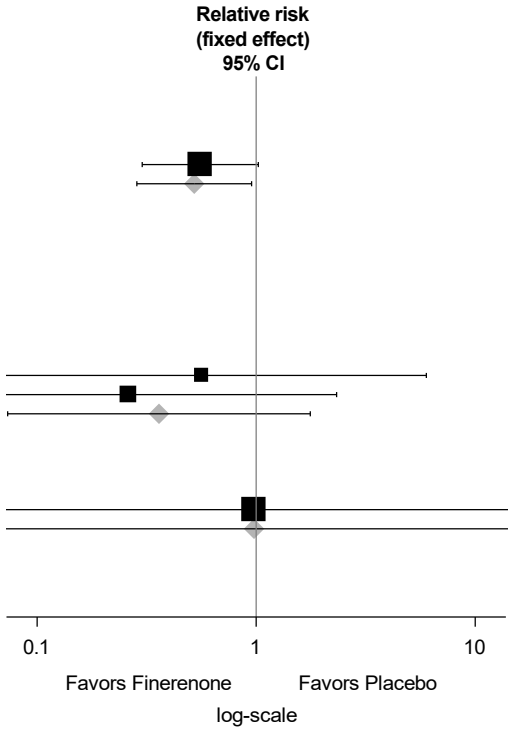
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	1 / 54	0.0	0.00 [0.00,69E295]	
FIGARO-DKD	4 / 693	10 / 699	100.0	0.40 [0.13,1.28]	
Total	4 / 757	11 / 753		0.36 [0.12,1.13]	Z=-1.75, p=0.0809
Heterogeneity:	Q=0.03 (df=1)	p=0.8551	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	3 / 156	8.0	0.38 [0.04,3.58]	
FIGARO-DKD	15 / 1560	20 / 1524	92.0	0.73 [0.38,1.43]	
Total	16 / 1698	23 / 1680		0.69 [0.37,1.30]	Z=-1.15, p=0.2511
Heterogeneity:	Q=0.31 (df=1)	p=0.5785	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	3 / 79	0.0	0.00 [0.00,91E295]	
Total	0 / 81	3 / 90		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.93 (df=2)	p=0.6266	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.123.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

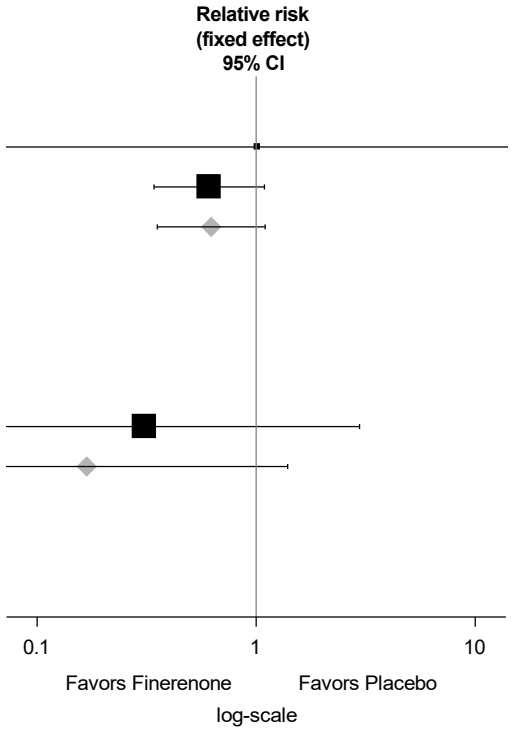
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	2 / 152	0.0	0.00 [0.00,97E295]	
FIGARO-DKD	16 / 1658	28 / 1612	100.0	0.56 [0.30,1.02]	
Total	16 / 1797	30 / 1764		0.52 [0.29,0.95]	Z=-2.12, p=0.0343
Heterogeneity:	Q=0.04 (df=1)	p=0.8382	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	0 / 74	0.0	202E9 [202E9,202E9]	
Total	1 / 80	0 / 83		2.15E7 [2.15E7,2.15E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	1 / 39	2 / 44	46.2	0.56 [0.05,5.98]	
FIGARO-DKD	1 / 464	4 / 485	53.8	0.26 [0.03,2.33]	
Total	2 / 503	6 / 529		0.36 [0.07,1.77]	Z=-1.26, p=0.2080
Heterogeneity:	Q=0.22 (df=1)	p=0.6380	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	1 / 134	1 / 131	100.0	0.98 [0.06,15.47]	
Total	1 / 156	1 / 147		0.98 [0.06,15.47]	Z=-0.02, p=0.9872
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=3)	p=0.9397	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.123.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

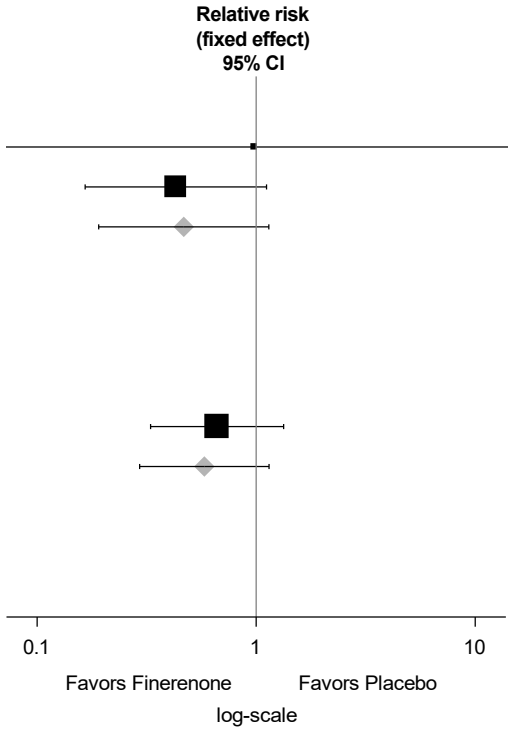
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1 / 152	1 / 154	4.2	1.01 [0.06,16.05]	
FIGARO-DKD	18 / 1610	30 / 1638	95.8	0.61 [0.34,1.09]	
Total	19 / 1762	31 / 1792		0.62 [0.35,1.10]	Z=-1.63, p=0.1024
Heterogeneity:	Q=0.12 (df=1)	p=0.7250	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	3 / 67	0.0	0.00 [0.00,77E295]	
FIGARO-DKD	1 / 716	3 / 664	100.0	0.31 [0.03,2.96]	
Total	1 / 774	6 / 731		0.17 [0.02,1.39]	Z=-1.65, p=0.0984
Heterogeneity:	Q=0.28 (df=1)	p=0.5985	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2410	I^2=27.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.123.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

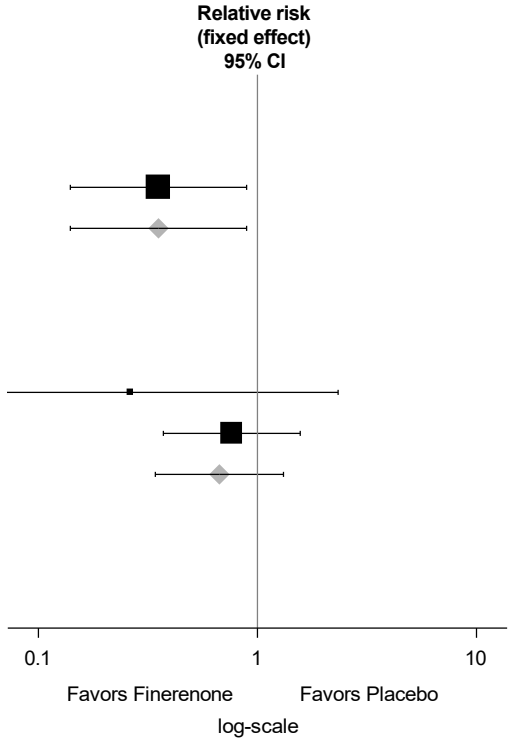
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	1 / 96	10.7	0.98 [0.06,15.44]	
FIGARO-DKD	6 / 1416	14 / 1420	89.3	0.43 [0.17,1.12]	
Total	7 / 1514	15 / 1516		0.47 [0.19,1.14]	Z=-1.67, p=0.0952
Heterogeneity:	Q=0.31 (df=1)	p=0.5799	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	3 / 125	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	13 / 910	19 / 882	100.0	0.66 [0.33,1.33]	
Total	13 / 1022	22 / 1007		0.58 [0.29,1.14]	Z=-1.57, p=0.1164
Heterogeneity:	Q=0.14 (df=1)	p=0.7071	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7057	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.123.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

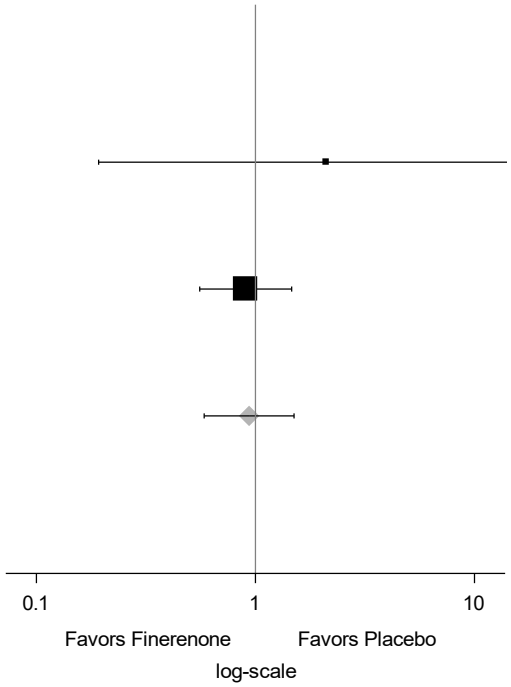
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	16 / 342	100.0	0.35 [0.14,0.89]	
Total	6 / 363	16 / 342		0.35 [0.14,0.89]	Z=-2.20, p=0.0277
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	1 / 210	4 / 221	9.8	0.26 [0.03,2.33]	
FIGARO-DKD	13 / 1963	17 / 1960	90.2	0.76 [0.37,1.57]	
Total	14 / 2173	21 / 2181		0.67 [0.34,1.31]	Z=-1.16, p=0.2445
Heterogeneity:	Q=0.83 (df=1)	p=0.3620	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.20 (df=1)	p=0.2731	I^2=16.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.124: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

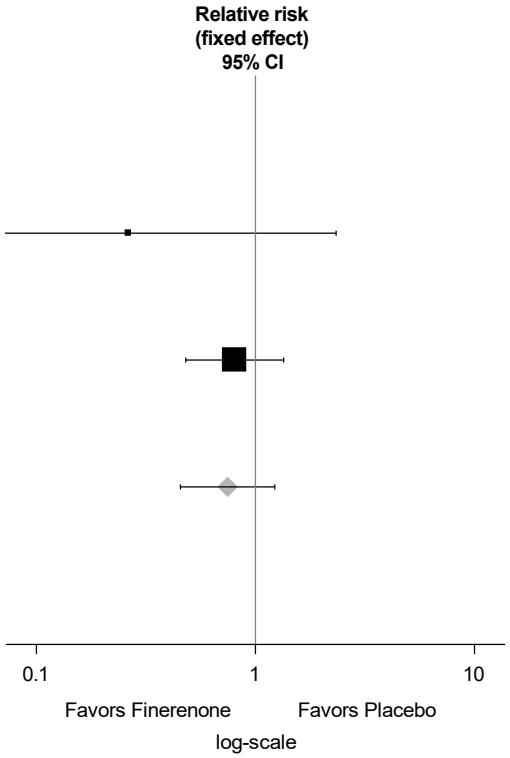
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	3.9	2.10 [0.19,23.04]	
FIGARO-DKD	31 / 2326	34 / 2302	96.1	0.90 [0.56,1.46]	
Total	33 / 2536	35 / 2523		0.94 [0.58,1.50]	Z=-0.28, p=0.7818
Heterogeneity:	Q=0.46 (df=1)	p=0.4965	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.125: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

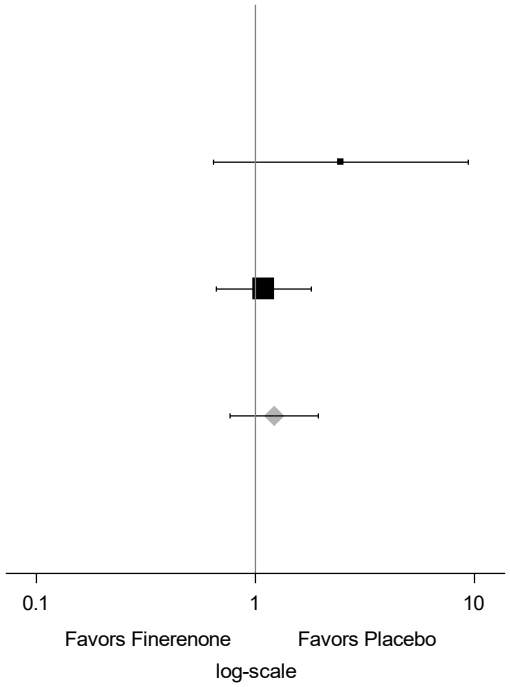
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	5.3	0.26 [0.03,2.33]	
FIGARO-DKD	26 / 2326	32 / 2302	94.7	0.80 [0.48,1.34]	
Total	27 / 2536	36 / 2523		0.75 [0.45,1.22]	Z=-1.16, p=0.2467
Heterogeneity:	Q=0.96 (df=1)	p=0.3279	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.126: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

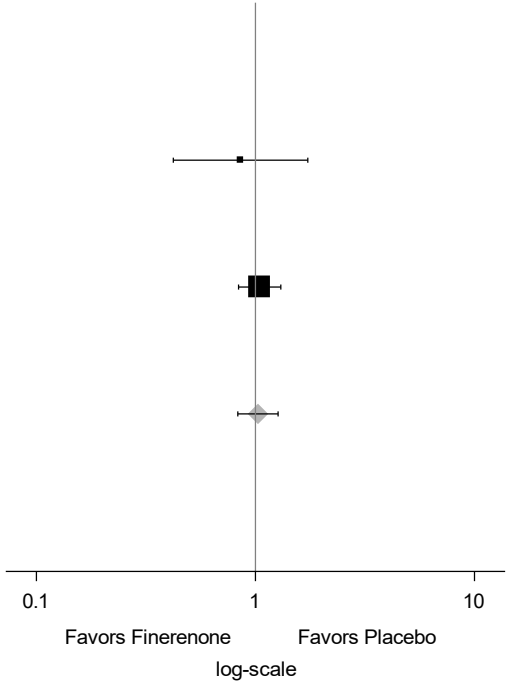
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	3 / 221	12.2	2.46 [0.64,9.37]	
FIGARO-DKD	32 / 2326	29 / 2302	87.8	1.09 [0.66,1.80]	
Total	39 / 2536	32 / 2523		1.22 [0.77,1.94]	Z=0.83, p=0.4053
Heterogeneity:	Q=1.24 (df=1)	p=0.2661	I^2=19.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.127: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

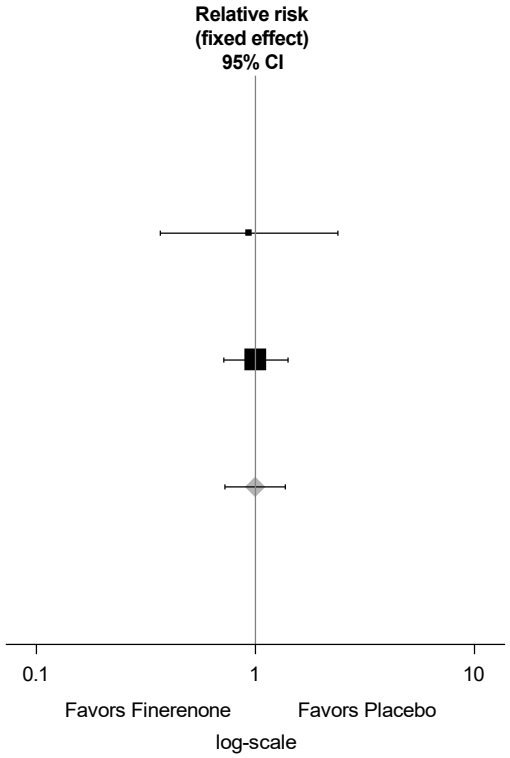
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	16 / 221	9.0	0.86 [0.42,1.73]	
FIGARO-DKD	150 / 2326	142 / 2302	91.0	1.05 [0.84,1.31]	
Total	163 / 2536	158 / 2523		1.03 [0.83,1.27]	Z=0.24, p=0.8080
Heterogeneity:	Q=0.28 (df=1)	p=0.5950	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.128: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

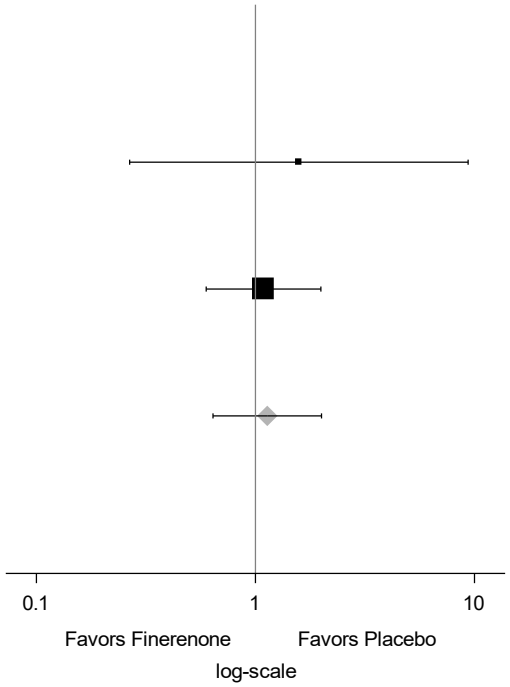
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	9 / 221	11.6	0.94 [0.37,2.38]	
FIGARO-DKD	66 / 2326	65 / 2302	88.4	1.00 [0.72,1.41]	
Total	74 / 2536	74 / 2523		1.00 [0.73,1.37]	Z=-0.02, p=0.9832
Heterogeneity:	Q=0.02 (df=1)	p=0.8875	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.129: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Erectile dysfunction (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

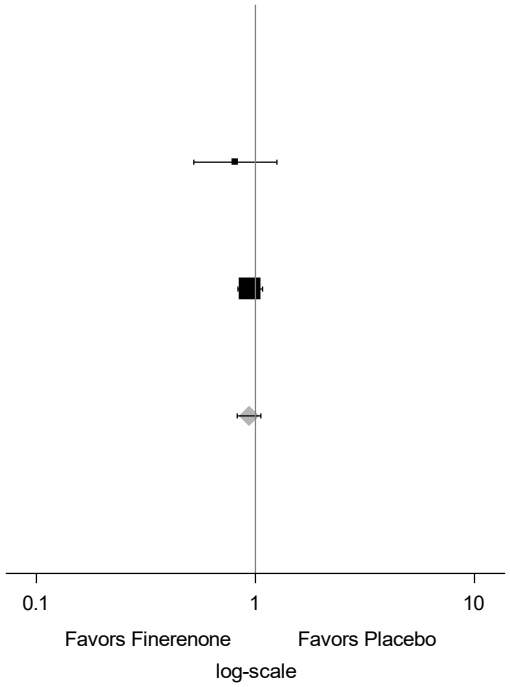
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	10.3	1.58 [0.27,9.35]	
FIGARO-DKD	22 / 2326	20 / 2302	89.7	1.09 [0.60,1.99]	
Total	25 / 2536	22 / 2523		1.13 [0.64,2.00]	Z=0.43, p=0.6698
Heterogeneity:	Q=0.15 (df=1)	p=0.6982	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.130: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

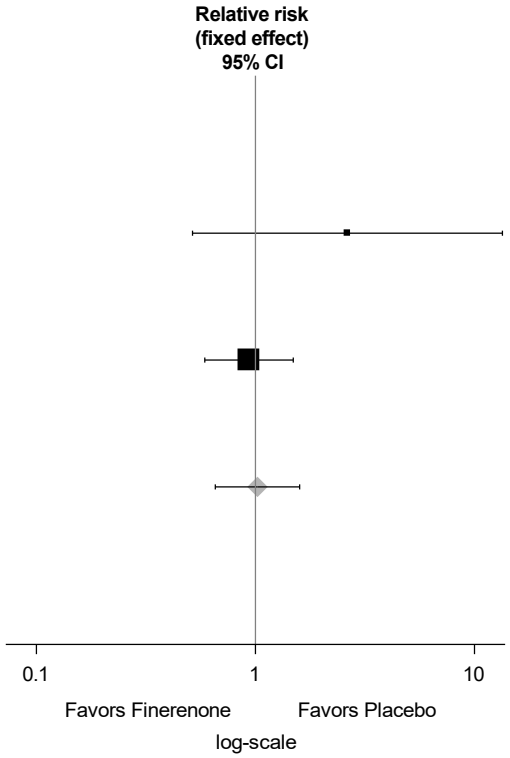
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	39 / 221	8.1	0.81 [0.52,1.25]	
FIGARO-DKD	374 / 2326	391 / 2302	91.9	0.95 [0.83,1.08]	
Total	404 / 2536	430 / 2523		0.93 [0.83,1.06]	Z=-1.07, p=0.2858
Heterogeneity:	Q=0.45 (df=1)	p=0.5009	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.131: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

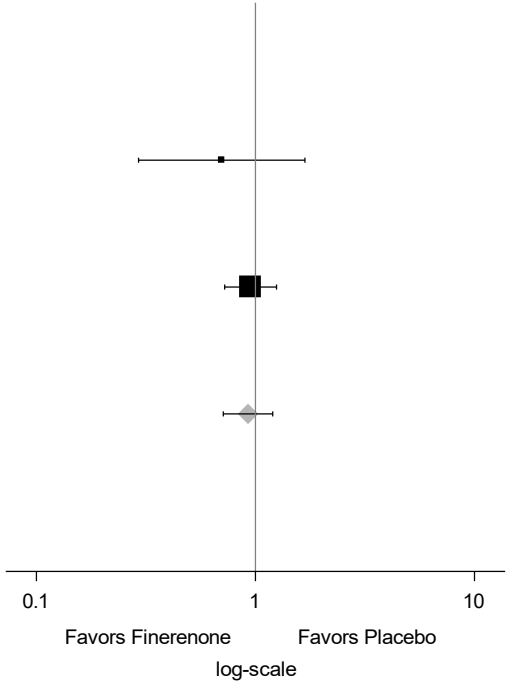
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	7.5	2.63 [0.52,13.41]	
FIGARO-DKD	34 / 2326	36 / 2302	92.5	0.93 [0.59,1.49]	
Total	39 / 2536	38 / 2523		1.02 [0.66,1.59]	Z=0.09, p=0.9250
Heterogeneity:	Q=1.44 (df=1)	p=0.2308	I^2=30.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.132: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

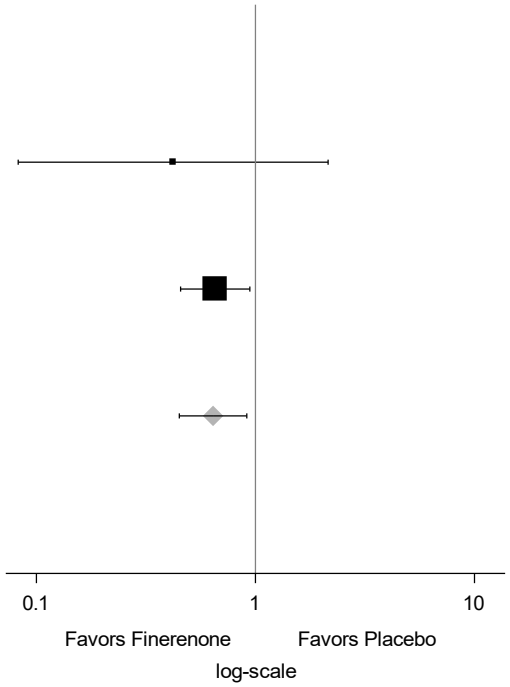
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	12 / 221	8.9	0.70 [0.29,1.68]	
FIGARO-DKD	97 / 2326	101 / 2302	91.1	0.95 [0.72,1.25]	
Total	105 / 2536	113 / 2523		0.92 [0.71,1.20]	Z=-0.59, p=0.5551
Heterogeneity:	Q=0.42 (df=1)	p=0.5159	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.133: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

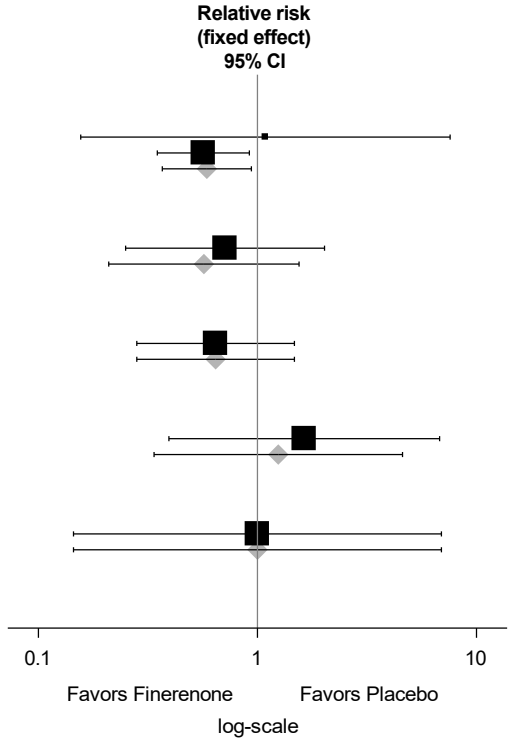
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	4.8	0.42 [0.08,2.15]	
FIGARO-DKD	47 / 2326	71 / 2302	95.2	0.66 [0.46,0.94]	
Total	49 / 2536	76 / 2523		0.64 [0.45,0.91]	Z=-2.46, p=0.0138
Heterogeneity:	Q=0.27 (df=1)	p=0.6034	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.133.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

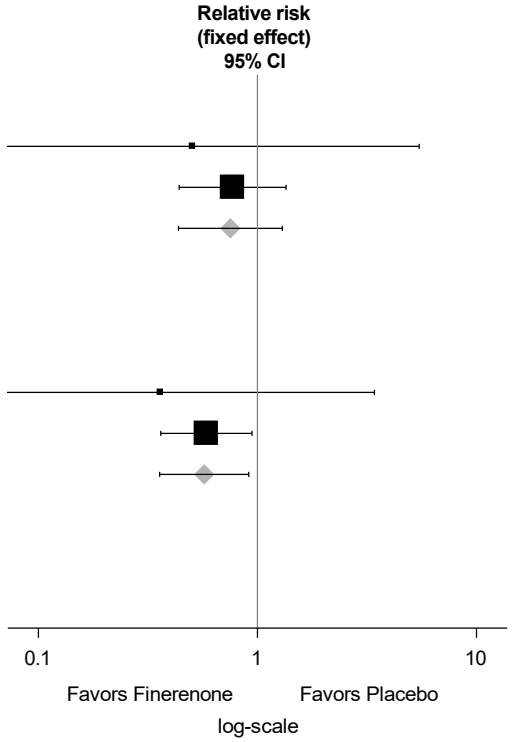
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	2 / 103	2 / 112	5.8	1.09 [0.16,7.58]	
FIGARO-DKD	25 / 1114	44 / 1110	94.2	0.57 [0.35,0.92]	
Total	27 / 1217	46 / 1222		0.59 [0.37,0.94]	Z=-2.23, p=0.0260
Heterogeneity:	Q=0.41 (df=1)	p=0.5226	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	2 / 40	0.0	0.00 [0.00,69E295]	
FIGARO-DKD	6 / 292	8 / 277	100.0	0.71 [0.25,2.02]	
Total	6 / 334	10 / 317		0.57 [0.21,1.55]	Z=-1.10, p=0.2700
Heterogeneity:	Q=0.17 (df=1)	p=0.6765	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	9 / 522	14 / 523	100.0	0.64 [0.28,1.47]	
Total	9 / 561	14 / 564		0.64 [0.28,1.47]	Z=-1.04, p=0.2980
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,83E295]	
FIGARO-DKD	5 / 322	3 / 316	100.0	1.64 [0.39,6.79]	
Total	5 / 343	4 / 340		1.24 [0.34,4.60]	Z=0.33, p=0.7424
Heterogeneity:	Q=0.14 (df=1)	p=0.7069	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	2 / 76	100.0	1.00 [0.14,6.92]	
Total	2 / 81	2 / 80		1.00 [0.14,6.92]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.38 (df=4)	p=0.8472	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.133.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

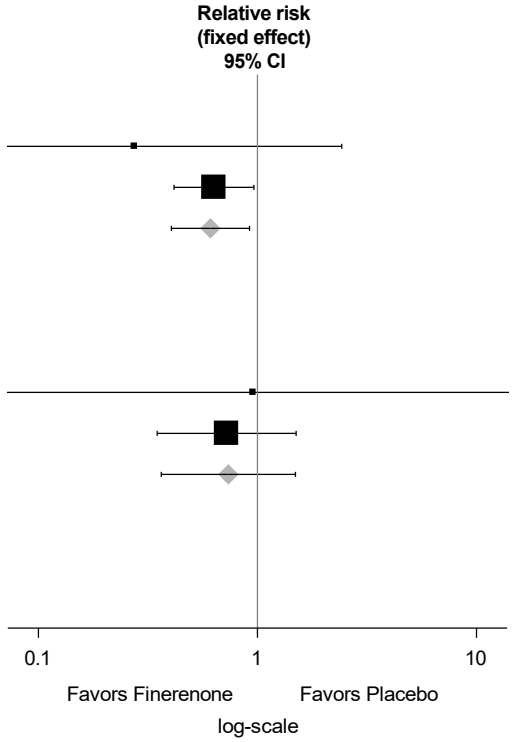
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	5.3	0.51 [0.05,5.48]	
FIGARO-DKD	21 / 811	27 / 803	94.7	0.77 [0.44,1.35]	
Total	22 / 899	29 / 892		0.75 [0.44,1.30]	Z=-1.02, p=0.3071
Heterogeneity:	Q=0.11 (df=1)	p=0.7362	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	3 / 132	4.3	0.36 [0.04,3.42]	
FIGARO-DKD	26 / 1515	44 / 1499	95.7	0.58 [0.36,0.94]	
Total	27 / 1637	47 / 1631		0.57 [0.36,0.91]	Z=-2.34, p=0.0191
Heterogeneity:	Q=0.17 (df=1)	p=0.6805	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4532	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.133.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

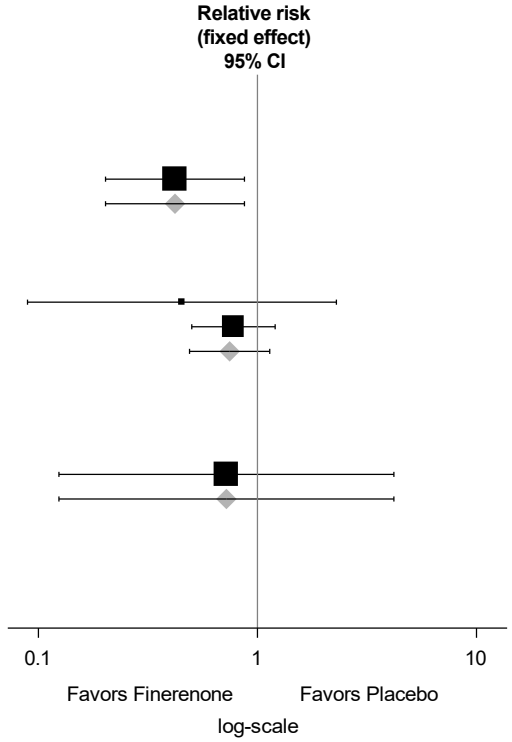
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	4 / 158	3.6	0.27 [0.03,2.43]	
FIGARO-DKD	35 / 1719	54 / 1679	96.4	0.63 [0.42,0.96]	
Total	36 / 1863	58 / 1837		0.61 [0.40,0.92]	Z=-2.36, p=0.0184
Heterogeneity:	Q=0.55 (df=1)	p=0.4598	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	1 / 63	6.6	0.95 [0.06,14.93]	
FIGARO-DKD	12 / 607	17 / 622	93.4	0.72 [0.35,1.50]	
Total	13 / 673	18 / 685		0.74 [0.36,1.49]	Z=-0.85, p=0.3956
Heterogeneity:	Q=0.04 (df=1)	p=0.8485	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6512	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.133.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

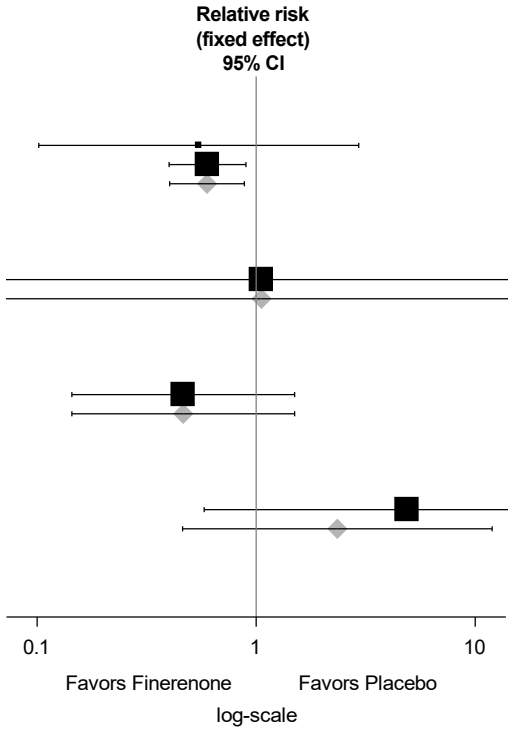
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	10 / 693	24 / 699	100.0	0.42 [0.20,0.87]	
Total	10 / 757	24 / 753		0.42 [0.20,0.87]	Z=-2.33, p=0.0200
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	5 / 156	6.8	0.45 [0.09,2.29]	
FIGARO-DKD	35 / 1560	44 / 1524	93.2	0.78 [0.50,1.20]	
Total	37 / 1698	49 / 1680		0.75 [0.49,1.14]	Z=-1.36, p=0.1740
Heterogeneity:	Q=0.40 (df=1)	p=0.5279	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	3 / 79	100.0	0.72 [0.12,4.20]	
Total	2 / 81	3 / 90		0.72 [0.12,4.20]	Z=-0.36, p=0.7163
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.80 (df=2)	p=0.4071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.133.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

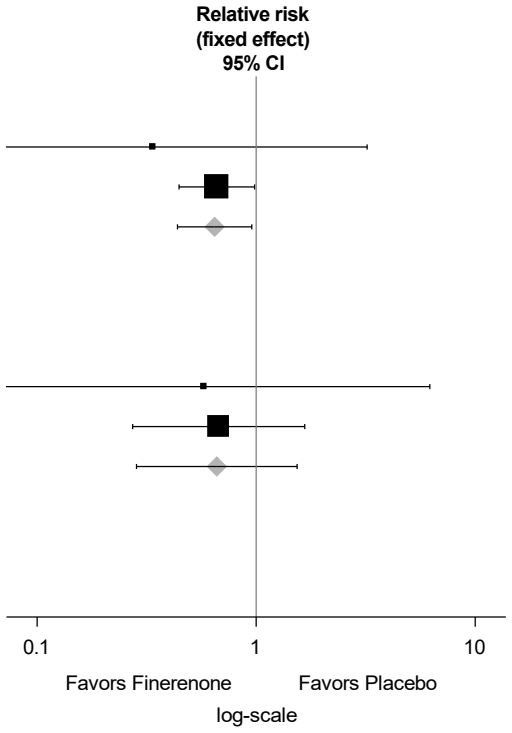
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	4 / 152	5.5	0.55 [0.10,2.94]	
FIGARO-DKD	37 / 1658	60 / 1612	94.5	0.60 [0.40,0.90]	
Total	39 / 1797	64 / 1764		0.60 [0.40,0.88]	Z=-2.58, p=0.0099
Heterogeneity:	Q=0.01 (df=1)	p=0.9168	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	1 / 74	100.0	1.06 [0.07,16.58]	
Total	1 / 80	1 / 83		1.06 [0.07,16.58]	Z=0.04, p=0.9684
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	4 / 464	9 / 485	100.0	0.46 [0.14,1.50]	
Total	4 / 503	9 / 529		0.46 [0.14,1.50]	Z=-1.28, p=0.1994
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,55E295]	
FIGARO-DKD	5 / 134	1 / 131	100.0	4.89 [0.58,41.28]	
Total	5 / 156	2 / 147		2.35 [0.46,11.95]	Z=1.03, p=0.3038
Heterogeneity:	Q=0.45 (df=1)	p=0.5006	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.98 (df=3)	p=0.3944	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.133.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

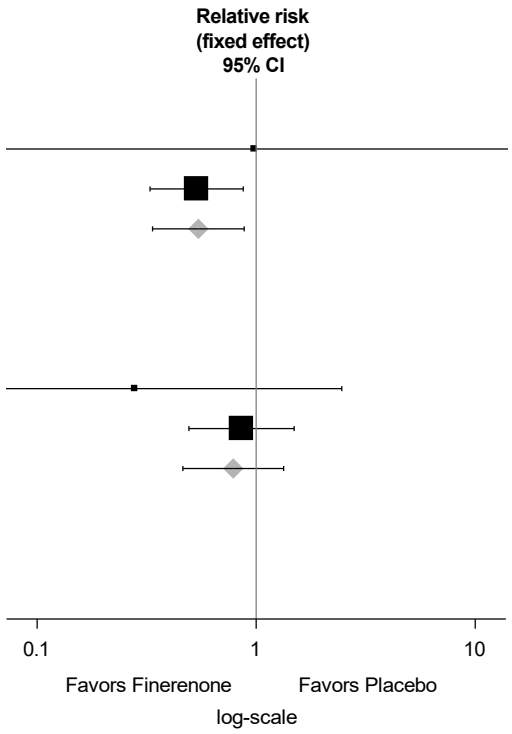
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1 / 152	3 / 154	3.0	0.34 [0.04,3.21]	
FIGARO-DKD	39 / 1610	60 / 1638	97.0	0.66 [0.44,0.98]	
Total	40 / 1762	63 / 1792		0.65 [0.44,0.95]	Z=-2.19, p=0.0284
Heterogeneity:	Q=0.33 (df=1)	p=0.5645	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	2 / 67	12.7	0.58 [0.05,6.21]	
FIGARO-DKD	8 / 716	11 / 664	87.3	0.67 [0.27,1.67]	
Total	9 / 774	13 / 731		0.66 [0.28,1.54]	Z=-0.96, p=0.3366
Heterogeneity:	Q=0.01 (df=1)	p=0.9048	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.133.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

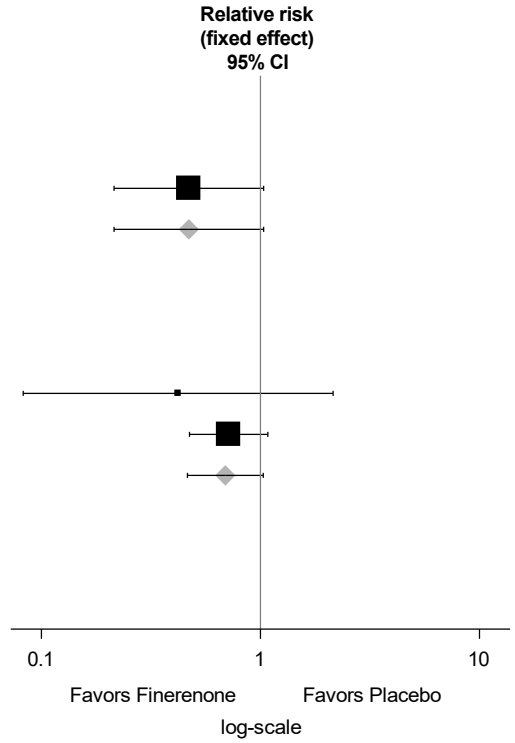
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	1 / 96	3.1	0.98 [0.06,15.44]	
FIGARO-DKD	24 / 1416	45 / 1420	96.9	0.53 [0.33,0.87]	
Total	25 / 1514	46 / 1516		0.54 [0.34,0.88]	Z=-2.47, p=0.0134
Heterogeneity:	Q=0.18 (df=1)	p=0.6719	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	4 / 125	6.1	0.28 [0.03,2.46]	
FIGARO-DKD	23 / 910	26 / 882	93.9	0.86 [0.49,1.49]	
Total	24 / 1022	30 / 1007		0.79 [0.46,1.33]	Z=-0.89, p=0.3727
Heterogeneity:	Q=0.96 (df=1)	p=0.3260	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.01 (df=1)	p=0.3151	I^2=0.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.133.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

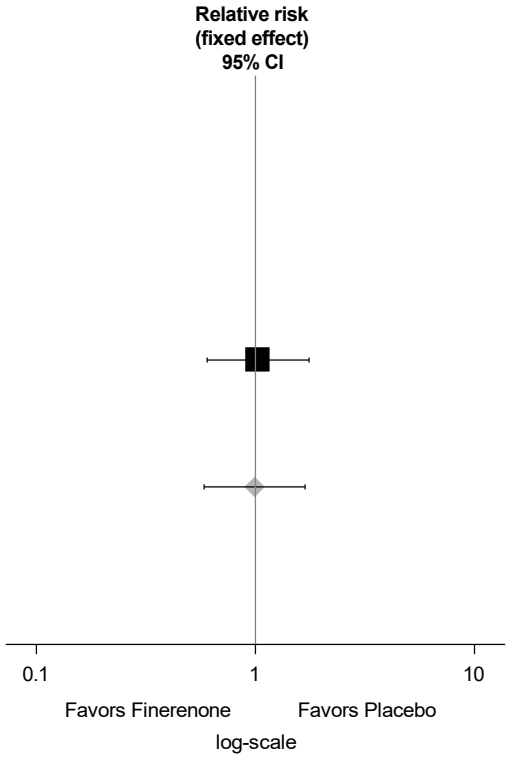
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	9 / 363	18 / 342	100.0	0.47 [0.21,1.03]	
Total	9 / 363	18 / 342		0.47 [0.21,1.03]	Z=-1.88, p=0.0606
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	5 / 221	6.0	0.42 [0.08,2.15]	
FIGARO-DKD	38 / 1963	53 / 1960	94.0	0.72 [0.47,1.08]	
Total	40 / 2173	58 / 2181		0.69 [0.46,1.03]	Z=-1.82, p=0.0694
Heterogeneity:	Q=0.38 (df=1)	p=0.5355	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=1)	p=0.3937	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.134: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oropharyngeal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

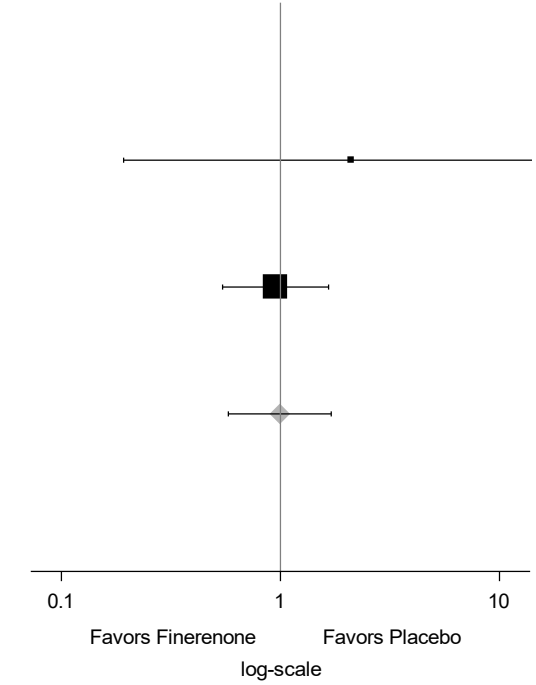
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	27 / 2326	26 / 2302	100.0	1.03 [0.60,1.76]	
Total	27 / 2536	27 / 2523		0.99 [0.58,1.68]	Z=-0.03, p=0.9737
Heterogeneity:	Q=0.02 (df=1)	p=0.8944	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.135: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

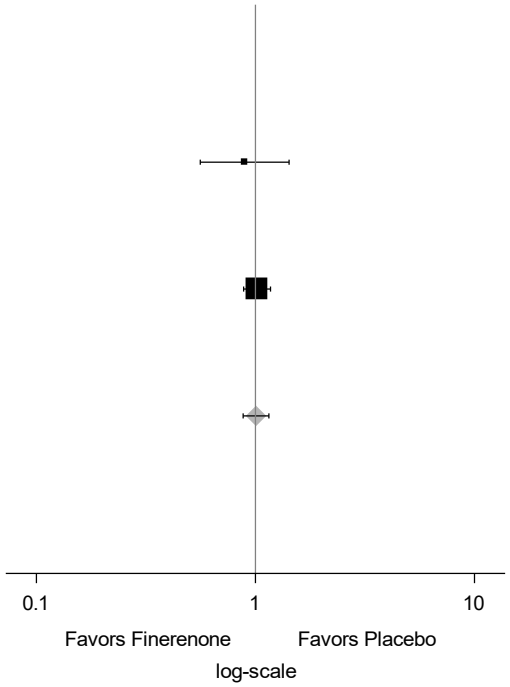
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.1	2.10 [0.19,23.04]	
FIGARO-DKD	24 / 2326	25 / 2302	94.9	0.95 [0.54,1.66]	
Total	26 / 2536	26 / 2523		0.99 [0.58,1.71]	Z=-0.03, p=0.9798
Heterogeneity:	Q=0.40 (df=1)	p=0.5257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.136: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

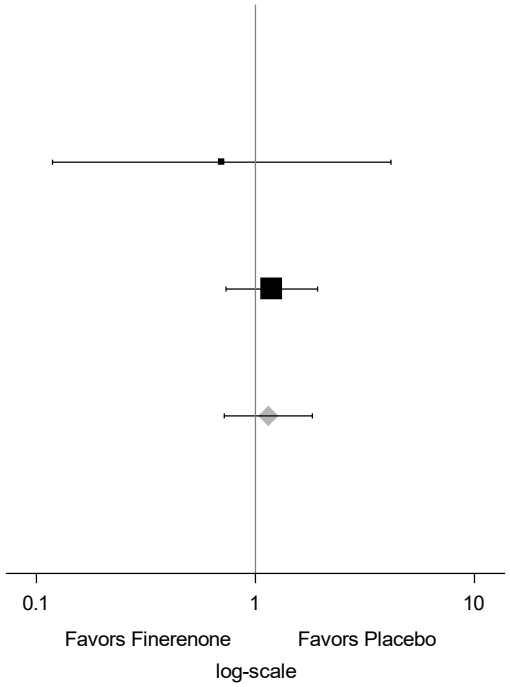
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 210	33 / 221	8.4	0.89 [0.56,1.42]	
FIGARO-DKD	334 / 2326	325 / 2302	91.6	1.02 [0.88,1.17]	
Total	362 / 2536	358 / 2523		1.01 [0.88,1.15]	Z=0.09, p=0.9313
Heterogeneity:	Q=0.27 (df=1)	p=0.6009	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.137: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

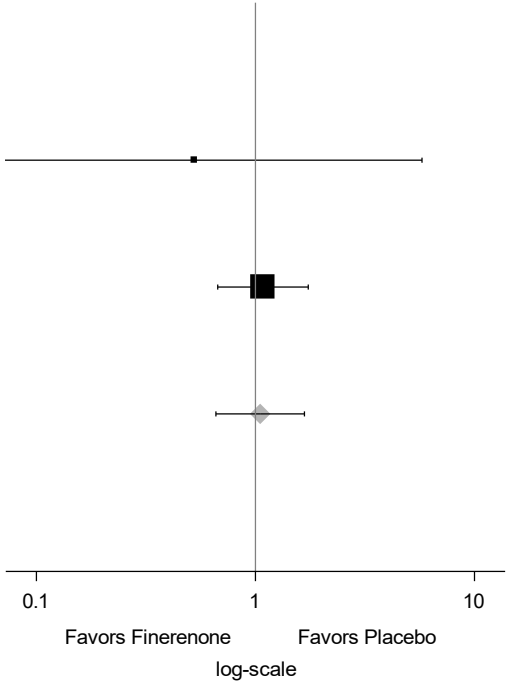
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	6.8	0.70 [0.12,4.16]	
FIGARO-DKD	36 / 2326	30 / 2302	93.2	1.19 [0.73,1.92]	
Total	38 / 2536	33 / 2523		1.14 [0.72,1.82]	Z=0.57, p=0.5674
Heterogeneity:	Q=0.31 (df=1)	p=0.5756	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.138: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

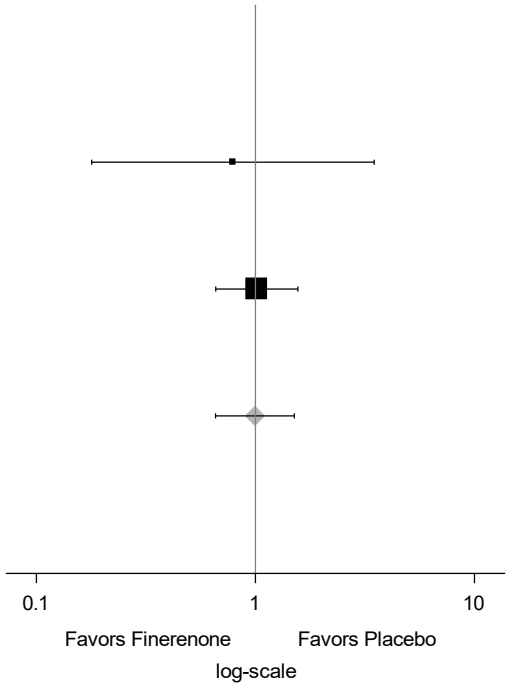
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	2 / 221	3.8	0.53 [0.05,5.76]	
FIGARO-DKD	35 / 2326	32 / 2302	96.2	1.08 [0.67,1.74]	
Total	36 / 2536	34 / 2523		1.05 [0.66,1.67]	Z=0.21, p=0.8344
Heterogeneity:	Q=0.34 (df=1)	p=0.5622	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.139: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

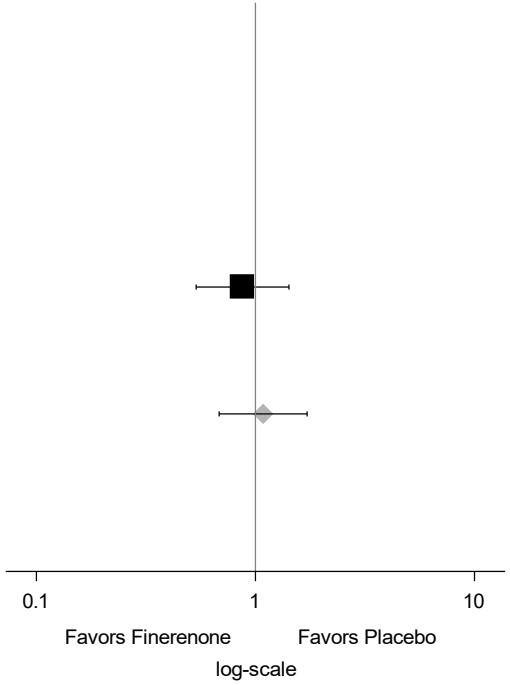
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	7.8	0.79 [0.18,3.48]	
FIGARO-DKD	41 / 2326	40 / 2302	92.2	1.01 [0.66,1.56]	
Total	44 / 2536	44 / 2523		0.99 [0.66,1.50]	Z=-0.03, p=0.9794
Heterogeneity:	Q=0.10 (df=1)	p=0.7504	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.140: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

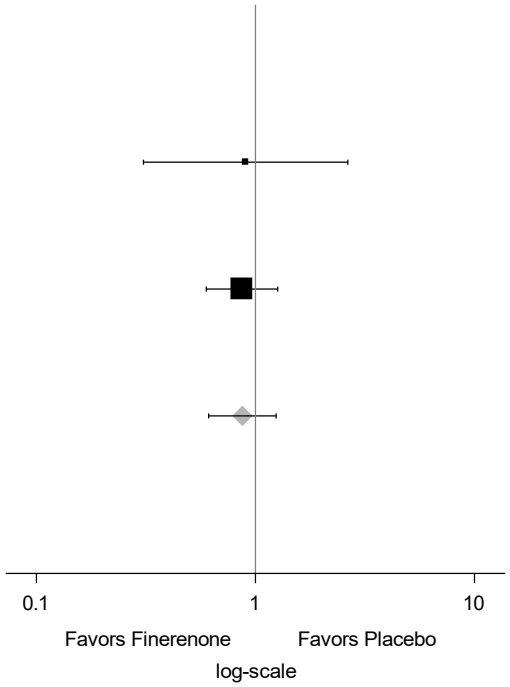
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	0 / 221	0.0	173E9 [173E9,173E9]	
FIGARO-DKD	30 / 2326	34 / 2302	100.0	0.87 [0.54,1.42]	
Total	37 / 2536	34 / 2523		1.08 [0.68,1.72]	Z=0.34, p=0.7322
Heterogeneity:	Q=0.76 (df=1)	p=0.3846	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.141: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

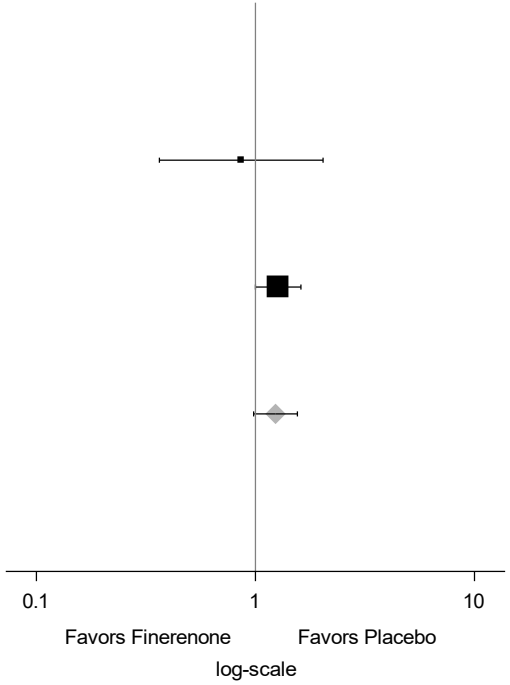
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	7 / 221	10.9	0.90 [0.31,2.64]	
FIGARO-DKD	50 / 2326	57 / 2302	89.1	0.87 [0.60,1.26]	
Total	56 / 2536	64 / 2523		0.87 [0.61,1.24]	Z=-0.76, p=0.4478
Heterogeneity:	Q=0.00 (df=1)	p=0.9474	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.142: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

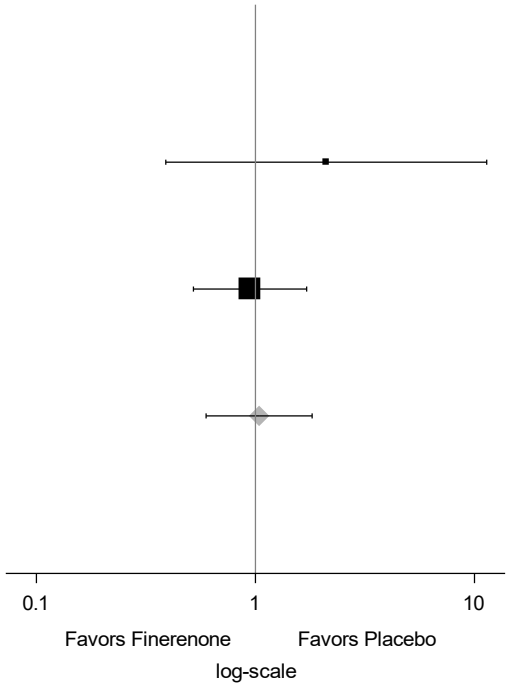
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	11 / 221	7.2	0.86 [0.36,2.04]	
FIGARO-DKD	145 / 2326	113 / 2302	92.8	1.27 [1.00,1.61]	
Total	154 / 2536	124 / 2523		1.23 [0.98,1.55]	Z=1.80, p=0.0721
Heterogeneity:	Q=0.73 (df=1)	p=0.3938	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.143: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

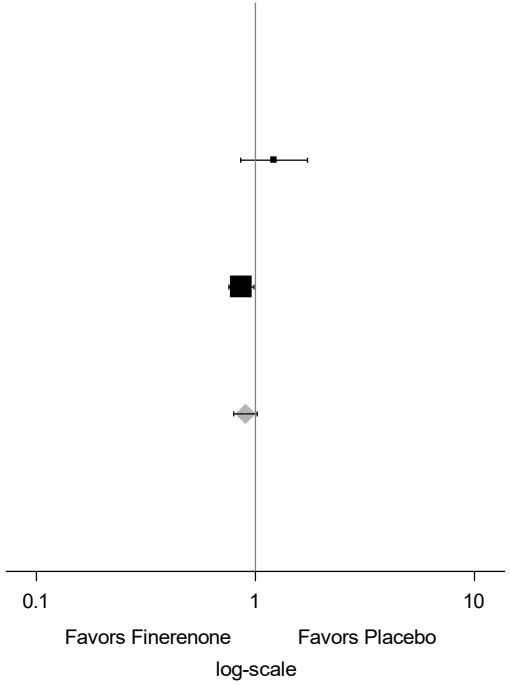
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	11.1	2.10 [0.39,11.37]	
FIGARO-DKD	21 / 2326	22 / 2302	88.9	0.94 [0.52,1.71]	
Total	25 / 2536	24 / 2523		1.04 [0.60,1.81]	Z=0.13, p=0.8927
Heterogeneity:	Q=0.77 (df=1)	p=0.3799	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.144: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

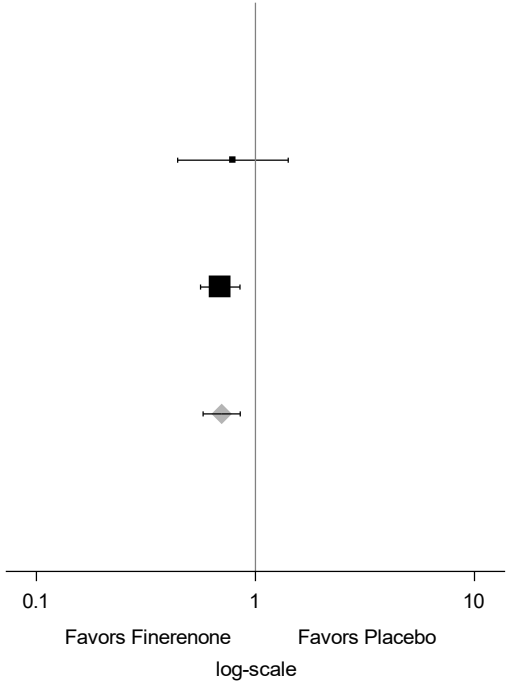
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 210	45 / 221	12.3	1.22 [0.86,1.73]	
FIGARO-DKD	347 / 2326	398 / 2302	87.7	0.86 [0.76,0.98]	
Total	399 / 2536	443 / 2523		0.90 [0.80,1.02]	Z=-1.67, p=0.0950
Heterogeneity:	Q=3.21 (df=1)	p=0.0733	I^2=68.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.145: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

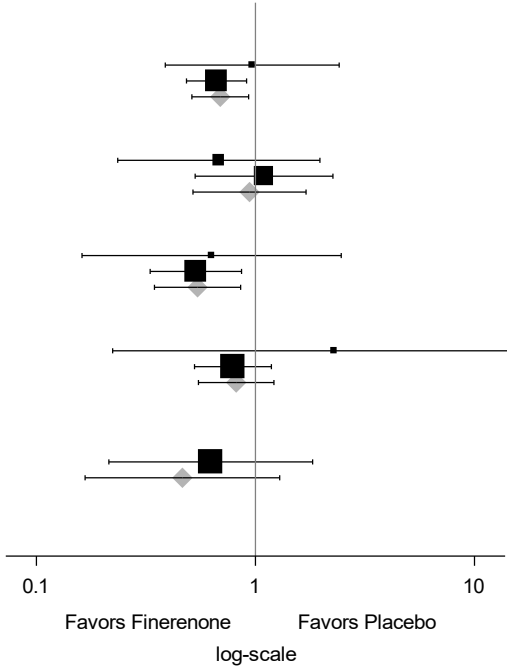
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 210	24 / 221	11.3	0.79 [0.44,1.41]	
FIGARO-DKD	141 / 2326	202 / 2302	88.7	0.69 [0.56,0.85]	
Total	159 / 2536	226 / 2523		0.70 [0.58,0.85]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.18 (df=1)	p=0.6721	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.145.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

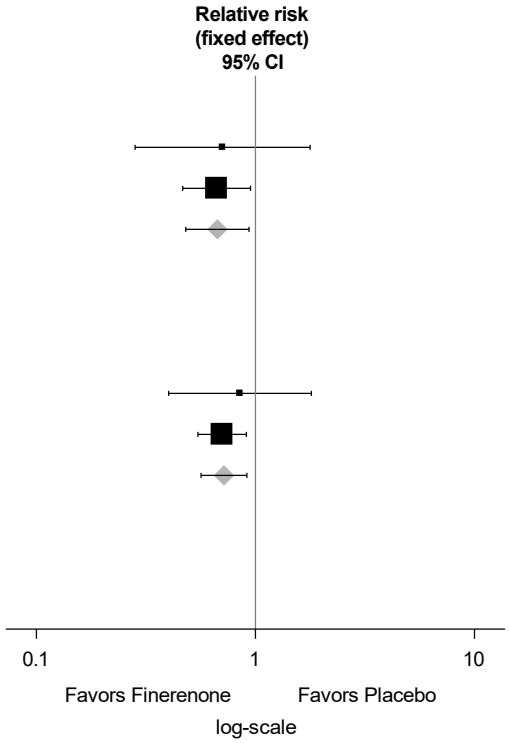
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	8 / 103	9 / 112	10.7	0.97 [0.39,2.41]	
FIGARO-DKD	60 / 1114	90 / 1110	89.3	0.66 [0.48,0.91]	
Total	68 / 1217	99 / 1222		0.69 [0.51,0.93]	Z=-2.43, p=0.0151
Heterogeneity:	Q=0.58 (df=1)	p=0.4472	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 42	7 / 40	31.7	0.68 [0.24,1.97]	
FIGARO-DKD	15 / 292	13 / 277	68.3	1.09 [0.53,2.26]	
Total	20 / 334	20 / 317		0.94 [0.52,1.70]	Z=-0.21, p=0.8367
Heterogeneity:	Q=0.53 (df=1)	p=0.4685	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	5 / 41	11.1	0.63 [0.16,2.46]	
FIGARO-DKD	24 / 522	45 / 523	88.9	0.53 [0.33,0.86]	
Total	27 / 561	50 / 564		0.54 [0.35,0.86]	Z=-2.63, p=0.0084
Heterogeneity:	Q=0.05 (df=1)	p=0.8219	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	1 / 24	2.9	2.29 [0.22,23.44]	
FIGARO-DKD	37 / 322	46 / 316	97.1	0.79 [0.53,1.18]	
Total	39 / 343	47 / 340		0.82 [0.55,1.21]	Z=-1.00, p=0.3170
Heterogeneity:	Q=0.78 (df=1)	p=0.3777	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	2 / 4	0.0	0.00 [0.00,19E295]	
FIGARO-DKD	5 / 76	8 / 76	100.0	0.63 [0.21,1.82]	
Total	5 / 81	10 / 80		0.46 [0.17,1.29]	Z=-1.47, p=0.1411
Heterogeneity:	Q=0.30 (df=1)	p=0.5856	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.34 (df=4)	p=0.5027	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.145.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

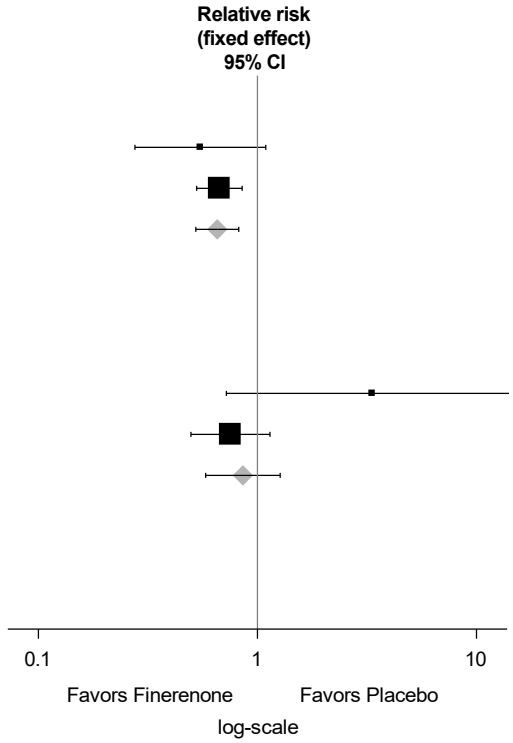
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	7 / 88	10 / 89	13.1	0.71 [0.28,1.78]	
FIGARO-DKD	47 / 811	70 / 803	86.9	0.66 [0.47,0.95]	
Total	54 / 899	80 / 892		0.67 [0.48,0.93]	Z=-2.36, p=0.0183
Heterogeneity:	Q=0.02 (df=1)	p=0.9006	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 122	14 / 132	10.3	0.85 [0.40,1.80]	
FIGARO-DKD	94 / 1515	132 / 1499	89.7	0.70 [0.55,0.91]	
Total	105 / 1637	146 / 1631		0.72 [0.56,0.91]	Z=-2.69, p=0.0071
Heterogeneity:	Q=0.22 (df=1)	p=0.6424	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7417	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.145.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	11 / 144	22 / 158	10.8	0.55 [0.28,1.09]	
FIGARO-DKD	105 / 1719	153 / 1679	89.2	0.67 [0.53,0.85]	
Total	116 / 1863	175 / 1837		0.66 [0.52,0.82]	Z=-3.67, p=0.0002
Heterogeneity:	Q=0.29 (df=1)	p=0.5896	I^2=0.0%		
> 4.5					
FIDELIO-DKD	7 / 66	2 / 63	6.8	3.34 [0.72,15.48]	
FIGARO-DKD	36 / 607	49 / 622	93.2	0.75 [0.50,1.14]	
Total	43 / 673	51 / 685		0.86 [0.58,1.27]	Z=-0.77, p=0.4440
Heterogeneity:	Q=3.40 (df=1)	p=0.0652	I^2=70.6%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2426	I^2=26.8%		

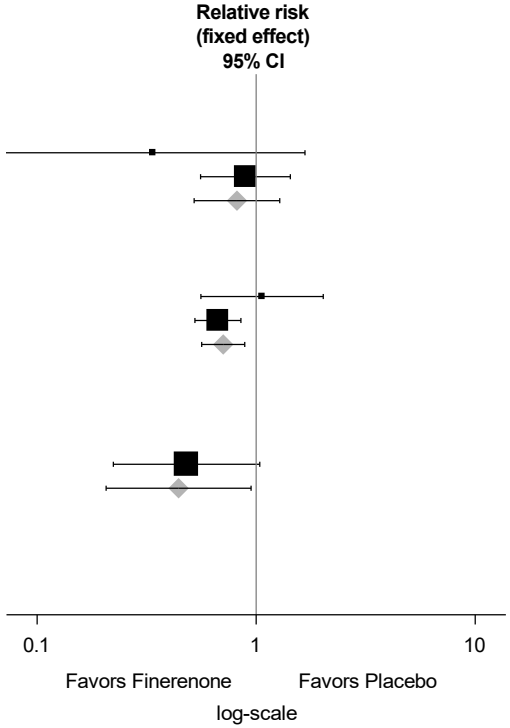


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.145.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

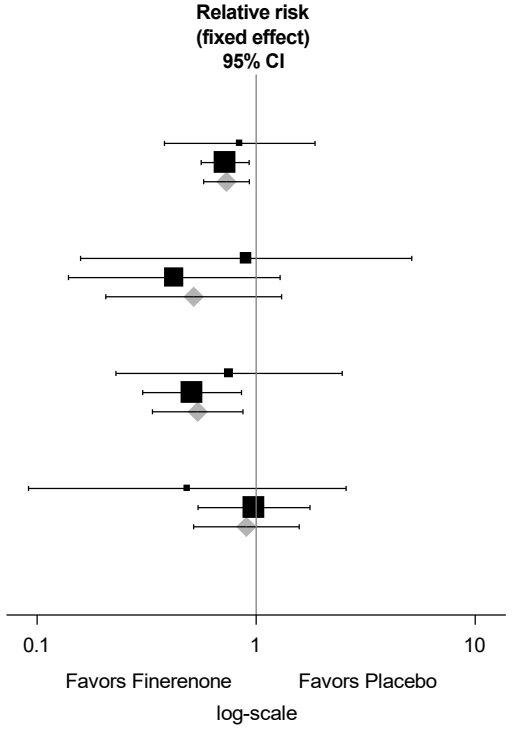
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	2 / 64	5 / 54	8.0	0.34 [0.07,1.67]	
FIGARO-DKD	31 / 693	35 / 699	92.0	0.89 [0.56,1.43]	
Total	33 / 757	40 / 753		0.82 [0.52,1.28]	Z=-0.88, p=0.3787
Heterogeneity:	Q=1.31 (df=1)	p=0.2521	I^2=23.8%		
130 - < 160					
FIDELIO-DKD	16 / 138	17 / 156	12.4	1.06 [0.56,2.02]	
FIGARO-DKD	102 / 1560	149 / 1524	87.6	0.67 [0.53,0.85]	
Total	118 / 1698	166 / 1680		0.71 [0.56,0.89]	Z=-3.00, p=0.0027
Heterogeneity:	Q=1.75 (df=1)	p=0.1853	I^2=43.0%		
>= 160					
FIDELIO-DKD	0 / 8	2 / 11	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	8 / 73	18 / 79	100.0	0.48 [0.22,1.04]	
Total	8 / 81	20 / 90		0.44 [0.21,0.95]	Z=-2.10, p=0.0359
Heterogeneity:	Q=0.05 (df=1)	p=0.8315	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.85 (df=2)	p=0.3965	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.145.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

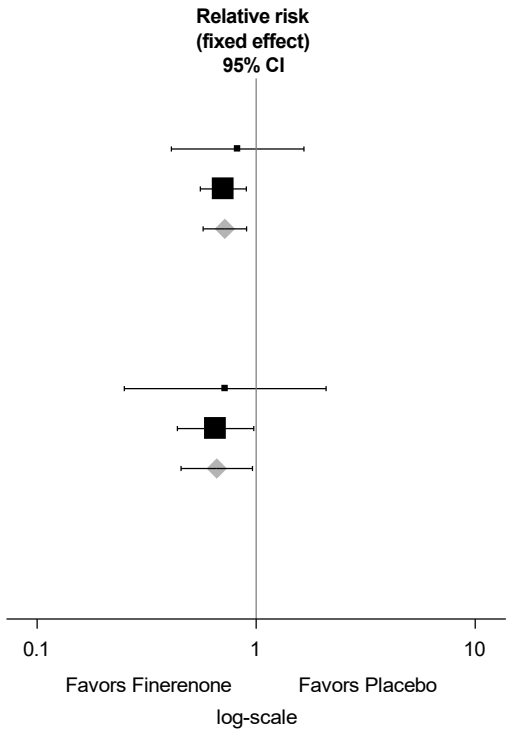
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	10 / 139	13 / 152	9.2	0.84 [0.38,1.86]	
FIGARO-DKD	98 / 1658	132 / 1612	90.8	0.72 [0.56,0.93]	
Total	108 / 1797	145 / 1764		0.73 [0.58,0.93]	Z=-2.54, p=0.0109
Heterogeneity:	Q=0.13 (df=1)	p=0.7181	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 10	2 / 9	29.0	0.90 [0.16,5.13]	
FIGARO-DKD	4 / 70	10 / 74	71.0	0.42 [0.14,1.29]	
Total	6 / 80	12 / 83		0.52 [0.21,1.31]	Z=-1.39, p=0.1637
Heterogeneity:	Q=0.51 (df=1)	p=0.4732	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 39	6 / 44	16.0	0.75 [0.23,2.47]	
FIGARO-DKD	20 / 464	41 / 485	84.0	0.51 [0.30,0.86]	
Total	24 / 503	47 / 529		0.54 [0.34,0.87]	Z=-2.53, p=0.0113
Heterogeneity:	Q=0.34 (df=1)	p=0.5571	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 22	3 / 16	11.1	0.48 [0.09,2.57]	
FIGARO-DKD	19 / 134	19 / 131	88.9	0.98 [0.54,1.76]	
Total	21 / 156	22 / 147		0.90 [0.52,1.57]	Z=-0.36, p=0.7168
Heterogeneity:	Q=0.60 (df=1)	p=0.4374	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.47 (df=3)	p=0.4808	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.145.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

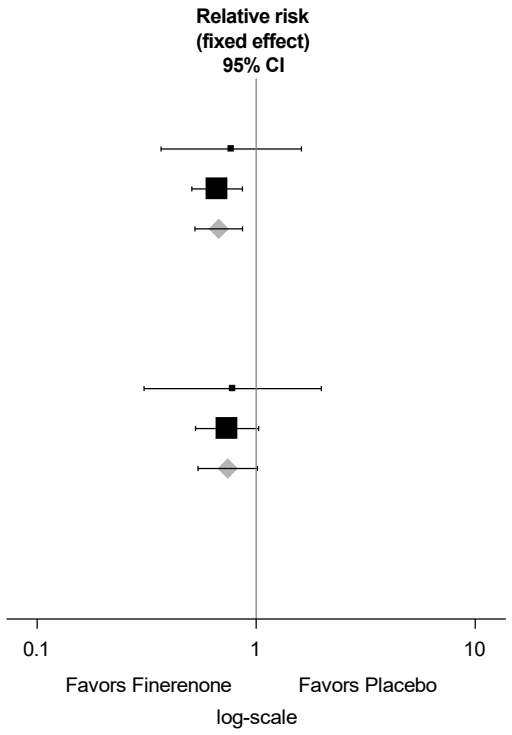
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	13 / 152	16 / 154	10.8	0.82 [0.41,1.65]	
FIGARO-DKD	103 / 1610	148 / 1638	89.2	0.71 [0.56,0.90]	
Total	116 / 1762	164 / 1792		0.72 [0.57,0.90]	Z=-2.82, p=0.0047
Heterogeneity:	Q=0.16 (df=1)	p=0.6888	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 58	8 / 67	12.5	0.72 [0.25,2.09]	
FIGARO-DKD	38 / 716	54 / 664	87.5	0.65 [0.44,0.97]	
Total	43 / 774	62 / 731		0.66 [0.45,0.96]	Z=-2.16, p=0.0306
Heterogeneity:	Q=0.03 (df=1)	p=0.8614	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7044	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.145.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

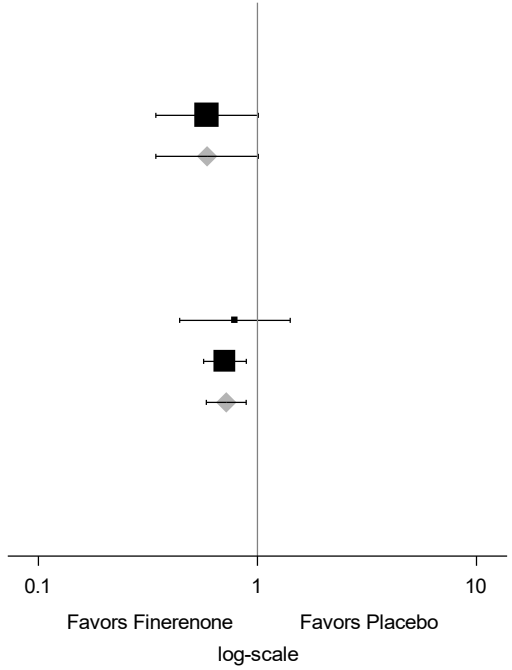
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 98	14 / 96	11.5	0.77 [0.37,1.61]	
FIGARO-DKD	84 / 1416	127 / 1420	88.5	0.66 [0.51,0.87]	
Total	95 / 1514	141 / 1516		0.67 [0.53,0.87]	Z=-3.09, p=0.0020
Heterogeneity:	Q=0.14 (df=1)	p=0.7100	I^2=0.0%		
>= 65					
FIDELIO-DKD	7 / 112	10 / 125	11.3	0.78 [0.31,1.98]	
FIGARO-DKD	57 / 910	75 / 882	88.7	0.74 [0.53,1.03]	
Total	64 / 1022	85 / 1007		0.74 [0.54,1.01]	Z=-1.88, p=0.0607
Heterogeneity:	Q=0.01 (df=1)	p=0.9072	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.145.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

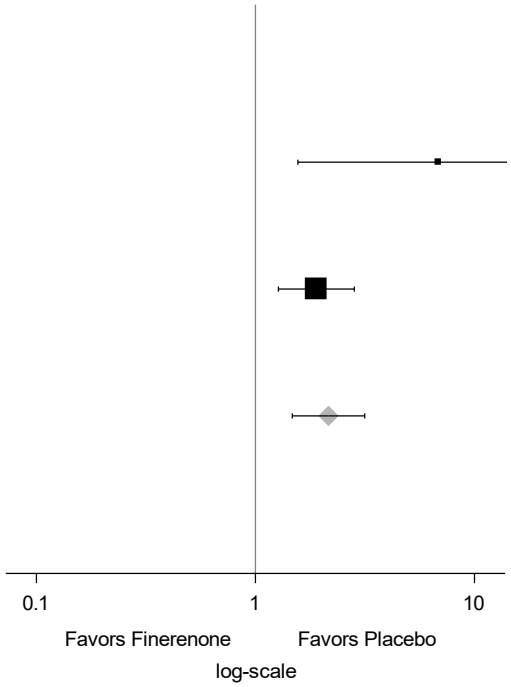
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	20 / 363	32 / 342	100.0	0.59 [0.34,1.01]	
Total	20 / 363	32 / 342		0.59 [0.34,1.01]	Z=-1.93, p=0.0540
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	18 / 210	24 / 221	13.0	0.79 [0.44,1.41]	
FIGARO-DKD	121 / 1963	170 / 1960	87.0	0.71 [0.57,0.89]	
Total	139 / 2173	194 / 2181		0.72 [0.58,0.89]	Z=-3.07, p=0.0021
Heterogeneity:	Q=0.11 (df=1)	p=0.7414	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4944	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.146: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

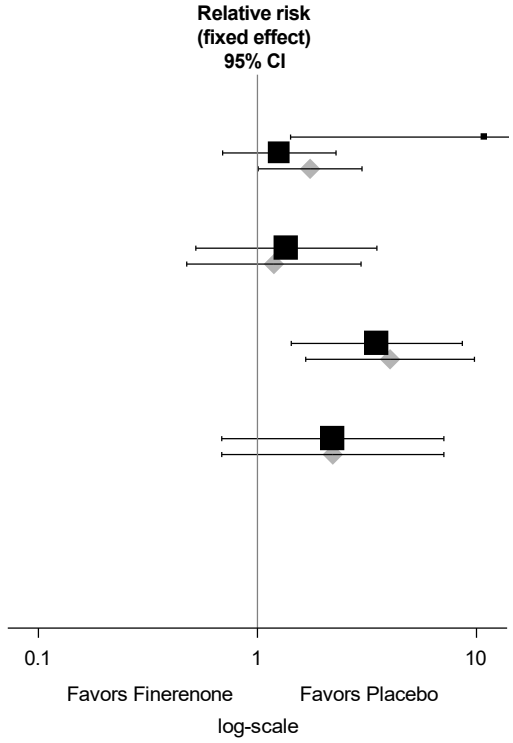
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	2 / 221	6.8	6.84 [1.56,29.95]	
FIGARO-DKD	69 / 2326	36 / 2302	93.2	1.90 [1.27,2.83]	
Total	82 / 2536	38 / 2523		2.16 [1.47,3.15]	Z=3.95, p=<.0001
Heterogeneity:	Q=2.74 (df=1)	p=0.0976	I^2=63.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.146.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

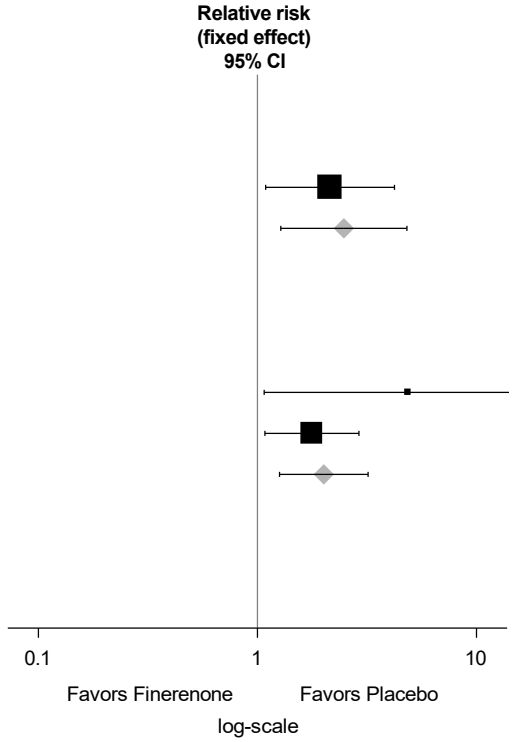
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 103	1 / 112	7.9	10.87 [1.42,83.47]	
FIGARO-DKD	24 / 1114	19 / 1110	92.1	1.26 [0.69,2.28]	
Total	34 / 1217	20 / 1222		1.74 [1.01,3.00]	Z=1.99, p=0.0469
Heterogeneity:	Q=4.24 (df=1)	p=0.0395	I^2=76.4%		
North America					
FIDELIO-DKD	0 / 42	1 / 40	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	10 / 292	7 / 277	100.0	1.36 [0.52,3.51]	
Total	10 / 334	8 / 317		1.19 [0.48,2.97]	Z=0.37, p=0.7116
Heterogeneity:	Q=0.07 (df=1)	p=0.7872	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	0 / 41	0.0	147E9 [147E9,147E9]	
FIGARO-DKD	21 / 522	6 / 523	100.0	3.51 [1.43,8.62]	
Total	24 / 561	6 / 564		4.03 [1.66,9.79]	Z=3.08, p=0.0021
Heterogeneity:	Q=0.09 (df=1)	p=0.7610	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	9 / 322	4 / 316	100.0	2.21 [0.69,7.10]	
Total	9 / 343	4 / 340		2.21 [0.69,7.10]	Z=1.33, p=0.1836
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	5 / 76	0 / 76	0.0	126E9 [126E9,126E9]	
Total	5 / 81	0 / 80		3.91E7 [3.91E7,3.91E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.91 (df=4)	p=0.4184	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.146.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

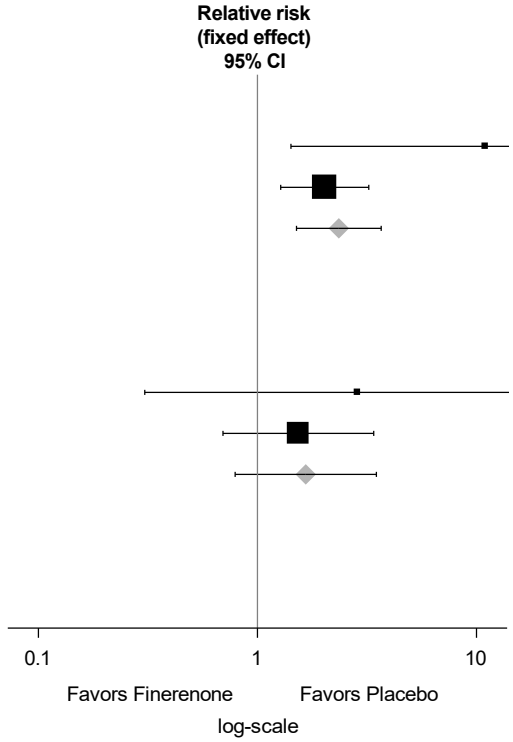
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	0 / 89	0.0	237E9 [237E9,237E9]	
FIGARO-DKD	26 / 811	12 / 803	100.0	2.15 [1.09,4.22]	
Total	30 / 899	12 / 892		2.48 [1.28,4.81]	Z=2.69, p=0.0073
Heterogeneity:	Q=0.18 (df=1)	p=0.6745	I^2=0.0%		
Absent					
FIDELIO-DKD	9 / 122	2 / 132	9.7	4.87 [1.07,22.09]	
FIGARO-DKD	43 / 1515	24 / 1499	90.3	1.77 [1.08,2.91]	
Total	52 / 1637	26 / 1631		2.01 [1.26,3.20]	Z=2.94, p=0.0033
Heterogeneity:	Q=1.56 (df=1)	p=0.2113	I^2=36.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6100	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.146.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	10 / 144	1 / 158	4.9	10.97 [1.42,84.65]	
FIGARO-DKD	54 / 1719	26 / 1679	95.1	2.03 [1.28,3.22]	
Total	64 / 1863	27 / 1837		2.35 [1.51,3.67]	Z=3.77, p=0.0002
Heterogeneity:	Q=2.58 (df=1)	p=0.1085	I^2=61.2%		
> 4.5					
FIDELIO-DKD	3 / 66	1 / 63	11.1	2.86 [0.31,26.81]	
FIGARO-DKD	15 / 607	10 / 622	88.9	1.54 [0.70,3.39]	
Total	18 / 673	11 / 685		1.66 [0.79,3.49]	Z=1.34, p=0.1800
Heterogeneity:	Q=0.26 (df=1)	p=0.6069	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.62 (df=1)	p=0.4311	I^2=0.0%		

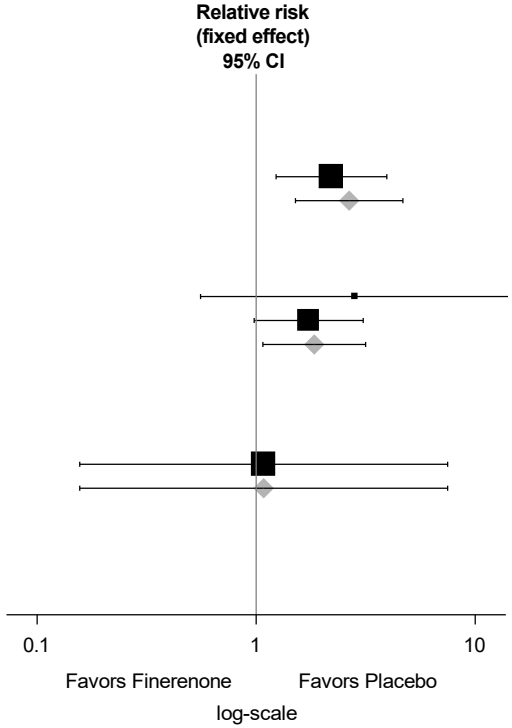


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.146.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

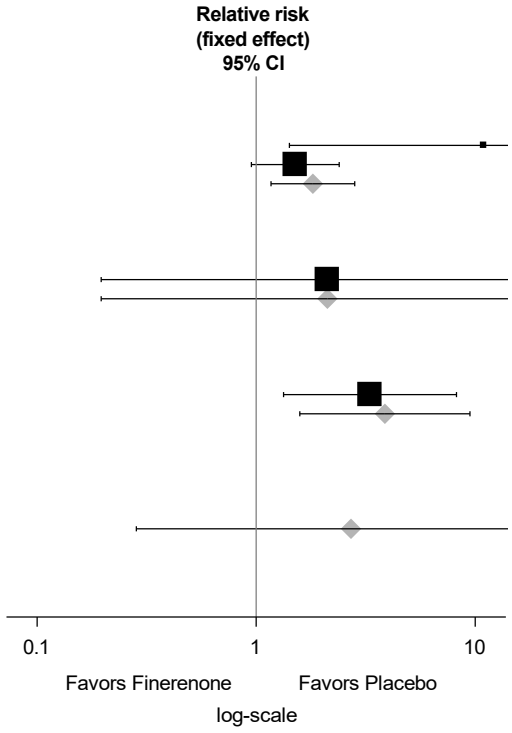
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 64	0 / 54	0.0	239E9 [239E9,239E9]	
FIGARO-DKD	35 / 693	16 / 699	100.0	2.21 [1.23,3.95]	
Total	43 / 757	16 / 753		2.66 [1.51,4.68]	Z=3.39, p=0.0007
Heterogeneity:	Q=0.39 (df=1)	p=0.5305	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	5 / 138	2 / 156	11.1	2.83 [0.56,14.33]	
FIGARO-DKD	32 / 1560	18 / 1524	88.9	1.74 [0.98,3.08]	
Total	37 / 1698	20 / 1680		1.84 [1.07,3.16]	Z=2.22, p=0.0267
Heterogeneity:	Q=0.31 (df=1)	p=0.5793	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	2 / 79	100.0	1.08 [0.16,7.49]	
Total	2 / 81	2 / 90		1.08 [0.16,7.49]	Z=0.08, p=0.9362
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=2)	p=0.5113	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.146.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

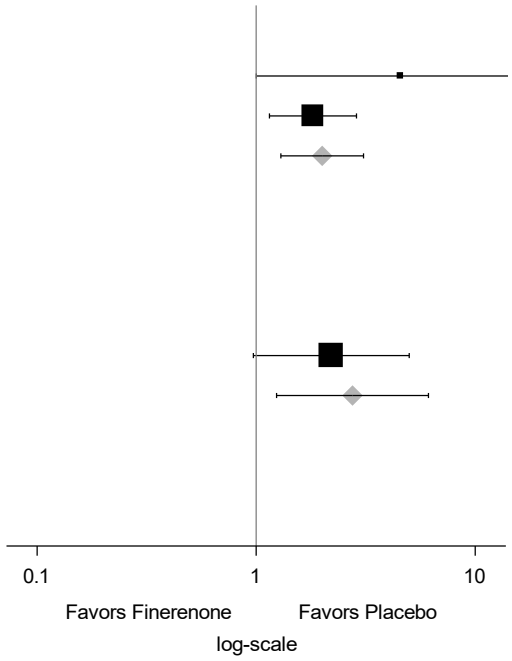
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	10 / 139	1 / 152	4.9	10.94 [1.42,84.33]	
FIGARO-DKD	45 / 1658	29 / 1612	95.1	1.51 [0.95,2.39]	
Total	55 / 1797	30 / 1764		1.81 [1.17,2.82]	Z=2.66, p=0.0079
Heterogeneity:	Q=3.58 (df=1)	p=0.0583	I^2=72.1%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	2 / 70	1 / 74	100.0	2.11 [0.20,22.80]	
Total	2 / 80	1 / 83		2.11 [0.20,22.80]	Z=0.62, p=0.5372
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	0 / 44	0.0	147E9 [147E9,147E9]	
FIGARO-DKD	19 / 464	6 / 485	100.0	3.31 [1.33,8.21]	
Total	22 / 503	6 / 529		3.87 [1.58,9.46]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.11 (df=1)	p=0.7364	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,55E295]	
FIGARO-DKD	3 / 134	0 / 131	0.0	117E9 [117E9,117E9]	
Total	3 / 156	1 / 147		2.71 [0.28,25.88]	Z=0.87, p=0.3867
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=2.26 (df=3)	p=0.5196	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.146.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

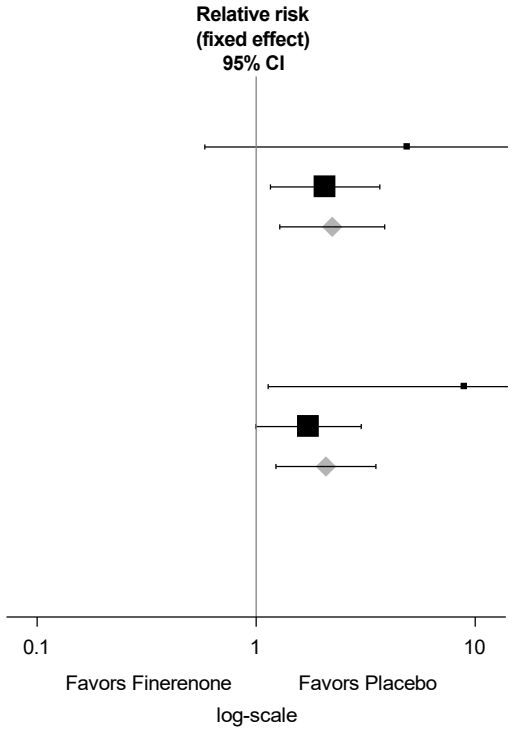
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 152	2 / 154	8.3	4.56 [1.00,20.76]	
FIGARO-DKD	50 / 1610	28 / 1638	91.7	1.82 [1.15,2.87]	
Total	59 / 1762	30 / 1792		2.00 [1.30,3.09]	Z=3.13, p=0.0017
Heterogeneity:	Q=1.31 (df=1)	p=0.2532	I^2=23.4%		
Female					
FIDELIO-DKD	4 / 58	0 / 67	0.0	359E9 [359E9,359E9]	
FIGARO-DKD	19 / 716	8 / 664	100.0	2.20 [0.97,5.00]	
Total	23 / 774	8 / 731		2.75 [1.24,6.12]	Z=2.49, p=0.0129
Heterogeneity:	Q=0.29 (df=1)	p=0.5934	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4919	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.146.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

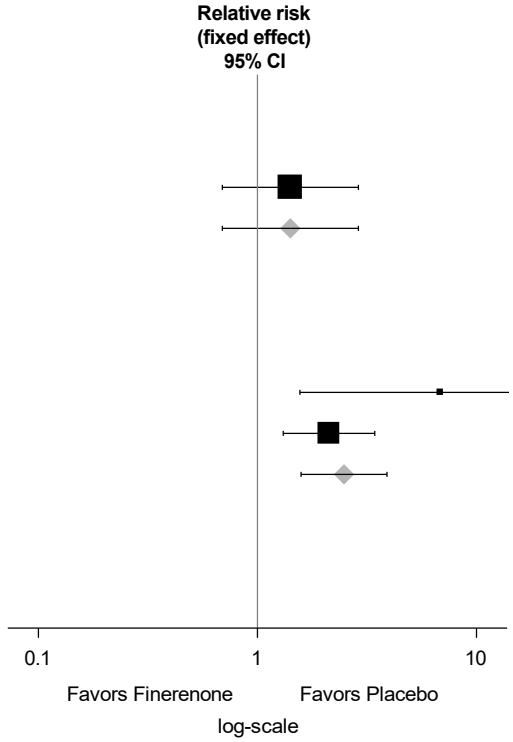
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	5 / 98	1 / 96	6.8	4.90 [0.58,41.15]	
FIGARO-DKD	35 / 1416	17 / 1420	93.2	2.06 [1.16,3.67]	
Total	40 / 1514	18 / 1516		2.22 [1.28,3.86]	Z=2.84, p=0.0045
Heterogeneity:	Q=0.59 (df=1)	p=0.4413	I^2=0.0%		
>= 65					
FIDELIO-DKD	8 / 112	1 / 125	6.7	8.93 [1.13,70.27]	
FIGARO-DKD	34 / 910	19 / 882	93.3	1.73 [1.00,3.02]	
Total	42 / 1022	20 / 1007		2.08 [1.23,3.52]	Z=2.73, p=0.0062
Heterogeneity:	Q=2.33 (df=1)	p=0.1269	I^2=57.1%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8641	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.146.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

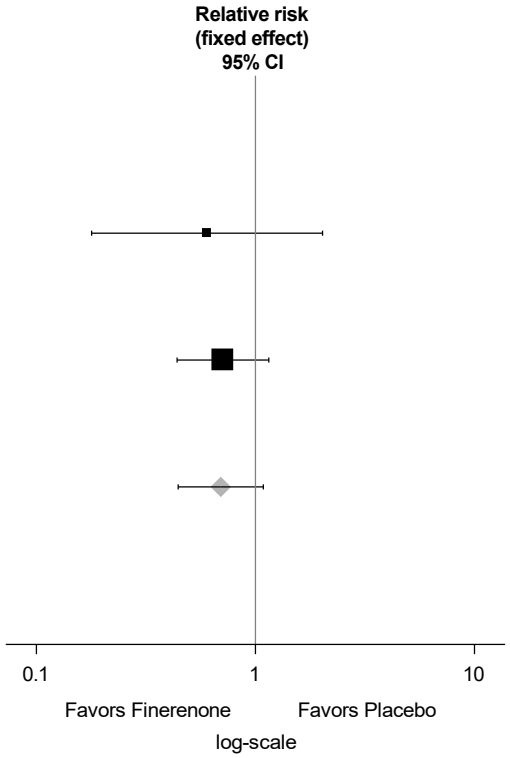
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	18 / 363	12 / 342	100.0	1.41 [0.69,2.89]	
Total	18 / 363	12 / 342		1.41 [0.69,2.89]	Z=0.95, p=0.3433
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	13 / 210	2 / 221	9.6	6.84 [1.56,29.95]	
FIGARO-DKD	51 / 1963	24 / 1960	90.4	2.12 [1.31,3.43]	
Total	64 / 2173	26 / 2181		2.48 [1.58,3.90]	Z=3.95, p=<.0001
Heterogeneity:	Q=2.22 (df=1)	p=0.1362	I^2=55.0%		
Subgroup Heterogeneity:	Q=1.71 (df=1)	p=0.1913	I^2=41.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.147: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

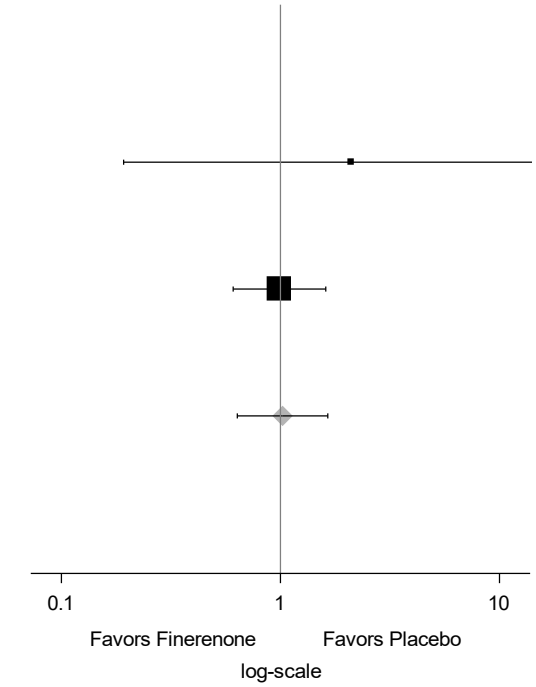
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	7 / 221	13.6	0.60 [0.18,2.02]	
FIGARO-DKD	28 / 2326	39 / 2302	86.4	0.71 [0.44,1.15]	
Total	32 / 2536	46 / 2523		0.69 [0.44,1.09]	Z=-1.60, p=0.1102
Heterogeneity:	Q=0.06 (df=1)	p=0.8023	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.148: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

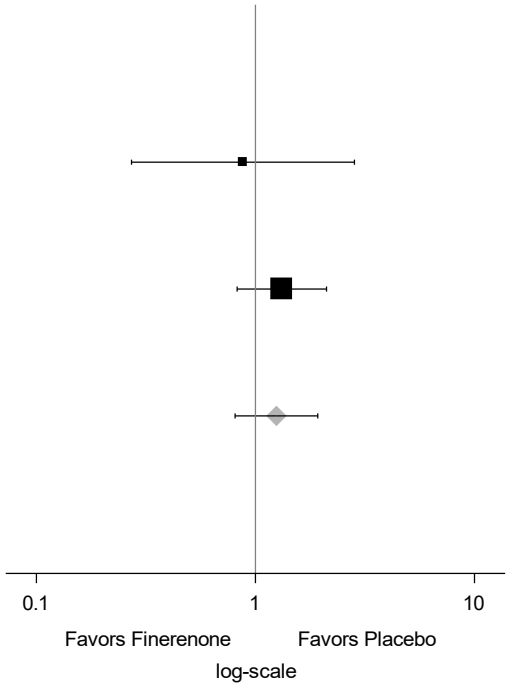
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.0	2.10 [0.19,23.04]	
FIGARO-DKD	32 / 2326	32 / 2302	96.0	0.99 [0.61,1.61]	
Total	34 / 2536	33 / 2523		1.02 [0.64,1.64]	Z=0.09, p=0.9277
Heterogeneity:	Q=0.37 (df=1)	p=0.5447	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.149: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

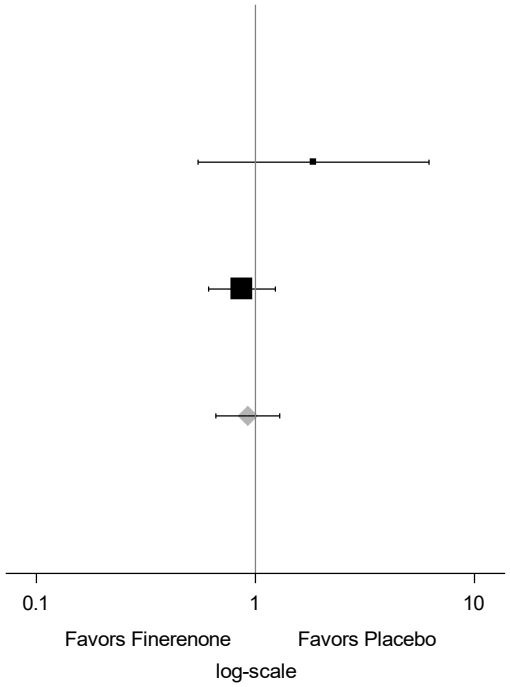
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	6 / 221	13.9	0.88 [0.27,2.83]	
FIGARO-DKD	40 / 2326	30 / 2302	86.1	1.32 [0.82,2.11]	
Total	45 / 2536	36 / 2523		1.25 [0.81,1.93]	Z=0.99, p=0.3198
Heterogeneity:	Q=0.40 (df=1)	p=0.5259	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.150: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

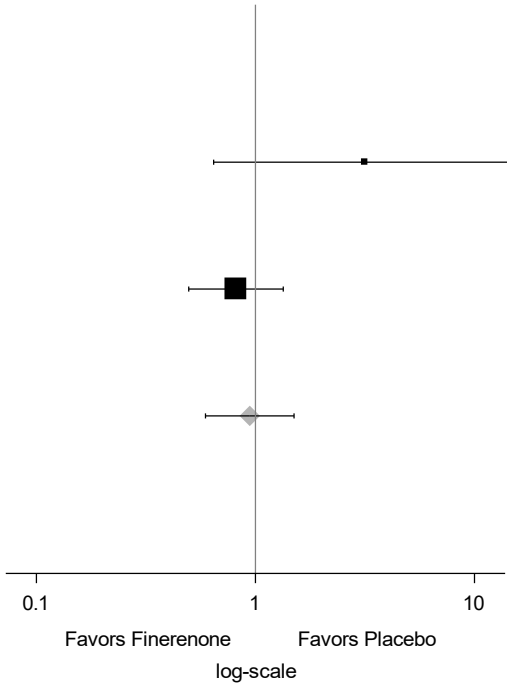
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	4 / 221	7.7	1.84 [0.55,6.20]	
FIGARO-DKD	57 / 2326	65 / 2302	92.3	0.87 [0.61,1.23]	
Total	64 / 2536	69 / 2523		0.92 [0.66,1.29]	Z=-0.47, p=0.6380
Heterogeneity:	Q=1.36 (df=1)	p=0.2431	I^2=26.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.151: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

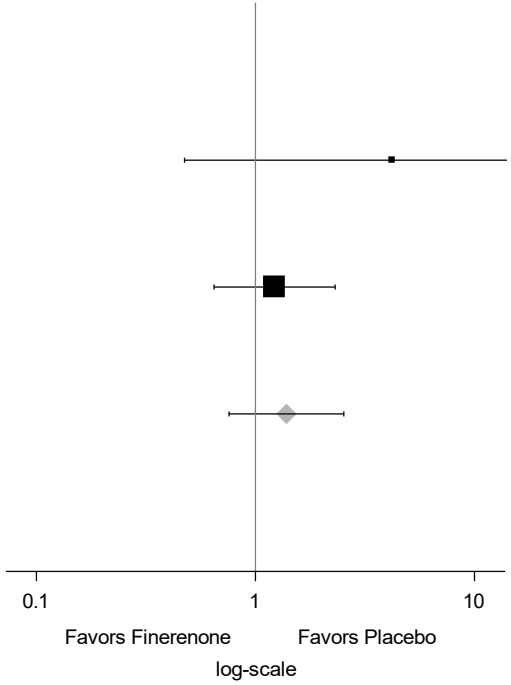
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	2 / 221	8.9	3.16 [0.64,15.47]	
FIGARO-DKD	28 / 2326	34 / 2302	91.1	0.82 [0.50,1.34]	
Total	34 / 2536	36 / 2523		0.94 [0.59,1.50]	Z=-0.25, p=0.8010
Heterogeneity:	Q=2.55 (df=1)	p=0.1102	I^2=60.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.152: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

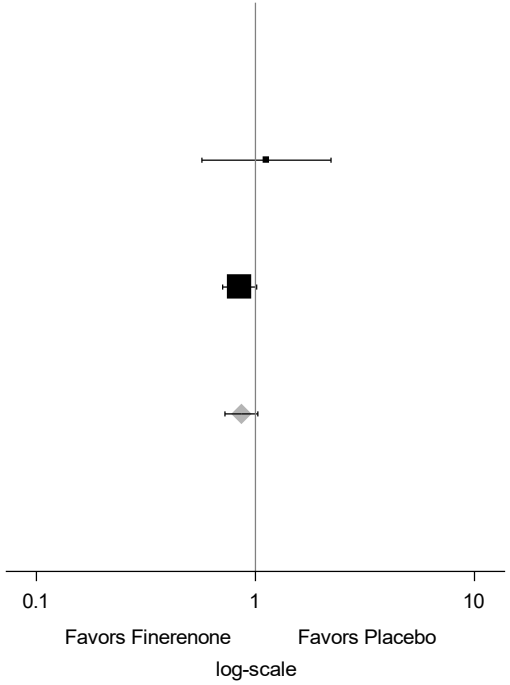
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	1 / 221	7.8	4.21 [0.47,37.36]	
FIGARO-DKD	21 / 2326	17 / 2302	92.2	1.22 [0.65,2.31]	
Total	25 / 2536	18 / 2523		1.38 [0.76,2.53]	Z=1.06, p=0.2901
Heterogeneity:	Q=1.14 (df=1)	p=0.2849	I^2=12.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.153: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

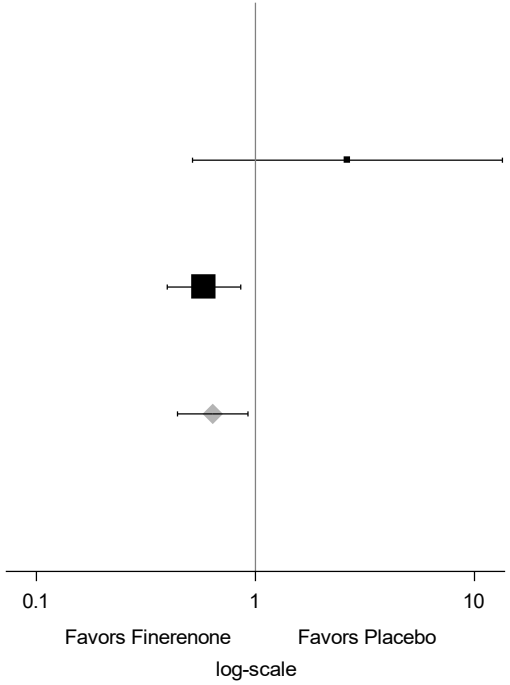
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	16 / 210	15 / 221	6.5	1.12 [0.57,2.21]	
FIGARO-DKD	202 / 2326	236 / 2302	93.5	0.85 [0.71,1.01]	
Total	218 / 2536	251 / 2523		0.86 [0.73,1.03]	Z=-1.67, p=0.0939
Heterogeneity:	Q=0.62 (df=1)	p=0.4317	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.154: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

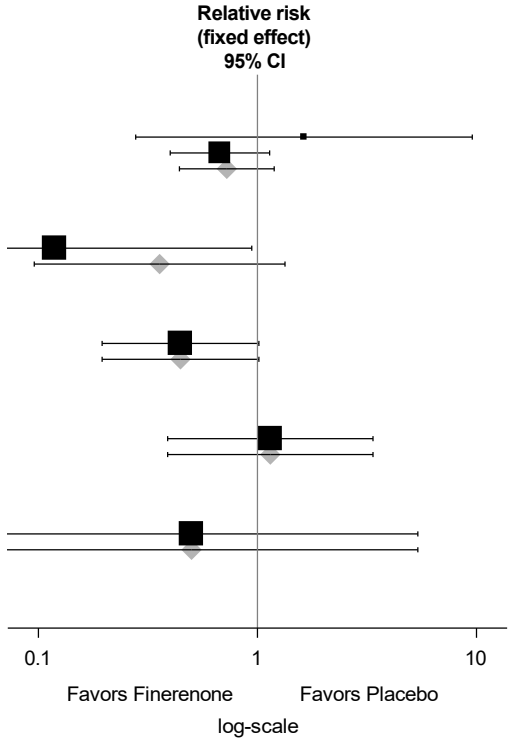
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	5.3	2.63 [0.52,13.41]	
FIGARO-DKD	40 / 2326	68 / 2302	94.7	0.58 [0.40,0.86]	
Total	45 / 2536	70 / 2523		0.64 [0.44,0.92]	Z=-2.38, p=0.0175
Heterogeneity:	Q=3.12 (df=1)	p=0.0772	I^2=68.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.154.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

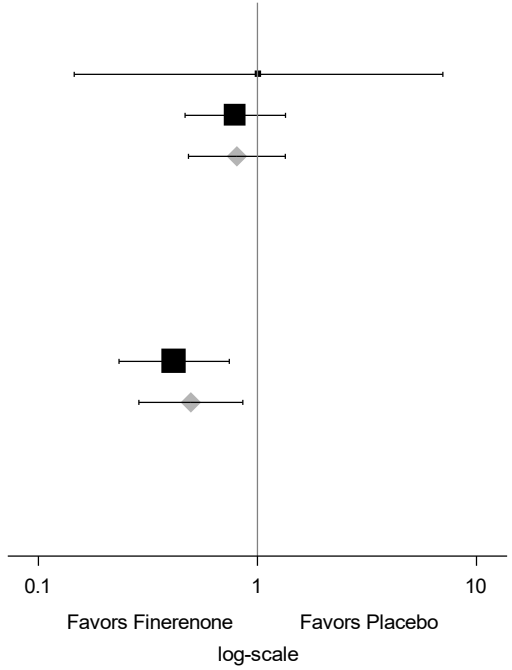
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	2 / 112	8.0	1.63 [0.28,9.57]	
FIGARO-DKD	23 / 1114	34 / 1110	92.0	0.67 [0.40,1.14]	
Total	26 / 1217	36 / 1222		0.72 [0.44,1.19]	Z=-1.27, p=0.2049
Heterogeneity:	Q=0.88 (df=1)	p=0.3478	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	0 / 40	0.0	248E9 [248E9,248E9]	
FIGARO-DKD	1 / 292	8 / 277	100.0	0.12 [0.01,0.94]	
Total	3 / 334	8 / 317		0.36 [0.10,1.34]	Z=-1.53, p=0.1261
Heterogeneity:	Q=1.09 (df=1)	p=0.2966	I^2=8.2%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	8 / 522	18 / 523	100.0	0.45 [0.20,1.02]	
Total	8 / 561	18 / 564		0.45 [0.20,1.02]	Z=-1.92, p=0.0543
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	7 / 322	6 / 316	100.0	1.14 [0.39,3.37]	
Total	7 / 343	6 / 340		1.14 [0.39,3.37]	Z=0.25, p=0.8059
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	2 / 76	100.0	0.50 [0.05,5.40]	
Total	1 / 81	2 / 80		0.50 [0.05,5.40]	Z=-0.57, p=0.5680
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.89 (df=4)	p=0.5772	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.154.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

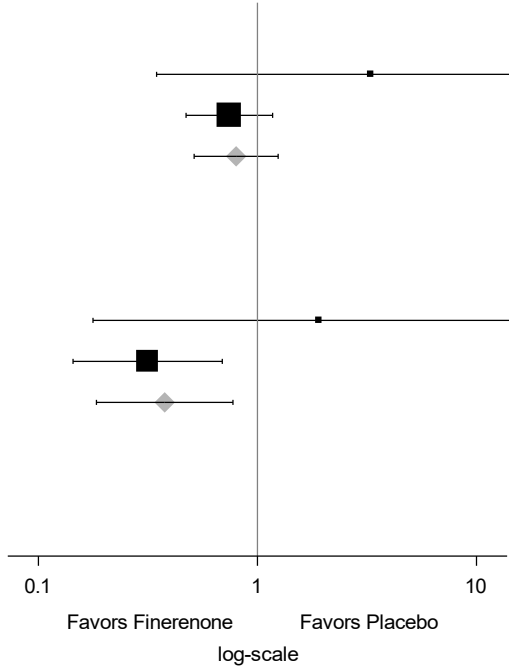
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	2 / 88	2 / 89	6.9	1.01 [0.15,7.02]	
FIGARO-DKD	24 / 811	30 / 803	93.1	0.79 [0.47,1.34]	
Total	26 / 899	32 / 892		0.81 [0.48,1.34]	Z=-0.83, p=0.4050
Heterogeneity:	Q=0.06 (df=1)	p=0.8115	I^2=0.0%		
Absent					
FIDELIO-DKD	3 / 122	0 / 132	0.0	128E9 [128E9,128E9]	
FIGARO-DKD	16 / 1515	38 / 1499	100.0	0.42 [0.23,0.74]	
Total	19 / 1637	38 / 1631		0.50 [0.29,0.86]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.35 (df=1)	p=0.5529	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.61 (df=1)	p=0.2042	I^2=38.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.154.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

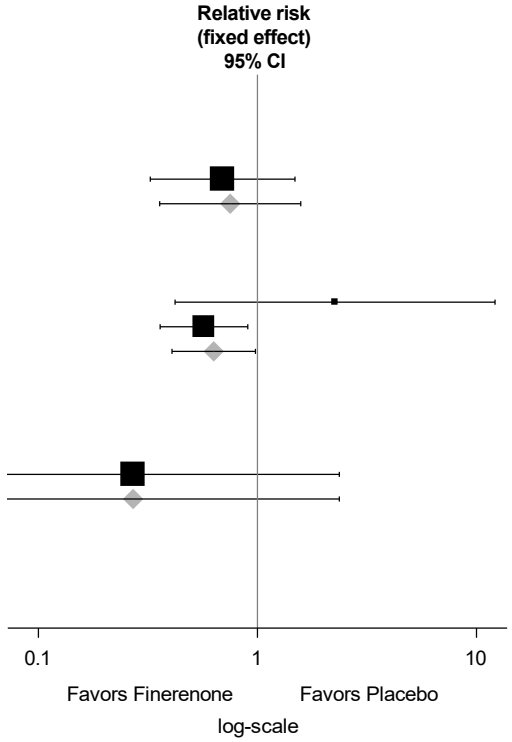
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	3 / 144	1 / 158	3.9	3.29 [0.35,31.29]	
FIGARO-DKD	32 / 1719	42 / 1679	96.1	0.74 [0.47,1.17]	
Total	35 / 1863	43 / 1837		0.80 [0.51,1.24]	Z=-0.99, p=0.3199
Heterogeneity:	Q=1.61 (df=1)	p=0.2042	I^2=38.0%		
> 4.5					
FIDELIO-DKD	2 / 66	1 / 63	9.8	1.91 [0.18,20.53]	
FIGARO-DKD	8 / 607	26 / 622	90.2	0.32 [0.14,0.69]	
Total	10 / 673	27 / 685		0.38 [0.18,0.77]	Z=-2.66, p=0.0077
Heterogeneity:	Q=1.99 (df=1)	p=0.1583	I^2=49.8%		
Subgroup Heterogeneity:	Q=3.05 (df=1)	p=0.0806	I^2=67.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.154.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

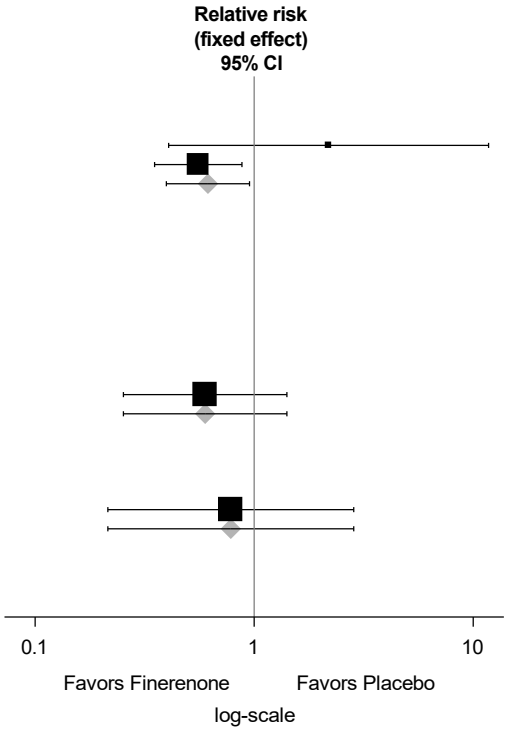
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	814E8 [814E8,814E8]	
FIGARO-DKD	11 / 693	16 / 699	100.0	0.69 [0.32,1.48]	
Total	12 / 757	16 / 753		0.75 [0.36,1.58]	Z=-0.76, p=0.4492
Heterogeneity:	Q=0.04 (df=1)	p=0.8371	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	4 / 138	2 / 156	7.0	2.26 [0.42,12.15]	
FIGARO-DKD	28 / 1560	48 / 1524	93.0	0.57 [0.36,0.90]	
Total	32 / 1698	50 / 1680		0.63 [0.41,0.98]	Z=-2.05, p=0.0400
Heterogeneity:	Q=2.40 (df=1)	p=0.1213	I^2=58.3%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	4 / 79	100.0	0.27 [0.03,2.36]	
Total	1 / 81	4 / 90		0.27 [0.03,2.36]	Z=-1.18, p=0.2373
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.79 (df=2)	p=0.6746	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.154.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

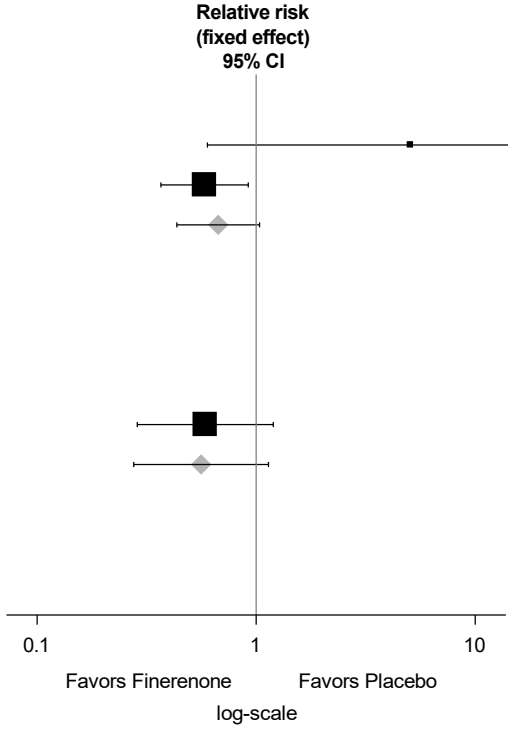
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	4 / 139	2 / 152	6.9	2.19 [0.41,11.75]	
FIGARO-DKD	28 / 1658	49 / 1612	93.1	0.56 [0.35,0.88]	
Total	32 / 1797	51 / 1764		0.61 [0.40,0.95]	Z=-2.18, p=0.0293
Heterogeneity:	Q=2.37 (df=1)	p=0.1233	I^2=57.9%		
Black					
FIDELIO-DKD	1 / 10	0 / 9	0.0	192E9 [192E9,192E9]	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	1 / 80	0 / 83		3.32E7 [3.32E7,3.32E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	8 / 464	14 / 485	100.0	0.60 [0.25,1.41]	
Total	8 / 503	14 / 529		0.60 [0.25,1.41]	Z=-1.18, p=0.2398
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	4 / 134	5 / 131	100.0	0.78 [0.21,2.85]	
Total	4 / 156	5 / 147		0.78 [0.21,2.85]	Z=-0.37, p=0.7094
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=3)	p=0.9878	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.154.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

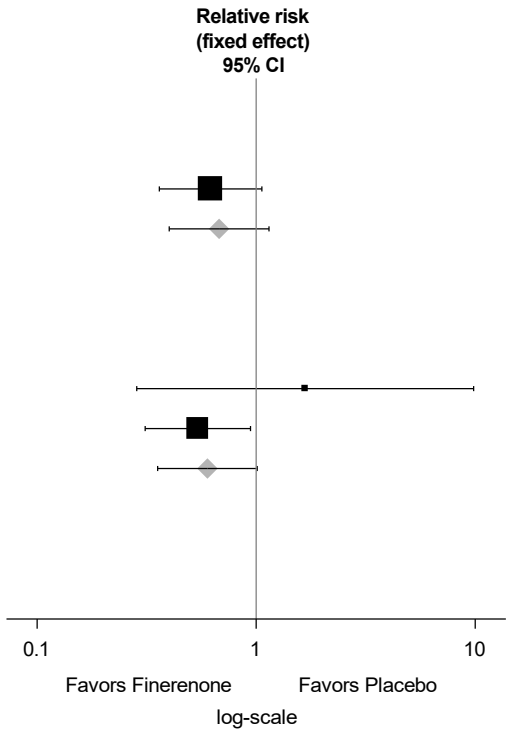
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	5 / 152	1 / 154	4.4	5.07 [0.60,42.85]	
FIGARO-DKD	28 / 1610	49 / 1638	95.6	0.58 [0.37,0.92]	
Total	33 / 1762	50 / 1792		0.67 [0.43,1.04]	Z=-1.80, p=0.0719
Heterogeneity:	Q=3.82 (df=1)	p=0.0507	I^2=73.8%		
Female					
FIDELIO-DKD	0 / 58	1 / 67	0.0	0.00 [0.00,23E296]	
FIGARO-DKD	12 / 716	19 / 664	100.0	0.59 [0.29,1.20]	
Total	12 / 774	20 / 731		0.56 [0.28,1.14]	Z=-1.60, p=0.1092
Heterogeneity:	Q=0.01 (df=1)	p=0.9040	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6715	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.154.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

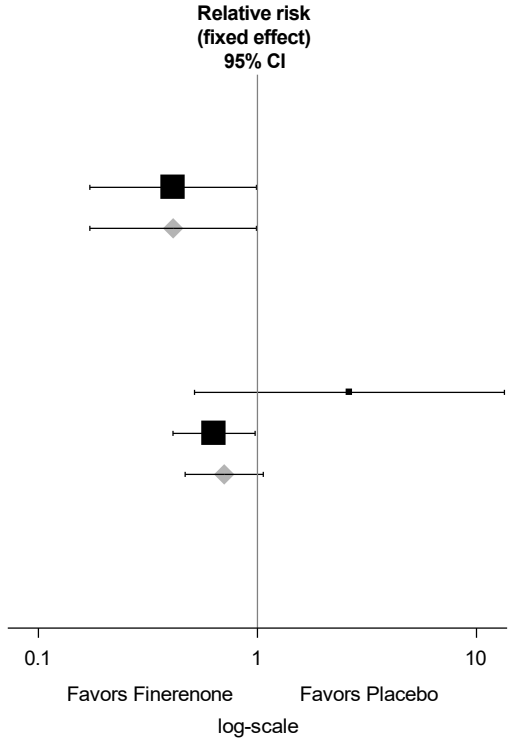
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	0 / 96	0.0	106E9 [106E9,106E9]	
FIGARO-DKD	21 / 1416	34 / 1420	100.0	0.62 [0.36,1.06]	
Total	23 / 1514	34 / 1516		0.68 [0.40,1.14]	Z=-1.46, p=0.1452
Heterogeneity:	Q=0.11 (df=1)	p=0.7451	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	2 / 125	8.9	1.67 [0.28,9.84]	
FIGARO-DKD	19 / 910	34 / 882	91.1	0.54 [0.31,0.94]	
Total	22 / 1022	36 / 1007		0.60 [0.35,1.01]	Z=-1.92, p=0.0549
Heterogeneity:	Q=1.42 (df=1)	p=0.2333	I^2=29.6%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7449	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.1.154.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

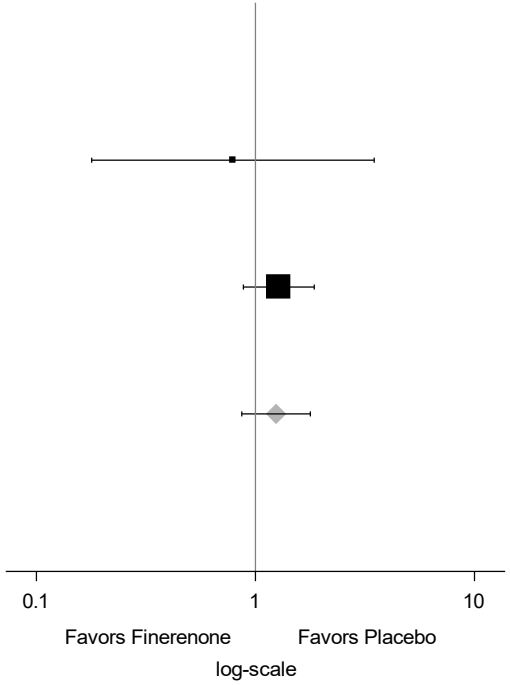
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	7 / 363	16 / 342	100.0	0.41 [0.17,0.99]	
Total	7 / 363	16 / 342		0.41 [0.17,0.99]	Z=-1.98, p=0.0473
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	5 / 210	2 / 221	6.6	2.63 [0.52,13.41]	
FIGARO-DKD	33 / 1963	52 / 1960	93.4	0.63 [0.41,0.98]	
Total	38 / 2173	54 / 2181		0.71 [0.47,1.06]	Z=-1.67, p=0.0954
Heterogeneity:	Q=2.75 (df=1)	p=0.0975	I^2=63.6%		
Subgroup Heterogeneity:	Q=1.18 (df=1)	p=0.2768	I^2=15.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.1.155: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

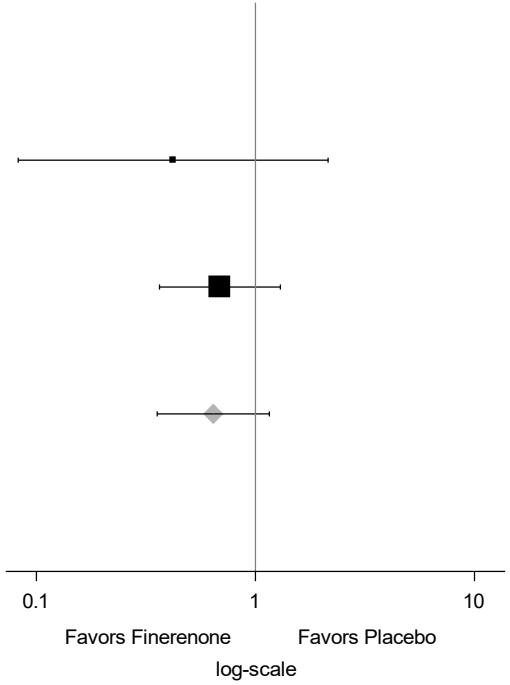
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	5.9	0.79 [0.18,3.48]	
FIGARO-DKD	62 / 2326	48 / 2302	94.1	1.28 [0.88,1.86]	
Total	65 / 2536	52 / 2523		1.24 [0.87,1.78]	Z=1.18, p=0.2387
Heterogeneity:	Q=0.38 (df=1)	p=0.5370	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.156: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

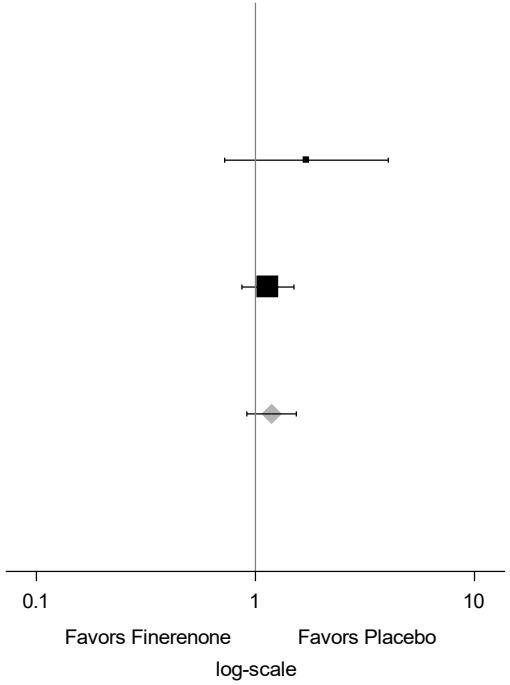
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	13.2	0.42 [0.08,2.15]	
FIGARO-DKD	16 / 2326	23 / 2302	86.8	0.69 [0.36,1.30]	
Total	18 / 2536	28 / 2523		0.64 [0.36,1.16]	Z=-1.47, p=0.1404
Heterogeneity:	Q=0.30 (df=1)	p=0.5811	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.157: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

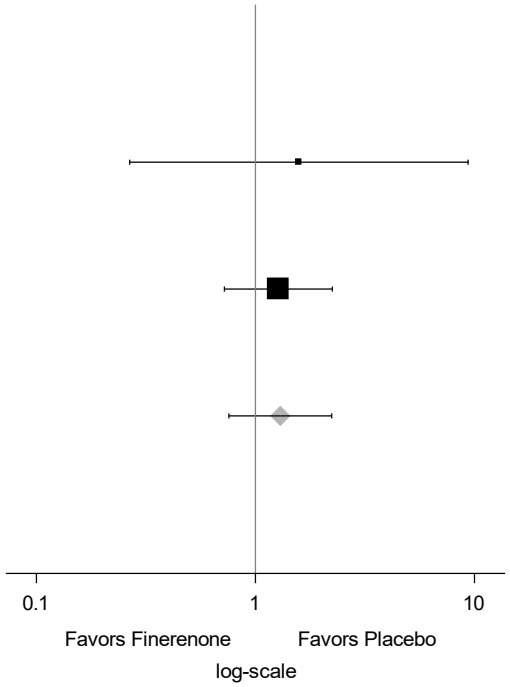
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	8 / 221	9.2	1.71 [0.72,4.04]	
FIGARO-DKD	106 / 2326	92 / 2302	90.8	1.14 [0.87,1.50]	
Total	119 / 2536	100 / 2523		1.18 [0.91,1.54]	Z=1.28, p=0.2010
Heterogeneity:	Q=0.77 (df=1)	p=0.3788	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.158: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

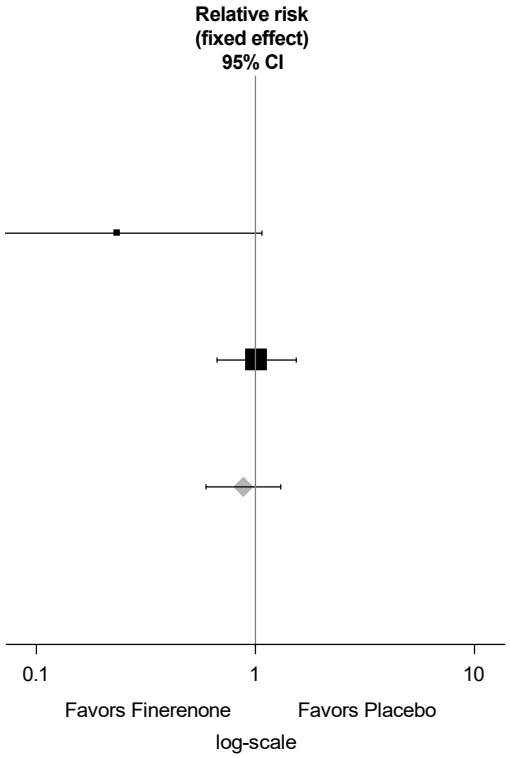
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	9.2	1.58 [0.27,9.35]	
FIGARO-DKD	27 / 2326	21 / 2302	90.8	1.27 [0.72,2.24]	
Total	30 / 2536	23 / 2523		1.30 [0.76,2.23]	Z=0.95, p=0.3435
Heterogeneity:	Q=0.05 (df=1)	p=0.8210	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.159: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

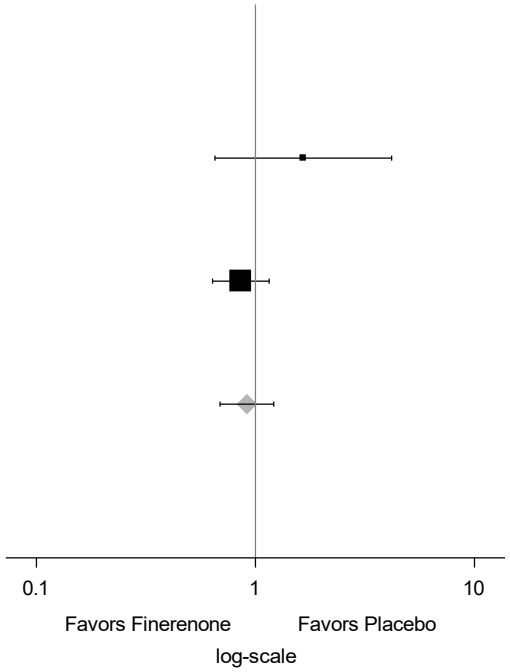
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	9 / 221	7.0	0.23 [0.05,1.07]	
FIGARO-DKD	44 / 2326	43 / 2302	93.0	1.01 [0.67,1.54]	
Total	46 / 2536	52 / 2523		0.88 [0.59,1.30]	Z=-0.63, p=0.5265
Heterogeneity:	Q=3.35 (df=1)	p=0.0671	I^2=70.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.160: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

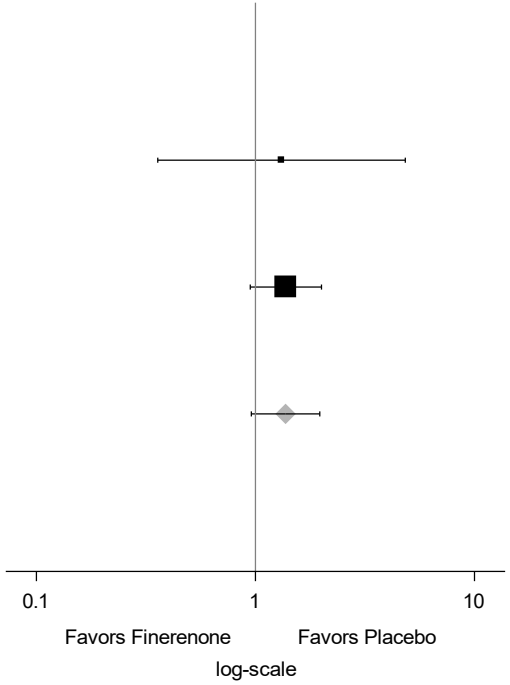
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	7 / 221	9.3	1.65 [0.65,4.19]	
FIGARO-DKD	78 / 2326	90 / 2302	90.7	0.86 [0.64,1.16]	
Total	89 / 2536	97 / 2523		0.91 [0.69,1.21]	Z=-0.63, p=0.5313
Heterogeneity:	Q=1.74 (df=1)	p=0.1870	I^2=42.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.161: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

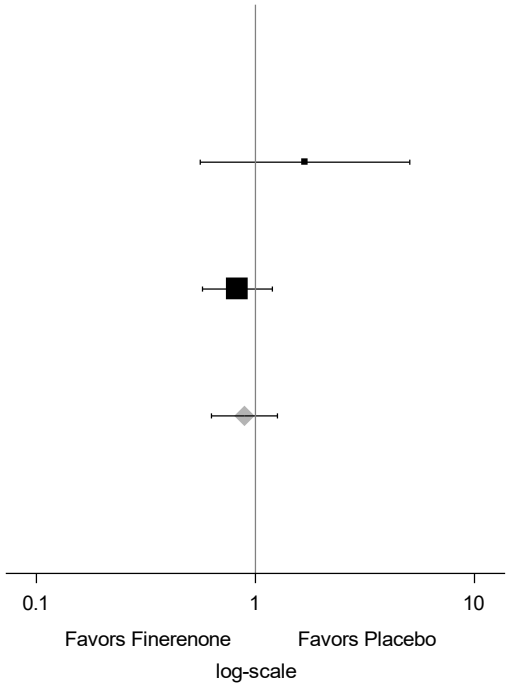
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	7.6	1.32 [0.36,4.83]	
FIGARO-DKD	64 / 2326	46 / 2302	92.4	1.38 [0.95,2.00]	
Total	69 / 2536	50 / 2523		1.37 [0.96,1.97]	Z=1.72, p=0.0848
Heterogeneity:	Q=0.00 (df=1)	p=0.9473	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.162: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

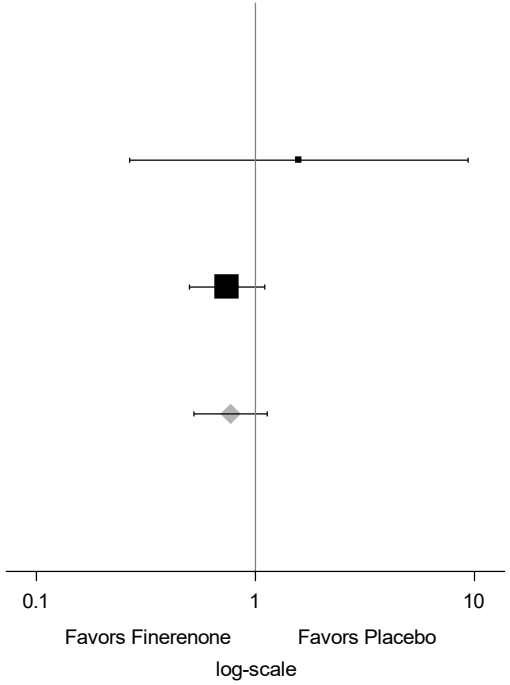
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	5 / 221	10.0	1.68 [0.56,5.06]	
FIGARO-DKD	51 / 2326	61 / 2302	90.0	0.83 [0.57,1.19]	
Total	59 / 2536	66 / 2523		0.89 [0.63,1.26]	Z=-0.65, p=0.5131
Heterogeneity:	Q=1.44 (df=1)	p=0.2303	I^2=30.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.163: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

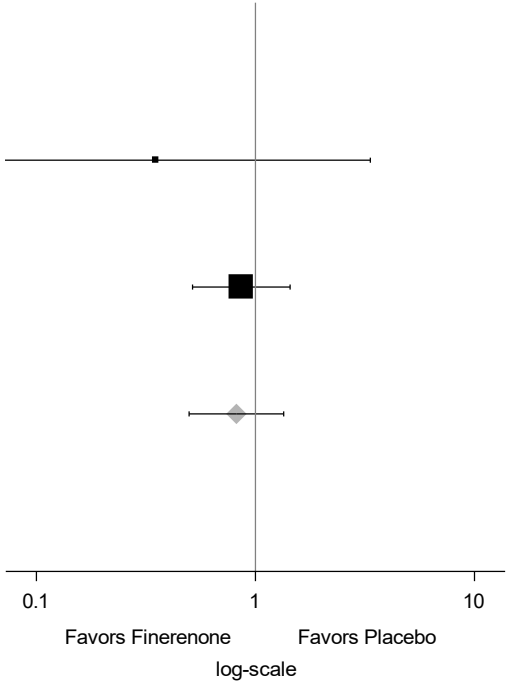
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	4.7	1.58 [0.27,9.35]	
FIGARO-DKD	42 / 2326	56 / 2302	95.3	0.74 [0.50,1.10]	
Total	45 / 2536	58 / 2523		0.77 [0.52,1.13]	Z=-1.33, p=0.1835
Heterogeneity:	Q=0.66 (df=1)	p=0.4171	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.164: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

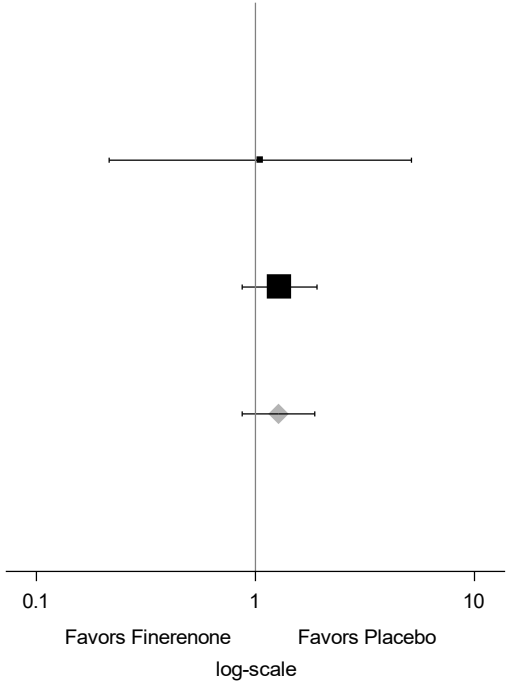
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	4.9	0.35 [0.04,3.35]	
FIGARO-DKD	27 / 2326	31 / 2302	95.1	0.86 [0.52,1.44]	
Total	28 / 2536	34 / 2523		0.82 [0.50,1.35]	Z=-0.79, p=0.4294
Heterogeneity:	Q=0.58 (df=1)	p=0.4458	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.165: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

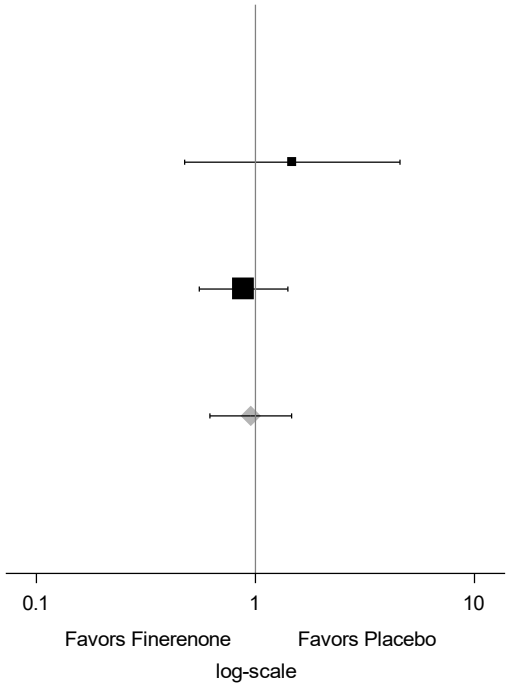
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	5.8	1.05 [0.21,5.16]	
FIGARO-DKD	56 / 2326	43 / 2302	94.2	1.29 [0.87,1.91]	
Total	59 / 2536	46 / 2523		1.27 [0.87,1.87]	Z=1.24, p=0.2135
Heterogeneity:	Q=0.06 (df=1)	p=0.8082	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.166: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

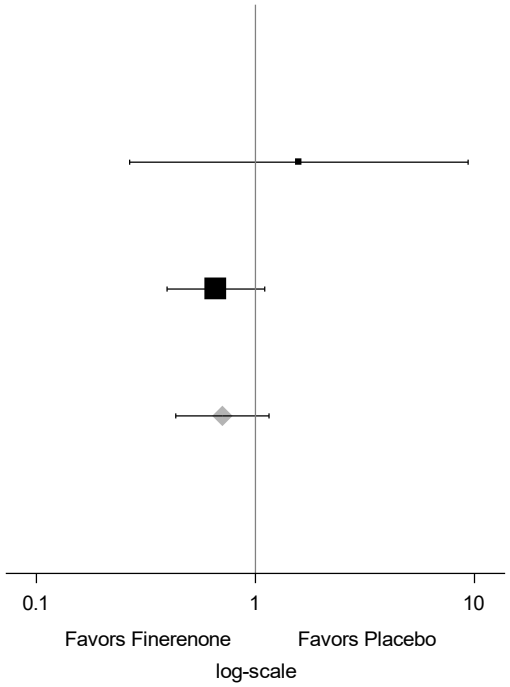
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	14.5	1.47 [0.47,4.57]	
FIGARO-DKD	33 / 2326	37 / 2302	85.5	0.88 [0.55,1.41]	
Total	40 / 2536	42 / 2523		0.95 [0.62,1.46]	Z=-0.23, p=0.8218
Heterogeneity:	Q=0.67 (df=1)	p=0.4120	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.167: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

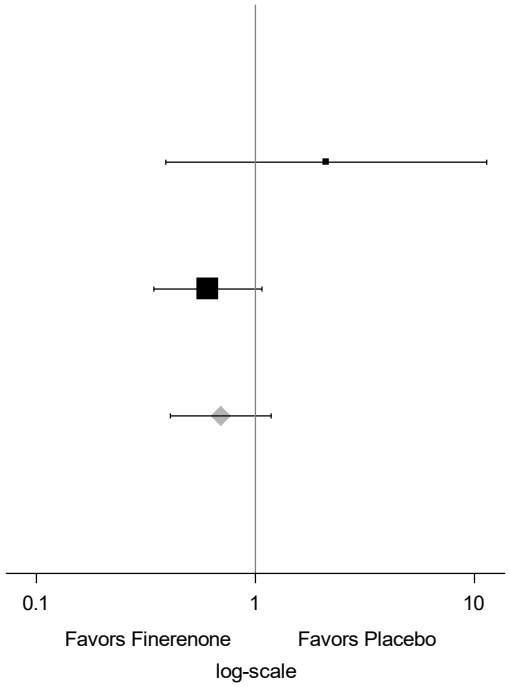
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	7.7	1.58 [0.27,9.35]	
FIGARO-DKD	24 / 2326	36 / 2302	92.3	0.66 [0.39,1.10]	
Total	27 / 2536	38 / 2523		0.71 [0.43,1.15]	Z=-1.39, p=0.1647
Heterogeneity:	Q=0.85 (df=1)	p=0.3558	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.168: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

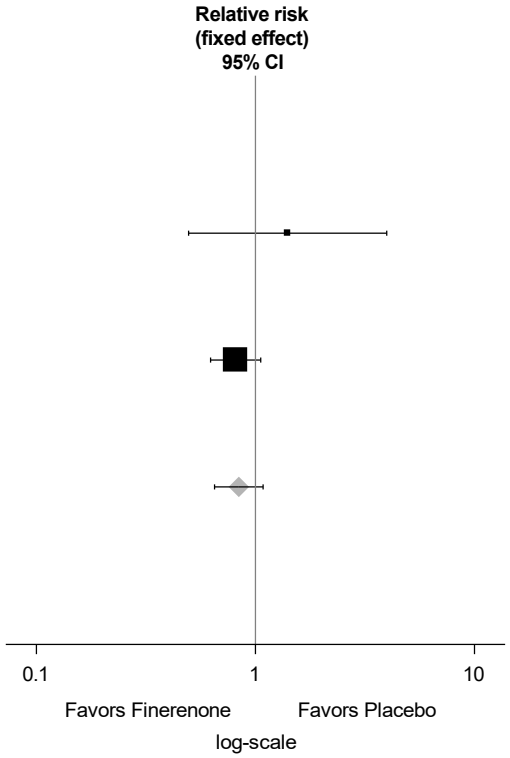
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	10.2	2.10 [0.39,11.37]	
FIGARO-DKD	19 / 2326	31 / 2302	89.8	0.61 [0.34,1.07]	
Total	23 / 2536	33 / 2523		0.69 [0.41,1.18]	Z=-1.35, p=0.1773
Heterogeneity:	Q=1.88 (df=1)	p=0.1706	I^2=46.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.169: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

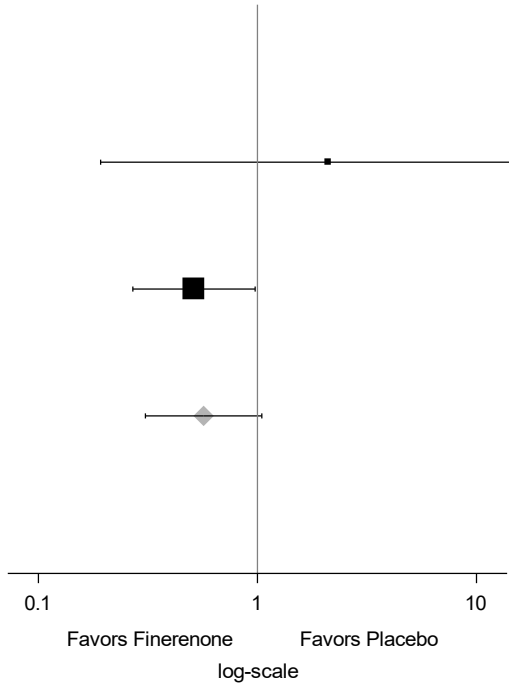
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	6 / 221	6.0	1.40 [0.50,3.98]	
FIGARO-DKD	96 / 2326	117 / 2302	94.0	0.81 [0.62,1.06]	
Total	104 / 2536	123 / 2523		0.84 [0.65,1.08]	Z=-1.34, p=0.1793
Heterogeneity:	Q=1.00 (df=1)	p=0.3184	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.170: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

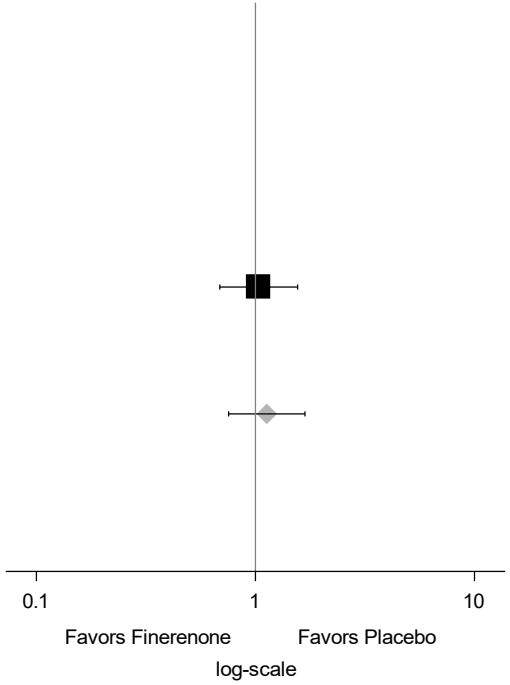
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	6.7	2.10 [0.19,23.04]	
FIGARO-DKD	14 / 2326	27 / 2302	93.3	0.51 [0.27,0.98]	
Total	16 / 2536	28 / 2523		0.57 [0.31,1.05]	Z=-1.81, p=0.0698
Heterogeneity:	Q=1.25 (df=1)	p=0.2642	I^2=19.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.171: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

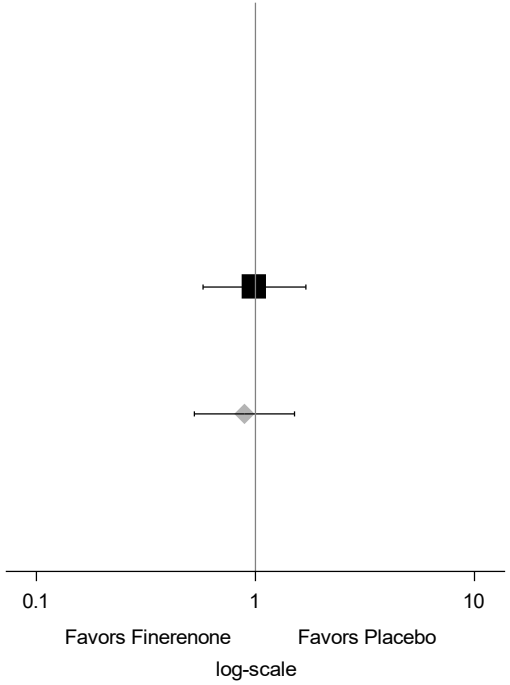
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	0 / 221	0.0	991E8 [991E8,991E8]	
FIGARO-DKD	46 / 2326	44 / 2302	100.0	1.03 [0.69,1.56]	
Total	50 / 2536	44 / 2523		1.13 [0.75,1.68]	Z=0.58, p=0.5603
Heterogeneity:	Q=0.17 (df=1)	p=0.6834	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.172: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

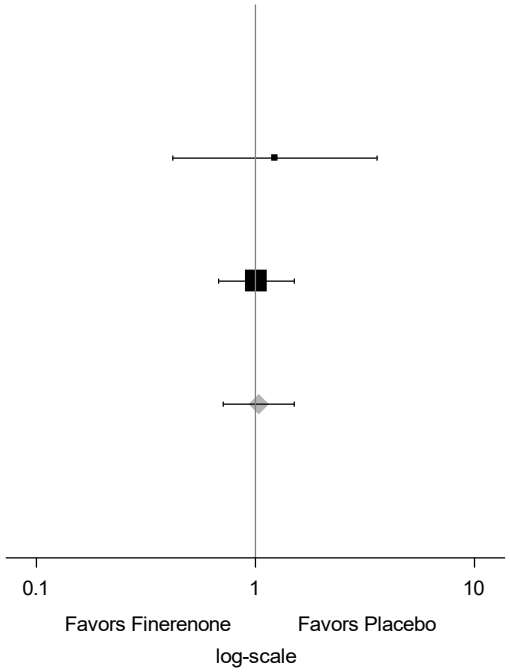
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	3 / 221	0.0	0.00 [0.00,94E295]	
FIGARO-DKD	26 / 2326	26 / 2302	100.0	0.99 [0.58,1.70]	
Total	26 / 2536	29 / 2523		0.89 [0.53,1.51]	Z=-0.43, p=0.6664
Heterogeneity:	Q=0.15 (df=1)	p=0.7023	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.173: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

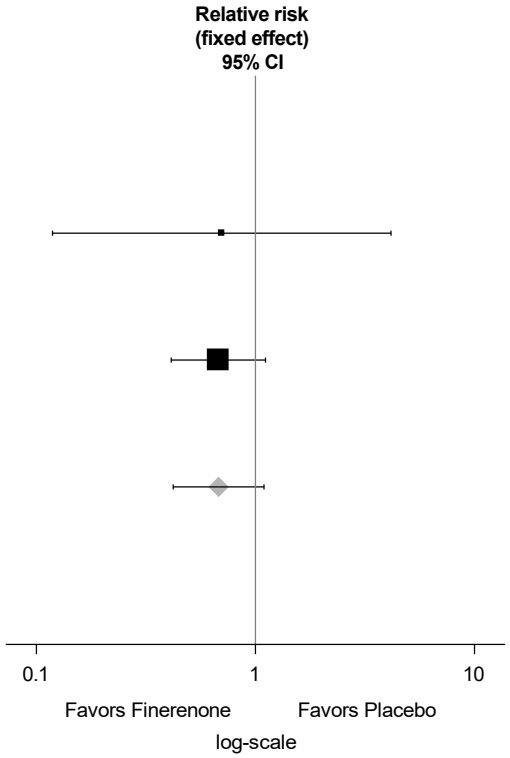
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	6 / 221	12.1	1.23 [0.42,3.59]	
FIGARO-DKD	48 / 2326	47 / 2302	87.9	1.01 [0.68,1.50]	
Total	55 / 2536	53 / 2523		1.03 [0.71,1.50]	Z=0.18, p=0.8572
Heterogeneity:	Q=0.11 (df=1)	p=0.7392	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.174: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

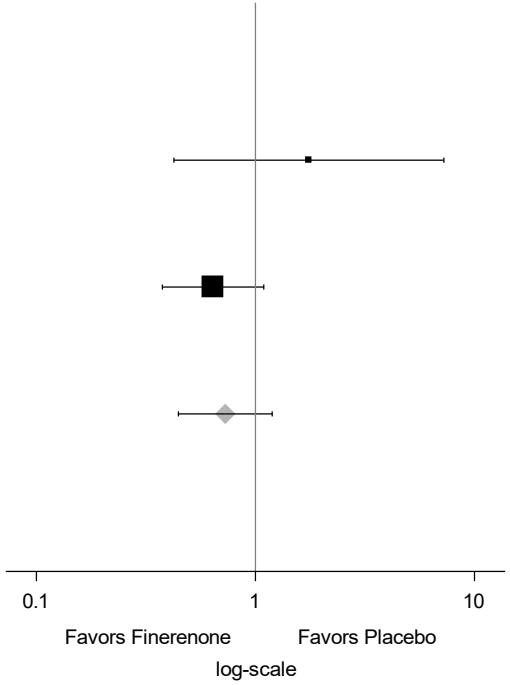
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.2	0.70 [0.12,4.16]	
FIGARO-DKD	26 / 2326	38 / 2302	92.8	0.68 [0.41,1.11]	
Total	28 / 2536	41 / 2523		0.68 [0.42,1.09]	Z=-1.59, p=0.1118
Heterogeneity:	Q=0.00 (df=1)	p=0.9700	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.175: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

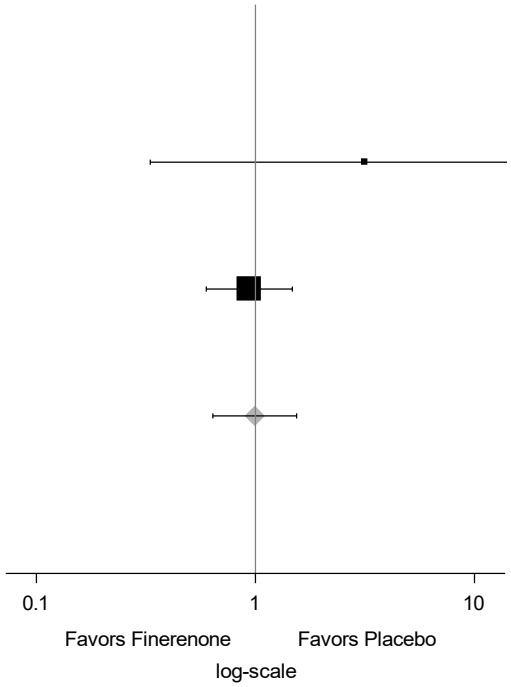
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	3 / 221	12.4	1.75 [0.42,7.25]	
FIGARO-DKD	22 / 2326	34 / 2302	87.6	0.64 [0.38,1.09]	
Total	27 / 2536	37 / 2523		0.73 [0.44,1.19]	Z=-1.26, p=0.2074
Heterogeneity:	Q=1.70 (df=1)	p=0.1926	I^2=41.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.176: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

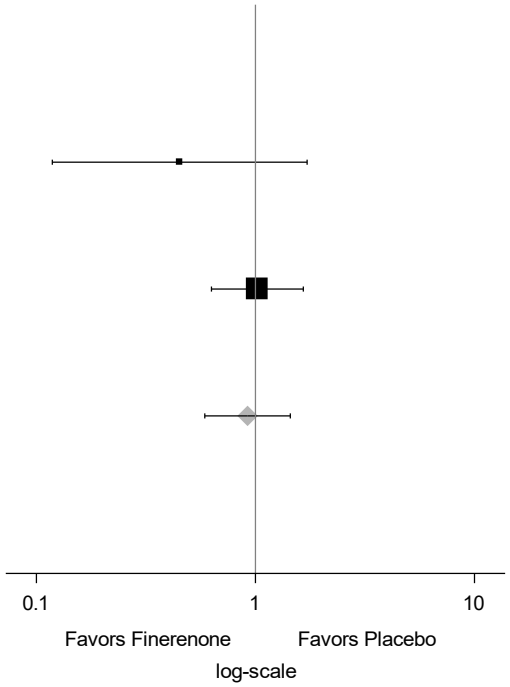
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	1 / 221	3.9	3.16 [0.33,30.11]	
FIGARO-DKD	36 / 2326	38 / 2302	96.1	0.94 [0.60,1.47]	
Total	39 / 2536	39 / 2523		0.99 [0.64,1.54]	Z=-0.03, p=0.9731
Heterogeneity:	Q=1.07 (df=1)	p=0.3005	I^2=6.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.177: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

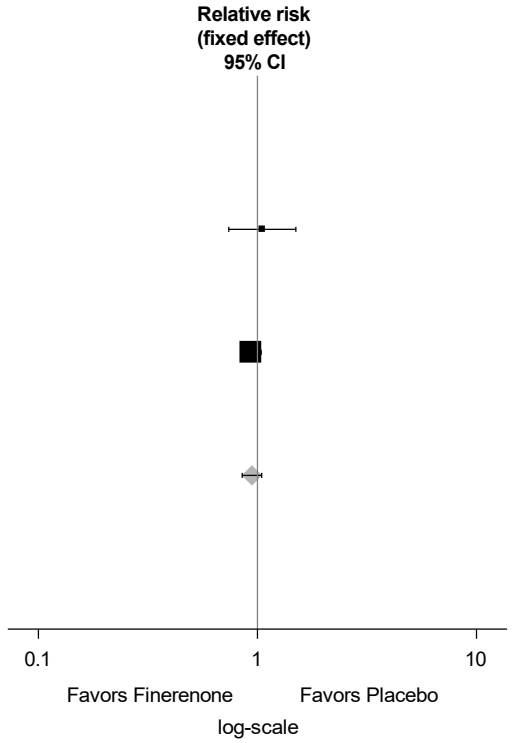
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	7 / 221	11.5	0.45 [0.12,1.72]	
FIGARO-DKD	33 / 2326	32 / 2302	88.5	1.02 [0.63,1.65]	
Total	36 / 2536	39 / 2523		0.92 [0.59,1.44]	Z=-0.36, p=0.7172
Heterogeneity:	Q=1.27 (df=1)	p=0.2606	I^2=21.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.178: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment AEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

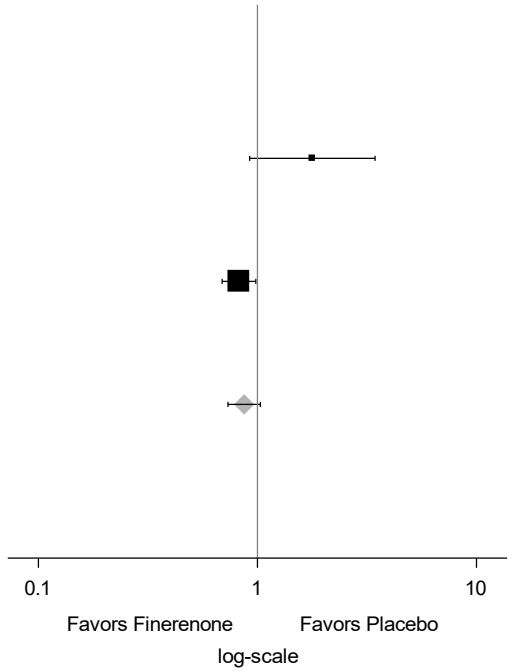
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 210	48 / 221	8.4	1.05 [0.74,1.50]	
FIGARO-DKD	505 / 2326	535 / 2302	91.6	0.93 [0.84,1.04]	
Total	553 / 2536	583 / 2523		0.94 [0.85,1.05]	Z=-1.11, p=0.2669
Heterogeneity:	Q=0.40 (df=1)	p=0.5264	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.179: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment SAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

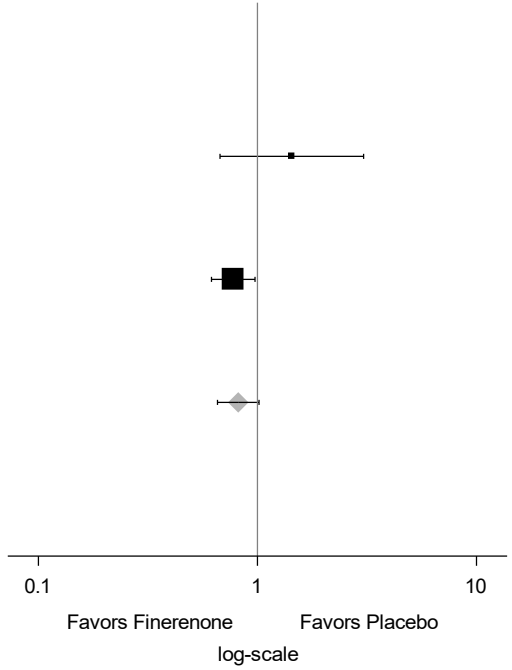
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	22 / 210	13 / 221	6.7	1.78 [0.92,3.44]	
FIGARO-DKD	203 / 2326	244 / 2302	93.3	0.82 [0.69,0.98]	
Total	225 / 2536	257 / 2523		0.87 [0.73,1.03]	Z=-1.61, p=0.1076
Heterogeneity:	Q=4.91 (df=1)	p=0.0267	I^2=79.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.1.180: Forestplot for Relative Risk of Proportion of Subjects with Severe Post-Treatment AEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

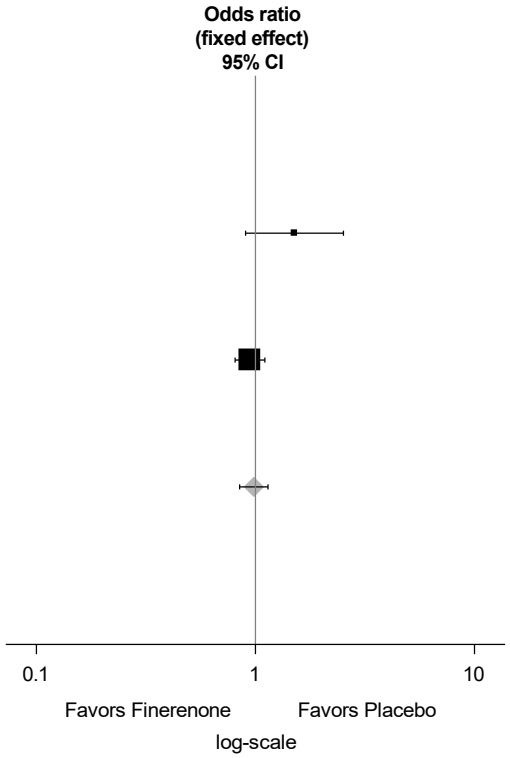
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	15 / 210	11 / 221	8.4	1.44 [0.67,3.05]	
FIGARO-DKD	123 / 2326	157 / 2302	91.6	0.78 [0.62,0.97]	
Total	138 / 2536	168 / 2523		0.82 [0.66,1.02]	Z=-1.81, p=0.0699
Heterogeneity:	Q=2.34 (df=1)	p=0.1260	I^2=57.3%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

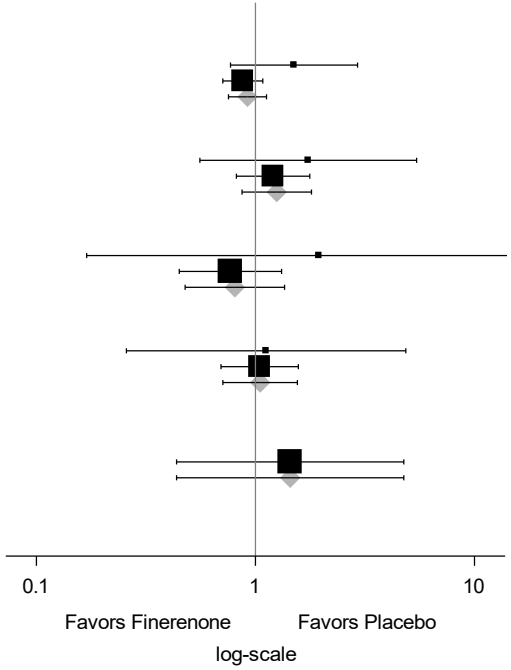
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 210	178 / 221	8.4	1.51 [0.90,2.52]	
FIGARO-DKD	1939 / 2326	1937 / 2302	91.6	0.94 [0.81,1.10]	
Total	2120 / 2536	2115 / 2523		0.98 [0.85,1.14]	Z=-0.23, p=0.8211
Heterogeneity:	Q=2.91 (df=1)	p=0.0879	I^2=65.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.1.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

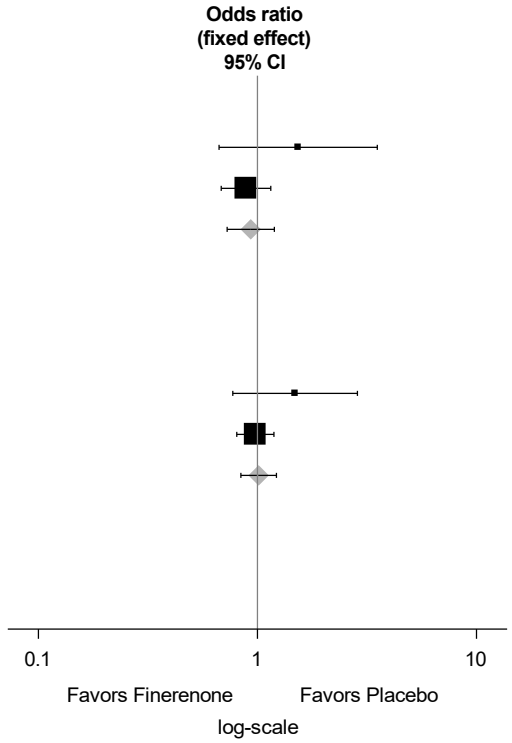
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	85 / 103	85 / 112	9.0	1.50 [0.77,2.93]	
FIGARO-DKD	885 / 1114	905 / 1110	91.0	0.88 [0.71,1.08]	
Total	970 / 1217	990 / 1222		0.92 [0.75,1.12]	Z=-0.82, p=0.4118
Heterogeneity:	Q=2.27 (df=1)	p=0.1317	I^2=56.0%		
North America					
FIDELIO-DKD	36 / 42	31 / 40	10.3	1.74 [0.56,5.44]	
FIGARO-DKD	227 / 292	206 / 277	89.7	1.20 [0.82,1.77]	
Total	263 / 334	237 / 317		1.25 [0.87,1.80]	Z=1.20, p=0.2290
Heterogeneity:	Q=0.36 (df=1)	p=0.5469	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 39	39 / 41	4.6	1.95 [0.17,22.40]	
FIGARO-DKD	490 / 522	498 / 523	95.4	0.77 [0.45,1.32]	
Total	528 / 561	537 / 564		0.81 [0.48,1.36]	Z=-0.81, p=0.4167
Heterogeneity:	Q=0.53 (df=1)	p=0.4658	I^2=0.0%		
Latin America					
FIDELIO-DKD	17 / 21	19 / 24	7.1	1.12 [0.26,4.86]	
FIGARO-DKD	266 / 322	259 / 316	92.9	1.05 [0.70,1.57]	
Total	283 / 343	278 / 340		1.05 [0.71,1.55]	Z=0.25, p=0.8056
Heterogeneity:	Q=0.01 (df=1)	p=0.9308	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 5	4 / 4	0.0	-	
FIGARO-DKD	71 / 76	69 / 76	100.0	1.44 [0.44,4.76]	
Total	76 / 81	73 / 80		1.44 [0.44,4.76]	Z=0.60, p=0.5492
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.16 (df=4)	p=0.5307	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.1.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

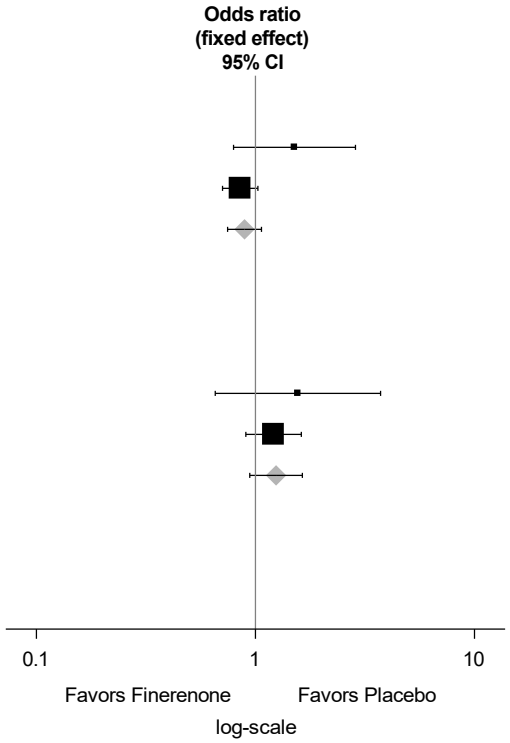
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	77 / 88	73 / 89	8.9	1.53 [0.67,3.52]	
FIGARO-DKD	667 / 811	674 / 803	91.1	0.89 [0.68,1.15]	
Total	744 / 899	747 / 892		0.93 [0.73,1.19]	Z=-0.56, p=0.5777
Heterogeneity:	Q=1.52 (df=1)	p=0.2174	I^2=34.3%		
Absent					
FIDELIO-DKD	104 / 122	105 / 132	8.2	1.49 [0.77,2.86]	
FIGARO-DKD	1272 / 1515	1263 / 1499	91.8	0.98 [0.80,1.19]	
Total	1376 / 1637	1368 / 1631		1.01 [0.84,1.22]	Z=0.13, p=0.8949
Heterogeneity:	Q=1.44 (df=1)	p=0.2307	I^2=30.4%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6001	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.1.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

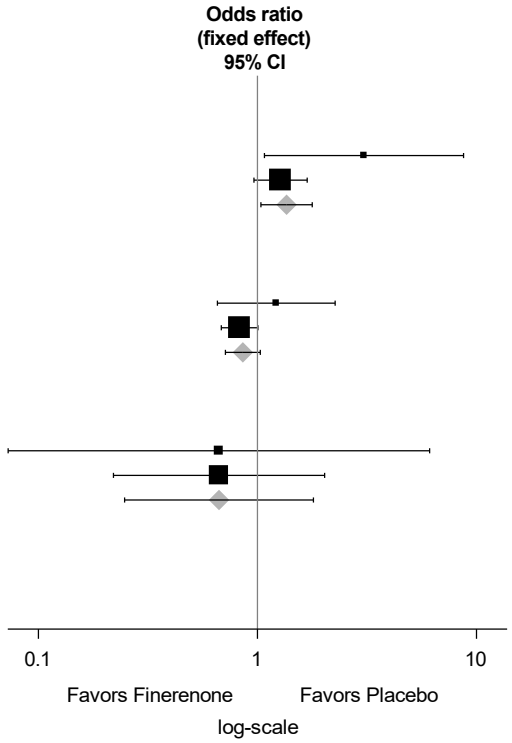
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	126 / 144	130 / 158	7.8	1.51 [0.79,2.86]	
FIGARO-DKD	1433 / 1719	1435 / 1679	92.2	0.85 [0.71,1.03]	
Total	1559 / 1863	1565 / 1837		0.89 [0.75,1.07]	Z=-1.26, p=0.2060
Heterogeneity:	Q=2.81 (df=1)	p=0.0936	I^2=64.4%		
> 4.5					
FIDELIO-DKD	55 / 66	48 / 63	10.1	1.56 [0.66,3.73]	
FIGARO-DKD	506 / 607	501 / 622	89.9	1.21 [0.90,1.62]	
Total	561 / 673	549 / 685		1.24 [0.94,1.64]	Z=1.54, p=0.1244
Heterogeneity:	Q=0.30 (df=1)	p=0.5846	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.91 (df=1)	p=0.0481	I^2=74.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.1.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

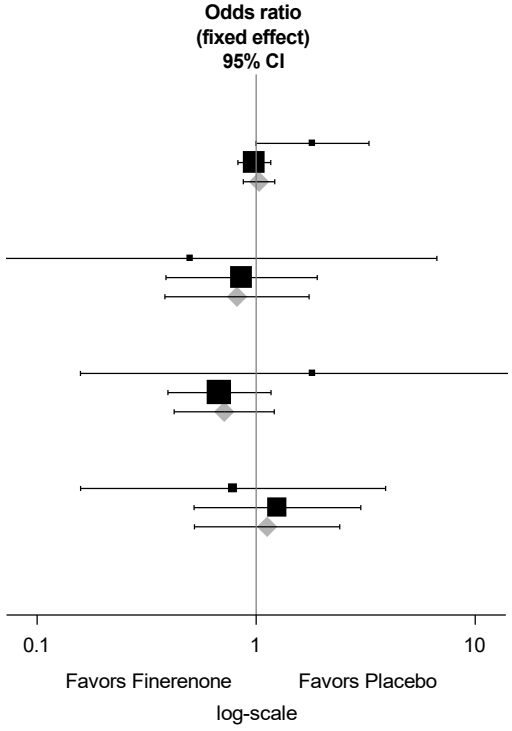
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	58 / 64	41 / 54	6.7	3.07 [1.08,8.73]	
FIGARO-DKD	586 / 693	567 / 699	93.3	1.27 [0.96,1.69]	
Total	644 / 757	608 / 753		1.36 [1.04,1.78]	Z=2.22, p=0.0262
Heterogeneity:	Q=2.52 (df=1)	p=0.1125	I^2=60.3%		
130 - < 160					
FIDELIO-DKD	117 / 138	128 / 156	8.8	1.22 [0.66,2.26]	
FIGARO-DKD	1288 / 1560	1297 / 1524	91.2	0.83 [0.68,1.00]	
Total	1405 / 1698	1425 / 1680		0.86 [0.71,1.03]	Z=-1.64, p=0.1008
Heterogeneity:	Q=1.36 (df=1)	p=0.2435	I^2=26.5%		
>= 160					
FIDELIO-DKD	6 / 8	9 / 11	20.1	0.67 [0.07,6.11]	
FIGARO-DKD	65 / 73	73 / 79	79.9	0.67 [0.22,2.03]	
Total	71 / 81	82 / 90		0.67 [0.25,1.80]	Z=-0.80, p=0.4248
Heterogeneity:	Q=0.00 (df=1)	p=0.9989	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.22 (df=2)	p=0.0164	I^2=75.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.1.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

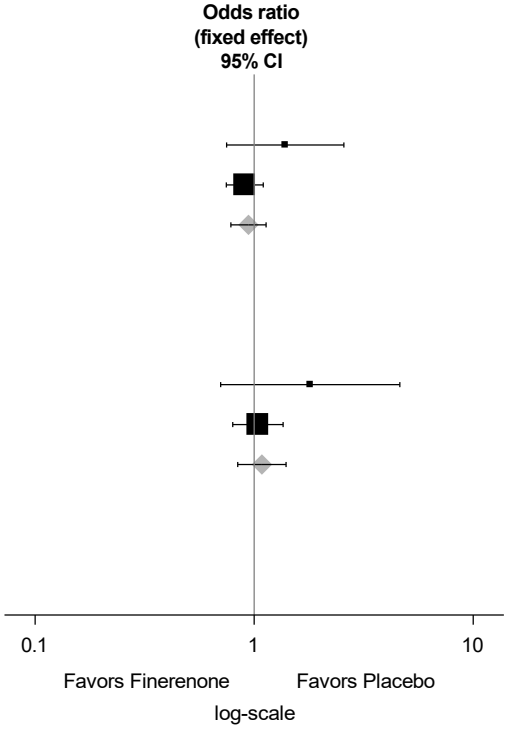
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	118 / 139	115 / 152	7.8	1.81 [1.00,3.27]	
FIGARO-DKD	1330 / 1658	1298 / 1612	92.2	0.98 [0.83,1.17]	
Total	1448 / 1797	1413 / 1764		1.03 [0.87,1.22]	Z=0.36, p=0.7219
Heterogeneity:	Q=3.75 (df=1)	p=0.0527	I^2=73.4%		
Black					
FIDELIO-DKD	8 / 10	8 / 9	8.6	0.50 [0.04,6.68]	
FIGARO-DKD	54 / 70	59 / 74	91.4	0.86 [0.39,1.90]	
Total	62 / 80	67 / 83		0.82 [0.38,1.74]	Z=-0.52, p=0.6020
Heterogeneity:	Q=0.15 (df=1)	p=0.6963	I^2=0.0%		
Asian					
FIDELIO-DKD	38 / 39	42 / 44	4.7	1.81 [0.16,20.77]	
FIGARO-DKD	431 / 464	461 / 485	95.3	0.68 [0.40,1.17]	
Total	469 / 503	503 / 529		0.71 [0.42,1.21]	Z=-1.25, p=0.2106
Heterogeneity:	Q=0.59 (df=1)	p=0.4427	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 22	13 / 16	23.0	0.78 [0.16,3.90]	
FIGARO-DKD	124 / 134	119 / 131	77.0	1.25 [0.52,3.00]	
Total	141 / 156	132 / 147		1.12 [0.52,2.41]	Z=0.29, p=0.7683
Heterogeneity:	Q=0.25 (df=1)	p=0.6171	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.05 (df=3)	p=0.5628	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.1.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

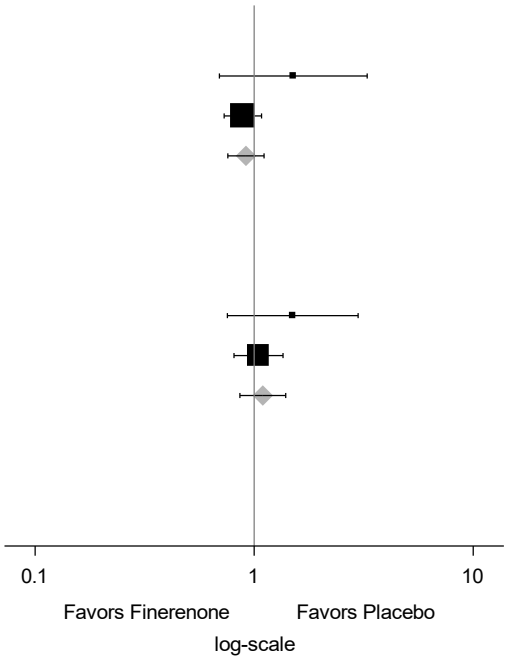
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	131 / 152	126 / 154	9.0	1.39 [0.75,2.57]	
FIGARO-DKD	1363 / 1610	1407 / 1638	91.0	0.91 [0.75,1.10]	
Total	1494 / 1762	1533 / 1792		0.94 [0.78,1.13]	Z=-0.63, p=0.5258
Heterogeneity:	Q=1.66 (df=1)	p=0.1971	I^2=39.9%		
Female					
FIDELIO-DKD	50 / 58	52 / 67	7.3	1.80 [0.70,4.62]	
FIGARO-DKD	576 / 716	530 / 664	92.7	1.04 [0.80,1.36]	
Total	626 / 774	582 / 731		1.08 [0.84,1.40]	Z=0.63, p=0.5309
Heterogeneity:	Q=1.21 (df=1)	p=0.2705	I^2=17.6%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3788	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.1.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

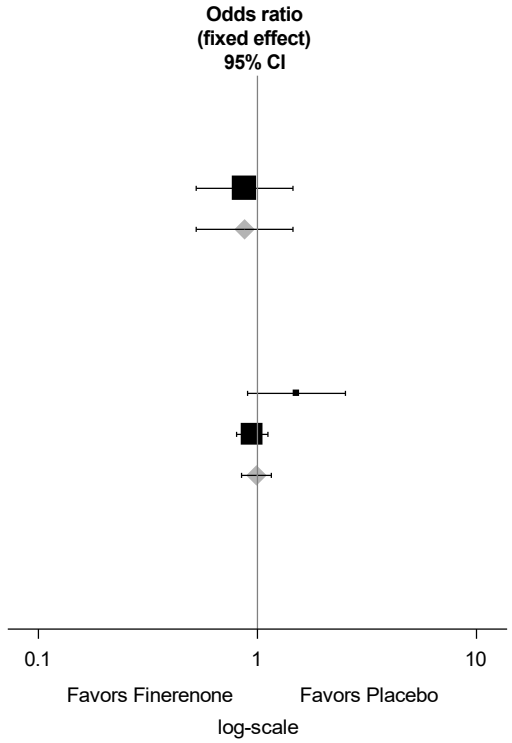
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	85 / 98	78 / 96	6.0	1.51 [0.69,3.28]	
FIGARO-DKD	1165 / 1416	1192 / 1420	94.0	0.89 [0.73,1.08]	
Total	1250 / 1514	1270 / 1516		0.92 [0.76,1.11]	Z=-0.89, p=0.3729
Heterogeneity:	Q=1.68 (df=1)	p=0.1945	I^2=40.6%		
>= 65					
FIDELIO-DKD	96 / 112	100 / 125	12.3	1.50 [0.75,2.98]	
FIGARO-DKD	774 / 910	745 / 882	87.7	1.05 [0.81,1.35]	
Total	870 / 1022	845 / 1007		1.09 [0.86,1.39]	Z=0.74, p=0.4606
Heterogeneity:	Q=0.92 (df=1)	p=0.3364	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=1)	p=0.2579	I^2=21.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.1.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

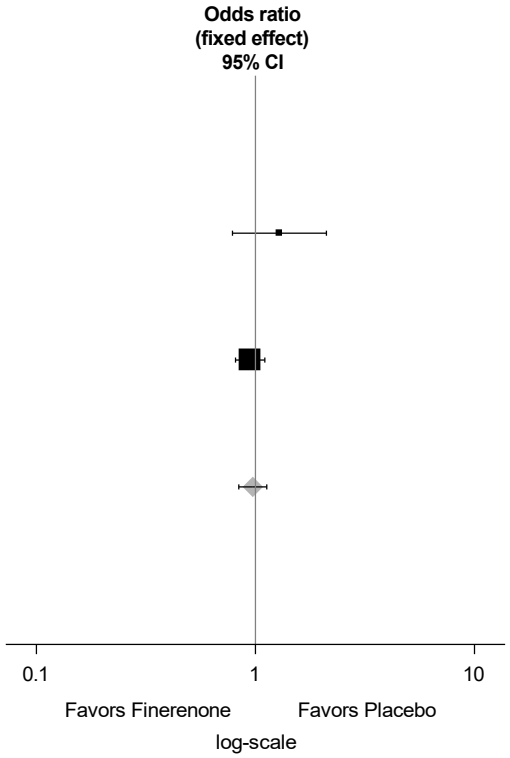
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	327 / 363	312 / 342	100.0	0.87 [0.53,1.45]	
Total	327 / 363	312 / 342		0.87 [0.53,1.45]	Z=-0.52, p=0.6020
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	181 / 210	178 / 221	9.3	1.51 [0.90,2.52]	
FIGARO-DKD	1612 / 1963	1625 / 1960	90.7	0.95 [0.80,1.12]	
Total	1793 / 2173	1803 / 2181		0.99 [0.85,1.16]	Z=-0.13, p=0.8947
Heterogeneity:	Q=2.85 (df=1)	p=0.0913	I^2=64.9%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

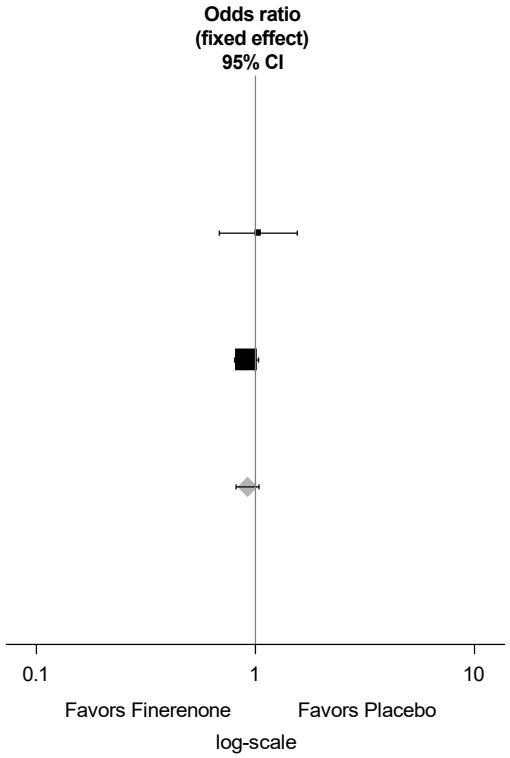
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	176 / 210	177 / 221	8.9	1.29 [0.79,2.11]	
FIGARO-DKD	1926 / 2326	1924 / 2302	91.1	0.95 [0.81,1.10]	
Total	2102 / 2536	2101 / 2523		0.97 [0.84,1.13]	Z=-0.37, p=0.7089
Heterogeneity:	Q=1.36 (df=1)	p=0.2437	I^2=26.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

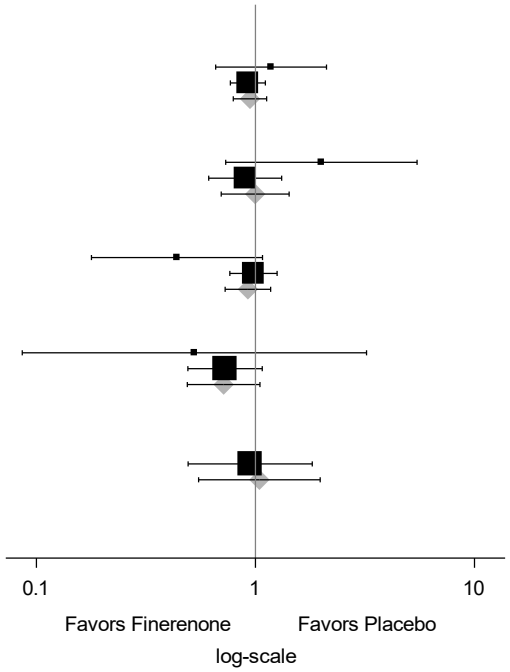
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 210	67 / 221	8.7	1.03 [0.68,1.55]	
FIGARO-DKD	666 / 2326	704 / 2302	91.3	0.91 [0.80,1.03]	
Total	731 / 2536	771 / 2523		0.92 [0.82,1.04]	Z=-1.35, p=0.1784
Heterogeneity:	Q=0.32 (df=1)	p=0.5725	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.3.1: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

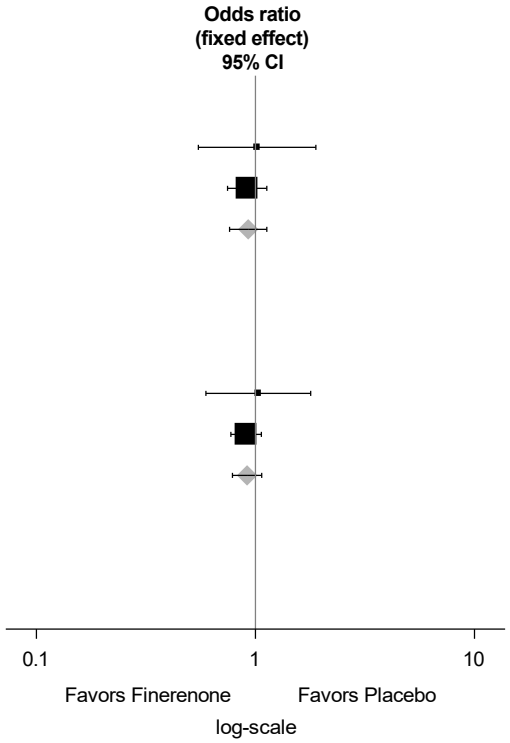
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	33 / 103	32 / 112	9.1	1.18 [0.66,2.11]	
FIGARO-DKD	310 / 1114	327 / 1110	90.9	0.92 [0.77,1.11]	
Total	343 / 1217	359 / 1222		0.94 [0.79,1.12]	Z=-0.65, p=0.5188
Heterogeneity:	Q=0.61 (df=1)	p=0.4334	I^2=0.0%		
North America					
FIDELIO-DKD	14 / 42	8 / 40	12.7	2.00 [0.73,5.47]	
FIGARO-DKD	68 / 292	70 / 277	87.3	0.90 [0.61,1.32]	
Total	82 / 334	78 / 317		1.00 [0.70,1.42]	Z=-0.02, p=0.9873
Heterogeneity:	Q=2.13 (df=1)	p=0.1447	I^2=53.0%		
Asia					
FIDELIO-DKD	14 / 39	23 / 41	7.1	0.44 [0.18,1.08]	
FIGARO-DKD	203 / 522	206 / 523	92.9	0.98 [0.76,1.26]	
Total	217 / 561	229 / 564		0.92 [0.73,1.17]	Z=-0.65, p=0.5147
Heterogeneity:	Q=2.85 (df=1)	p=0.0912	I^2=65.0%		
Latin America					
FIDELIO-DKD	2 / 21	4 / 24	4.5	0.53 [0.09,3.22]	
FIGARO-DKD	56 / 322	71 / 316	95.5	0.73 [0.49,1.07]	
Total	58 / 343	75 / 340		0.72 [0.49,1.05]	Z=-1.72, p=0.0860
Heterogeneity:	Q=0.12 (df=1)	p=0.7330	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 5	0 / 4	0.0	511E9 [511E9,511E9]	
FIGARO-DKD	29 / 76	30 / 76	100.0	0.95 [0.49,1.82]	
Total	31 / 81	30 / 80		1.04 [0.55,1.97]	Z=0.13, p=0.8991
Heterogeneity:	Q=0.08 (df=1)	p=0.7714	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=4)	p=0.7201	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.3.2: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

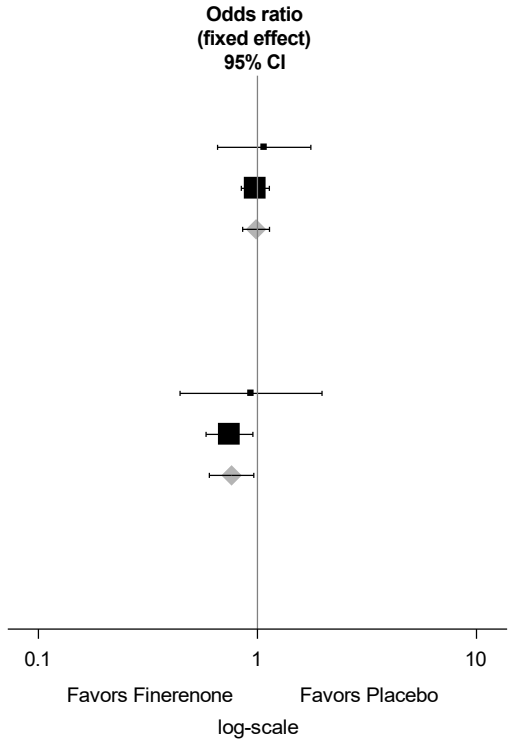
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	31 / 88	31 / 89	10.0	1.02 [0.55,1.89]	
FIGARO-DKD	266 / 811	279 / 803	90.0	0.92 [0.75,1.13]	
Total	297 / 899	310 / 892		0.93 [0.76,1.13]	Z=-0.77, p=0.4435
Heterogeneity:	Q=0.10 (df=1)	p=0.7533	I^2=0.0%		
Absent					
FIDELIO-DKD	34 / 122	36 / 132	7.8	1.03 [0.59,1.79]	
FIGARO-DKD	400 / 1515	425 / 1499	92.2	0.91 [0.77,1.06]	
Total	434 / 1637	461 / 1631		0.92 [0.79,1.07]	Z=-1.12, p=0.2615
Heterogeneity:	Q=0.19 (df=1)	p=0.6620	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9273	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.3.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

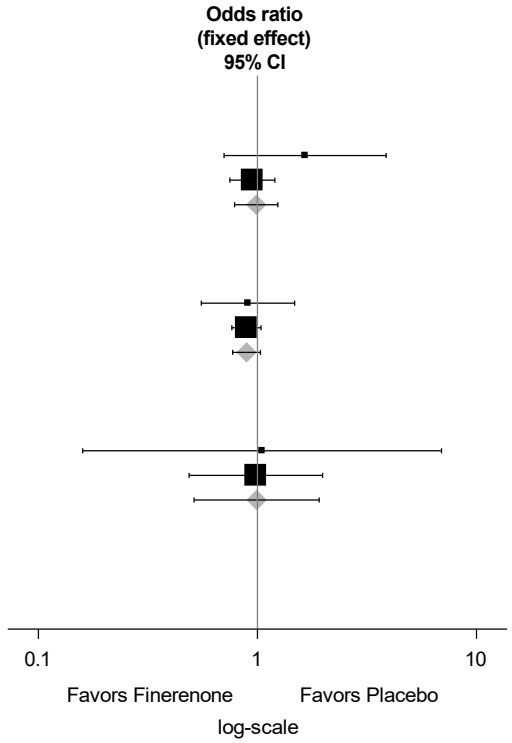
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	45 / 144	47 / 158	8.3	1.07 [0.66,1.75]	
FIGARO-DKD	505 / 1719	501 / 1679	91.7	0.98 [0.84,1.13]	
Total	550 / 1863	548 / 1837		0.99 [0.86,1.14]	Z=-0.20, p=0.8409
Heterogeneity:	Q=0.13 (df=1)	p=0.7217	I^2=0.0%		
> 4.5					
FIDELIO-DKD	20 / 66	20 / 63	9.8	0.93 [0.44,1.97]	
FIGARO-DKD	161 / 607	203 / 622	90.2	0.75 [0.58,0.95]	
Total	181 / 673	223 / 685		0.76 [0.60,0.96]	Z=-2.28, p=0.0225
Heterogeneity:	Q=0.32 (df=1)	p=0.5716	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.42 (df=1)	p=0.0643	I^2=70.8%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.3.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

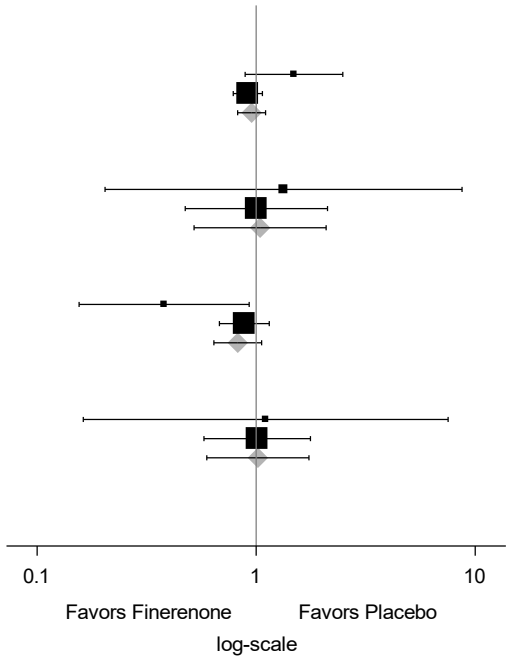
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	19 / 64	11 / 54	7.2	1.65 [0.70,3.87]	
FIGARO-DKD	184 / 693	193 / 699	92.8	0.95 [0.75,1.20]	
Total	203 / 757	204 / 753		0.99 [0.79,1.24]	Z=-0.11, p=0.9114
Heterogeneity:	Q=1.51 (df=1)	p=0.2189	I^2=33.9%		
130 - < 160					
FIDELIO-DKD	43 / 138	52 / 156	8.9	0.91 [0.55,1.48]	
FIGARO-DKD	461 / 1560	488 / 1524	91.1	0.89 [0.76,1.04]	
Total	504 / 1698	540 / 1680		0.89 [0.77,1.03]	Z=-1.54, p=0.1244
Heterogeneity:	Q=0.00 (df=1)	p=0.9501	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 8	4 / 11	12.2	1.05 [0.16,6.92]	
FIGARO-DKD	21 / 73	23 / 79	87.8	0.98 [0.49,1.98]	
Total	24 / 81	27 / 90		0.99 [0.51,1.91]	Z=-0.03, p=0.9789
Heterogeneity:	Q=0.00 (df=1)	p=0.9490	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=2)	p=0.7437	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.3.5: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

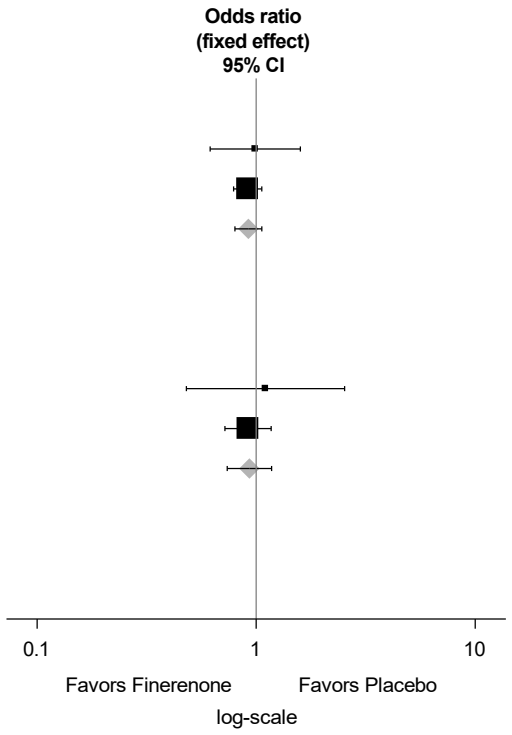
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 139	37 / 152	8.2	1.49 [0.89,2.49]	
FIGARO-DKD	444 / 1658	460 / 1612	91.8	0.92 [0.79,1.07]	
Total	489 / 1797	497 / 1764		0.95 [0.82,1.10]	Z=-0.64, p=0.5230
Heterogeneity:	Q=3.15 (df=1)	p=0.0759	I^2=68.3%		
Black					
FIDELIO-DKD	4 / 10	3 / 9	13.7	1.33 [0.20,8.71]	
FIGARO-DKD	18 / 70	19 / 74	86.3	1.00 [0.47,2.12]	
Total	22 / 80	22 / 83		1.04 [0.52,2.09]	Z=0.12, p=0.9070
Heterogeneity:	Q=0.08 (df=1)	p=0.7817	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 39	25 / 44	7.9	0.38 [0.16,0.93]	
FIGARO-DKD	171 / 464	193 / 485	92.1	0.88 [0.68,1.15]	
Total	184 / 503	218 / 529		0.82 [0.64,1.06]	Z=-1.51, p=0.1307
Heterogeneity:	Q=3.15 (df=1)	p=0.0760	I^2=68.2%		
Others					
FIDELIO-DKD	3 / 22	2 / 16	7.8	1.11 [0.16,7.52]	
FIGARO-DKD	33 / 134	32 / 131	92.2	1.01 [0.58,1.77]	
Total	36 / 156	34 / 147		1.02 [0.59,1.74]	Z=0.07, p=0.9482
Heterogeneity:	Q=0.01 (df=1)	p=0.9302	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.21 (df=3)	p=0.7505	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.3.6: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

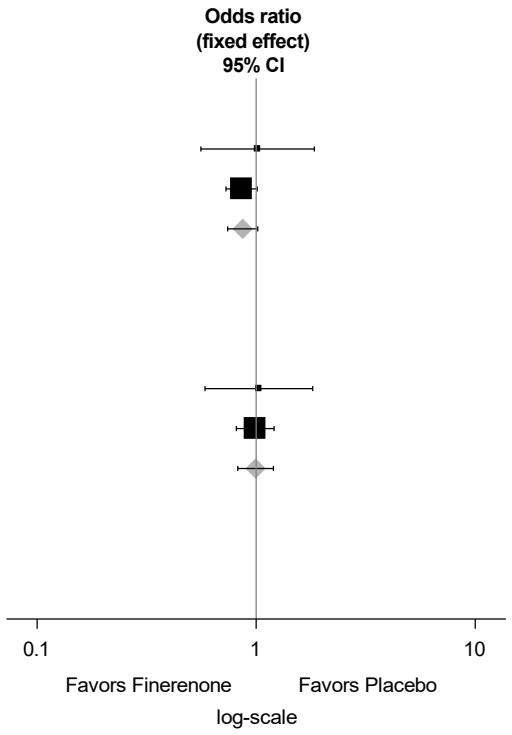
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 152	52 / 154	8.9	0.99 [0.62,1.59]	
FIGARO-DKD	491 / 1610	531 / 1638	91.1	0.91 [0.79,1.06]	
Total	542 / 1762	583 / 1792		0.92 [0.80,1.06]	Z=-1.14, p=0.2557
Heterogeneity:	Q=0.10 (df=1)	p=0.7537	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 58	15 / 67	7.9	1.10 [0.48,2.53]	
FIGARO-DKD	175 / 716	173 / 664	92.1	0.92 [0.72,1.17]	
Total	189 / 774	188 / 731		0.93 [0.74,1.18]	Z=-0.60, p=0.5506
Heterogeneity:	Q=0.17 (df=1)	p=0.6780	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9373	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.3.7: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

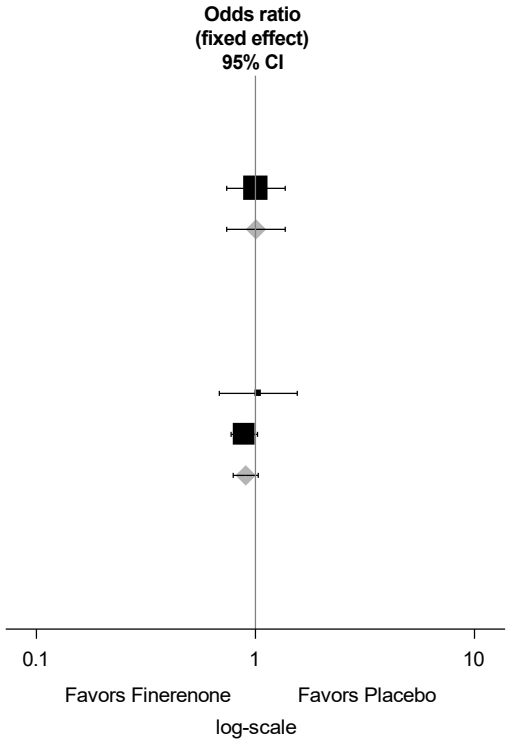
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 98	32 / 96	7.0	1.02 [0.56,1.84]	
FIGARO-DKD	375 / 1416	420 / 1420	93.0	0.86 [0.73,1.01]	
Total	408 / 1514	452 / 1516		0.87 [0.74,1.02]	Z=-1.75, p=0.0793
Heterogeneity:	Q=0.29 (df=1)	p=0.5927	I^2=0.0%		
>= 65					
FIDELIO-DKD	32 / 112	35 / 125	10.9	1.03 [0.58,1.81]	
FIGARO-DKD	291 / 910	284 / 882	89.1	0.99 [0.81,1.21]	
Total	323 / 1022	319 / 1007		0.99 [0.82,1.20]	Z=-0.06, p=0.9501
Heterogeneity:	Q=0.02 (df=1)	p=0.9003	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.18 (df=1)	p=0.2780	I^2=15.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.3.8: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

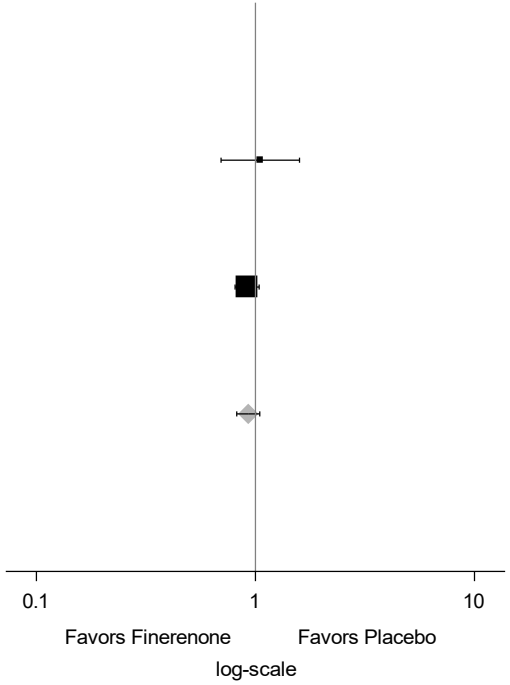
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	131 / 363	123 / 342	100.0	1.01 [0.74,1.37]	
Total	131 / 363	123 / 342		1.01 [0.74,1.37]	Z=0.03, p=0.9728
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	65 / 210	67 / 221	10.3	1.03 [0.68,1.55]	
FIGARO-DKD	535 / 1963	581 / 1960	89.7	0.89 [0.77,1.02]	
Total	600 / 2173	648 / 2181		0.90 [0.79,1.03]	Z=-1.52, p=0.1274
Heterogeneity:	Q=0.45 (df=1)	p=0.5045	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=1)	p=0.5285	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

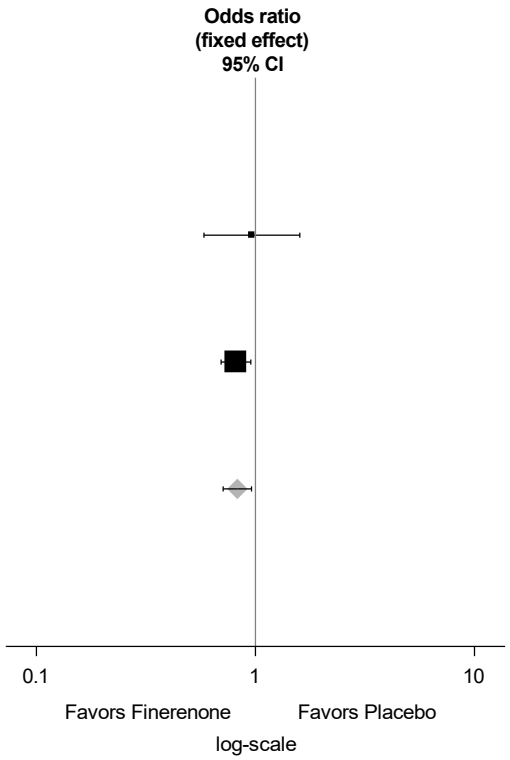
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 210	65 / 221	8.6	1.05 [0.70,1.59]	
FIGARO-DKD	661 / 2326	696 / 2302	91.4	0.92 [0.81,1.04]	
Total	725 / 2536	761 / 2523		0.93 [0.82,1.05]	Z=-1.23, p=0.2199
Heterogeneity:	Q=0.40 (df=1)	p=0.5294	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

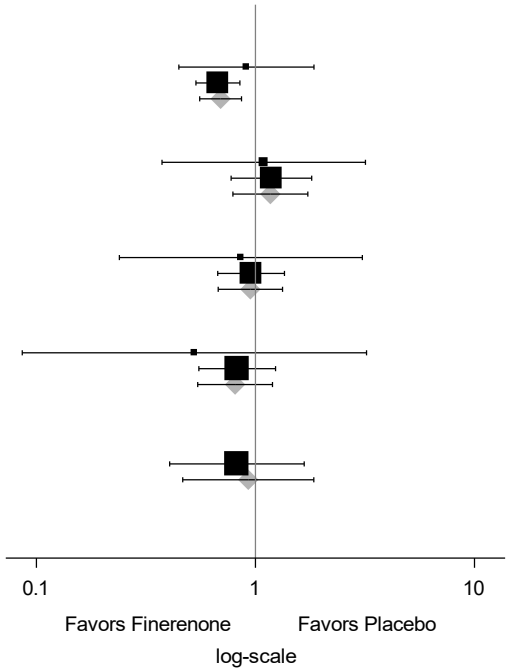
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 210	38 / 221	8.8	0.96 [0.58,1.59]	
FIGARO-DKD	349 / 2326	410 / 2302	91.2	0.81 [0.70,0.95]	
Total	384 / 2536	448 / 2523		0.83 [0.71,0.96]	Z=-2.50, p=0.0123
Heterogeneity:	Q=0.39 (df=1)	p=0.5336	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.5.1: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

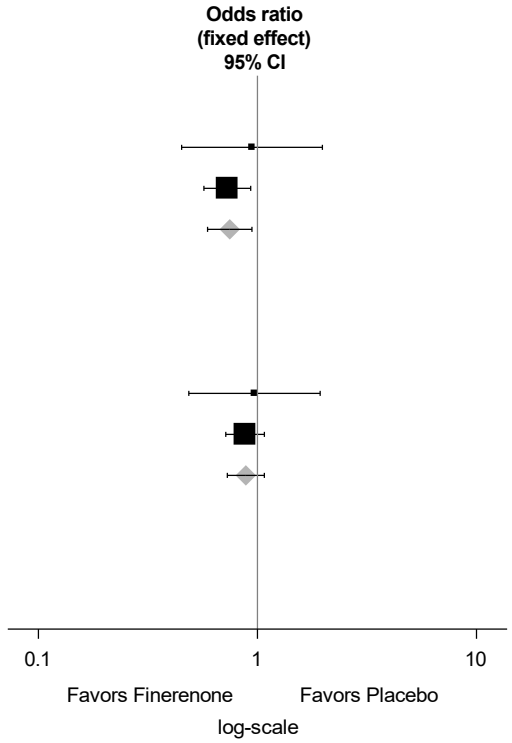
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	17 / 103	20 / 112	9.6	0.91 [0.45,1.85]	
FIGARO-DKD	146 / 1114	203 / 1110	90.4	0.67 [0.53,0.85]	
Total	163 / 1217	223 / 1222		0.69 [0.56,0.86]	Z=-3.27, p=0.0011
Heterogeneity:	Q=0.62 (df=1)	p=0.4318	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 42	8 / 40	13.6	1.09 [0.37,3.18]	
FIGARO-DKD	58 / 292	48 / 277	86.4	1.18 [0.77,1.81]	
Total	67 / 334	56 / 317		1.17 [0.79,1.73]	Z=0.78, p=0.4354
Heterogeneity:	Q=0.02 (df=1)	p=0.8907	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 39	6 / 41	7.0	0.86 [0.24,3.08]	
FIGARO-DKD	71 / 522	74 / 523	93.0	0.96 [0.67,1.36]	
Total	76 / 561	80 / 564		0.95 [0.68,1.33]	Z=-0.31, p=0.7570
Heterogeneity:	Q=0.03 (df=1)	p=0.8736	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	4 / 24	4.7	0.53 [0.09,3.22]	
FIGARO-DKD	54 / 322	62 / 316	95.3	0.83 [0.55,1.24]	
Total	56 / 343	66 / 340		0.81 [0.54,1.20]	Z=-1.07, p=0.2857
Heterogeneity:	Q=0.23 (df=1)	p=0.6342	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 5	0 / 4	0.0	511E9 [511E9,511E9]	
FIGARO-DKD	20 / 76	23 / 76	100.0	0.82 [0.41,1.67]	
Total	22 / 81	23 / 80		0.93 [0.47,1.85]	Z=-0.21, p=0.8299
Heterogeneity:	Q=0.11 (df=1)	p=0.7409	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.20 (df=4)	p=0.1850	I^2=35.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.5.2: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

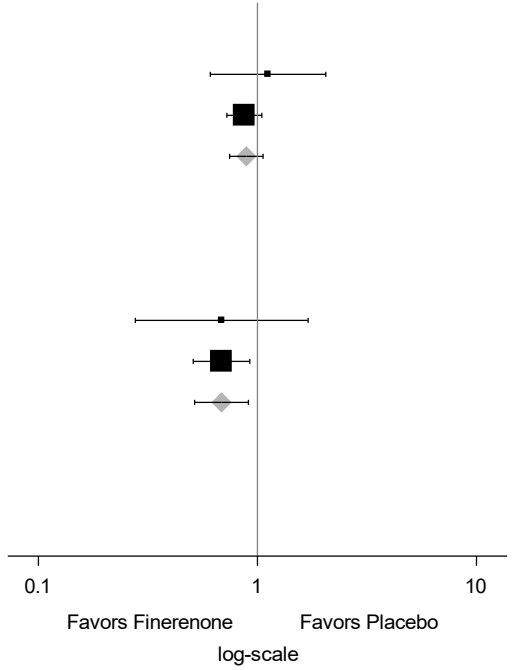
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 88	18 / 89	9.9	0.94 [0.45,1.98]	
FIGARO-DKD	141 / 811	180 / 803	90.1	0.73 [0.57,0.93]	
Total	158 / 899	198 / 892		0.75 [0.59,0.94]	Z=-2.45, p=0.0144
Heterogeneity:	Q=0.43 (df=1)	p=0.5138	I^2=0.0%		
Absent					
FIDELIO-DKD	18 / 122	20 / 132	7.9	0.97 [0.49,1.93]	
FIGARO-DKD	208 / 1515	230 / 1499	92.1	0.88 [0.72,1.08]	
Total	226 / 1637	250 / 1631		0.88 [0.73,1.08]	Z=-1.23, p=0.2184
Heterogeneity:	Q=0.07 (df=1)	p=0.7879	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.19 (df=1)	p=0.2756	I^2=15.9%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.5.3: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

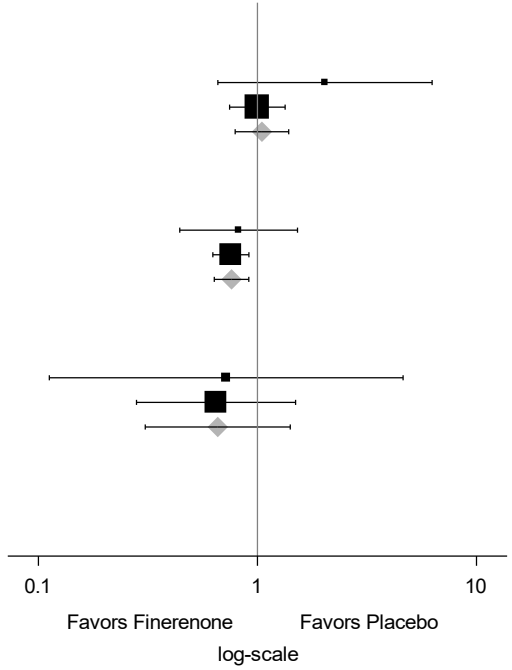
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	25 / 158	8.4	1.12 [0.61,2.05]	
FIGARO-DKD	259 / 1719	284 / 1679	91.6	0.87 [0.73,1.05]	
Total	284 / 1863	309 / 1837		0.89 [0.75,1.06]	Z=-1.30, p=0.1927
Heterogeneity:	Q=0.59 (df=1)	p=0.4417	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 66	13 / 63	9.7	0.69 [0.28,1.70]	
FIGARO-DKD	90 / 607	126 / 622	90.3	0.69 [0.51,0.92]	
Total	100 / 673	139 / 685		0.69 [0.52,0.91]	Z=-2.62, p=0.0088
Heterogeneity:	Q=0.00 (df=1)	p=0.9963	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.36 (df=1)	p=0.1244	I^2=57.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.5.4: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

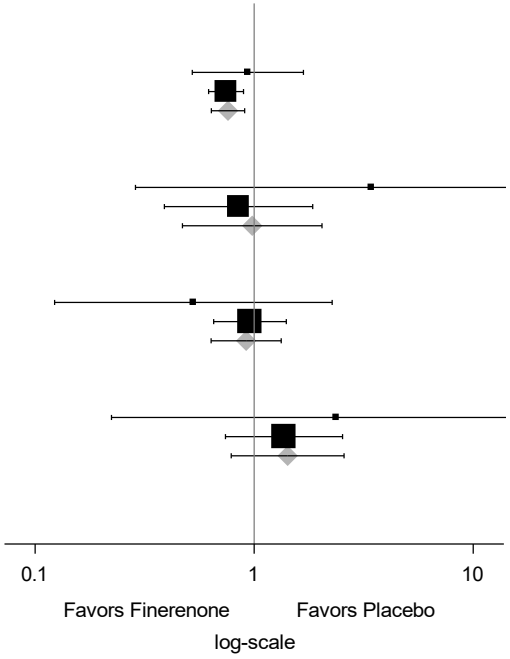
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	11 / 64	5 / 54	6.3	2.03 [0.66,6.27]	
FIGARO-DKD	106 / 693	107 / 699	93.7	1.00 [0.75,1.34]	
Total	117 / 757	112 / 753		1.05 [0.79,1.39]	Z=0.33, p=0.7434
Heterogeneity:	Q=1.43 (df=1)	p=0.2310	I^2=30.3%		
130 - < 160					
FIDELIO-DKD	21 / 138	28 / 156	8.6	0.82 [0.44,1.52]	
FIGARO-DKD	232 / 1560	286 / 1524	91.4	0.76 [0.63,0.91]	
Total	253 / 1698	314 / 1680		0.76 [0.64,0.91]	Z=-2.94, p=0.0032
Heterogeneity:	Q=0.06 (df=1)	p=0.8048	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 8	5 / 11	16.8	0.72 [0.11,4.62]	
FIGARO-DKD	11 / 73	17 / 79	83.2	0.65 [0.28,1.49]	
Total	14 / 81	22 / 90		0.66 [0.31,1.41]	Z=-1.07, p=0.2831
Heterogeneity:	Q=0.01 (df=1)	p=0.9182	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.86 (df=2)	p=0.1451	I^2=48.2%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.5.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

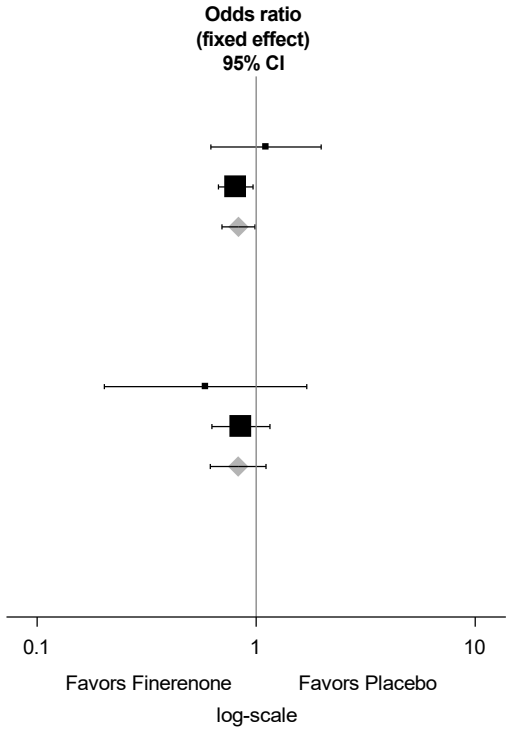
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	26 / 139	30 / 152	9.0	0.94 [0.52,1.68]	
FIGARO-DKD	247 / 1658	307 / 1612	91.0	0.74 [0.62,0.89]	
Total	273 / 1797	337 / 1764		0.76 [0.64,0.90]	Z=-3.08, p=0.0021
Heterogeneity:	Q=0.54 (df=1)	p=0.4634	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 10	1 / 9	9.0	3.43 [0.29,40.95]	
FIGARO-DKD	15 / 70	18 / 74	91.0	0.85 [0.39,1.85]	
Total	18 / 80	19 / 83		0.98 [0.47,2.04]	Z=-0.05, p=0.9562
Heterogeneity:	Q=1.11 (df=1)	p=0.2919	I^2=10.0%		
Asian					
FIDELIO-DKD	3 / 39	6 / 44	6.4	0.53 [0.12,2.27]	
FIGARO-DKD	58 / 464	63 / 485	93.6	0.96 [0.65,1.40]	
Total	61 / 503	69 / 529		0.92 [0.64,1.33]	Z=-0.45, p=0.6537
Heterogeneity:	Q=0.60 (df=1)	p=0.4393	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 22	1 / 16	6.4	2.37 [0.22,25.14]	
FIGARO-DKD	29 / 134	22 / 131	93.6	1.37 [0.74,2.53]	
Total	32 / 156	23 / 147		1.42 [0.79,2.57]	Z=1.16, p=0.2451
Heterogeneity:	Q=0.19 (df=1)	p=0.6595	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.63 (df=3)	p=0.2010	I^2=35.2%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.5.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

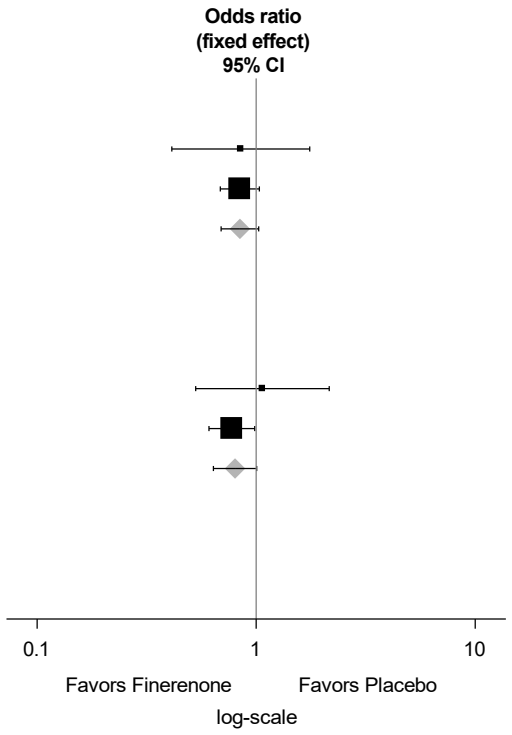
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 152	27 / 154	9.0	1.11 [0.62,1.98]	
FIGARO-DKD	256 / 1610	311 / 1638	91.0	0.81 [0.67,0.97]	
Total	285 / 1762	338 / 1792		0.83 [0.70,0.99]	Z=-2.10, p=0.0353
Heterogeneity:	Q=1.05 (df=1)	p=0.3047	I^2=5.1%		
Female					
FIDELIO-DKD	6 / 58	11 / 67	7.6	0.59 [0.20,1.70]	
FIGARO-DKD	93 / 716	99 / 664	92.4	0.85 [0.63,1.16]	
Total	99 / 774	110 / 731		0.83 [0.62,1.11]	Z=-1.27, p=0.2048
Heterogeneity:	Q=0.43 (df=1)	p=0.5103	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9859	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.5.7: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

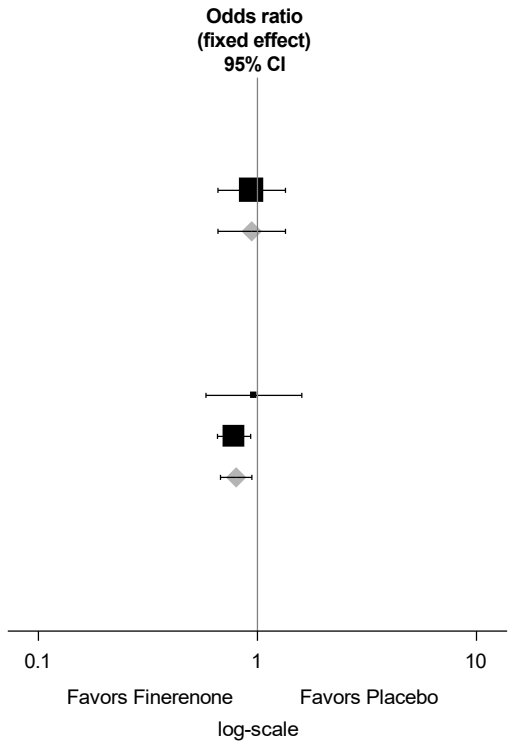
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	17 / 98	19 / 96	7.4	0.85 [0.41,1.76]	
FIGARO-DKD	200 / 1416	232 / 1420	92.6	0.84 [0.69,1.03]	
Total	217 / 1514	251 / 1516		0.84 [0.69,1.03]	Z=-1.70, p=0.0898
Heterogeneity:	Q=0.00 (df=1)	p=0.9796	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 112	19 / 125	10.5	1.07 [0.53,2.16]	
FIGARO-DKD	149 / 910	178 / 882	89.5	0.77 [0.61,0.98]	
Total	167 / 1022	197 / 1007		0.80 [0.64,1.01]	Z=-1.91, p=0.0558
Heterogeneity:	Q=0.72 (df=1)	p=0.3954	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7395	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.5.8: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

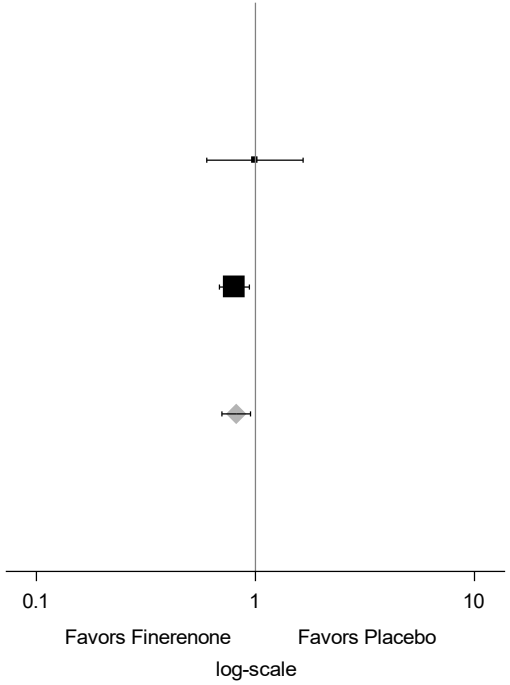
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	79 / 363	78 / 342	100.0	0.94 [0.66,1.34]	
Total	79 / 363	78 / 342		0.94 [0.66,1.34]	Z=-0.33, p=0.7392
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	35 / 210	38 / 221	10.7	0.96 [0.58,1.59]	
FIGARO-DKD	270 / 1963	332 / 1960	89.3	0.78 [0.66,0.93]	
Total	305 / 2173	370 / 2181		0.80 [0.68,0.94]	Z=-2.66, p=0.0078
Heterogeneity:	Q=0.59 (df=1)	p=0.4437	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=1)	p=0.4132	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

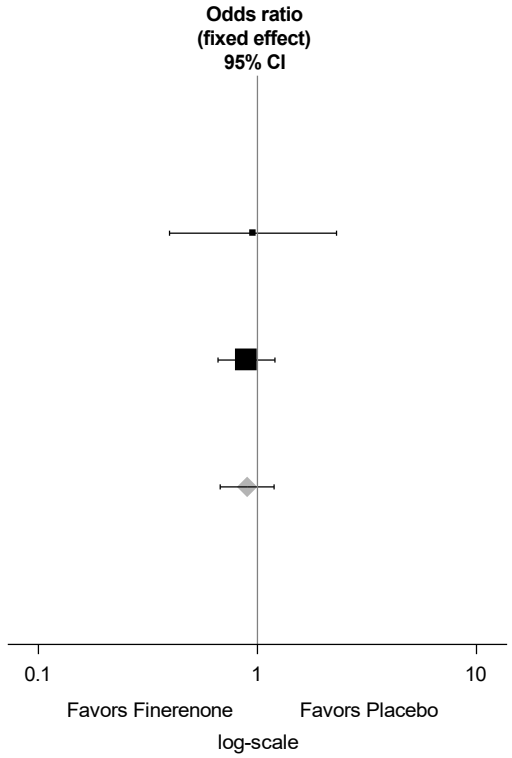
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 210	37 / 221	8.8	0.99 [0.60,1.65]	
FIGARO-DKD	339 / 2326	404 / 2302	91.2	0.80 [0.68,0.94]	
Total	374 / 2536	441 / 2523		0.82 [0.70,0.95]	Z=-2.64, p=0.0084
Heterogeneity:	Q=0.64 (df=1)	p=0.4251	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

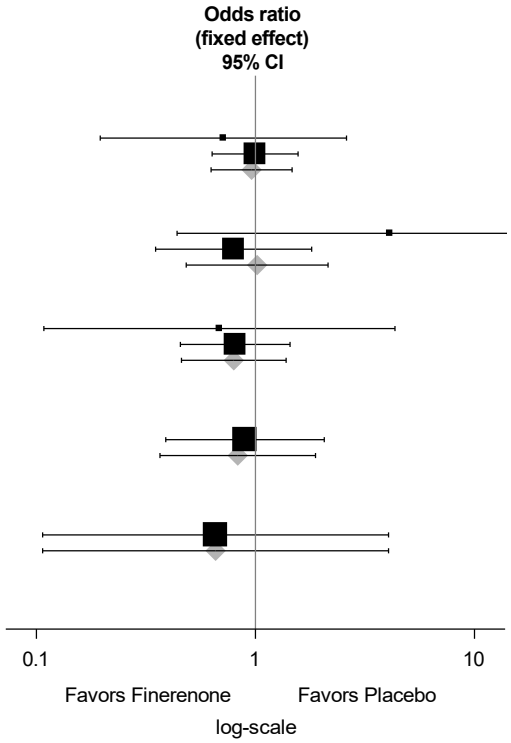
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	11 / 221	10.4	0.95 [0.40,2.30]	
FIGARO-DKD	85 / 2326	94 / 2302	89.6	0.89 [0.66,1.20]	
Total	95 / 2536	105 / 2523		0.90 [0.68,1.19]	Z=-0.75, p=0.4535
Heterogeneity:	Q=0.02 (df=1)	p=0.8841	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.7.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

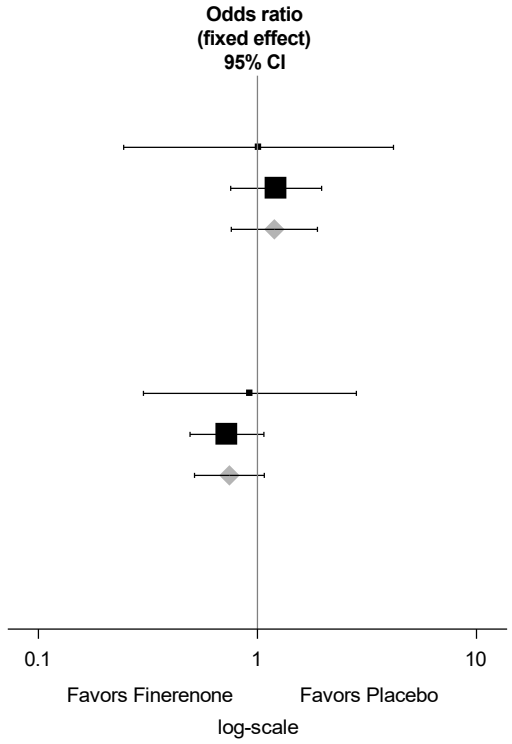
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	4 / 103	6 / 112	10.9	0.71 [0.20,2.60]	
FIGARO-DKD	39 / 1114	39 / 1110	89.1	1.00 [0.63,1.57]	
Total	43 / 1217	45 / 1222		0.96 [0.63,1.47]	Z=-0.19, p=0.8517
Heterogeneity:	Q=0.23 (df=1)	p=0.6336	I^2=0.0%		
North America					
FIDELIO-DKD	4 / 42	1 / 40	11.9	4.11 [0.44,38.42]	
FIGARO-DKD	11 / 292	13 / 277	88.1	0.79 [0.35,1.81]	
Total	15 / 334	14 / 317		1.02 [0.48,2.15]	Z=0.05, p=0.9628
Heterogeneity:	Q=1.84 (df=1)	p=0.1747	I^2=45.7%		
Asia					
FIDELIO-DKD	2 / 39	3 / 41	8.9	0.68 [0.11,4.34]	
FIGARO-DKD	22 / 522	27 / 523	91.1	0.81 [0.45,1.44]	
Total	24 / 561	30 / 564		0.80 [0.46,1.38]	Z=-0.81, p=0.4171
Heterogeneity:	Q=0.03 (df=1)	p=0.8664	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	11 / 322	12 / 316	100.0	0.90 [0.39,2.06]	
Total	11 / 343	13 / 340		0.83 [0.37,1.88]	Z=-0.45, p=0.6554
Heterogeneity:	Q=0.03 (df=1)	p=0.8574	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	3 / 76	100.0	0.66 [0.11,4.05]	
Total	2 / 81	3 / 80		0.66 [0.11,4.05]	Z=-0.45, p=0.6514
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=4)	p=0.9700	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.7.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

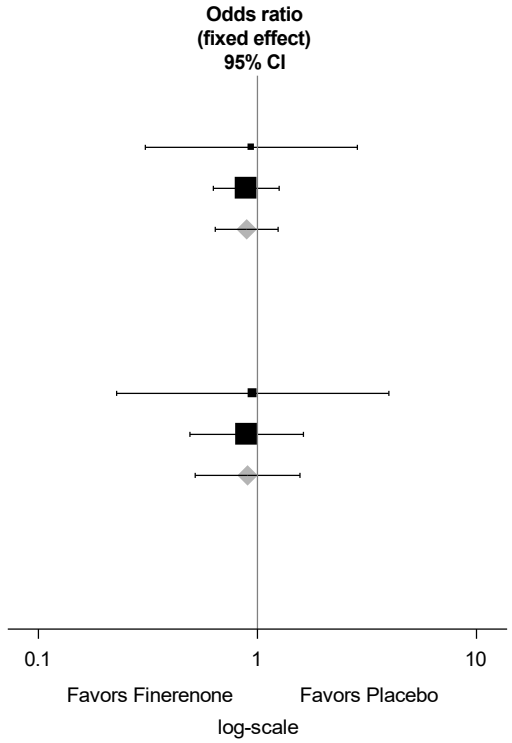
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	4 / 89	10.2	1.01 [0.25,4.18]	
FIGARO-DKD	39 / 811	32 / 803	89.8	1.22 [0.75,1.96]	
Total	43 / 899	36 / 892		1.19 [0.76,1.88]	Z=0.77, p=0.4417
Heterogeneity:	Q=0.06 (df=1)	p=0.8089	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 122	7 / 132	10.7	0.92 [0.30,2.83]	
FIGARO-DKD	46 / 1515	62 / 1499	89.3	0.73 [0.49,1.07]	
Total	52 / 1637	69 / 1631		0.74 [0.52,1.07]	Z=-1.58, p=0.1150
Heterogeneity:	Q=0.16 (df=1)	p=0.6900	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.53 (df=1)	p=0.1119	I^2=60.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.7.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

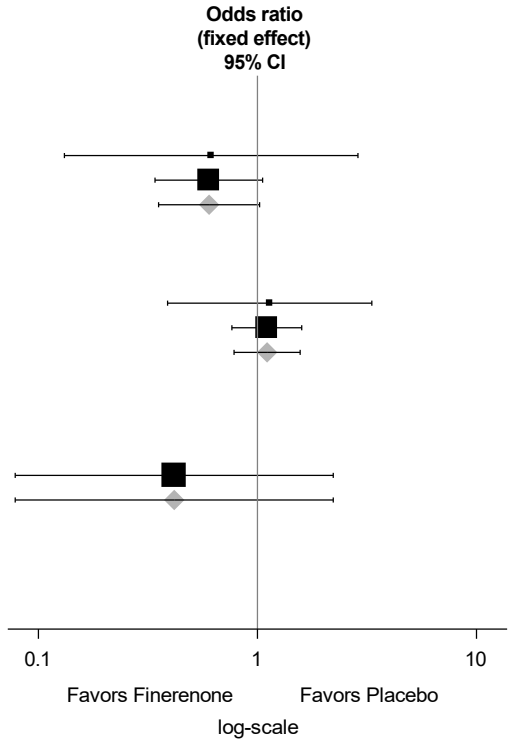
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	7 / 158	8.8	0.94 [0.31,2.86]	
FIGARO-DKD	64 / 1719	70 / 1679	91.2	0.89 [0.63,1.26]	
Total	70 / 1863	77 / 1837		0.89 [0.64,1.24]	Z=-0.67, p=0.5022
Heterogeneity:	Q=0.01 (df=1)	p=0.9282	I^2=0.0%		
> 4.5					
FIDELIO-DKD	4 / 66	4 / 63	14.8	0.95 [0.23,3.98]	
FIGARO-DKD	21 / 607	24 / 622	85.2	0.89 [0.49,1.62]	
Total	25 / 673	28 / 685		0.90 [0.52,1.56]	Z=-0.37, p=0.7116
Heterogeneity:	Q=0.01 (df=1)	p=0.9359	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9775	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.7.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

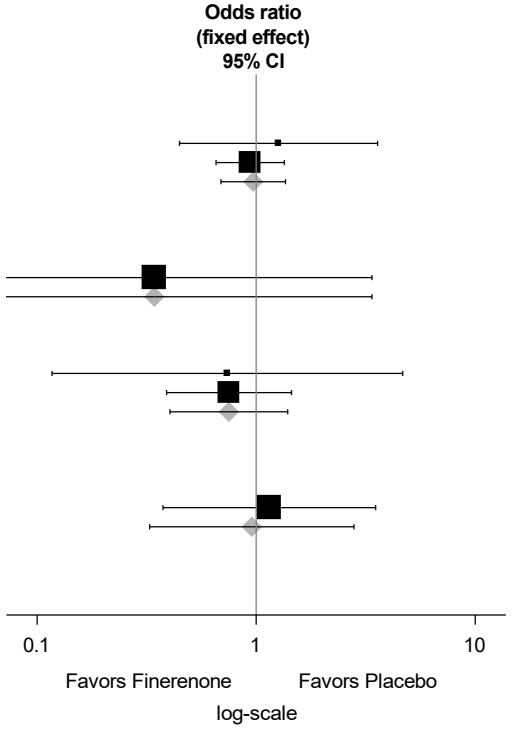
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	4 / 54	11.8	0.61 [0.13,2.88]	
FIGARO-DKD	20 / 693	33 / 699	88.2	0.60 [0.34,1.06]	
Total	23 / 757	37 / 753		0.60 [0.35,1.02]	Z=-1.88, p=0.0606
Heterogeneity:	Q=0.00 (df=1)	p=0.9765	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	7 / 138	7 / 156	10.5	1.14 [0.39,3.33]	
FIGARO-DKD	63 / 1560	56 / 1524	89.5	1.10 [0.76,1.59]	
Total	70 / 1698	63 / 1680		1.11 [0.78,1.57]	Z=0.57, p=0.5672
Heterogeneity:	Q=0.00 (df=1)	p=0.9579	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	5 / 79	100.0	0.42 [0.08,2.22]	
Total	2 / 81	5 / 90		0.42 [0.08,2.22]	Z=-1.03, p=0.3050
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.39 (df=2)	p=0.1115	I^2=54.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.7.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

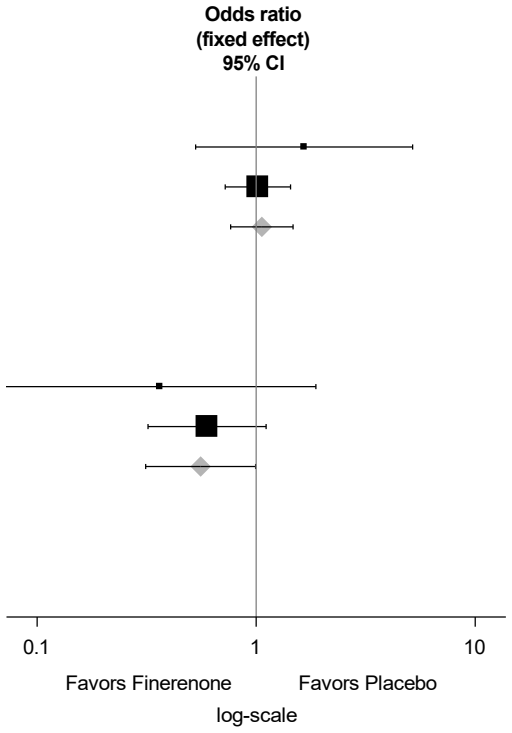
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 139	7 / 152	10.6	1.26 [0.45,3.58]	
FIGARO-DKD	61 / 1658	63 / 1612	89.4	0.94 [0.66,1.34]	
Total	69 / 1797	70 / 1764		0.97 [0.69,1.36]	Z=-0.18, p=0.8575
Heterogeneity:	Q=0.28 (df=1)	p=0.5962	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	3 / 74	100.0	0.34 [0.03,3.38]	
Total	1 / 80	3 / 83		0.34 [0.03,3.38]	Z=-0.92, p=0.3592
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 39	3 / 44	11.3	0.74 [0.12,4.67]	
FIGARO-DKD	16 / 464	22 / 485	88.7	0.75 [0.39,1.45]	
Total	18 / 503	25 / 529		0.75 [0.40,1.39]	Z=-0.91, p=0.3626
Heterogeneity:	Q=0.00 (df=1)	p=0.9862	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,48E295]	
FIGARO-DKD	7 / 134	6 / 131	100.0	1.15 [0.38,3.51]	
Total	7 / 156	7 / 147		0.96 [0.33,2.80]	Z=-0.08, p=0.9334
Heterogeneity:	Q=0.10 (df=1)	p=0.7469	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.21 (df=3)	p=0.7502	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.7.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

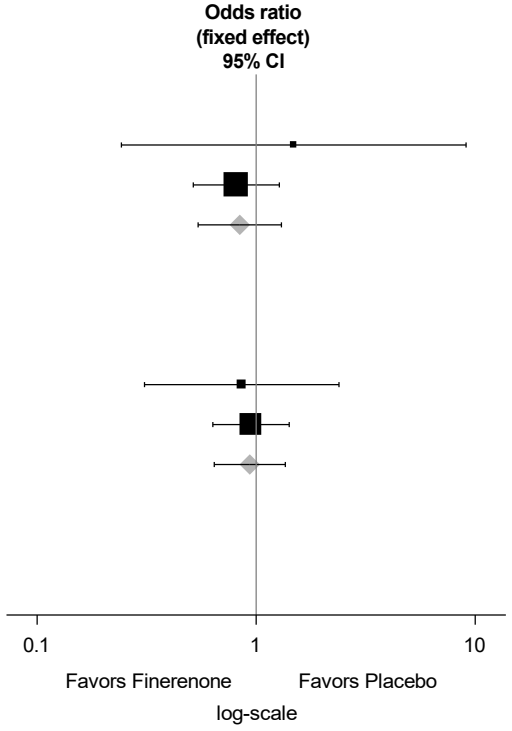
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	5 / 154	8.3	1.66 [0.53,5.18]	
FIGARO-DKD	68 / 1610	68 / 1638	91.7	1.02 [0.72,1.44]	
Total	76 / 1762	73 / 1792		1.06 [0.76,1.47]	Z=0.36, p=0.7216
Heterogeneity:	Q=0.64 (df=1)	p=0.4237	I^2=0.0%		
Female					
FIDELIO-DKD	2 / 58	6 / 67	12.5	0.36 [0.07,1.87]	
FIGARO-DKD	17 / 716	26 / 664	87.5	0.60 [0.32,1.11]	
Total	19 / 774	32 / 731		0.56 [0.31,0.99]	Z=-1.98, p=0.0477
Heterogeneity:	Q=0.31 (df=1)	p=0.5786	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.60 (df=1)	p=0.0577	I^2=72.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.7.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

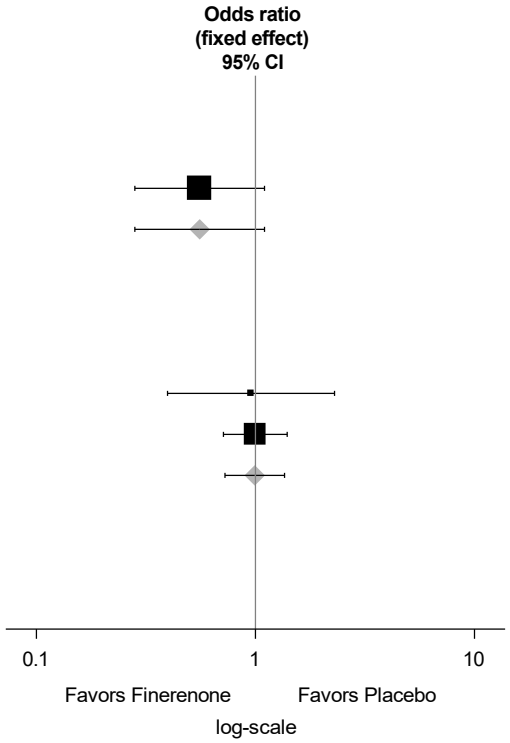
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 98	2 / 96	5.9	1.48 [0.24,9.09]	
FIGARO-DKD	35 / 1416	43 / 1420	94.1	0.81 [0.52,1.28]	
Total	38 / 1514	45 / 1516		0.84 [0.54,1.30]	Z=-0.77, p=0.4403
Heterogeneity:	Q=0.40 (df=1)	p=0.5264	I^2=0.0%		
>= 65					
FIDELIO-DKD	7 / 112	9 / 125	13.4	0.86 [0.31,2.39]	
FIGARO-DKD	50 / 910	51 / 882	86.6	0.95 [0.63,1.42]	
Total	57 / 1022	60 / 1007		0.94 [0.64,1.36]	Z=-0.35, p=0.7245
Heterogeneity:	Q=0.03 (df=1)	p=0.8618	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7202	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.7.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

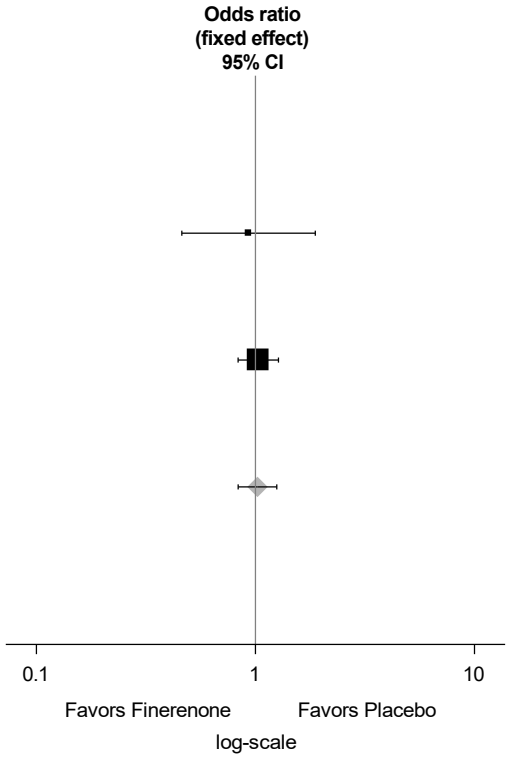
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	14 / 363	23 / 342	100.0	0.56 [0.28,1.10]	
Total	14 / 363	23 / 342		0.56 [0.28,1.10]	Z=-1.69, p=0.0918
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	10 / 210	11 / 221	12.7	0.95 [0.40,2.30]	
FIGARO-DKD	71 / 1963	71 / 1960	87.3	1.00 [0.71,1.40]	
Total	81 / 2173	82 / 2181		0.99 [0.73,1.36]	Z=-0.05, p=0.9635
Heterogeneity:	Q=0.01 (df=1)	p=0.9253	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.29 (df=1)	p=0.1302	I^2=56.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

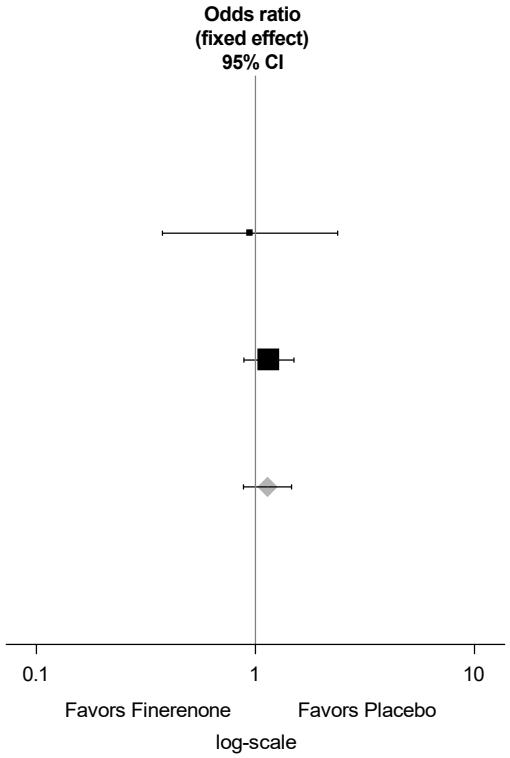
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	16 / 210	18 / 221	8.4	0.93 [0.46,1.88]	
FIGARO-DKD	189 / 2326	182 / 2302	91.6	1.03 [0.83,1.27]	
Total	205 / 2536	200 / 2523		1.02 [0.83,1.25]	Z=0.20, p=0.8381
Heterogeneity:	Q=0.07 (df=1)	p=0.7847	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

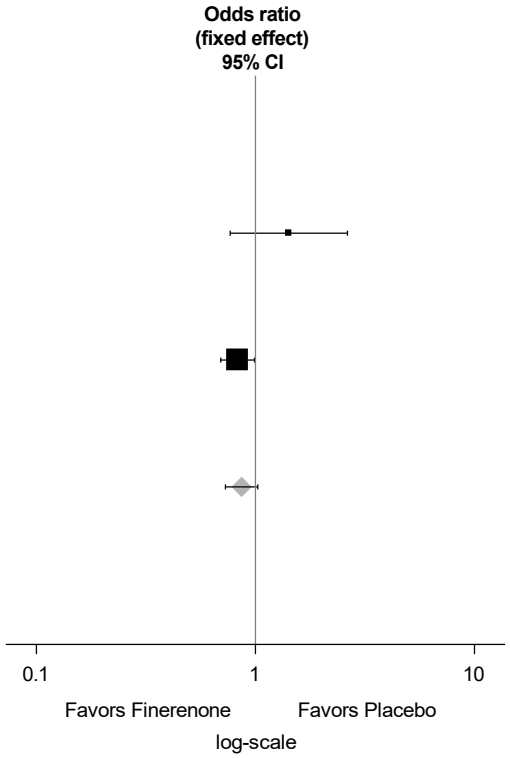
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	10 / 221	7.5	0.94 [0.38,2.37]	
FIGARO-DKD	126 / 2326	109 / 2302	92.5	1.15 [0.89,1.50]	
Total	135 / 2536	119 / 2523		1.14 [0.88,1.46]	Z=0.98, p=0.3259
Heterogeneity:	Q=0.17 (df=1)	p=0.6845	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.10: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

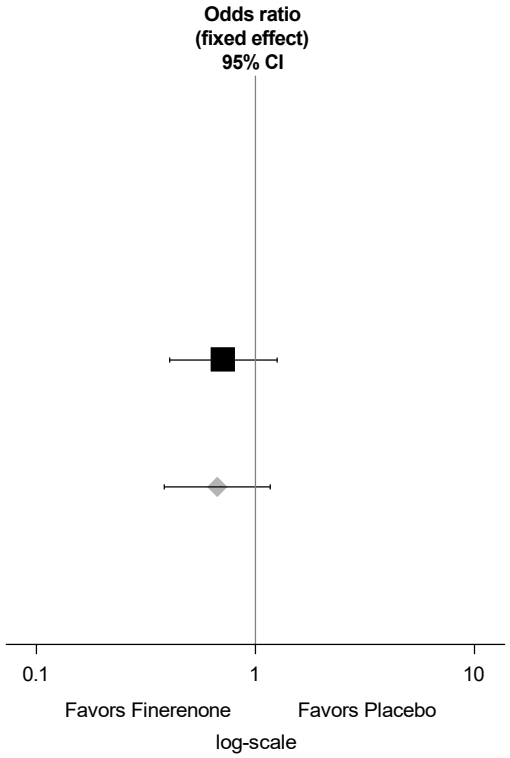
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 210	20 / 221	7.6	1.42 [0.77,2.63]	
FIGARO-DKD	258 / 2326	301 / 2302	92.4	0.83 [0.69,0.99]	
Total	284 / 2536	321 / 2523		0.86 [0.73,1.02]	Z=-1.68, p=0.0935
Heterogeneity:	Q=2.70 (df=1)	p=0.1002	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.11: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

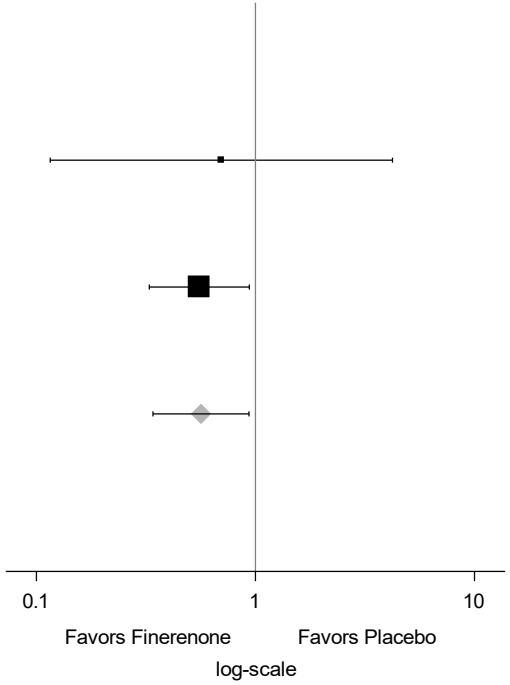
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	21 / 2326	29 / 2302	100.0	0.71 [0.41,1.26]	
Total	21 / 2536	31 / 2523		0.67 [0.38,1.17]	Z=-1.41, p=0.1574
Heterogeneity:	Q=0.05 (df=1)	p=0.8217	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.12: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

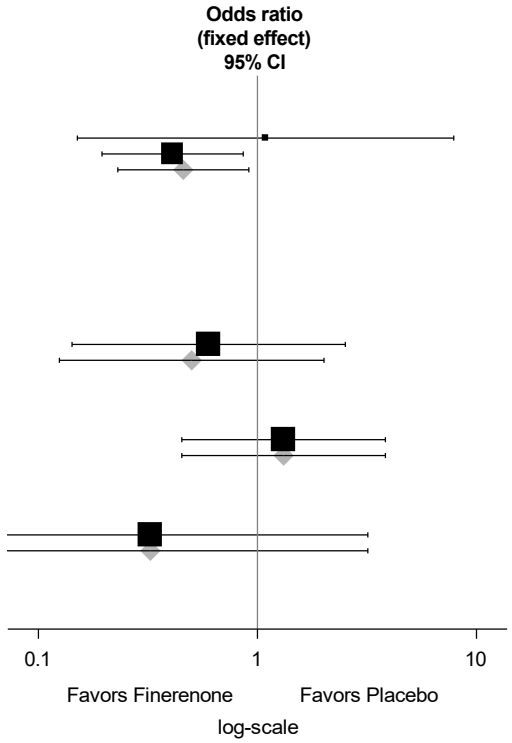
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.9	0.70 [0.12,4.22]	
FIGARO-DKD	22 / 2326	39 / 2302	92.1	0.55 [0.33,0.94]	
Total	24 / 2536	42 / 2523		0.56 [0.34,0.93]	Z=-2.22, p=0.0261
Heterogeneity:	Q=0.06 (df=1)	p=0.8084	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.12.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

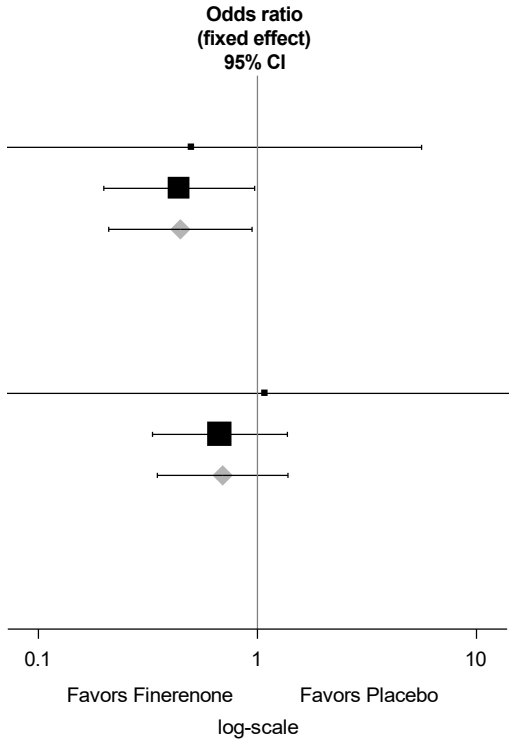
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	2 / 103	2 / 112	12.3	1.09 [0.15,7.88]	
FIGARO-DKD	10 / 1114	24 / 1110	87.7	0.41 [0.20,0.86]	
Total	12 / 1217	26 / 1222		0.46 [0.23,0.91]	Z=-2.22, p=0.0266
Heterogeneity:	Q=0.82 (df=1)	p=0.3646	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	0 / 292	1 / 277	0.0	0.00 [0.00,11E296]	
Total	0 / 334	1 / 317		0.00 [0.00,14E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	3 / 522	5 / 523	100.0	0.60 [0.14,2.52]	
Total	3 / 561	6 / 564		0.50 [0.12,2.01]	Z=-0.97, p=0.3300
Heterogeneity:	Q=0.06 (df=1)	p=0.8075	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	8 / 322	6 / 316	100.0	1.32 [0.45,3.84]	
Total	8 / 343	6 / 340		1.32 [0.45,3.84]	Z=0.50, p=0.6147
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	3 / 76	100.0	0.32 [0.03,3.19]	
Total	1 / 81	3 / 80		0.32 [0.03,3.19]	Z=-0.97, p=0.3345
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.99 (df=4)	p=0.5597	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.12.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

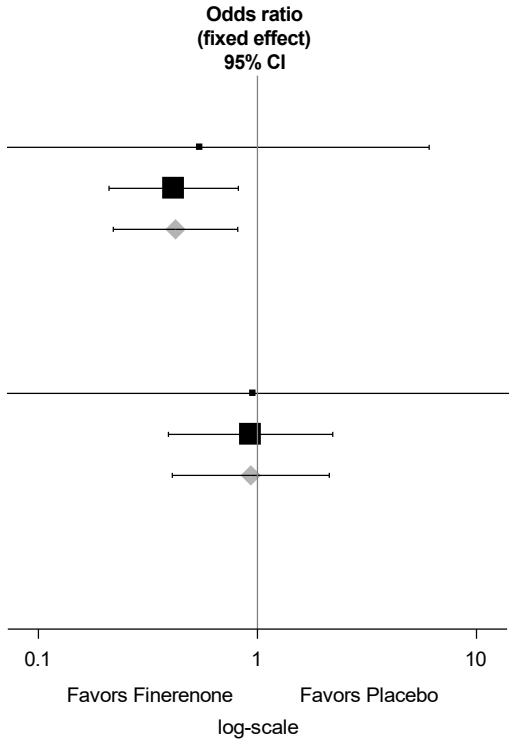
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	9.7	0.50 [0.04,5.62]	
FIGARO-DKD	9 / 811	20 / 803	90.3	0.44 [0.20,0.97]	
Total	10 / 899	22 / 892		0.44 [0.21,0.94]	Z=-2.11, p=0.0350
Heterogeneity:	Q=0.01 (df=1)	p=0.9207	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	1 / 132	6.1	1.08 [0.07,17.50]	
FIGARO-DKD	13 / 1515	19 / 1499	93.9	0.67 [0.33,1.37]	
Total	14 / 1637	20 / 1631		0.69 [0.35,1.38]	Z=-1.04, p=0.2962
Heterogeneity:	Q=0.10 (df=1)	p=0.7465	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=1)	p=0.3929	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.12.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	2 / 158	7.4	0.55 [0.05,6.08]	
FIGARO-DKD	12 / 1719	28 / 1679	92.6	0.41 [0.21,0.82]	
Total	13 / 1863	30 / 1837		0.42 [0.22,0.81]	Z=-2.58, p=0.0099
Heterogeneity:	Q=0.05 (df=1)	p=0.8299	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	1 / 63	8.7	0.95 [0.06,15.58]	
FIGARO-DKD	10 / 607	11 / 622	91.3	0.93 [0.39,2.21]	
Total	11 / 673	12 / 685		0.93 [0.41,2.13]	Z=-0.17, p=0.8680
Heterogeneity:	Q=0.00 (df=1)	p=0.9867	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.17 (df=1)	p=0.1407	I^2=53.9%		

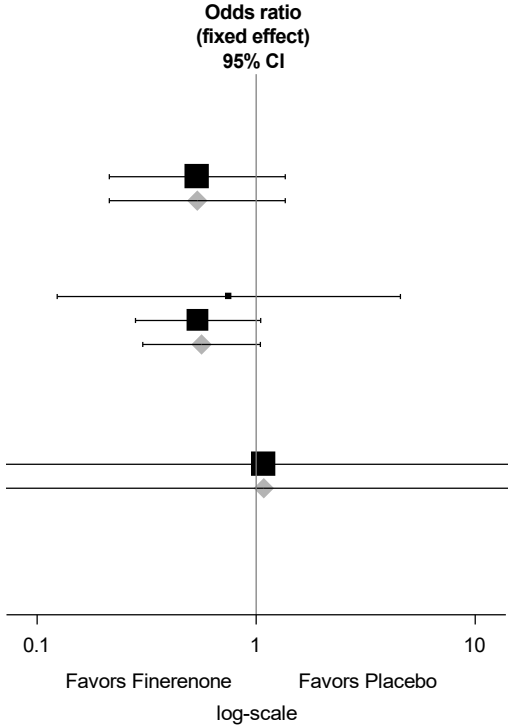


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.12.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

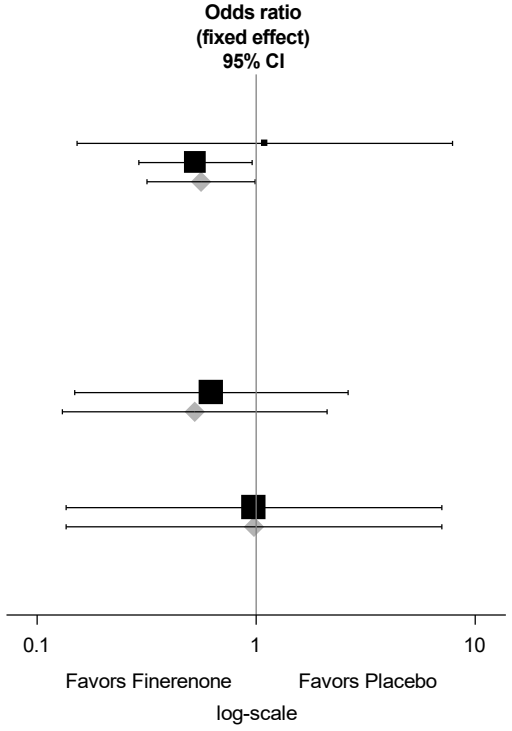
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	7 / 693	13 / 699	100.0	0.54 [0.21,1.36]	
Total	7 / 757	13 / 753		0.54 [0.21,1.36]	Z=-1.31, p=0.1896
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	3 / 156	11.7	0.75 [0.12,4.56]	
FIGARO-DKD	14 / 1560	25 / 1524	88.3	0.54 [0.28,1.05]	
Total	16 / 1698	28 / 1680		0.56 [0.30,1.05]	Z=-1.82, p=0.0687
Heterogeneity:	Q=0.11 (df=1)	p=0.7416	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	1 / 79	100.0	1.08 [0.07,17.64]	
Total	1 / 81	1 / 90		1.08 [0.07,17.64]	Z=0.06, p=0.9552
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=2)	p=0.8962	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.12.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

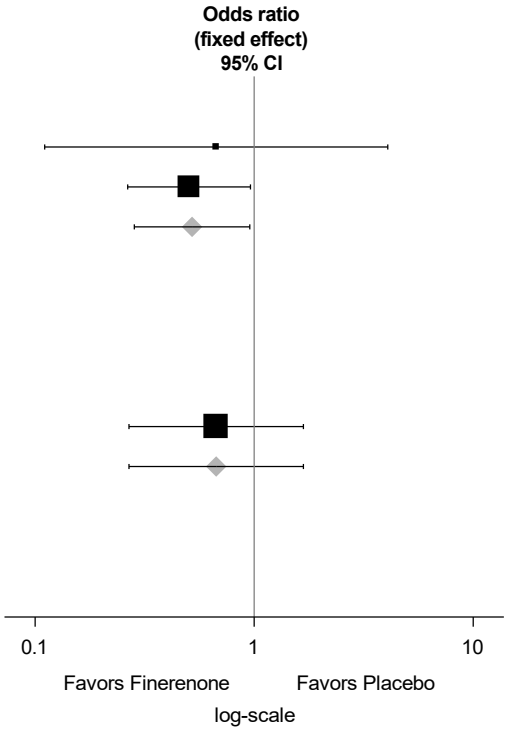
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	2 / 152	8.3	1.09 [0.15,7.88]	
FIGARO-DKD	17 / 1658	31 / 1612	91.7	0.53 [0.29,0.96]	
Total	19 / 1797	33 / 1764		0.56 [0.32,0.99]	Z=-2.00, p=0.0457
Heterogeneity:	Q=0.48 (df=1)	p=0.4884	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,85E295]	
Total	0 / 80	1 / 83		0.00 [0.00,1E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	3 / 464	5 / 485	100.0	0.62 [0.15,2.63]	
Total	3 / 503	6 / 529		0.52 [0.13,2.11]	Z=-0.91, p=0.3629
Heterogeneity:	Q=0.06 (df=1)	p=0.8108	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	2 / 131	100.0	0.98 [0.14,7.04]	
Total	2 / 156	2 / 147		0.98 [0.14,7.04]	Z=-0.02, p=0.9818
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=3)	p=0.9596	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.12.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

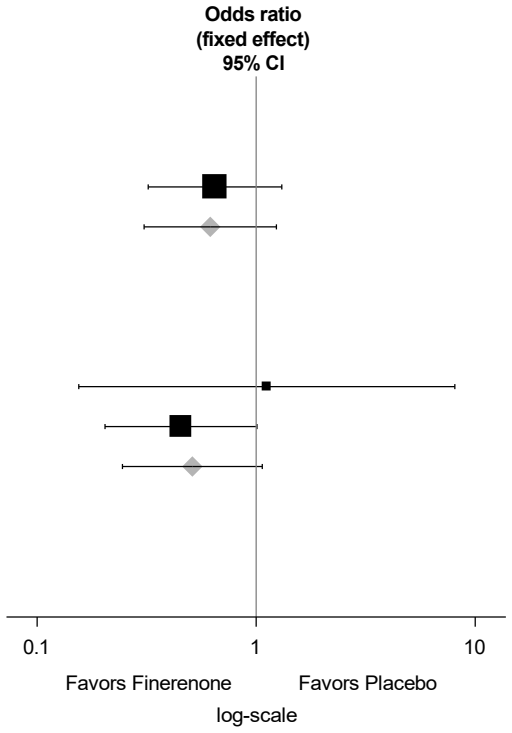
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	11.3	0.67 [0.11,4.07]	
FIGARO-DKD	14 / 1610	28 / 1638	88.7	0.50 [0.26,0.96]	
Total	16 / 1762	31 / 1792		0.52 [0.28,0.96]	Z=-2.11, p=0.0350
Heterogeneity:	Q=0.09 (df=1)	p=0.7701	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	8 / 716	11 / 664	100.0	0.67 [0.27,1.68]	
Total	8 / 774	11 / 731		0.67 [0.27,1.68]	Z=-0.85, p=0.3933
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6512	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.12.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

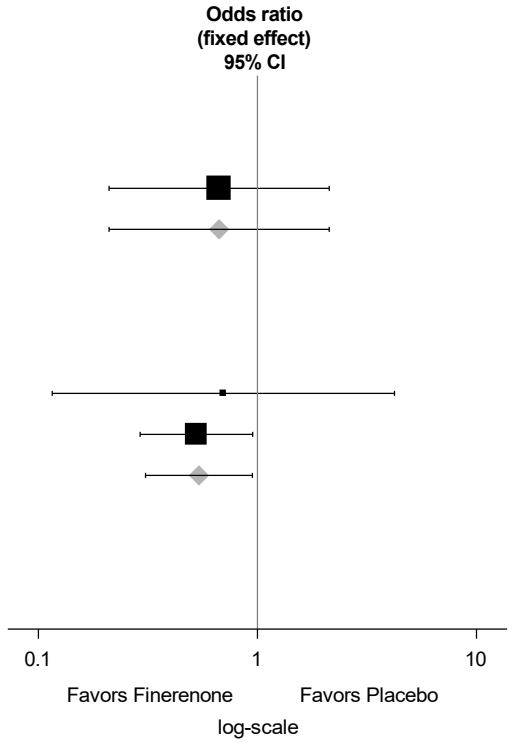
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	1 / 96	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	13 / 1416	20 / 1420	100.0	0.65 [0.32,1.31]	
Total	13 / 1514	21 / 1516		0.62 [0.31,1.24]	Z=-1.36, p=0.1736
Heterogeneity:	Q=0.02 (df=1)	p=0.8891	I^2=0.0%		
>= 65					
FIDELIO-DKD	2 / 112	2 / 125	14.0	1.12 [0.15,8.07]	
FIGARO-DKD	9 / 910	19 / 882	86.0	0.45 [0.20,1.01]	
Total	11 / 1022	21 / 1007		0.51 [0.25,1.07]	Z=-1.79, p=0.0736
Heterogeneity:	Q=0.69 (df=1)	p=0.4069	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7158	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.12.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

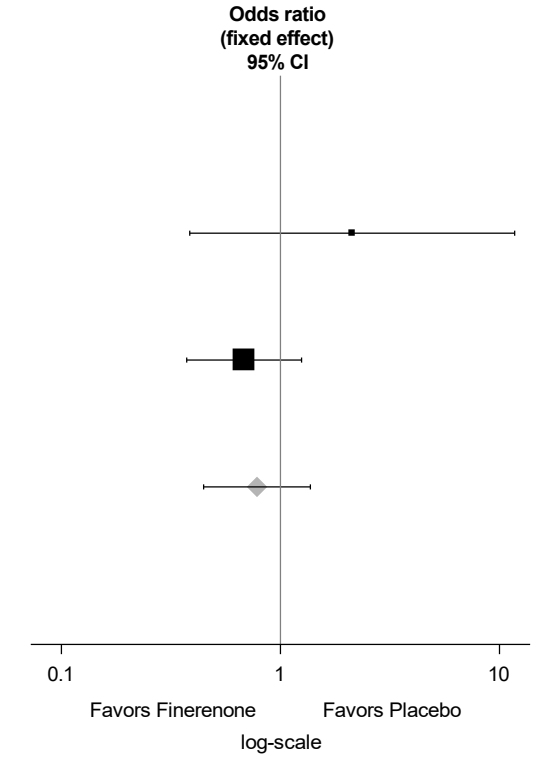
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	7 / 342	100.0	0.67 [0.21,2.13]	
Total	5 / 363	7 / 342		0.67 [0.21,2.13]	Z=-0.68, p=0.4950
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	3 / 221	9.8	0.70 [0.12,4.22]	
FIGARO-DKD	17 / 1963	32 / 1960	90.2	0.53 [0.29,0.95]	
Total	19 / 2173	35 / 2181		0.54 [0.31,0.95]	Z=-2.15, p=0.0319
Heterogeneity:	Q=0.09 (df=1)	p=0.7694	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7465	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.13: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

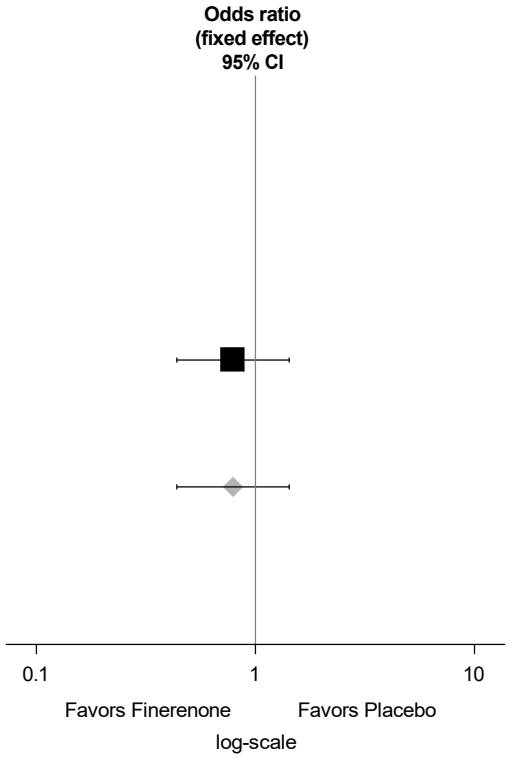
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	11.1	2.13 [0.39,11.73]	
FIGARO-DKD	18 / 2326	26 / 2302	88.9	0.68 [0.37,1.25]	
Total	22 / 2536	28 / 2523		0.78 [0.45,1.37]	Z=-0.86, p=0.3890
Heterogeneity:	Q=1.51 (df=1)	p=0.2189	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.14: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

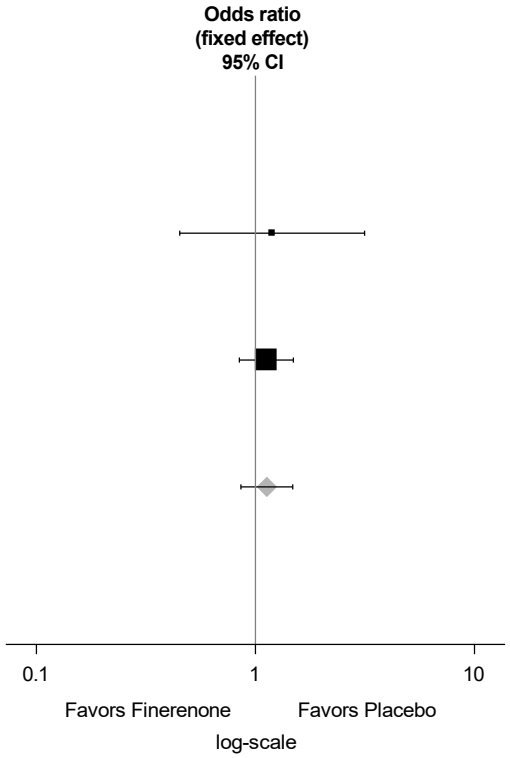
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	20 / 2326	25 / 2302	100.0	0.79 [0.44,1.43]	
Total	20 / 2536	25 / 2523		0.79 [0.44,1.43]	Z=-0.78, p=0.4341
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.15: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

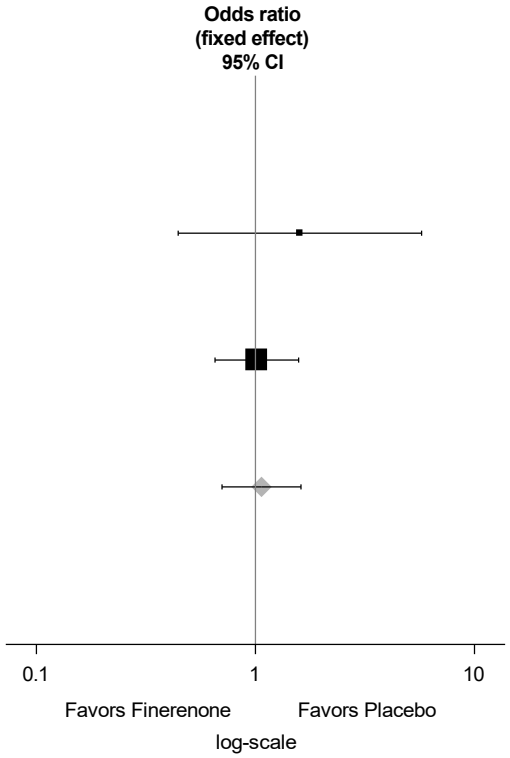
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	8 / 221	7.9	1.19 [0.45,3.15]	
FIGARO-DKD	106 / 2326	94 / 2302	92.1	1.12 [0.84,1.49]	
Total	115 / 2536	102 / 2523		1.13 [0.86,1.48]	Z=0.86, p=0.3899
Heterogeneity:	Q=0.01 (df=1)	p=0.9059	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.16: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

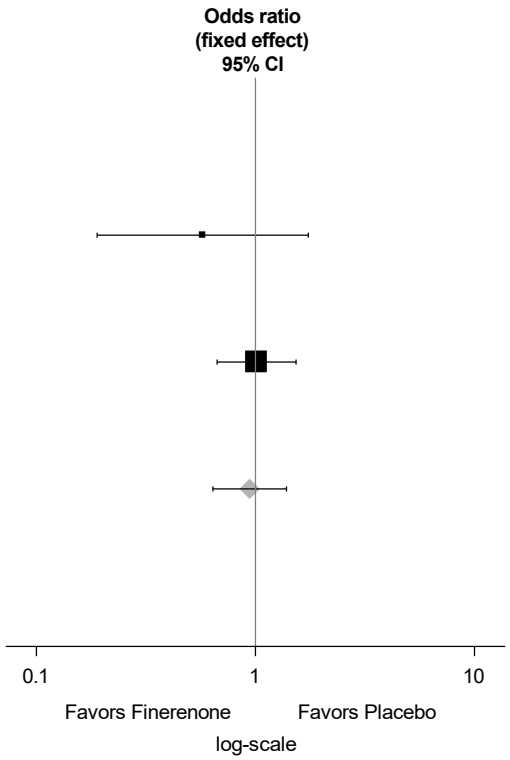
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	4 / 221	10.6	1.60 [0.44,5.74]	
FIGARO-DKD	41 / 2326	40 / 2302	89.4	1.01 [0.65,1.57]	
Total	47 / 2536	44 / 2523		1.07 [0.70,1.61]	Z=0.30, p=0.7643
Heterogeneity:	Q=0.43 (df=1)	p=0.5119	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.17: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

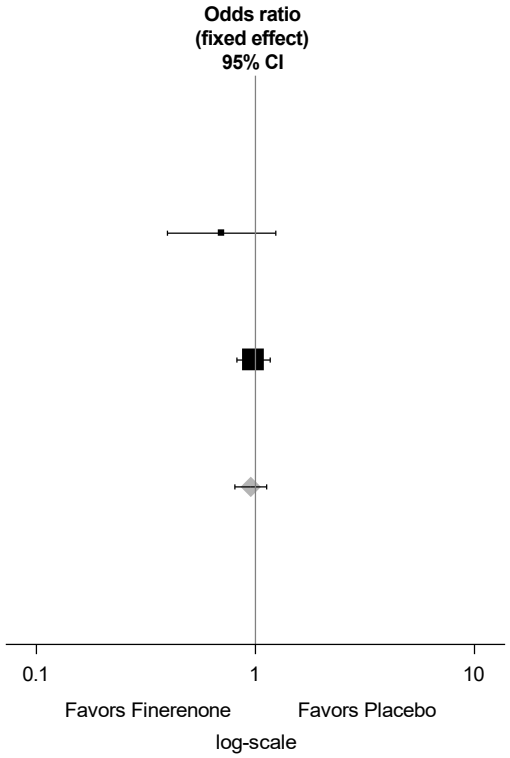
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	9 / 221	12.3	0.57 [0.19,1.74]	
FIGARO-DKD	46 / 2326	45 / 2302	87.7	1.01 [0.67,1.53]	
Total	51 / 2536	54 / 2523		0.94 [0.64,1.39]	Z=-0.31, p=0.7587
Heterogeneity:	Q=0.88 (df=1)	p=0.3491	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.18: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

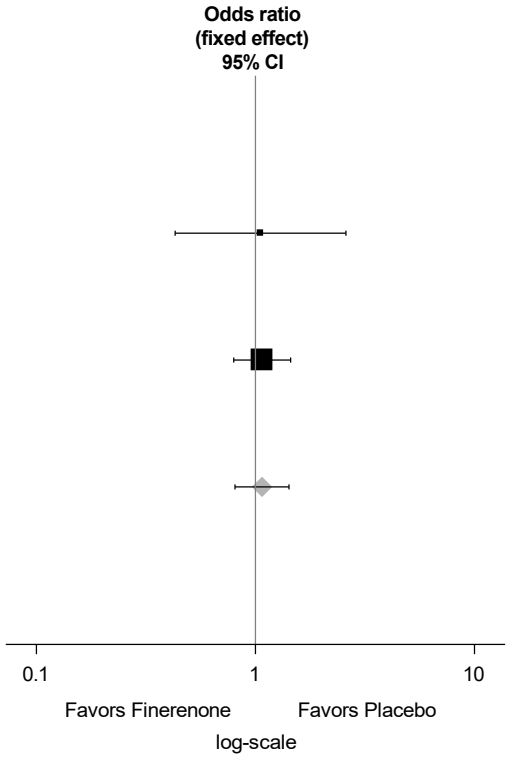
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 210	33 / 221	8.6	0.70 [0.40,1.24]	
FIGARO-DKD	285 / 2326	287 / 2302	91.4	0.98 [0.82,1.17]	
Total	308 / 2536	320 / 2523		0.95 [0.81,1.13]	Z=-0.58, p=0.5638
Heterogeneity:	Q=1.22 (df=1)	p=0.2693	I^2=18.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.19: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

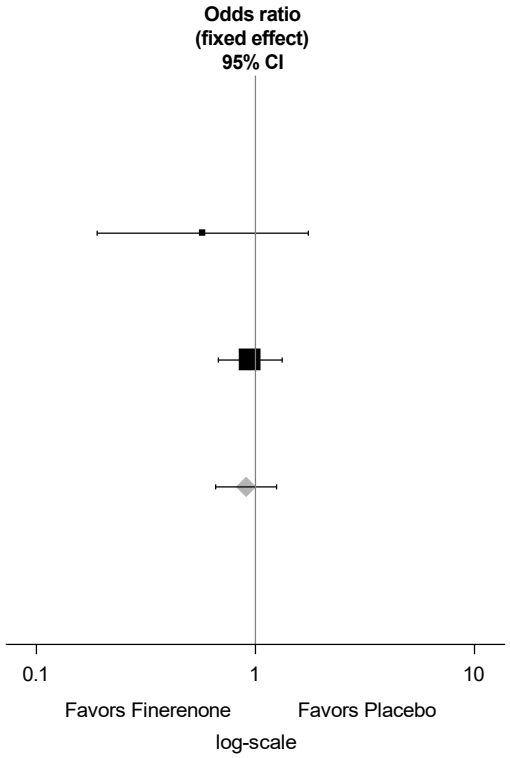
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	10 / 221	10.0	1.05 [0.43,2.59]	
FIGARO-DKD	93 / 2326	86 / 2302	90.0	1.07 [0.80,1.45]	
Total	103 / 2536	96 / 2523		1.07 [0.81,1.42]	Z=0.48, p=0.6341
Heterogeneity:	Q=0.00 (df=1)	p=0.9718	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.20: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

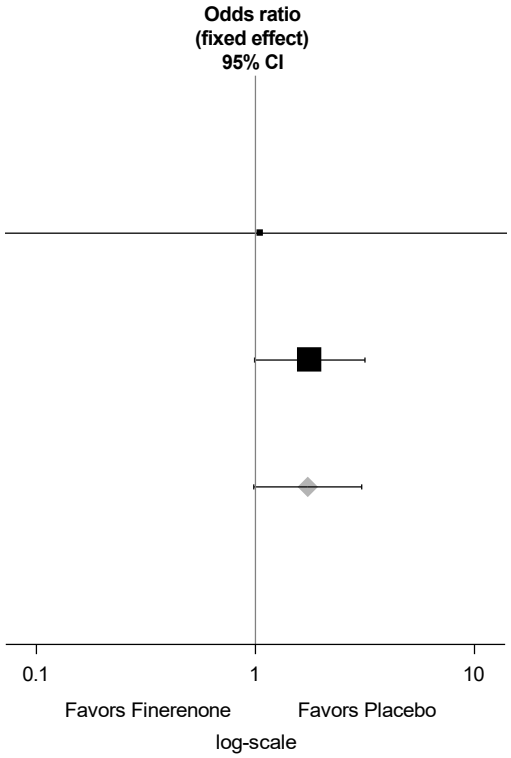
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	9 / 221	8.4	0.57 [0.19,1.74]	
FIGARO-DKD	69 / 2326	72 / 2302	91.6	0.95 [0.68,1.32]	
Total	74 / 2536	81 / 2523		0.91 [0.66,1.25]	Z=-0.60, p=0.5476
Heterogeneity:	Q=0.71 (df=1)	p=0.3983	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.21: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

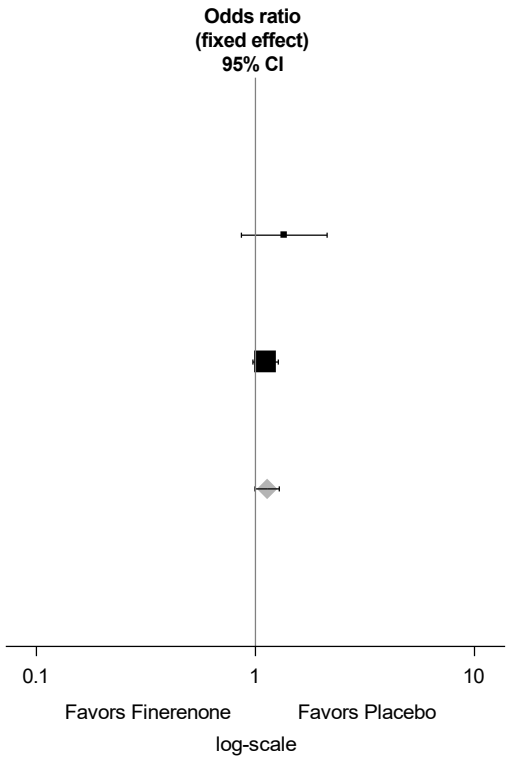
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	1 / 221	4.2	1.05 [0.07,16.94]	
FIGARO-DKD	32 / 2326	18 / 2302	95.8	1.77 [0.99,3.16]	
Total	33 / 2536	19 / 2523		1.73 [0.98,3.06]	Z=1.90, p=0.0575
Heterogeneity:	Q=0.13 (df=1)	p=0.7197	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.22: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

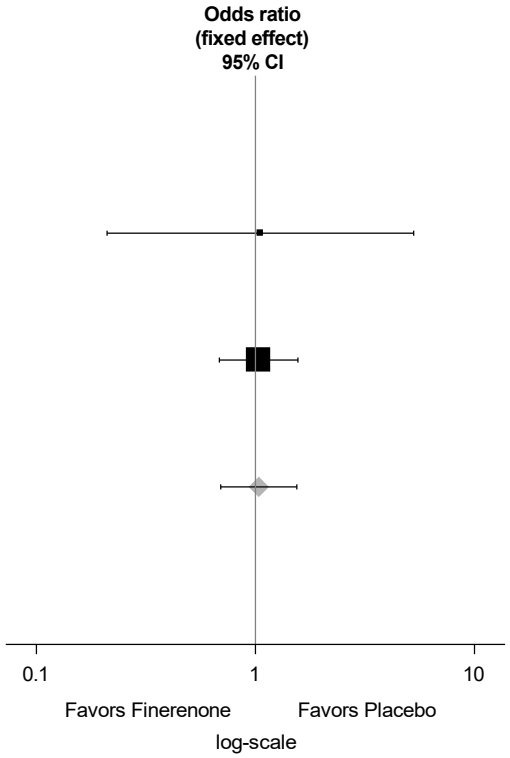
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 210	45 / 221	8.1	1.35 [0.86,2.12]	
FIGARO-DKD	600 / 2326	548 / 2302	91.9	1.11 [0.97,1.27]	
Total	654 / 2536	593 / 2523		1.13 [0.99,1.28]	Z=1.88, p=0.0604
Heterogeneity:	Q=0.67 (df=1)	p=0.4131	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.23: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

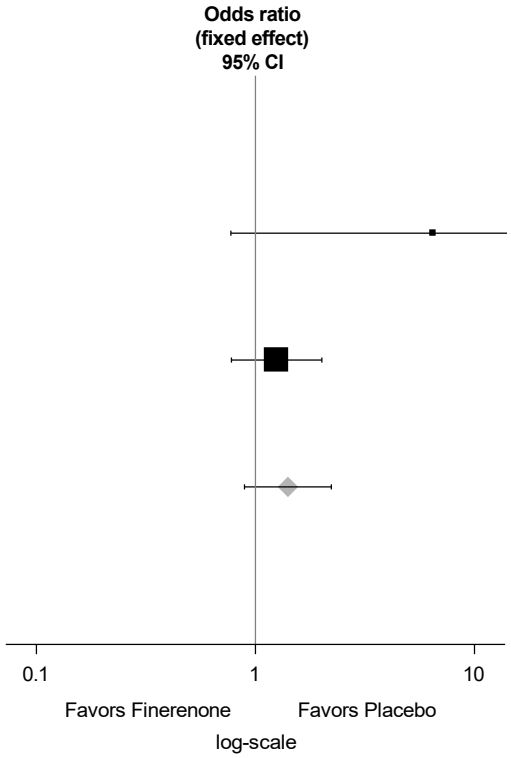
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	6.2	1.05 [0.21,5.28]	
FIGARO-DKD	47 / 2326	45 / 2302	93.8	1.03 [0.68,1.56]	
Total	50 / 2536	48 / 2523		1.04 [0.69,1.54]	Z=0.17, p=0.8642
Heterogeneity:	Q=0.00 (df=1)	p=0.9831	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.24: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

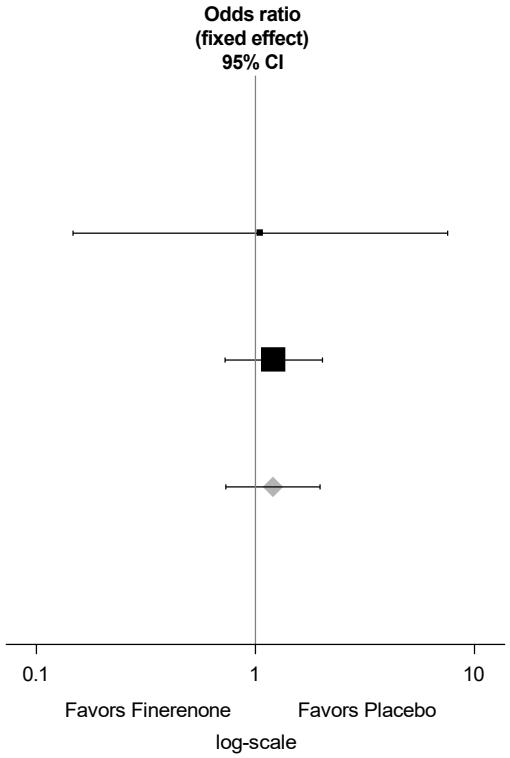
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	1 / 221	4.8	6.47 [0.77,54.21]	
FIGARO-DKD	39 / 2326	31 / 2302	95.2	1.25 [0.78,2.01]	
Total	45 / 2536	32 / 2523		1.41 [0.89,2.22]	Z=1.46, p=0.1429
Heterogeneity:	Q=2.22 (df=1)	p=0.1362	I^2=55.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.25: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

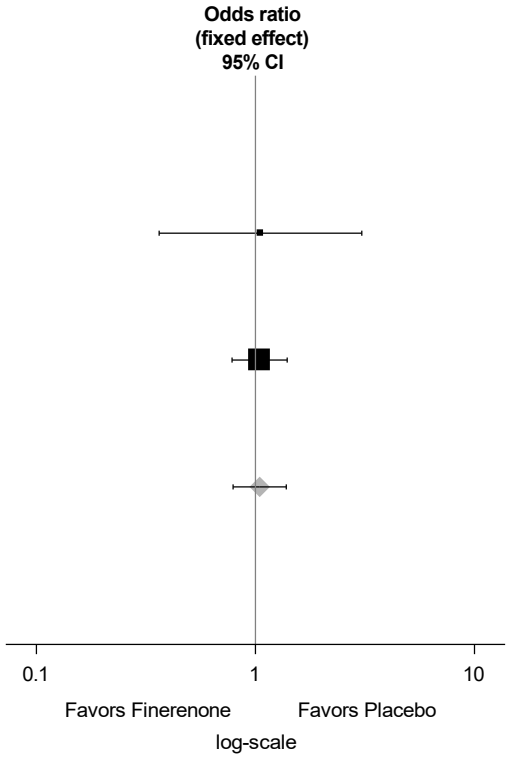
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	6.3	1.05 [0.15,7.54]	
FIGARO-DKD	33 / 2326	27 / 2302	93.7	1.21 [0.73,2.02]	
Total	35 / 2536	29 / 2523		1.20 [0.73,1.97]	Z=0.73, p=0.4669
Heterogeneity:	Q=0.02 (df=1)	p=0.8918	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.26: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

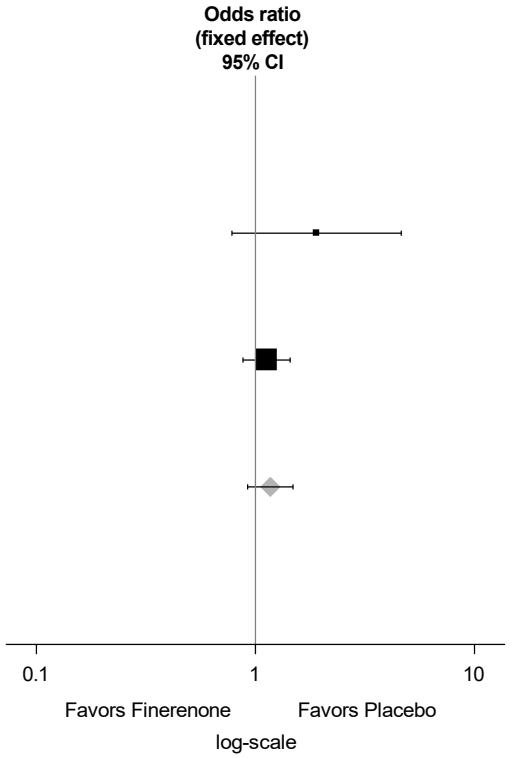
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	7 / 221	6.9	1.05 [0.36,3.06]	
FIGARO-DKD	98 / 2326	93 / 2302	93.1	1.04 [0.78,1.40]	
Total	105 / 2536	100 / 2523		1.05 [0.79,1.38]	Z=0.31, p=0.7555
Heterogeneity:	Q=0.00 (df=1)	p=0.9873	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.27: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

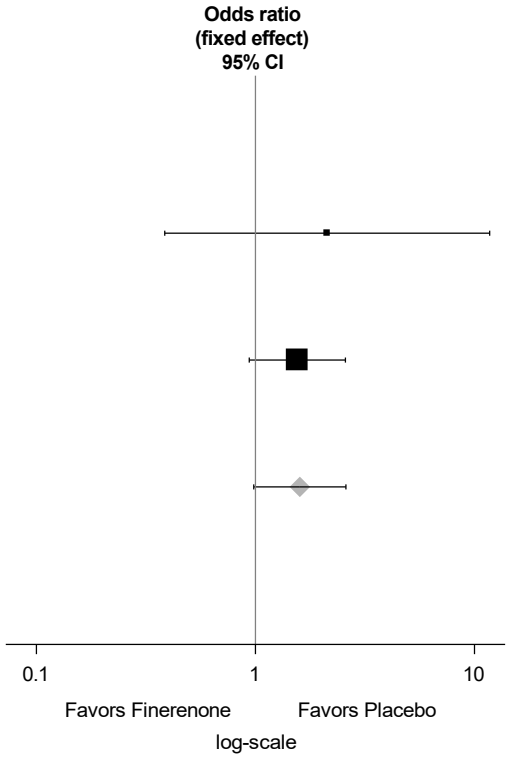
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	8 / 221	7.2	1.90 [0.78,4.63]	
FIGARO-DKD	141 / 2326	125 / 2302	92.8	1.12 [0.88,1.44]	
Total	155 / 2536	133 / 2523		1.17 [0.92,1.48]	Z=1.28, p=0.1990
Heterogeneity:	Q=1.25 (df=1)	p=0.2645	I^2=19.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.28: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

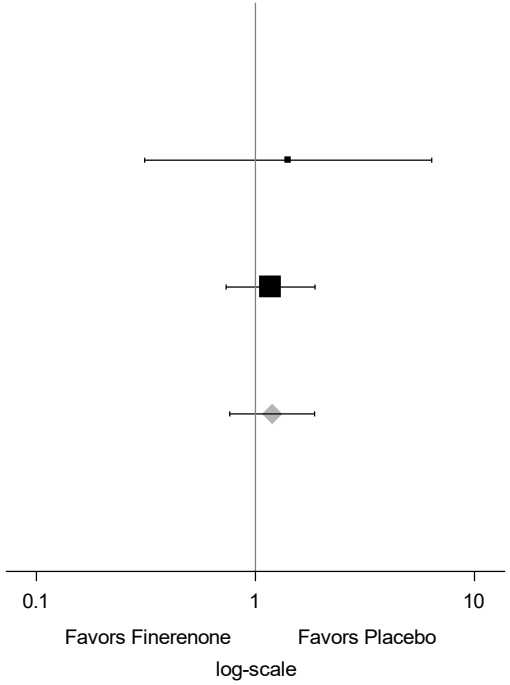
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	8.1	2.13 [0.39,11.73]	
FIGARO-DKD	39 / 2326	25 / 2302	91.9	1.55 [0.94,2.57]	
Total	43 / 2536	27 / 2523		1.59 [0.98,2.59]	Z=1.89, p=0.0591
Heterogeneity:	Q=0.12 (df=1)	p=0.7297	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.29: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

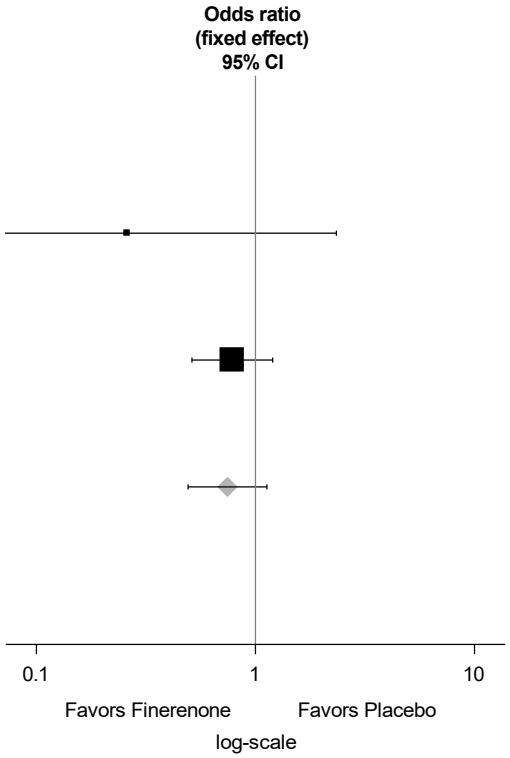
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.7	1.41 [0.31,6.38]	
FIGARO-DKD	39 / 2326	33 / 2302	91.3	1.17 [0.73,1.87]	
Total	43 / 2536	36 / 2523		1.19 [0.76,1.86]	Z=0.77, p=0.4408
Heterogeneity:	Q=0.05 (df=1)	p=0.8183	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.30: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

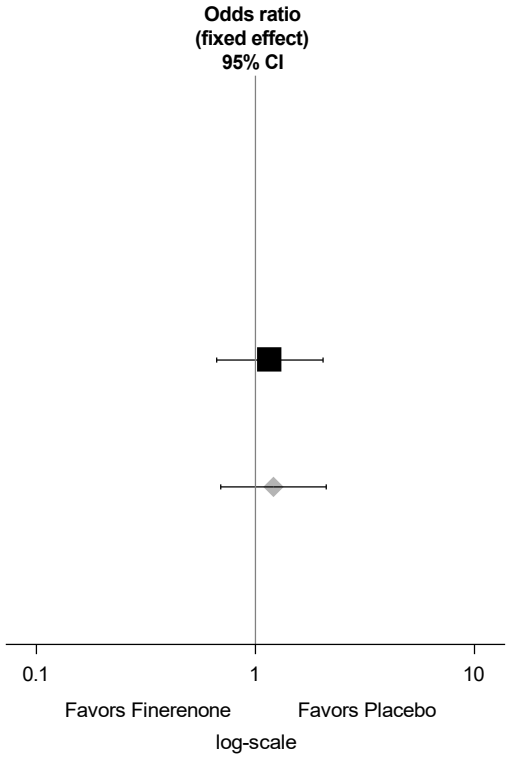
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	3.6	0.26 [0.03,2.34]	
FIGARO-DKD	39 / 2326	49 / 2302	96.4	0.78 [0.51,1.20]	
Total	40 / 2536	53 / 2523		0.75 [0.49,1.13]	Z=-1.39, p=0.1644
Heterogeneity:	Q=0.94 (df=1)	p=0.3327	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.31: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

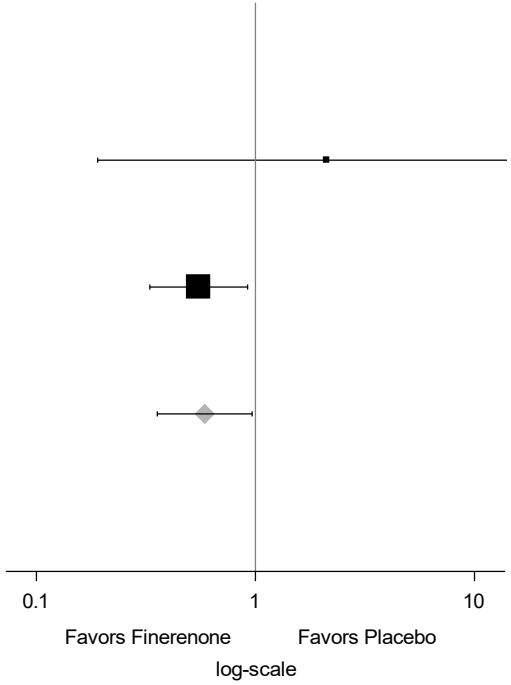
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	0 / 221	0.0	2E11 [2E11,2E11]	
FIGARO-DKD	27 / 2326	23 / 2302	100.0	1.16 [0.67,2.04]	
Total	28 / 2536	23 / 2523		1.21 [0.69,2.10]	Z=0.67, p=0.5028
Heterogeneity:	Q=0.02 (df=1)	p=0.8942	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.32: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

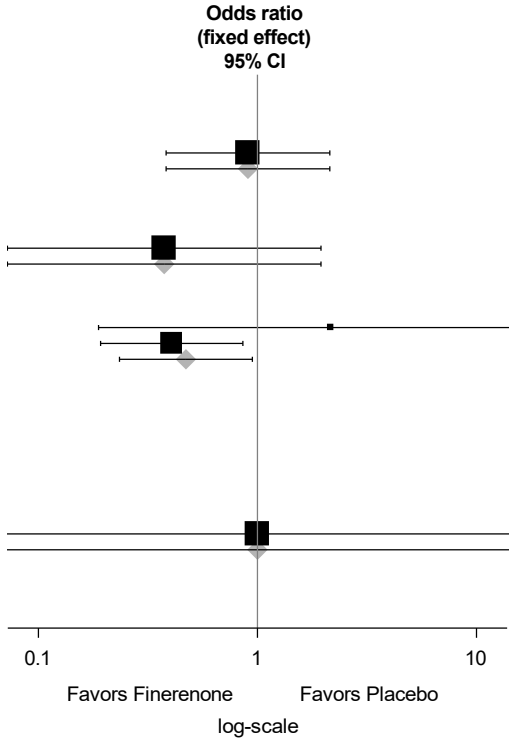
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.4	2.12 [0.19,23.50]	
FIGARO-DKD	23 / 2326	41 / 2302	95.6	0.55 [0.33,0.92]	
Total	25 / 2536	42 / 2523		0.59 [0.36,0.97]	Z=-2.10, p=0.0359
Heterogeneity:	Q=1.15 (df=1)	p=0.2840	I^2=12.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.32.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

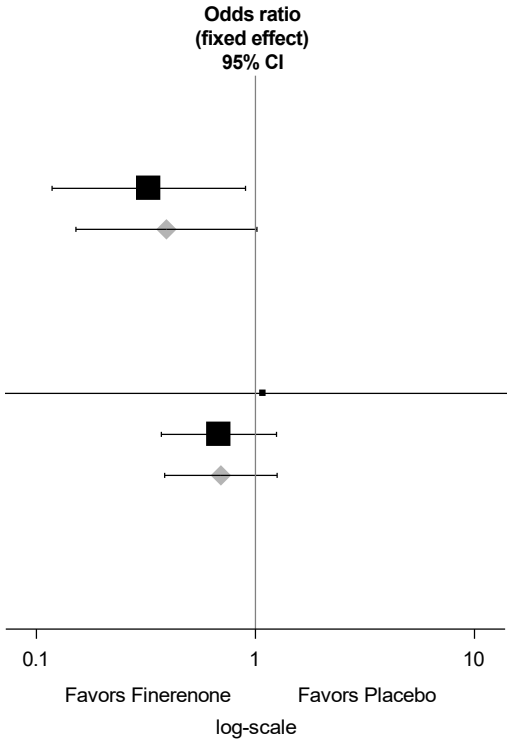
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	10 / 1114	11 / 1110	100.0	0.90 [0.38,2.14]	
Total	10 / 1217	11 / 1222		0.90 [0.38,2.14]	Z=-0.23, p=0.8201
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	2 / 292	5 / 277	100.0	0.38 [0.07,1.95]	
Total	2 / 334	5 / 317		0.38 [0.07,1.95]	Z=-1.17, p=0.2437
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	1 / 41	8.6	2.16 [0.19,24.85]	
FIGARO-DKD	10 / 522	24 / 523	91.4	0.41 [0.19,0.86]	
Total	12 / 561	25 / 564		0.47 [0.23,0.95]	Z=-2.11, p=0.0349
Heterogeneity:	Q=1.65 (df=1)	p=0.1993	I^2=39.3%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	0 / 316	0.0	-	
Total	0 / 343	0 / 340		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	1 / 76	100.0	1.00 [0.06,16.28]	
Total	1 / 81	1 / 80		1.00 [0.06,16.28]	Z=-0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=4)	p=0.7775	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.32.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

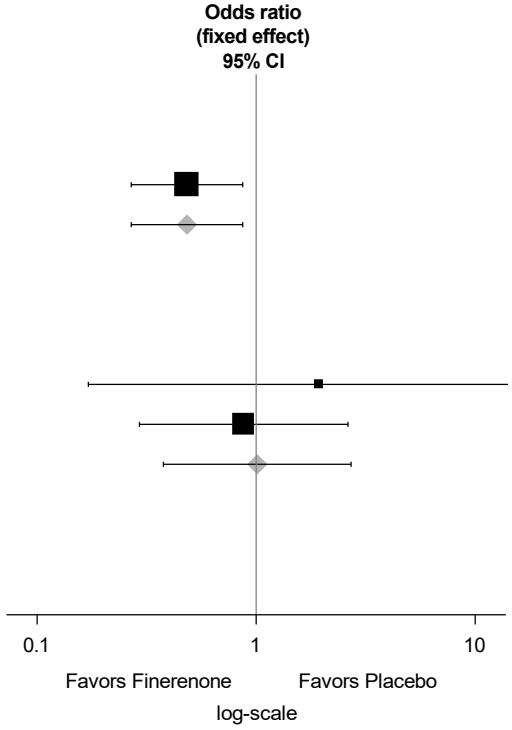
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	0 / 89	0.0	177E9 [177E9,177E9]	
FIGARO-DKD	5 / 811	15 / 803	100.0	0.33 [0.12,0.90]	
Total	6 / 899	15 / 892		0.39 [0.15,1.02]	Z=-1.93, p=0.0539
Heterogeneity:	Q=0.13 (df=1)	p=0.7208	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	1 / 132	4.5	1.08 [0.07,17.50]	
FIGARO-DKD	18 / 1515	26 / 1499	95.5	0.68 [0.37,1.25]	
Total	19 / 1637	27 / 1631		0.70 [0.39,1.26]	Z=-1.20, p=0.2283
Heterogeneity:	Q=0.10 (df=1)	p=0.7498	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.00 (df=1)	p=0.3165	I^2=0.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.32.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

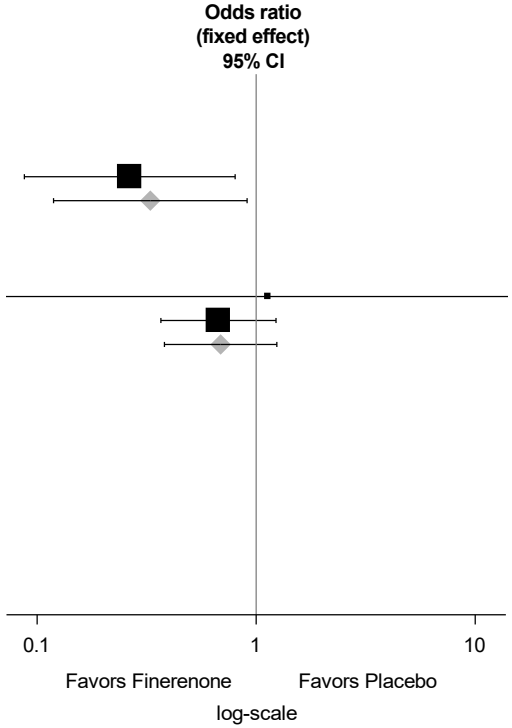
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	0 / 158	0.0	-	
FIGARO-DKD	17 / 1719	34 / 1679	100.0	0.48 [0.27,0.87]	
Total	17 / 1863	34 / 1837		0.48 [0.27,0.87]	Z=-2.43, p=0.0150
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
> 4.5					
FIDELIO-DKD	2 / 66	1 / 63	17.0	1.94 [0.17,21.91]	
FIGARO-DKD	6 / 607	7 / 622	83.0	0.88 [0.29,2.62]	
Total	8 / 673	8 / 685		1.01 [0.38,2.71]	Z=0.02, p=0.9822
Heterogeneity:	Q=0.34 (df=1)	p=0.5594	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.59 (df=1)	p=0.2072	I^2=37.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.32.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

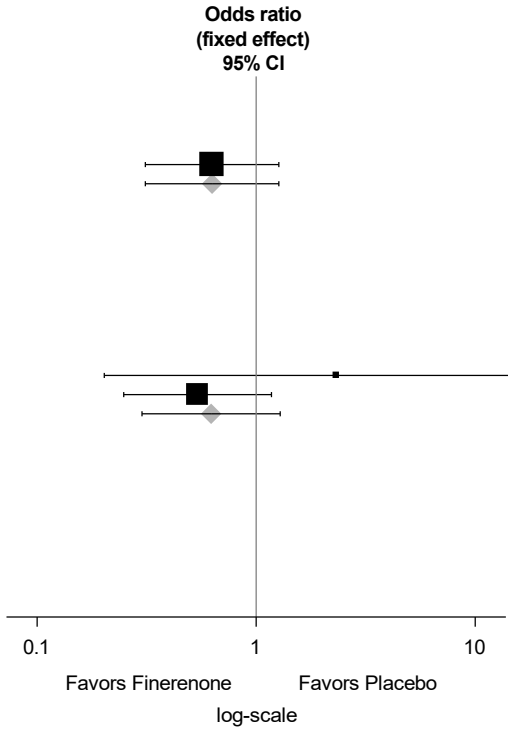
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	899E8 [899E8,899E8]	
FIGARO-DKD	4 / 693	15 / 699	100.0	0.26 [0.09,0.80]	
Total	5 / 757	15 / 753		0.33 [0.12,0.91]	Z=-2.14, p=0.0320
Heterogeneity:	Q=0.15 (df=1)	p=0.7021	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	1 / 156	4.5	1.13 [0.07,18.26]	
FIGARO-DKD	18 / 1560	26 / 1524	95.5	0.67 [0.37,1.23]	
Total	19 / 1698	27 / 1680		0.69 [0.38,1.24]	Z=-1.24, p=0.2153
Heterogeneity:	Q=0.13 (df=1)	p=0.7202	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	0 / 79	0.0	214E9 [214E9,214E9]	
Total	1 / 81	0 / 90		181E9 [181E9,181E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.52 (df=2)	p=0.4686	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.32.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

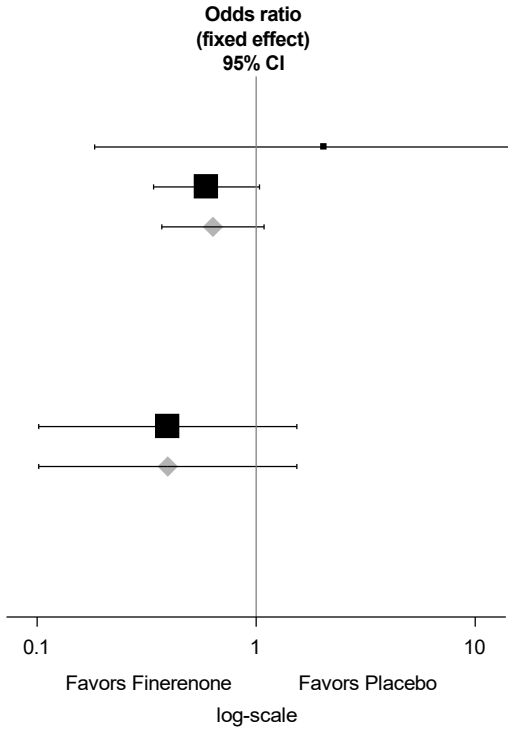
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	13 / 1658	20 / 1612	100.0	0.63 [0.31,1.27]	
Total	13 / 1797	20 / 1764		0.63 [0.31,1.27]	Z=-1.29, p=0.1954
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,85E295]	
Total	0 / 80	1 / 83		0.00 [0.00,1E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	2 / 39	1 / 44	9.2	2.32 [0.20,26.68]	
FIGARO-DKD	10 / 464	19 / 485	90.8	0.54 [0.25,1.17]	
Total	12 / 503	20 / 529		0.62 [0.30,1.29]	Z=-1.28, p=0.2010
Heterogeneity:	Q=1.25 (df=1)	p=0.2640	I^2=19.8%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,15E296]	
Total	0 / 156	1 / 147		0.00 [0.00,68E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.00 (df=3)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.32.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

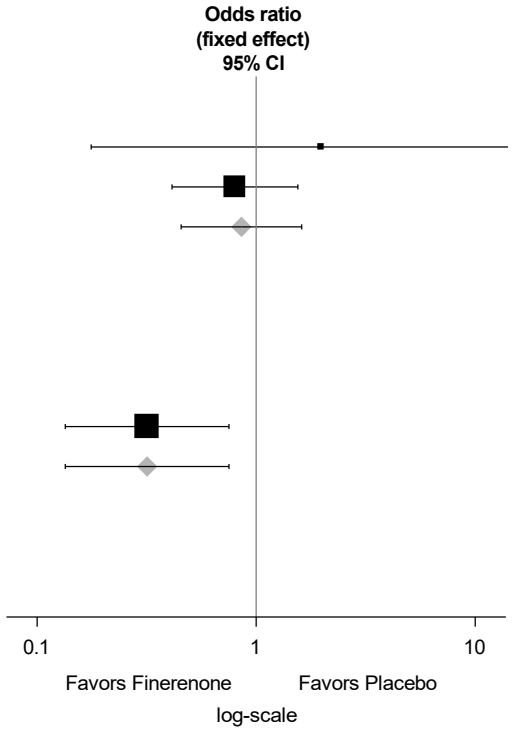
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	1 / 154	5.1	2.04 [0.18,22.74]	
FIGARO-DKD	20 / 1610	34 / 1638	94.9	0.59 [0.34,1.04]	
Total	22 / 1762	35 / 1792		0.63 [0.37,1.09]	Z=-1.66, p=0.0974
Heterogeneity:	Q=0.96 (df=1)	p=0.3280	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	3 / 716	7 / 664	100.0	0.39 [0.10,1.53]	
Total	3 / 774	7 / 731		0.39 [0.10,1.53]	Z=-1.34, p=0.1795
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5239	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.32.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

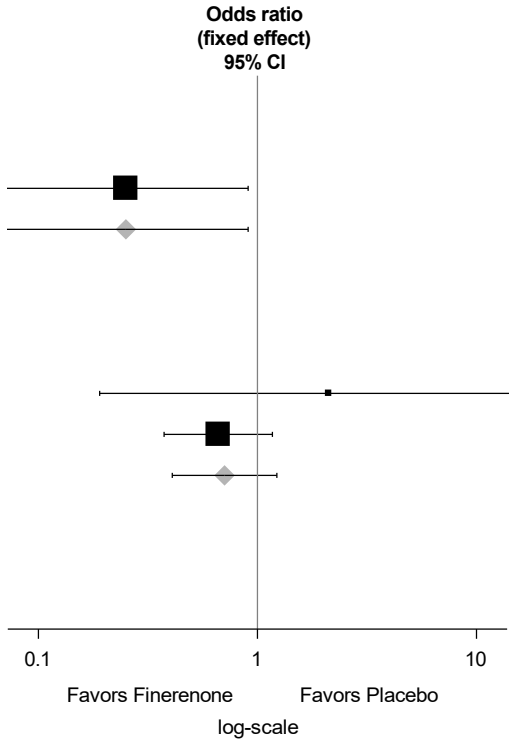
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	1 / 96	7.0	1.98 [0.18,22.19]	
FIGARO-DKD	16 / 1416	20 / 1420	93.0	0.80 [0.41,1.55]	
Total	18 / 1514	21 / 1516		0.86 [0.45,1.61]	Z=-0.48, p=0.6313
Heterogeneity:	Q=0.50 (df=1)	p=0.4786	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	0 / 125	0.0	-	
FIGARO-DKD	7 / 910	21 / 882	100.0	0.32 [0.13,0.75]	
Total	7 / 1022	21 / 1007		0.32 [0.13,0.75]	Z=-2.61, p=0.0090
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.30 (df=1)	p=0.0691	I^2=69.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.32.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

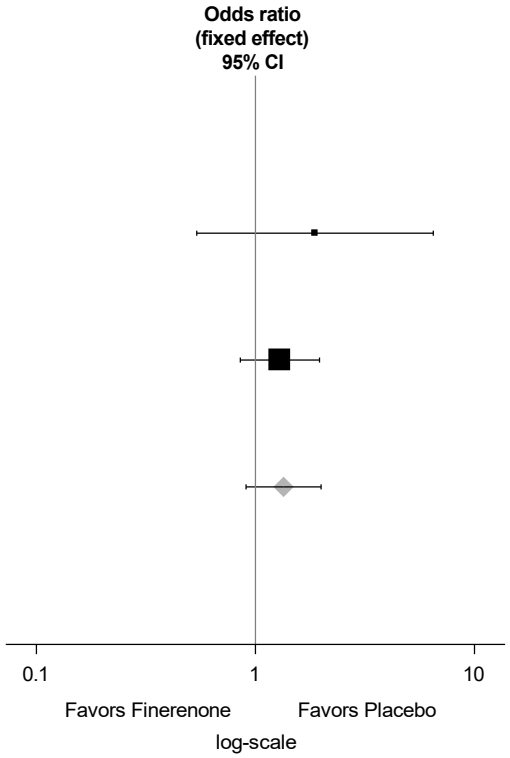
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	3 / 363	11 / 342	100.0	0.25 [0.07,0.91]	
Total	3 / 363	11 / 342		0.25 [0.07,0.91]	Z=-2.11, p=0.0349
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	1 / 221	5.3	2.12 [0.19,23.50]	
FIGARO-DKD	20 / 1963	30 / 1960	94.7	0.66 [0.37,1.17]	
Total	22 / 2173	31 / 2181		0.71 [0.41,1.23]	Z=-1.23, p=0.2177
Heterogeneity:	Q=0.85 (df=1)	p=0.3575	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.12 (df=1)	p=0.1458	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.33: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

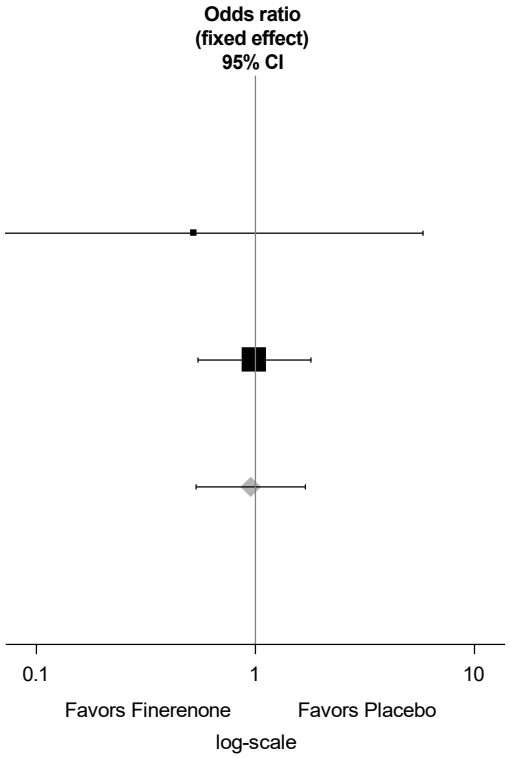
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	4 / 221	10.1	1.87 [0.54,6.49]	
FIGARO-DKD	52 / 2326	40 / 2302	89.9	1.29 [0.85,1.96]	
Total	59 / 2536	44 / 2523		1.34 [0.91,1.99]	Z=1.47, p=0.1419
Heterogeneity:	Q=0.30 (df=1)	p=0.5810	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.34: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Toothache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

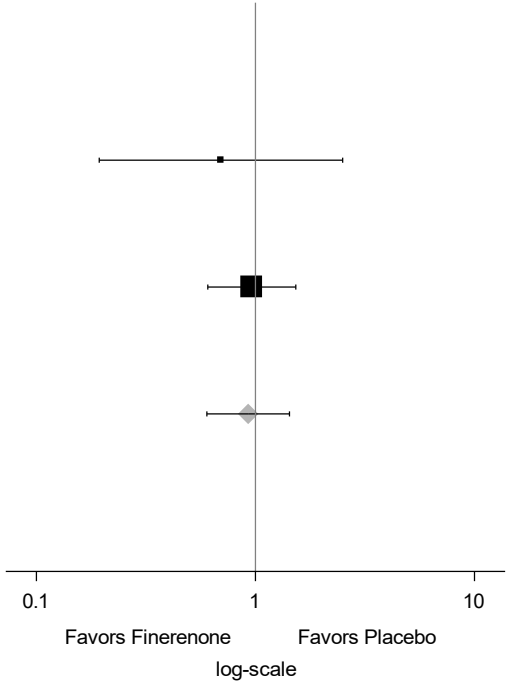
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	2 / 221	5.7	0.52 [0.05,5.82]	
FIGARO-DKD	22 / 2326	22 / 2302	94.3	0.99 [0.55,1.79]	
Total	23 / 2536	24 / 2523		0.95 [0.54,1.69]	Z=-0.17, p=0.8660
Heterogeneity:	Q=0.25 (df=1)	p=0.6152	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.35: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

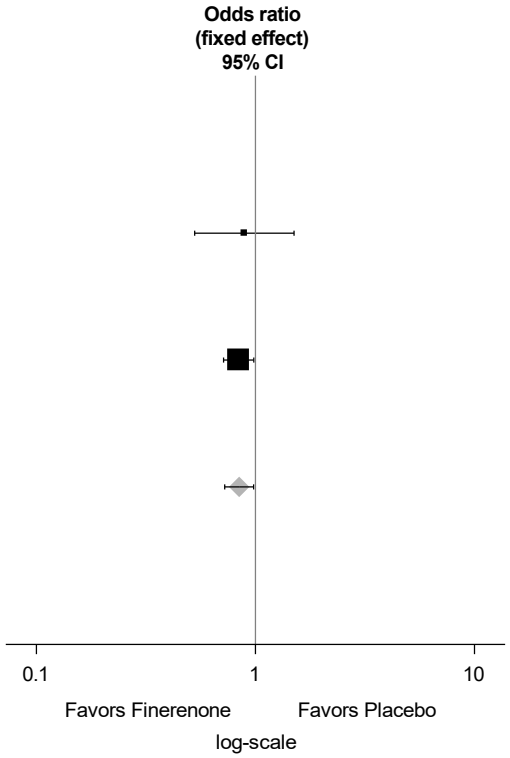
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	6 / 221	11.6	0.70 [0.19,2.50]	
FIGARO-DKD	36 / 2326	37 / 2302	88.4	0.96 [0.61,1.53]	
Total	40 / 2536	43 / 2523		0.93 [0.60,1.43]	Z=-0.35, p=0.7296
Heterogeneity:	Q=0.22 (df=1)	p=0.6403	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.36: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

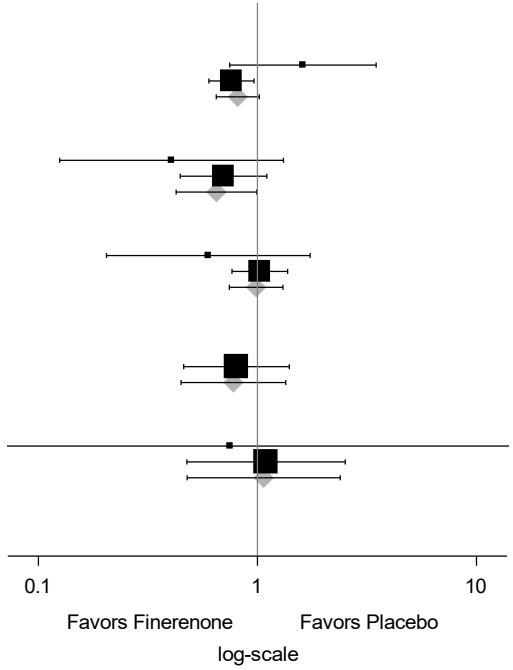
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 210	36 / 221	8.5	0.89 [0.53,1.50]	
FIGARO-DKD	337 / 2326	387 / 2302	91.5	0.84 [0.72,0.98]	
Total	368 / 2536	423 / 2523		0.84 [0.72,0.98]	Z=-2.21, p=0.0273
Heterogeneity:	Q=0.05 (df=1)	p=0.8303	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.36.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 103	13 / 112	8.7	1.61 [0.75,3.48]	
FIGARO-DKD	143 / 1114	180 / 1110	91.3	0.76 [0.60,0.96]	
Total	161 / 1217	193 / 1222		0.81 [0.65,1.02]	Z=-1.80, p=0.0724
Heterogeneity:	Q=3.34 (df=1)	p=0.0677	I^2=70.0%		
North America					
FIDELIO-DKD	5 / 42	10 / 40	13.0	0.41 [0.13,1.31]	
FIGARO-DKD	39 / 292	50 / 277	87.0	0.70 [0.44,1.10]	
Total	44 / 334	60 / 317		0.65 [0.43,0.99]	Z=-1.99, p=0.0462
Heterogeneity:	Q=0.72 (df=1)	p=0.3963	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 39	11 / 41	7.0	0.60 [0.20,1.74]	
FIGARO-DKD	116 / 522	114 / 523	93.0	1.03 [0.76,1.37]	
Total	123 / 561	125 / 564		0.99 [0.74,1.31]	Z=-0.10, p=0.9238
Heterogeneity:	Q=0.91 (df=1)	p=0.3391	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	25 / 322	30 / 316	100.0	0.80 [0.46,1.40]	
Total	25 / 343	31 / 340		0.78 [0.45,1.35]	Z=-0.90, p=0.3684
Heterogeneity:	Q=0.01 (df=1)	p=0.9084	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 5	1 / 4	6.5	0.75 [0.03,17.51]	
FIGARO-DKD	14 / 76	13 / 76	93.5	1.09 [0.48,2.52]	
Total	15 / 81	14 / 80		1.07 [0.48,2.39]	Z=0.16, p=0.8732
Heterogeneity:	Q=0.05 (df=1)	p=0.8202	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.16 (df=4)	p=0.5320	I^2=0.0%		

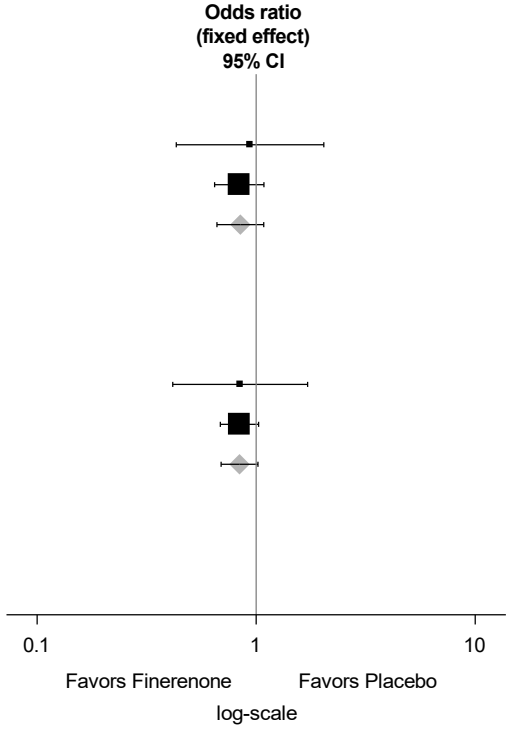


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.36.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

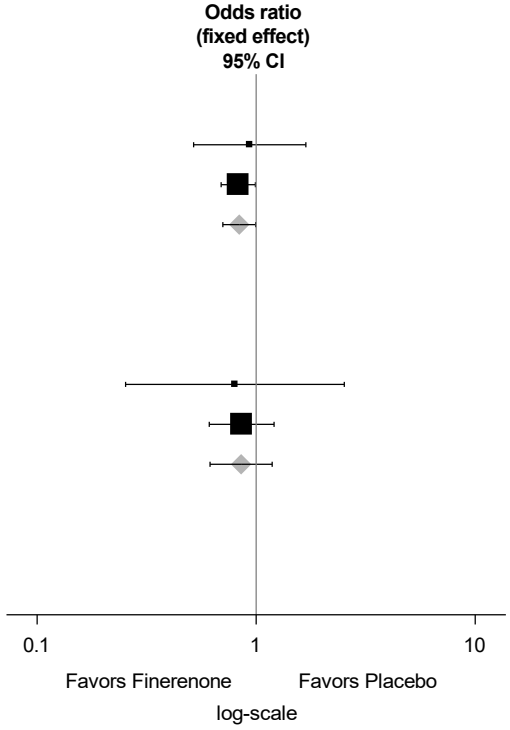
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 88	16 / 89	10.1	0.94 [0.43,2.04]	
FIGARO-DKD	129 / 811	148 / 803	89.9	0.84 [0.65,1.08]	
Total	144 / 899	164 / 892		0.85 [0.66,1.08]	Z=-1.33, p=0.1847
Heterogeneity:	Q=0.07 (df=1)	p=0.7860	I^2=0.0%		
Absent					
FIDELIO-DKD	16 / 122	20 / 132	7.5	0.85 [0.42,1.72]	
FIGARO-DKD	208 / 1515	239 / 1499	92.5	0.84 [0.69,1.03]	
Total	224 / 1637	259 / 1631		0.84 [0.69,1.02]	Z=-1.77, p=0.0766
Heterogeneity:	Q=0.00 (df=1)	p=0.9842	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9572	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.36.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

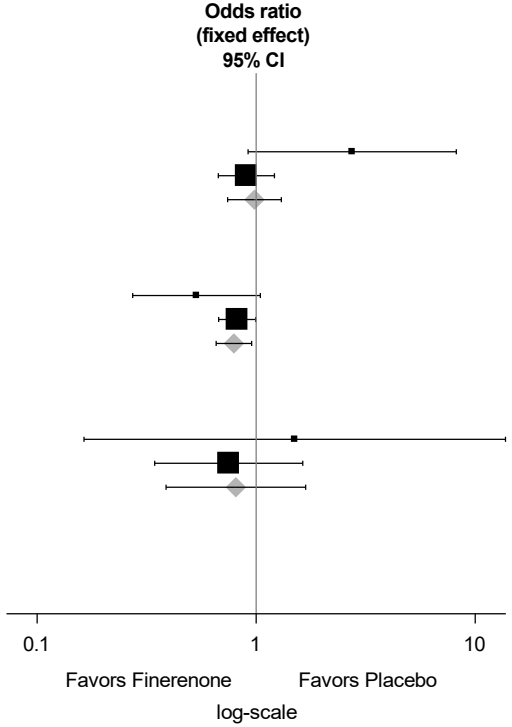
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 144	29 / 158	8.5	0.93 [0.52,1.69]	
FIGARO-DKD	267 / 1719	305 / 1679	91.5	0.83 [0.69,0.99]	
Total	292 / 1863	334 / 1837		0.84 [0.70,0.99]	Z=-2.03, p=0.0428
Heterogeneity:	Q=0.15 (df=1)	p=0.7017	I^2=0.0%		
> 4.5					
FIDELIO-DKD	6 / 66	7 / 63	8.1	0.80 [0.25,2.53]	
FIGARO-DKD	70 / 607	82 / 622	91.9	0.86 [0.61,1.21]	
Total	76 / 673	89 / 685		0.85 [0.62,1.18]	Z=-0.95, p=0.3419
Heterogeneity:	Q=0.01 (df=1)	p=0.9083	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9167	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.36.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

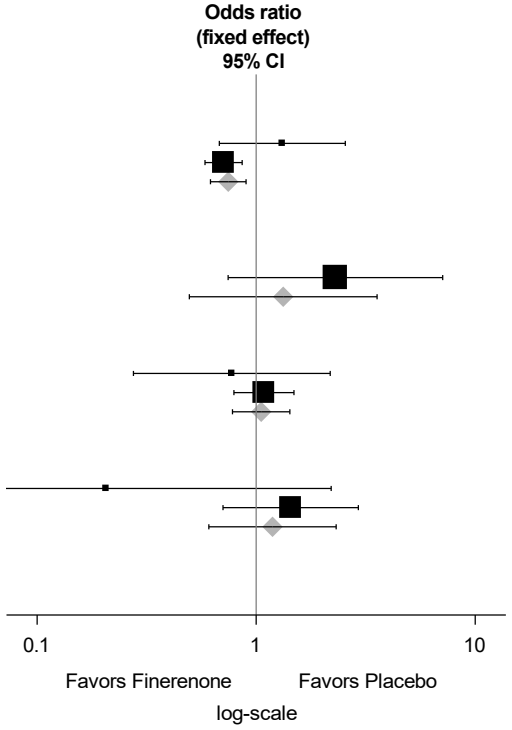
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 64	5 / 54	6.8	2.74 [0.92,8.20]	
FIGARO-DKD	99 / 693	109 / 699	93.2	0.90 [0.67,1.21]	
Total	113 / 757	114 / 753		0.98 [0.74,1.30]	Z=-0.12, p=0.9018
Heterogeneity:	Q=3.70 (df=1)	p=0.0543	I^2=73.0%		
130 - < 160					
FIDELIO-DKD	15 / 138	29 / 156	7.8	0.53 [0.27,1.04]	
FIGARO-DKD	224 / 1560	259 / 1524	92.2	0.82 [0.67,0.99]	
Total	239 / 1698	288 / 1680		0.79 [0.66,0.95]	Z=-2.46, p=0.0139
Heterogeneity:	Q=1.44 (df=1)	p=0.2304	I^2=30.5%		
>= 160					
FIDELIO-DKD	2 / 8	2 / 11	11.0	1.50 [0.16,13.75]	
FIGARO-DKD	14 / 73	19 / 79	89.0	0.75 [0.34,1.63]	
Total	16 / 81	21 / 90		0.81 [0.39,1.68]	Z=-0.57, p=0.5687
Heterogeneity:	Q=0.34 (df=1)	p=0.5624	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.58 (df=2)	p=0.4527	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.36.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

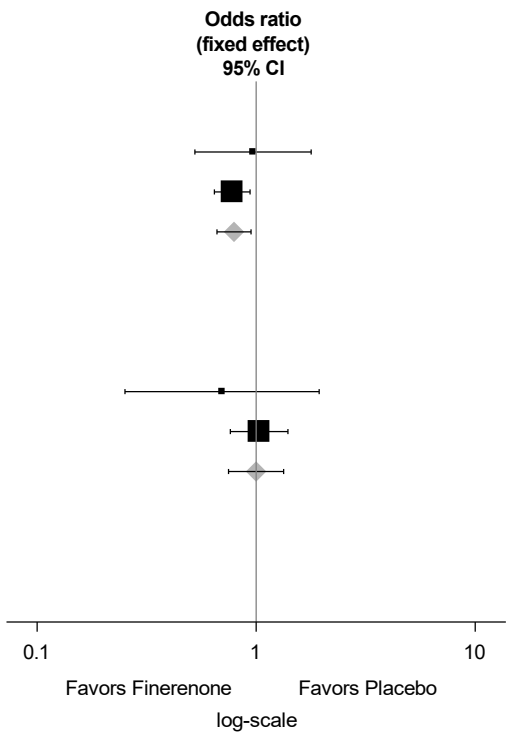
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 139	19 / 152	8.0	1.32 [0.68,2.55]	
FIGARO-DKD	208 / 1658	271 / 1612	92.0	0.71 [0.58,0.86]	
Total	230 / 1797	290 / 1764		0.75 [0.62,0.90]	Z=-3.07, p=0.0021
Heterogeneity:	Q=3.07 (df=1)	p=0.0796	I^2=67.5%		
Black					
FIDELIO-DKD	0 / 10	3 / 9	0.0	0.00 [0.00,17E295]	
FIGARO-DKD	10 / 70	5 / 74	100.0	2.30 [0.74,7.11]	
Total	10 / 80	8 / 83		1.33 [0.50,3.56]	Z=0.56, p=0.5725
Heterogeneity:	Q=0.91 (df=1)	p=0.3403	I^2=0.0%		
Asian					
FIDELIO-DKD	8 / 39	11 / 44	8.5	0.77 [0.28,2.18]	
FIGARO-DKD	98 / 464	96 / 485	91.5	1.08 [0.79,1.49]	
Total	106 / 503	107 / 529		1.05 [0.78,1.42]	Z=0.34, p=0.7328
Heterogeneity:	Q=0.37 (df=1)	p=0.5407	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	3 / 16	8.3	0.21 [0.02,2.20]	
FIGARO-DKD	21 / 134	15 / 131	91.7	1.44 [0.71,2.93]	
Total	22 / 156	18 / 147		1.19 [0.61,2.32]	Z=0.50, p=0.6150
Heterogeneity:	Q=2.38 (df=1)	p=0.1231	I^2=57.9%		
Subgroup Heterogeneity:	Q=5.58 (df=3)	p=0.1341	I^2=46.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.36.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 152	25 / 154	8.6	0.97 [0.53,1.78]	
FIGARO-DKD	234 / 1610	294 / 1638	91.4	0.78 [0.64,0.94]	
Total	258 / 1762	319 / 1792		0.79 [0.66,0.95]	Z=-2.55, p=0.0108
Heterogeneity:	Q=0.45 (df=1)	p=0.5024	I^2=0.0%		
Female					
FIDELIO-DKD	7 / 58	11 / 67	8.1	0.70 [0.25,1.94]	
FIGARO-DKD	103 / 716	93 / 664	91.9	1.03 [0.76,1.40]	
Total	110 / 774	104 / 731		1.00 [0.75,1.33]	Z=-0.01, p=0.9947
Heterogeneity:	Q=0.51 (df=1)	p=0.4732	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.78 (df=1)	p=0.1816	I^2=44.0%		

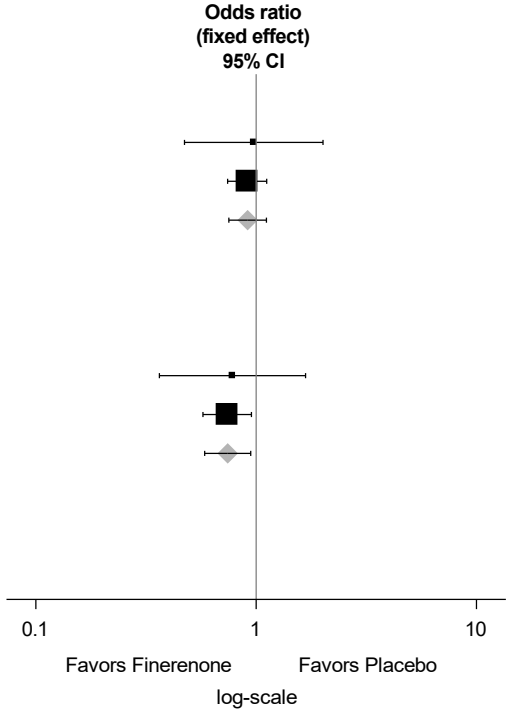


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.36.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

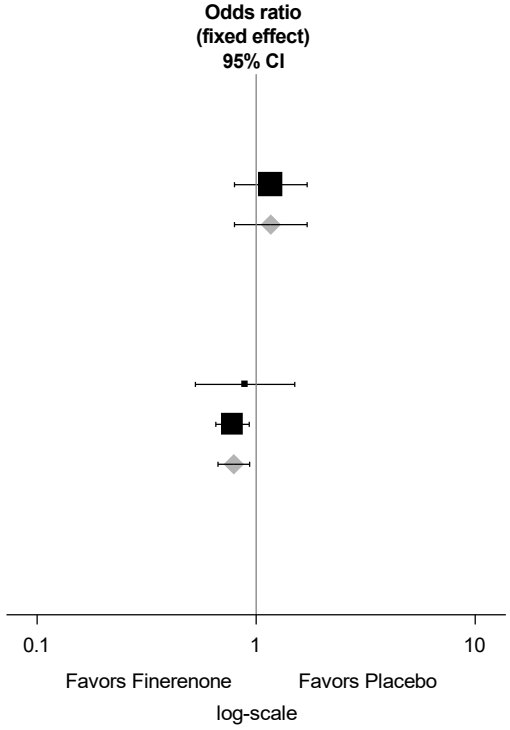
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 98	18 / 96	7.4	0.98 [0.47,2.01]	
FIGARO-DKD	209 / 1416	227 / 1420	92.6	0.91 [0.74,1.12]	
Total	227 / 1514	245 / 1516		0.91 [0.75,1.11]	Z=-0.89, p=0.3737
Heterogeneity:	Q=0.03 (df=1)	p=0.8574	I^2=0.0%		
>= 65					
FIDELIO-DKD	13 / 112	18 / 125	9.9	0.78 [0.36,1.68]	
FIGARO-DKD	128 / 910	160 / 882	90.1	0.74 [0.57,0.95]	
Total	141 / 1022	178 / 1007		0.74 [0.58,0.94]	Z=-2.42, p=0.0154
Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.73 (df=1)	p=0.1888	I^2=42.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.36.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

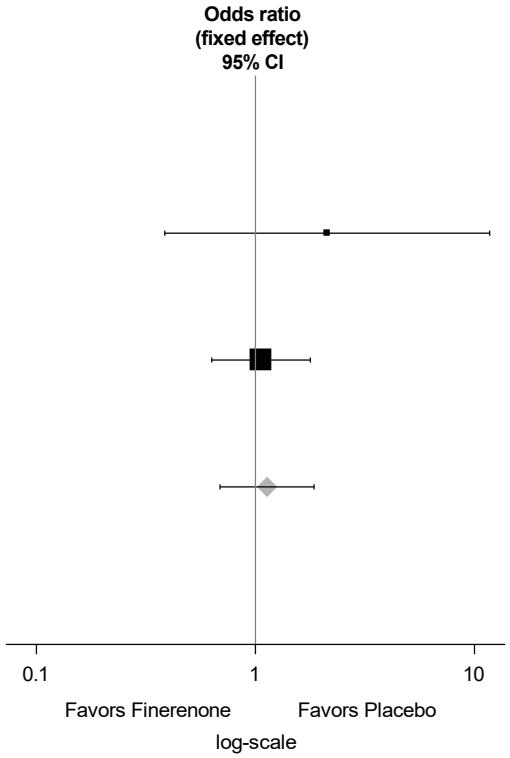
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	71 / 363	59 / 342	100.0	1.17 [0.80,1.71]	
Total	71 / 363	59 / 342		1.17 [0.80,1.71]	Z=0.79, p=0.4300
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	31 / 210	36 / 221	10.1	0.89 [0.53,1.50]	
FIGARO-DKD	266 / 1963	328 / 1960	89.9	0.78 [0.65,0.93]	
Total	297 / 2173	364 / 2181		0.79 [0.67,0.93]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.22 (df=1)	p=0.6387	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.35 (df=1)	p=0.0672	I^2=70.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.37: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

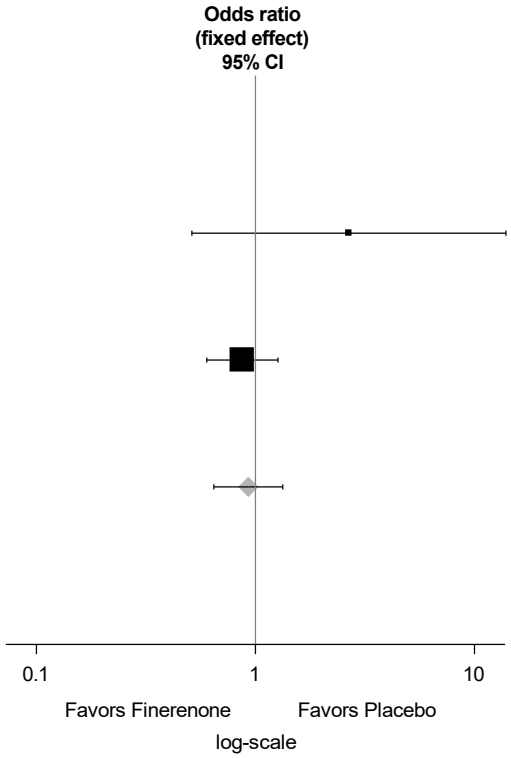
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	8.4	2.13 [0.39,11.73]	
FIGARO-DKD	30 / 2326	28 / 2302	91.6	1.06 [0.63,1.78]	
Total	34 / 2536	30 / 2523		1.13 [0.69,1.85]	Z=0.48, p=0.6281
Heterogeneity:	Q=0.58 (df=1)	p=0.4453	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.38: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

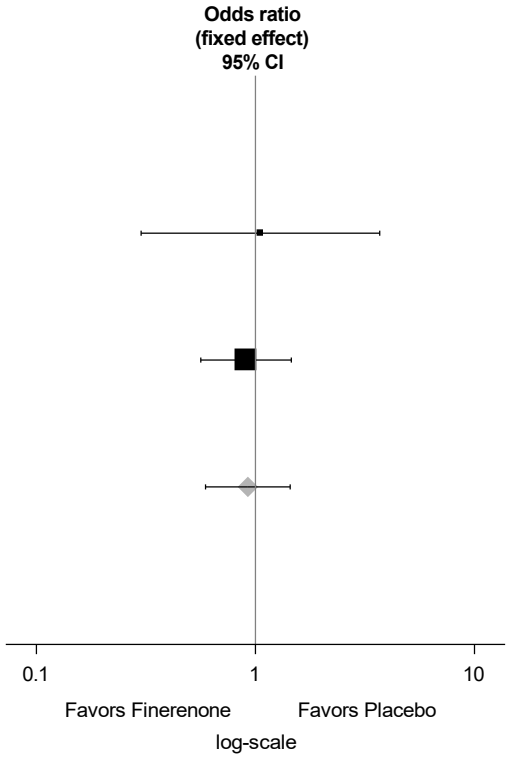
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	4.9	2.67 [0.51,13.92]	
FIGARO-DKD	53 / 2326	60 / 2302	95.1	0.87 [0.60,1.27]	
Total	58 / 2536	62 / 2523		0.93 [0.65,1.33]	Z=-0.41, p=0.6839
Heterogeneity:	Q=1.68 (df=1)	p=0.1944	I^2=40.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.39: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

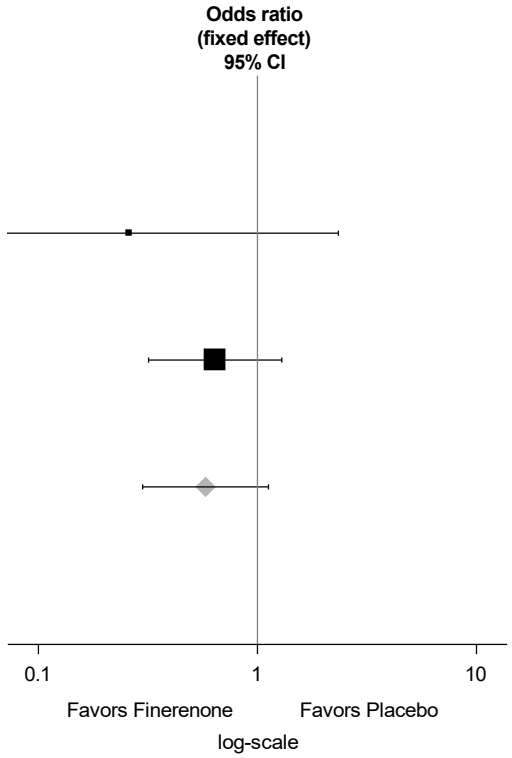
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	5 / 221	12.6	1.05 [0.30,3.69]	
FIGARO-DKD	33 / 2326	36 / 2302	87.4	0.91 [0.56,1.46]	
Total	38 / 2536	41 / 2523		0.92 [0.59,1.44]	Z=-0.35, p=0.7250
Heterogeneity:	Q=0.05 (df=1)	p=0.8253	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.40: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

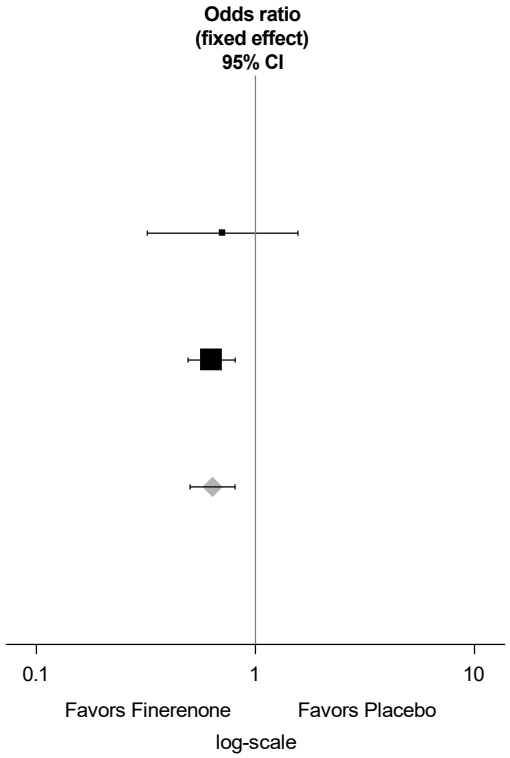
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	9.2	0.26 [0.03,2.34]	
FIGARO-DKD	13 / 2326	20 / 2302	90.8	0.64 [0.32,1.29]	
Total	14 / 2536	24 / 2523		0.58 [0.30,1.12]	Z=-1.62, p=0.1061
Heterogeneity:	Q=0.59 (df=1)	p=0.4415	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.41: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

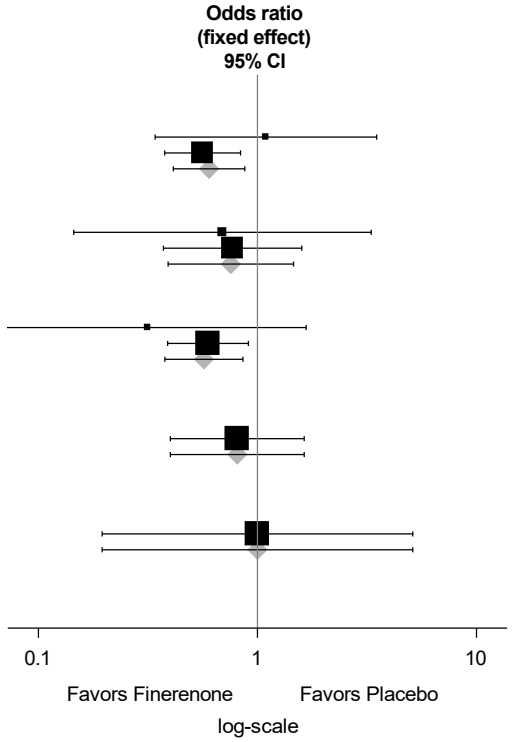
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	16 / 221	8.9	0.71 [0.32,1.56]	
FIGARO-DKD	110 / 2326	168 / 2302	91.1	0.63 [0.49,0.81]	
Total	121 / 2536	184 / 2523		0.64 [0.50,0.81]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.08 (df=1)	p=0.7837	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.41.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

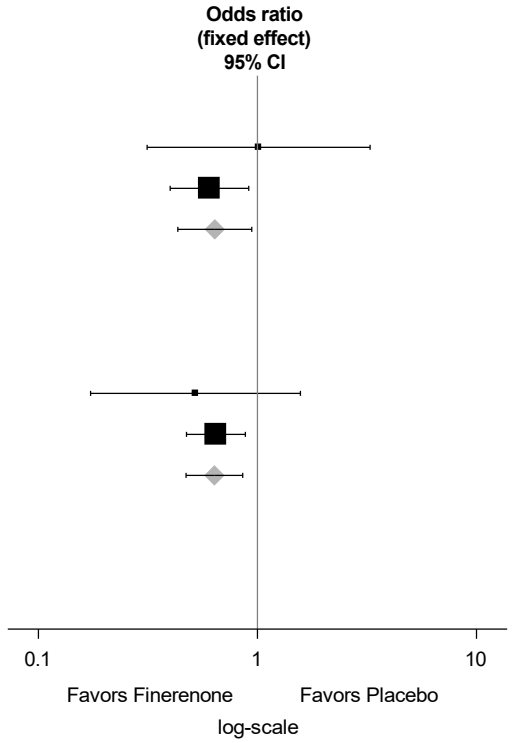
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 103	6 / 112	10.5	1.09 [0.34,3.50]	
FIGARO-DKD	40 / 1114	69 / 1110	89.5	0.56 [0.38,0.84]	
Total	46 / 1217	75 / 1222		0.60 [0.41,0.88]	Z=-2.65, p=0.0080
Heterogeneity:	Q=1.12 (df=1)	p=0.2895	I^2=10.9%		
North America					
FIDELIO-DKD	3 / 42	4 / 40	17.8	0.69 [0.14,3.31]	
FIGARO-DKD	14 / 292	17 / 277	82.2	0.77 [0.37,1.59]	
Total	17 / 334	21 / 317		0.76 [0.39,1.46]	Z=-0.83, p=0.4050
Heterogeneity:	Q=0.01 (df=1)	p=0.9036	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	6 / 41	6.1	0.32 [0.06,1.67]	
FIGARO-DKD	38 / 522	61 / 523	93.9	0.59 [0.39,0.91]	
Total	40 / 561	67 / 564		0.57 [0.38,0.86]	Z=-2.69, p=0.0072
Heterogeneity:	Q=0.52 (df=1)	p=0.4693	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	15 / 322	18 / 316	100.0	0.81 [0.40,1.63]	
Total	15 / 343	18 / 340		0.81 [0.40,1.63]	Z=-0.59, p=0.5546
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	3 / 76	100.0	1.00 [0.20,5.12]	
Total	3 / 81	3 / 80		1.00 [0.20,5.12]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=4)	p=0.8495	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.41.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

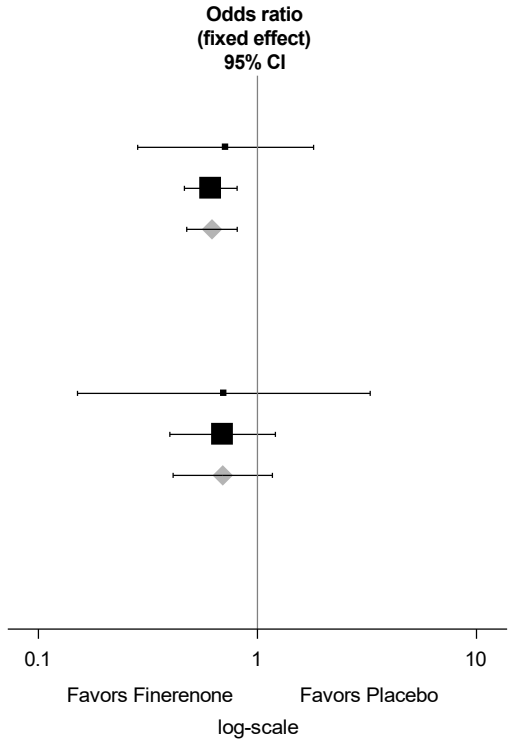
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	6 / 88	6 / 89	11.0	1.01 [0.31,3.27]	
FIGARO-DKD	39 / 811	62 / 803	89.0	0.60 [0.40,0.91]	
Total	45 / 899	68 / 892		0.64 [0.43,0.94]	Z=-2.26, p=0.0237
Heterogeneity:	Q=0.66 (df=1)	p=0.4151	I^2=0.0%		
Absent					
FIDELIO-DKD	5 / 122	10 / 132	7.3	0.52 [0.17,1.57]	
FIGARO-DKD	71 / 1515	106 / 1499	92.7	0.65 [0.47,0.88]	
Total	76 / 1637	116 / 1631		0.64 [0.47,0.86]	Z=-2.98, p=0.0029
Heterogeneity:	Q=0.13 (df=1)	p=0.7135	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9862	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.41.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	8 / 144	12 / 158	8.2	0.72 [0.28,1.80]	
FIGARO-DKD	88 / 1719	136 / 1679	91.8	0.61 [0.46,0.81]	
Total	96 / 1863	148 / 1837		0.62 [0.48,0.81]	Z=-3.53, p=0.0004
Heterogeneity:	Q=0.10 (df=1)	p=0.7510	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 66	4 / 63	11.5	0.70 [0.15,3.27]	
FIGARO-DKD	22 / 607	32 / 622	88.5	0.69 [0.40,1.21]	
Total	25 / 673	36 / 685		0.69 [0.41,1.17]	Z=-1.37, p=0.1708
Heterogeneity:	Q=0.00 (df=1)	p=0.9877	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7042	I^2=0.0%		

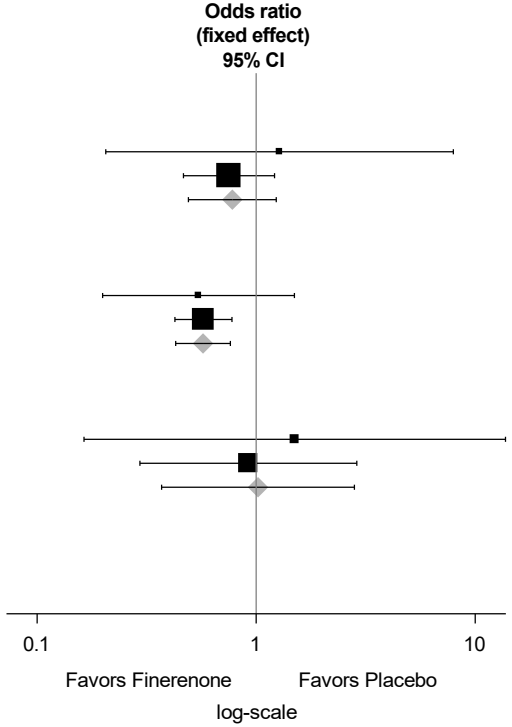


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.41.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

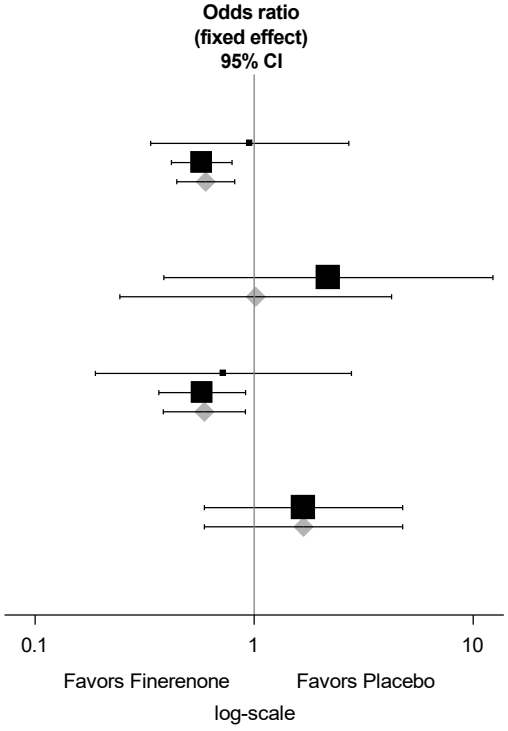
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	2 / 54	6.4	1.28 [0.21,7.95]	
FIGARO-DKD	31 / 693	41 / 699	93.6	0.75 [0.47,1.21]	
Total	34 / 757	43 / 753		0.78 [0.49,1.23]	Z=-1.06, p=0.2873
Heterogeneity:	Q=0.30 (df=1)	p=0.5813	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	6 / 138	12 / 156	8.1	0.55 [0.20,1.49]	
FIGARO-DKD	73 / 1560	120 / 1524	91.9	0.57 [0.43,0.78]	
Total	79 / 1698	132 / 1680		0.57 [0.43,0.76]	Z=-3.81, p=0.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9233	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 8	2 / 11	20.9	1.50 [0.16,13.75]	
FIGARO-DKD	6 / 73	7 / 79	79.1	0.92 [0.29,2.88]	
Total	8 / 81	9 / 90		1.02 [0.37,2.81]	Z=0.04, p=0.9701
Heterogeneity:	Q=0.15 (df=1)	p=0.7013	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=2)	p=0.3520	I^2=4.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.41.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

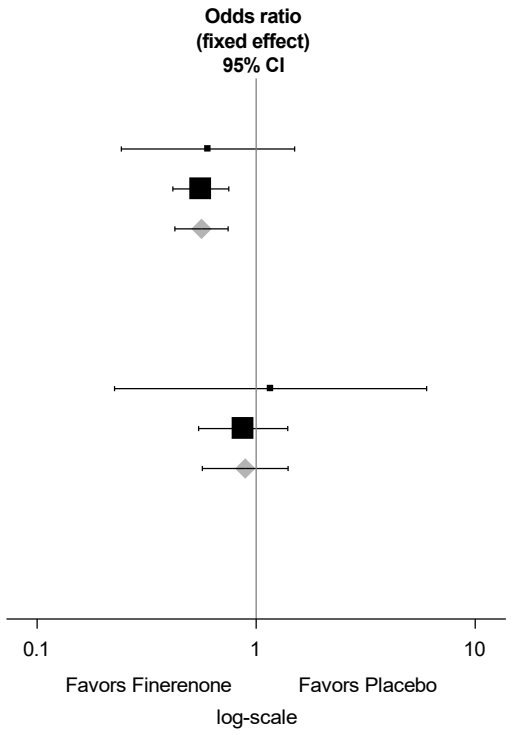
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	7 / 139	8 / 152	8.6	0.95 [0.34,2.70]	
FIGARO-DKD	64 / 1658	105 / 1612	91.4	0.58 [0.42,0.79]	
Total	71 / 1797	113 / 1764		0.60 [0.44,0.81]	Z=-3.28, p=0.0010
Heterogeneity:	Q=0.82 (df=1)	p=0.3638	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	2 / 9	0.0	0.00 [0.00,3E296]	
FIGARO-DKD	4 / 70	2 / 74	100.0	2.18 [0.39,12.31]	
Total	4 / 80	4 / 83		1.02 [0.24,4.24]	Z=0.02, p=0.9821
Heterogeneity:	Q=0.75 (df=1)	p=0.3868	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 39	6 / 44	10.3	0.72 [0.19,2.78]	
FIGARO-DKD	32 / 464	55 / 485	89.7	0.58 [0.37,0.91]	
Total	36 / 503	61 / 529		0.59 [0.38,0.91]	Z=-2.38, p=0.0174
Heterogeneity:	Q=0.09 (df=1)	p=0.7584	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	10 / 134	6 / 131	100.0	1.68 [0.59,4.76]	
Total	10 / 156	6 / 147		1.68 [0.59,4.76]	Z=0.98, p=0.3292
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.99 (df=3)	p=0.2630	I^2=24.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.41.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

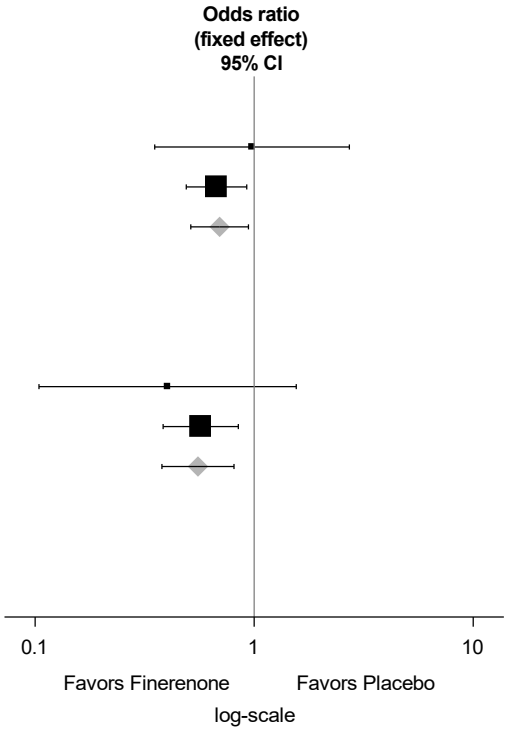
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	13 / 154	9.4	0.60 [0.24,1.50]	
FIGARO-DKD	74 / 1610	130 / 1638	90.6	0.56 [0.42,0.75]	
Total	82 / 1762	143 / 1792		0.56 [0.43,0.74]	Z=-4.03, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8774	I^2=0.0%		
Female					
FIDELIO-DKD	3 / 58	3 / 67	7.5	1.16 [0.23,6.00]	
FIGARO-DKD	36 / 716	38 / 664	92.5	0.87 [0.55,1.39]	
Total	39 / 774	41 / 731		0.89 [0.57,1.40]	Z=-0.50, p=0.6165
Heterogeneity:	Q=0.11 (df=1)	p=0.7404	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.88 (df=1)	p=0.0895	I^2=65.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.41.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

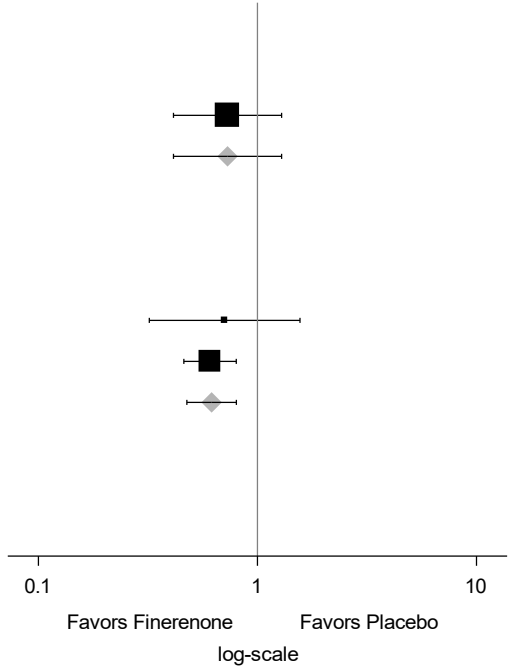
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	8 / 96	8.8	0.98 [0.35,2.72]	
FIGARO-DKD	68 / 1416	99 / 1420	91.2	0.67 [0.49,0.93]	
Total	76 / 1514	107 / 1516		0.70 [0.51,0.94]	Z=-2.35, p=0.0188
Heterogeneity:	Q=0.47 (df=1)	p=0.4946	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	8 / 125	7.9	0.40 [0.10,1.56]	
FIGARO-DKD	42 / 910	69 / 882	92.1	0.57 [0.38,0.85]	
Total	45 / 1022	77 / 1007		0.55 [0.38,0.81]	Z=-3.06, p=0.0022
Heterogeneity:	Q=0.23 (df=1)	p=0.6281	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.85 (df=1)	p=0.3576	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.41.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

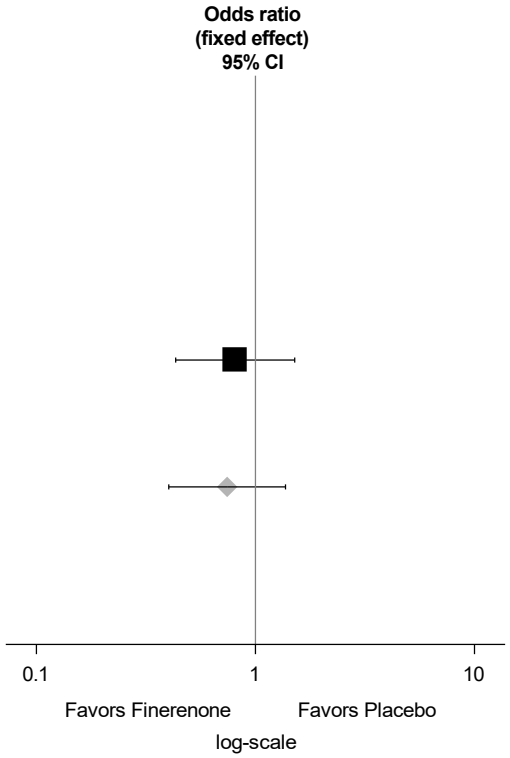
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	23 / 363	29 / 342	100.0	0.73 [0.41,1.29]	
Total	23 / 363	29 / 342		0.73 [0.41,1.29]	Z=-1.08, p=0.2781
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	11 / 210	16 / 221	10.8	0.71 [0.32,1.56]	
FIGARO-DKD	87 / 1963	139 / 1960	89.2	0.61 [0.46,0.80]	
Total	98 / 2173	155 / 2181		0.62 [0.48,0.80]	Z=-3.63, p=0.0003
Heterogeneity:	Q=0.13 (df=1)	p=0.7201	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5996	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.42: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

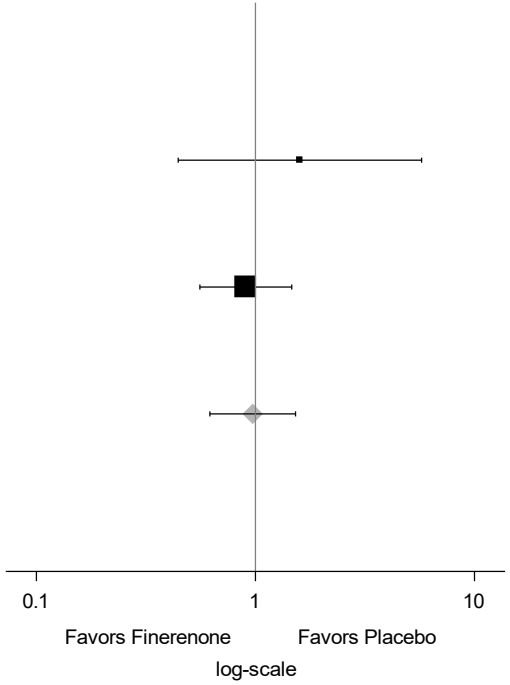
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	18 / 2326	22 / 2302	100.0	0.81 [0.43,1.51]	
Total	18 / 2536	24 / 2523		0.74 [0.40,1.37]	Z=-0.95, p=0.3418
Heterogeneity:	Q=0.07 (df=1)	p=0.7906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.43: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

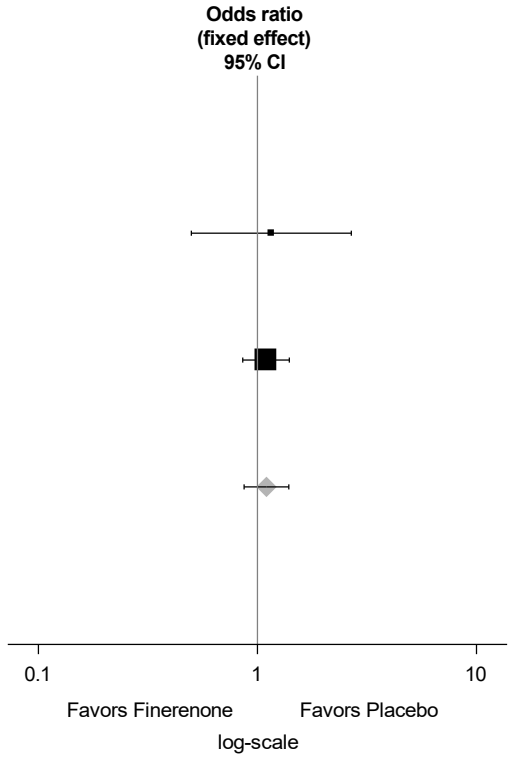
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	4 / 221	12.5	1.60 [0.44,5.74]	
FIGARO-DKD	32 / 2326	35 / 2302	87.5	0.90 [0.56,1.46]	
Total	38 / 2536	39 / 2523		0.97 [0.62,1.52]	Z=-0.13, p=0.9002
Heterogeneity:	Q=0.66 (df=1)	p=0.4150	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.44: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

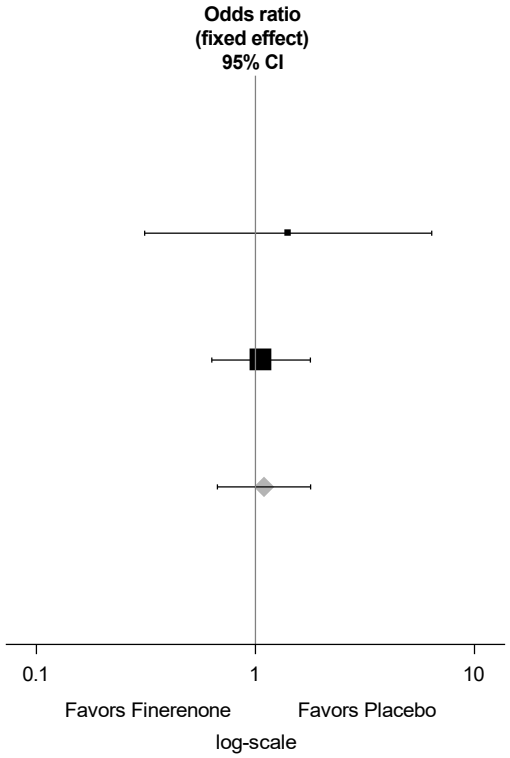
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	11 / 221	7.8	1.16 [0.50,2.68]	
FIGARO-DKD	143 / 2326	130 / 2302	92.2	1.09 [0.86,1.40]	
Total	155 / 2536	141 / 2523		1.10 [0.87,1.39]	Z=0.79, p=0.4302
Heterogeneity:	Q=0.02 (df=1)	p=0.9010	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.45: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

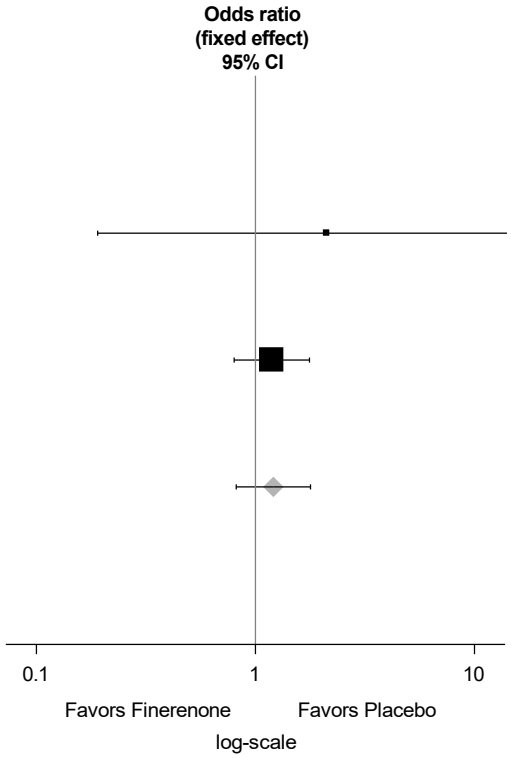
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	10.6	1.41 [0.31,6.38]	
FIGARO-DKD	30 / 2326	28 / 2302	89.4	1.06 [0.63,1.78]	
Total	34 / 2536	31 / 2523		1.09 [0.67,1.79]	Z=0.36, p=0.7195
Heterogeneity:	Q=0.12 (df=1)	p=0.7263	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.46: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

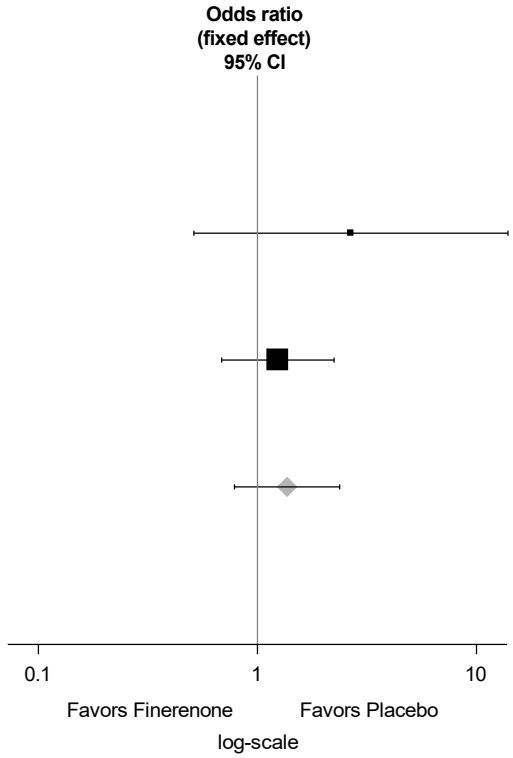
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	2.6	2.12 [0.19,23.50]	
FIGARO-DKD	55 / 2326	46 / 2302	97.4	1.19 [0.80,1.76]	
Total	57 / 2536	47 / 2523		1.21 [0.82,1.78]	Z=0.95, p=0.3443
Heterogeneity:	Q=0.21 (df=1)	p=0.6429	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.47: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

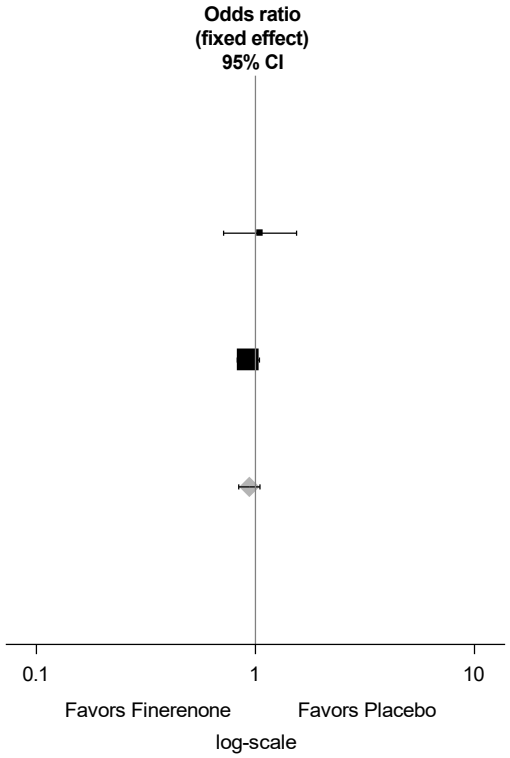
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	11.4	2.67 [0.51,13.92]	
FIGARO-DKD	25 / 2326	20 / 2302	88.6	1.24 [0.69,2.24]	
Total	30 / 2536	22 / 2523		1.37 [0.79,2.37]	Z=1.10, p=0.2698
Heterogeneity:	Q=0.74 (df=1)	p=0.3906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.48: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

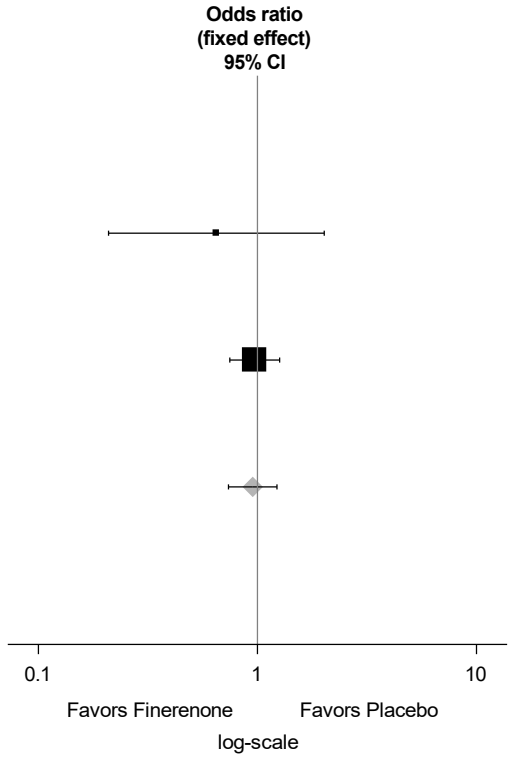
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	88 / 210	90 / 221	8.4	1.05 [0.72,1.54]	
FIGARO-DKD	973 / 2326	1005 / 2302	91.6	0.93 [0.83,1.04]	
Total	1061 / 2536	1095 / 2523		0.94 [0.84,1.05]	Z=-1.13, p=0.2588
Heterogeneity:	Q=0.36 (df=1)	p=0.5465	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.49: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

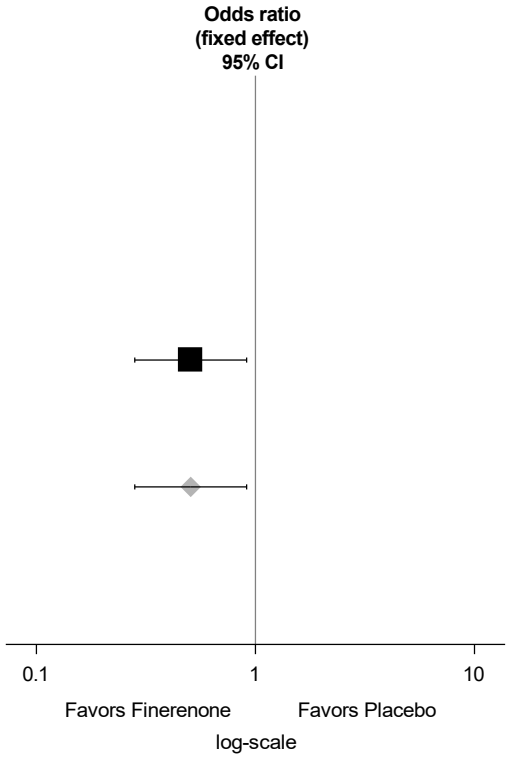
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	8 / 221	5.1	0.65 [0.21,2.02]	
FIGARO-DKD	117 / 2326	119 / 2302	94.9	0.97 [0.75,1.26]	
Total	122 / 2536	127 / 2523		0.95 [0.74,1.23]	Z=-0.38, p=0.7017
Heterogeneity:	Q=0.46 (df=1)	p=0.4973	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.50: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

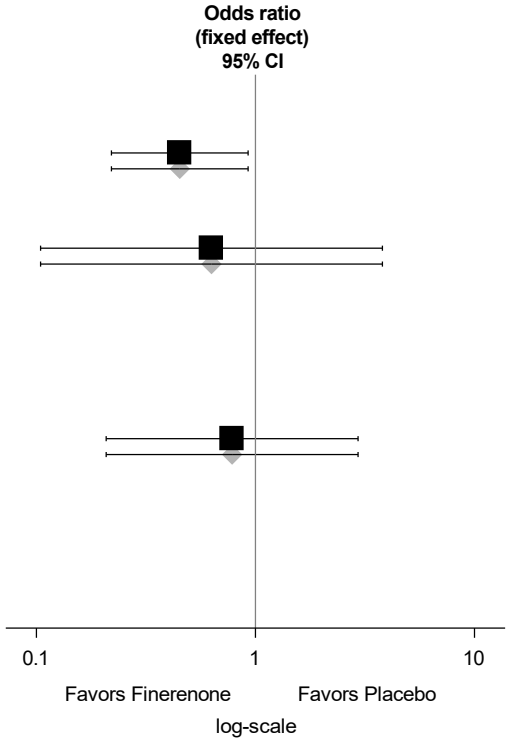
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	17 / 2326	33 / 2302	100.0	0.51 [0.28,0.91]	
Total	17 / 2536	33 / 2523		0.51 [0.28,0.91]	Z=-2.27, p=0.0233
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.50.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

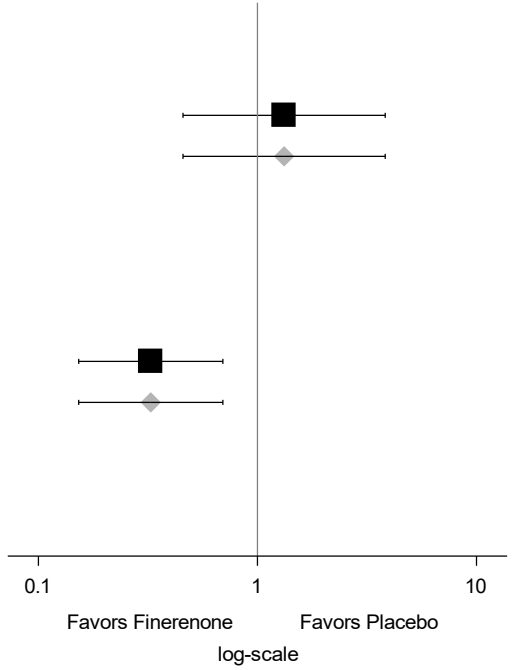
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	11 / 1114	24 / 1110	100.0	0.45 [0.22,0.93]	
Total	11 / 1217	24 / 1222		0.45 [0.22,0.93]	Z=-2.17, p=0.0300
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	2 / 292	3 / 277	100.0	0.63 [0.10,3.80]	
Total	2 / 334	3 / 317		0.63 [0.10,3.80]	Z=-0.50, p=0.6141
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	0 / 522	0 / 523	0.0	-	
Total	0 / 561	0 / 564		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	4 / 322	5 / 316	100.0	0.78 [0.21,2.94]	
Total	4 / 343	5 / 340		0.78 [0.21,2.94]	Z=-0.36, p=0.7164
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	1 / 76	0.0	0.00 [0.00,88E295]	
Total	0 / 81	1 / 80		0.00 [0.00,95E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.56 (df=4)	p=0.9676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.50.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

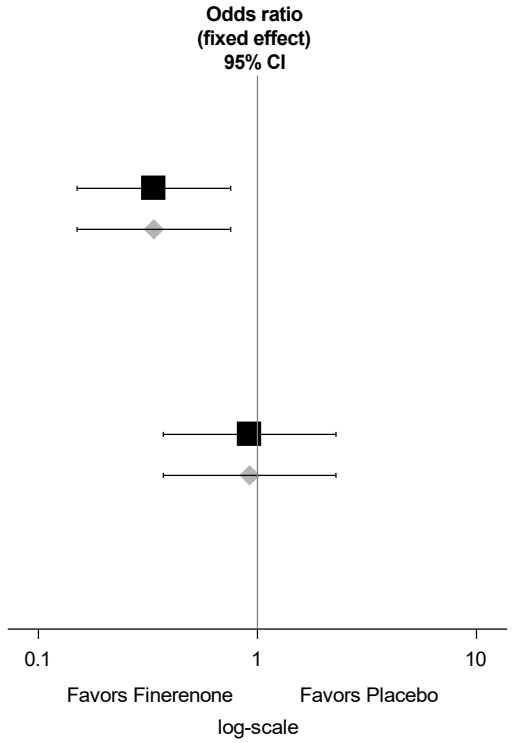
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	8 / 811	6 / 803	100.0	1.32 [0.46,3.83]	
Total	8 / 899	6 / 892		1.32 [0.46,3.83]	Z=0.52, p=0.6054
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	0 / 132	0.0	-	
FIGARO-DKD	9 / 1515	27 / 1499	100.0	0.33 [0.15,0.70]	
Total	9 / 1637	27 / 1631		0.33 [0.15,0.70]	Z=-2.90, p=0.0037
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.43 (df=1)	p=0.0354	I^2=77.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.50.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

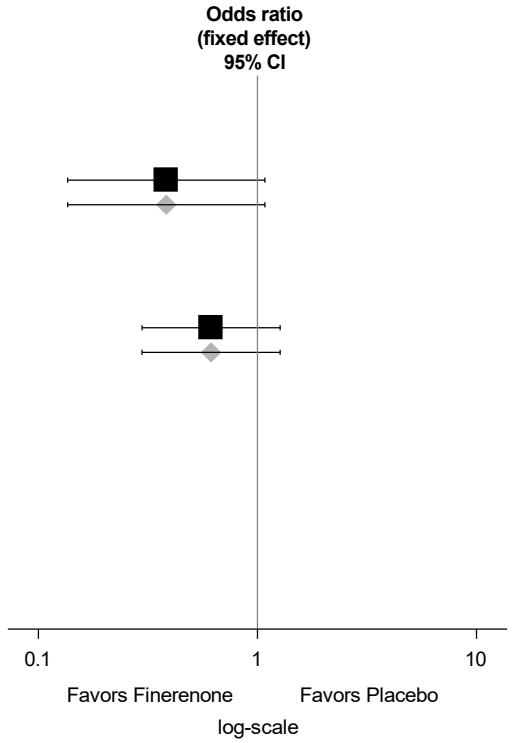
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	0 / 158	0.0	-	
FIGARO-DKD	8 / 1719	23 / 1679	100.0	0.34 [0.15,0.75]	
Total	8 / 1863	23 / 1837		0.34 [0.15,0.75]	Z=-2.64, p=0.0082
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	9 / 607	10 / 622	100.0	0.92 [0.37,2.28]	
Total	9 / 673	10 / 685		0.92 [0.37,2.28]	Z=-0.18, p=0.8591
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.64 (df=1)	p=0.1044	I^2=62.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.50.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

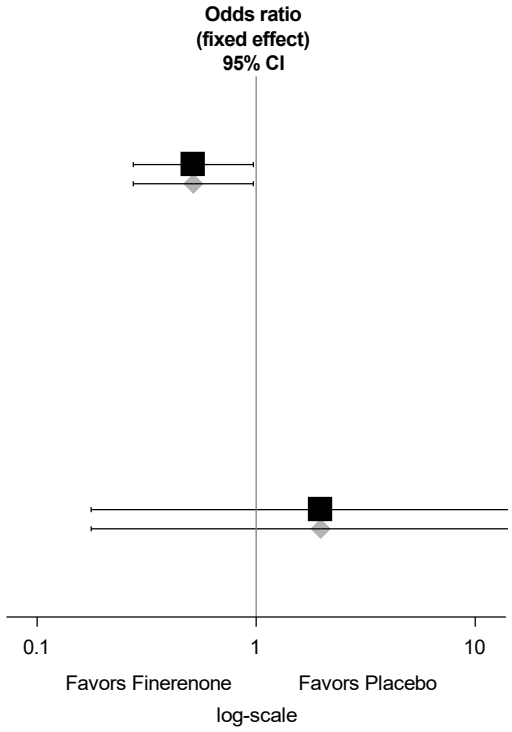
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	5 / 693	13 / 699	100.0	0.38 [0.14,1.08]	
Total	5 / 757	13 / 753		0.38 [0.14,1.08]	Z=-1.81, p=0.0700
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	0 / 156	0.0	-	
FIGARO-DKD	12 / 1560	19 / 1524	100.0	0.61 [0.30,1.27]	
Total	12 / 1698	19 / 1680		0.61 [0.30,1.27]	Z=-1.32, p=0.1881
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,91E295]	
Total	0 / 81	1 / 90		0.00 [0.00,1E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.53 (df=2)	p=0.7667	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.50.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

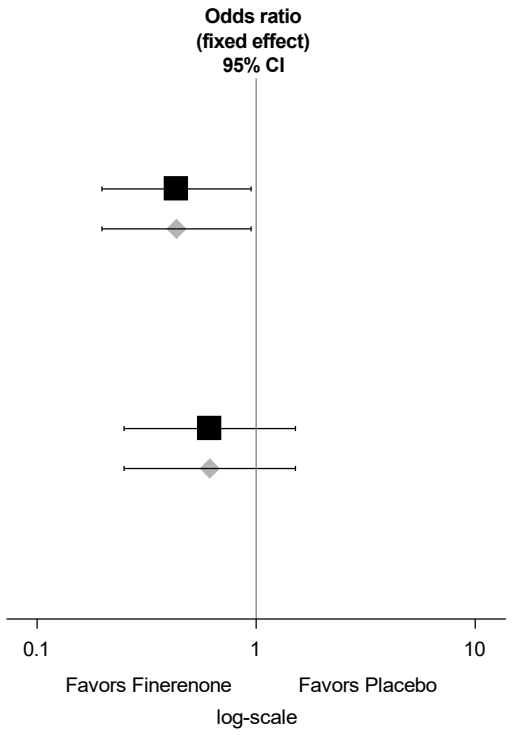
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	15 / 1658	28 / 1612	100.0	0.52 [0.27,0.97]	
Total	15 / 1797	28 / 1764		0.52 [0.27,0.97]	Z=-2.05, p=0.0401
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	2 / 74	0.0	0.00 [0.00,11E296]	
Total	0 / 80	2 / 83		0.00 [0.00,14E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	0 / 464	2 / 485	0.0	0.00 [0.00,1E297]	
Total	0 / 503	2 / 529		0.00 [0.00,11E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	1 / 131	100.0	1.97 [0.18,21.99]	
Total	2 / 156	1 / 147		1.97 [0.18,21.99]	Z=0.55, p=0.5818
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.11 (df=3)	p=0.7754	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.50.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

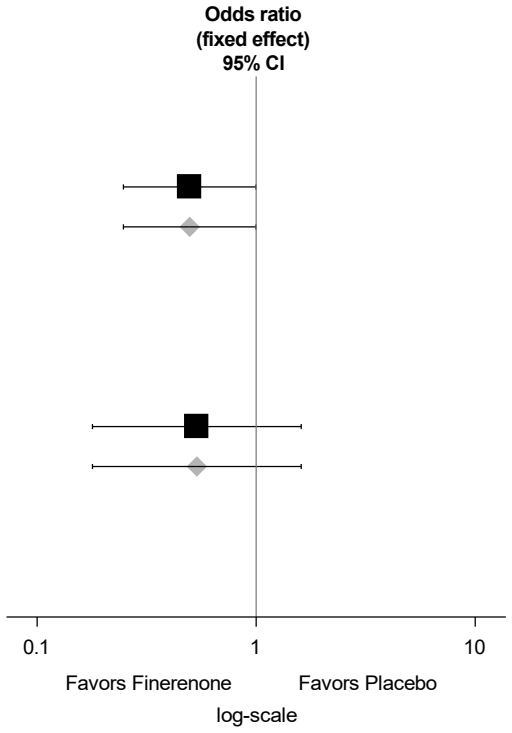
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	0 / 154	0.0	-	
FIGARO-DKD	9 / 1610	21 / 1638	100.0	0.43 [0.20,0.95]	
Total	9 / 1762	21 / 1792		0.43 [0.20,0.95]	Z=-2.09, p=0.0363
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	8 / 716	12 / 664	100.0	0.61 [0.25,1.51]	
Total	8 / 774	12 / 731		0.61 [0.25,1.51]	Z=-1.06, p=0.2885
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=1)	p=0.5662	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.50.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

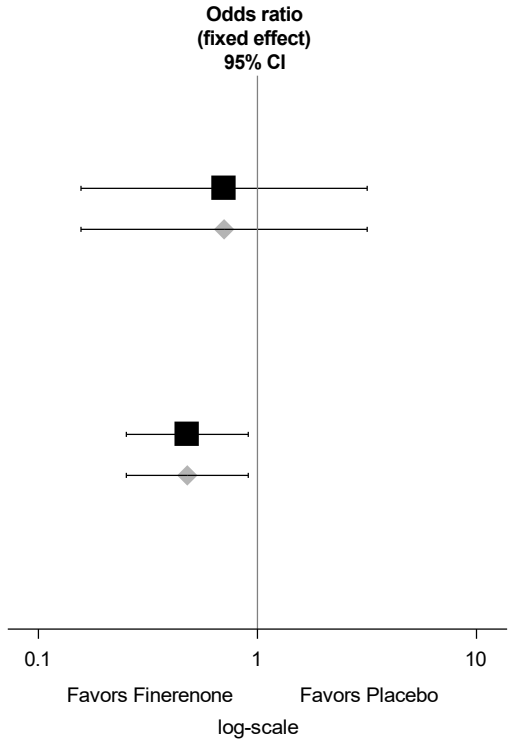
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	12 / 1416	24 / 1420	100.0	0.50 [0.25,1.00]	
Total	12 / 1514	24 / 1516		0.50 [0.25,1.00]	Z=-1.97, p=0.0494
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	0 / 125	0.0	-	
FIGARO-DKD	5 / 910	9 / 882	100.0	0.54 [0.18,1.61]	
Total	5 / 1022	9 / 1007		0.54 [0.18,1.61]	Z=-1.11, p=0.2651
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9099	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.50.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

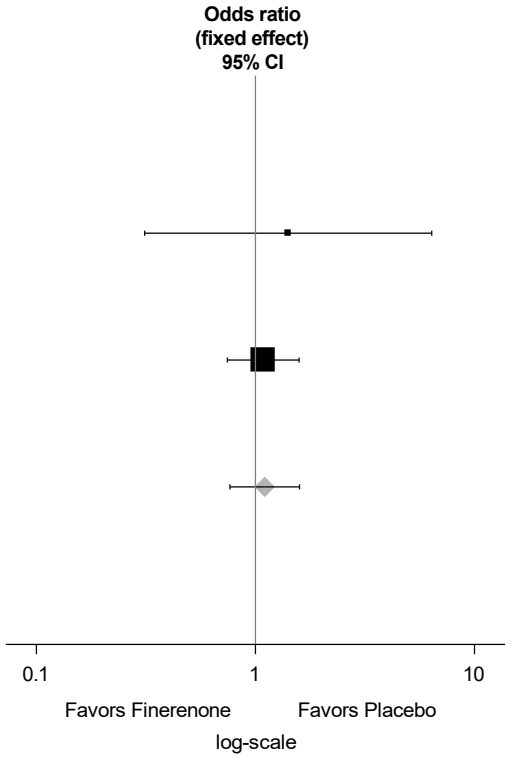
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	3 / 363	4 / 342	100.0	0.70 [0.16,3.17]	
Total	3 / 363	4 / 342		0.70 [0.16,3.17]	Z=-0.46, p=0.6477
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	0 / 210	0 / 221	0.0	-	
FIGARO-DKD	14 / 1963	29 / 1960	100.0	0.48 [0.25,0.91]	
Total	14 / 2173	29 / 2181		0.48 [0.25,0.91]	Z=-2.26, p=0.0241
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6429	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.51: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

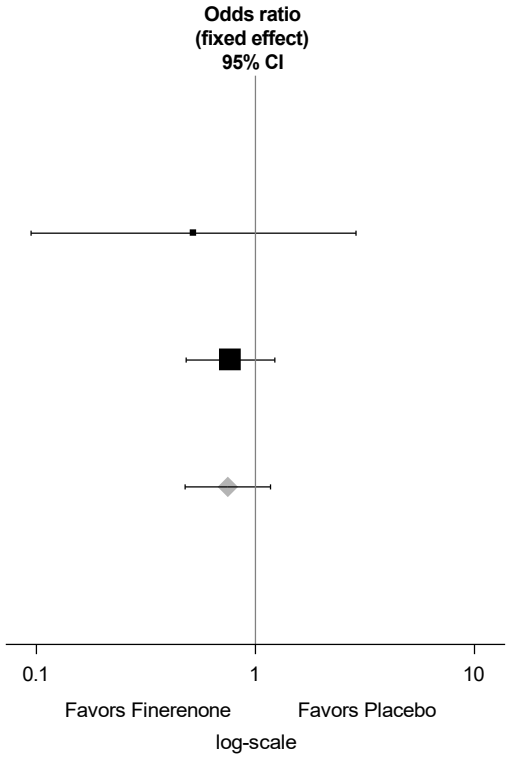
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	5.9	1.41 [0.31,6.38]	
FIGARO-DKD	58 / 2326	53 / 2302	94.1	1.09 [0.74,1.58]	
Total	62 / 2536	56 / 2523		1.10 [0.76,1.59]	Z=0.52, p=0.6018
Heterogeneity:	Q=0.11 (df=1)	p=0.7408	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.52: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

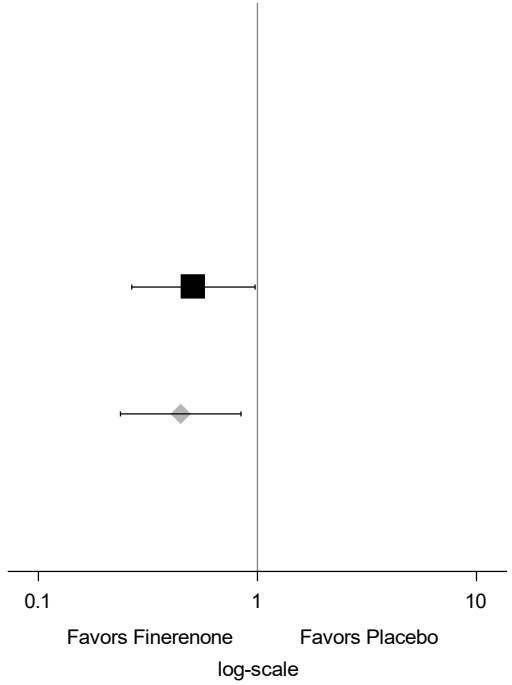
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	6.9	0.52 [0.09,2.88]	
FIGARO-DKD	32 / 2326	41 / 2302	93.1	0.77 [0.48,1.23]	
Total	34 / 2536	45 / 2523		0.75 [0.48,1.17]	Z=-1.27, p=0.2045
Heterogeneity:	Q=0.18 (df=1)	p=0.6671	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.53: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

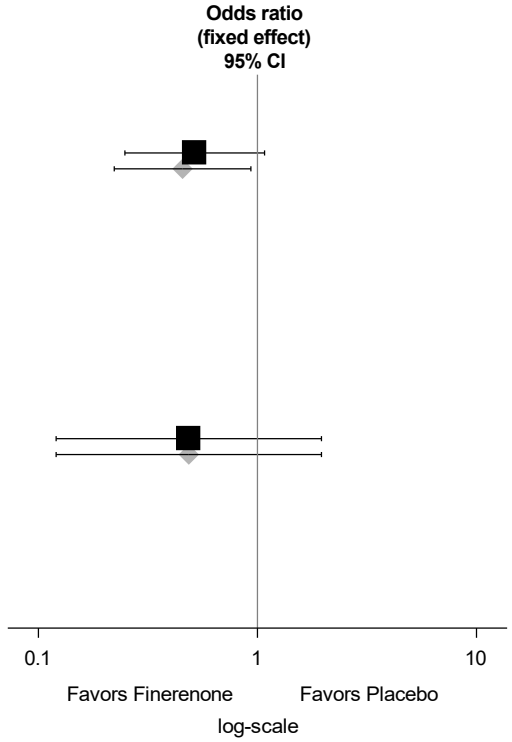
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	4 / 221	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	14 / 2326	27 / 2302	100.0	0.51 [0.27,0.98]	
Total	14 / 2536	31 / 2523		0.45 [0.24,0.84]	Z=-2.50, p=0.0126
Heterogeneity:	Q=0.16 (df=1)	p=0.6857	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.53.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

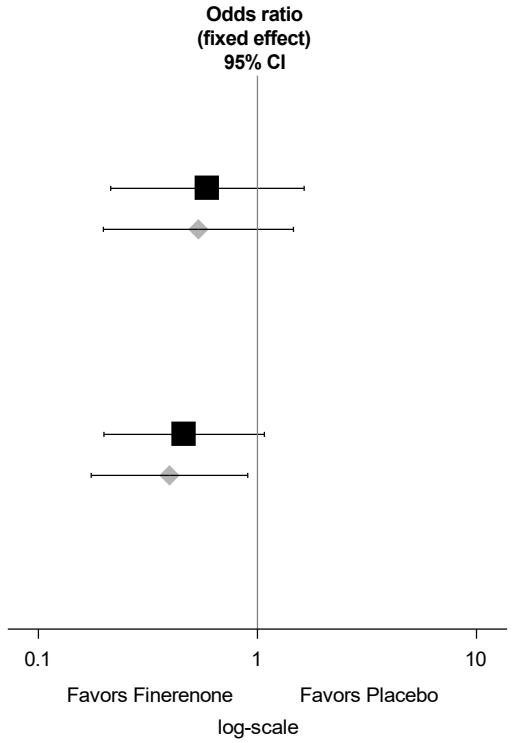
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	3 / 112	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	11 / 1114	21 / 1110	100.0	0.52 [0.25,1.08]	
Total	11 / 1217	24 / 1222		0.46 [0.22,0.93]	Z=-2.15, p=0.0317
Heterogeneity:	Q=0.12 (df=1)	p=0.7331	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	0 / 292	0 / 277	0.0	-	
Total	0 / 334	0 / 317		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	0 / 522	0 / 523	0.0	-	
Total	0 / 561	1 / 564		0.00 [0.00,51E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	3 / 322	6 / 316	100.0	0.49 [0.12,1.96]	
Total	3 / 343	6 / 340		0.49 [0.12,1.96]	Z=-1.01, p=0.3104
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	0 / 76	0.0	-	
Total	0 / 81	0 / 80		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.01 (df=4)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.53.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

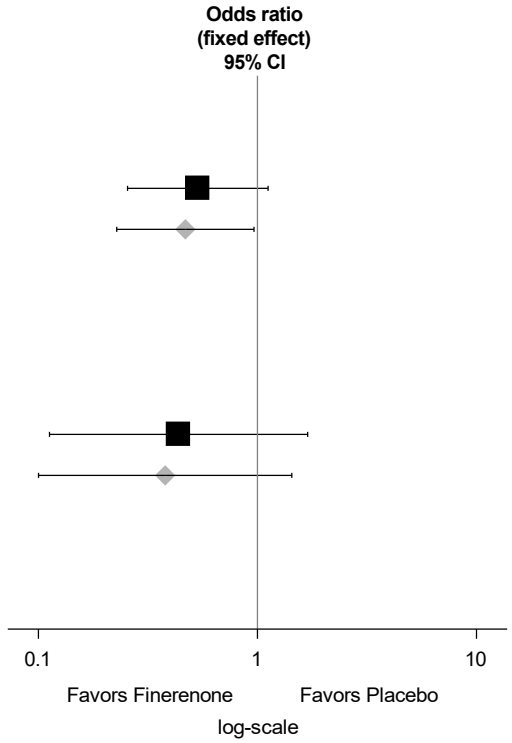
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	1 / 89	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	6 / 811	10 / 803	100.0	0.59 [0.21,1.63]	
Total	6 / 899	11 / 892		0.54 [0.20,1.46]	Z=-1.22, p=0.2234
Heterogeneity:	Q=0.03 (df=1)	p=0.8550	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	3 / 132	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	8 / 1515	17 / 1499	100.0	0.46 [0.20,1.08]	
Total	8 / 1637	20 / 1631		0.40 [0.17,0.90]	Z=-2.20, p=0.0276
Heterogeneity:	Q=0.13 (df=1)	p=0.7196	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6449	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.53.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

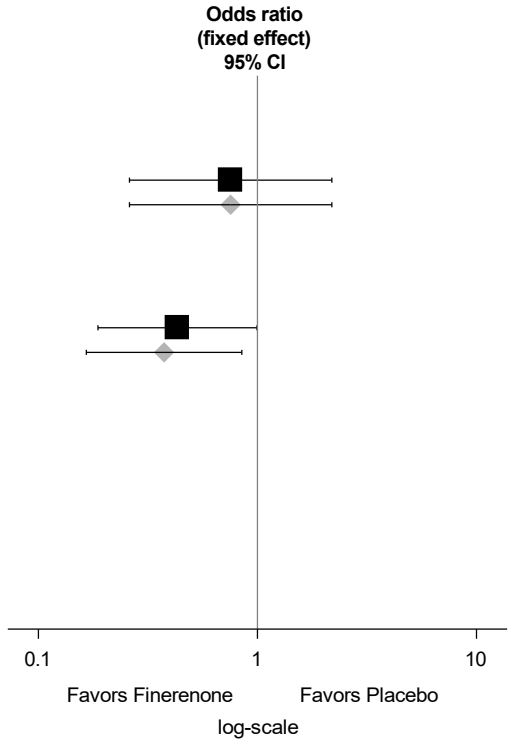
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	3 / 158	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	11 / 1719	20 / 1679	100.0	0.53 [0.26,1.12]	
Total	11 / 1863	23 / 1837		0.47 [0.23,0.96]	Z=-2.06, p=0.0395
Heterogeneity:	Q=0.12 (df=1)	p=0.7286	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	1 / 63	0.0	0.00 [0.00,72E295]	
FIGARO-DKD	3 / 607	7 / 622	100.0	0.44 [0.11,1.70]	
Total	3 / 673	8 / 685		0.38 [0.10,1.43]	Z=-1.43, p=0.1532
Heterogeneity:	Q=0.04 (df=1)	p=0.8387	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7833	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.53.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

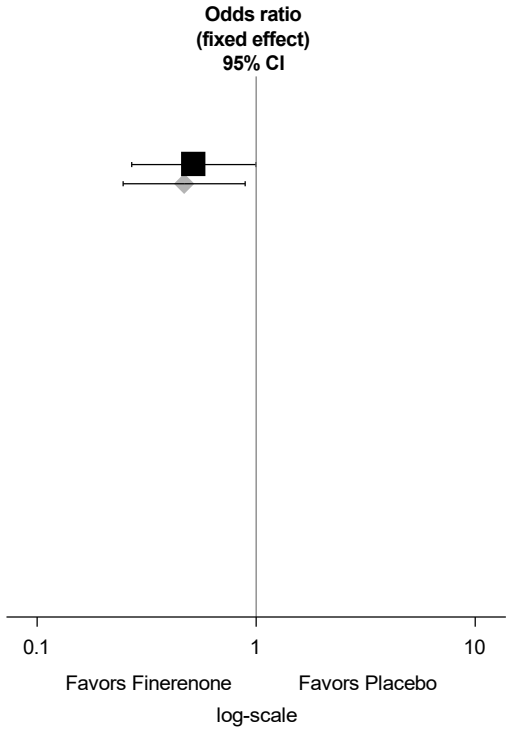
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	8 / 699	100.0	0.75 [0.26,2.19]	
Total	6 / 757	8 / 753		0.75 [0.26,2.19]	Z=-0.52, p=0.6035
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	3 / 156	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	8 / 1560	18 / 1524	100.0	0.43 [0.19,0.99]	
Total	8 / 1698	21 / 1680		0.37 [0.17,0.85]	Z=-2.35, p=0.0186
Heterogeneity:	Q=0.11 (df=1)	p=0.7416	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	1 / 11	0.0	0.00 [0.00,86E295]	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,91E295]	
Total	0 / 81	2 / 90		0.00 [0.00,16E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.05 (df=2)	p=0.5930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.53.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

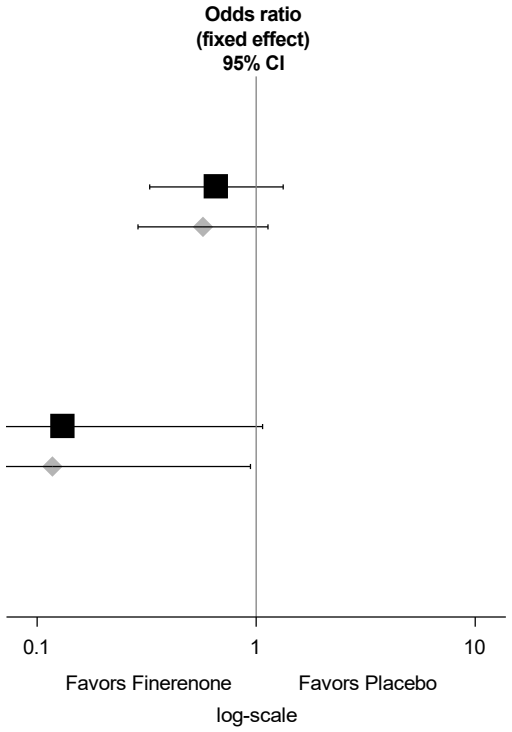
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	3 / 152	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	14 / 1658	26 / 1612	100.0	0.52 [0.27,1.00]	
Total	14 / 1797	29 / 1764		0.47 [0.25,0.89]	Z=-2.31, p=0.0207
Heterogeneity:	Q=0.09 (df=1)	p=0.7592	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	0 / 80	0 / 83		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	0 / 464	0 / 485	0.0	-	
Total	0 / 503	1 / 529		0.00 [0.00,49E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,15E296]	
Total	0 / 156	1 / 147		0.00 [0.00,68E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.00 (df=3)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.53.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

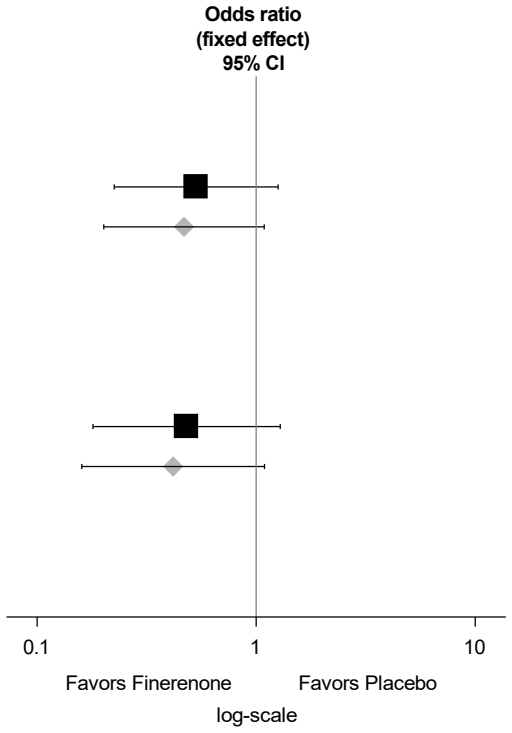
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	3 / 154	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	13 / 1610	20 / 1638	100.0	0.66 [0.33,1.33]	
Total	13 / 1762	23 / 1792		0.57 [0.29,1.13]	Z=-1.60, p=0.1087
Heterogeneity:	Q=0.16 (df=1)	p=0.6928	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	1 / 67	0.0	0.00 [0.00,21E296]	
FIGARO-DKD	1 / 716	7 / 664	100.0	0.13 [0.02,1.07]	
Total	1 / 774	8 / 731		0.12 [0.01,0.94]	Z=-2.02, p=0.0437
Heterogeneity:	Q=0.01 (df=1)	p=0.9171	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.00 (df=1)	p=0.1568	I^2=50.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.53.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

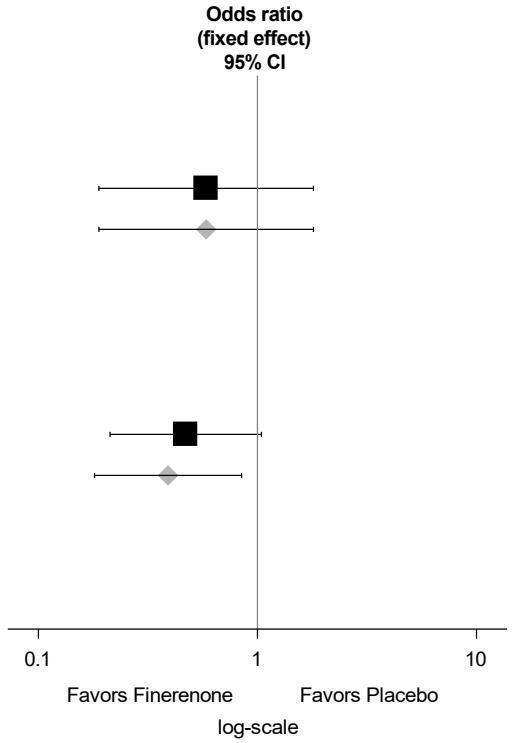
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	2 / 96	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	8 / 1416	15 / 1420	100.0	0.53 [0.22,1.26]	
Total	8 / 1514	17 / 1516		0.47 [0.20,1.09]	Z=-1.76, p=0.0778
Heterogeneity:	Q=0.08 (df=1)	p=0.7707	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	2 / 125	0.0	0.00 [0.00,2E297]	
FIGARO-DKD	6 / 910	12 / 882	100.0	0.48 [0.18,1.29]	
Total	6 / 1022	14 / 1007		0.42 [0.16,1.09]	Z=-1.78, p=0.0749
Heterogeneity:	Q=0.08 (df=1)	p=0.7782	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8611	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.53.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

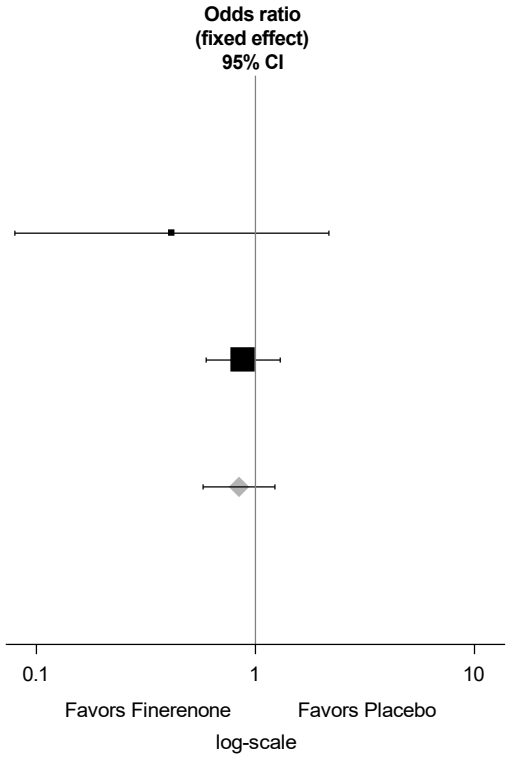
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	8 / 342	100.0	0.58 [0.19,1.80]	
Total	5 / 363	8 / 342		0.58 [0.19,1.80]	Z=-0.94, p=0.3483
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	0 / 210	4 / 221	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	9 / 1963	19 / 1960	100.0	0.47 [0.21,1.04]	
Total	9 / 2173	23 / 2181		0.39 [0.18,0.85]	Z=-2.38, p=0.0172
Heterogeneity:	Q=0.21 (df=1)	p=0.6470	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=1)	p=0.5659	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.54: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

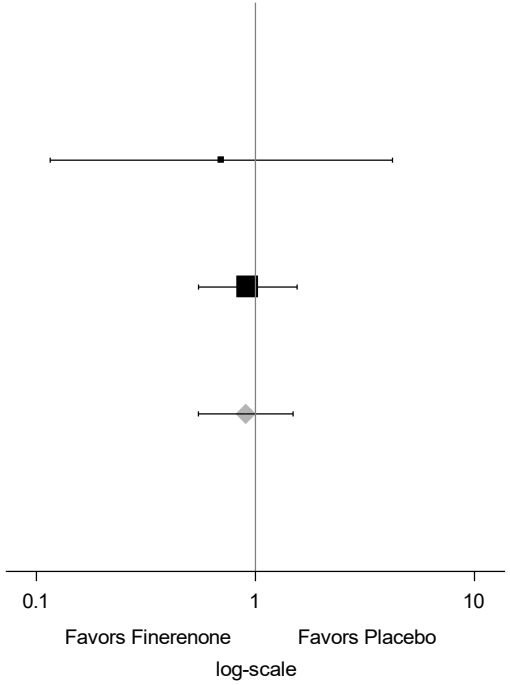
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	5.3	0.42 [0.08,2.16]	
FIGARO-DKD	49 / 2326	55 / 2302	94.7	0.88 [0.60,1.30]	
Total	51 / 2536	60 / 2523		0.84 [0.58,1.23]	Z=-0.90, p=0.3695
Heterogeneity:	Q=0.75 (df=1)	p=0.3861	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.55: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

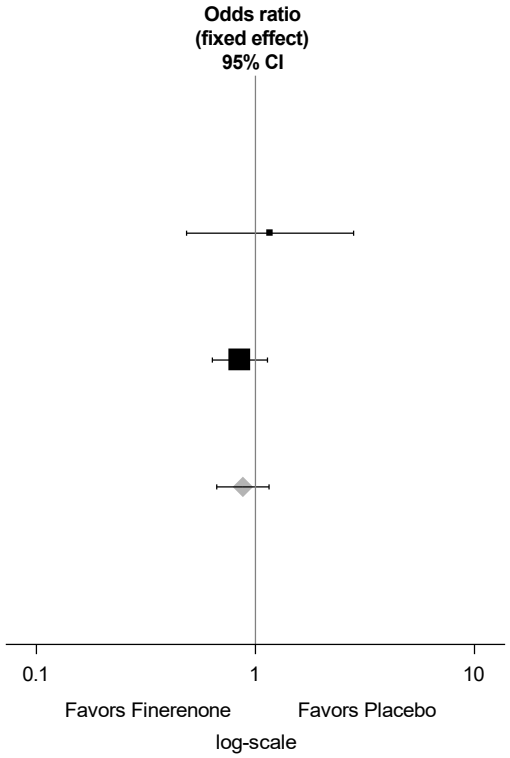
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.7	0.70 [0.12,4.22]	
FIGARO-DKD	28 / 2326	30 / 2302	92.3	0.92 [0.55,1.55]	
Total	30 / 2536	33 / 2523		0.90 [0.55,1.49]	Z=-0.40, p=0.6876
Heterogeneity:	Q=0.08 (df=1)	p=0.7709	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.56: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

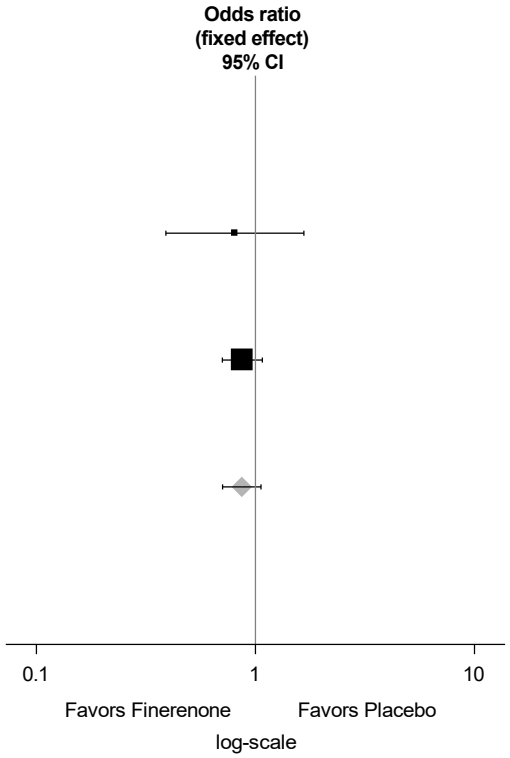
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	10 / 221	9.8	1.17 [0.48,2.81]	
FIGARO-DKD	89 / 2326	103 / 2302	90.2	0.85 [0.64,1.13]	
Total	100 / 2536	113 / 2523		0.88 [0.67,1.15]	Z=-0.94, p=0.3463
Heterogeneity:	Q=0.45 (df=1)	p=0.5015	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.57: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

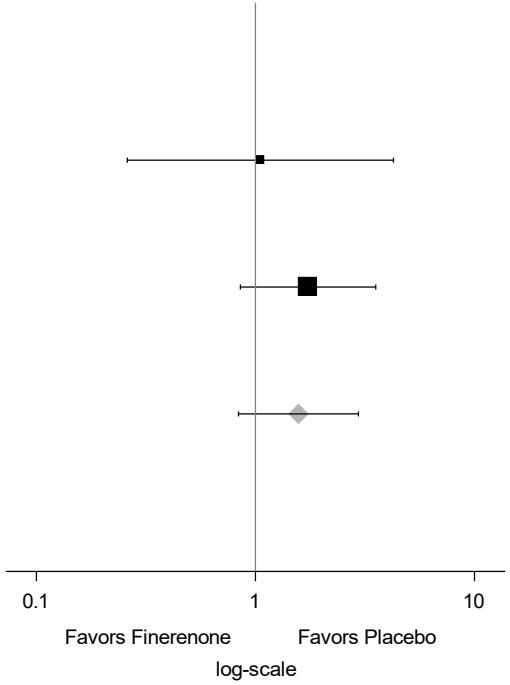
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	18 / 221	7.7	0.81 [0.39,1.66]	
FIGARO-DKD	179 / 2326	201 / 2302	92.3	0.87 [0.71,1.08]	
Total	193 / 2536	219 / 2523		0.87 [0.71,1.06]	Z=-1.39, p=0.1630
Heterogeneity:	Q=0.04 (df=1)	p=0.8383	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.58: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Periodontitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

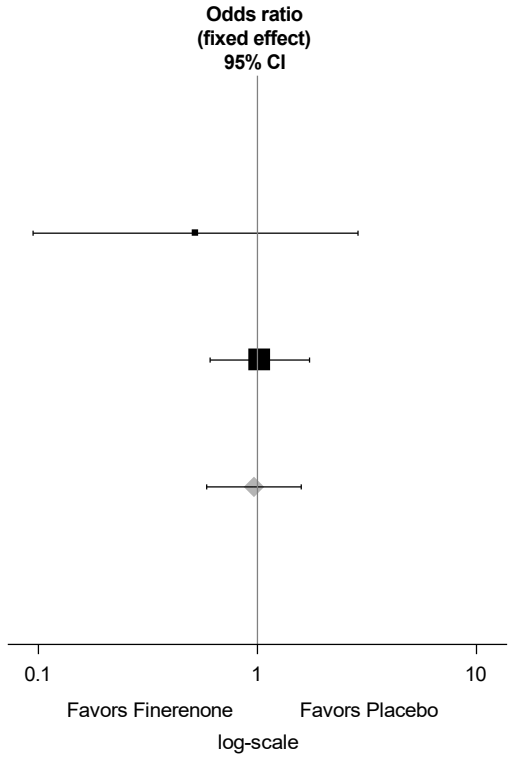
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	4 / 221	20.6	1.05 [0.26,4.27]	
FIGARO-DKD	21 / 2326	12 / 2302	79.4	1.74 [0.85,3.54]	
Total	25 / 2536	16 / 2523		1.57 [0.84,2.95]	Z=1.41, p=0.1598
Heterogeneity:	Q=0.39 (df=1)	p=0.5315	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.59: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

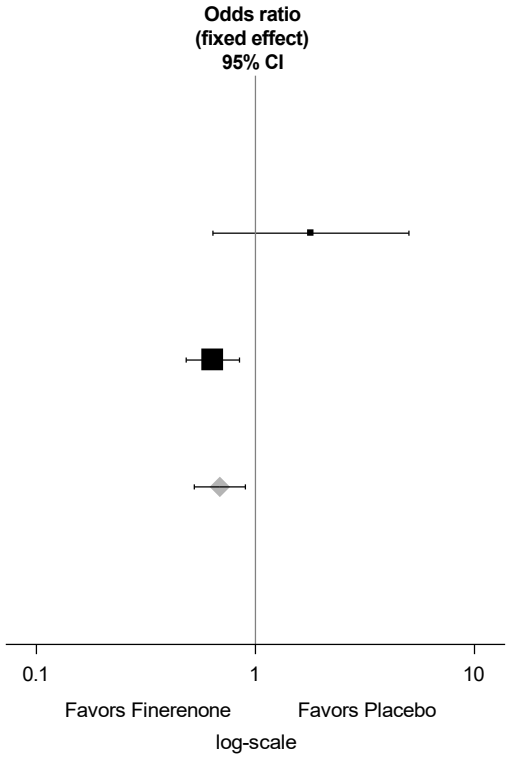
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	8.6	0.52 [0.09,2.88]	
FIGARO-DKD	29 / 2326	28 / 2302	91.4	1.03 [0.61,1.73]	
Total	31 / 2536	32 / 2523		0.96 [0.59,1.58]	Z=-0.14, p=0.8848
Heterogeneity:	Q=0.55 (df=1)	p=0.4582	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.60: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

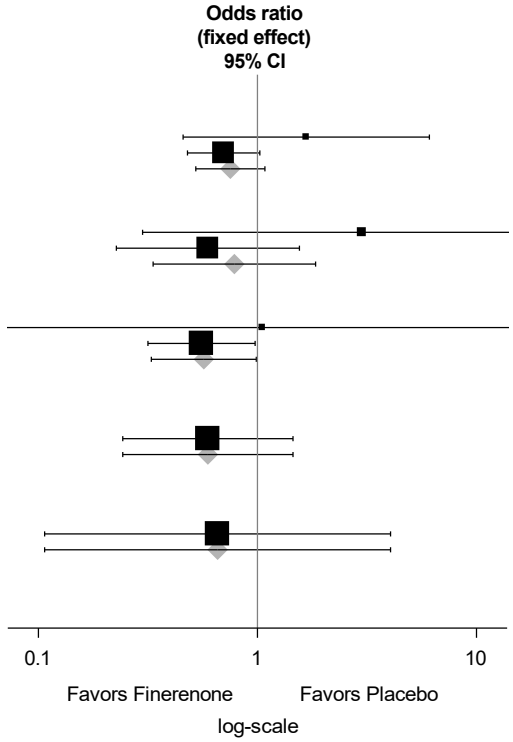
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	10 / 210	6 / 221	6.9	1.79 [0.64,5.02]	
FIGARO-DKD	85 / 2326	129 / 2302	93.1	0.64 [0.48,0.85]	
Total	95 / 2536	135 / 2523		0.69 [0.53,0.90]	Z=-2.73, p=0.0063
Heterogeneity:	Q=3.58 (df=1)	p=0.0584	I^2=72.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.60.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

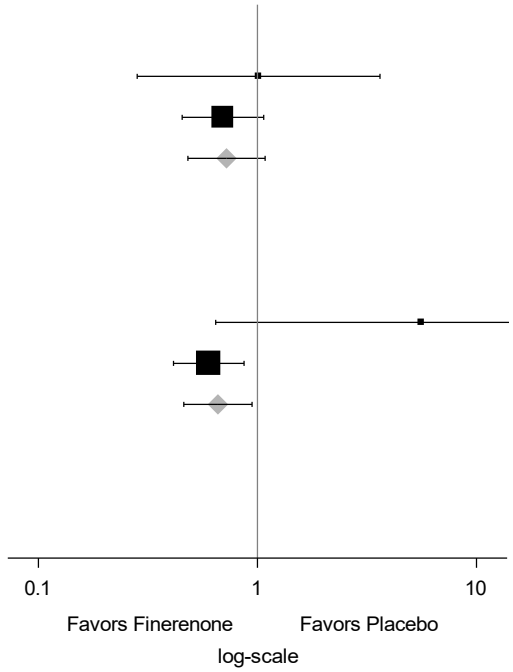
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 103	4 / 112	7.9	1.67 [0.46,6.09]	
FIGARO-DKD	48 / 1114	67 / 1110	92.1	0.70 [0.48,1.03]	
Total	54 / 1217	71 / 1222		0.75 [0.52,1.08]	Z=-1.54, p=0.1242
Heterogeneity:	Q=1.59 (df=1)	p=0.2072	I^2=37.1%		
North America					
FIDELIO-DKD	3 / 42	1 / 40	14.8	3.00 [0.30,30.11]	
FIGARO-DKD	7 / 292	11 / 277	85.2	0.59 [0.23,1.55]	
Total	10 / 334	12 / 317		0.78 [0.33,1.84]	Z=-0.56, p=0.5775
Heterogeneity:	Q=1.62 (df=1)	p=0.2030	I^2=38.3%		
Asia					
FIDELIO-DKD	1 / 39	1 / 41	3.9	1.05 [0.06,17.43]	
FIGARO-DKD	20 / 522	35 / 523	96.1	0.56 [0.32,0.98]	
Total	21 / 561	36 / 564		0.57 [0.33,0.99]	Z=-2.00, p=0.0451
Heterogeneity:	Q=0.19 (df=1)	p=0.6617	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	8 / 322	13 / 316	100.0	0.59 [0.24,1.45]	
Total	8 / 343	13 / 340		0.59 [0.24,1.45]	Z=-1.14, p=0.2536
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	3 / 76	100.0	0.66 [0.11,4.05]	
Total	2 / 81	3 / 80		0.66 [0.11,4.05]	Z=-0.45, p=0.6514
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.88 (df=4)	p=0.9270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.60.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

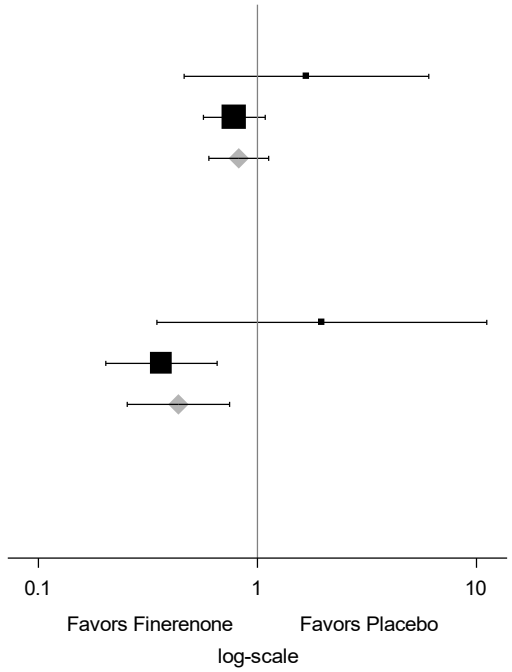
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	5 / 88	5 / 89	10.1	1.01 [0.28,3.63]	
FIGARO-DKD	38 / 811	53 / 803	89.9	0.70 [0.45,1.07]	
Total	43 / 899	58 / 892		0.72 [0.48,1.08]	Z=-1.57, p=0.1162
Heterogeneity:	Q=0.30 (df=1)	p=0.5852	I^2=0.0%		
Absent					
FIDELIO-DKD	5 / 122	1 / 132	2.9	5.60 [0.64,48.61]	
FIGARO-DKD	47 / 1515	76 / 1499	97.1	0.60 [0.41,0.87]	
Total	52 / 1637	77 / 1631		0.66 [0.46,0.94]	Z=-2.27, p=0.0232
Heterogeneity:	Q=4.02 (df=1)	p=0.0450	I^2=75.1%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7441	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.60.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

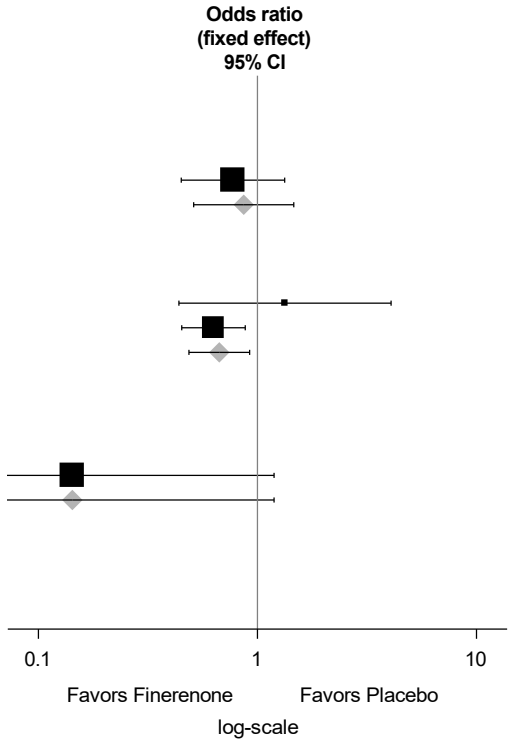
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	4 / 158	6.0	1.67 [0.46,6.06]	
FIGARO-DKD	69 / 1719	85 / 1679	94.0	0.78 [0.57,1.09]	
Total	75 / 1863	89 / 1837		0.82 [0.60,1.13]	Z=-1.22, p=0.2207
Heterogeneity:	Q=1.26 (df=1)	p=0.2625	I^2=20.4%		
> 4.5					
FIDELIO-DKD	4 / 66	2 / 63	10.2	1.97 [0.35,11.14]	
FIGARO-DKD	16 / 607	43 / 622	89.8	0.36 [0.20,0.65]	
Total	20 / 673	45 / 685		0.44 [0.25,0.75]	Z=-3.03, p=0.0025
Heterogeneity:	Q=3.26 (df=1)	p=0.0709	I^2=69.3%		
Subgroup Heterogeneity:	Q=3.99 (df=1)	p=0.0459	I^2=74.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.60.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

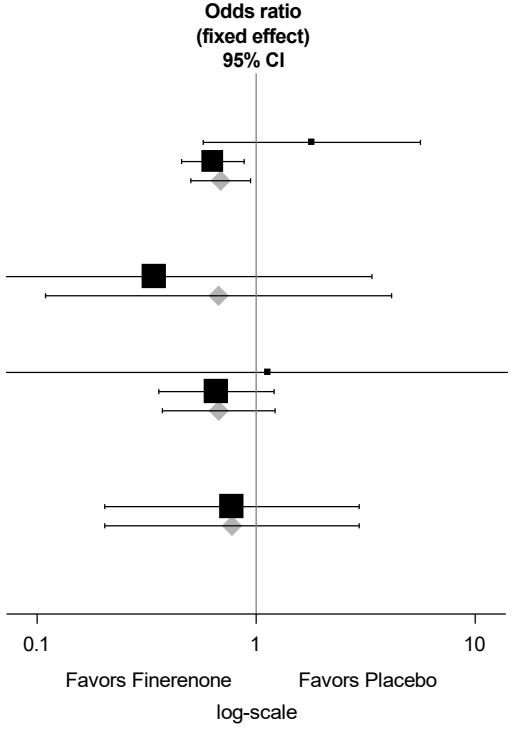
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 64	0 / 54	0.0	102E9 [102E9,102E9]	
FIGARO-DKD	24 / 693	31 / 699	100.0	0.77 [0.45,1.33]	
Total	27 / 757	31 / 753		0.87 [0.51,1.47]	Z=-0.54, p=0.5908
Heterogeneity:	Q=0.17 (df=1)	p=0.6836	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	7 / 138	6 / 156	8.2	1.34 [0.44,4.08]	
FIGARO-DKD	60 / 1560	91 / 1524	91.8	0.63 [0.45,0.88]	
Total	67 / 1698	97 / 1680		0.67 [0.49,0.92]	Z=-2.47, p=0.0137
Heterogeneity:	Q=1.60 (df=1)	p=0.2056	I^2=37.6%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	7 / 79	100.0	0.14 [0.02,1.19]	
Total	1 / 81	7 / 90		0.14 [0.02,1.19]	Z=-1.80, p=0.0721
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.86 (df=2)	p=0.2396	I^2=30.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.60.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

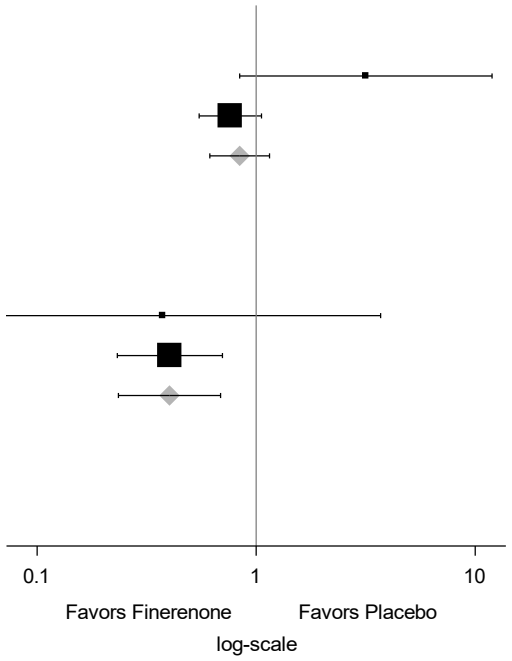
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 139	5 / 152	7.7	1.80 [0.57,5.62]	
FIGARO-DKD	62 / 1658	93 / 1612	92.3	0.63 [0.46,0.88]	
Total	70 / 1797	98 / 1764		0.69 [0.50,0.94]	Z=-2.33, p=0.0199
Heterogeneity:	Q=2.94 (df=1)	p=0.0862	I^2=66.0%		
Black					
FIDELIO-DKD	1 / 10	0 / 9	0.0	232E9 [232E9,232E9]	
FIGARO-DKD	1 / 70	3 / 74	100.0	0.34 [0.03,3.38]	
Total	2 / 80	3 / 83		0.67 [0.11,4.15]	Z=-0.43, p=0.6702
Heterogeneity:	Q=0.33 (df=1)	p=0.5631	I^2=0.0%		
Asian					
FIDELIO-DKD	1 / 39	1 / 44	4.5	1.13 [0.07,18.72]	
FIGARO-DKD	18 / 464	28 / 485	95.5	0.66 [0.36,1.21]	
Total	19 / 503	29 / 529		0.67 [0.37,1.22]	Z=-1.30, p=0.1924
Heterogeneity:	Q=0.14 (df=1)	p=0.7118	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	4 / 134	5 / 131	100.0	0.78 [0.20,2.95]	
Total	4 / 156	5 / 147		0.78 [0.20,2.95]	Z=-0.37, p=0.7093
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=3)	p=0.9982	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.60.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

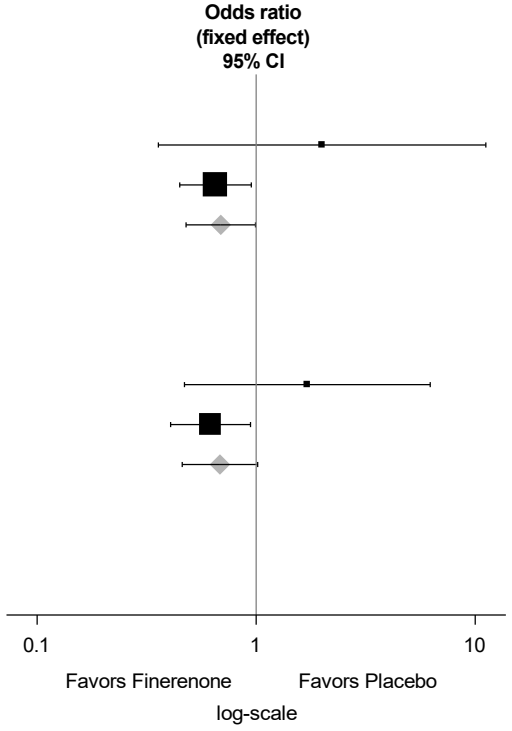
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 152	3 / 154	5.7	3.17 [0.84,11.94]	
FIGARO-DKD	66 / 1610	87 / 1638	94.3	0.76 [0.55,1.06]	
Total	75 / 1762	90 / 1792		0.84 [0.61,1.15]	Z=-1.08, p=0.2787
Heterogeneity:	Q=4.19 (df=1)	p=0.0407	I^2=76.1%		
Female					
FIDELIO-DKD	1 / 58	3 / 67	5.5	0.37 [0.04,3.70]	
FIGARO-DKD	19 / 716	42 / 664	94.5	0.40 [0.23,0.70]	
Total	20 / 774	45 / 731		0.40 [0.23,0.69]	Z=-3.33, p=0.0009
Heterogeneity:	Q=0.00 (df=1)	p=0.9498	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.41 (df=1)	p=0.0201	I^2=81.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.60.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

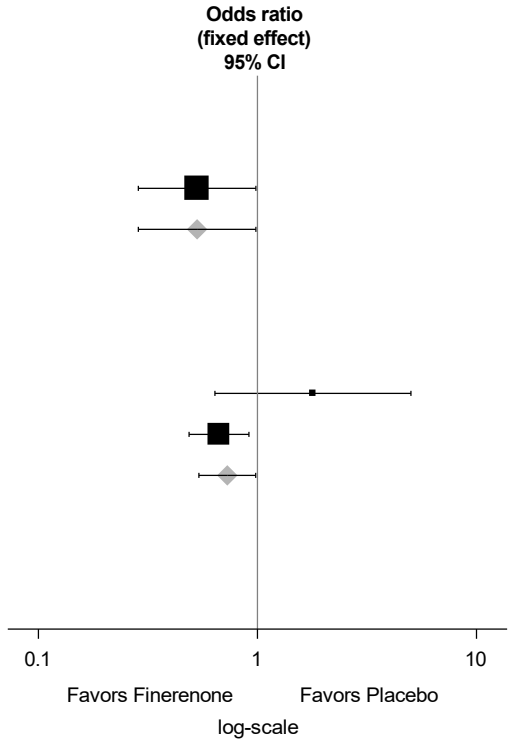
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	4 / 98	2 / 96	4.6	2.00 [0.36,11.18]	
FIGARO-DKD	47 / 1416	71 / 1420	95.4	0.65 [0.45,0.95]	
Total	51 / 1514	73 / 1516		0.69 [0.48,0.99]	Z=-2.00, p=0.0457
Heterogeneity:	Q=1.55 (df=1)	p=0.2126	I^2=35.6%		
>= 65					
FIDELIO-DKD	6 / 112	4 / 125	9.6	1.71 [0.47,6.23]	
FIGARO-DKD	38 / 910	58 / 882	90.4	0.62 [0.41,0.94]	
Total	44 / 1022	62 / 1007		0.68 [0.46,1.02]	Z=-1.88, p=0.0599
Heterogeneity:	Q=2.15 (df=1)	p=0.1421	I^2=53.6%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9745	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.60.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

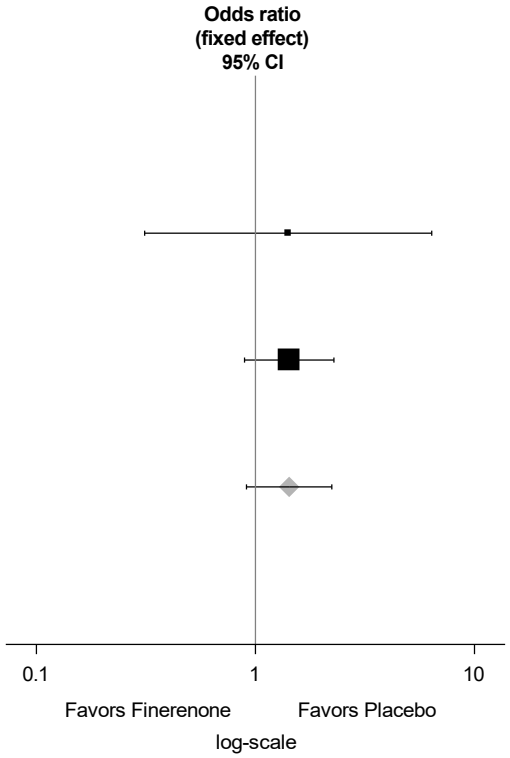
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	17 / 363	29 / 342	100.0	0.53 [0.29,0.98]	
Total	17 / 363	29 / 342		0.53 [0.29,0.98]	Z=-2.01, p=0.0442
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	10 / 210	6 / 221	8.5	1.79 [0.64,5.02]	
FIGARO-DKD	68 / 1963	100 / 1960	91.5	0.67 [0.49,0.91]	
Total	78 / 2173	106 / 2181		0.73 [0.54,0.98]	Z=-2.08, p=0.0375
Heterogeneity:	Q=3.23 (df=1)	p=0.0724	I^2=69.0%		
Subgroup Heterogeneity:	Q=0.82 (df=1)	p=0.3649	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.61: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

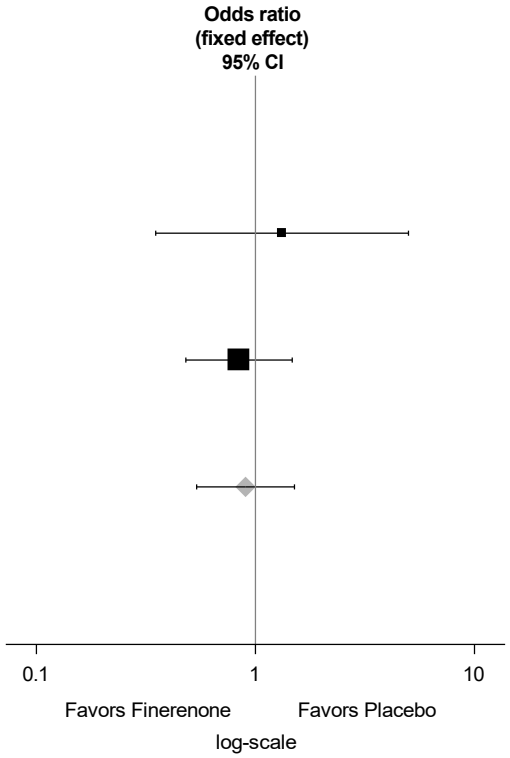
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.8	1.41 [0.31,6.38]	
FIGARO-DKD	43 / 2326	30 / 2302	91.2	1.43 [0.89,2.28]	
Total	47 / 2536	33 / 2523		1.43 [0.91,2.23]	Z=1.55, p=0.1217
Heterogeneity:	Q=0.00 (df=1)	p=0.9892	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.62: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

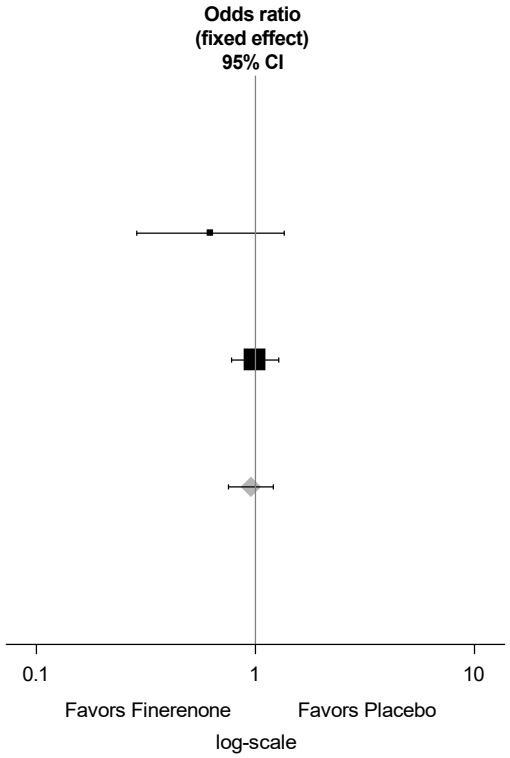
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	15.0	1.32 [0.35,5.00]	
FIGARO-DKD	23 / 2326	27 / 2302	85.0	0.84 [0.48,1.47]	
Total	28 / 2536	31 / 2523		0.90 [0.54,1.51]	Z=-0.40, p=0.6916
Heterogeneity:	Q=0.38 (df=1)	p=0.5383	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.63: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

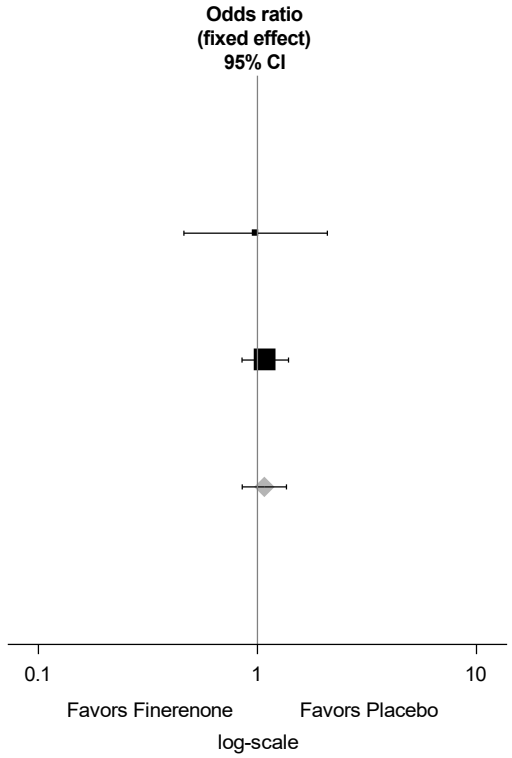
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	18 / 221	9.3	0.62 [0.29,1.35]	
FIGARO-DKD	133 / 2326	132 / 2302	90.7	1.00 [0.78,1.28]	
Total	144 / 2536	150 / 2523		0.95 [0.75,1.21]	Z=-0.40, p=0.6901
Heterogeneity:	Q=1.28 (df=1)	p=0.2581	I^2=21.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.64: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

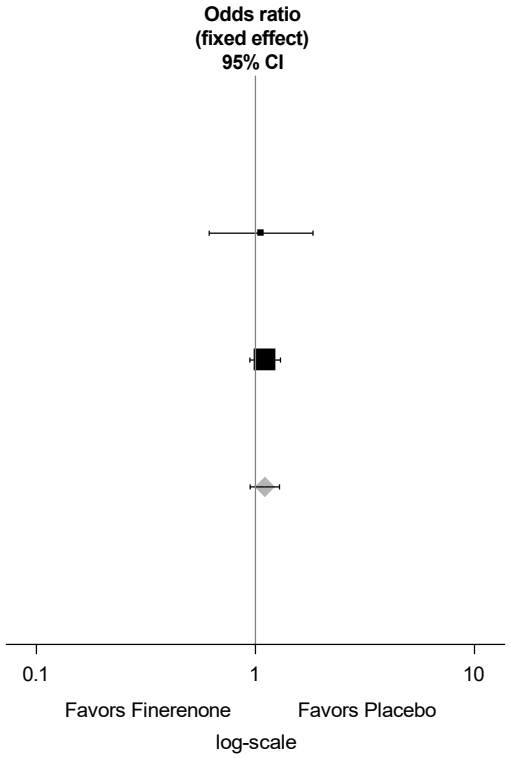
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	15 / 221	9.5	0.98 [0.46,2.09]	
FIGARO-DKD	143 / 2326	131 / 2302	90.5	1.09 [0.85,1.39]	
Total	157 / 2536	146 / 2523		1.08 [0.85,1.36]	Z=0.61, p=0.5410
Heterogeneity:	Q=0.06 (df=1)	p=0.8021	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.65: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

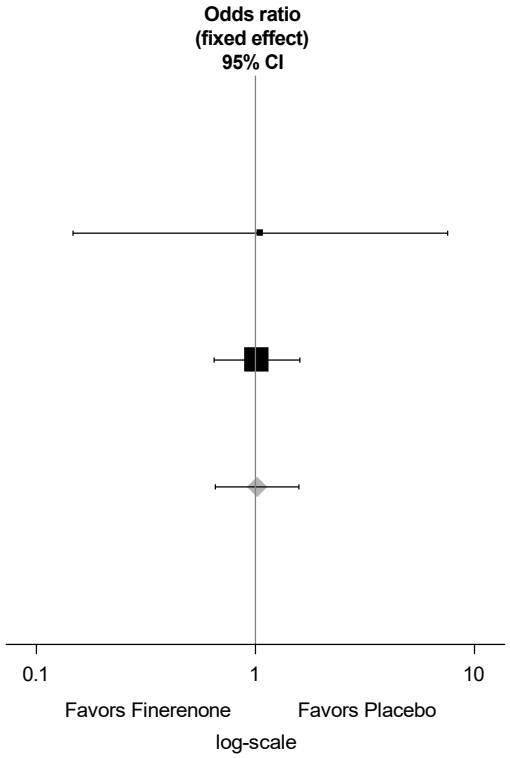
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	30 / 221	8.0	1.06 [0.61,1.83]	
FIGARO-DKD	368 / 2326	334 / 2302	92.0	1.11 [0.94,1.30]	
Total	398 / 2536	364 / 2523		1.10 [0.95,1.29]	Z=1.25, p=0.2101
Heterogeneity:	Q=0.02 (df=1)	p=0.8829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.66: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

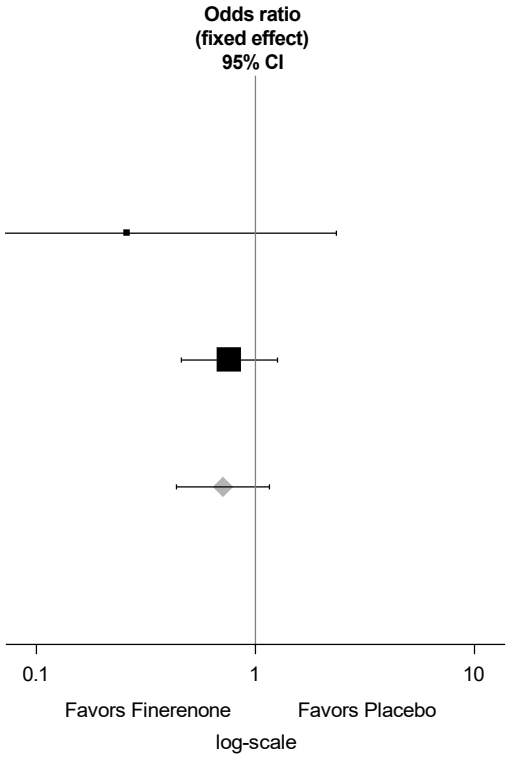
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	5.0	1.05 [0.15,7.54]	
FIGARO-DKD	39 / 2326	38 / 2302	95.0	1.02 [0.65,1.59]	
Total	41 / 2536	40 / 2523		1.02 [0.66,1.58]	Z=0.08, p=0.9372
Heterogeneity:	Q=0.00 (df=1)	p=0.9724	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.67: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

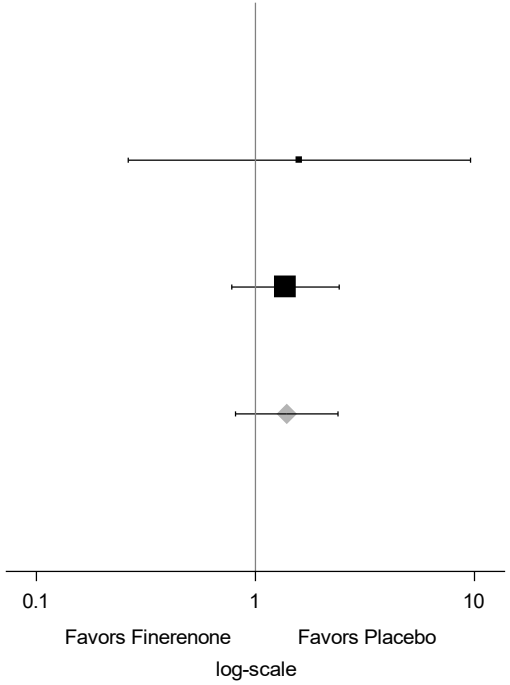
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	5.0	0.26 [0.03,2.34]	
FIGARO-DKD	27 / 2326	35 / 2302	95.0	0.76 [0.46,1.26]	
Total	28 / 2536	39 / 2523		0.71 [0.44,1.16]	Z=-1.37, p=0.1706
Heterogeneity:	Q=0.88 (df=1)	p=0.3495	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.68: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

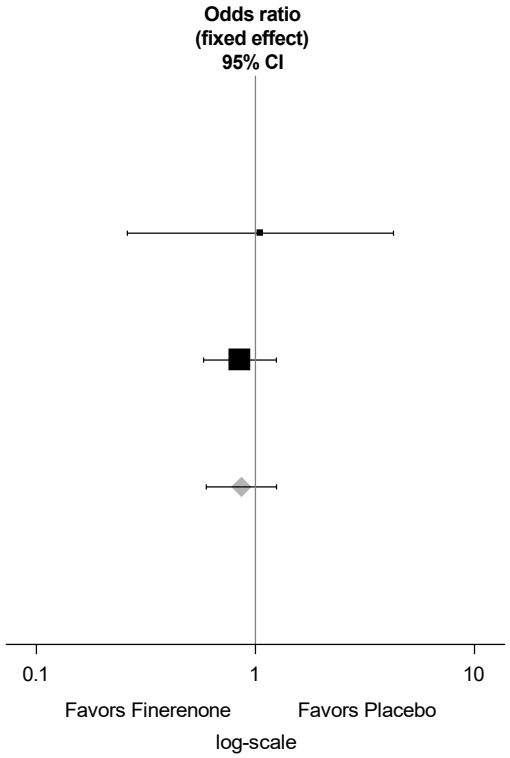
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	9.0	1.59 [0.26,9.59]	
FIGARO-DKD	29 / 2326	21 / 2302	91.0	1.37 [0.78,2.41]	
Total	32 / 2536	23 / 2523		1.39 [0.81,2.38]	Z=1.20, p=0.2312
Heterogeneity:	Q=0.02 (df=1)	p=0.8794	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.69: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

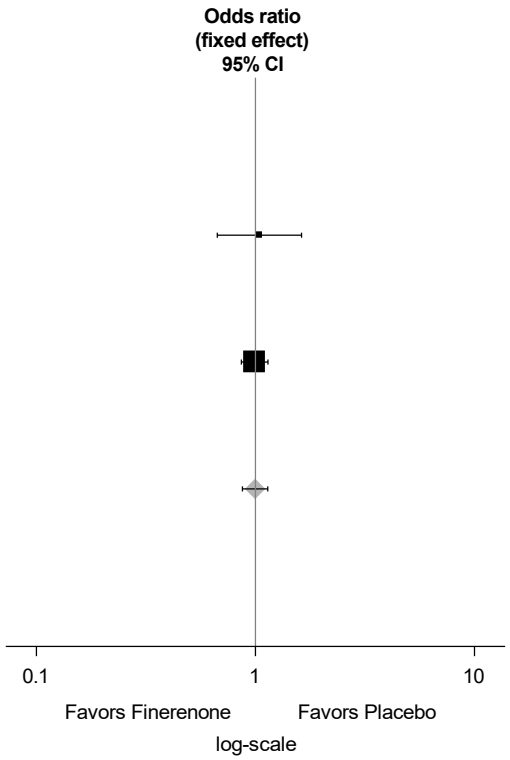
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	4 / 221	7.0	1.05 [0.26,4.27]	
FIGARO-DKD	50 / 2326	58 / 2302	93.0	0.85 [0.58,1.25]	
Total	54 / 2536	62 / 2523		0.86 [0.60,1.25]	Z=-0.78, p=0.4329
Heterogeneity:	Q=0.08 (df=1)	p=0.7718	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.70: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

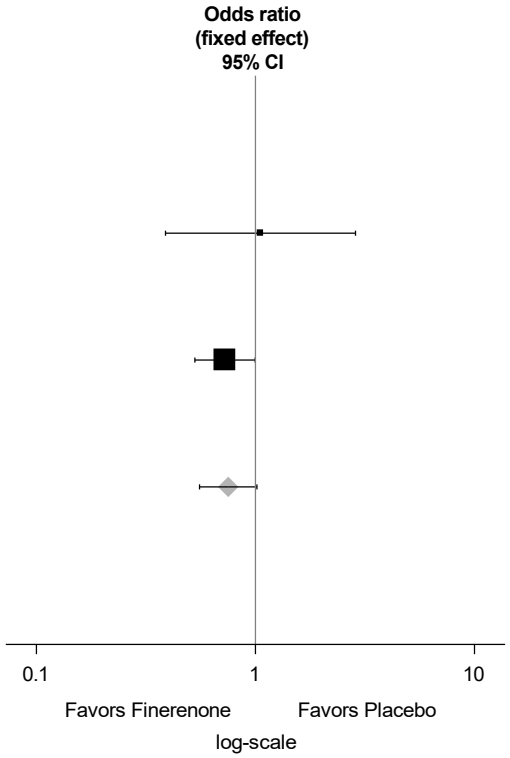
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 210	52 / 221	9.1	1.04 [0.67,1.62]	
FIGARO-DKD	504 / 2326	502 / 2302	90.9	0.99 [0.86,1.14]	
Total	555 / 2536	554 / 2523		1.00 [0.87,1.14]	Z=-0.05, p=0.9570
Heterogeneity:	Q=0.04 (df=1)	p=0.8337	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.71: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

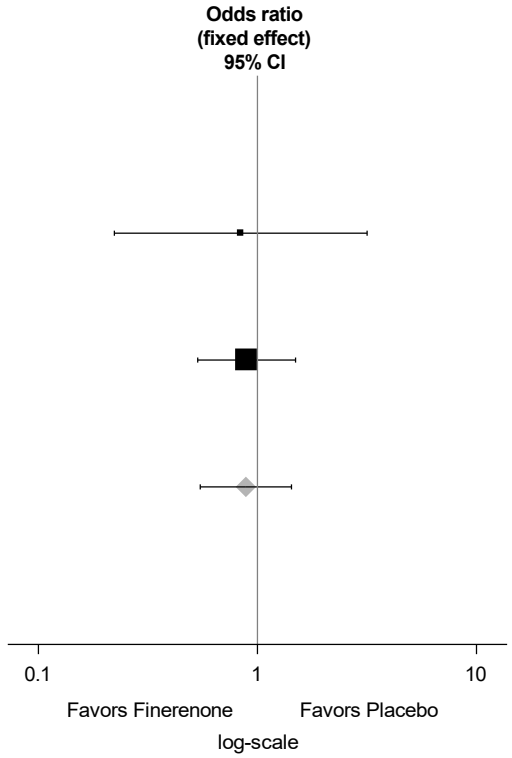
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	8 / 221	9.1	1.05 [0.39,2.86]	
FIGARO-DKD	69 / 2326	93 / 2302	90.9	0.73 [0.53,1.00]	
Total	77 / 2536	101 / 2523		0.75 [0.56,1.02]	Z=-1.86, p=0.0631
Heterogeneity:	Q=0.49 (df=1)	p=0.4853	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.72: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

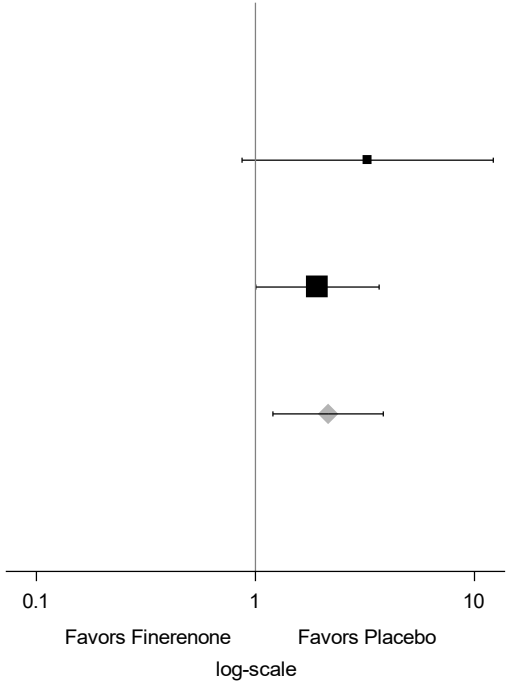
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	13.0	0.84 [0.22,3.17]	
FIGARO-DKD	28 / 2326	31 / 2302	87.0	0.89 [0.53,1.49]	
Total	32 / 2536	36 / 2523		0.89 [0.55,1.43]	Z=-0.50, p=0.6188
Heterogeneity:	Q=0.01 (df=1)	p=0.9319	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.73: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

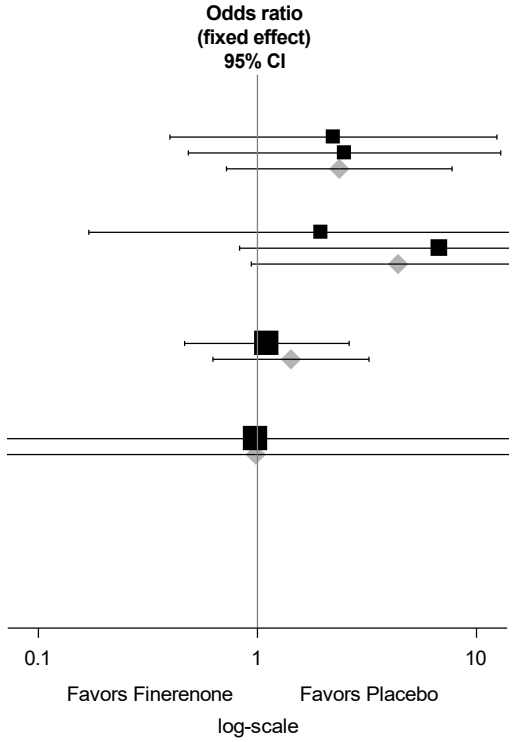
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	3 / 221	19.4	3.25 [0.87,12.19]	
FIGARO-DKD	27 / 2326	14 / 2302	80.6	1.92 [1.00,3.67]	
Total	36 / 2536	17 / 2523		2.15 [1.20,3.83]	Z=2.58, p=0.0099
Heterogeneity:	Q=0.50 (df=1)	p=0.4815	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.73.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

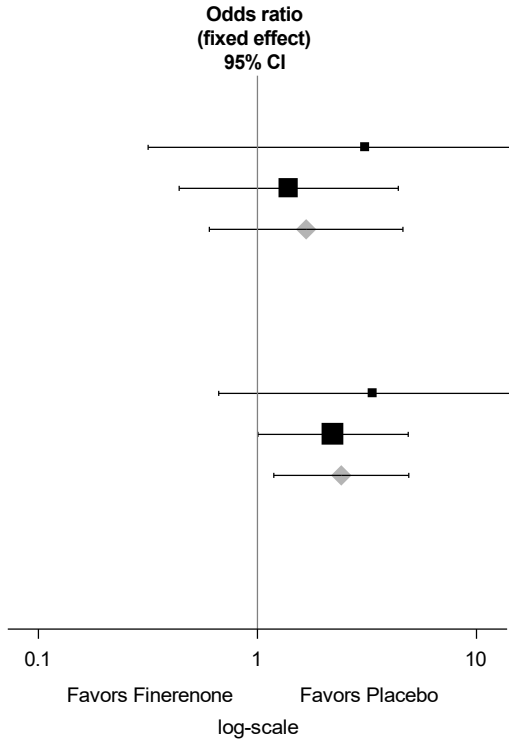
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	4 / 103	2 / 112	47.7	2.22 [0.40,12.40]	
FIGARO-DKD	5 / 1114	2 / 1110	52.3	2.50 [0.48,12.90]	
Total	9 / 1217	4 / 1222		2.36 [0.72,7.74]	Z=1.42, p=0.1551
Heterogeneity:	Q=0.01 (df=1)	p=0.9232	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	1 / 40	42.6	1.95 [0.17,22.39]	
FIGARO-DKD	7 / 292	1 / 277	57.4	6.78 [0.83,55.46]	
Total	9 / 334	2 / 317		4.38 [0.94,20.48]	Z=1.88, p=0.0603
Heterogeneity:	Q=0.59 (df=1)	p=0.4430	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	0 / 41	0.0	174E9 [174E9,174E9]	
FIGARO-DKD	11 / 522	10 / 523	100.0	1.10 [0.46,2.62]	
Total	14 / 561	10 / 564		1.42 [0.63,3.23]	Z=0.84, p=0.4002
Heterogeneity:	Q=0.33 (df=1)	p=0.5665	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	1 / 316	100.0	0.98 [0.06,15.76]	
Total	1 / 343	1 / 340		0.98 [0.06,15.76]	Z=-0.01, p=0.9894
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	0 / 76	0.0	233E9 [233E9,233E9]	
Total	3 / 81	0 / 80		218E9 [218E9,218E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.96 (df=4)	p=0.7439	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.73.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	3 / 88	1 / 89	20.3	3.11 [0.32,30.45]	
FIGARO-DKD	7 / 811	5 / 803	79.7	1.39 [0.44,4.40]	
Total	10 / 899	6 / 892		1.67 [0.60,4.62]	Z=0.99, p=0.3242
Heterogeneity:	Q=0.38 (df=1)	p=0.5368	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 122	2 / 132	19.2	3.36 [0.67,16.98]	
FIGARO-DKD	20 / 1515	9 / 1499	80.8	2.21 [1.01,4.88]	
Total	26 / 1637	11 / 1631		2.41 [1.19,4.91]	Z=2.43, p=0.0149
Heterogeneity:	Q=0.21 (df=1)	p=0.6496	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5594	I^2=0.0%		

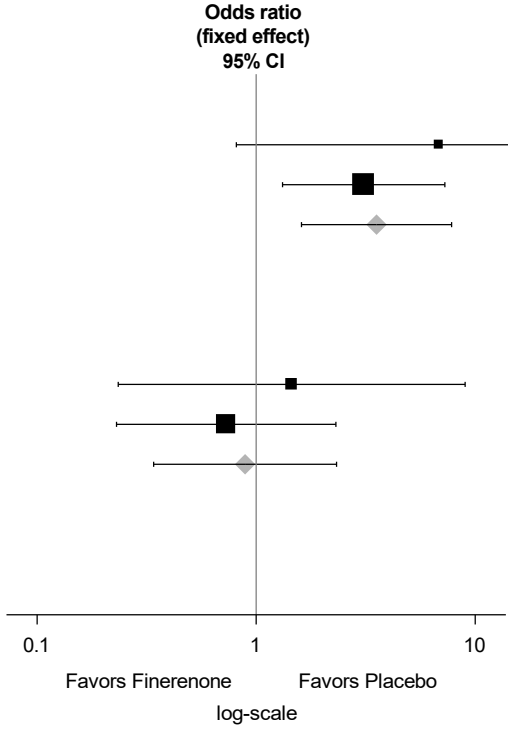


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.73.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

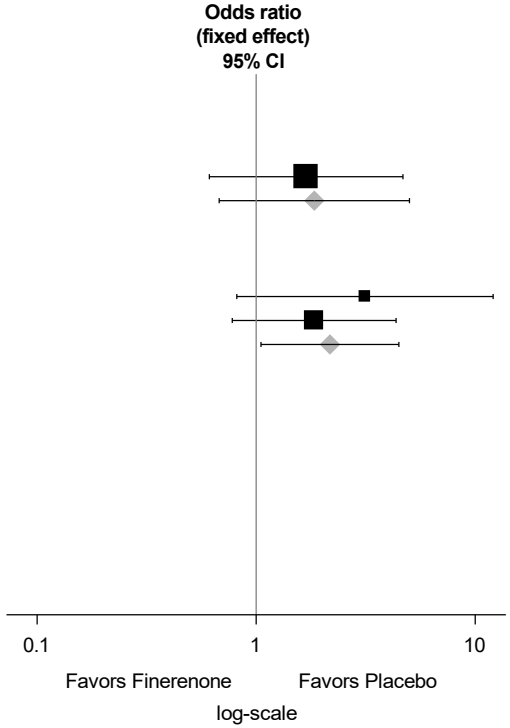
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	6 / 144	1 / 158	13.8	6.83 [0.81,57.40]	
FIGARO-DKD	22 / 1719	7 / 1679	86.2	3.10 [1.32,7.27]	
Total	28 / 1863	8 / 1837		3.54 [1.61,7.80]	Z=3.14, p=0.0017
Heterogeneity:	Q=0.46 (df=1)	p=0.4975	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 66	2 / 63	28.6	1.45 [0.23,9.00]	
FIGARO-DKD	5 / 607	7 / 622	71.4	0.73 [0.23,2.31]	
Total	8 / 673	9 / 685		0.89 [0.34,2.33]	Z=-0.24, p=0.8124
Heterogeneity:	Q=0.39 (df=1)	p=0.5318	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.74 (df=1)	p=0.0294	I^2=78.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.73.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

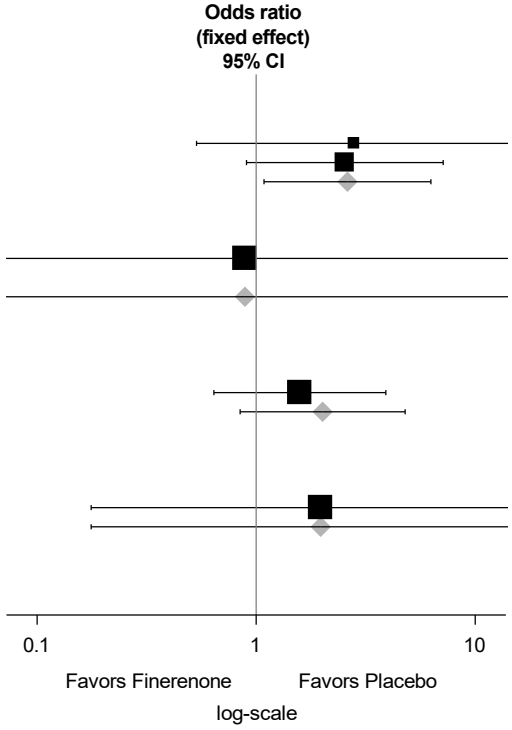
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	899E8 [899E8,899E8]	
FIGARO-DKD	10 / 693	6 / 699	100.0	1.69 [0.61,4.68]	
Total	11 / 757	6 / 753		1.84 [0.68,5.01]	Z=1.20, p=0.2310
Heterogeneity:	Q=0.03 (df=1)	p=0.8686	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	8 / 138	3 / 156	29.0	3.14 [0.82,12.07]	
FIGARO-DKD	15 / 1560	8 / 1524	71.0	1.84 [0.78,4.35]	
Total	23 / 1698	11 / 1680		2.17 [1.05,4.48]	Z=2.10, p=0.0360
Heterogeneity:	Q=0.43 (df=1)	p=0.5123	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	0 / 79	0.0	16E10 [16E10,16E10]	
Total	2 / 81	0 / 90		366E9 [366E9,366E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.07 (df=2)	p=0.9666	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.73.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

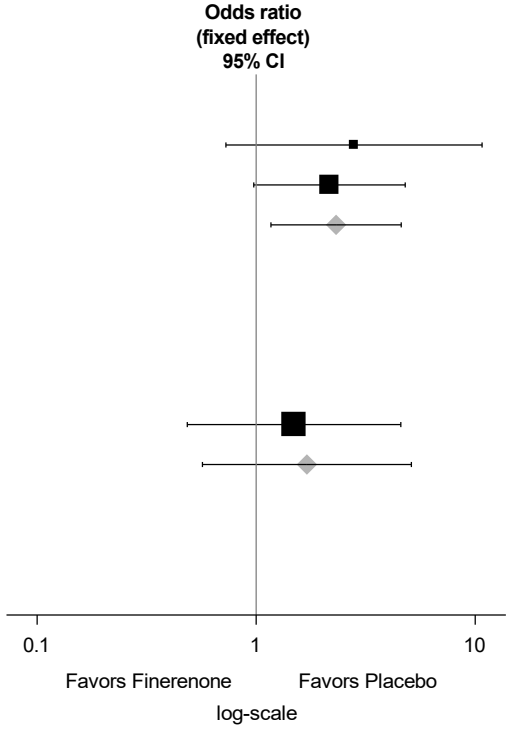
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	5 / 139	2 / 152	28.0	2.80 [0.53,14.66]	
FIGARO-DKD	13 / 1658	5 / 1612	72.0	2.54 [0.90,7.14]	
Total	18 / 1797	7 / 1764		2.61 [1.09,6.28]	Z=2.14, p=0.0320
Heterogeneity:	Q=0.01 (df=1)	p=0.9225	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 10	1 / 9	100.0	0.89 [0.05,16.66]	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	1 / 80	1 / 83		0.89 [0.05,16.66]	Z=-0.08, p=0.9372
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	0 / 44	0.0	174E9 [174E9,174E9]	
FIGARO-DKD	12 / 464	8 / 485	100.0	1.58 [0.64,3.91]	
Total	15 / 503	8 / 529		2.01 [0.84,4.79]	Z=1.58, p=0.1144
Heterogeneity:	Q=0.27 (df=1)	p=0.6038	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	2 / 134	1 / 131	100.0	1.97 [0.18,21.99]	
Total	2 / 156	1 / 147		1.97 [0.18,21.99]	Z=0.55, p=0.5818
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=3)	p=0.9050	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.73.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

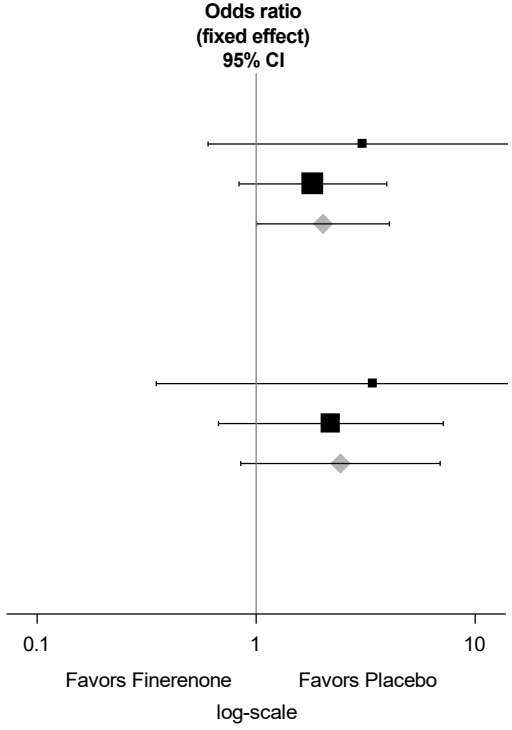
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	8 / 152	3 / 154	25.9	2.80 [0.73,10.75]	
FIGARO-DKD	19 / 1610	9 / 1638	74.1	2.16 [0.98,4.79]	
Total	27 / 1762	12 / 1792		2.32 [1.17,4.59]	Z=2.40, p=0.0162
Heterogeneity:	Q=0.10 (df=1)	p=0.7469	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	0 / 67	0.0	27E10 [27E10,27E10]	
FIGARO-DKD	8 / 716	5 / 664	100.0	1.49 [0.48,4.58]	
Total	9 / 774	5 / 731		1.70 [0.57,5.11]	Z=0.95, p=0.3413
Heterogeneity:	Q=0.06 (df=1)	p=0.8136	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6423	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.73.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

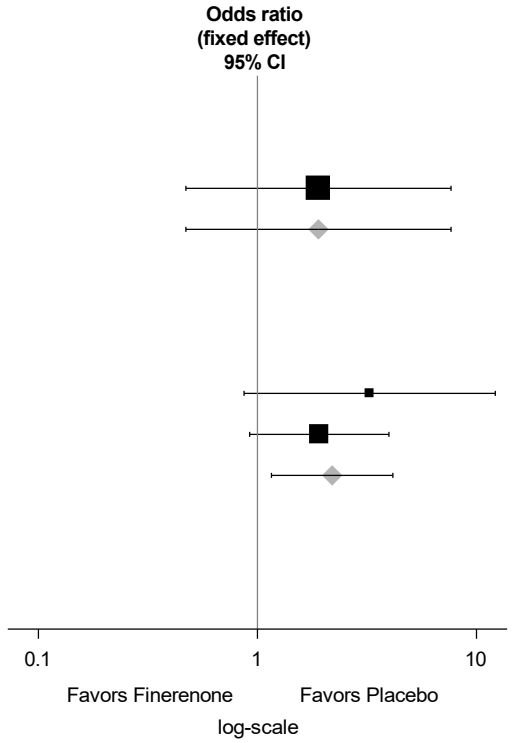
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	6 / 98	2 / 96	18.6	3.07 [0.60,15.58]	
FIGARO-DKD	18 / 1416	10 / 1420	81.4	1.82 [0.84,3.95]	
Total	24 / 1514	12 / 1516		2.02 [1.00,4.06]	Z=1.97, p=0.0487
Heterogeneity:	Q=0.33 (df=1)	p=0.5685	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	1 / 125	21.2	3.41 [0.35,33.29]	
FIGARO-DKD	9 / 910	4 / 882	78.8	2.19 [0.67,7.15]	
Total	12 / 1022	5 / 1007		2.43 [0.85,6.92]	Z=1.66, p=0.0974
Heterogeneity:	Q=0.11 (df=1)	p=0.7352	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7745	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.73.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

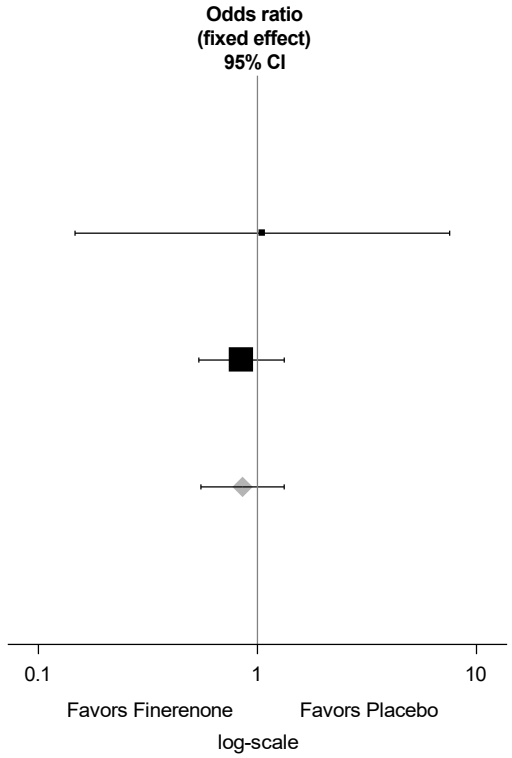
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	3 / 342	100.0	1.90 [0.47,7.65]	
Total	6 / 363	3 / 342		1.90 [0.47,7.65]	Z=0.90, p=0.3671
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	9 / 210	3 / 221	23.5	3.25 [0.87,12.19]	
FIGARO-DKD	21 / 1963	11 / 1960	76.5	1.92 [0.92,3.98]	
Total	30 / 2173	14 / 2181		2.19 [1.16,4.15]	Z=2.41, p=0.0159
Heterogeneity:	Q=0.47 (df=1)	p=0.4914	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8540	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.74: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

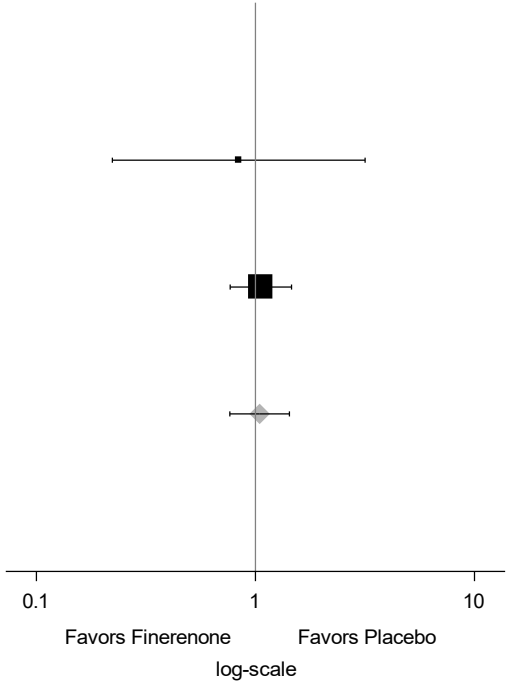
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	2 / 221	4.9	1.05 [0.15,7.54]	
FIGARO-DKD	36 / 2326	42 / 2302	95.1	0.85 [0.54,1.33]	
Total	38 / 2536	44 / 2523		0.86 [0.55,1.32]	Z=-0.70, p=0.4832
Heterogeneity:	Q=0.05 (df=1)	p=0.8318	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.75: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

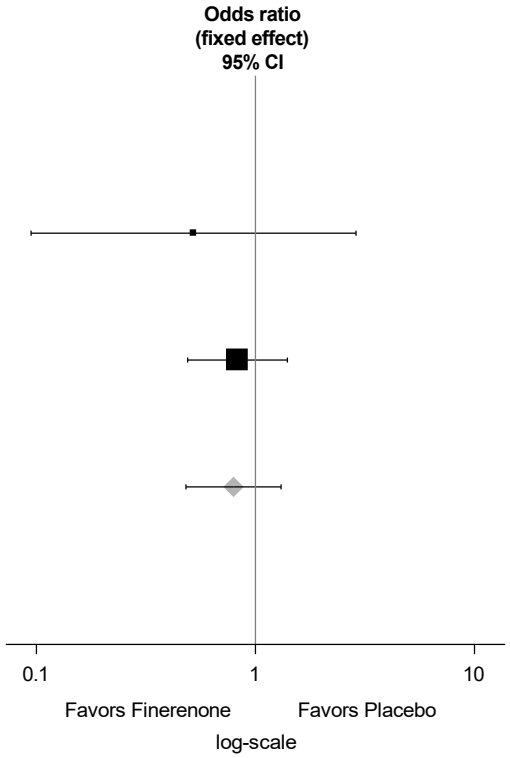
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	5.6	0.84 [0.22,3.17]	
FIGARO-DKD	79 / 2326	74 / 2302	94.4	1.06 [0.77,1.46]	
Total	83 / 2536	79 / 2523		1.04 [0.76,1.43]	Z=0.27, p=0.7837
Heterogeneity:	Q=0.11 (df=1)	p=0.7388	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.76: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

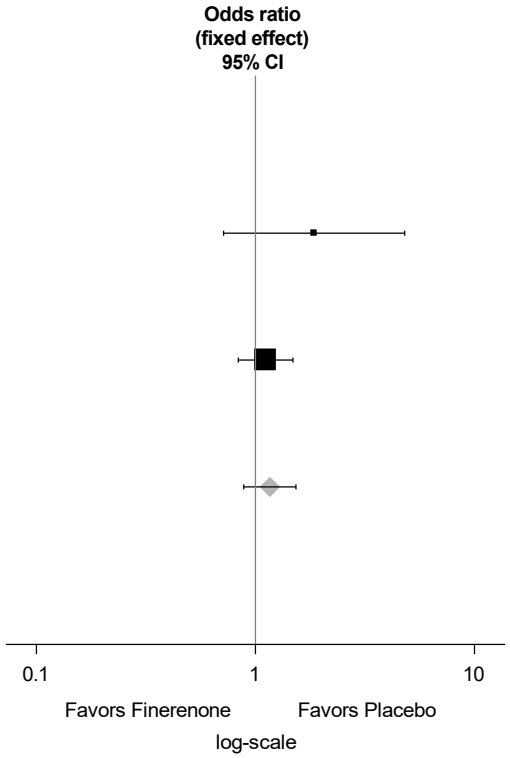
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	4 / 221	8.6	0.52 [0.09,2.88]	
FIGARO-DKD	26 / 2326	31 / 2302	91.4	0.83 [0.49,1.40]	
Total	28 / 2536	35 / 2523		0.79 [0.48,1.31]	Z=-0.90, p=0.3662
Heterogeneity:	Q=0.26 (df=1)	p=0.6121	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.77: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

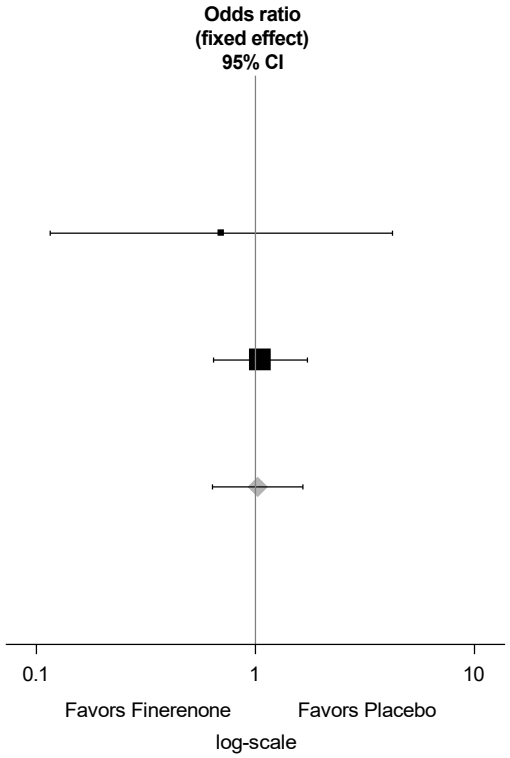
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	7 / 221	8.3	1.85 [0.72,4.80]	
FIGARO-DKD	103 / 2326	92 / 2302	91.7	1.11 [0.84,1.48]	
Total	115 / 2536	99 / 2523		1.16 [0.88,1.53]	Z=1.08, p=0.2801
Heterogeneity:	Q=1.01 (df=1)	p=0.3151	I^2=0.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.78: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

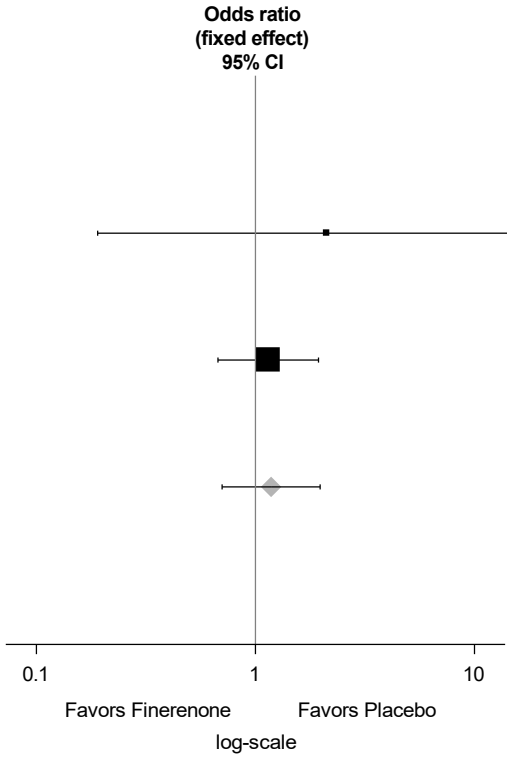
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.0	0.70 [0.12,4.22]	
FIGARO-DKD	33 / 2326	31 / 2302	93.0	1.05 [0.64,1.73]	
Total	35 / 2536	34 / 2523		1.02 [0.64,1.65]	Z=0.10, p=0.9232
Heterogeneity:	Q=0.19 (df=1)	p=0.6656	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.79: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

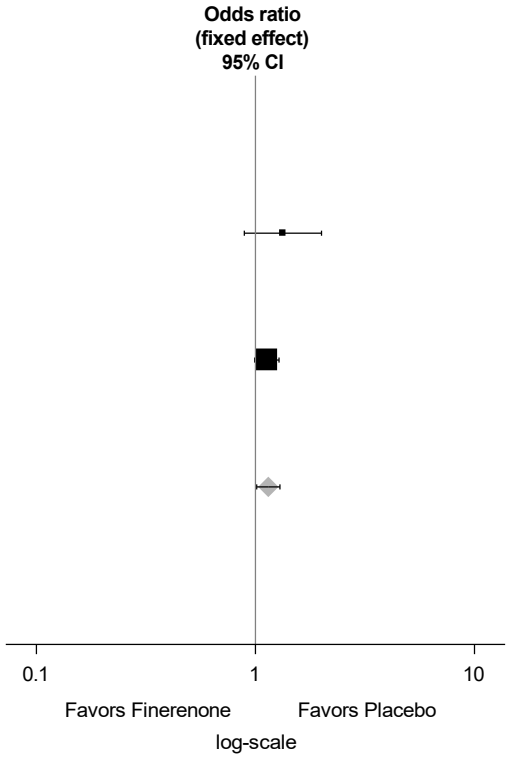
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.6	2.12 [0.19,23.50]	
FIGARO-DKD	30 / 2326	26 / 2302	95.4	1.14 [0.67,1.94]	
Total	32 / 2536	27 / 2523		1.18 [0.70,1.97]	Z=0.63, p=0.5312
Heterogeneity:	Q=0.24 (df=1)	p=0.6249	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.80: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

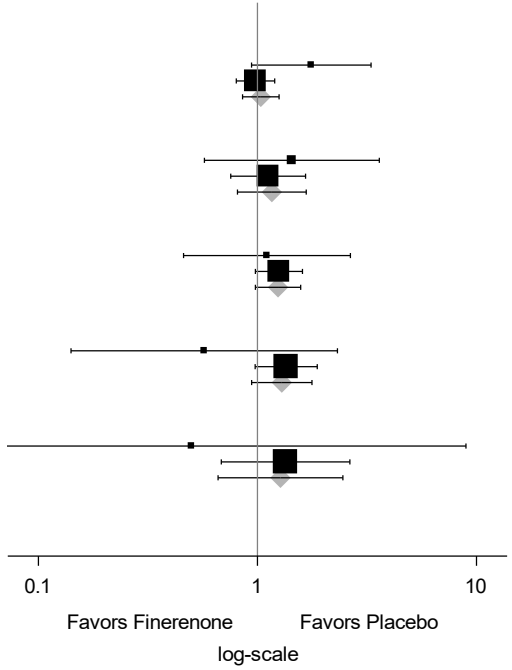
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	74 / 210	64 / 221	9.1	1.33 [0.89,2.00]	
FIGARO-DKD	686 / 2326	623 / 2302	90.9	1.13 [0.99,1.28]	
Total	760 / 2536	687 / 2523		1.14 [1.01,1.29]	Z=2.17, p=0.0300
Heterogeneity:	Q=0.61 (df=1)	p=0.4365	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.80.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

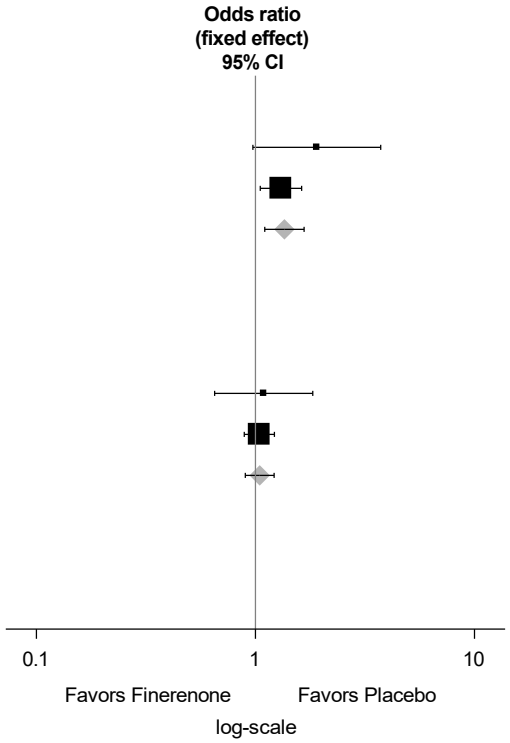
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	31 / 103	22 / 112	9.4	1.76 [0.94,3.30]	
FIGARO-DKD	239 / 1114	242 / 1110	90.6	0.98 [0.80,1.20]	
Total	270 / 1217	264 / 1222		1.04 [0.85,1.26]	Z=0.36, p=0.7187
Heterogeneity:	Q=3.04 (df=1)	p=0.0814	I^2=67.1%		
North America					
FIDELIO-DKD	16 / 42	12 / 40	15.5	1.44 [0.57,3.60]	
FIGARO-DKD	69 / 292	60 / 277	84.5	1.12 [0.76,1.66]	
Total	85 / 334	72 / 317		1.16 [0.81,1.67]	Z=0.82, p=0.4122
Heterogeneity:	Q=0.24 (df=1)	p=0.6251	I^2=0.0%		
Asia					
FIDELIO-DKD	20 / 39	20 / 41	7.4	1.11 [0.46,2.66]	
FIGARO-DKD	226 / 522	198 / 523	92.6	1.25 [0.98,1.60]	
Total	246 / 561	218 / 564		1.24 [0.98,1.58]	Z=1.78, p=0.0747
Heterogeneity:	Q=0.07 (df=1)	p=0.7870	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 21	7 / 24	5.2	0.57 [0.14,2.32]	
FIGARO-DKD	124 / 322	100 / 316	94.8	1.35 [0.98,1.87]	
Total	128 / 343	107 / 340		1.29 [0.94,1.77]	Z=1.58, p=0.1136
Heterogeneity:	Q=1.38 (df=1)	p=0.2401	I^2=27.5%		
Others					
FIDELIO-DKD	3 / 5	3 / 4	5.2	0.50 [0.03,8.95]	
FIGARO-DKD	28 / 76	23 / 76	94.8	1.34 [0.68,2.64]	
Total	31 / 81	26 / 80		1.27 [0.66,2.45]	Z=0.72, p=0.4697
Heterogeneity:	Q=0.43 (df=1)	p=0.5130	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.15 (df=4)	p=0.7083	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.80.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

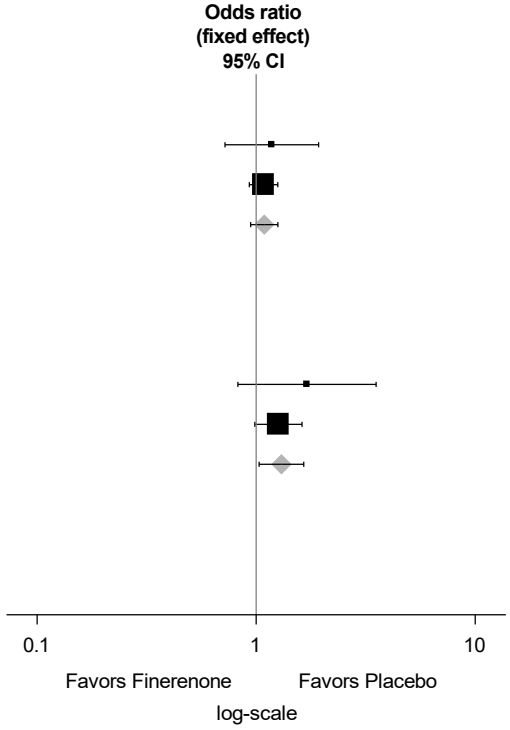
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	30 / 88	19 / 89	9.5	1.91 [0.97,3.73]	
FIGARO-DKD	251 / 811	205 / 803	90.5	1.31 [1.05,1.63]	
Total	281 / 899	224 / 892		1.36 [1.10,1.67]	Z=2.88, p=0.0039
Heterogeneity:	Q=1.09 (df=1)	p=0.2958	I^2=8.5%		
Absent					
FIDELIO-DKD	44 / 122	45 / 132	8.6	1.09 [0.65,1.83]	
FIGARO-DKD	435 / 1515	418 / 1499	91.4	1.04 [0.89,1.22]	
Total	479 / 1637	463 / 1631		1.05 [0.90,1.22]	Z=0.58, p=0.5627
Heterogeneity:	Q=0.03 (df=1)	p=0.8675	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.94 (df=1)	p=0.0471	I^2=74.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.80.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

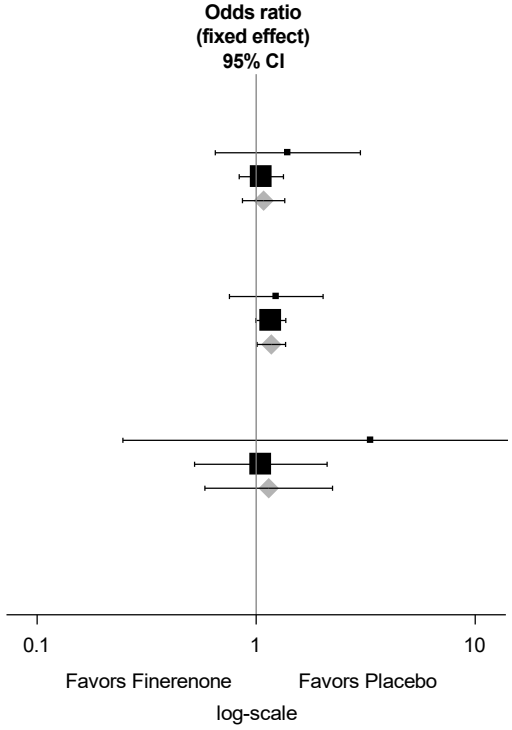
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 144	45 / 158	8.5	1.18 [0.72,1.93]	
FIGARO-DKD	498 / 1719	460 / 1679	91.5	1.08 [0.93,1.26]	
Total	544 / 1863	505 / 1837		1.09 [0.94,1.26]	Z=1.17, p=0.2439
Heterogeneity:	Q=0.11 (df=1)	p=0.7412	I^2=0.0%		
> 4.5					
FIDELIO-DKD	28 / 66	19 / 63	10.4	1.71 [0.83,3.53]	
FIGARO-DKD	188 / 607	163 / 622	89.6	1.26 [0.99,1.62]	
Total	216 / 673	182 / 685		1.30 [1.03,1.65]	Z=2.22, p=0.0266
Heterogeneity:	Q=0.59 (df=1)	p=0.4430	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.66 (df=1)	p=0.1981	I^2=39.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.80.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

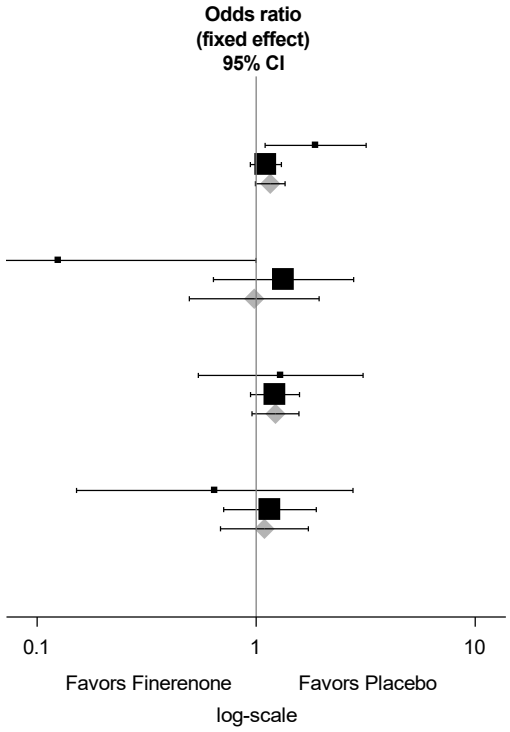
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	25 / 64	17 / 54	8.5	1.40 [0.65,2.99]	
FIGARO-DKD	202 / 693	196 / 699	91.5	1.06 [0.84,1.33]	
Total	227 / 757	213 / 753		1.08 [0.87,1.35]	Z=0.69, p=0.4907
Heterogeneity:	Q=0.47 (df=1)	p=0.4934	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	47 / 138	46 / 156	9.3	1.24 [0.75,2.02]	
FIGARO-DKD	462 / 1560	404 / 1524	90.7	1.17 [1.00,1.37]	
Total	509 / 1698	450 / 1680		1.17 [1.01,1.36]	Z=2.08, p=0.0372
Heterogeneity:	Q=0.05 (df=1)	p=0.8285	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 8	1 / 11	6.7	3.33 [0.25,45.11]	
FIGARO-DKD	22 / 73	23 / 79	93.3	1.05 [0.52,2.11]	
Total	24 / 81	24 / 90		1.14 [0.58,2.23]	Z=0.39, p=0.7001
Heterogeneity:	Q=0.70 (df=1)	p=0.4012	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=2)	p=0.8388	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.80.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

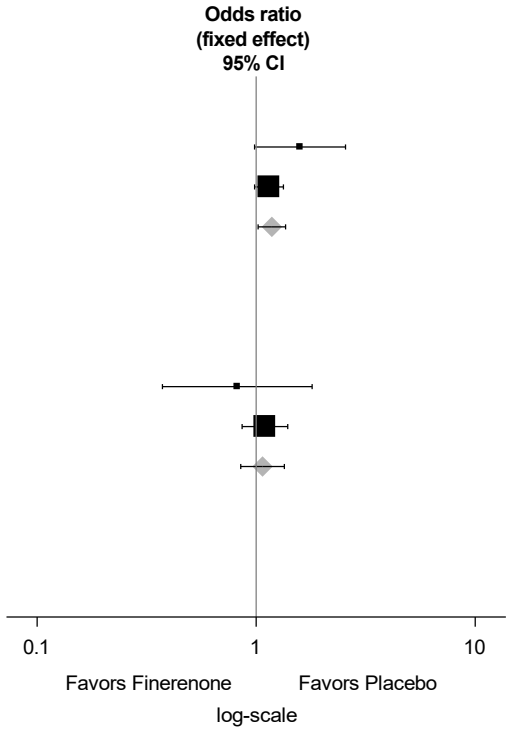
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 139	31 / 152	8.6	1.87 [1.10,3.18]	
FIGARO-DKD	395 / 1658	355 / 1612	91.4	1.11 [0.94,1.30]	
Total	440 / 1797	386 / 1764		1.16 [0.99,1.36]	Z=1.86, p=0.0629
Heterogeneity:	Q=3.41 (df=1)	p=0.0649	I^2=70.7%		
Black					
FIDELIO-DKD	2 / 10	6 / 9	11.2	0.13 [0.02,1.00]	
FIGARO-DKD	21 / 70	18 / 74	88.8	1.33 [0.64,2.79]	
Total	23 / 80	24 / 83		0.98 [0.50,1.94]	Z=-0.06, p=0.9531
Heterogeneity:	Q=4.44 (df=1)	p=0.0351	I^2=77.5%		
Asian					
FIDELIO-DKD	22 / 39	22 / 44	8.1	1.29 [0.54,3.08]	
FIGARO-DKD	210 / 464	196 / 485	91.9	1.22 [0.94,1.58]	
Total	232 / 503	218 / 529		1.23 [0.96,1.57]	Z=1.61, p=0.1071
Heterogeneity:	Q=0.02 (df=1)	p=0.8969	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 22	5 / 16	10.1	0.65 [0.15,2.77]	
FIGARO-DKD	60 / 134	54 / 131	89.9	1.16 [0.71,1.88]	
Total	65 / 156	59 / 147		1.09 [0.69,1.73]	Z=0.37, p=0.7125
Heterogeneity:	Q=0.55 (df=1)	p=0.4579	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.49 (df=3)	p=0.9215	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.80.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

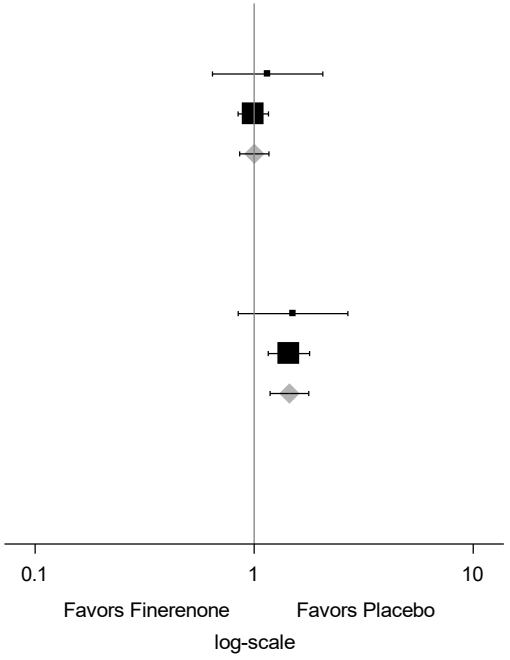
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	59 / 152	44 / 154	9.1	1.59 [0.98,2.56]	
FIGARO-DKD	491 / 1610	454 / 1638	90.9	1.14 [0.98,1.33]	
Total	550 / 1762	498 / 1792		1.18 [1.02,1.36]	Z=2.24, p=0.0253
Heterogeneity:	Q=1.63 (df=1)	p=0.2021	I^2=38.5%		
Female					
FIDELIO-DKD	15 / 58	20 / 67	8.5	0.82 [0.37,1.80]	
FIGARO-DKD	195 / 716	169 / 664	91.5	1.10 [0.86,1.39]	
Total	210 / 774	189 / 731		1.07 [0.85,1.34]	Z=0.57, p=0.5666
Heterogeneity:	Q=0.48 (df=1)	p=0.4887	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4793	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.80.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

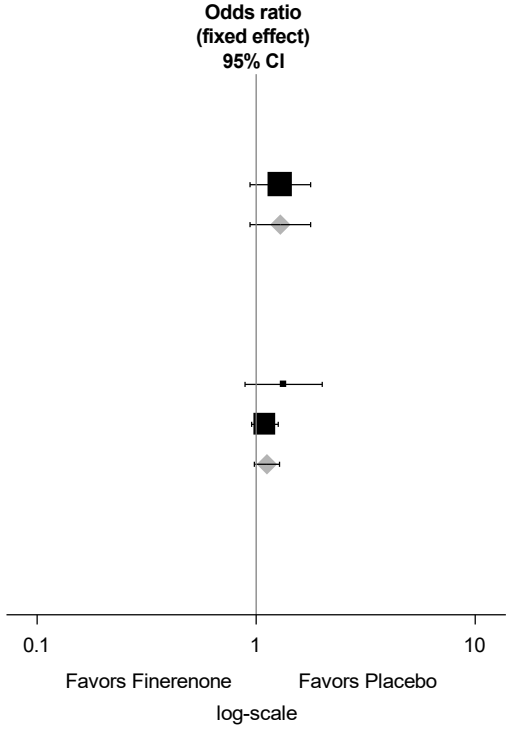
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	39 / 98	35 / 96	7.0	1.15 [0.65,2.06]	
FIGARO-DKD	433 / 1416	437 / 1420	93.0	0.99 [0.84,1.16]	
Total	472 / 1514	472 / 1516		1.00 [0.86,1.17]	Z=0.02, p=0.9855
Heterogeneity:	Q=0.24 (df=1)	p=0.6233	I^2=0.0%		
>= 65					
FIDELIO-DKD	35 / 112	29 / 125	12.4	1.50 [0.85,2.68]	
FIGARO-DKD	253 / 910	186 / 882	87.6	1.44 [1.16,1.79]	
Total	288 / 1022	215 / 1007		1.45 [1.18,1.78]	Z=3.57, p=0.0004
Heterogeneity:	Q=0.02 (df=1)	p=0.8904	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.06 (df=1)	p=0.0045	I^2=87.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.80.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

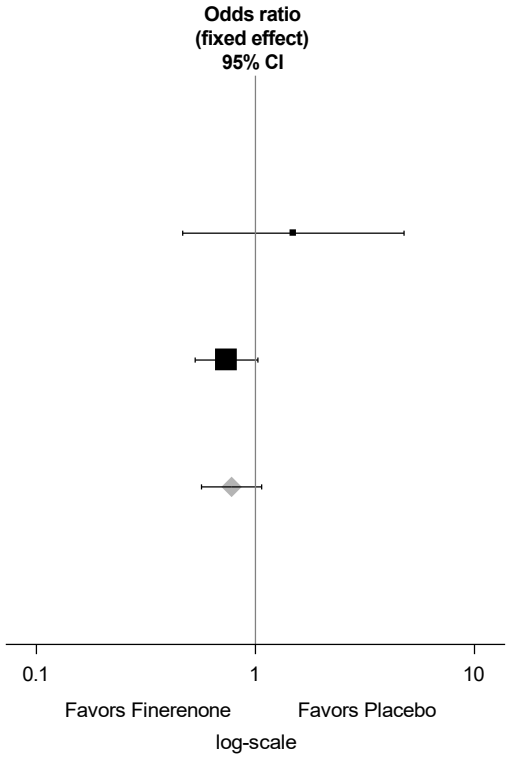
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	125 / 363	99 / 342	100.0	1.29 [0.94,1.77]	
Total	125 / 363	99 / 342		1.29 [0.94,1.77]	Z=1.56, p=0.1181
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	74 / 210	64 / 221	10.6	1.33 [0.89,2.00]	
FIGARO-DKD	561 / 1963	524 / 1960	89.4	1.10 [0.95,1.26]	
Total	635 / 2173	588 / 2181		1.12 [0.98,1.28]	Z=1.68, p=0.0937
Heterogeneity:	Q=0.81 (df=1)	p=0.3694	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4236	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.81: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

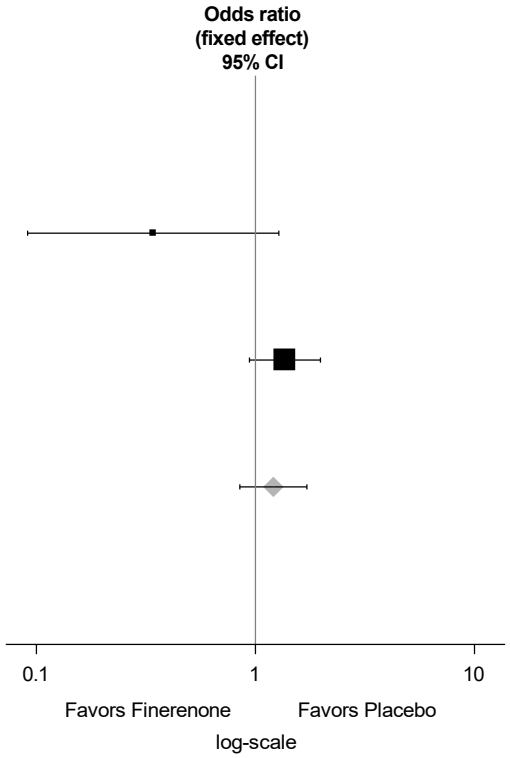
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	7.4	1.49 [0.47,4.77]	
FIGARO-DKD	64 / 2326	85 / 2302	92.6	0.74 [0.53,1.03]	
Total	71 / 2536	90 / 2523		0.78 [0.57,1.07]	Z=-1.56, p=0.1198
Heterogeneity:	Q=1.30 (df=1)	p=0.2549	I^2=22.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.82: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

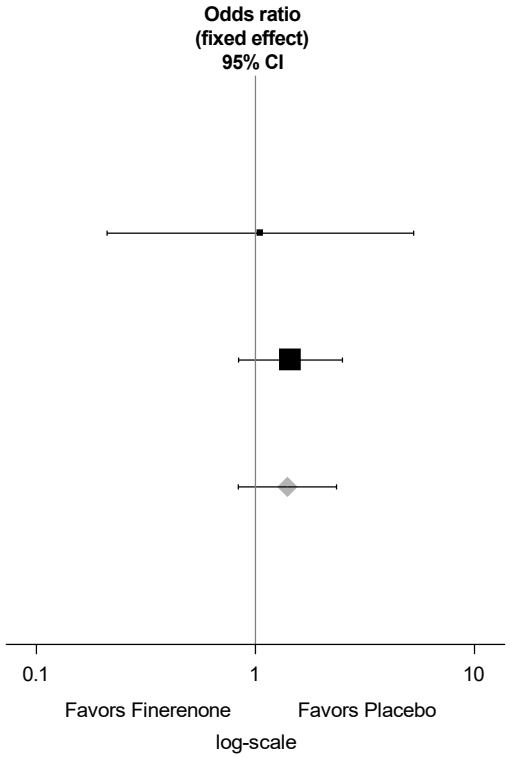
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	9 / 221	7.4	0.34 [0.09,1.28]	
FIGARO-DKD	67 / 2326	49 / 2302	92.6	1.36 [0.94,1.98]	
Total	70 / 2536	58 / 2523		1.21 [0.85,1.72]	Z=1.05, p=0.2953
Heterogeneity:	Q=3.92 (df=1)	p=0.0476	I^2=74.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.83: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

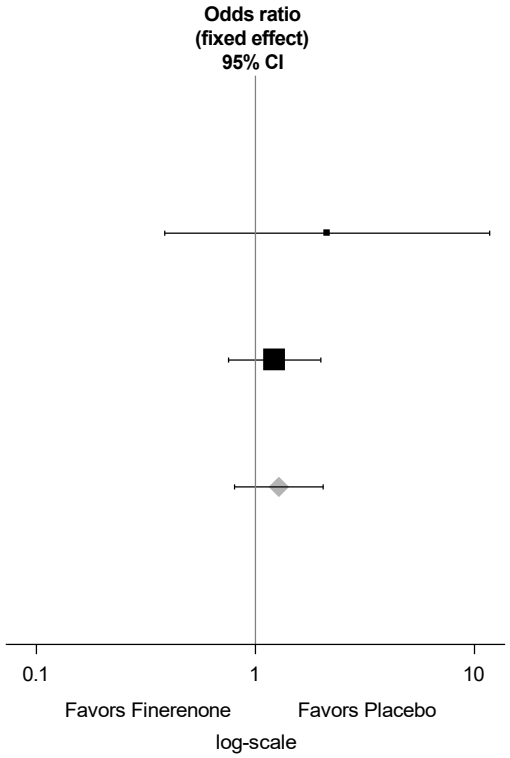
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	10.3	1.05 [0.21,5.28]	
FIGARO-DKD	32 / 2326	22 / 2302	89.7	1.45 [0.84,2.50]	
Total	35 / 2536	25 / 2523		1.40 [0.84,2.35]	Z=1.28, p=0.2018
Heterogeneity:	Q=0.13 (df=1)	p=0.7152	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.84: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

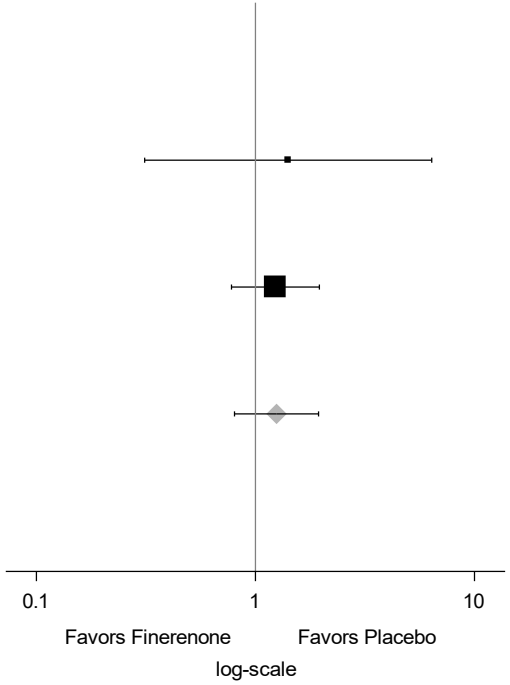
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	7.5	2.13 [0.39,11.73]	
FIGARO-DKD	37 / 2326	30 / 2302	92.5	1.22 [0.75,1.99]	
Total	41 / 2536	32 / 2523		1.28 [0.80,2.04]	Z=1.04, p=0.3004
Heterogeneity:	Q=0.37 (df=1)	p=0.5422	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.85: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

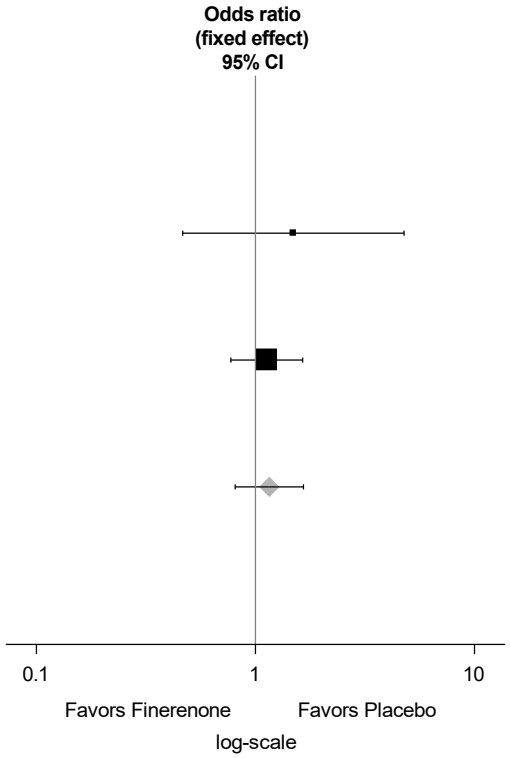
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	8.6	1.41 [0.31,6.38]	
FIGARO-DKD	41 / 2326	33 / 2302	91.4	1.23 [0.78,1.96]	
Total	45 / 2536	36 / 2523		1.25 [0.80,1.94]	Z=0.98, p=0.3255
Heterogeneity:	Q=0.03 (df=1)	p=0.8676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.86: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

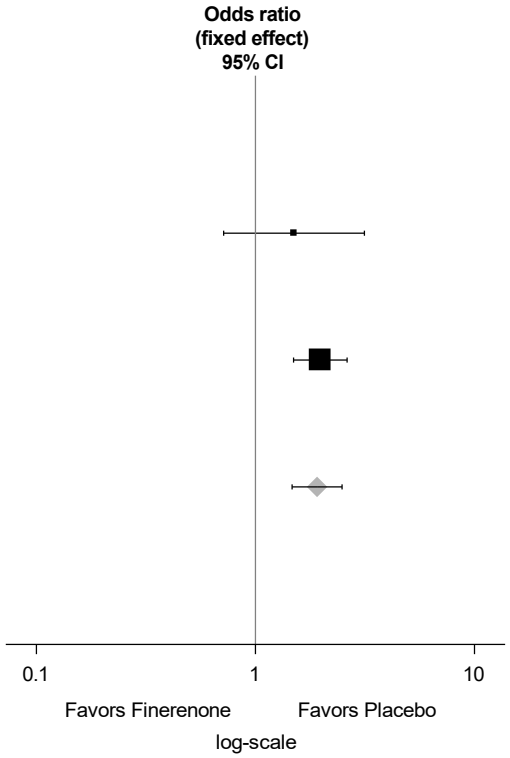
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	9.5	1.49 [0.47,4.77]	
FIGARO-DKD	59 / 2326	52 / 2302	90.5	1.13 [0.77,1.64]	
Total	66 / 2536	57 / 2523		1.16 [0.81,1.66]	Z=0.80, p=0.4258
Heterogeneity:	Q=0.20 (df=1)	p=0.6539	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.87: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

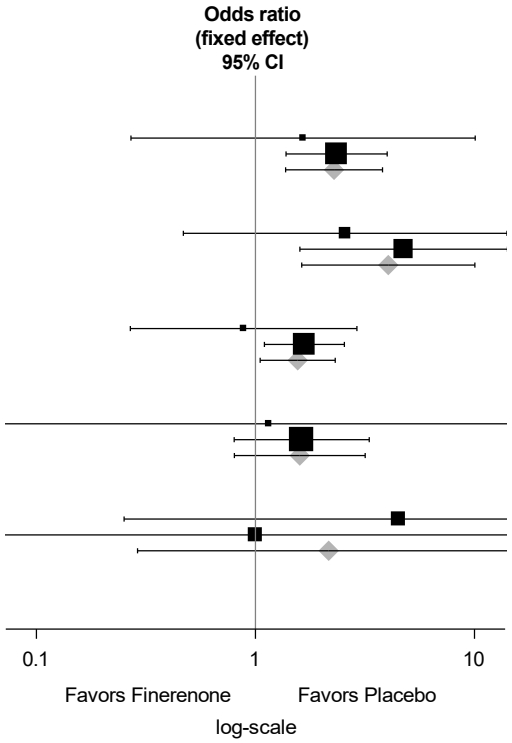
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 210	13 / 221	12.6	1.50 [0.72,3.14]	
FIGARO-DKD	149 / 2326	77 / 2302	87.4	1.98 [1.49,2.62]	
Total	167 / 2536	90 / 2523		1.91 [1.47,2.49]	Z=4.83, p=<.0001
Heterogeneity:	Q=0.47 (df=1)	p=0.4936	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.87.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

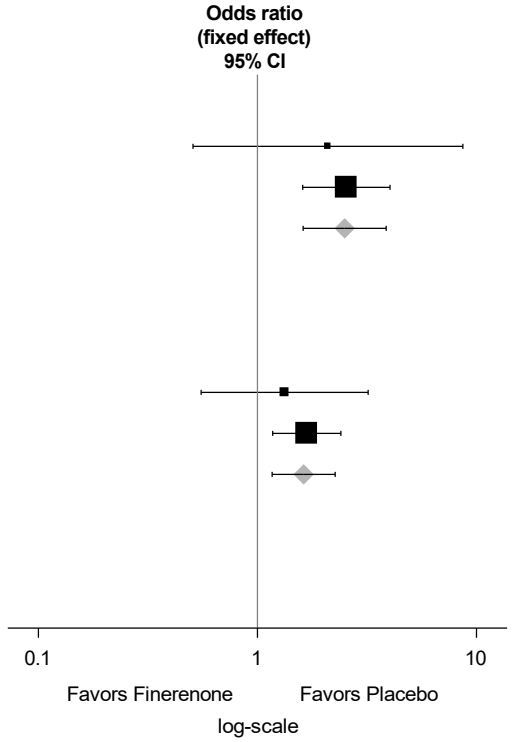
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	2 / 112	7.9	1.65 [0.27,10.08]	
FIGARO-DKD	46 / 1114	20 / 1110	92.1	2.35 [1.38,3.99]	
Total	49 / 1217	22 / 1222		2.29 [1.37,3.80]	Z=3.18, p=0.0015
Heterogeneity:	Q=0.13 (df=1)	p=0.7141	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 42	2 / 40	29.2	2.57 [0.47,14.07]	
FIGARO-DKD	19 / 292	4 / 277	70.8	4.75 [1.60,14.14]	
Total	24 / 334	6 / 317		4.04 [1.63,10.04]	Z=3.01, p=0.0026
Heterogeneity:	Q=0.36 (df=1)	p=0.5500	I^2=0.0%		
Asia					
FIDELIO-DKD	6 / 39	7 / 41	11.1	0.88 [0.27,2.91]	
FIGARO-DKD	62 / 522	39 / 523	88.9	1.67 [1.10,2.55]	
Total	68 / 561	46 / 564		1.56 [1.05,2.31]	Z=2.21, p=0.0274
Heterogeneity:	Q=0.98 (df=1)	p=0.3216	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 21	1 / 24	5.9	1.15 [0.07,19.60]	
FIGARO-DKD	21 / 322	13 / 316	94.1	1.63 [0.80,3.31]	
Total	22 / 343	14 / 340		1.59 [0.80,3.17]	Z=1.33, p=0.1842
Heterogeneity:	Q=0.05 (df=1)	p=0.8163	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 5	1 / 4	48.3	4.50 [0.25,80.57]	
FIGARO-DKD	1 / 76	1 / 76	51.7	1.00 [0.06,16.28]	
Total	4 / 81	2 / 80		2.16 [0.29,16.11]	Z=0.75, p=0.4527
Heterogeneity:	Q=0.54 (df=1)	p=0.4619	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.38 (df=4)	p=0.3574	I^2=8.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.87.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

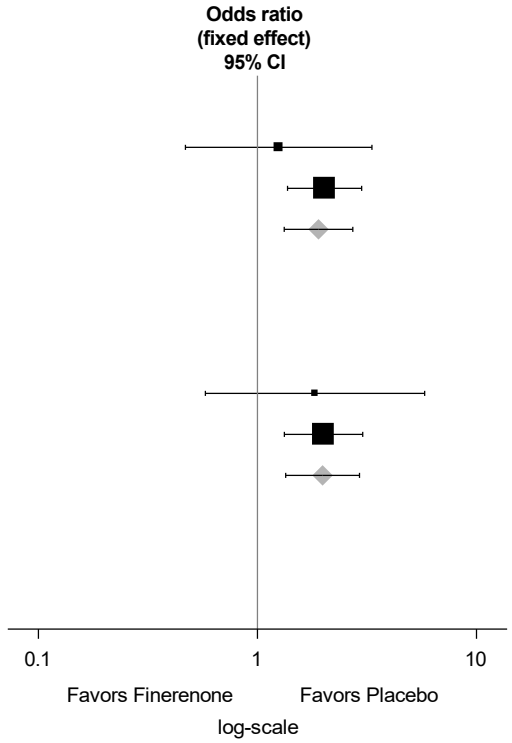
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	6 / 88	3 / 89	9.5	2.10 [0.51,8.67]	
FIGARO-DKD	66 / 811	27 / 803	90.5	2.55 [1.61,4.03]	
Total	72 / 899	30 / 892		2.50 [1.62,3.87]	Z=4.12, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.7989	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 122	10 / 132	14.3	1.33 [0.55,3.20]	
FIGARO-DKD	83 / 1515	50 / 1499	85.7	1.68 [1.17,2.40]	
Total	95 / 1637	60 / 1631		1.63 [1.17,2.26]	Z=2.87, p=0.0041
Heterogeneity:	Q=0.23 (df=1)	p=0.6304	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.38 (df=1)	p=0.1232	I^2=57.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.87.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

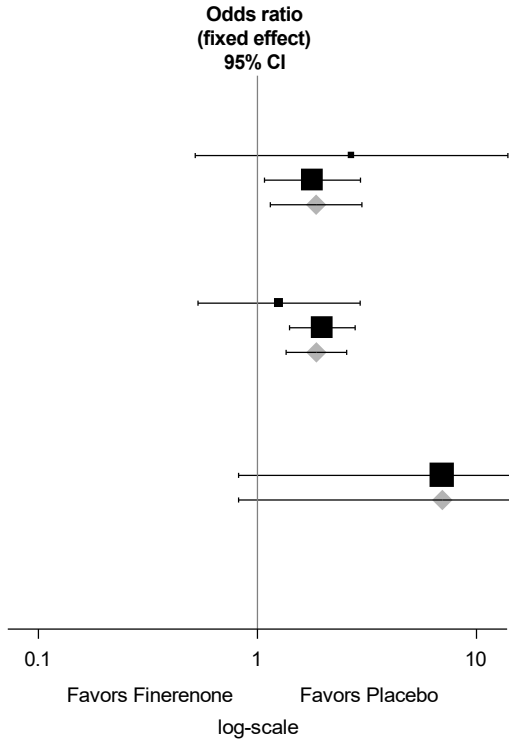
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	9 / 144	8 / 158	13.6	1.25 [0.47,3.33]	
FIGARO-DKD	79 / 1719	39 / 1679	86.4	2.03 [1.37,2.99]	
Total	88 / 1863	47 / 1837		1.90 [1.33,2.72]	Z=3.49, p=0.0005
Heterogeneity:	Q=0.80 (df=1)	p=0.3697	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 66	5 / 63	11.3	1.83 [0.58,5.80]	
FIGARO-DKD	70 / 607	38 / 622	88.7	2.00 [1.33,3.02]	
Total	79 / 673	43 / 685		1.98 [1.35,2.92]	Z=3.46, p=0.0005
Heterogeneity:	Q=0.02 (df=1)	p=0.8859	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8739	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.87.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

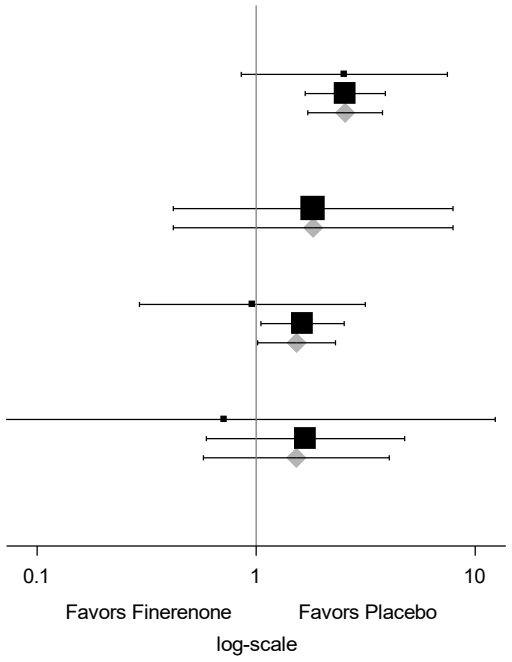
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 64	2 / 54	8.6	2.69 [0.52,13.91]	
FIGARO-DKD	43 / 693	25 / 699	91.4	1.78 [1.08,2.95]	
Total	49 / 757	27 / 753		1.85 [1.15,3.00]	Z=2.51, p=0.0120
Heterogeneity:	Q=0.22 (df=1)	p=0.6394	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 138	11 / 156	14.1	1.26 [0.54,2.94]	
FIGARO-DKD	100 / 1560	51 / 1524	85.9	1.98 [1.40,2.79]	
Total	112 / 1698	62 / 1680		1.86 [1.35,2.55]	Z=3.82, p=0.0001
Heterogeneity:	Q=0.94 (df=1)	p=0.3323	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	6 / 73	1 / 79	100.0	6.99 [0.82,59.49]	
Total	6 / 81	1 / 90		6.99 [0.82,59.49]	Z=1.78, p=0.0753
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.45 (df=2)	p=0.4849	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.87.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

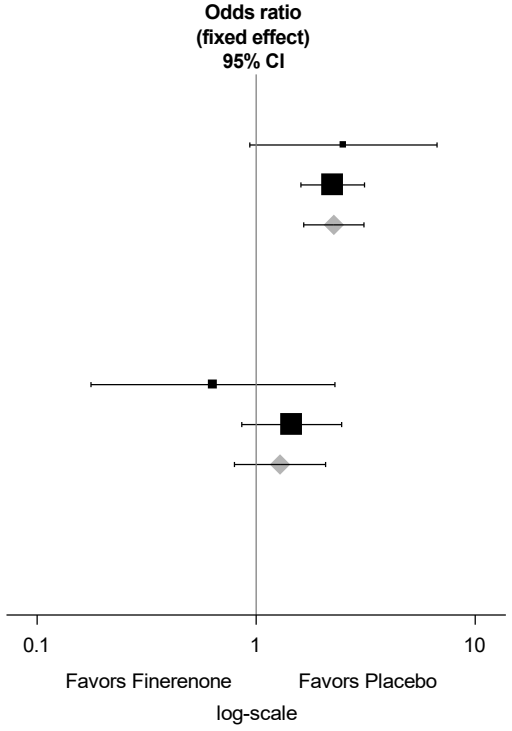
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	11 / 139	5 / 152	13.1	2.53 [0.86,7.46]	
FIGARO-DKD	79 / 1658	31 / 1612	86.9	2.55 [1.67,3.89]	
Total	90 / 1797	36 / 1764		2.55 [1.72,3.77]	Z=4.67, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9867	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	5 / 70	3 / 74	100.0	1.82 [0.42,7.92]	
Total	5 / 80	3 / 83		1.82 [0.42,7.92]	Z=0.80, p=0.4245
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 39	7 / 44	12.0	0.96 [0.29,3.15]	
FIGARO-DKD	55 / 464	37 / 485	88.0	1.63 [1.05,2.52]	
Total	61 / 503	44 / 529		1.53 [1.02,2.30]	Z=2.03, p=0.0420
Heterogeneity:	Q=0.67 (df=1)	p=0.4141	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	1 / 16	11.8	0.71 [0.04,12.35]	
FIGARO-DKD	10 / 134	6 / 131	88.2	1.68 [0.59,4.76]	
Total	11 / 156	7 / 147		1.53 [0.57,4.05]	Z=0.85, p=0.3968
Heterogeneity:	Q=0.31 (df=1)	p=0.5806	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.39 (df=3)	p=0.3348	I^2=11.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.87.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

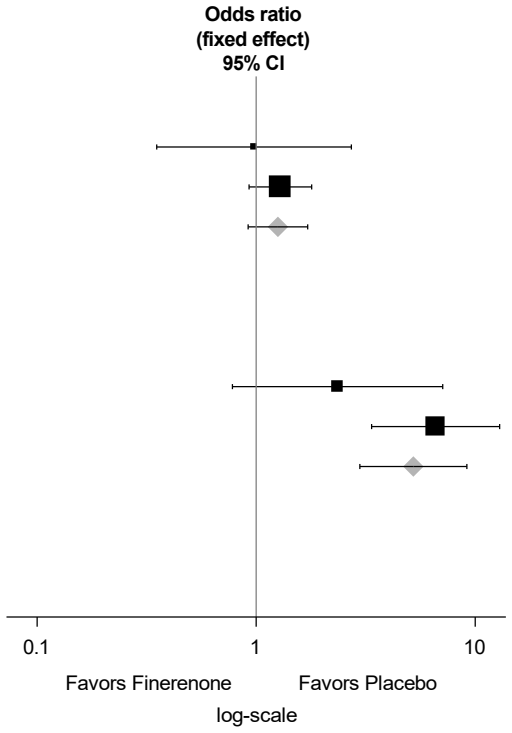
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	14 / 152	6 / 154	10.3	2.50 [0.94,6.69]	
FIGARO-DKD	112 / 1610	53 / 1638	89.7	2.24 [1.60,3.12]	
Total	126 / 1762	59 / 1792		2.26 [1.65,3.11]	Z=5.06, p=<.0001
Heterogeneity:	Q=0.05 (df=1)	p=0.8318	I^2=0.0%		
Female					
FIDELIO-DKD	4 / 58	7 / 67	14.4	0.63 [0.18,2.29]	
FIGARO-DKD	37 / 716	24 / 664	85.6	1.45 [0.86,2.46]	
Total	41 / 774	31 / 731		1.29 [0.80,2.07]	Z=1.03, p=0.3048
Heterogeneity:	Q=1.37 (df=1)	p=0.2415	I^2=27.1%		
Subgroup Heterogeneity:	Q=3.73 (df=1)	p=0.0535	I^2=73.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.87.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

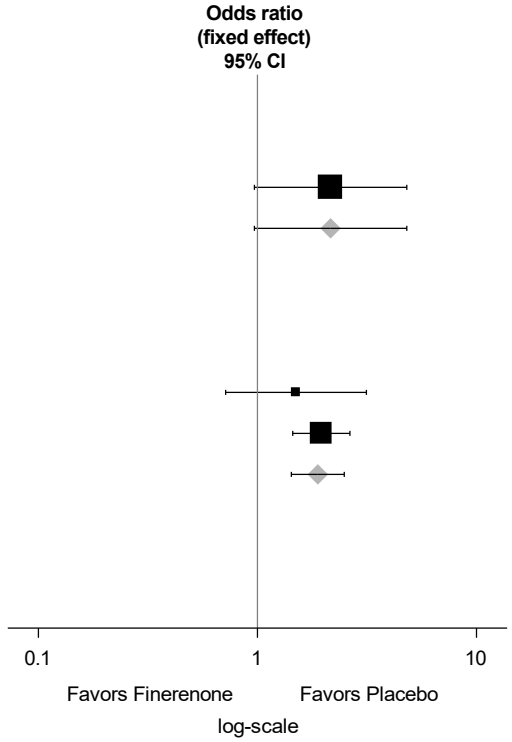
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	8 / 96	9.4	0.98 [0.35,2.72]	
FIGARO-DKD	85 / 1416	67 / 1420	90.6	1.29 [0.93,1.79]	
Total	93 / 1514	75 / 1516		1.26 [0.92,1.72]	Z=1.43, p=0.1525
Heterogeneity:	Q=0.25 (df=1)	p=0.6137	I^2=0.0%		
>= 65					
FIDELIO-DKD	10 / 112	5 / 125	27.0	2.35 [0.78,7.11]	
FIGARO-DKD	64 / 910	10 / 882	73.0	6.60 [3.37,12.93]	
Total	74 / 1022	15 / 1007		5.22 [2.97,9.16]	Z=5.76, p=<.0001
Heterogeneity:	Q=2.46 (df=1)	p=0.1168	I^2=59.4%		
Subgroup Heterogeneity:	Q=18.79 (df=1)	p=<.0001	I^2=94.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.87.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

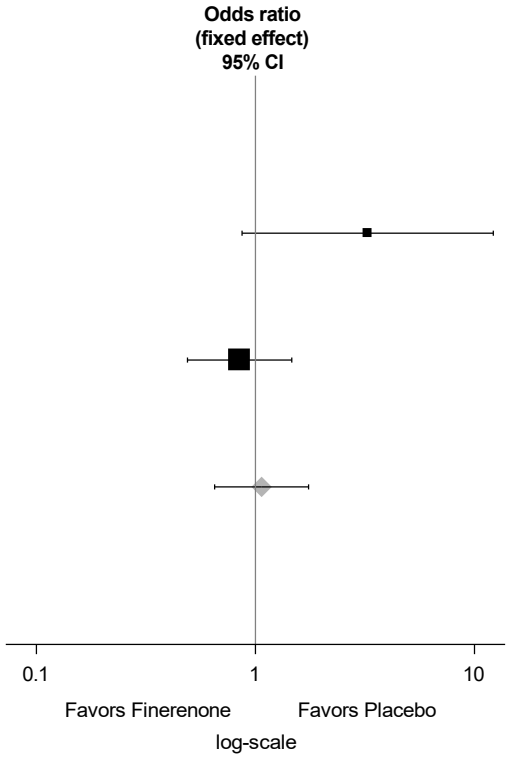
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	20 / 363	9 / 342	100.0	2.16 [0.97,4.81]	
Total	20 / 363	9 / 342		2.16 [0.97,4.81]	Z=1.88, p=0.0599
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	18 / 210	13 / 221	14.2	1.50 [0.72,3.14]	
FIGARO-DKD	129 / 1963	68 / 1960	85.8	1.96 [1.45,2.64]	
Total	147 / 2173	81 / 2181		1.89 [1.43,2.49]	Z=4.47, p=<.0001
Heterogeneity:	Q=0.43 (df=1)	p=0.5139	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7561	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.88: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

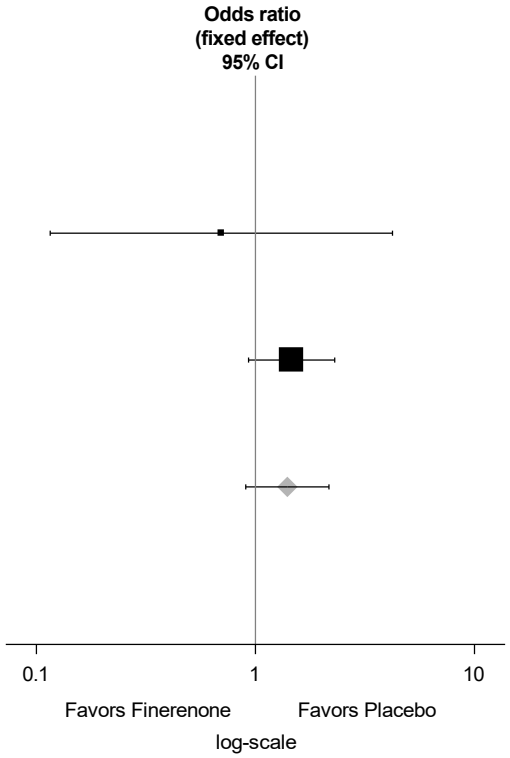
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	3 / 221	14.7	3.25 [0.87,12.19]	
FIGARO-DKD	24 / 2326	28 / 2302	85.3	0.85 [0.49,1.47]	
Total	33 / 2536	31 / 2523		1.07 [0.65,1.75]	Z=0.26, p=0.7976
Heterogeneity:	Q=3.42 (df=1)	p=0.0644	I^2=70.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.89: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

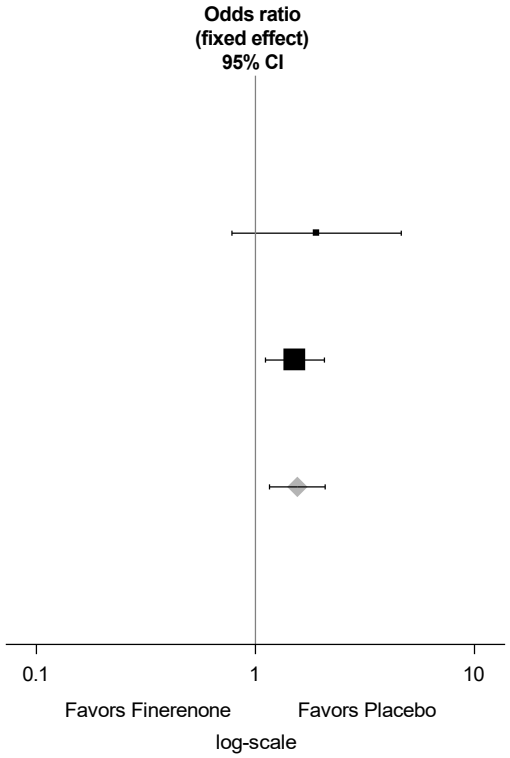
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	6.0	0.70 [0.12,4.22]	
FIGARO-DKD	47 / 2326	32 / 2302	94.0	1.46 [0.93,2.30]	
Total	49 / 2536	35 / 2523		1.40 [0.90,2.17]	Z=1.50, p=0.1329
Heterogeneity:	Q=0.61 (df=1)	p=0.4350	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.90: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

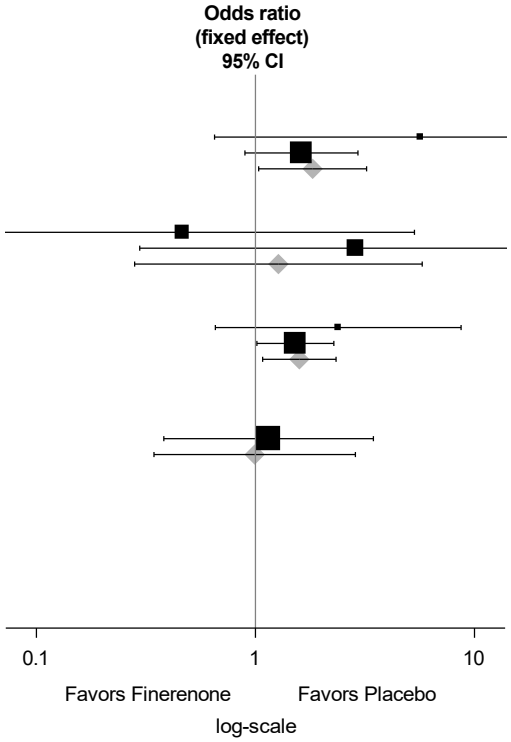
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 210	8 / 221	10.8	1.90 [0.78,4.63]	
FIGARO-DKD	104 / 2326	69 / 2302	89.2	1.51 [1.11,2.07]	
Total	118 / 2536	77 / 2523		1.55 [1.16,2.08]	Z=2.95, p=0.0032
Heterogeneity:	Q=0.22 (df=1)	p=0.6360	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.90.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

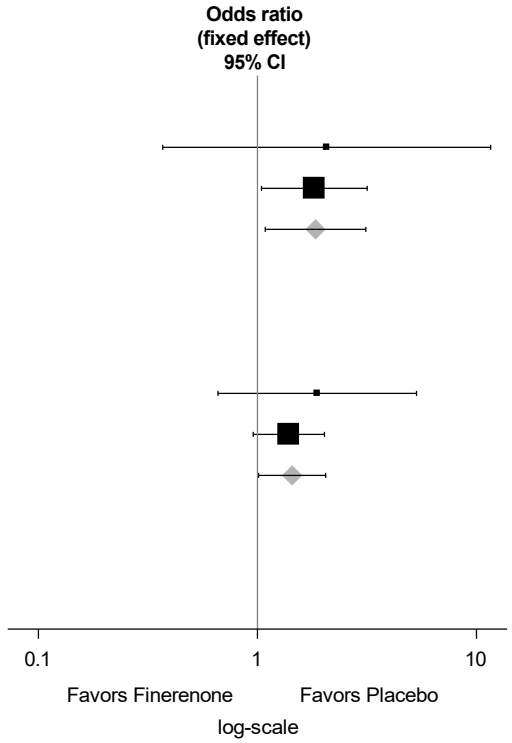
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	5 / 103	1 / 112	7.0	5.66 [0.65,49.31]	
FIGARO-DKD	29 / 1114	18 / 1110	93.0	1.62 [0.90,2.94]	
Total	34 / 1217	19 / 1222		1.82 [1.03,3.22]	Z=2.08, p=0.0378
Heterogeneity:	Q=1.20 (df=1)	p=0.2726	I^2=16.9%		
North America					
FIDELIO-DKD	1 / 42	2 / 40	46.4	0.46 [0.04,5.32]	
FIGARO-DKD	3 / 292	1 / 277	53.6	2.87 [0.30,27.71]	
Total	4 / 334	3 / 317		1.27 [0.28,5.77]	Z=0.31, p=0.7543
Heterogeneity:	Q=1.15 (df=1)	p=0.2837	I^2=13.0%		
Asia					
FIDELIO-DKD	8 / 39	4 / 41	8.9	2.39 [0.66,8.69]	
FIGARO-DKD	64 / 522	44 / 523	91.1	1.52 [1.01,2.28]	
Total	72 / 561	48 / 564		1.59 [1.08,2.33]	Z=2.34, p=0.0191
Heterogeneity:	Q=0.43 (df=1)	p=0.5141	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	7 / 322	6 / 316	100.0	1.15 [0.38,3.45]	
Total	7 / 343	7 / 340		0.99 [0.34,2.86]	Z=-0.02, p=0.9880
Heterogeneity:	Q=0.07 (df=1)	p=0.7947	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	0 / 76	0.0	205E9 [205E9,205E9]	
Total	1 / 81	0 / 80		192E9 [192E9,192E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.07 (df=4)	p=0.8993	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.90.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

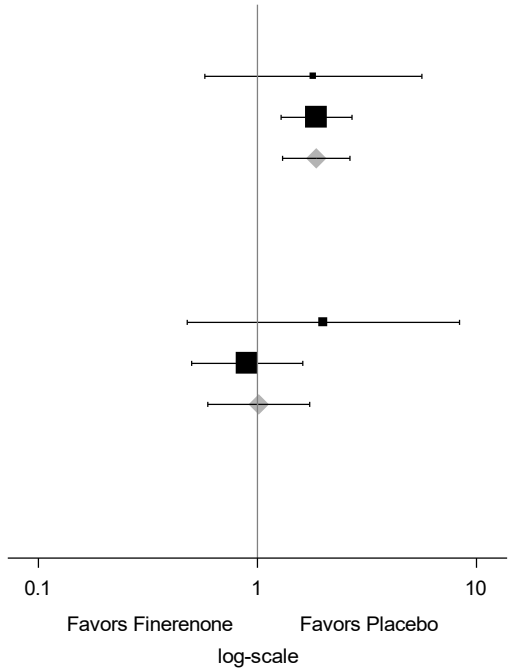
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	2 / 89	9.4	2.07 [0.37,11.61]	
FIGARO-DKD	36 / 811	20 / 803	90.6	1.82 [1.04,3.17]	
Total	40 / 899	22 / 892		1.84 [1.09,3.12]	Z=2.26, p=0.0236
Heterogeneity:	Q=0.02 (df=1)	p=0.8880	I^2=0.0%		
Absent					
FIDELIO-DKD	10 / 122	6 / 132	11.4	1.87 [0.66,5.32]	
FIGARO-DKD	68 / 1515	49 / 1499	88.6	1.39 [0.96,2.02]	
Total	78 / 1637	55 / 1631		1.44 [1.01,2.05]	Z=2.03, p=0.0425
Heterogeneity:	Q=0.28 (df=1)	p=0.5973	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.58 (df=1)	p=0.4482	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.90.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

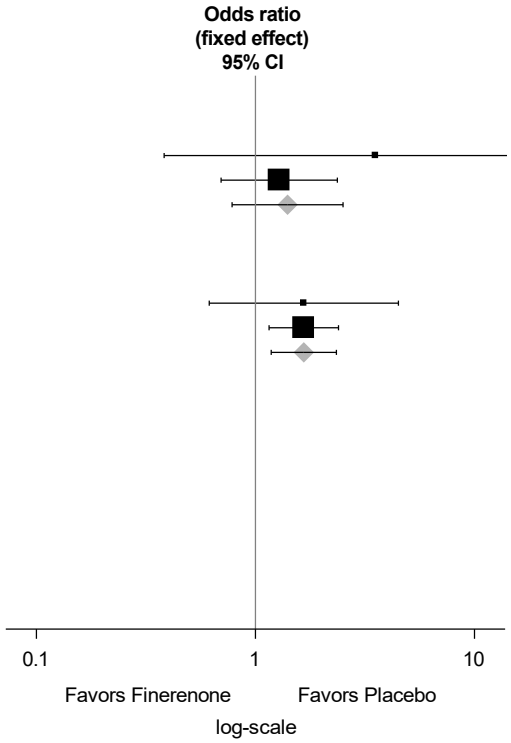
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	8 / 144	5 / 158	9.6	1.80 [0.58,5.63]	
FIGARO-DKD	82 / 1719	44 / 1679	90.4	1.86 [1.28,2.70]	
Total	90 / 1863	49 / 1837		1.86 [1.30,2.64]	Z=3.42, p=0.0006
Heterogeneity:	Q=0.00 (df=1)	p=0.9563	I^2=0.0%		
> 4.5					
FIDELIO-DKD	6 / 66	3 / 63	14.3	2.00 [0.48,8.37]	
FIGARO-DKD	22 / 607	25 / 622	85.7	0.90 [0.50,1.61]	
Total	28 / 673	28 / 685		1.01 [0.59,1.73]	Z=0.05, p=0.9603
Heterogeneity:	Q=1.03 (df=1)	p=0.3099	I^2=3.0%		
Subgroup Heterogeneity:	Q=3.40 (df=1)	p=0.0650	I^2=70.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.90.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

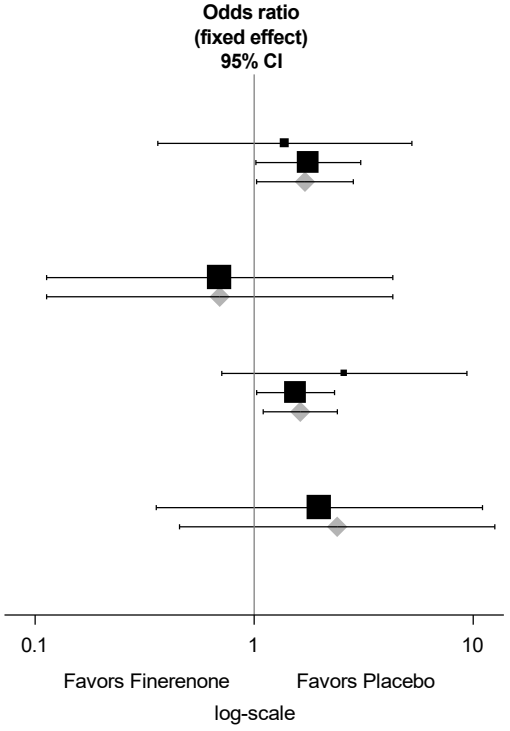
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 64	1 / 54	7.0	3.53 [0.38,32.61]	
FIGARO-DKD	24 / 693	19 / 699	93.0	1.28 [0.70,2.37]	
Total	28 / 757	20 / 753		1.40 [0.78,2.51]	Z=1.13, p=0.2567
Heterogeneity:	Q=0.74 (df=1)	p=0.3884	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	10 / 138	7 / 156	11.9	1.66 [0.62,4.49]	
FIGARO-DKD	80 / 1560	48 / 1524	88.1	1.66 [1.15,2.39]	
Total	90 / 1698	55 / 1680		1.66 [1.18,2.34]	Z=2.91, p=0.0037
Heterogeneity:	Q=0.00 (df=1)	p=0.9993	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	2 / 79	0.0	0.00 [0.00,12E296]	
Total	0 / 81	2 / 90		0.00 [0.00,14E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.24 (df=2)	p=0.8849	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.90.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

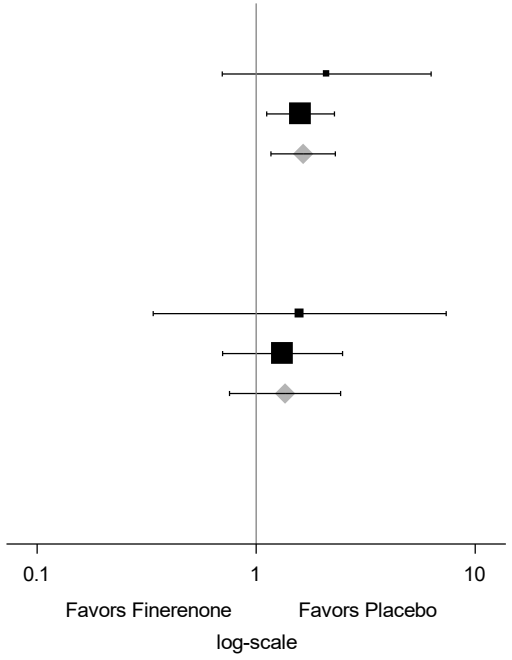
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	5 / 139	4 / 152	14.5	1.38 [0.36,5.25]	
FIGARO-DKD	36 / 1658	20 / 1612	85.5	1.77 [1.02,3.07]	
Total	41 / 1797	24 / 1764		1.71 [1.03,2.84]	Z=2.06, p=0.0396
Heterogeneity:	Q=0.11 (df=1)	p=0.7379	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	2 / 70	3 / 74	100.0	0.70 [0.11,4.30]	
Total	2 / 80	3 / 83		0.70 [0.11,4.30]	Z=-0.39, p=0.6964
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	8 / 39	4 / 44	9.2	2.58 [0.71,9.36]	
FIGARO-DKD	62 / 464	44 / 485	90.8	1.55 [1.03,2.33]	
Total	70 / 503	48 / 529		1.62 [1.10,2.40]	Z=2.44, p=0.0148
Heterogeneity:	Q=0.55 (df=1)	p=0.4575	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	0 / 16	0.0	992E8 [992E8,992E8]	
FIGARO-DKD	4 / 134	2 / 131	100.0	1.98 [0.36,11.03]	
Total	5 / 156	2 / 147		2.39 [0.46,12.55]	Z=1.03, p=0.3021
Heterogeneity:	Q=0.05 (df=1)	p=0.8306	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=3)	p=0.7828	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.90.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

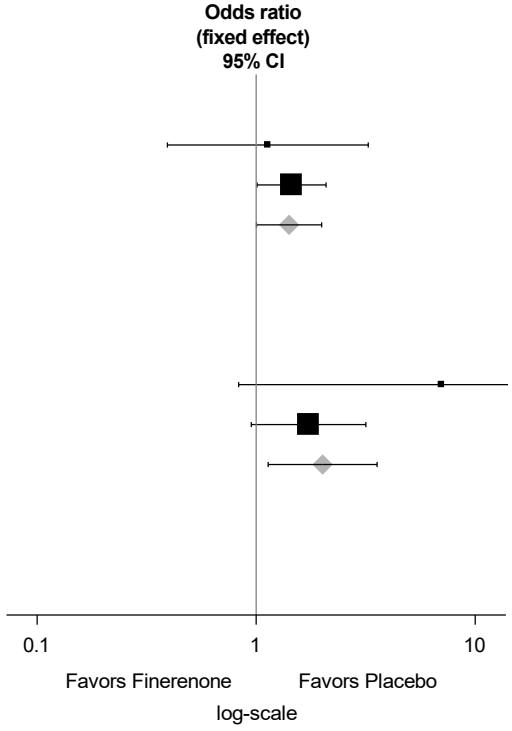
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	10 / 152	5 / 154	9.5	2.10 [0.70,6.29]	
FIGARO-DKD	80 / 1610	52 / 1638	90.5	1.59 [1.12,2.28]	
Total	90 / 1762	57 / 1792		1.64 [1.17,2.30]	Z=2.86, p=0.0043
Heterogeneity:	Q=0.22 (df=1)	p=0.6410	I^2=0.0%		
Female					
FIDELIO-DKD	4 / 58	3 / 67	14.4	1.58 [0.34,7.37]	
FIGARO-DKD	24 / 716	17 / 664	85.6	1.32 [0.70,2.48]	
Total	28 / 774	20 / 731		1.35 [0.76,2.43]	Z=1.02, p=0.3081
Heterogeneity:	Q=0.04 (df=1)	p=0.8321	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5810	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.90.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

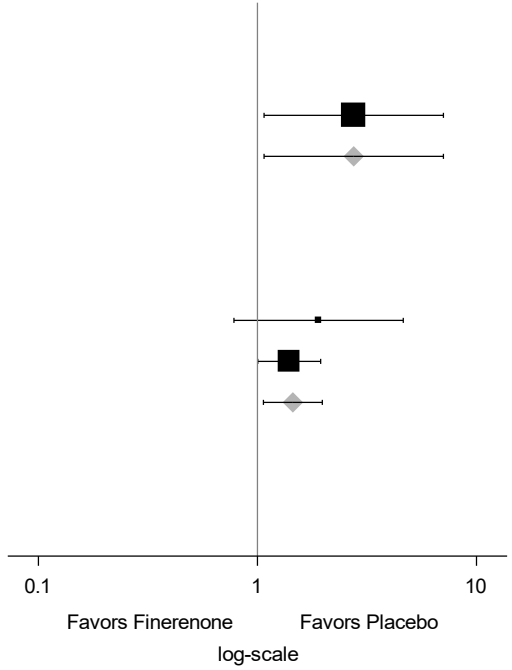
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 98	7 / 96	10.5	1.13 [0.39,3.25]	
FIGARO-DKD	74 / 1416	52 / 1420	89.5	1.45 [1.01,2.08]	
Total	82 / 1514	59 / 1516		1.41 [1.00,1.99]	Z=1.98, p=0.0479
Heterogeneity:	Q=0.19 (df=1)	p=0.6612	I^2=0.0%		
>= 65					
FIDELIO-DKD	6 / 112	1 / 125	7.4	7.02 [0.83,59.23]	
FIGARO-DKD	30 / 910	17 / 882	92.6	1.73 [0.95,3.17]	
Total	36 / 1022	18 / 1007		2.01 [1.13,3.57]	Z=2.39, p=0.0168
Heterogeneity:	Q=1.55 (df=1)	p=0.2130	I^2=35.5%		
Subgroup Heterogeneity:	Q=1.07 (df=1)	p=0.3006	I^2=6.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.90.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

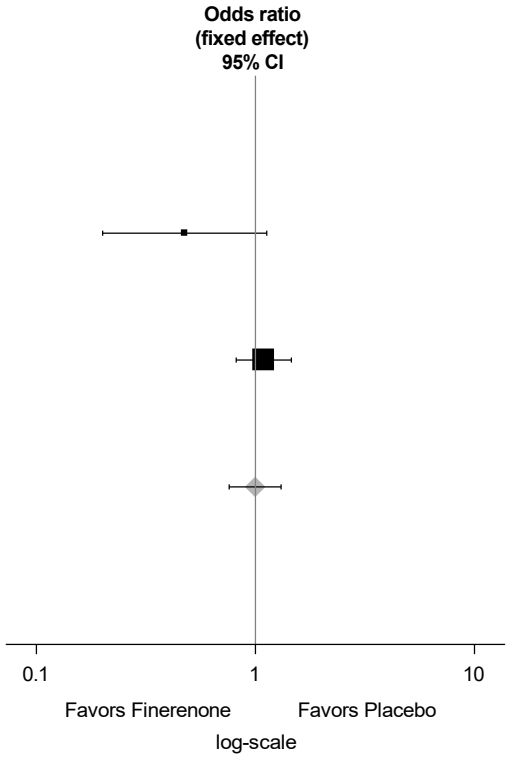
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	17 / 363	6 / 342	100.0	2.75 [1.07,7.06]	
Total	17 / 363	6 / 342		2.75 [1.07,7.06]	Z=2.10, p=0.0354
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	14 / 210	8 / 221	12.1	1.90 [0.78,4.63]	
FIGARO-DKD	87 / 1963	63 / 1960	87.9	1.40 [1.00,1.94]	
Total	101 / 2173	71 / 2181		1.45 [1.06,1.98]	Z=2.36, p=0.0184
Heterogeneity:	Q=0.41 (df=1)	p=0.5237	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2064	I^2=37.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.91: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

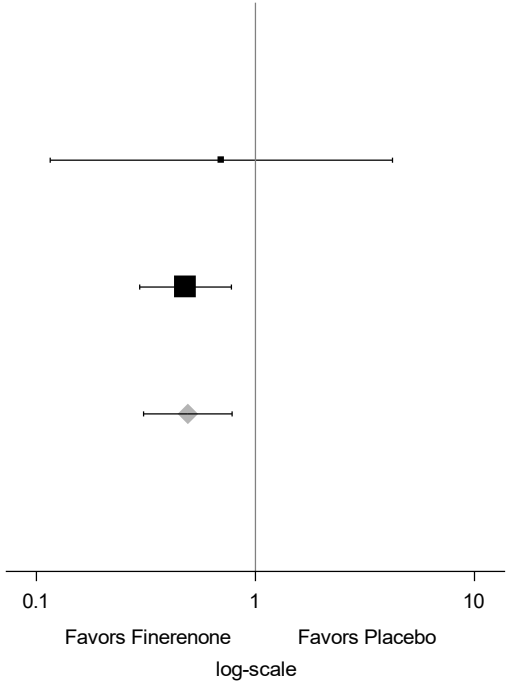
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	17 / 221	10.2	0.48 [0.20,1.13]	
FIGARO-DKD	100 / 2326	91 / 2302	89.8	1.09 [0.82,1.46]	
Total	108 / 2536	108 / 2523		1.00 [0.76,1.31]	Z=-0.02, p=0.9804
Heterogeneity:	Q=3.21 (df=1)	p=0.0732	I^2=68.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.92: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

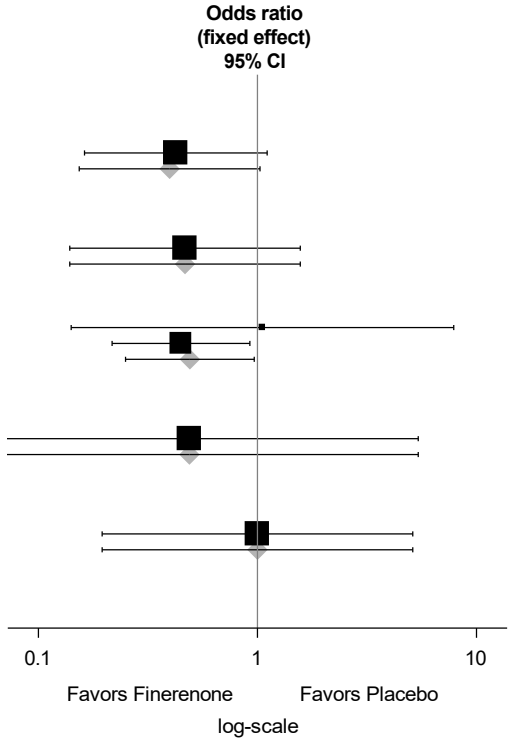
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	6.7	0.70 [0.12,4.22]	
FIGARO-DKD	25 / 2326	51 / 2302	93.3	0.48 [0.30,0.78]	
Total	27 / 2536	54 / 2523		0.49 [0.31,0.78]	Z=-2.99, p=0.0028
Heterogeneity:	Q=0.16 (df=1)	p=0.6920	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.92.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

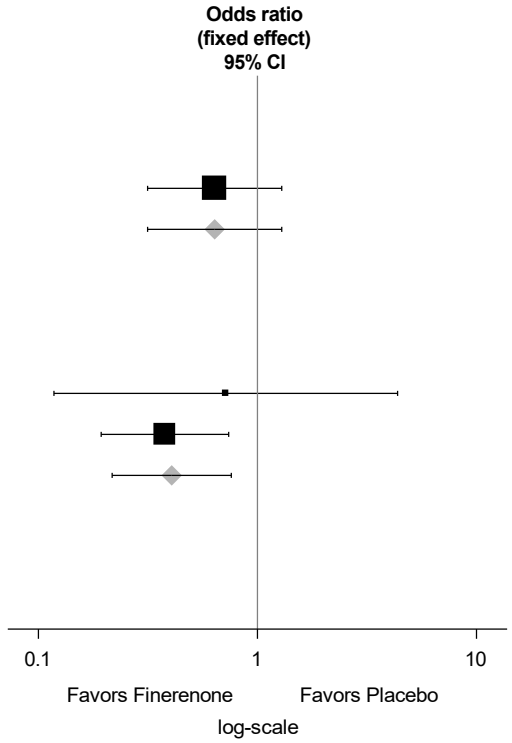
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	1 / 112	0.0	0.00 [0.00,13E296]	
FIGARO-DKD	6 / 1114	14 / 1110	100.0	0.42 [0.16,1.11]	
Total	6 / 1217	15 / 1222		0.40 [0.15,1.03]	Z=-1.90, p=0.0568
Heterogeneity:	Q=0.02 (df=1)	p=0.8941	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	4 / 292	8 / 277	100.0	0.47 [0.14,1.57]	
Total	4 / 334	8 / 317		0.47 [0.14,1.57]	Z=-1.23, p=0.2181
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	2 / 39	2 / 41	11.5	1.05 [0.14,7.87]	
FIGARO-DKD	11 / 522	24 / 523	88.5	0.45 [0.22,0.92]	
Total	13 / 561	26 / 564		0.49 [0.25,0.97]	Z=-2.06, p=0.0396
Heterogeneity:	Q=0.62 (df=1)	p=0.4321	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	2 / 316	100.0	0.49 [0.04,5.42]	
Total	1 / 343	2 / 340		0.49 [0.04,5.42]	Z=-0.58, p=0.5601
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	3 / 76	3 / 76	100.0	1.00 [0.20,5.12]	
Total	3 / 81	3 / 80		1.00 [0.20,5.12]	Z=0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=4)	p=0.9207	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.92.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

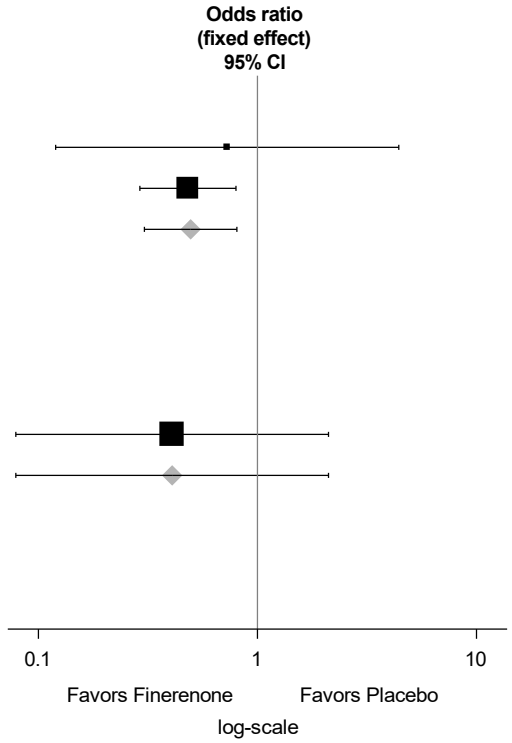
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	13 / 811	20 / 803	100.0	0.64 [0.32,1.29]	
Total	13 / 899	20 / 892		0.64 [0.32,1.29]	Z=-1.25, p=0.2113
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	2 / 122	3 / 132	12.1	0.72 [0.12,4.36]	
FIGARO-DKD	12 / 1515	31 / 1499	87.9	0.38 [0.19,0.74]	
Total	14 / 1637	34 / 1631		0.41 [0.22,0.76]	Z=-2.82, p=0.0048
Heterogeneity:	Q=0.42 (df=1)	p=0.5152	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.88 (df=1)	p=0.3481	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.92.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

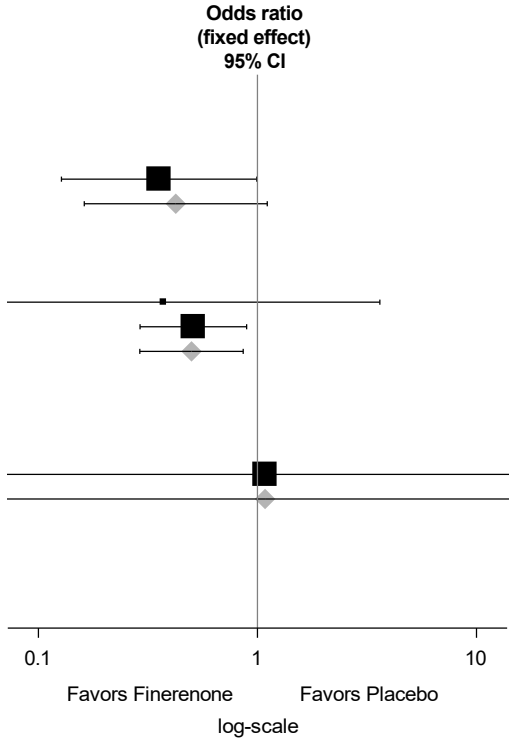
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	3 / 158	7.3	0.73 [0.12,4.42]	
FIGARO-DKD	23 / 1719	46 / 1679	92.7	0.48 [0.29,0.80]	
Total	25 / 1863	49 / 1837		0.50 [0.30,0.81]	Z=-2.83, p=0.0046
Heterogeneity:	Q=0.19 (df=1)	p=0.6655	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	2 / 607	5 / 622	100.0	0.41 [0.08,2.11]	
Total	2 / 673	5 / 685		0.41 [0.08,2.11]	Z=-1.07, p=0.2850
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8242	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.92.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

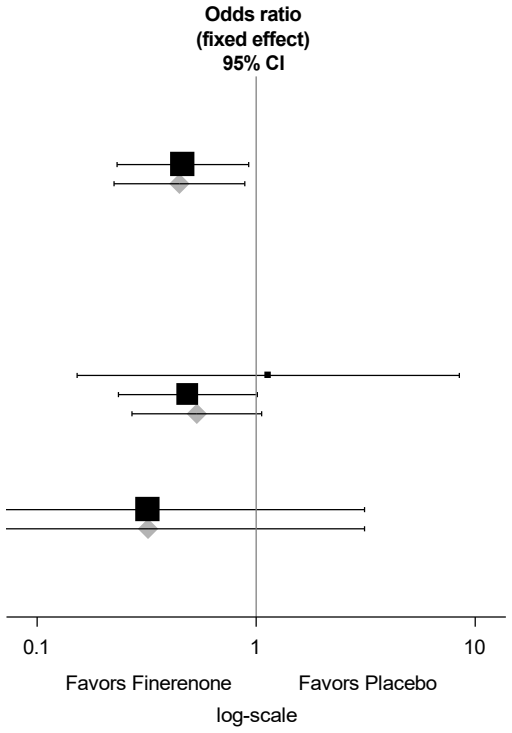
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	899E8 [899E8,899E8]	
FIGARO-DKD	5 / 693	14 / 699	100.0	0.36 [0.13,0.99]	
Total	6 / 757	14 / 753		0.42 [0.16,1.11]	Z=-1.75, p=0.0802
Heterogeneity:	Q=0.11 (df=1)	p=0.7379	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	3 / 156	5.7	0.37 [0.04,3.62]	
FIGARO-DKD	19 / 1560	36 / 1524	94.3	0.51 [0.29,0.89]	
Total	20 / 1698	39 / 1680		0.50 [0.29,0.86]	Z=-2.50, p=0.0124
Heterogeneity:	Q=0.07 (df=1)	p=0.7927	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	1 / 79	100.0	1.08 [0.07,17.64]	
Total	1 / 81	1 / 90		1.08 [0.07,17.64]	Z=0.06, p=0.9552
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=2)	p=0.8173	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.92.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

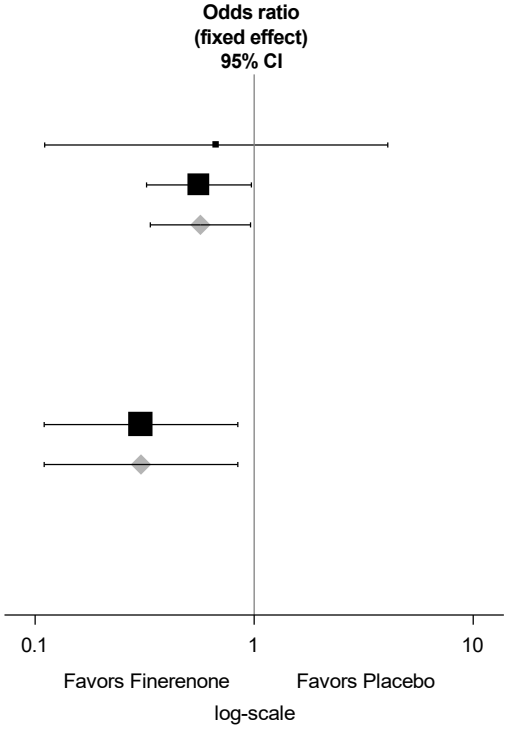
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	1 / 152	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	12 / 1658	25 / 1612	100.0	0.46 [0.23,0.92]	
Total	12 / 1797	26 / 1764		0.45 [0.22,0.89]	Z=-2.30, p=0.0214
Heterogeneity:	Q=0.01 (df=1)	p=0.9179	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	0 / 74	0.0	223E9 [223E9,223E9]	
Total	1 / 80	0 / 83		192E9 [192E9,192E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	2 / 39	2 / 44	11.7	1.14 [0.15,8.46]	
FIGARO-DKD	11 / 464	23 / 485	88.3	0.49 [0.24,1.01]	
Total	13 / 503	25 / 529		0.54 [0.27,1.06]	Z=-1.79, p=0.0728
Heterogeneity:	Q=0.60 (df=1)	p=0.4386	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	1 / 134	3 / 131	100.0	0.32 [0.03,3.12]	
Total	1 / 156	3 / 147		0.32 [0.03,3.12]	Z=-0.98, p=0.3276
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=3)	p=0.9667	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.92.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

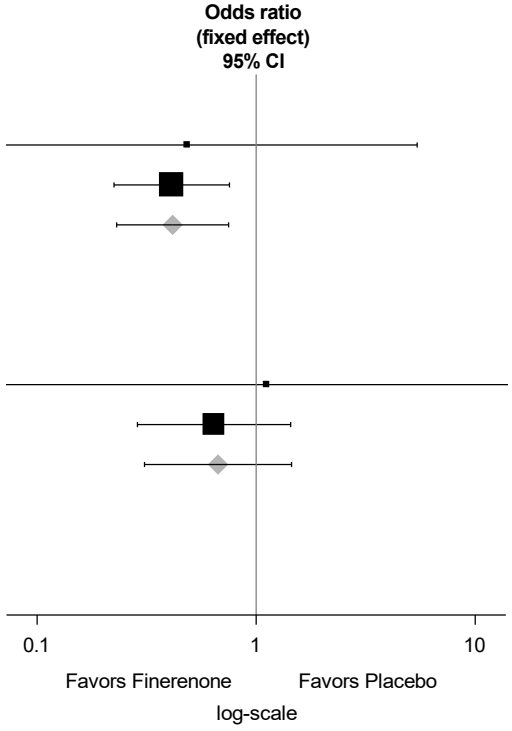
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	8.5	0.67 [0.11,4.07]	
FIGARO-DKD	20 / 1610	36 / 1638	91.5	0.56 [0.32,0.97]	
Total	22 / 1762	39 / 1792		0.57 [0.34,0.96]	Z=-2.10, p=0.0355
Heterogeneity:	Q=0.04 (df=1)	p=0.8504	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	5 / 716	15 / 664	100.0	0.30 [0.11,0.84]	
Total	5 / 774	15 / 731		0.30 [0.11,0.84]	Z=-2.29, p=0.0219
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.14 (df=1)	p=0.2853	I^2=12.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.92.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

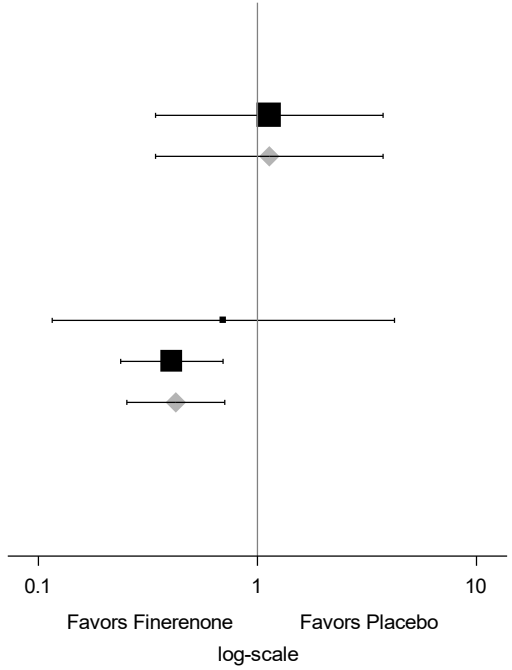
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	2 / 96	5.9	0.48 [0.04,5.43]	
FIGARO-DKD	15 / 1416	36 / 1420	94.1	0.41 [0.22,0.76]	
Total	16 / 1514	38 / 1516		0.42 [0.23,0.75]	Z=-2.92, p=0.0034
Heterogeneity:	Q=0.02 (df=1)	p=0.8979	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	1 / 125	7.7	1.12 [0.07,18.07]	
FIGARO-DKD	10 / 910	15 / 882	92.3	0.64 [0.29,1.44]	
Total	11 / 1022	16 / 1007		0.67 [0.31,1.45]	Z=-1.02, p=0.3092
Heterogeneity:	Q=0.14 (df=1)	p=0.7081	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=1)	p=0.3356	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.92.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

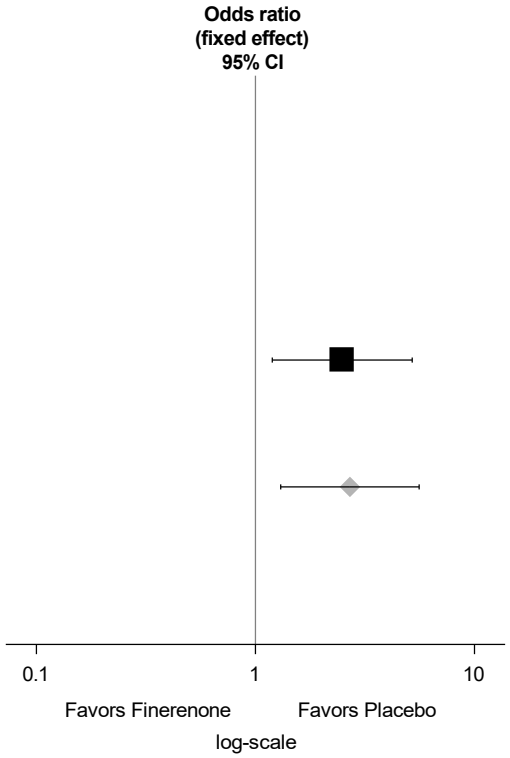
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	5 / 342	100.0	1.13 [0.34,3.75]	
Total	6 / 363	5 / 342		1.13 [0.34,3.75]	Z=0.20, p=0.8381
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	3 / 221	8.2	0.70 [0.12,4.22]	
FIGARO-DKD	19 / 1963	46 / 1960	91.8	0.41 [0.24,0.70]	
Total	21 / 2173	49 / 2181		0.42 [0.25,0.71]	Z=-3.27, p=0.0011
Heterogeneity:	Q=0.32 (df=1)	p=0.5721	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.19 (df=1)	p=0.1390	I^2=54.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.93: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

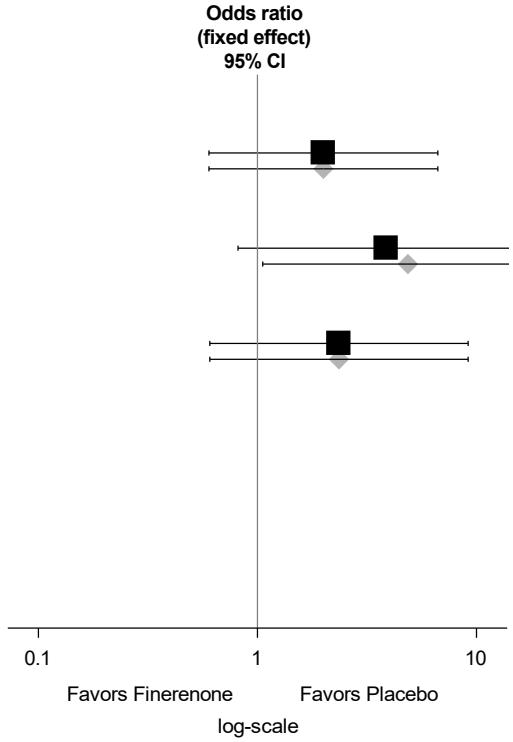
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	0 / 221	0.0	148E9 [148E9,148E9]	
FIGARO-DKD	25 / 2326	10 / 2302	100.0	2.49 [1.19,5.20]	
Total	27 / 2536	10 / 2523		2.70 [1.30,5.59]	Z=2.67, p=0.0075
Heterogeneity:	Q=0.05 (df=1)	p=0.8298	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.93.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

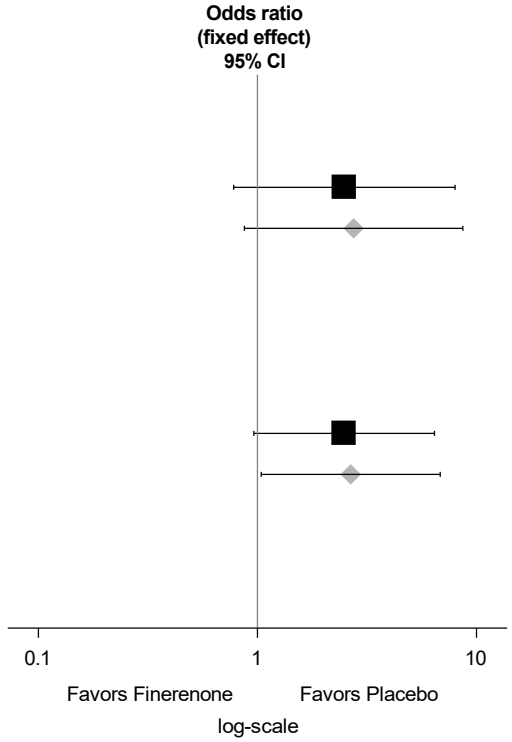
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	8 / 1114	4 / 1110	100.0	2.00 [0.60,6.66]	
Total	8 / 1217	4 / 1222		2.00 [0.60,6.66]	Z=1.13, p=0.2588
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	0 / 40	0.0	283E9 [283E9,283E9]	
FIGARO-DKD	8 / 292	2 / 277	100.0	3.87 [0.82,18.40]	
Total	10 / 334	2 / 317		4.86 [1.06,22.38]	Z=2.03, p=0.0422
Heterogeneity:	Q=0.08 (df=1)	p=0.7746	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	7 / 522	3 / 523	100.0	2.36 [0.61,9.16]	
Total	7 / 561	3 / 564		2.36 [0.61,9.16]	Z=1.24, p=0.2161
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	1 / 316	0.0	0.00 [0.00,14E296]	
Total	0 / 343	1 / 340		0.00 [0.00,15E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	0 / 76	0.0	153E9 [153E9,153E9]	
Total	2 / 81	0 / 80		143E9 [143E9,143E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.85 (df=4)	p=0.9320	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.93.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

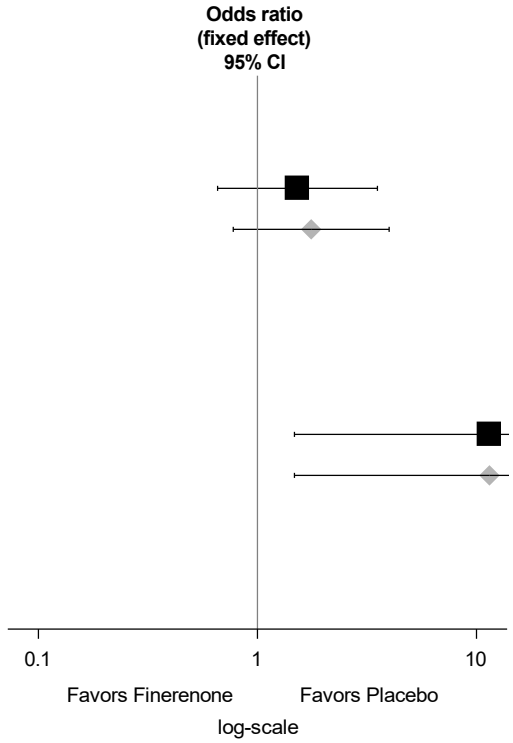
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	0 / 89	0.0	177E9 [177E9,177E9]	
FIGARO-DKD	10 / 811	4 / 803	100.0	2.49 [0.78,7.98]	
Total	11 / 899	4 / 892		2.75 [0.87,8.66]	Z=1.73, p=0.0844
Heterogeneity:	Q=0.03 (df=1)	p=0.8699	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	0 / 132	0.0	127E9 [127E9,127E9]	
FIGARO-DKD	15 / 1515	6 / 1499	100.0	2.49 [0.96,6.43]	
Total	16 / 1637	6 / 1631		2.67 [1.04,6.83]	Z=2.04, p=0.0411
Heterogeneity:	Q=0.02 (df=1)	p=0.8868	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9679	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.93.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

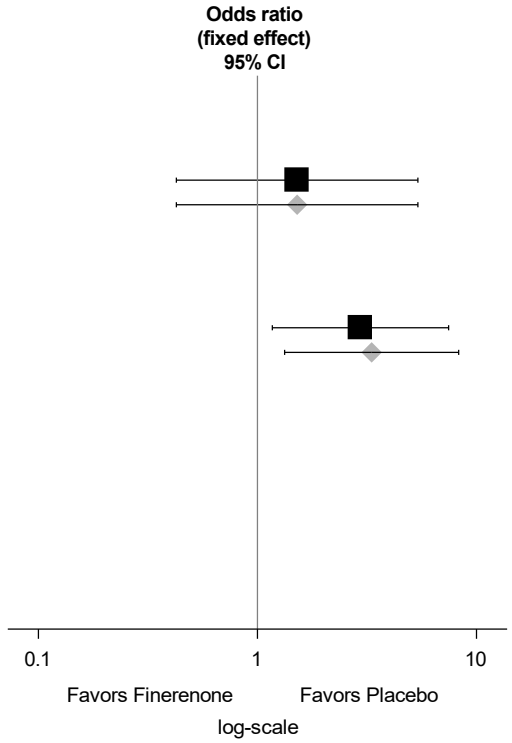
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	0 / 158	0.0	217E9 [217E9,217E9]	
FIGARO-DKD	14 / 1719	9 / 1679	100.0	1.52 [0.66,3.53]	
Total	16 / 1863	9 / 1837		1.76 [0.78,3.99]	Z=1.35, p=0.1765
Heterogeneity:	Q=0.11 (df=1)	p=0.7371	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	11 / 607	1 / 622	100.0	11.46 [1.48,89.05]	
Total	11 / 673	1 / 685		11.46 [1.48,89.05]	Z=2.33, p=0.0197
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.77 (df=1)	p=0.0962	I^2=63.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.93.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

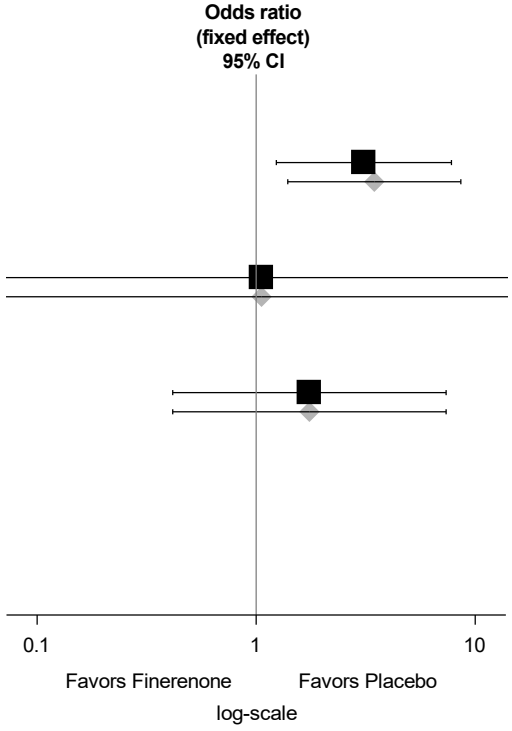
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	4 / 699	100.0	1.52 [0.43,5.40]	
Total	6 / 757	4 / 753		1.52 [0.43,5.40]	Z=0.64, p=0.5197
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	0 / 156	0.0	226E9 [226E9,226E9]	
FIGARO-DKD	18 / 1560	6 / 1524	100.0	2.95 [1.17,7.46]	
Total	20 / 1698	6 / 1680		3.32 [1.33,8.29]	Z=2.57, p=0.0101
Heterogeneity:	Q=0.06 (df=1)	p=0.8036	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	0 / 79	0.0	214E9 [214E9,214E9]	
Total	1 / 81	0 / 90		181E9 [181E9,181E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.96 (df=2)	p=0.6179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.93.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

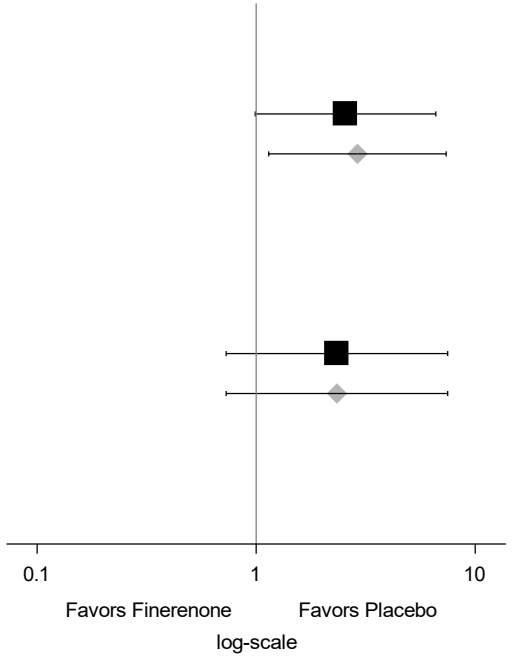
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	0 / 152	0.0	225E9 [225E9,225E9]	
FIGARO-DKD	19 / 1658	6 / 1612	100.0	3.10 [1.24,7.79]	
Total	21 / 1797	6 / 1764		3.46 [1.39,8.60]	Z=2.68, p=0.0075
Heterogeneity:	Q=0.05 (df=1)	p=0.8155	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	1 / 74	100.0	1.06 [0.06,17.25]	
Total	1 / 80	1 / 83		1.06 [0.06,17.25]	Z=0.04, p=0.9684
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	5 / 464	3 / 485	100.0	1.75 [0.42,7.37]	
Total	5 / 503	3 / 529		1.75 [0.42,7.37]	Z=0.76, p=0.4452
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	0 / 131	0.0	-	
Total	0 / 156	0 / 147		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.07 (df=3)	p=0.7849	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.93.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

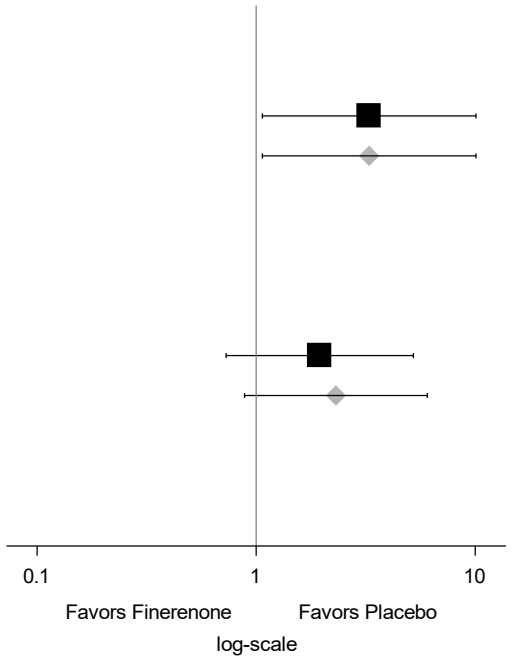
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	0 / 154	0.0	205E9 [205E9,205E9]	
FIGARO-DKD	15 / 1610	6 / 1638	100.0	2.56 [0.99,6.61]	
Total	17 / 1762	6 / 1792		2.90 [1.14,7.37]	Z=2.24, p=0.0253
Heterogeneity:	Q=0.07 (df=1)	p=0.7956	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	10 / 716	4 / 664	100.0	2.34 [0.73,7.49]	
Total	10 / 774	4 / 731		2.34 [0.73,7.49]	Z=1.43, p=0.1530
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7769	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.93.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

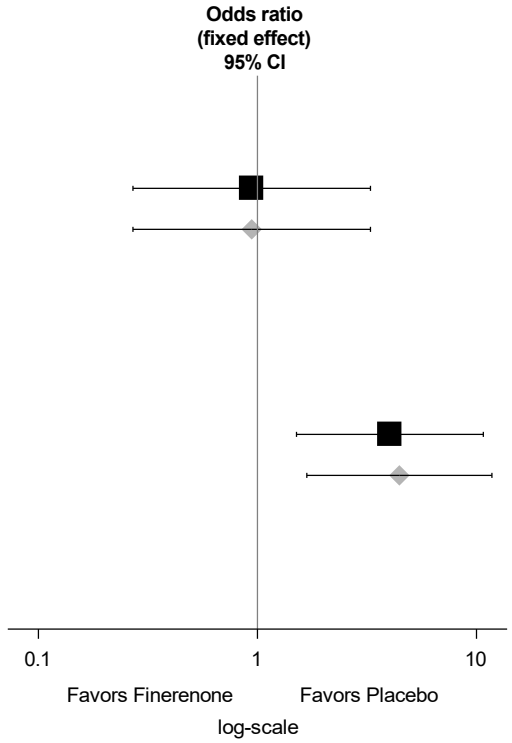
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	13 / 1416	4 / 1420	100.0	3.28 [1.07,10.08]	
Total	13 / 1514	4 / 1516		3.28 [1.07,10.08]	Z=2.07, p=0.0382
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	2 / 112	0 / 125	0.0	103E9 [103E9,103E9]	
FIGARO-DKD	12 / 910	6 / 882	100.0	1.95 [0.73,5.22]	
Total	14 / 1022	6 / 1007		2.31 [0.88,6.04]	Z=1.71, p=0.0872
Heterogeneity:	Q=0.11 (df=1)	p=0.7351	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6429	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.93.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

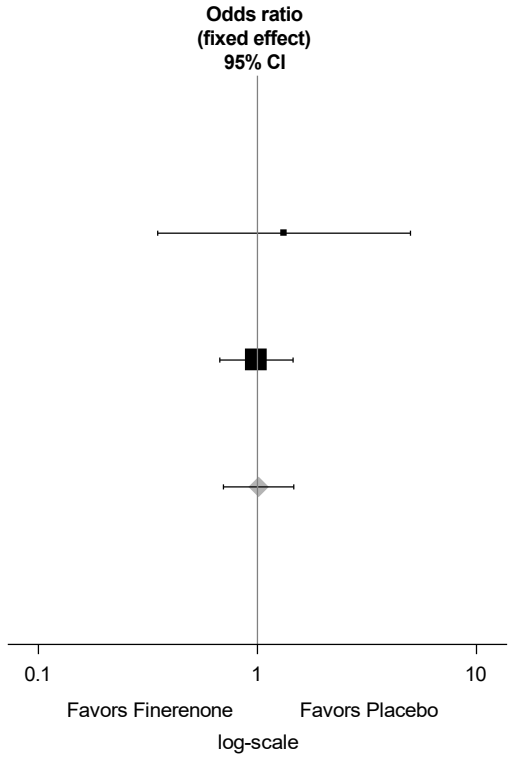
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	5 / 363	5 / 342	100.0	0.94 [0.27,3.28]	
Total	5 / 363	5 / 342		0.94 [0.27,3.28]	Z=-0.09, p=0.9244
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	0 / 221	0.0	148E9 [148E9,148E9]	
FIGARO-DKD	20 / 1963	5 / 1960	100.0	4.02 [1.51,10.75]	
Total	22 / 2173	5 / 2181		4.45 [1.68,11.76]	Z=3.01, p=0.0026
Heterogeneity:	Q=0.04 (df=1)	p=0.8426	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.70 (df=1)	p=0.0546	I^2=72.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.94: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

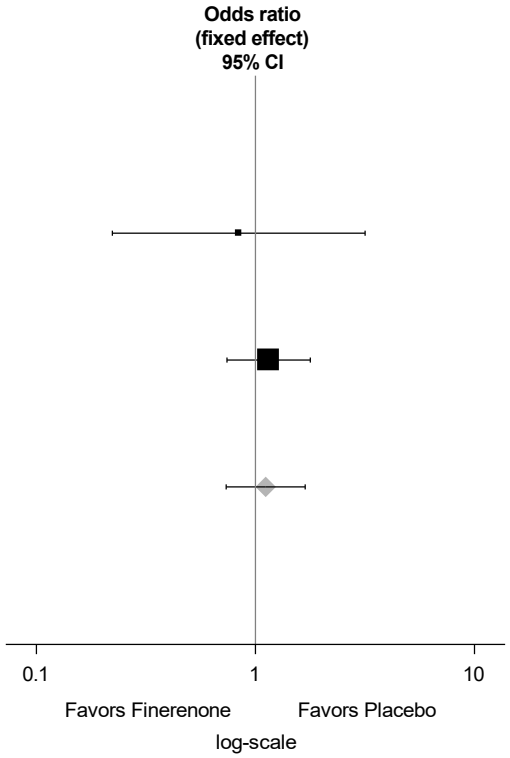
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	7.8	1.32 [0.35,5.00]	
FIGARO-DKD	53 / 2326	53 / 2302	92.2	0.99 [0.67,1.45]	
Total	58 / 2536	57 / 2523		1.01 [0.70,1.47]	Z=0.06, p=0.9489
Heterogeneity:	Q=0.17 (df=1)	p=0.6805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.95: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

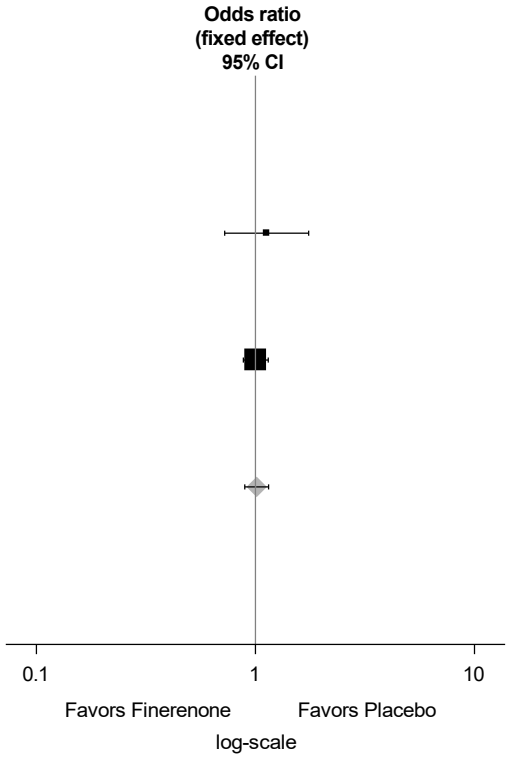
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	9.8	0.84 [0.22,3.17]	
FIGARO-DKD	44 / 2326	38 / 2302	90.2	1.15 [0.74,1.78]	
Total	48 / 2536	43 / 2523		1.11 [0.74,1.69]	Z=0.51, p=0.6114
Heterogeneity:	Q=0.19 (df=1)	p=0.6595	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.96: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

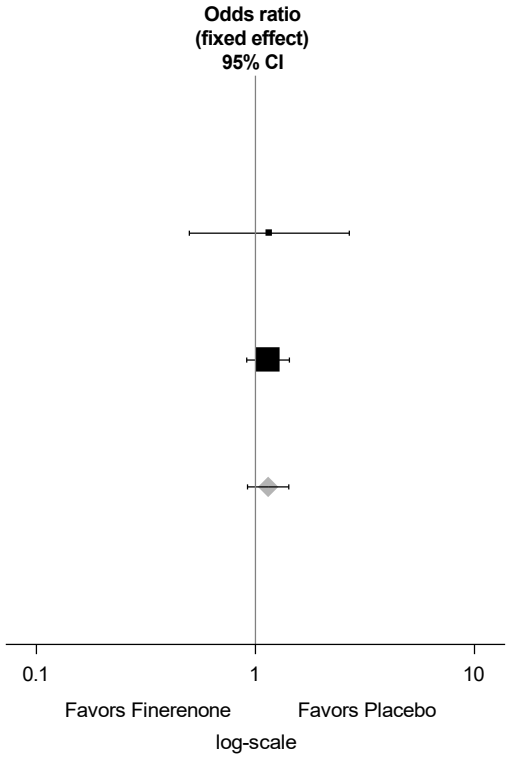
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 210	51 / 221	8.1	1.13 [0.72,1.75]	
FIGARO-DKD	615 / 2326	607 / 2302	91.9	1.00 [0.88,1.14]	
Total	668 / 2536	658 / 2523		1.01 [0.89,1.15]	Z=0.20, p=0.8399
Heterogeneity:	Q=0.24 (df=1)	p=0.6265	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.97: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

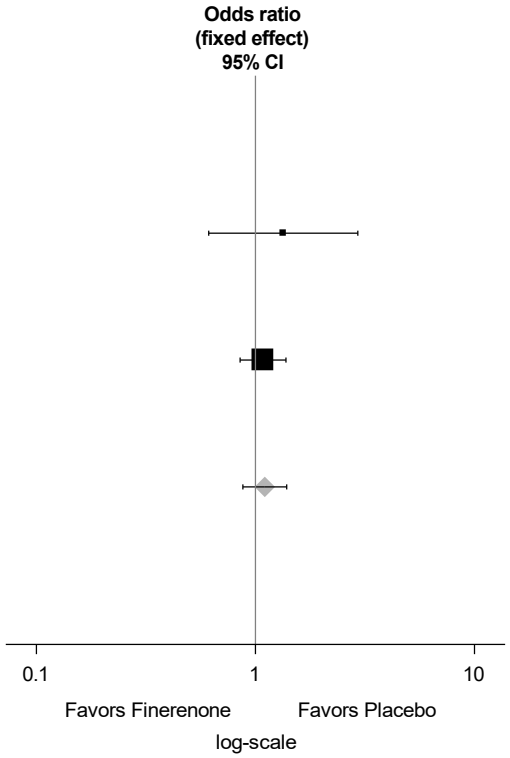
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	12 / 210	11 / 221	6.6	1.16 [0.50,2.68]	
FIGARO-DKD	176 / 2326	154 / 2302	93.4	1.14 [0.91,1.43]	
Total	188 / 2536	165 / 2523		1.14 [0.92,1.42]	Z=1.21, p=0.2275
Heterogeneity:	Q=0.00 (df=1)	p=0.9762	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.98: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

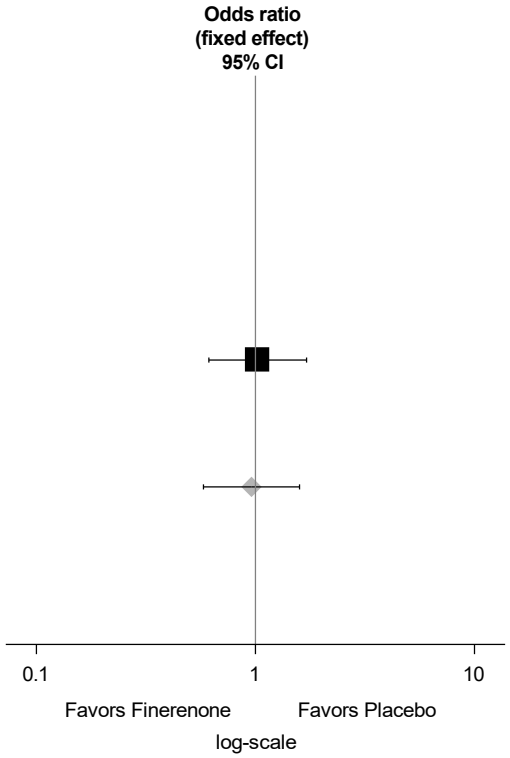
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	15 / 210	12 / 221	8.6	1.34 [0.61,2.93]	
FIGARO-DKD	147 / 2326	135 / 2302	91.4	1.08 [0.85,1.38]	
Total	162 / 2536	147 / 2523		1.10 [0.88,1.39]	Z=0.83, p=0.4037
Heterogeneity:	Q=0.26 (df=1)	p=0.6109	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.99: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

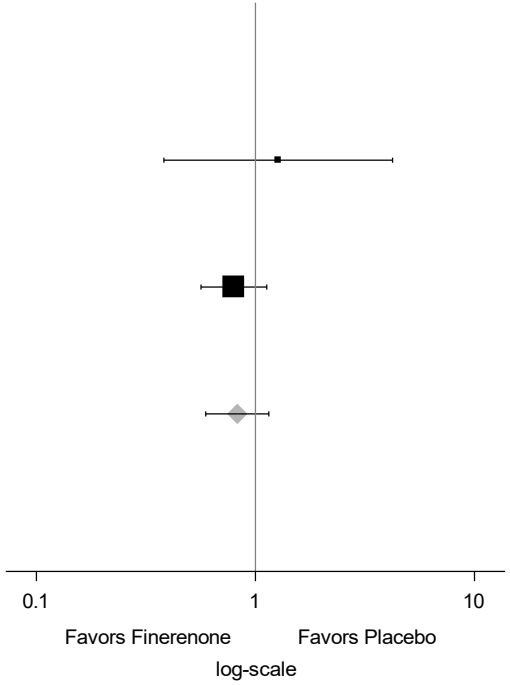
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	2 / 221	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	30 / 2326	29 / 2302	100.0	1.02 [0.61,1.71]	
Total	30 / 2536	31 / 2523		0.96 [0.58,1.59]	Z=-0.16, p=0.8716
Heterogeneity:	Q=0.06 (df=1)	p=0.8026	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.100: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

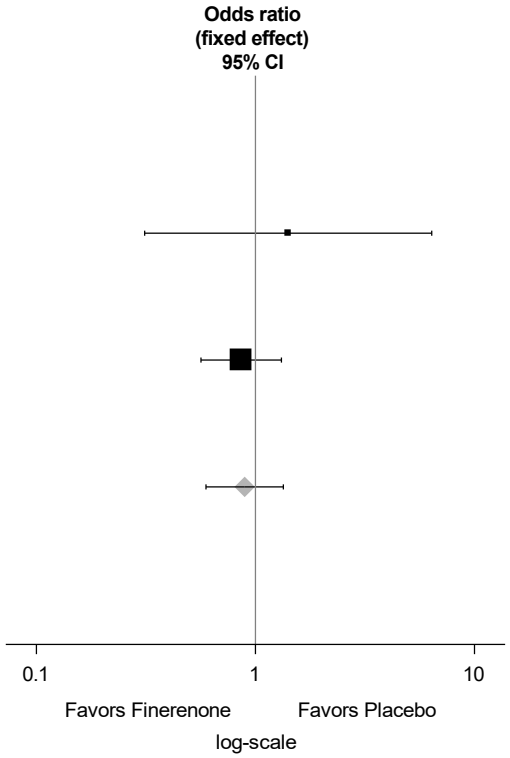
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	5 / 221	7.6	1.27 [0.38,4.23]	
FIGARO-DKD	60 / 2326	74 / 2302	92.4	0.80 [0.56,1.13]	
Total	66 / 2536	79 / 2523		0.83 [0.59,1.15]	Z=-1.13, p=0.2590
Heterogeneity:	Q=0.53 (df=1)	p=0.4652	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.101: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

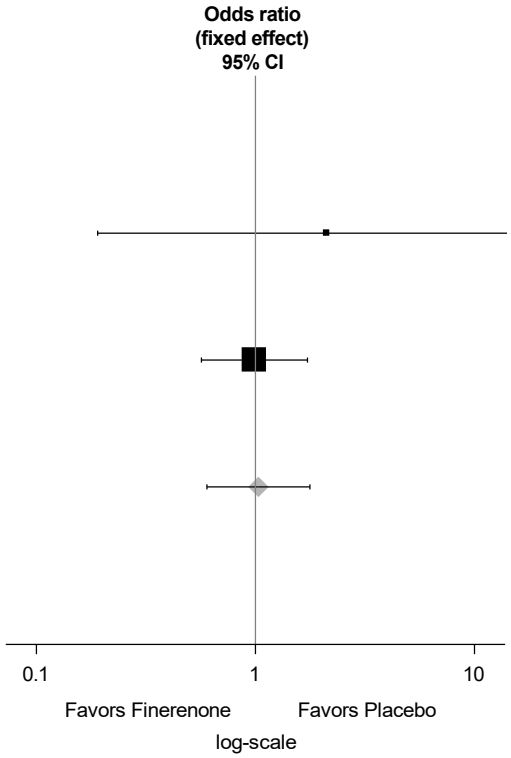
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	3 / 221	7.3	1.41 [0.31,6.38]	
FIGARO-DKD	41 / 2326	47 / 2302	92.7	0.86 [0.56,1.31]	
Total	45 / 2536	50 / 2523		0.89 [0.59,1.34]	Z=-0.55, p=0.5848
Heterogeneity:	Q=0.38 (df=1)	p=0.5366	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.102: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

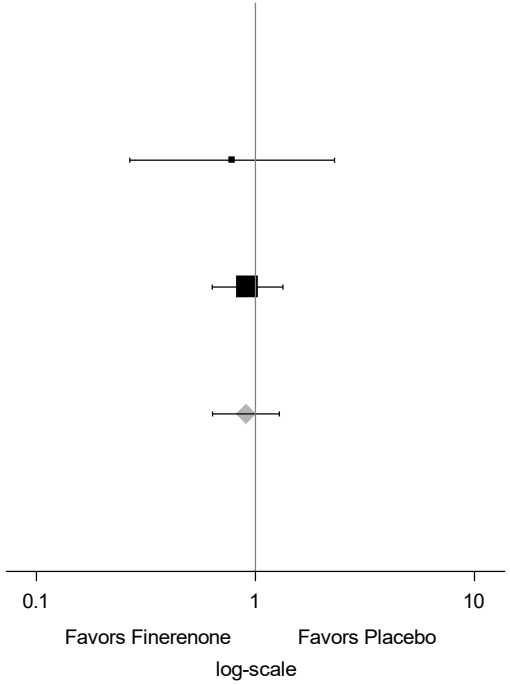
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.1	2.12 [0.19,23.50]	
FIGARO-DKD	25 / 2326	25 / 2302	94.9	0.99 [0.57,1.73]	
Total	27 / 2536	26 / 2523		1.03 [0.60,1.77]	Z=0.11, p=0.9101
Heterogeneity:	Q=0.36 (df=1)	p=0.5468	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.103: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

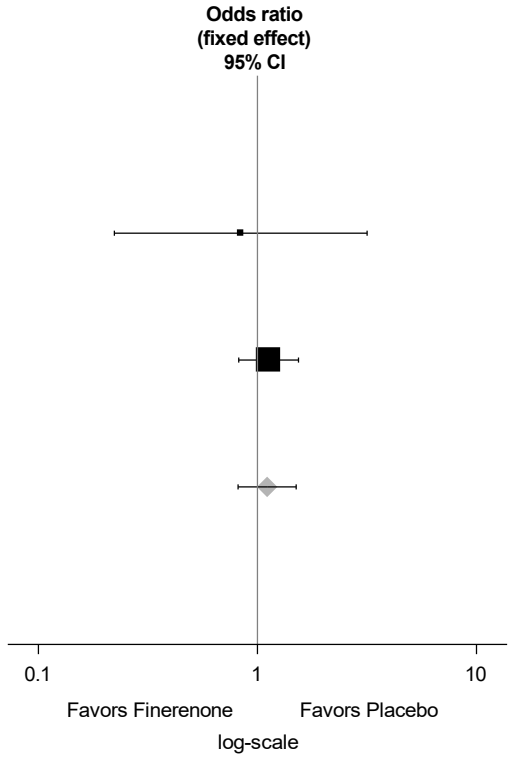
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	8 / 221	10.7	0.78 [0.27,2.30]	
FIGARO-DKD	55 / 2326	59 / 2302	89.3	0.92 [0.63,1.34]	
Total	61 / 2536	67 / 2523		0.90 [0.64,1.29]	Z=-0.56, p=0.5769
Heterogeneity:	Q=0.08 (df=1)	p=0.7804	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.104: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

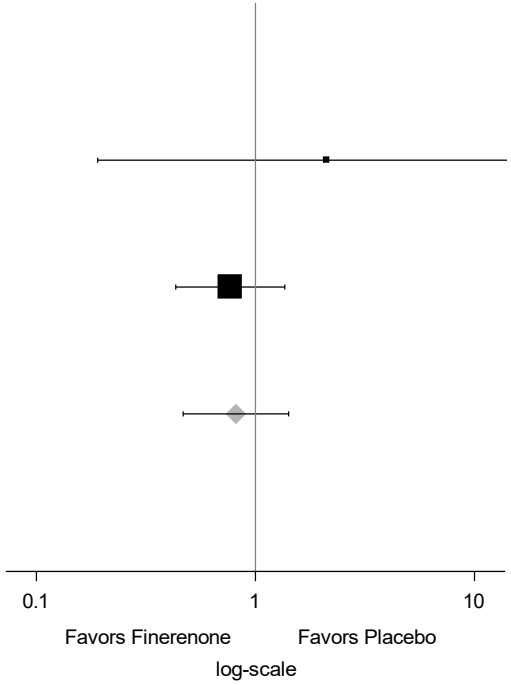
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	5 / 221	5.3	0.84 [0.22,3.17]	
FIGARO-DKD	86 / 2326	76 / 2302	94.7	1.12 [0.82,1.54]	
Total	90 / 2536	81 / 2523		1.11 [0.82,1.50]	Z=0.65, p=0.5140
Heterogeneity:	Q=0.18 (df=1)	p=0.6739	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.105: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Rotator cuff syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

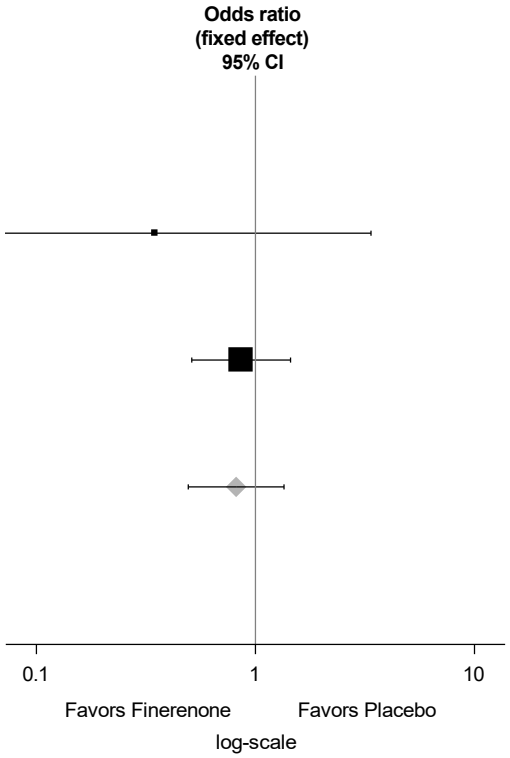
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.4	2.12 [0.19,23.50]	
FIGARO-DKD	21 / 2326	27 / 2302	94.6	0.77 [0.43,1.36]	
Total	23 / 2536	28 / 2523		0.81 [0.47,1.42]	Z=-0.73, p=0.4674
Heterogeneity:	Q=0.64 (df=1)	p=0.4221	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.106: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

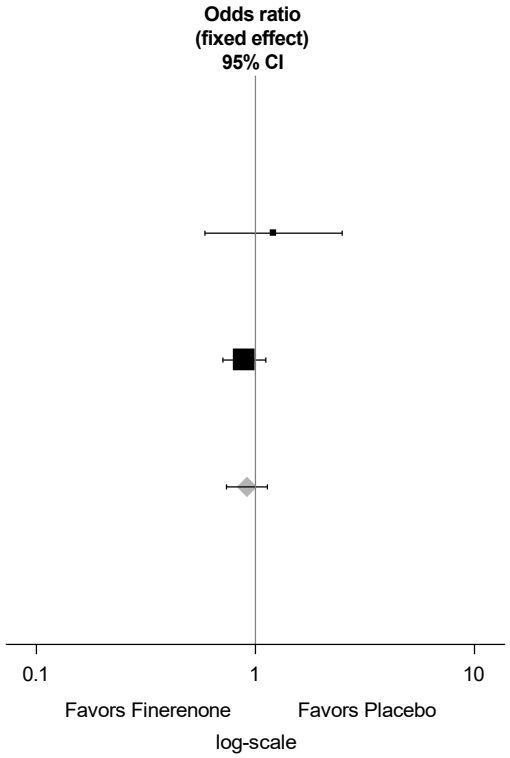
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	5.0	0.35 [0.04,3.37]	
FIGARO-DKD	27 / 2326	31 / 2302	95.0	0.86 [0.51,1.45]	
Total	28 / 2536	34 / 2523		0.82 [0.49,1.35]	Z=-0.79, p=0.4290
Heterogeneity:	Q=0.58 (df=1)	p=0.4456	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.107: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

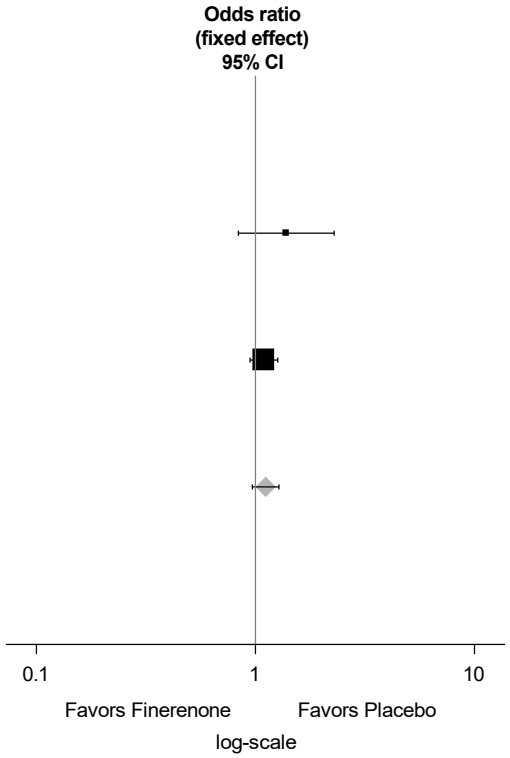
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 210	15 / 221	8.9	1.21 [0.59,2.49]	
FIGARO-DKD	155 / 2326	171 / 2302	91.1	0.89 [0.71,1.11]	
Total	172 / 2536	186 / 2523		0.91 [0.74,1.13]	Z=-0.82, p=0.4149
Heterogeneity:	Q=0.63 (df=1)	p=0.4258	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.108: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

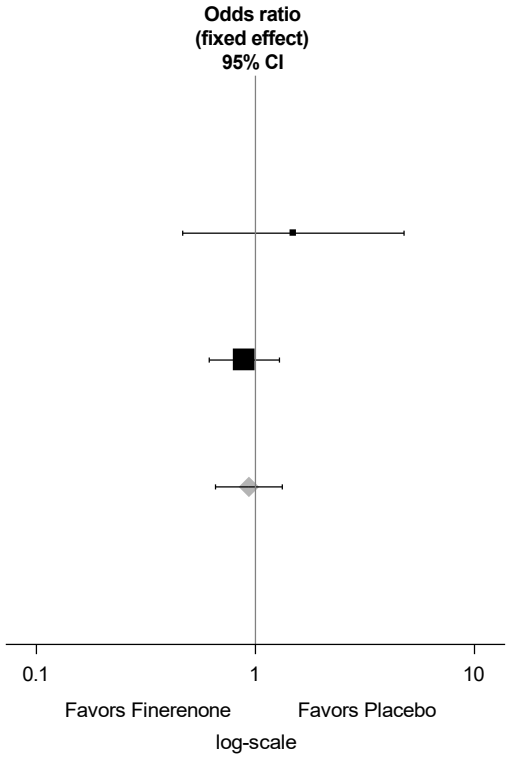
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 210	33 / 221	7.7	1.38 [0.84,2.29]	
FIGARO-DKD	470 / 2326	433 / 2302	92.3	1.09 [0.95,1.26]	
Total	511 / 2536	466 / 2523		1.11 [0.97,1.28]	Z=1.50, p=0.1328
Heterogeneity:	Q=0.77 (df=1)	p=0.3800	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.109: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

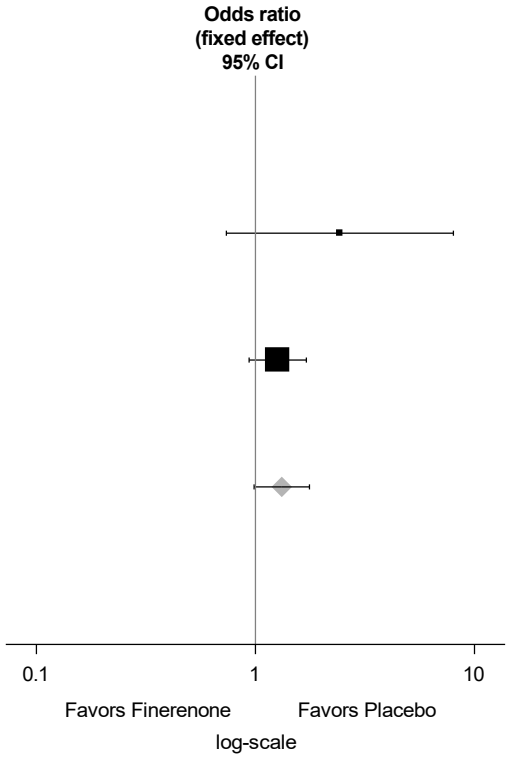
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	9.1	1.49 [0.47,4.77]	
FIGARO-DKD	55 / 2326	61 / 2302	90.9	0.89 [0.62,1.29]	
Total	62 / 2536	66 / 2523		0.93 [0.66,1.33]	Z=-0.38, p=0.7006
Heterogeneity:	Q=0.68 (df=1)	p=0.4079	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.110: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

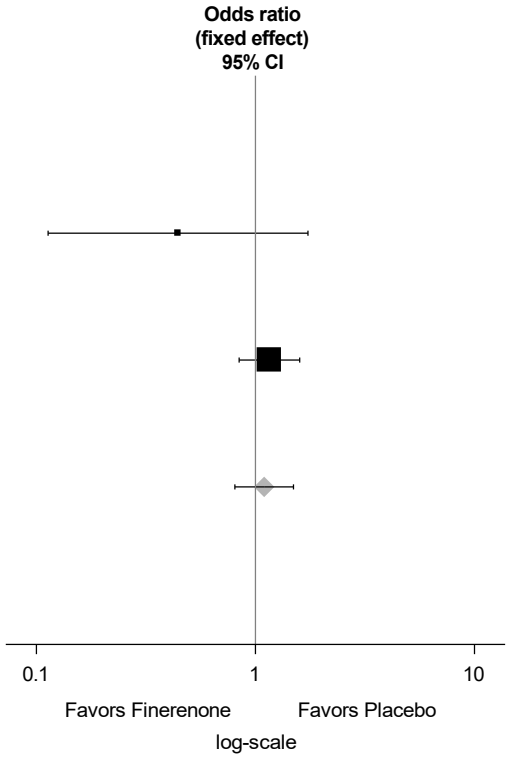
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	4 / 221	6.0	2.43 [0.74,8.01]	
FIGARO-DKD	100 / 2326	79 / 2302	94.0	1.26 [0.94,1.71]	
Total	109 / 2536	83 / 2523		1.32 [0.99,1.76]	Z=1.86, p=0.0623
Heterogeneity:	Q=1.08 (df=1)	p=0.2981	I^2=7.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.111: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

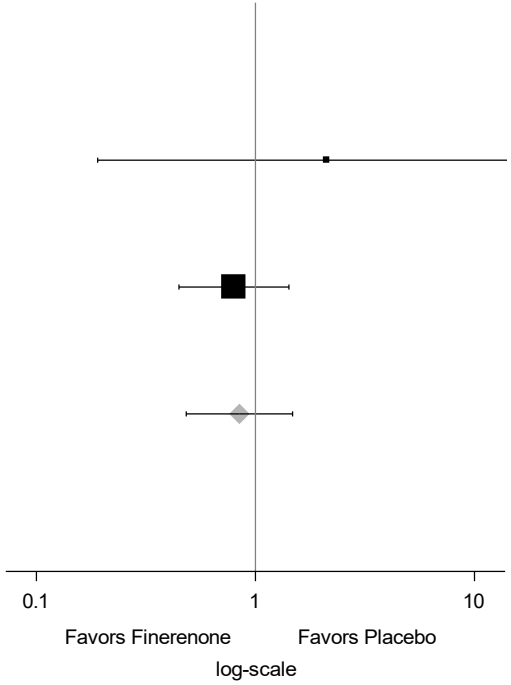
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	7 / 221	5.1	0.44 [0.11,1.74]	
FIGARO-DKD	85 / 2326	73 / 2302	94.9	1.16 [0.84,1.59]	
Total	88 / 2536	80 / 2523		1.10 [0.81,1.49]	Z=0.58, p=0.5596
Heterogeneity:	Q=1.80 (df=1)	p=0.1792	I^2=44.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.112: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

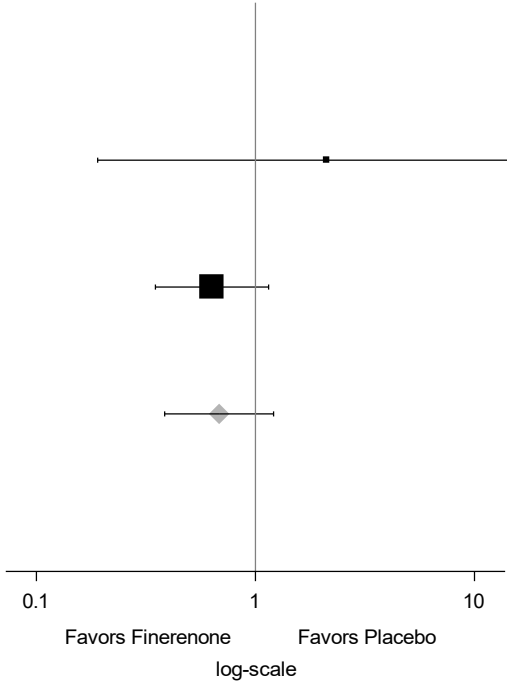
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.4	2.12 [0.19,23.50]	
FIGARO-DKD	21 / 2326	26 / 2302	94.6	0.80 [0.45,1.42]	
Total	23 / 2536	27 / 2523		0.84 [0.48,1.48]	Z=-0.59, p=0.5541
Heterogeneity:	Q=0.60 (df=1)	p=0.4400	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.113: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

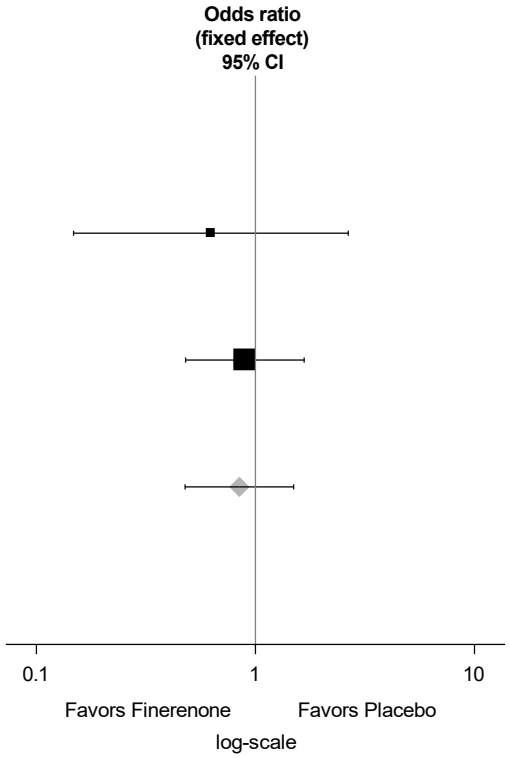
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.8	2.12 [0.19,23.50]	
FIGARO-DKD	18 / 2326	28 / 2302	94.2	0.63 [0.35,1.15]	
Total	20 / 2536	29 / 2523		0.68 [0.39,1.21]	Z=-1.31, p=0.1910
Heterogeneity:	Q=0.91 (df=1)	p=0.3405	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.114: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

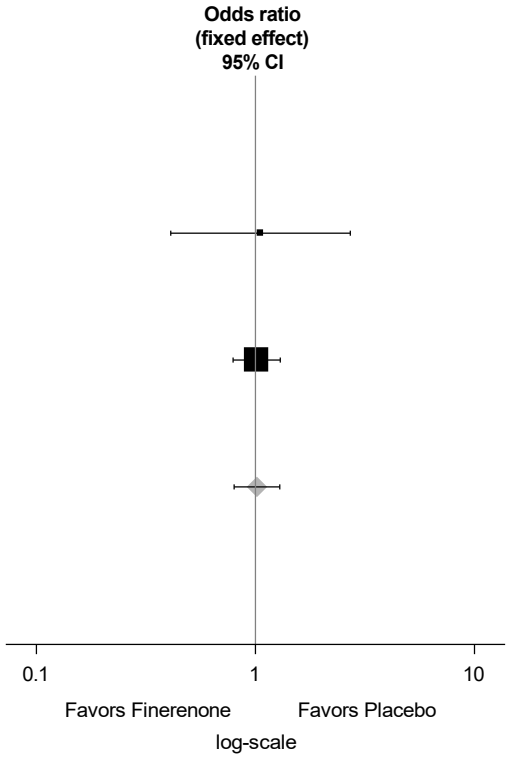
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	5 / 221	15.7	0.63 [0.15,2.65]	
FIGARO-DKD	19 / 2326	21 / 2302	84.3	0.89 [0.48,1.67]	
Total	22 / 2536	26 / 2523		0.84 [0.48,1.49]	Z=-0.58, p=0.5618
Heterogeneity:	Q=0.20 (df=1)	p=0.6565	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.115: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

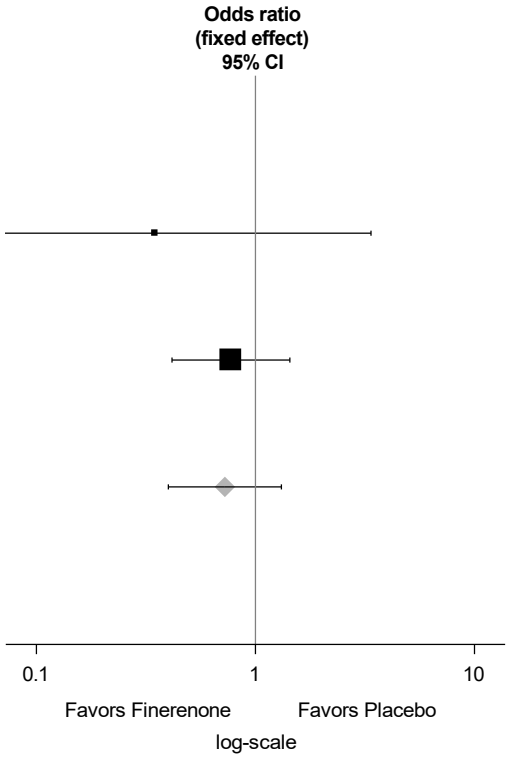
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	9 / 221	6.5	1.05 [0.41,2.71]	
FIGARO-DKD	134 / 2326	131 / 2302	93.5	1.01 [0.79,1.30]	
Total	143 / 2536	140 / 2523		1.02 [0.80,1.29]	Z=0.13, p=0.8985
Heterogeneity:	Q=0.01 (df=1)	p=0.9355	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.116: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

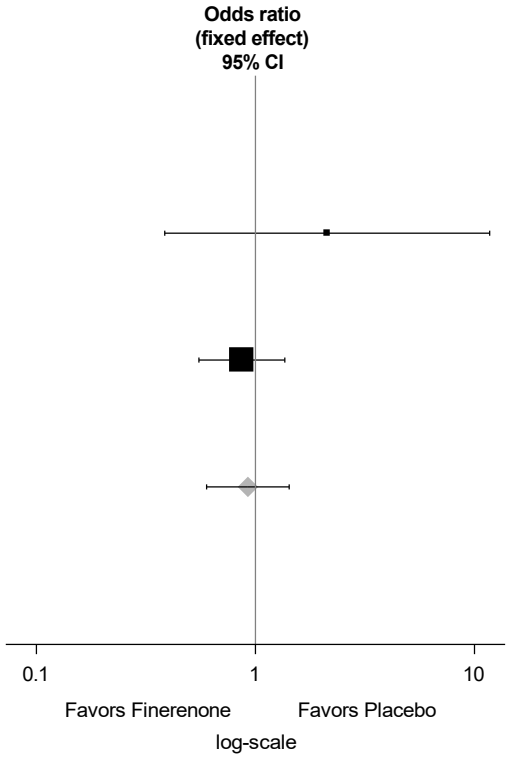
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	6.9	0.35 [0.04,3.37]	
FIGARO-DKD	18 / 2326	23 / 2302	93.1	0.77 [0.42,1.44]	
Total	19 / 2536	26 / 2523		0.73 [0.40,1.31]	Z=-1.06, p=0.2890
Heterogeneity:	Q=0.44 (df=1)	p=0.5057	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.117: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

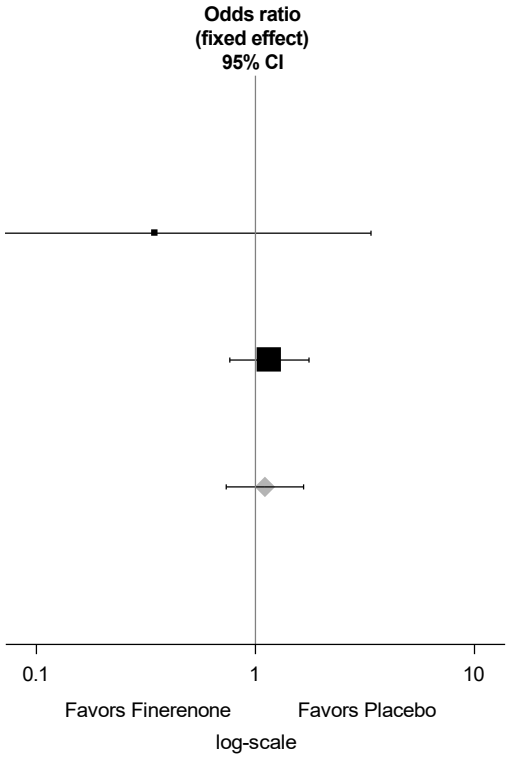
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	6.5	2.13 [0.39,11.73]	
FIGARO-DKD	36 / 2326	41 / 2302	93.5	0.87 [0.55,1.36]	
Total	40 / 2536	43 / 2523		0.92 [0.60,1.43]	Z=-0.36, p=0.7194
Heterogeneity:	Q=0.99 (df=1)	p=0.3195	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.118: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

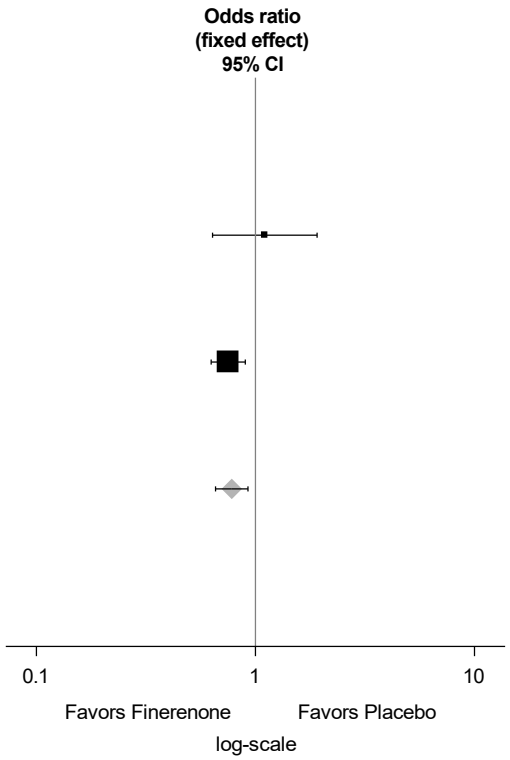
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	3.2	0.35 [0.04,3.37]	
FIGARO-DKD	49 / 2326	42 / 2302	96.8	1.16 [0.76,1.76]	
Total	50 / 2536	45 / 2523		1.10 [0.74,1.66]	Z=0.48, p=0.6316
Heterogeneity:	Q=1.04 (df=1)	p=0.3068	I^2=4.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.119: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

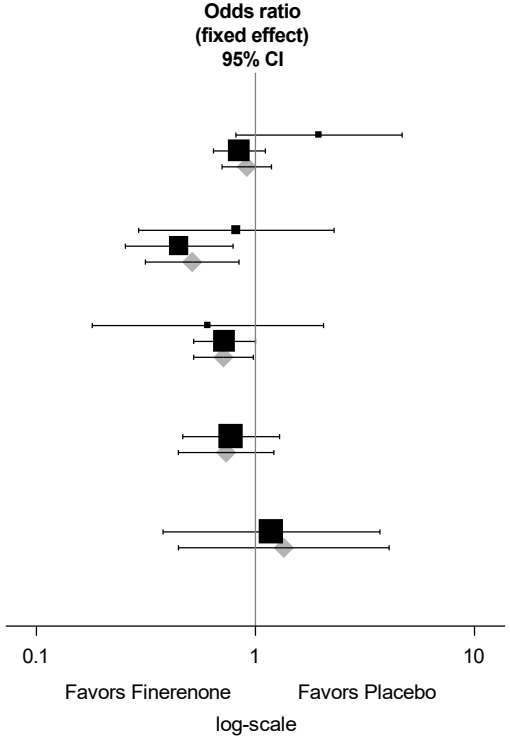
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	29 / 221	9.6	1.10 [0.64,1.91]	
FIGARO-DKD	241 / 2326	307 / 2302	90.4	0.75 [0.63,0.90]	
Total	271 / 2536	336 / 2523		0.78 [0.66,0.92]	Z=-2.87, p=0.0042
Heterogeneity:	Q=1.70 (df=1)	p=0.1922	I^2=41.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.119.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

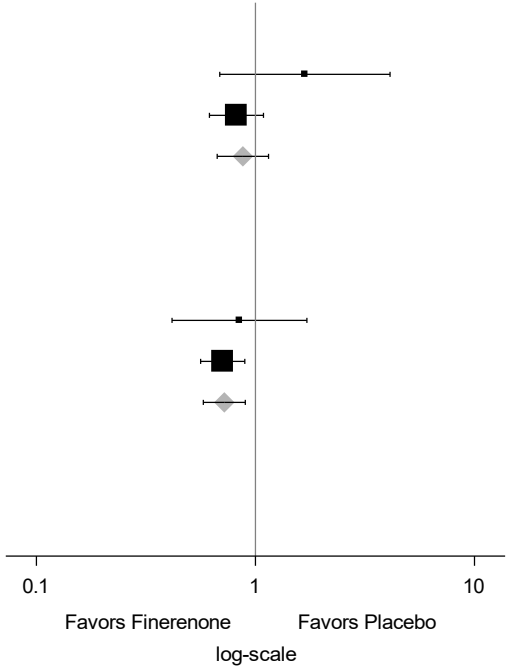
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 103	9 / 112	8.9	1.95 [0.81,4.67]	
FIGARO-DKD	107 / 1114	124 / 1110	91.1	0.84 [0.64,1.11]	
Total	122 / 1217	133 / 1222		0.91 [0.70,1.18]	Z=-0.69, p=0.4909
Heterogeneity:	Q=3.21 (df=1)	p=0.0733	I^2=68.8%		
North America					
FIDELIO-DKD	9 / 42	10 / 40	23.3	0.82 [0.29,2.29]	
FIGARO-DKD	20 / 292	39 / 277	76.7	0.45 [0.25,0.79]	
Total	29 / 334	49 / 317		0.51 [0.31,0.84]	Z=-2.65, p=0.0081
Heterogeneity:	Q=1.01 (df=1)	p=0.3155	I^2=0.7%		
Asia					
FIDELIO-DKD	5 / 39	8 / 41	6.7	0.61 [0.18,2.05]	
FIGARO-DKD	77 / 522	101 / 523	93.3	0.72 [0.52,1.00]	
Total	82 / 561	109 / 564		0.71 [0.52,0.98]	Z=-2.10, p=0.0358
Heterogeneity:	Q=0.07 (df=1)	p=0.7846	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	2 / 24	0.0	0.00 [0.00,95E295]	
FIGARO-DKD	30 / 322	37 / 316	100.0	0.77 [0.47,1.29]	
Total	30 / 343	39 / 340		0.73 [0.44,1.21]	Z=-1.20, p=0.2286
Heterogeneity:	Q=0.04 (df=1)	p=0.8374	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 5	0 / 4	0.0	192E9 [192E9,192E9]	
FIGARO-DKD	7 / 76	6 / 76	100.0	1.18 [0.38,3.70]	
Total	8 / 81	6 / 80		1.35 [0.45,4.08]	Z=0.53, p=0.5981
Heterogeneity:	Q=0.05 (df=1)	p=0.8241	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.45 (df=4)	p=0.2443	I^2=26.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.119.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

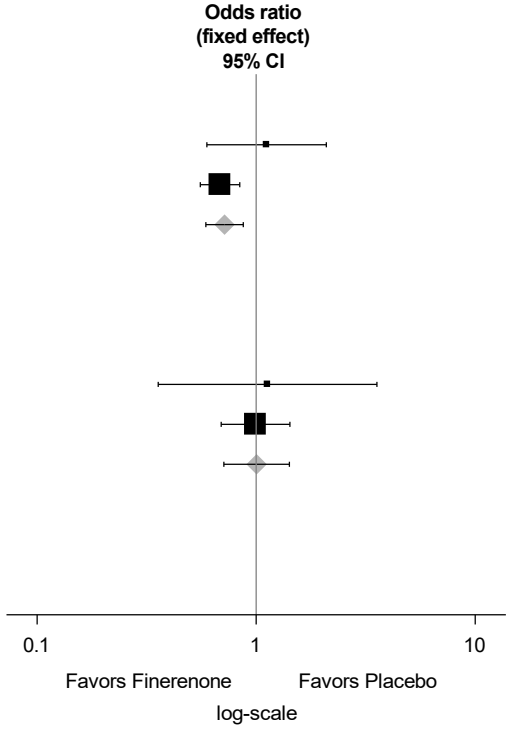
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	14 / 88	9 / 89	9.2	1.68 [0.69,4.12]	
FIGARO-DKD	102 / 811	120 / 803	90.8	0.82 [0.62,1.09]	
Total	116 / 899	129 / 892		0.88 [0.67,1.15]	Z=-0.96, p=0.3369
Heterogeneity:	Q=2.26 (df=1)	p=0.1331	I^2=55.7%		
Absent					
FIDELIO-DKD	16 / 122	20 / 132	9.7	0.85 [0.42,1.72]	
FIGARO-DKD	139 / 1515	187 / 1499	90.3	0.71 [0.56,0.89]	
Total	155 / 1637	207 / 1631		0.72 [0.58,0.90]	Z=-2.91, p=0.0036
Heterogeneity:	Q=0.21 (df=1)	p=0.6435	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.20 (df=1)	p=0.2726	I^2=16.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.119.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

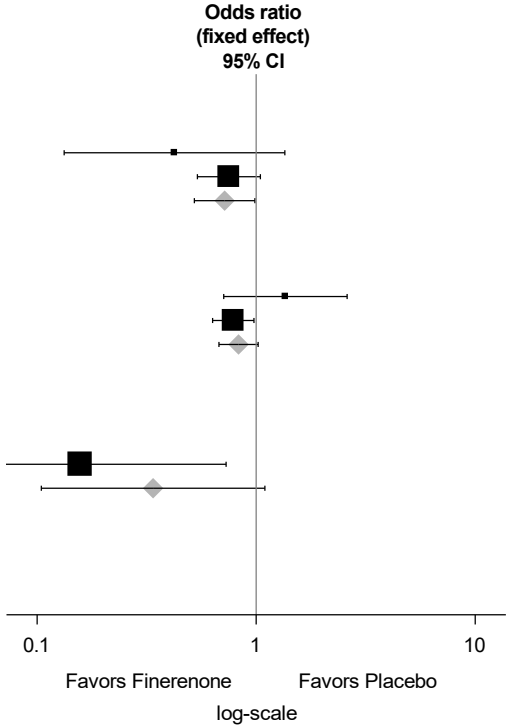
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 144	23 / 158	9.8	1.12 [0.60,2.09]	
FIGARO-DKD	176 / 1719	240 / 1679	90.2	0.68 [0.56,0.84]	
Total	199 / 1863	263 / 1837		0.72 [0.59,0.87]	Z=-3.31, p=0.0009
Heterogeneity:	Q=2.10 (df=1)	p=0.1469	I^2=52.5%		
> 4.5					
FIDELIO-DKD	7 / 66	6 / 63	9.0	1.13 [0.36,3.56]	
FIGARO-DKD	65 / 607	67 / 622	91.0	0.99 [0.69,1.43]	
Total	72 / 673	73 / 685		1.00 [0.71,1.42]	Z=0.03, p=0.9784
Heterogeneity:	Q=0.04 (df=1)	p=0.8373	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.77 (df=1)	p=0.0958	I^2=64.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.119.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

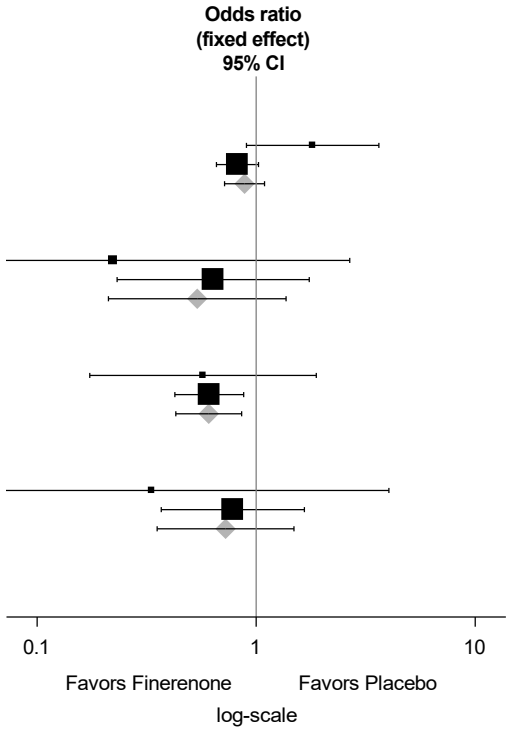
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 64	9 / 54	7.5	0.42 [0.13,1.35]	
FIGARO-DKD	70 / 693	91 / 699	92.5	0.75 [0.54,1.05]	
Total	75 / 757	100 / 753		0.72 [0.52,0.99]	Z=-2.04, p=0.0410
Heterogeneity:	Q=0.86 (df=1)	p=0.3527	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 138	20 / 156	10.1	1.36 [0.71,2.60]	
FIGARO-DKD	169 / 1560	204 / 1524	89.9	0.79 [0.63,0.98]	
Total	192 / 1698	224 / 1680		0.83 [0.68,1.02]	Z=-1.76, p=0.0776
Heterogeneity:	Q=2.47 (df=1)	p=0.1163	I^2=59.4%		
>= 160					
FIDELIO-DKD	2 / 8	0 / 11	0.0	695E9 [695E9,695E9]	
FIGARO-DKD	2 / 73	12 / 79	100.0	0.16 [0.03,0.73]	
Total	4 / 81	12 / 90		0.34 [0.10,1.10]	Z=-1.81, p=0.0707
Heterogeneity:	Q=0.96 (df=1)	p=0.3275	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.56 (df=2)	p=0.2776	I^2=22.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.119.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

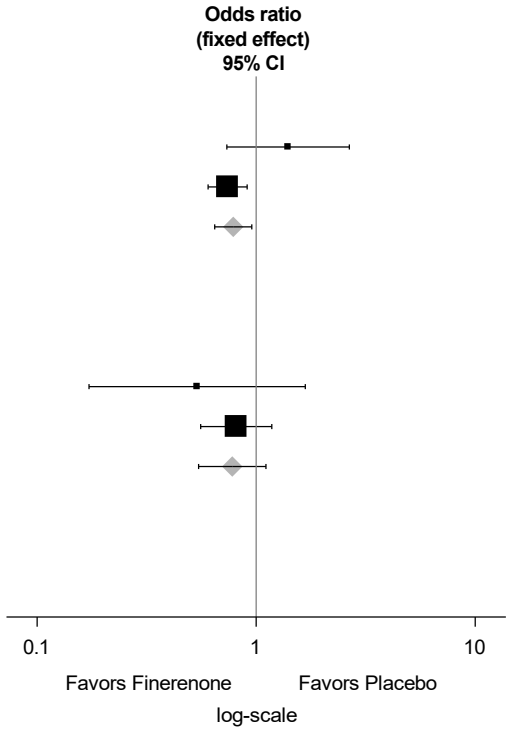
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	23 / 139	15 / 152	9.2	1.81 [0.90,3.63]	
FIGARO-DKD	164 / 1658	190 / 1612	90.8	0.82 [0.66,1.02]	
Total	187 / 1797	205 / 1764		0.89 [0.72,1.09]	Z=-1.14, p=0.2545
Heterogeneity:	Q=4.50 (df=1)	p=0.0339	I^2=77.8%		
Black					
FIDELIO-DKD	1 / 10	3 / 9	14.1	0.22 [0.02,2.67]	
FIGARO-DKD	7 / 70	11 / 74	85.9	0.64 [0.23,1.75]	
Total	8 / 80	14 / 83		0.54 [0.21,1.37]	Z=-1.30, p=0.1935
Heterogeneity:	Q=0.59 (df=1)	p=0.4419	I^2=0.0%		
Asian					
FIDELIO-DKD	5 / 39	9 / 44	8.5	0.57 [0.17,1.88]	
FIGARO-DKD	56 / 464	89 / 485	91.5	0.61 [0.43,0.88]	
Total	61 / 503	98 / 529		0.61 [0.43,0.86]	Z=-2.82, p=0.0047
Heterogeneity:	Q=0.01 (df=1)	p=0.9176	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 22	2 / 16	8.3	0.33 [0.03,4.04]	
FIGARO-DKD	14 / 134	17 / 131	91.7	0.78 [0.37,1.66]	
Total	15 / 156	19 / 147		0.72 [0.35,1.49]	Z=-0.88, p=0.3803
Heterogeneity:	Q=0.41 (df=1)	p=0.5208	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.04 (df=3)	p=0.2574	I^2=25.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.119.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

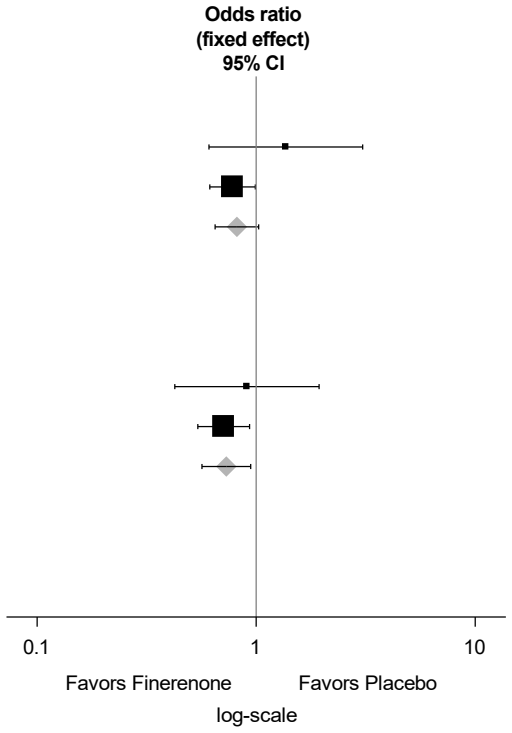
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 152	19 / 154	9.2	1.40 [0.73,2.66]	
FIGARO-DKD	184 / 1610	243 / 1638	90.8	0.74 [0.60,0.91]	
Total	209 / 1762	262 / 1792		0.79 [0.65,0.96]	Z=-2.42, p=0.0154
Heterogeneity:	Q=3.40 (df=1)	p=0.0653	I^2=70.6%		
Female					
FIDELIO-DKD	5 / 58	10 / 67	9.8	0.54 [0.17,1.68]	
FIGARO-DKD	57 / 716	64 / 664	90.2	0.81 [0.56,1.18]	
Total	62 / 774	74 / 731		0.78 [0.55,1.11]	Z=-1.39, p=0.1643
Heterogeneity:	Q=0.45 (df=1)	p=0.5011	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9603	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.119.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

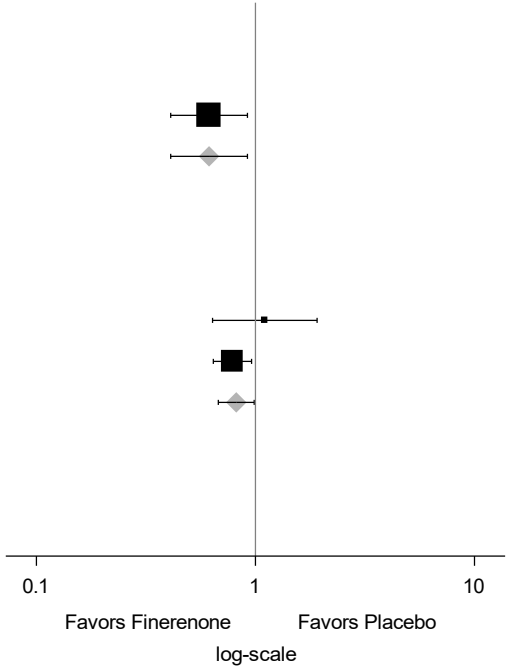
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	16 / 98	12 / 96	8.1	1.37 [0.61,3.06]	
FIGARO-DKD	135 / 1416	169 / 1420	91.9	0.78 [0.61,0.99]	
Total	151 / 1514	181 / 1516		0.82 [0.65,1.03]	Z=-1.74, p=0.0827
Heterogeneity:	Q=1.70 (df=1)	p=0.1926	I^2=41.1%		
>= 65					
FIDELIO-DKD	14 / 112	17 / 125	11.4	0.91 [0.43,1.94]	
FIGARO-DKD	106 / 910	138 / 882	88.6	0.71 [0.54,0.93]	
Total	120 / 1022	155 / 1007		0.73 [0.57,0.94]	Z=-2.40, p=0.0163
Heterogeneity:	Q=0.35 (df=1)	p=0.5522	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=1)	p=0.5261	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.119.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

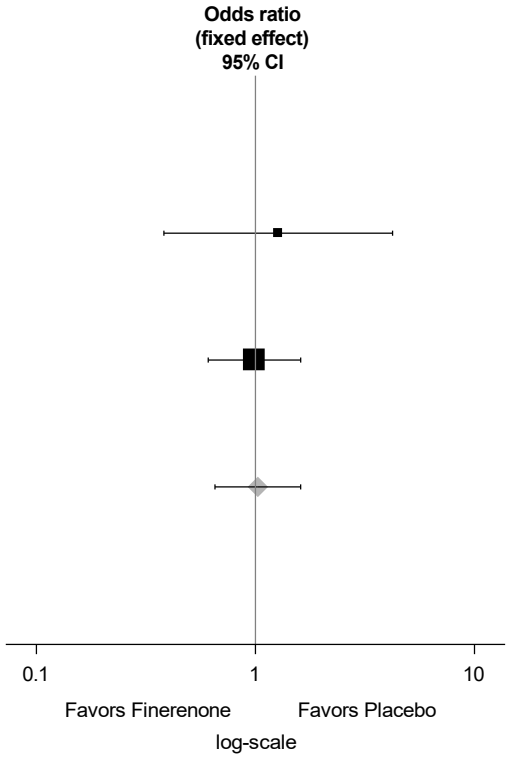
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	48 / 363	68 / 342	100.0	0.61 [0.41,0.92]	
Total	48 / 363	68 / 342		0.61 [0.41,0.92]	Z=-2.37, p=0.0178
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	30 / 210	29 / 221	11.8	1.10 [0.64,1.91]	
FIGARO-DKD	193 / 1963	239 / 1960	88.2	0.79 [0.64,0.96]	
Total	223 / 2173	268 / 2181		0.82 [0.68,0.99]	Z=-2.10, p=0.0359
Heterogeneity:	Q=1.30 (df=1)	p=0.2543	I^2=23.1%		
Subgroup Heterogeneity:	Q=1.58 (df=1)	p=0.2083	I^2=36.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.120: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

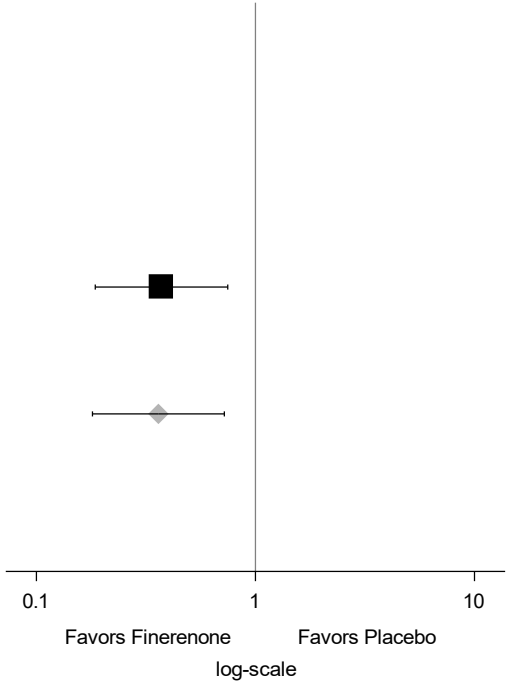
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	5 / 221	14.0	1.27 [0.38,4.23]	
FIGARO-DKD	33 / 2326	33 / 2302	86.0	0.99 [0.61,1.61]	
Total	39 / 2536	38 / 2523		1.03 [0.65,1.61]	Z=0.11, p=0.9141
Heterogeneity:	Q=0.14 (df=1)	p=0.7055	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.121: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

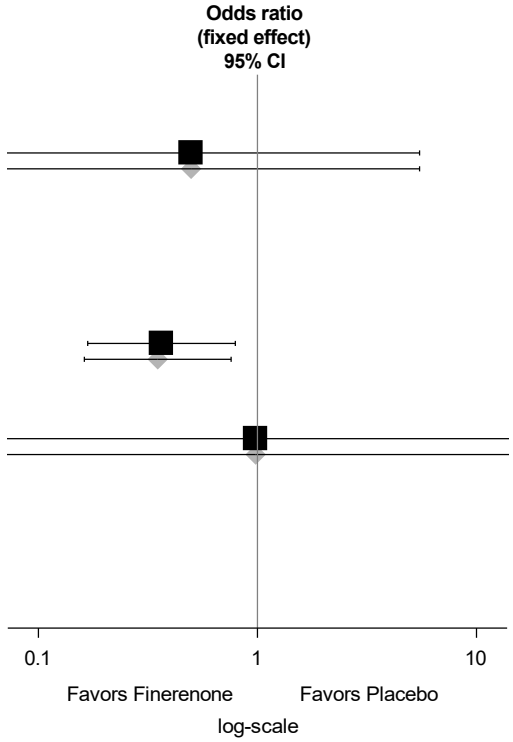
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,26E296]	
FIGARO-DKD	11 / 2326	29 / 2302	100.0	0.37 [0.19,0.75]	
Total	11 / 2536	30 / 2523		0.36 [0.18,0.72]	Z=-2.88, p=0.0039
Heterogeneity:	Q=0.01 (df=1)	p=0.9271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.121.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

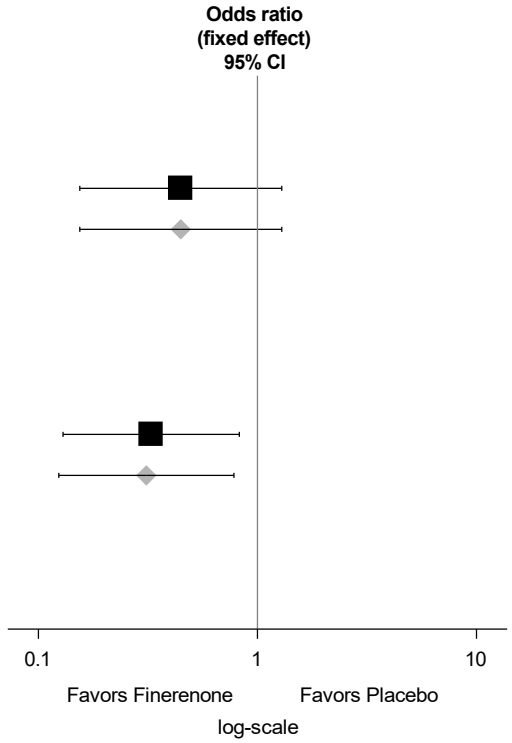
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	0 / 112	0.0	-	
FIGARO-DKD	1 / 1114	2 / 1110	100.0	0.50 [0.05,5.50]	
Total	1 / 1217	2 / 1222		0.50 [0.05,5.50]	Z=-0.57, p=0.5692
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	0 / 40	0.0	-	
FIGARO-DKD	0 / 292	1 / 277	0.0	0.00 [0.00,11E296]	
Total	0 / 334	1 / 317		0.00 [0.00,14E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	9 / 522	24 / 523	100.0	0.36 [0.17,0.79]	
Total	9 / 561	25 / 564		0.35 [0.16,0.76]	Z=-2.66, p=0.0077
Heterogeneity:	Q=0.01 (df=1)	p=0.9197	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	1 / 322	1 / 316	100.0	0.98 [0.06,15.76]	
Total	1 / 343	1 / 340		0.98 [0.06,15.76]	Z=-0.01, p=0.9894
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	1 / 76	0.0	0.00 [0.00,88E295]	
Total	0 / 81	1 / 80		0.00 [0.00,95E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.54 (df=4)	p=0.9698	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.121.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	0 / 88	0 / 89	0.0	-	
FIGARO-DKD	5 / 811	11 / 803	100.0	0.45 [0.15,1.29]	
Total	5 / 899	11 / 892		0.45 [0.15,1.29]	Z=-1.49, p=0.1368
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	1 / 132	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	6 / 1515	18 / 1499	100.0	0.33 [0.13,0.83]	
Total	6 / 1637	19 / 1631		0.31 [0.12,0.78]	Z=-2.49, p=0.0129
Heterogeneity:	Q=0.01 (df=1)	p=0.9146	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6135	I^2=0.0%		

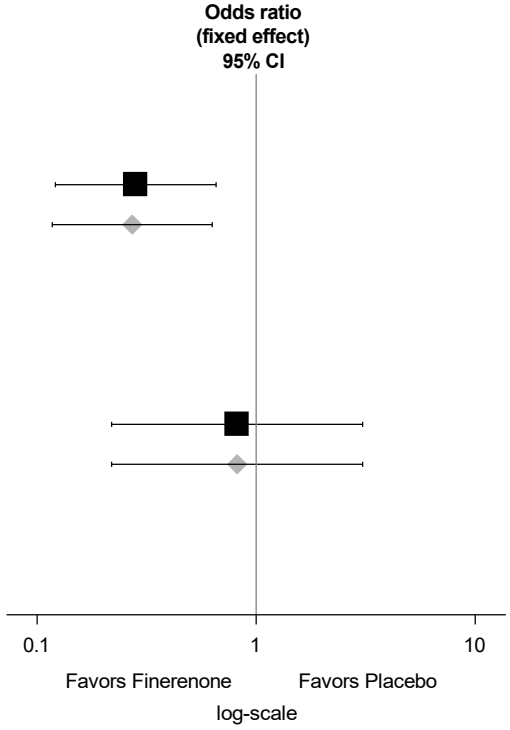


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.121.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetic nephropathy (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

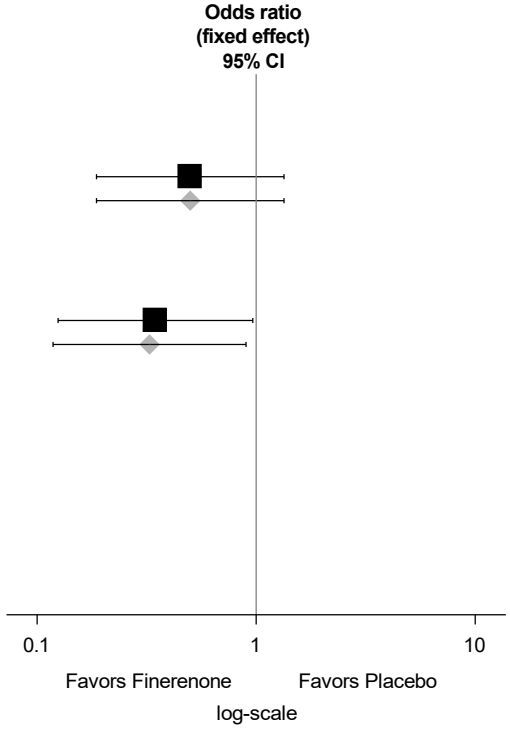
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	0 / 144	1 / 158	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	7 / 1719	24 / 1679	100.0	0.28 [0.12,0.66]	
Total	7 / 1863	25 / 1837		0.27 [0.12,0.63]	Z=-3.04, p=0.0024
Heterogeneity:	Q=0.01 (df=1)	p=0.9310	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	4 / 607	5 / 622	100.0	0.82 [0.22,3.06]	
Total	4 / 673	5 / 685		0.82 [0.22,3.06]	Z=-0.30, p=0.7662
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.91 (df=1)	p=0.1670	I^2=47.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.121.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

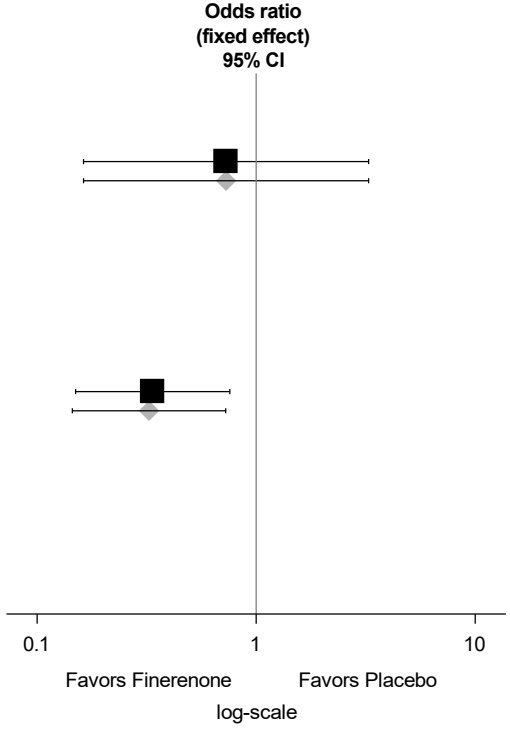
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	6 / 693	12 / 699	100.0	0.50 [0.19,1.34]	
Total	6 / 757	12 / 753		0.50 [0.19,1.34]	Z=-1.38, p=0.1681
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	0 / 138	1 / 156	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	5 / 1560	14 / 1524	100.0	0.35 [0.12,0.97]	
Total	5 / 1698	15 / 1680		0.33 [0.12,0.90]	Z=-2.17, p=0.0303
Heterogeneity:	Q=0.01 (df=1)	p=0.9053	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	3 / 79	0.0	0.00 [0.00,8E296]	
Total	0 / 81	3 / 90		0.00 [0.00,92E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.35 (df=2)	p=0.8388	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.121.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

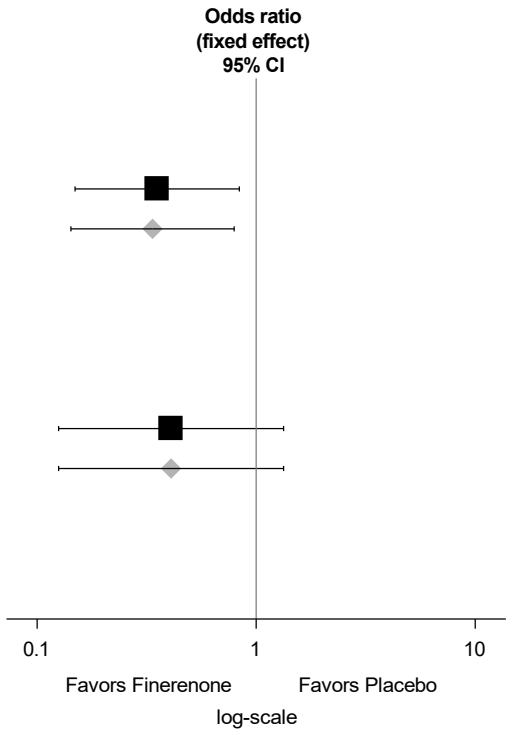
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	0 / 152	0.0	-	
FIGARO-DKD	3 / 1658	4 / 1612	100.0	0.73 [0.16,3.26]	
Total	3 / 1797	4 / 1764		0.73 [0.16,3.26]	Z=-0.41, p=0.6789
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	0 / 80	0 / 83		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	1 / 44	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	8 / 464	24 / 485	100.0	0.34 [0.15,0.76]	
Total	8 / 503	25 / 529		0.32 [0.14,0.73]	Z=-2.74, p=0.0062
Heterogeneity:	Q=0.01 (df=1)	p=0.9251	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,15E296]	
Total	0 / 156	1 / 147		0.00 [0.00,68E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.87 (df=3)	p=0.8325	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.121.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

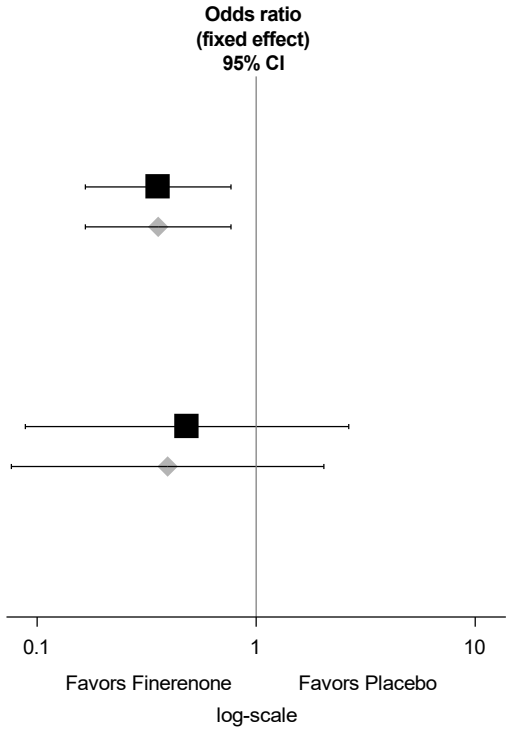
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	0 / 152	1 / 154	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	7 / 1610	20 / 1638	100.0	0.35 [0.15,0.84]	
Total	7 / 1762	21 / 1792		0.34 [0.14,0.79]	Z=-2.49, p=0.0128
Heterogeneity:	Q=0.01 (df=1)	p=0.9113	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	0 / 67	0.0	-	
FIGARO-DKD	4 / 716	9 / 664	100.0	0.41 [0.13,1.33]	
Total	4 / 774	9 / 731		0.41 [0.13,1.33]	Z=-1.48, p=0.1383
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7934	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.121.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

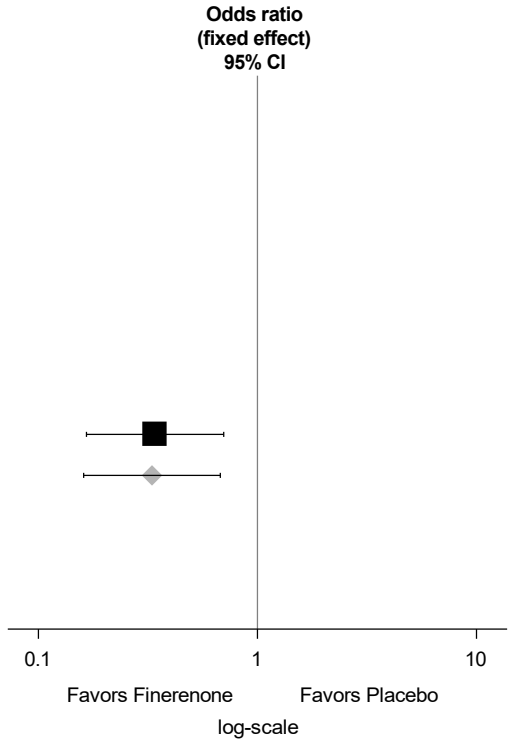
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	0 / 98	0 / 96	0.0	-	
FIGARO-DKD	9 / 1416	25 / 1420	100.0	0.36 [0.17,0.77]	
Total	9 / 1514	25 / 1516		0.36 [0.17,0.77]	Z=-2.64, p=0.0083
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	1 / 125	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	2 / 910	4 / 882	100.0	0.48 [0.09,2.65]	
Total	2 / 1022	5 / 1007		0.39 [0.08,2.04]	Z=-1.11, p=0.2666
Heterogeneity:	Q=0.06 (df=1)	p=0.8139	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9145	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.121.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

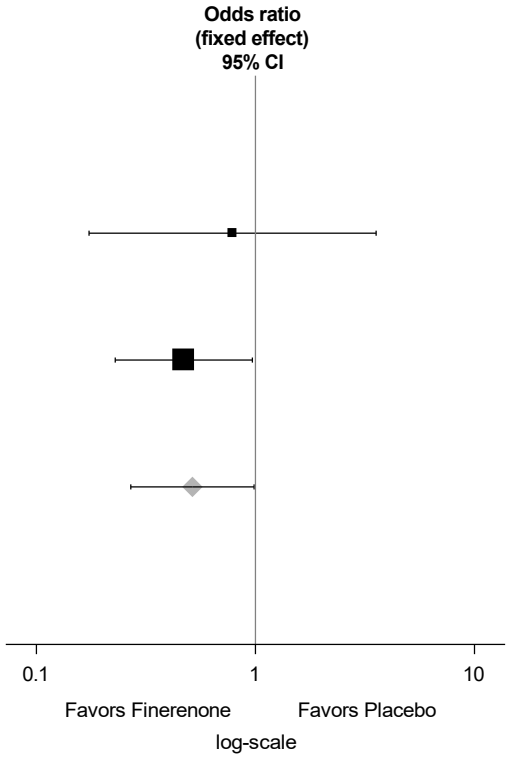
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	1 / 363	0 / 342	0.0	116E9 [116E9,116E9]	
Total	1 / 363	0 / 342		116E9 [116E9,116E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Very High					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,26E296]	
FIGARO-DKD	10 / 1963	29 / 1960	100.0	0.34 [0.17,0.70]	
Total	10 / 2173	30 / 2181		0.33 [0.16,0.68]	Z=-3.03, p=0.0025
Heterogeneity:	Q=0.01 (df=1)	p=0.9293	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.122: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

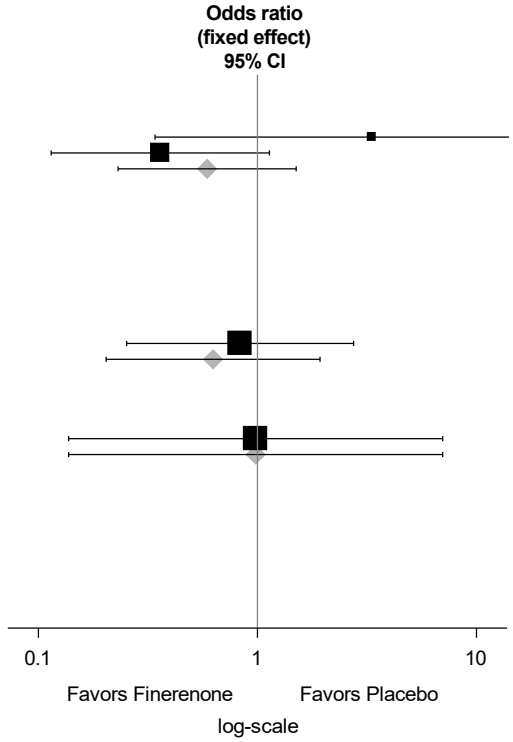
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	18.6	0.79 [0.17,3.56]	
FIGARO-DKD	11 / 2326	23 / 2302	81.4	0.47 [0.23,0.97]	
Total	14 / 2536	27 / 2523		0.52 [0.27,0.99]	Z=-2.00, p=0.0452
Heterogeneity:	Q=0.36 (df=1)	p=0.5478	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.122.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

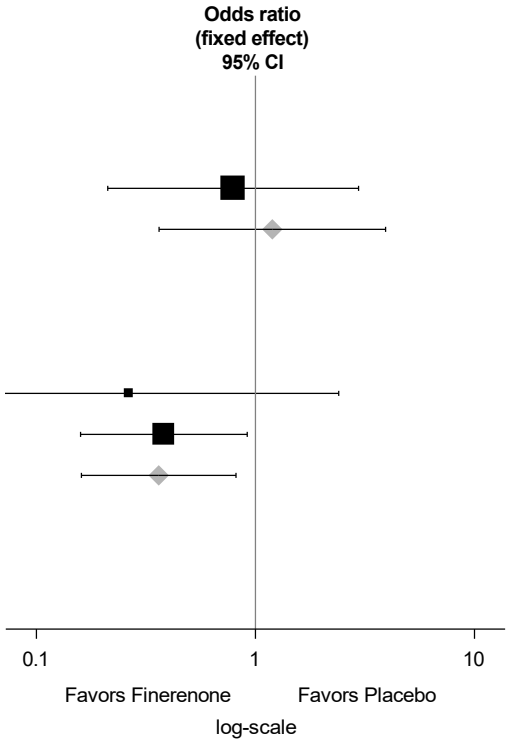
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	1 / 112	20.2	3.33 [0.34,32.53]	
FIGARO-DKD	4 / 1114	11 / 1110	79.8	0.36 [0.11,1.13]	
Total	7 / 1217	12 / 1222		0.59 [0.23,1.50]	Z=-1.11, p=0.2680
Heterogeneity:	Q=2.93 (df=1)	p=0.0872	I^2=65.8%		
North America					
FIDELIO-DKD	0 / 42	1 / 40	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	0 / 292	4 / 277	0.0	0.00 [0.00,8E296]	
Total	0 / 334	5 / 317		0.00 [0.00,73E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	0 / 39	2 / 41	0.0	0.00 [0.00,62E295]	
FIGARO-DKD	5 / 522	6 / 523	100.0	0.83 [0.25,2.75]	
Total	5 / 561	8 / 564		0.63 [0.20,1.93]	Z=-0.81, p=0.4160
Heterogeneity:	Q=0.22 (df=1)	p=0.6405	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	2 / 322	2 / 316	100.0	0.98 [0.14,7.01]	
Total	2 / 343	2 / 340		0.98 [0.14,7.01]	Z=-0.02, p=0.9849
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	0 / 76	0.0	-	
Total	0 / 81	0 / 80		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.21 (df=4)	p=0.9947	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.122.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

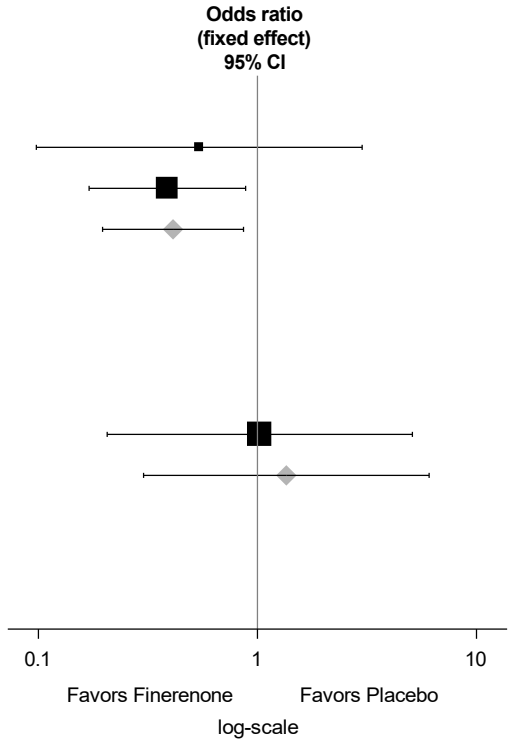
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	2 / 88	0 / 89	0.0	132E9 [132E9,132E9]	
FIGARO-DKD	4 / 811	5 / 803	100.0	0.79 [0.21,2.96]	
Total	6 / 899	5 / 892		1.19 [0.36,3.93]	Z=0.29, p=0.7702
Heterogeneity:	Q=0.37 (df=1)	p=0.5404	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	4 / 132	13.6	0.26 [0.03,2.40]	
FIGARO-DKD	7 / 1515	18 / 1499	86.4	0.38 [0.16,0.92]	
Total	8 / 1637	22 / 1631		0.36 [0.16,0.81]	Z=-2.45, p=0.0141
Heterogeneity:	Q=0.09 (df=1)	p=0.7613	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.64 (df=1)	p=0.1044	I^2=62.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.122.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

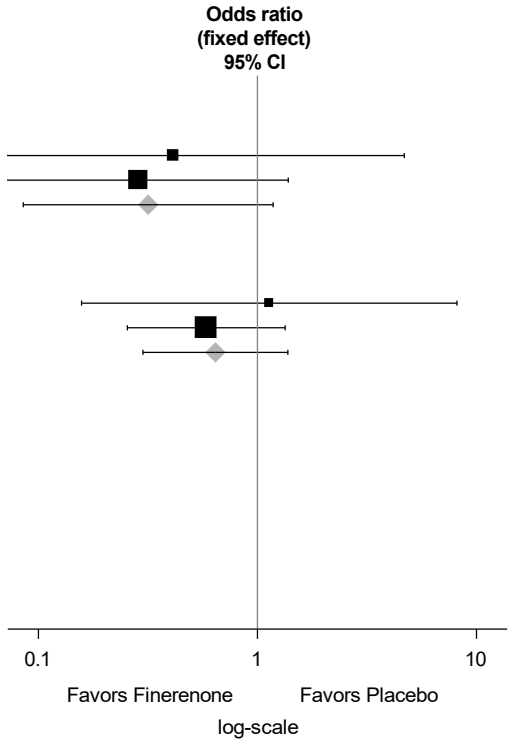
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	2 / 144	4 / 158	18.7	0.54 [0.10,3.01]	
FIGARO-DKD	8 / 1719	20 / 1679	81.3	0.39 [0.17,0.88]	
Total	10 / 1863	24 / 1837		0.41 [0.20,0.86]	Z=-2.35, p=0.0189
Heterogeneity:	Q=0.12 (df=1)	p=0.7295	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	0 / 63	0.0	872E8 [872E8,872E8]	
FIGARO-DKD	3 / 607	3 / 622	100.0	1.02 [0.21,5.10]	
Total	4 / 673	3 / 685		1.35 [0.30,6.08]	Z=0.40, p=0.6918
Heterogeneity:	Q=0.12 (df=1)	p=0.7331	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.94 (df=1)	p=0.1632	I^2=48.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.122.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

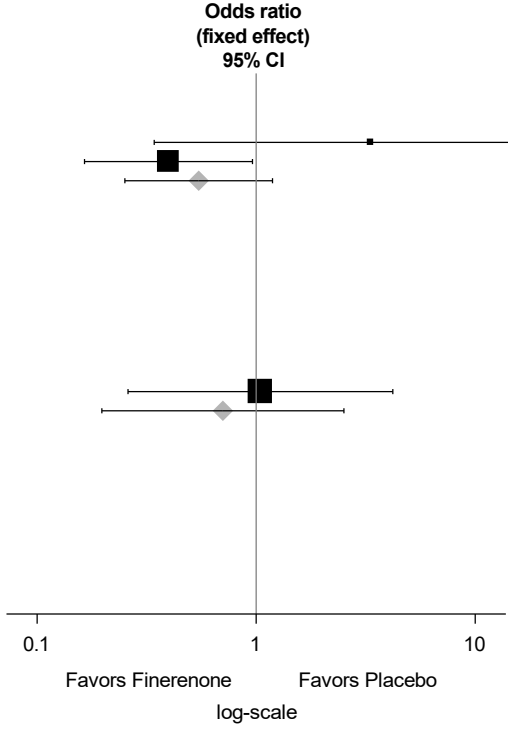
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	2 / 54	29.6	0.41 [0.04,4.68]	
FIGARO-DKD	2 / 693	7 / 699	70.4	0.29 [0.06,1.38]	
Total	3 / 757	9 / 753		0.32 [0.09,1.18]	Z=-1.71, p=0.0866
Heterogeneity:	Q=0.06 (df=1)	p=0.8040	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	2 / 156	15.0	1.13 [0.16,8.15]	
FIGARO-DKD	9 / 1560	15 / 1524	85.0	0.58 [0.25,1.34]	
Total	11 / 1698	17 / 1680		0.64 [0.30,1.38]	Z=-1.14, p=0.2556
Heterogeneity:	Q=0.37 (df=1)	p=0.5441	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	1 / 79	0.0	0.00 [0.00,91E295]	
Total	0 / 81	1 / 90		0.00 [0.00,1E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.83 (df=2)	p=0.6597	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.122.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

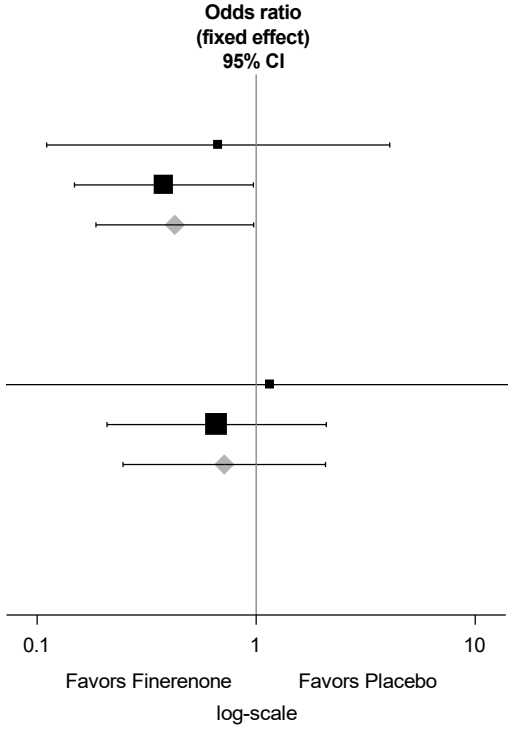
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	3 / 139	1 / 152	13.1	3.33 [0.34,32.40]	
FIGARO-DKD	7 / 1658	17 / 1612	86.9	0.40 [0.16,0.96]	
Total	10 / 1797	18 / 1764		0.55 [0.25,1.19]	Z=-1.53, p=0.1270
Heterogeneity:	Q=2.92 (df=1)	p=0.0874	I^2=65.8%		
Black					
FIDELIO-DKD	0 / 10	1 / 9	0.0	0.00 [0.00,69E295]	
FIGARO-DKD	0 / 70	1 / 74	0.0	0.00 [0.00,85E295]	
Total	0 / 80	2 / 83		0.00 [0.00,12E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	2 / 44	0.0	0.00 [0.00,67E295]	
FIGARO-DKD	4 / 464	4 / 485	100.0	1.05 [0.26,4.21]	
Total	4 / 503	6 / 529		0.70 [0.20,2.52]	Z=-0.54, p=0.5898
Heterogeneity:	Q=0.31 (df=1)	p=0.5784	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	0 / 134	1 / 131	0.0	0.00 [0.00,15E296]	
Total	0 / 156	1 / 147		0.00 [0.00,68E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.11 (df=3)	p=0.9904	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.122.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

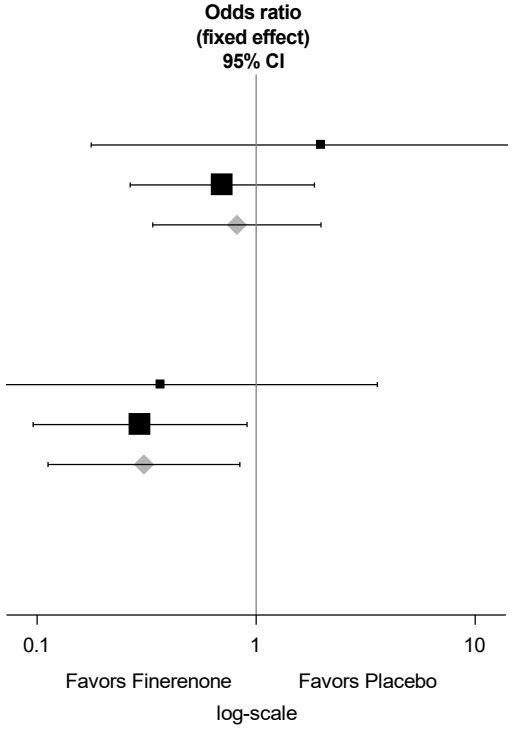
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	2 / 152	3 / 154	21.4	0.67 [0.11,4.07]	
FIGARO-DKD	6 / 1610	16 / 1638	78.6	0.38 [0.15,0.97]	
Total	8 / 1762	19 / 1792		0.43 [0.19,0.97]	Z=-2.02, p=0.0431
Heterogeneity:	Q=0.30 (df=1)	p=0.5821	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	1 / 67	14.5	1.16 [0.07,18.93]	
FIGARO-DKD	5 / 716	7 / 664	85.5	0.66 [0.21,2.09]	
Total	6 / 774	8 / 731		0.72 [0.25,2.07]	Z=-0.62, p=0.5368
Heterogeneity:	Q=0.13 (df=1)	p=0.7155	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4500	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.122.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

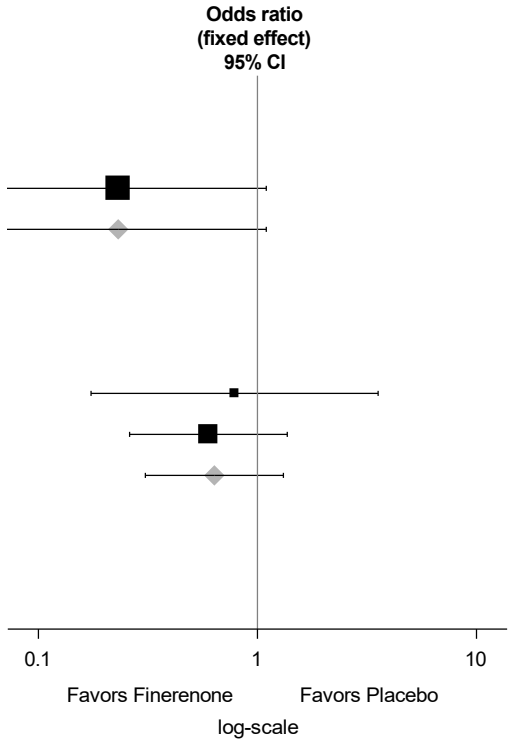
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	1 / 96	13.8	1.98 [0.18,22.19]	
FIGARO-DKD	7 / 1416	10 / 1420	86.2	0.70 [0.27,1.85]	
Total	9 / 1514	11 / 1516		0.82 [0.34,1.98]	Z=-0.45, p=0.6529
Heterogeneity:	Q=0.61 (df=1)	p=0.4342	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	3 / 125	19.6	0.37 [0.04,3.57]	
FIGARO-DKD	4 / 910	13 / 882	80.4	0.30 [0.10,0.91]	
Total	5 / 1022	16 / 1007		0.31 [0.11,0.84]	Z=-2.29, p=0.0218
Heterogeneity:	Q=0.03 (df=1)	p=0.8675	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.04 (df=1)	p=0.1534	I^2=50.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.122.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Dysuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

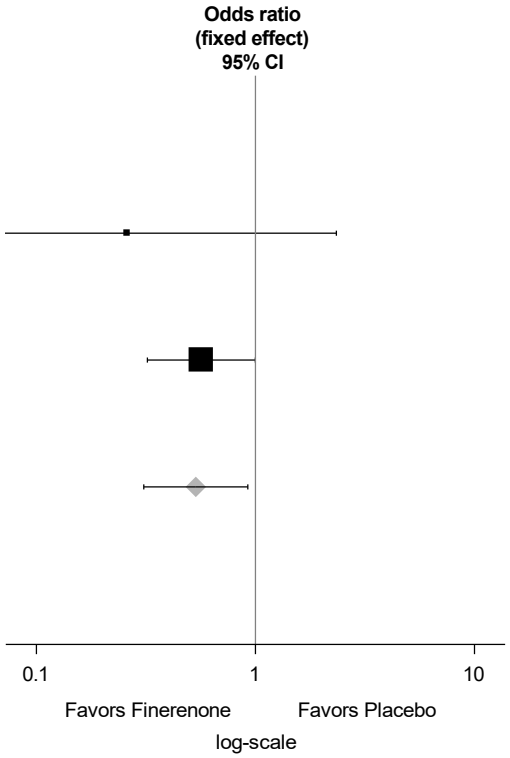
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	2 / 363	8 / 342	100.0	0.23 [0.05,1.10]	
Total	2 / 363	8 / 342		0.23 [0.05,1.10]	Z=-1.84, p=0.0653
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	3 / 210	4 / 221	23.2	0.79 [0.17,3.56]	
FIGARO-DKD	9 / 1963	15 / 1960	76.8	0.60 [0.26,1.37]	
Total	12 / 2173	19 / 2181		0.64 [0.31,1.31]	Z=-1.22, p=0.2211
Heterogeneity:	Q=0.10 (df=1)	p=0.7543	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2486	I^2=24.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.123: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

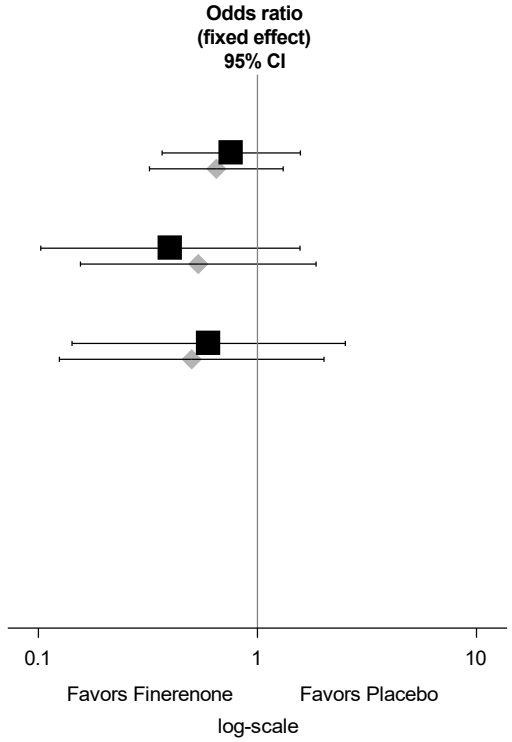
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	6.2	0.26 [0.03,2.34]	
FIGARO-DKD	19 / 2326	33 / 2302	93.8	0.57 [0.32,1.00]	
Total	20 / 2536	37 / 2523		0.53 [0.31,0.92]	Z=-2.25, p=0.0246
Heterogeneity:	Q=0.45 (df=1)	p=0.5003	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.123.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

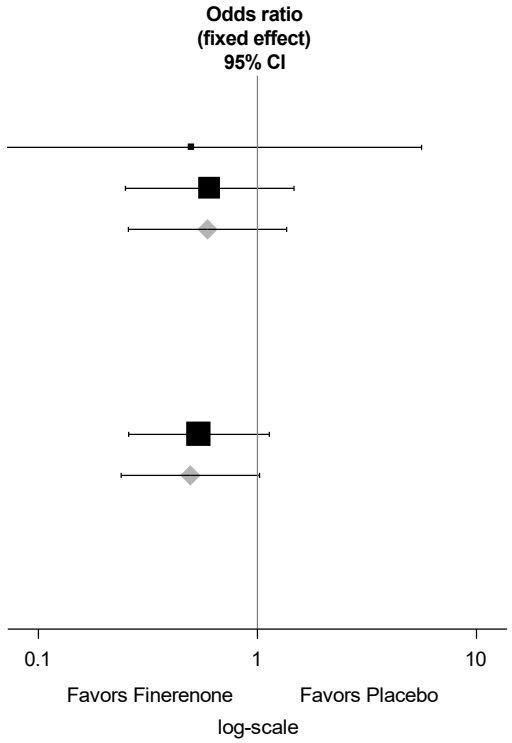
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	0 / 103	3 / 112	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	13 / 1114	17 / 1110	100.0	0.76 [0.37,1.57]	
Total	13 / 1217	20 / 1222		0.65 [0.32,1.31]	Z=-1.21, p=0.2281
Heterogeneity:	Q=0.18 (df=1)	p=0.6727	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 42	0 / 40	0.0	138E9 [138E9,138E9]	
FIGARO-DKD	3 / 292	7 / 277	100.0	0.40 [0.10,1.56]	
Total	4 / 334	7 / 317		0.54 [0.16,1.85]	Z=-0.99, p=0.3246
Heterogeneity:	Q=0.18 (df=1)	p=0.6735	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	1 / 41	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	3 / 522	5 / 523	100.0	0.60 [0.14,2.52]	
Total	3 / 561	6 / 564		0.50 [0.12,2.01]	Z=-0.97, p=0.3300
Heterogeneity:	Q=0.06 (df=1)	p=0.8075	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	0 / 322	2 / 316	0.0	0.00 [0.00,18E296]	
Total	0 / 343	2 / 340		0.00 [0.00,2E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	0 / 76	2 / 76	0.0	0.00 [0.00,11E296]	
Total	0 / 81	2 / 80		0.00 [0.00,12E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.14 (df=4)	p=0.9975	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.123.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

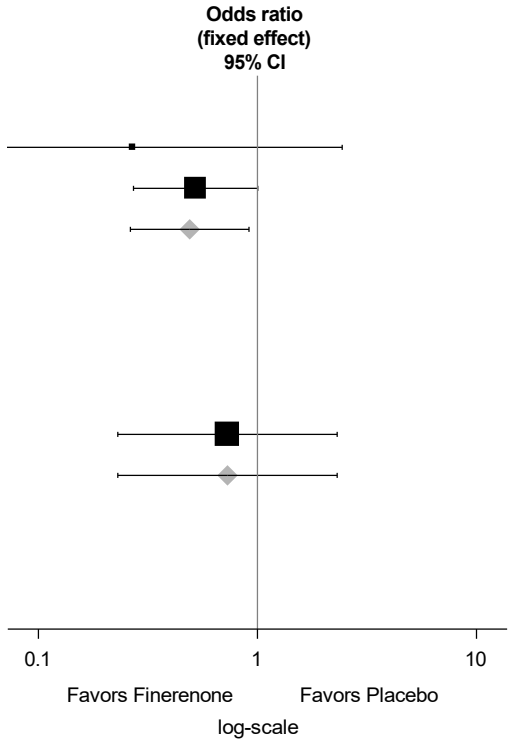
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	11.8	0.50 [0.04,5.62]	
FIGARO-DKD	8 / 811	13 / 803	88.2	0.61 [0.25,1.47]	
Total	9 / 899	15 / 892		0.59 [0.26,1.36]	Z=-1.24, p=0.2160
Heterogeneity:	Q=0.02 (df=1)	p=0.8843	I^2=0.0%		
Absent					
FIDELIO-DKD	0 / 122	2 / 132	0.0	0.00 [0.00,21E296]	
FIGARO-DKD	11 / 1515	20 / 1499	100.0	0.54 [0.26,1.13]	
Total	11 / 1637	22 / 1631		0.49 [0.24,1.02]	Z=-1.90, p=0.0573
Heterogeneity:	Q=0.06 (df=1)	p=0.8099	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7491	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.123.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

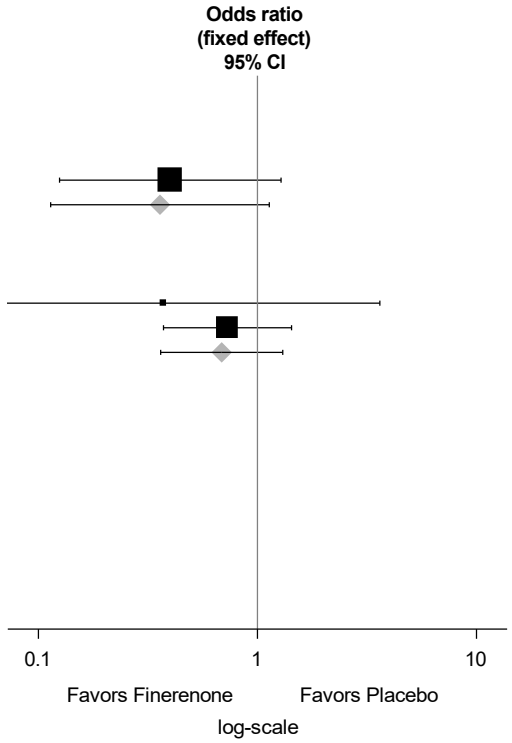
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	4 / 158	8.1	0.27 [0.03,2.44]	
FIGARO-DKD	14 / 1719	26 / 1679	91.9	0.52 [0.27,1.00]	
Total	15 / 1863	30 / 1837		0.49 [0.26,0.91]	Z=-2.24, p=0.0251
Heterogeneity:	Q=0.32 (df=1)	p=0.5717	I^2=0.0%		
> 4.5					
FIDELIO-DKD	0 / 66	0 / 63	0.0	-	
FIGARO-DKD	5 / 607	7 / 622	100.0	0.73 [0.23,2.31]	
Total	5 / 673	7 / 685		0.73 [0.23,2.31]	Z=-0.54, p=0.5922
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5525	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.123.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

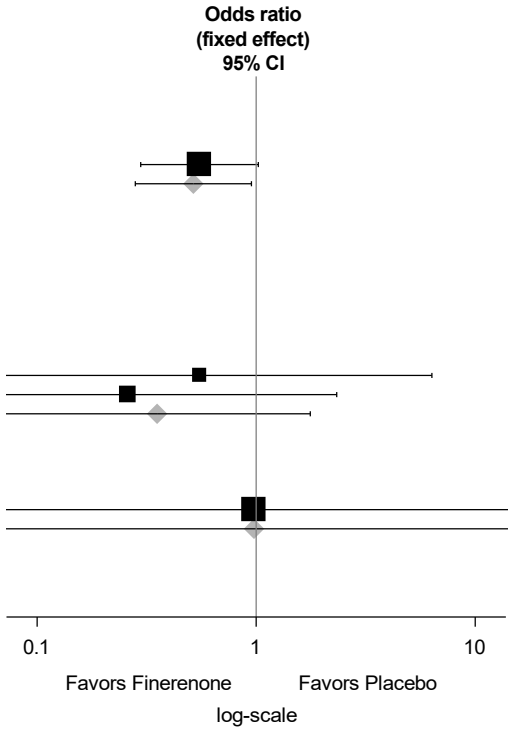
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	1 / 54	0.0	0.00 [0.00,62E295]	
FIGARO-DKD	4 / 693	10 / 699	100.0	0.40 [0.12,1.28]	
Total	4 / 757	11 / 753		0.36 [0.11,1.13]	Z=-1.75, p=0.0805
Heterogeneity:	Q=0.03 (df=1)	p=0.8551	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	1 / 138	3 / 156	8.1	0.37 [0.04,3.62]	
FIGARO-DKD	15 / 1560	20 / 1524	91.9	0.73 [0.37,1.43]	
Total	16 / 1698	23 / 1680		0.69 [0.36,1.30]	Z=-1.15, p=0.2511
Heterogeneity:	Q=0.31 (df=1)	p=0.5776	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	0 / 73	3 / 79	0.0	0.00 [0.00,8E296]	
Total	0 / 81	3 / 90		0.00 [0.00,92E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.93 (df=2)	p=0.6269	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.123.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

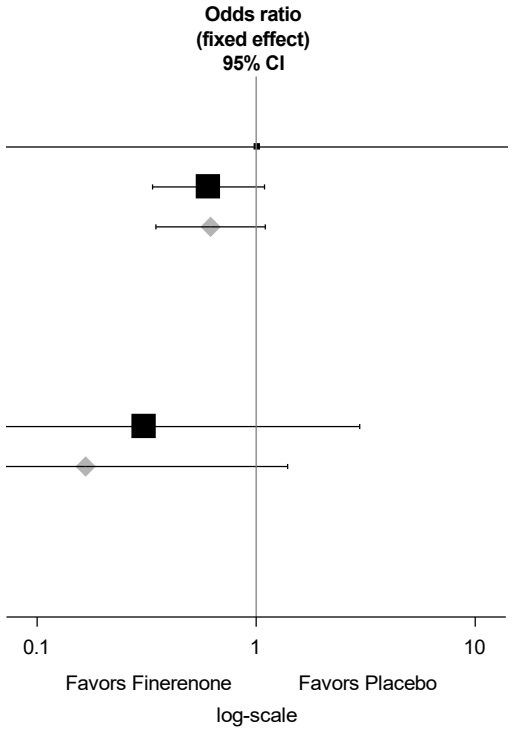
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	0 / 139	2 / 152	0.0	0.00 [0.00,88E295]	
FIGARO-DKD	16 / 1658	28 / 1612	100.0	0.55 [0.30,1.02]	
Total	16 / 1797	30 / 1764		0.52 [0.28,0.95]	Z=-2.12, p=0.0340
Heterogeneity:	Q=0.04 (df=1)	p=0.8377	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	0 / 74	0.0	223E9 [223E9,223E9]	
Total	1 / 80	0 / 83		192E9 [192E9,192E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	1 / 39	2 / 44	44.7	0.55 [0.05,6.34]	
FIGARO-DKD	1 / 464	4 / 485	55.3	0.26 [0.03,2.33]	
Total	2 / 503	6 / 529		0.35 [0.07,1.77]	Z=-1.27, p=0.2049
Heterogeneity:	Q=0.20 (df=1)	p=0.6509	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	1 / 134	1 / 131	100.0	0.98 [0.06,15.79]	
Total	1 / 156	1 / 147		0.98 [0.06,15.79]	Z=-0.02, p=0.9872
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=3)	p=0.9377	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.123.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

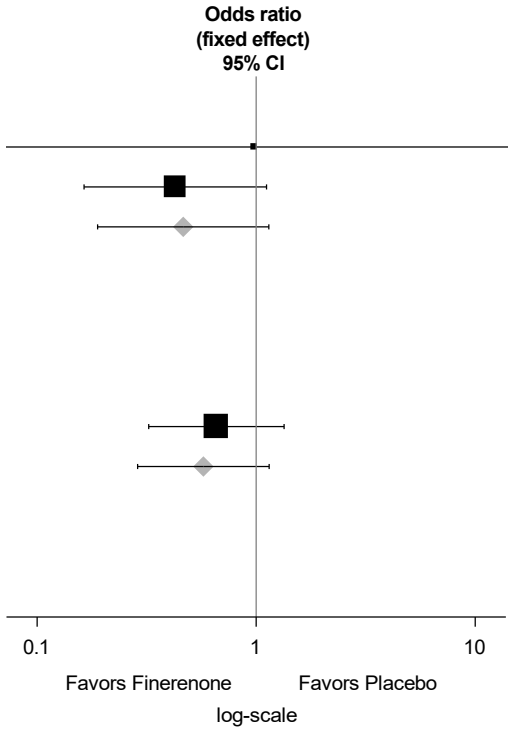
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1 / 152	1 / 154	4.3	1.01 [0.06,16.35]	
FIGARO-DKD	18 / 1610	30 / 1638	95.7	0.61 [0.34,1.09]	
Total	19 / 1762	31 / 1792		0.62 [0.35,1.10]	Z=-1.63, p=0.1023
Heterogeneity:	Q=0.13 (df=1)	p=0.7230	I^2=0.0%		
Female					
FIDELIO-DKD	0 / 58	3 / 67	0.0	0.00 [0.00,68E295]	
FIGARO-DKD	1 / 716	3 / 664	100.0	0.31 [0.03,2.97]	
Total	1 / 774	6 / 731		0.17 [0.02,1.39]	Z=-1.65, p=0.0980
Heterogeneity:	Q=0.28 (df=1)	p=0.5943	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2420	I^2=27.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.123.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

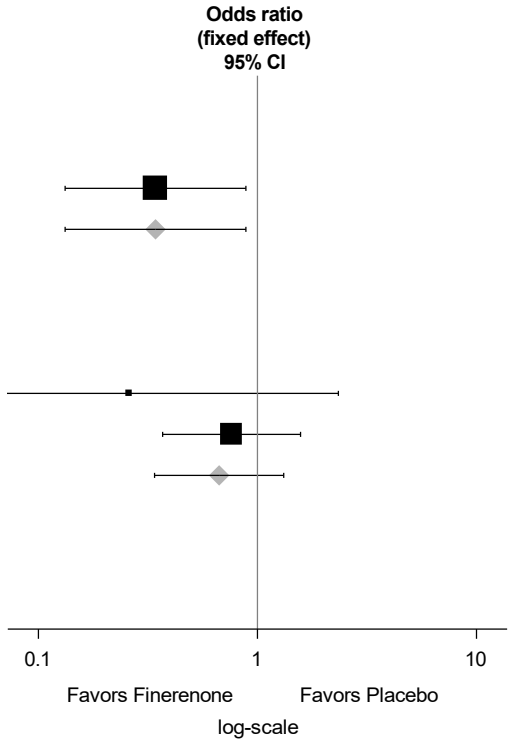
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	1 / 96	10.6	0.98 [0.06,15.88]	
FIGARO-DKD	6 / 1416	14 / 1420	89.4	0.43 [0.16,1.12]	
Total	7 / 1514	15 / 1516		0.46 [0.19,1.14]	Z=-1.67, p=0.0949
Heterogeneity:	Q=0.30 (df=1)	p=0.5812	I^2=0.0%		
>= 65					
FIDELIO-DKD	0 / 112	3 / 125	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	13 / 910	19 / 882	100.0	0.66 [0.32,1.34]	
Total	13 / 1022	22 / 1007		0.57 [0.29,1.15]	Z=-1.57, p=0.1157
Heterogeneity:	Q=0.14 (df=1)	p=0.7063	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7144	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.123.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

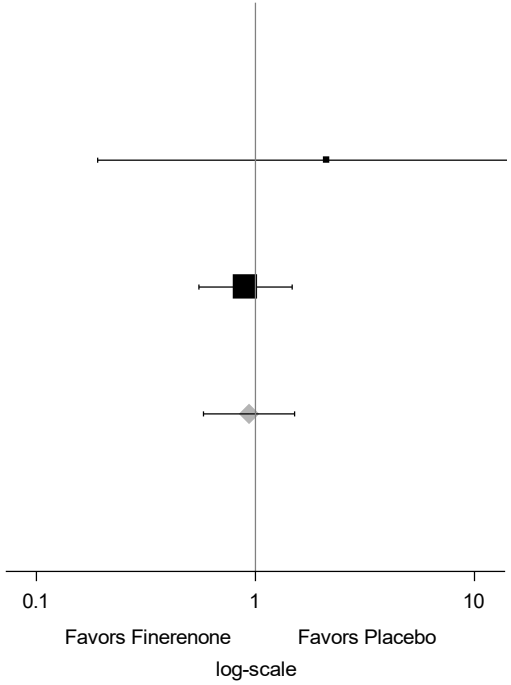
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	6 / 363	16 / 342	100.0	0.34 [0.13,0.89]	
Total	6 / 363	16 / 342		0.34 [0.13,0.89]	Z=-2.21, p=0.0271
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	1 / 210	4 / 221	9.8	0.26 [0.03,2.34]	
FIGARO-DKD	13 / 1963	17 / 1960	90.2	0.76 [0.37,1.57]	
Total	14 / 2173	21 / 2181		0.67 [0.34,1.32]	Z=-1.16, p=0.2449
Heterogeneity:	Q=0.84 (df=1)	p=0.3606	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.26 (df=1)	p=0.2616	I^2=20.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.124: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

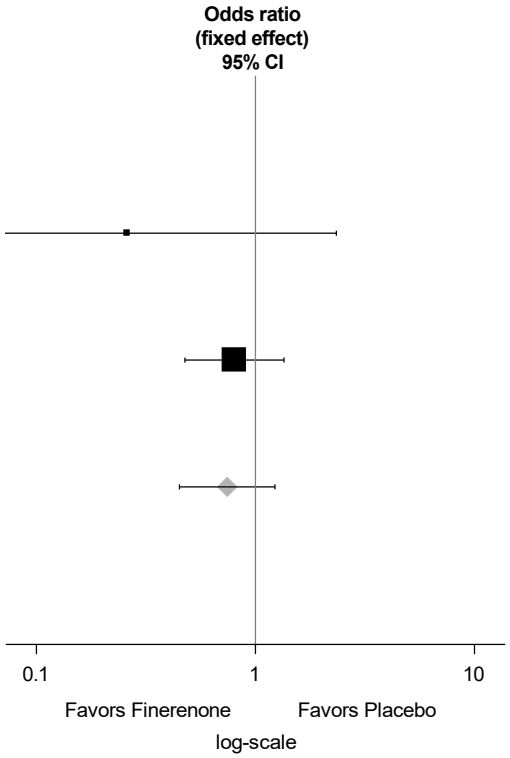
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.0	2.12 [0.19,23.50]	
FIGARO-DKD	31 / 2326	34 / 2302	96.0	0.90 [0.55,1.47]	
Total	33 / 2536	35 / 2523		0.93 [0.58,1.51]	Z=-0.28, p=0.7826
Heterogeneity:	Q=0.46 (df=1)	p=0.4960	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.125: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

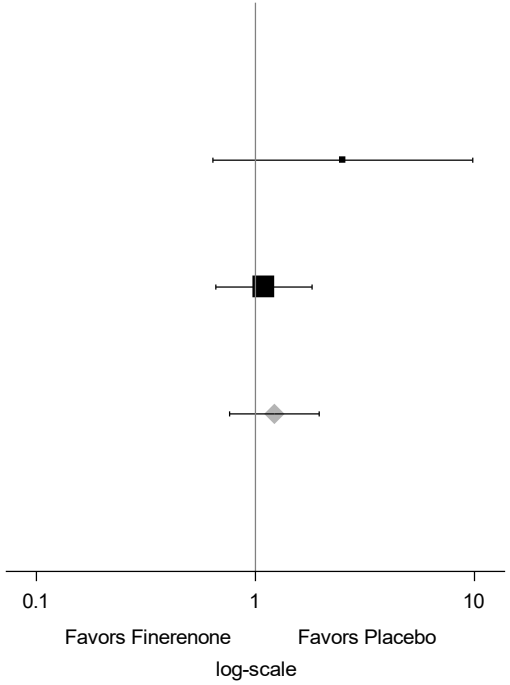
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	4 / 221	5.3	0.26 [0.03,2.34]	
FIGARO-DKD	26 / 2326	32 / 2302	94.7	0.80 [0.48,1.35]	
Total	27 / 2536	36 / 2523		0.74 [0.45,1.23]	Z=-1.16, p=0.2465
Heterogeneity:	Q=0.96 (df=1)	p=0.3270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.126: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

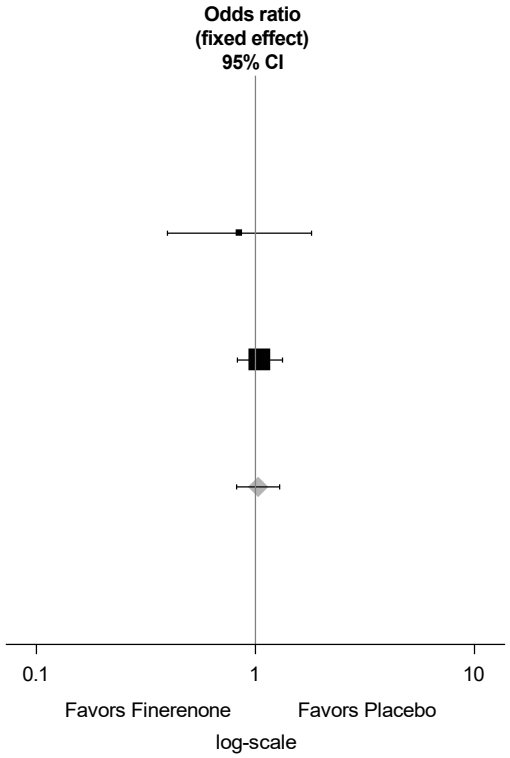
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	3 / 221	12.1	2.51 [0.64,9.82]	
FIGARO-DKD	32 / 2326	29 / 2302	87.9	1.09 [0.66,1.81]	
Total	39 / 2536	32 / 2523		1.22 [0.76,1.95]	Z=0.83, p=0.4075
Heterogeneity:	Q=1.25 (df=1)	p=0.2641	I^2=19.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.127: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

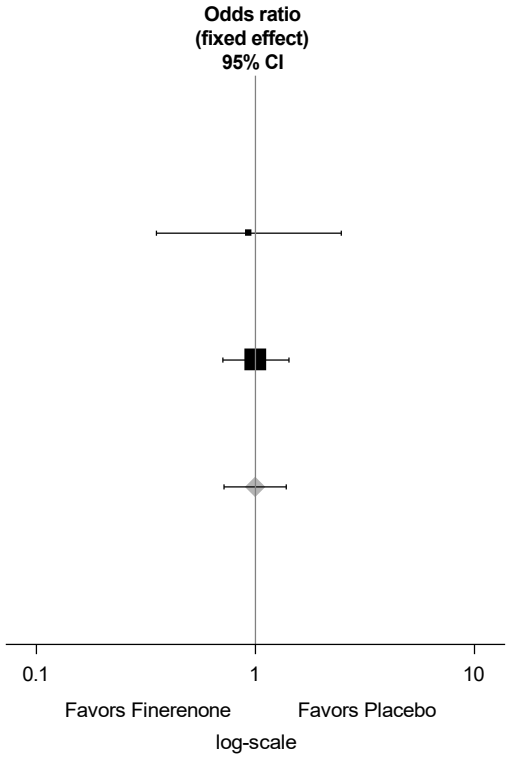
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	16 / 221	8.9	0.85 [0.40,1.80]	
FIGARO-DKD	150 / 2326	142 / 2302	91.1	1.05 [0.83,1.33]	
Total	163 / 2536	158 / 2523		1.03 [0.82,1.29]	Z=0.24, p=0.8074
Heterogeneity:	Q=0.28 (df=1)	p=0.5950	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.128: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

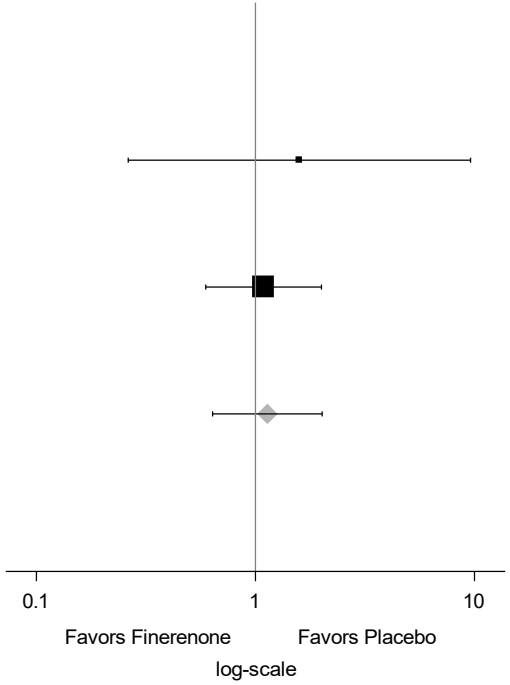
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	9 / 221	11.3	0.93 [0.35,2.47]	
FIGARO-DKD	66 / 2326	65 / 2302	88.7	1.01 [0.71,1.42]	
Total	74 / 2536	74 / 2523		1.00 [0.72,1.38]	Z=-0.02, p=0.9837
Heterogeneity:	Q=0.02 (df=1)	p=0.8875	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.129: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Erectile dysfunction (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

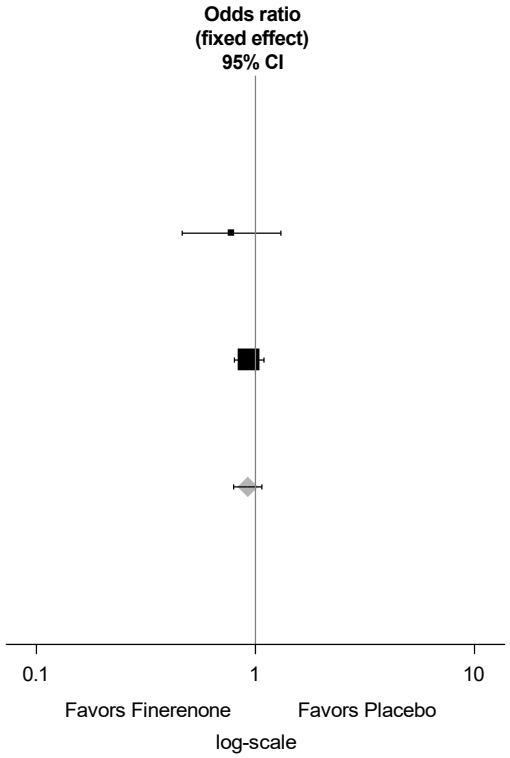
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	10.3	1.59 [0.26,9.59]	
FIGARO-DKD	22 / 2326	20 / 2302	89.7	1.09 [0.59,2.00]	
Total	25 / 2536	22 / 2523		1.13 [0.64,2.02]	Z=0.43, p=0.6700
Heterogeneity:	Q=0.15 (df=1)	p=0.6979	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.130: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

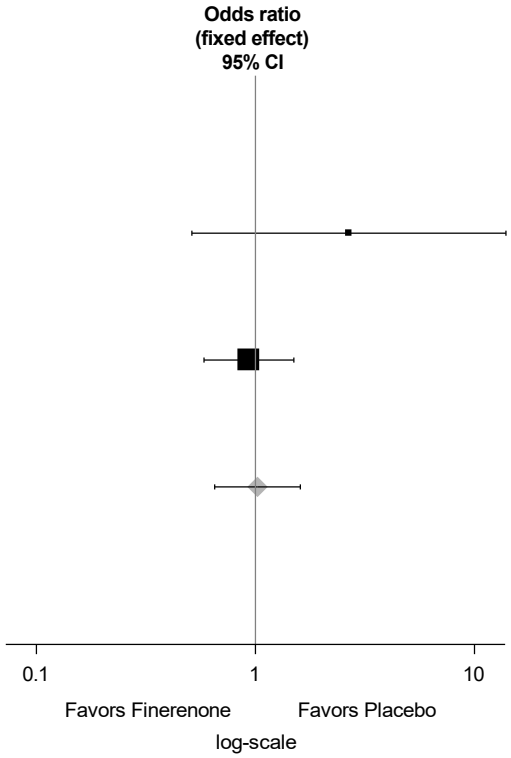
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 210	39 / 221	8.2	0.78 [0.46,1.31]	
FIGARO-DKD	374 / 2326	391 / 2302	91.8	0.94 [0.80,1.09]	
Total	404 / 2536	430 / 2523		0.92 [0.79,1.07]	Z=-1.07, p=0.2852
Heterogeneity:	Q=0.45 (df=1)	p=0.5015	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.131: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

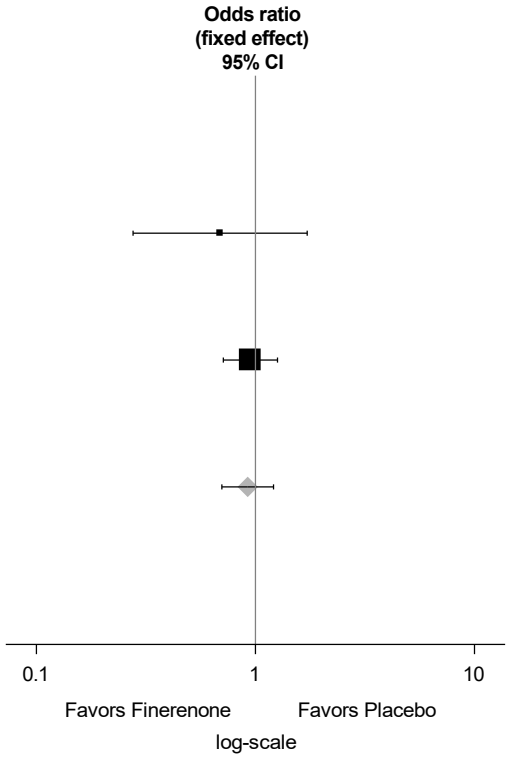
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	7.6	2.67 [0.51,13.92]	
FIGARO-DKD	34 / 2326	36 / 2302	92.4	0.93 [0.58,1.50]	
Total	39 / 2536	38 / 2523		1.02 [0.65,1.60]	Z=0.09, p=0.9254
Heterogeneity:	Q=1.44 (df=1)	p=0.2300	I^2=30.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.132: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

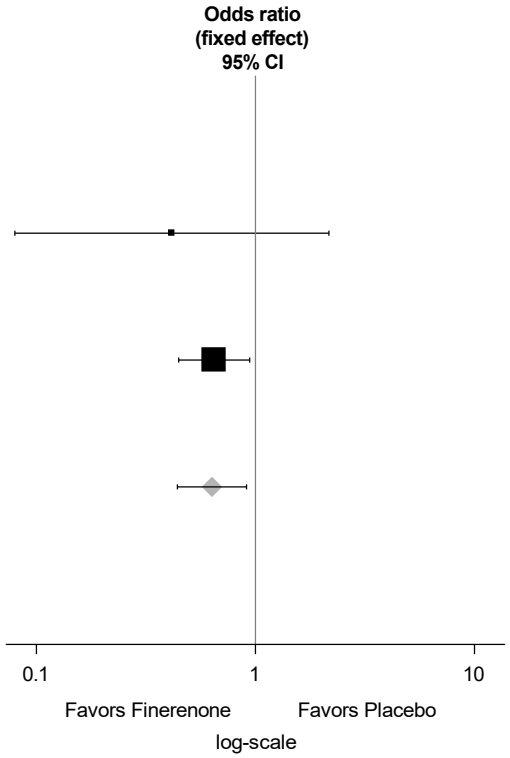
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	12 / 221	8.8	0.69 [0.28,1.72]	
FIGARO-DKD	97 / 2326	101 / 2302	91.2	0.95 [0.71,1.26]	
Total	105 / 2536	113 / 2523		0.92 [0.70,1.21]	Z=-0.59, p=0.5555
Heterogeneity:	Q=0.42 (df=1)	p=0.5151	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.133: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

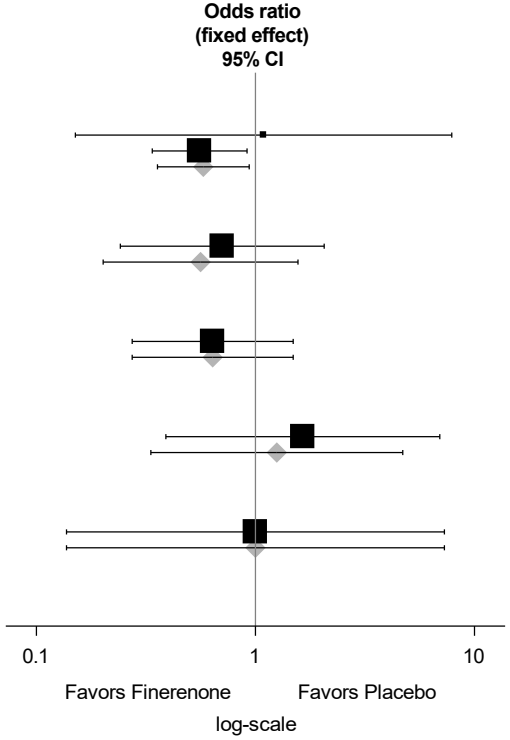
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	4.9	0.42 [0.08,2.16]	
FIGARO-DKD	47 / 2326	71 / 2302	95.1	0.65 [0.45,0.94]	
Total	49 / 2536	76 / 2523		0.63 [0.44,0.91]	Z=-2.47, p=0.0137
Heterogeneity:	Q=0.27 (df=1)	p=0.6065	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.133.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

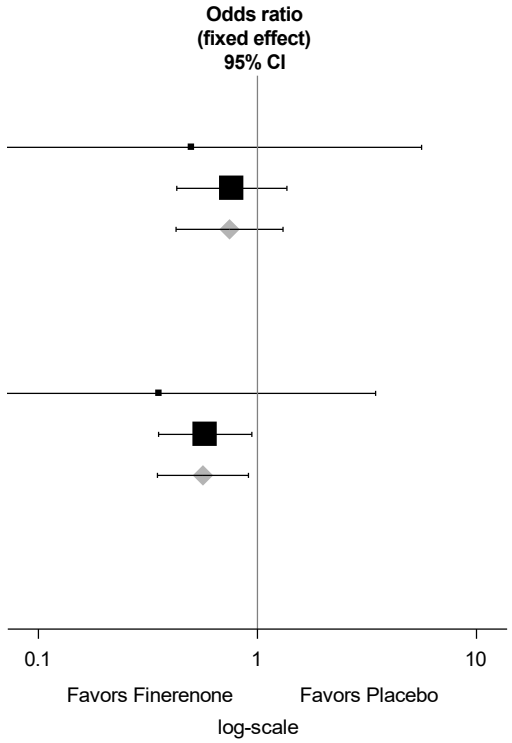
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	2 / 103	2 / 112	6.0	1.09 [0.15,7.88]	
FIGARO-DKD	25 / 1114	44 / 1110	94.0	0.56 [0.34,0.92]	
Total	27 / 1217	46 / 1222		0.58 [0.36,0.94]	Z=-2.23, p=0.0259
Heterogeneity:	Q=0.42 (df=1)	p=0.5185	I^2=0.0%		
North America					
FIDELIO-DKD	0 / 42	2 / 40	0.0	0.00 [0.00,6E296]	
FIGARO-DKD	6 / 292	8 / 277	100.0	0.71 [0.24,2.06]	
Total	6 / 334	10 / 317		0.56 [0.20,1.56]	Z=-1.10, p=0.2694
Heterogeneity:	Q=0.17 (df=1)	p=0.6766	I^2=0.0%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	9 / 522	14 / 523	100.0	0.64 [0.27,1.49]	
Total	9 / 561	14 / 564		0.64 [0.27,1.49]	Z=-1.04, p=0.2977
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	1 / 24	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	5 / 322	3 / 316	100.0	1.65 [0.39,6.94]	
Total	5 / 343	4 / 340		1.25 [0.33,4.70]	Z=0.33, p=0.7398
Heterogeneity:	Q=0.14 (df=1)	p=0.7095	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	2 / 76	2 / 76	100.0	1.00 [0.14,7.29]	
Total	2 / 81	2 / 80		1.00 [0.14,7.29]	Z=-0.00, p=1.0000
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.41 (df=4)	p=0.8424	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.133.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

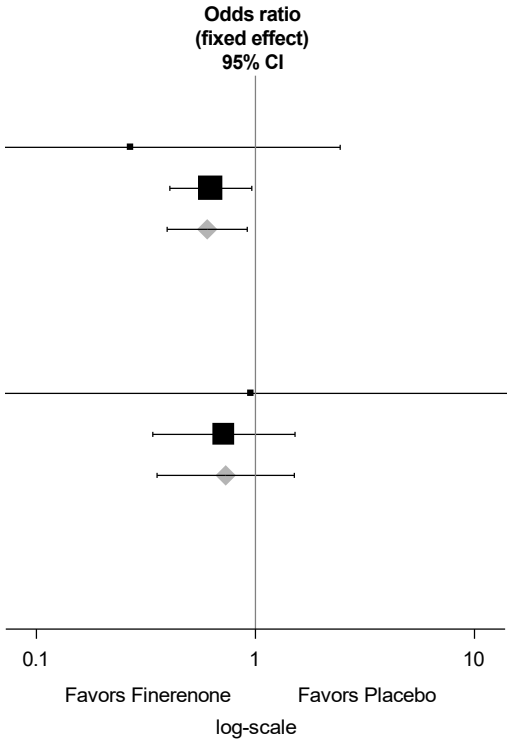
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1 / 88	2 / 89	5.4	0.50 [0.04,5.62]	
FIGARO-DKD	21 / 811	27 / 803	94.6	0.76 [0.43,1.36]	
Total	22 / 899	29 / 892		0.75 [0.43,1.31]	Z=-1.02, p=0.3064
Heterogeneity:	Q=0.11 (df=1)	p=0.7383	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 122	3 / 132	4.4	0.36 [0.04,3.46]	
FIGARO-DKD	26 / 1515	44 / 1499	95.6	0.58 [0.35,0.94]	
Total	27 / 1637	47 / 1631		0.56 [0.35,0.91]	Z=-2.35, p=0.0189
Heterogeneity:	Q=0.17 (df=1)	p=0.6828	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4580	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.133.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

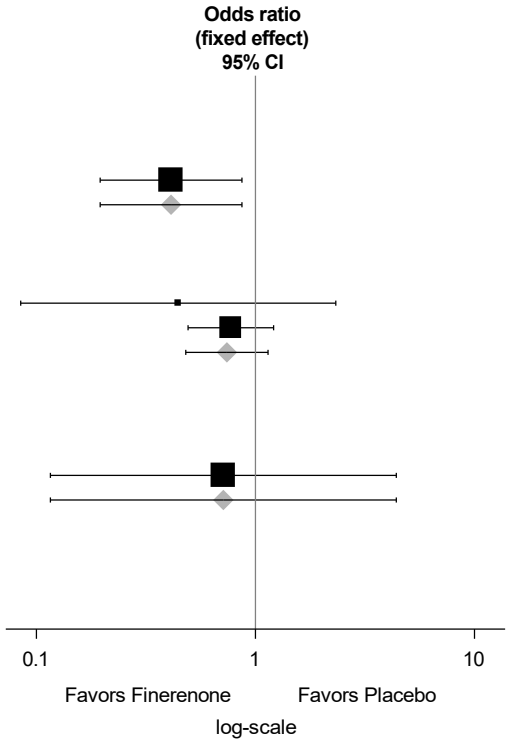
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1 / 144	4 / 158	3.7	0.27 [0.03,2.44]	
FIGARO-DKD	35 / 1719	54 / 1679	96.3	0.63 [0.41,0.96]	
Total	36 / 1863	58 / 1837		0.60 [0.40,0.92]	Z=-2.36, p=0.0182
Heterogeneity:	Q=0.54 (df=1)	p=0.4614	I^2=0.0%		
> 4.5					
FIDELIO-DKD	1 / 66	1 / 63	6.7	0.95 [0.06,15.58]	
FIGARO-DKD	12 / 607	17 / 622	93.3	0.72 [0.34,1.52]	
Total	13 / 673	18 / 685		0.73 [0.36,1.51]	Z=-0.85, p=0.3956
Heterogeneity:	Q=0.04 (df=1)	p=0.8472	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6483	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.133.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

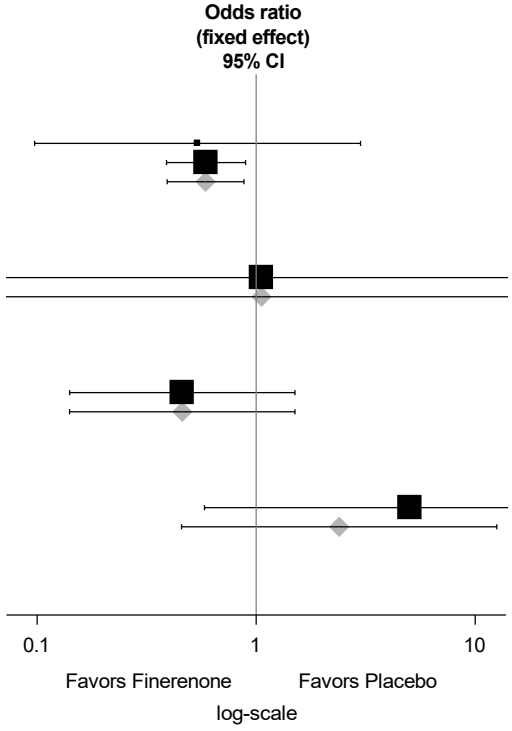
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	0 / 64	0 / 54	0.0	-	
FIGARO-DKD	10 / 693	24 / 699	100.0	0.41 [0.20,0.87]	
Total	10 / 757	24 / 753		0.41 [0.20,0.87]	Z=-2.33, p=0.0196
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	2 / 138	5 / 156	6.9	0.44 [0.08,2.33]	
FIGARO-DKD	35 / 1560	44 / 1524	93.1	0.77 [0.49,1.21]	
Total	37 / 1698	49 / 1680		0.74 [0.48,1.14]	Z=-1.36, p=0.1737
Heterogeneity:	Q=0.40 (df=1)	p=0.5276	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	3 / 79	100.0	0.71 [0.12,4.40]	
Total	2 / 81	3 / 90		0.71 [0.12,4.40]	Z=-0.36, p=0.7161
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.80 (df=2)	p=0.4071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.133.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

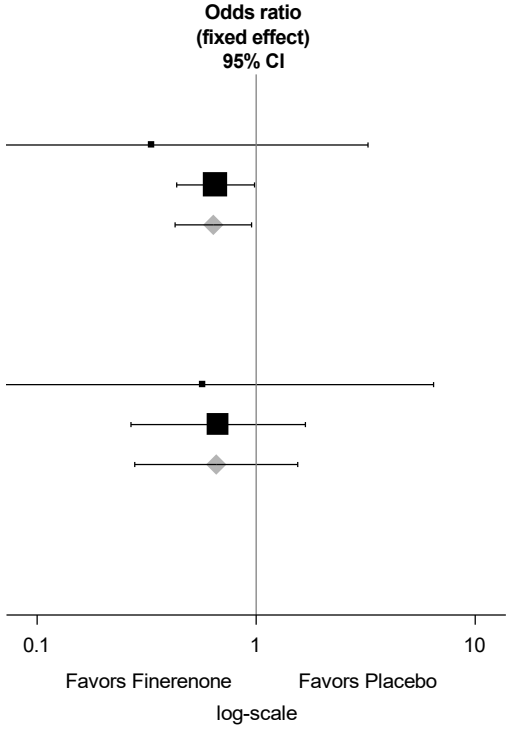
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	2 / 139	4 / 152	5.6	0.54 [0.10,3.00]	
FIGARO-DKD	37 / 1658	60 / 1612	94.4	0.59 [0.39,0.89]	
Total	39 / 1797	64 / 1764		0.59 [0.39,0.88]	Z=-2.58, p=0.0098
Heterogeneity:	Q=0.01 (df=1)	p=0.9212	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	1 / 70	1 / 74	100.0	1.06 [0.06,17.25]	
Total	1 / 80	1 / 83		1.06 [0.06,17.25]	Z=0.04, p=0.9684
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	4 / 464	9 / 485	100.0	0.46 [0.14,1.50]	
Total	4 / 503	9 / 529		0.46 [0.14,1.50]	Z=-1.28, p=0.1988
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,48E295]	
FIGARO-DKD	5 / 134	1 / 131	100.0	5.04 [0.58,43.73]	
Total	5 / 156	2 / 147		2.39 [0.46,12.55]	Z=1.03, p=0.3021
Heterogeneity:	Q=0.46 (df=1)	p=0.4994	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.00 (df=3)	p=0.3909	I^2=0.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.133.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

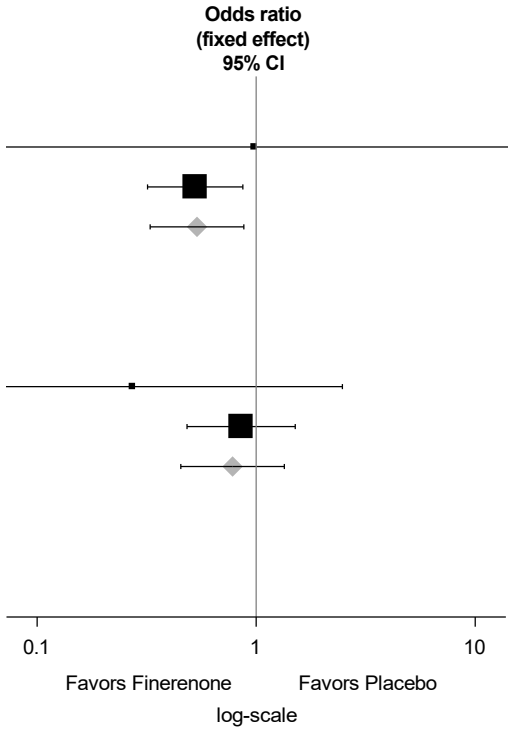
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1 / 152	3 / 154	3.1	0.33 [0.03,3.24]	
FIGARO-DKD	39 / 1610	60 / 1638	96.9	0.65 [0.43,0.98]	
Total	40 / 1762	63 / 1792		0.64 [0.43,0.95]	Z=-2.20, p=0.0281
Heterogeneity:	Q=0.33 (df=1)	p=0.5684	I^2=0.0%		
Female					
FIDELIO-DKD	1 / 58	2 / 67	12.5	0.57 [0.05,6.45]	
FIGARO-DKD	8 / 716	11 / 664	87.5	0.67 [0.27,1.68]	
Total	9 / 774	13 / 731		0.66 [0.28,1.55]	Z=-0.96, p=0.3366
Heterogeneity:	Q=0.02 (df=1)	p=0.9023	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9499	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.133.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

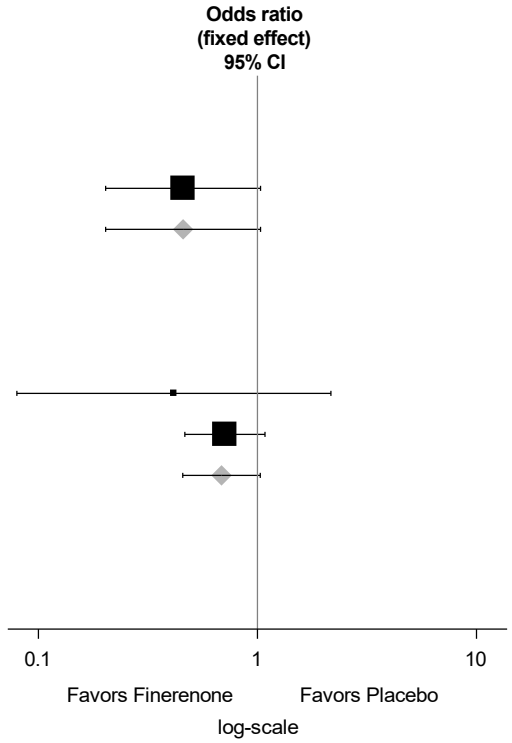
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1 / 98	1 / 96	3.1	0.98 [0.06,15.88]	
FIGARO-DKD	24 / 1416	45 / 1420	96.9	0.53 [0.32,0.87]	
Total	25 / 1514	46 / 1516		0.54 [0.33,0.88]	Z=-2.48, p=0.0133
Heterogeneity:	Q=0.18 (df=1)	p=0.6677	I^2=0.0%		
>= 65					
FIDELIO-DKD	1 / 112	4 / 125	6.2	0.27 [0.03,2.48]	
FIGARO-DKD	23 / 910	26 / 882	93.8	0.85 [0.48,1.51]	
Total	24 / 1022	30 / 1007		0.78 [0.45,1.34]	Z=-0.89, p=0.3716
Heterogeneity:	Q=0.97 (df=1)	p=0.3249	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.00 (df=1)	p=0.3179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.133.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

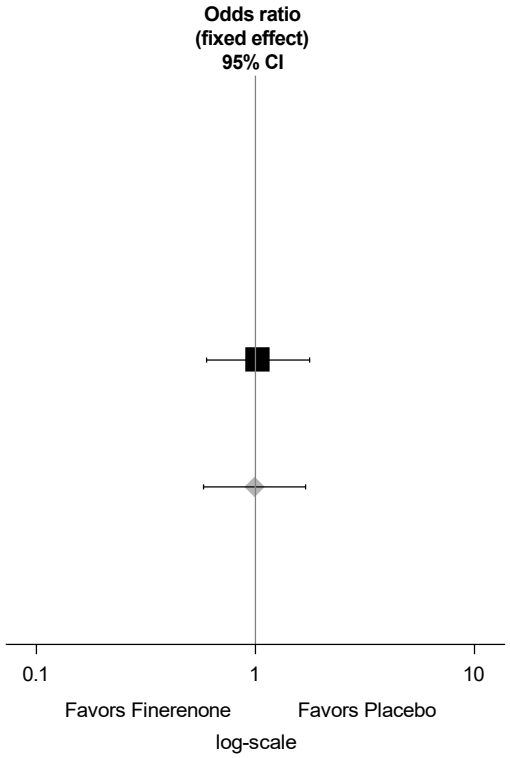
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	9 / 363	18 / 342	100.0	0.46 [0.20,1.03]	
Total	9 / 363	18 / 342		0.46 [0.20,1.03]	Z=-1.88, p=0.0599
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	2 / 210	5 / 221	6.1	0.42 [0.08,2.16]	
FIGARO-DKD	38 / 1963	53 / 1960	93.9	0.71 [0.47,1.08]	
Total	40 / 2173	58 / 2181		0.69 [0.46,1.03]	Z=-1.82, p=0.0691
Heterogeneity:	Q=0.38 (df=1)	p=0.5371	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=1)	p=0.3846	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.134: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oropharyngeal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

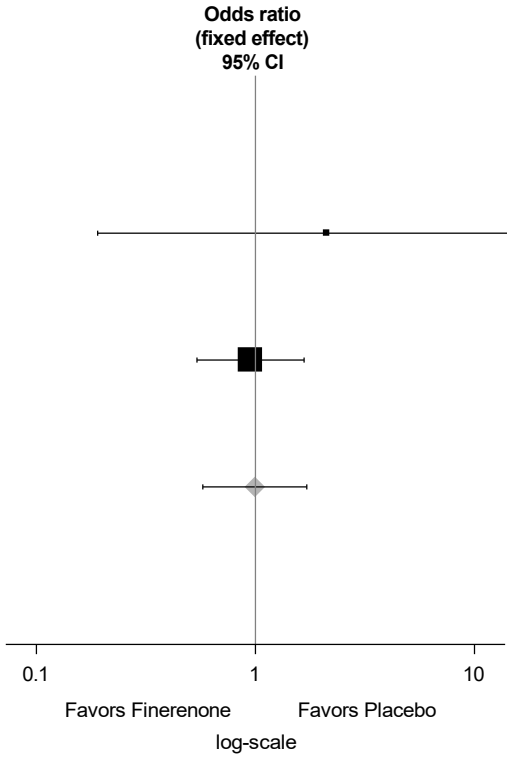
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	1 / 221	0.0	0.00 [0.00,26E296]	
FIGARO-DKD	27 / 2326	26 / 2302	100.0	1.03 [0.60,1.77]	
Total	27 / 2536	27 / 2523		0.99 [0.58,1.69]	Z=-0.03, p=0.9728
Heterogeneity:	Q=0.02 (df=1)	p=0.8934	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.135: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

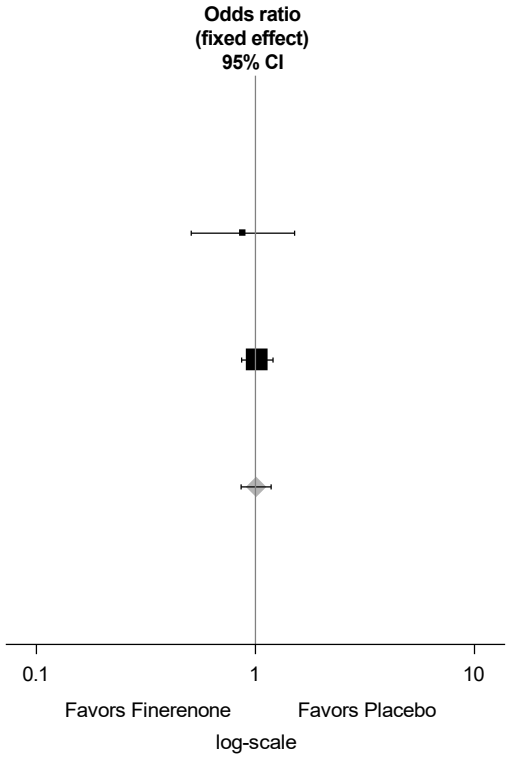
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	5.2	2.12 [0.19,23.50]	
FIGARO-DKD	24 / 2326	25 / 2302	94.8	0.95 [0.54,1.67]	
Total	26 / 2536	26 / 2523		0.99 [0.58,1.72]	Z=-0.02, p=0.9803
Heterogeneity:	Q=0.40 (df=1)	p=0.5255	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.136: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

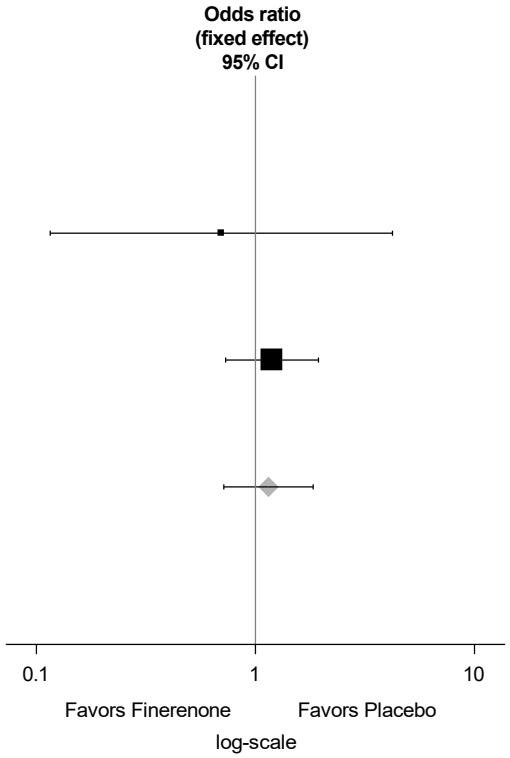
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 210	33 / 221	8.4	0.88 [0.51,1.51]	
FIGARO-DKD	334 / 2326	325 / 2302	91.6	1.02 [0.86,1.20]	
Total	362 / 2536	358 / 2523		1.01 [0.86,1.18]	Z=0.09, p=0.9314
Heterogeneity:	Q=0.27 (df=1)	p=0.6007	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.137: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

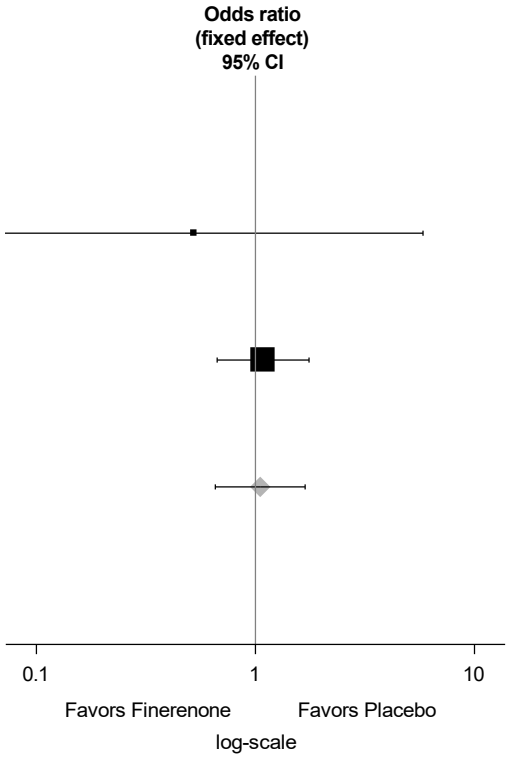
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	6.9	0.70 [0.12,4.22]	
FIGARO-DKD	36 / 2326	30 / 2302	93.1	1.19 [0.73,1.94]	
Total	38 / 2536	33 / 2523		1.15 [0.72,1.83]	Z=0.57, p=0.5676
Heterogeneity:	Q=0.31 (df=1)	p=0.5753	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.138: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

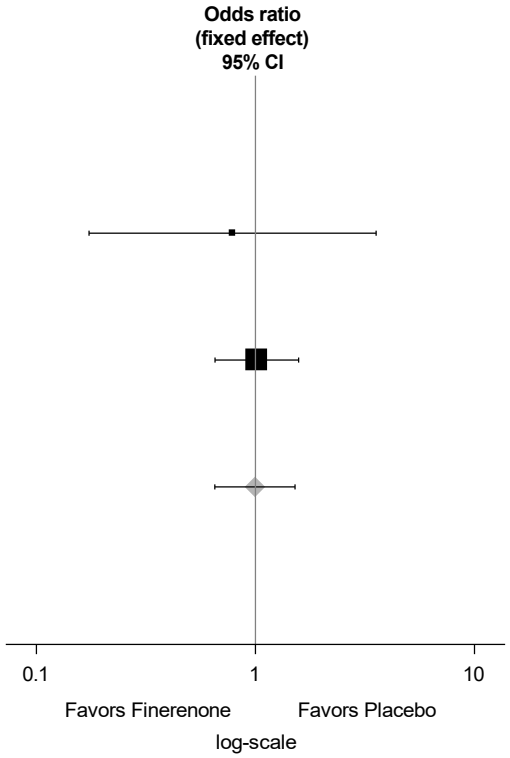
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	2 / 221	3.9	0.52 [0.05,5.82]	
FIGARO-DKD	35 / 2326	32 / 2302	96.1	1.08 [0.67,1.76]	
Total	36 / 2536	34 / 2523		1.05 [0.66,1.69]	Z=0.21, p=0.8351
Heterogeneity:	Q=0.34 (df=1)	p=0.5618	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.139: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

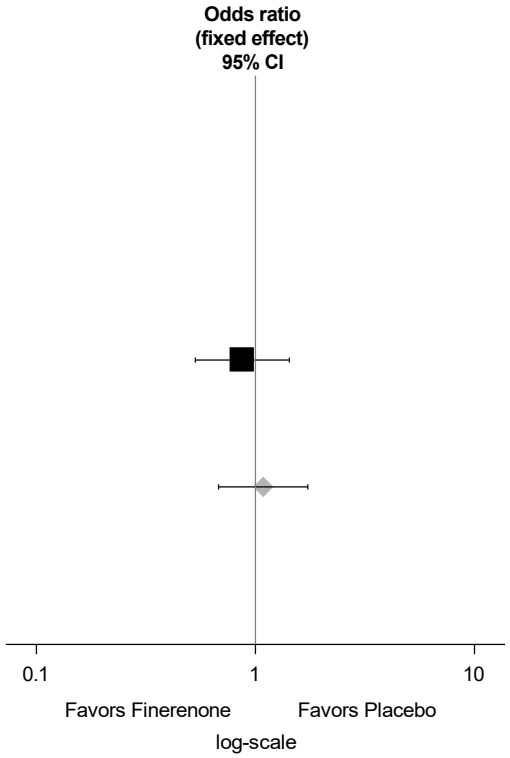
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	7.8	0.79 [0.17,3.56]	
FIGARO-DKD	41 / 2326	40 / 2302	92.2	1.01 [0.65,1.57]	
Total	44 / 2536	44 / 2523		0.99 [0.65,1.52]	Z=-0.03, p=0.9793
Heterogeneity:	Q=0.10 (df=1)	p=0.7504	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.140: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

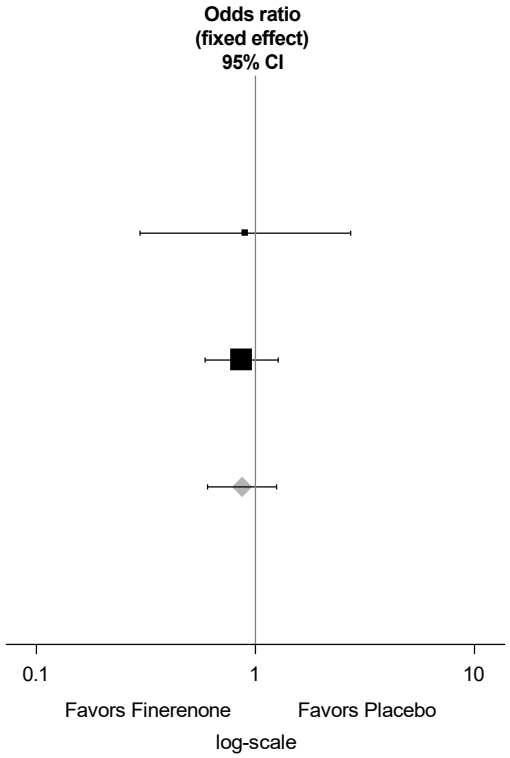
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	0 / 221	0.0	195E9 [195E9,195E9]	
FIGARO-DKD	30 / 2326	34 / 2302	100.0	0.87 [0.53,1.43]	
Total	37 / 2536	34 / 2523		1.08 [0.68,1.73]	Z=0.34, p=0.7337
Heterogeneity:	Q=0.75 (df=1)	p=0.3856	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.141: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

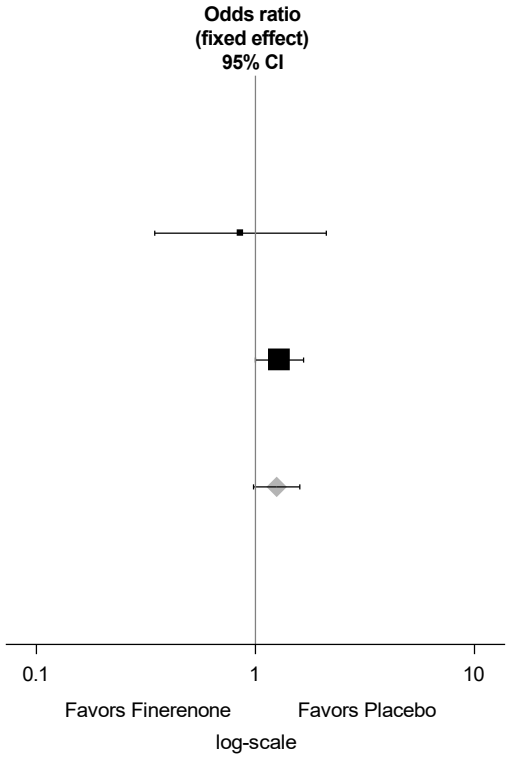
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	7 / 221	10.7	0.90 [0.30,2.72]	
FIGARO-DKD	50 / 2326	57 / 2302	89.3	0.87 [0.59,1.27]	
Total	56 / 2536	64 / 2523		0.87 [0.60,1.25]	Z=-0.76, p=0.4477
Heterogeneity:	Q=0.00 (df=1)	p=0.9487	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.142: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

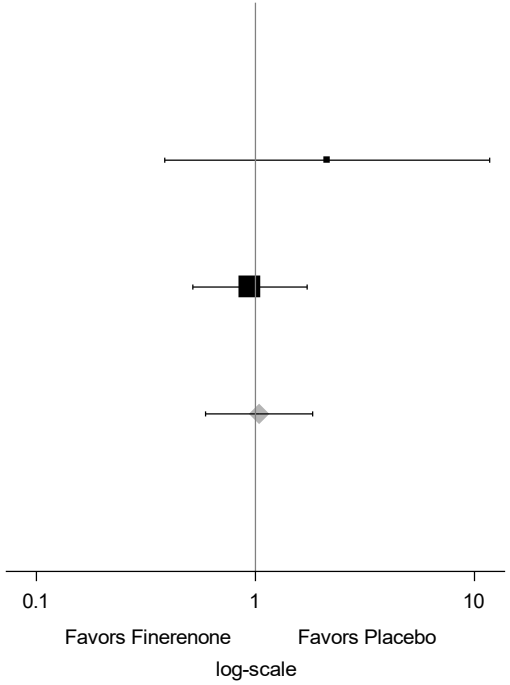
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	9 / 210	11 / 221	7.3	0.85 [0.35,2.11]	
FIGARO-DKD	145 / 2326	113 / 2302	92.7	1.29 [1.00,1.66]	
Total	154 / 2536	124 / 2523		1.25 [0.98,1.59]	Z=1.80, p=0.0724
Heterogeneity:	Q=0.74 (df=1)	p=0.3911	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.143: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

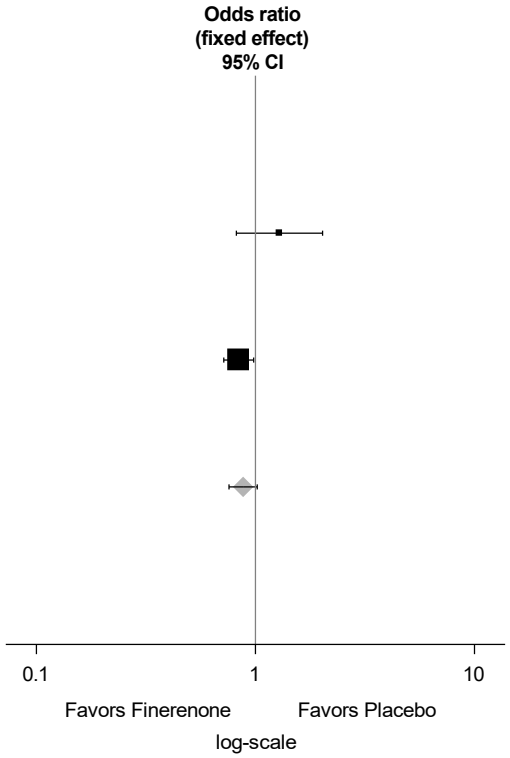
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	11.0	2.13 [0.39,11.73]	
FIGARO-DKD	21 / 2326	22 / 2302	89.0	0.94 [0.52,1.72]	
Total	25 / 2536	24 / 2523		1.04 [0.59,1.82]	Z=0.13, p=0.8938
Heterogeneity:	Q=0.77 (df=1)	p=0.3794	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.144: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

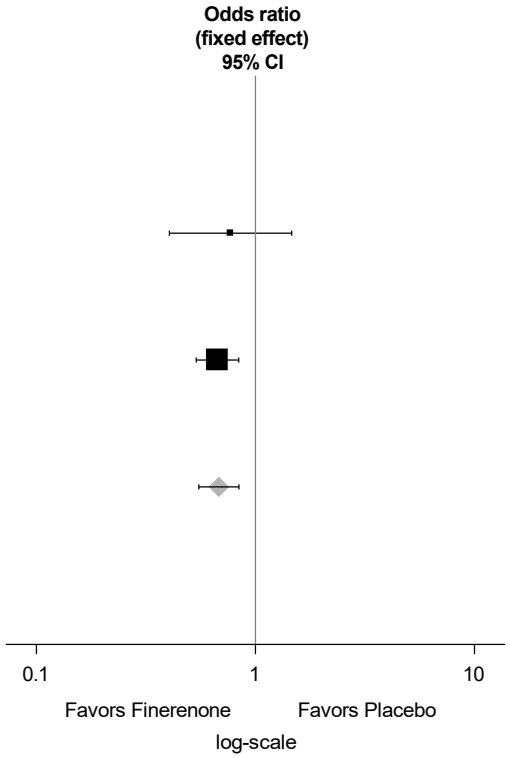
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 210	45 / 221	10.7	1.29 [0.82,2.03]	
FIGARO-DKD	347 / 2326	398 / 2302	89.3	0.84 [0.72,0.98]	
Total	399 / 2536	443 / 2523		0.88 [0.76,1.02]	Z=-1.71, p=0.0864
Heterogeneity:	Q=3.06 (df=1)	p=0.0801	I^2=67.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.145: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

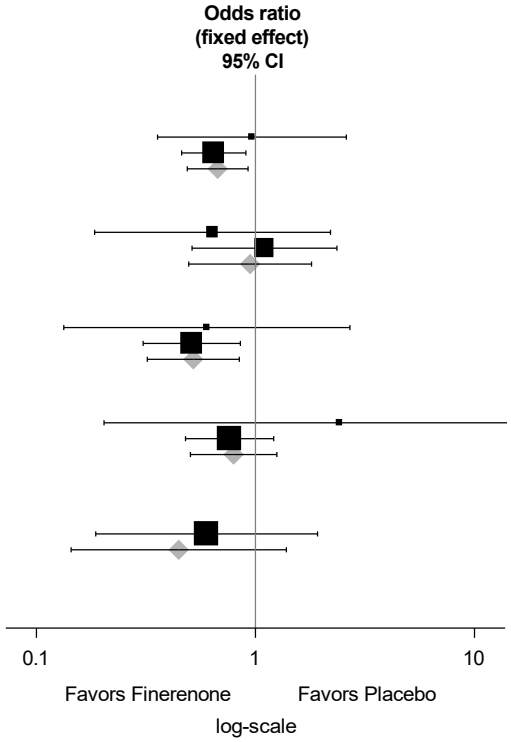
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 210	24 / 221	10.8	0.77 [0.40,1.46]	
FIGARO-DKD	141 / 2326	202 / 2302	89.2	0.67 [0.54,0.84]	
Total	159 / 2536	226 / 2523		0.68 [0.55,0.84]	Z=-3.57, p=0.0004
Heterogeneity:	Q=0.16 (df=1)	p=0.6926	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.145.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

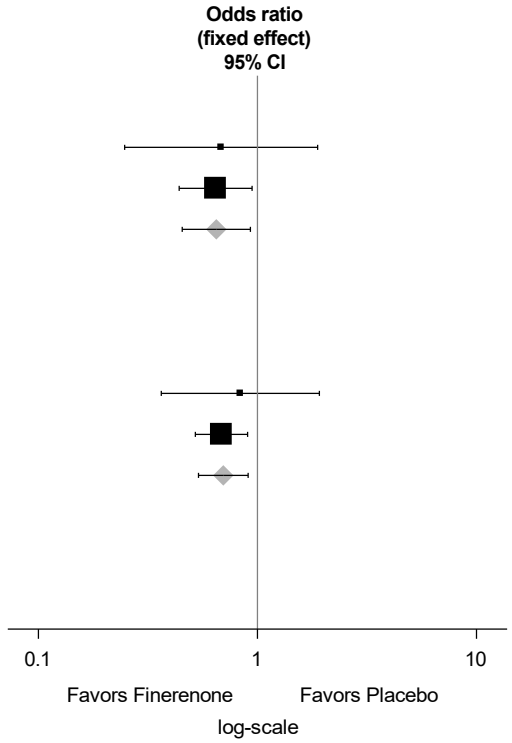
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	8 / 103	9 / 112	10.4	0.96 [0.36,2.60]	
FIGARO-DKD	60 / 1114	90 / 1110	89.6	0.65 [0.46,0.90]	
Total	68 / 1217	99 / 1222		0.67 [0.49,0.93]	Z=-2.44, p=0.0148
Heterogeneity:	Q=0.56 (df=1)	p=0.4530	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 42	7 / 40	27.4	0.64 [0.18,2.20]	
FIGARO-DKD	15 / 292	13 / 277	72.6	1.10 [0.51,2.36]	
Total	20 / 334	20 / 317		0.95 [0.50,1.80]	Z=-0.17, p=0.8652
Heterogeneity:	Q=0.54 (df=1)	p=0.4621	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	5 / 41	10.4	0.60 [0.13,2.70]	
FIGARO-DKD	24 / 522	45 / 523	89.6	0.51 [0.31,0.85]	
Total	27 / 561	50 / 564		0.52 [0.32,0.84]	Z=-2.65, p=0.0081
Heterogeneity:	Q=0.04 (df=1)	p=0.8447	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 21	1 / 24	3.4	2.42 [0.20,28.80]	
FIGARO-DKD	37 / 322	46 / 316	96.6	0.76 [0.48,1.21]	
Total	39 / 343	47 / 340		0.79 [0.50,1.25]	Z=-0.99, p=0.3224
Heterogeneity:	Q=0.81 (df=1)	p=0.3684	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	2 / 4	0.0	0.00 [0.00,86E294]	
FIGARO-DKD	5 / 76	8 / 76	100.0	0.60 [0.19,1.92]	
Total	5 / 81	10 / 80		0.45 [0.14,1.38]	Z=-1.40, p=0.1624
Heterogeneity:	Q=0.24 (df=1)	p=0.6219	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.17 (df=4)	p=0.5299	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.145.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

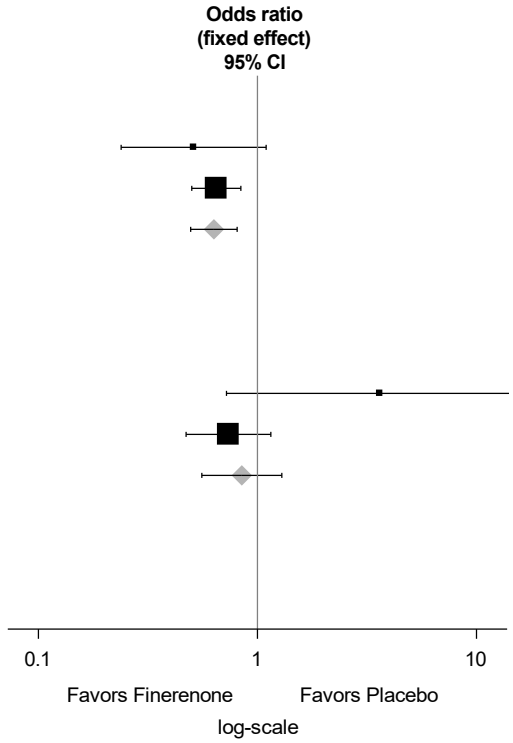
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	7 / 88	10 / 89	12.5	0.68 [0.25,1.88]	
FIGARO-DKD	47 / 811	70 / 803	87.5	0.64 [0.44,0.95]	
Total	54 / 899	80 / 892		0.65 [0.45,0.93]	Z=-2.36, p=0.0180
Heterogeneity:	Q=0.01 (df=1)	p=0.9164	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 122	14 / 132	9.9	0.84 [0.36,1.92]	
FIGARO-DKD	94 / 1515	132 / 1499	90.1	0.69 [0.52,0.90]	
Total	105 / 1637	146 / 1631		0.70 [0.54,0.91]	Z=-2.70, p=0.0070
Heterogeneity:	Q=0.20 (df=1)	p=0.6571	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7449	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.145.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

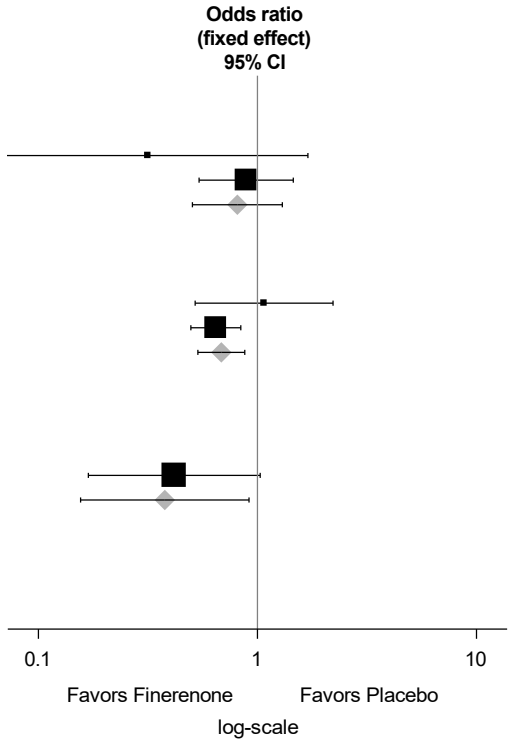
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	11 / 144	22 / 158	10.3	0.51 [0.24,1.10]	
FIGARO-DKD	105 / 1719	153 / 1679	89.7	0.65 [0.50,0.84]	
Total	116 / 1863	175 / 1837		0.63 [0.50,0.81]	Z=-3.67, p=0.0002
Heterogeneity:	Q=0.34 (df=1)	p=0.5616	I^2=0.0%		
> 4.5					
FIDELIO-DKD	7 / 66	2 / 63	7.1	3.62 [0.72,18.13]	
FIGARO-DKD	36 / 607	49 / 622	92.9	0.74 [0.47,1.15]	
Total	43 / 673	51 / 685		0.85 [0.56,1.29]	Z=-0.77, p=0.4436
Heterogeneity:	Q=3.49 (df=1)	p=0.0616	I^2=71.4%		
Subgroup Heterogeneity:	Q=1.40 (df=1)	p=0.2371	I^2=28.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.145.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

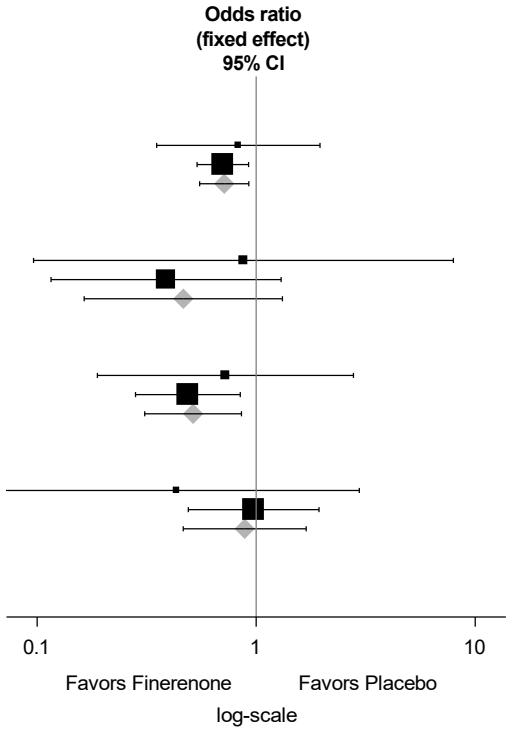
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	2 / 64	5 / 54	8.0	0.32 [0.06,1.70]	
FIGARO-DKD	31 / 693	35 / 699	92.0	0.89 [0.54,1.46]	
Total	33 / 757	40 / 753		0.81 [0.50,1.30]	Z=-0.88, p=0.3811
Heterogeneity:	Q=1.34 (df=1)	p=0.2478	I^2=25.1%		
130 - < 160					
FIDELIO-DKD	16 / 138	17 / 156	11.6	1.07 [0.52,2.21]	
FIGARO-DKD	102 / 1560	149 / 1524	88.4	0.65 [0.50,0.84]	
Total	118 / 1698	166 / 1680		0.68 [0.53,0.88]	Z=-3.02, p=0.0025
Heterogeneity:	Q=1.66 (df=1)	p=0.1969	I^2=39.9%		
>= 160					
FIDELIO-DKD	0 / 8	2 / 11	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	8 / 73	18 / 79	100.0	0.42 [0.17,1.03]	
Total	8 / 81	20 / 90		0.38 [0.16,0.92]	Z=-2.16, p=0.0310
Heterogeneity:	Q=0.05 (df=1)	p=0.8289	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.22 (df=2)	p=0.3296	I^2=9.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.145.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

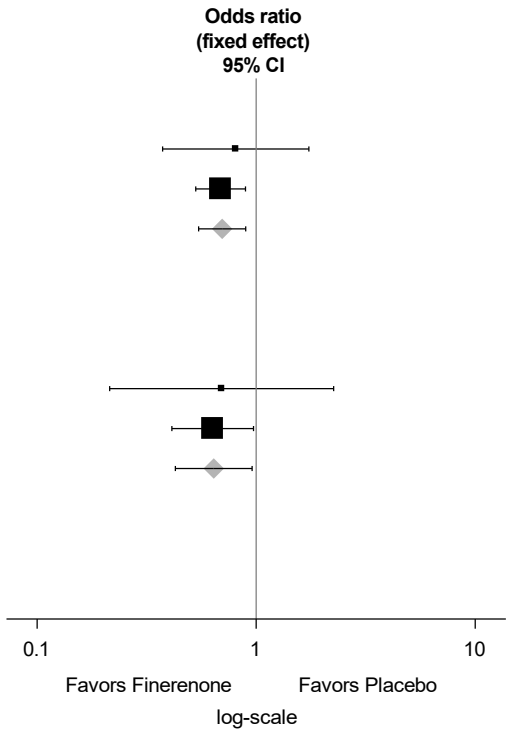
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	10 / 139	13 / 152	9.1	0.83 [0.35,1.96]	
FIGARO-DKD	98 / 1658	132 / 1612	90.9	0.70 [0.54,0.92]	
Total	108 / 1797	145 / 1764		0.71 [0.55,0.93]	Z=-2.55, p=0.0108
Heterogeneity:	Q=0.13 (df=1)	p=0.7230	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 10	2 / 9	23.1	0.88 [0.10,7.95]	
FIGARO-DKD	4 / 70	10 / 74	76.9	0.39 [0.12,1.30]	
Total	6 / 80	12 / 83		0.46 [0.16,1.32]	Z=-1.44, p=0.1496
Heterogeneity:	Q=0.40 (df=1)	p=0.5263	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 39	6 / 44	14.3	0.72 [0.19,2.78]	
FIGARO-DKD	20 / 464	41 / 485	85.7	0.49 [0.28,0.85]	
Total	24 / 503	47 / 529		0.52 [0.31,0.86]	Z=-2.56, p=0.0106
Heterogeneity:	Q=0.28 (df=1)	p=0.5948	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 22	3 / 16	11.3	0.43 [0.06,2.96]	
FIGARO-DKD	19 / 134	19 / 131	88.7	0.97 [0.49,1.94]	
Total	21 / 156	22 / 147		0.89 [0.46,1.69]	Z=-0.37, p=0.7145
Heterogeneity:	Q=0.61 (df=1)	p=0.4365	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.44 (df=3)	p=0.4854	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.145.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

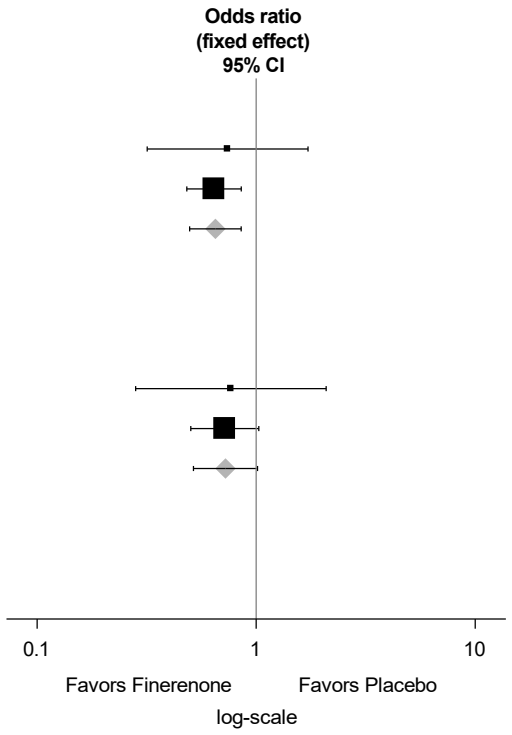
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	13 / 152	16 / 154	10.4	0.81 [0.37,1.74]	
FIGARO-DKD	103 / 1610	148 / 1638	89.6	0.69 [0.53,0.89]	
Total	116 / 1762	164 / 1792		0.70 [0.55,0.90]	Z=-2.83, p=0.0046
Heterogeneity:	Q=0.15 (df=1)	p=0.7012	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 58	8 / 67	11.7	0.70 [0.21,2.26]	
FIGARO-DKD	38 / 716	54 / 664	88.3	0.63 [0.41,0.97]	
Total	43 / 774	62 / 731		0.64 [0.43,0.96]	Z=-2.17, p=0.0302
Heterogeneity:	Q=0.02 (df=1)	p=0.8827	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7135	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.145.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

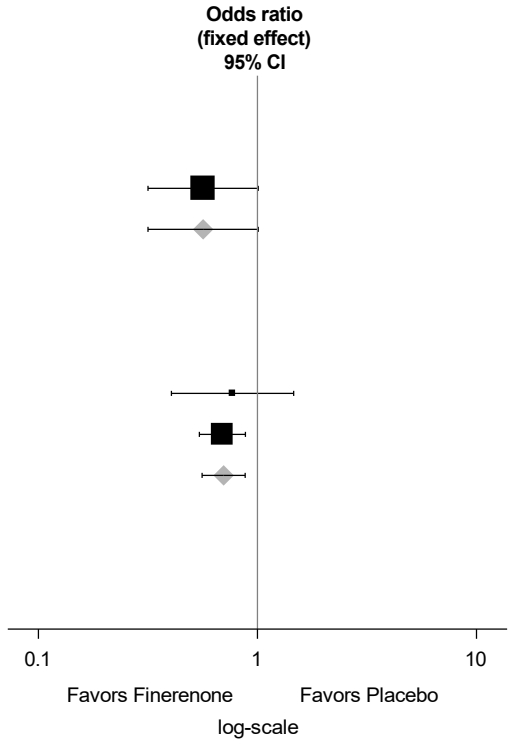
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 98	14 / 96	10.3	0.74 [0.32,1.72]	
FIGARO-DKD	84 / 1416	127 / 1420	89.7	0.64 [0.48,0.85]	
Total	95 / 1514	141 / 1516		0.65 [0.50,0.85]	Z=-3.10, p=0.0019
Heterogeneity:	Q=0.10 (df=1)	p=0.7539	I^2=0.0%		
>= 65					
FIDELIO-DKD	7 / 112	10 / 125	11.3	0.77 [0.28,2.09]	
FIGARO-DKD	57 / 910	75 / 882	88.7	0.72 [0.50,1.03]	
Total	64 / 1022	85 / 1007		0.72 [0.52,1.01]	Z=-1.88, p=0.0605
Heterogeneity:	Q=0.01 (df=1)	p=0.9059	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6311	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.145.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

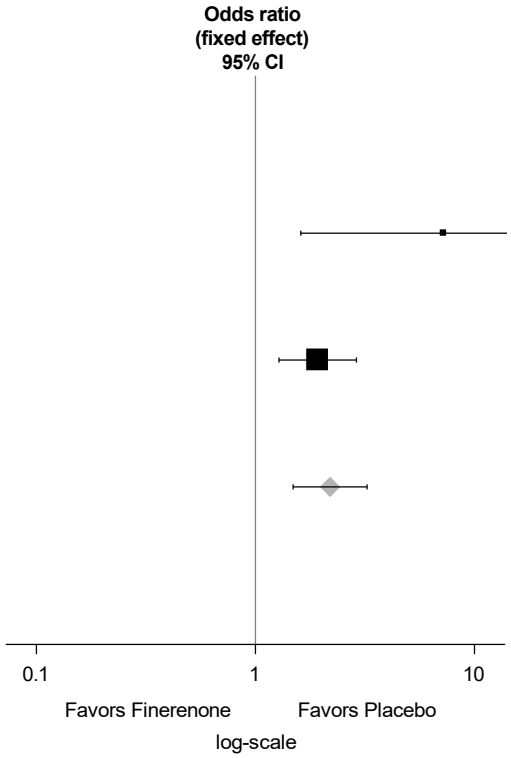
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	20 / 363	32 / 342	100.0	0.56 [0.32,1.01]	
Total	20 / 363	32 / 342		0.56 [0.32,1.01]	Z=-1.93, p=0.0533
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	18 / 210	24 / 221	12.4	0.77 [0.40,1.46]	
FIGARO-DKD	121 / 1963	170 / 1960	87.6	0.69 [0.54,0.88]	
Total	139 / 2173	194 / 2181		0.70 [0.56,0.88]	Z=-3.08, p=0.0021
Heterogeneity:	Q=0.09 (df=1)	p=0.7608	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4968	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.146: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

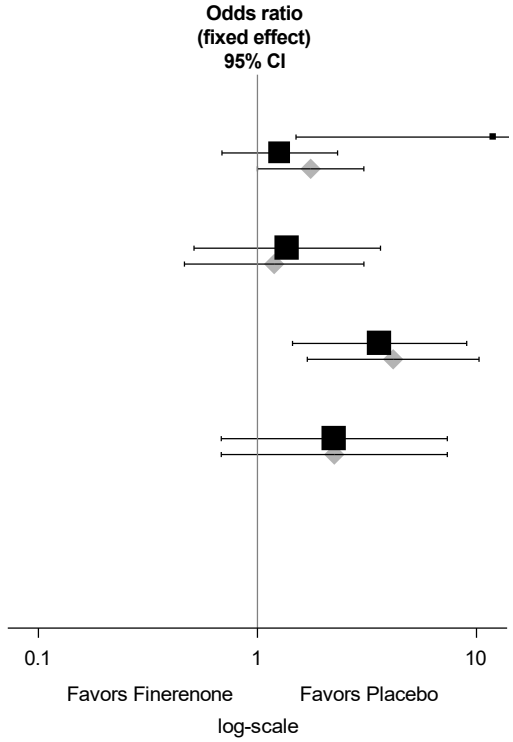
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	2 / 221	6.9	7.23 [1.61,32.42]	
FIGARO-DKD	69 / 2326	36 / 2302	93.1	1.92 [1.28,2.89]	
Total	82 / 2536	38 / 2523		2.19 [1.49,3.23]	Z=3.96, p=<.0001
Heterogeneity:	Q=2.82 (df=1)	p=0.0932	I^2=64.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.146.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

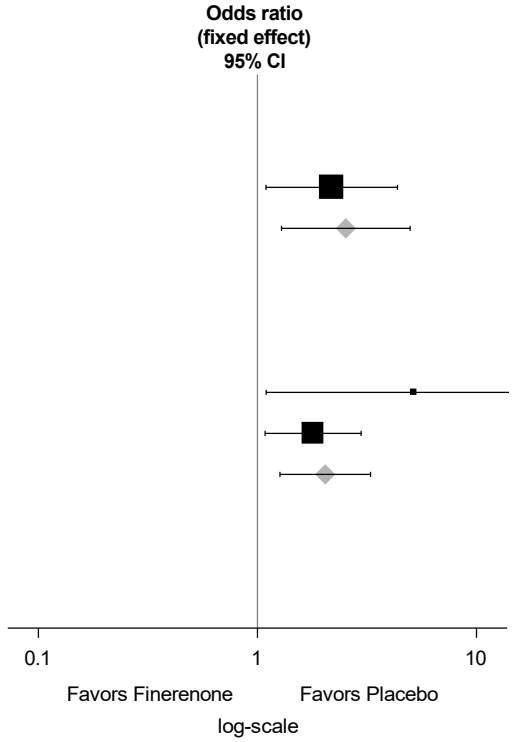
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 103	1 / 112	7.9	11.94 [1.50,94.97]	
FIGARO-DKD	24 / 1114	19 / 1110	92.1	1.26 [0.69,2.32]	
Total	34 / 1217	20 / 1222		1.75 [1.00,3.06]	Z=1.96, p=0.0500
Heterogeneity:	Q=4.39 (df=1)	p=0.0362	I^2=77.2%		
North America					
FIDELIO-DKD	0 / 42	1 / 40	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	10 / 292	7 / 277	100.0	1.37 [0.51,3.65]	
Total	10 / 334	8 / 317		1.19 [0.46,3.06]	Z=0.37, p=0.7151
Heterogeneity:	Q=0.08 (df=1)	p=0.7833	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 39	0 / 41	0.0	174E9 [174E9,174E9]	
FIGARO-DKD	21 / 522	6 / 523	100.0	3.61 [1.45,9.02]	
Total	24 / 561	6 / 564		4.16 [1.69,10.27]	Z=3.10, p=0.0019
Heterogeneity:	Q=0.09 (df=1)	p=0.7604	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	9 / 322	4 / 316	100.0	2.24 [0.68,7.36]	
Total	9 / 343	4 / 340		2.24 [0.68,7.36]	Z=1.33, p=0.1827
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	5 / 76	0 / 76	0.0	147E9 [147E9,147E9]	
Total	5 / 81	0 / 80		373E9 [373E9,373E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.95 (df=4)	p=0.4130	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.146.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

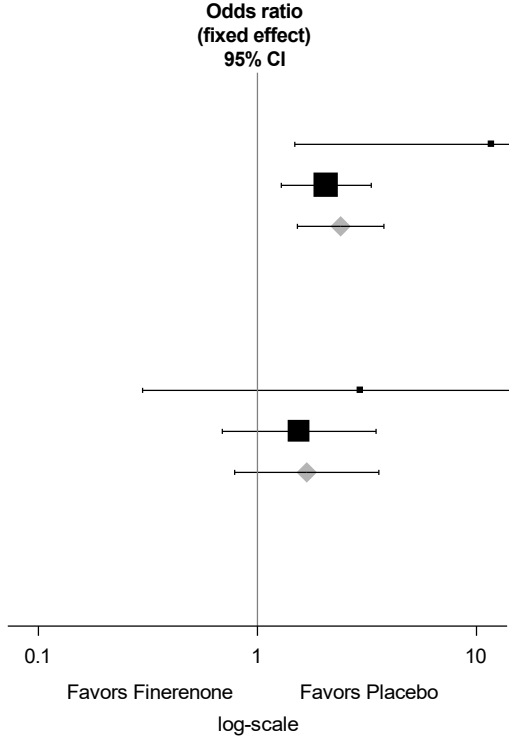
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	4 / 88	0 / 89	0.0	27E10 [27E10,27E10]	
FIGARO-DKD	26 / 811	12 / 803	100.0	2.18 [1.09,4.36]	
Total	30 / 899	12 / 892		2.53 [1.29,4.98]	Z=2.69, p=0.0071
Heterogeneity:	Q=0.18 (df=1)	p=0.6747	I^2=0.0%		
Absent					
FIDELIO-DKD	9 / 122	2 / 132	9.6	5.18 [1.10,24.46]	
FIGARO-DKD	43 / 1515	24 / 1499	90.4	1.80 [1.08,2.97]	
Total	52 / 1637	26 / 1631		2.04 [1.27,3.28]	Z=2.93, p=0.0034
Heterogeneity:	Q=1.63 (df=1)	p=0.2020	I^2=38.6%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6085	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.146.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

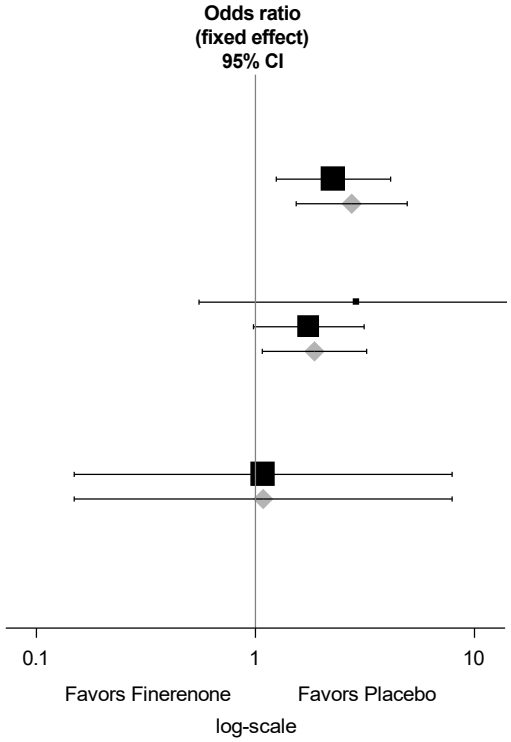
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	10 / 144	1 / 158	5.0	11.72 [1.48,92.71]	
FIGARO-DKD	54 / 1719	26 / 1679	95.0	2.06 [1.29,3.31]	
Total	64 / 1863	27 / 1837		2.40 [1.52,3.78]	Z=3.77, p=0.0002
Heterogeneity:	Q=2.65 (df=1)	p=0.1035	I^2=62.3%		
> 4.5					
FIDELIO-DKD	3 / 66	1 / 63	11.1	2.95 [0.30,29.16]	
FIGARO-DKD	15 / 607	10 / 622	88.9	1.55 [0.69,3.48]	
Total	18 / 673	11 / 685		1.68 [0.79,3.58]	Z=1.34, p=0.1802
Heterogeneity:	Q=0.27 (df=1)	p=0.6030	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.62 (df=1)	p=0.4294	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.146.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

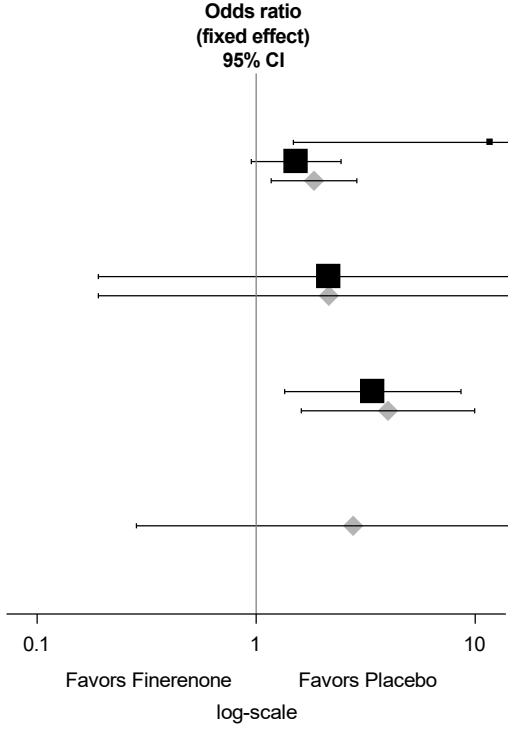
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 64	0 / 54	0.0	298E9 [298E9,298E9]	
FIGARO-DKD	35 / 693	16 / 699	100.0	2.27 [1.24,4.14]	
Total	43 / 757	16 / 753		2.75 [1.53,4.93]	Z=3.40, p=0.0007
Heterogeneity:	Q=0.39 (df=1)	p=0.5316	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	5 / 138	2 / 156	11.0	2.89 [0.55,15.17]	
FIGARO-DKD	32 / 1560	18 / 1524	89.0	1.75 [0.98,3.14]	
Total	37 / 1698	20 / 1680		1.86 [1.07,3.22]	Z=2.22, p=0.0266
Heterogeneity:	Q=0.31 (df=1)	p=0.5750	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	2 / 73	2 / 79	100.0	1.08 [0.15,7.90]	
Total	2 / 81	2 / 90		1.08 [0.15,7.90]	Z=0.08, p=0.9362
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.41 (df=2)	p=0.4949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.146.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

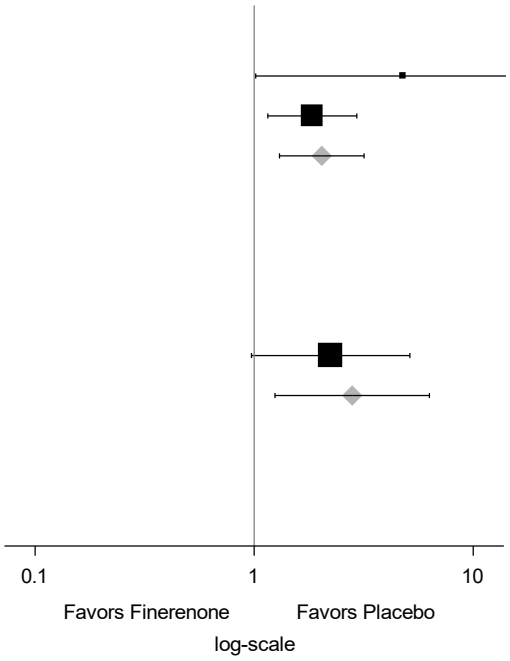
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	10 / 139	1 / 152	4.9	11.71 [1.48,92.67]	
FIGARO-DKD	45 / 1658	29 / 1612	95.1	1.52 [0.95,2.44]	
Total	55 / 1797	30 / 1764		1.84 [1.17,2.88]	Z=2.65, p=0.0081
Heterogeneity:	Q=3.68 (df=1)	p=0.0549	I^2=72.9%		
Black					
FIDELIO-DKD	0 / 10	0 / 9	0.0	-	
FIGARO-DKD	2 / 70	1 / 74	100.0	2.15 [0.19,24.22]	
Total	2 / 80	1 / 83		2.15 [0.19,24.22]	Z=0.62, p=0.5365
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 39	0 / 44	0.0	174E9 [174E9,174E9]	
FIGARO-DKD	19 / 464	6 / 485	100.0	3.41 [1.35,8.61]	
Total	22 / 503	6 / 529		4.00 [1.61,9.94]	Z=2.98, p=0.0029
Heterogeneity:	Q=0.11 (df=1)	p=0.7361	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	1 / 16	0.0	0.00 [0.00,48E295]	
FIGARO-DKD	3 / 134	0 / 131	0.0	13E10 [13E10,13E10]	
Total	3 / 156	1 / 147		2.77 [0.28,27.06]	Z=0.88, p=0.3805
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=2.30 (df=3)	p=0.5131	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.146.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

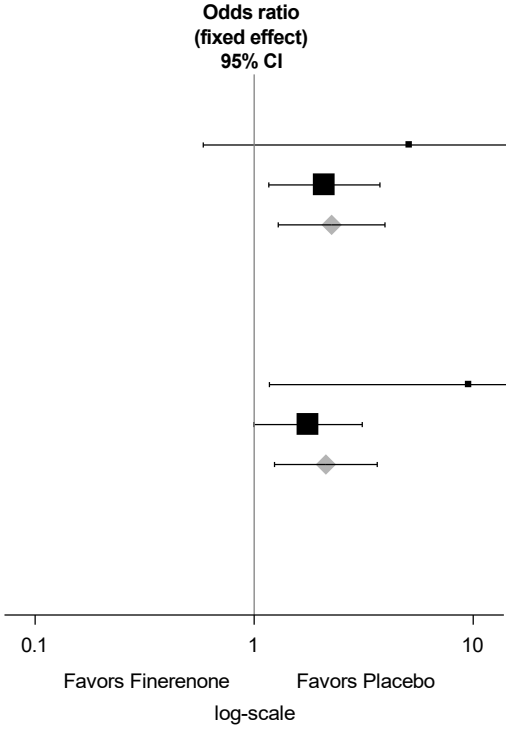
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 152	2 / 154	8.4	4.78 [1.02,22.52]	
FIGARO-DKD	50 / 1610	28 / 1638	91.6	1.84 [1.15,2.94]	
Total	59 / 1762	30 / 1792		2.04 [1.30,3.17]	Z=3.13, p=0.0017
Heterogeneity:	Q=1.34 (df=1)	p=0.2467	I^2=25.5%		
Female					
FIDELIO-DKD	4 / 58	0 / 67	0.0	154E9 [154E9,154E9]	
FIGARO-DKD	19 / 716	8 / 664	100.0	2.24 [0.97,5.14]	
Total	23 / 774	8 / 731		2.80 [1.24,6.31]	Z=2.49, p=0.0128
Heterogeneity:	Q=0.28 (df=1)	p=0.5947	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4981	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.146.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

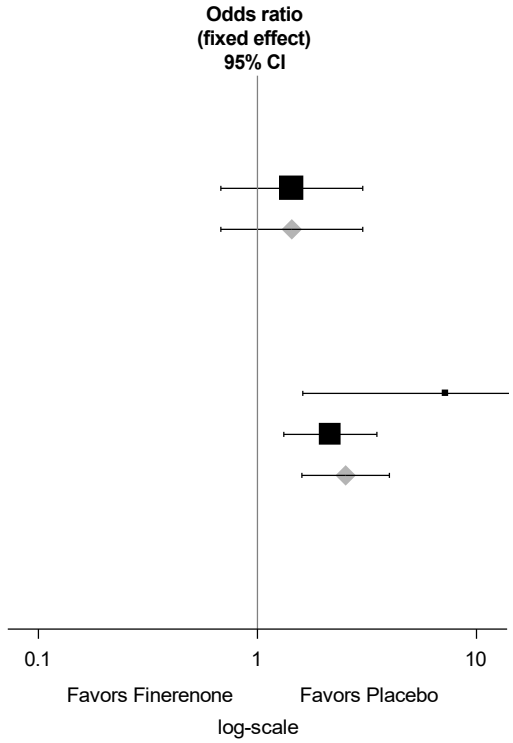
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	5 / 98	1 / 96	6.8	5.11 [0.59,44.55]	
FIGARO-DKD	35 / 1416	17 / 1420	93.2	2.09 [1.17,3.75]	
Total	40 / 1514	18 / 1516		2.26 [1.29,3.96]	Z=2.84, p=0.0045
Heterogeneity:	Q=0.61 (df=1)	p=0.4343	I^2=0.0%		
>= 65					
FIDELIO-DKD	8 / 112	1 / 125	6.9	9.54 [1.17,77.51]	
FIGARO-DKD	34 / 910	19 / 882	93.1	1.76 [1.00,3.11]	
Total	42 / 1022	20 / 1007		2.13 [1.24,3.65]	Z=2.74, p=0.0062
Heterogeneity:	Q=2.39 (df=1)	p=0.1223	I^2=58.1%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8795	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.146.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

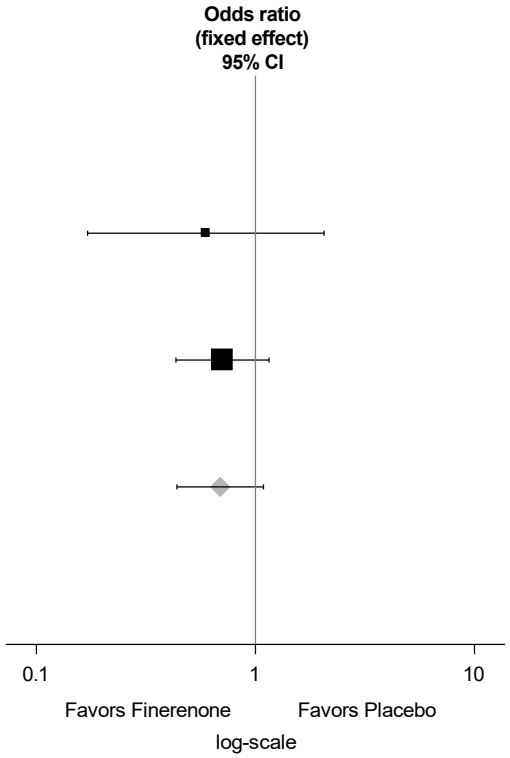
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	18 / 363	12 / 342	100.0	1.43 [0.68,3.02]	
Total	18 / 363	12 / 342		1.43 [0.68,3.02]	Z=0.95, p=0.3428
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	13 / 210	2 / 221	9.6	7.23 [1.61,32.42]	
FIGARO-DKD	51 / 1963	24 / 1960	90.4	2.15 [1.32,3.51]	
Total	64 / 2173	26 / 2181		2.53 [1.60,4.00]	Z=3.95, p=<.0001
Heterogeneity:	Q=2.30 (df=1)	p=0.1296	I^2=56.5%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2055	I^2=37.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.147: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

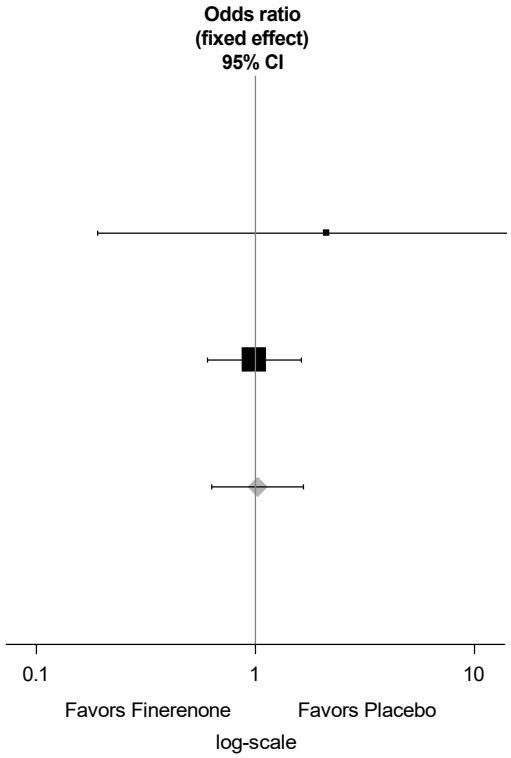
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	7 / 221	13.4	0.59 [0.17,2.06]	
FIGARO-DKD	28 / 2326	39 / 2302	86.6	0.71 [0.43,1.15]	
Total	32 / 2536	46 / 2523		0.69 [0.44,1.09]	Z=-1.60, p=0.1103
Heterogeneity:	Q=0.07 (df=1)	p=0.7976	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.148: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

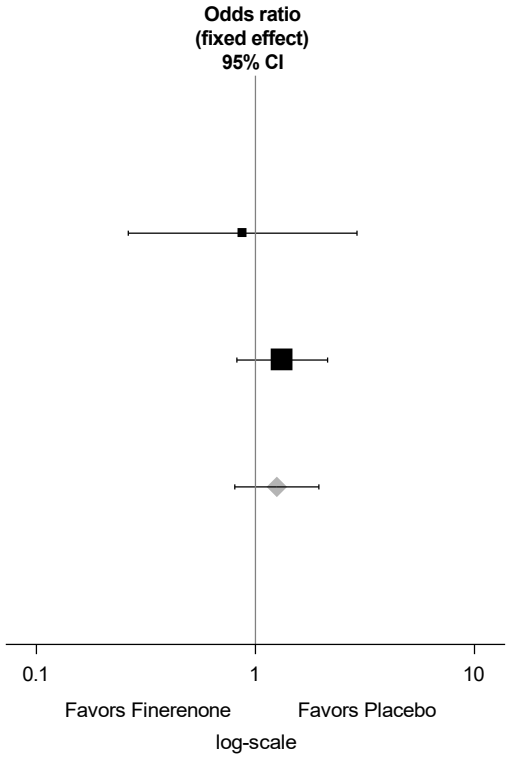
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	4.0	2.12 [0.19,23.50]	
FIGARO-DKD	32 / 2326	32 / 2302	96.0	0.99 [0.60,1.62]	
Total	34 / 2536	33 / 2523		1.02 [0.63,1.66]	Z=0.09, p=0.9270
Heterogeneity:	Q=0.37 (df=1)	p=0.5446	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.149: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

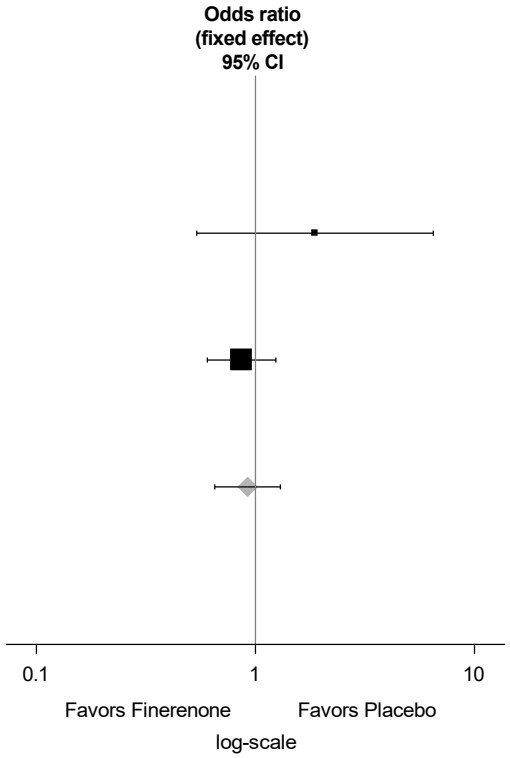
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	6 / 221	13.6	0.87 [0.26,2.91]	
FIGARO-DKD	40 / 2326	30 / 2302	86.4	1.33 [0.82,2.13]	
Total	45 / 2536	36 / 2523		1.25 [0.80,1.95]	Z=1.00, p=0.3187
Heterogeneity:	Q=0.40 (df=1)	p=0.5282	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.150: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

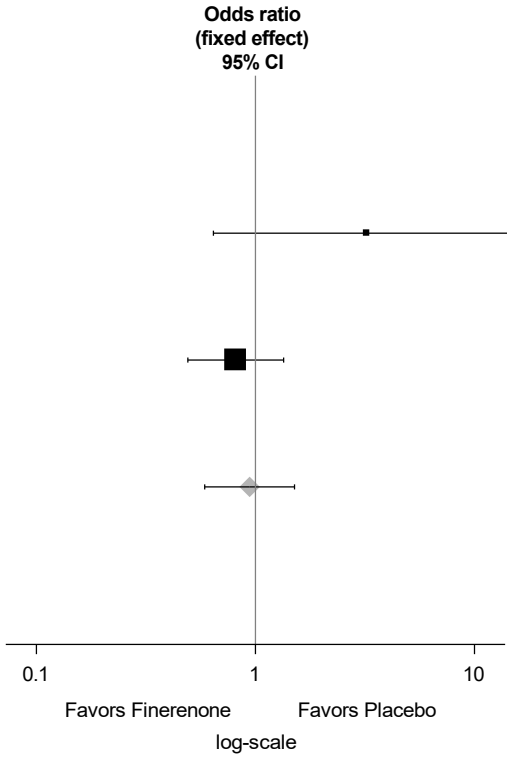
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	4 / 221	7.8	1.87 [0.54,6.49]	
FIGARO-DKD	57 / 2326	65 / 2302	92.2	0.86 [0.60,1.24]	
Total	64 / 2536	69 / 2523		0.92 [0.65,1.30]	Z=-0.47, p=0.6382
Heterogeneity:	Q=1.37 (df=1)	p=0.2425	I^2=26.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.151: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

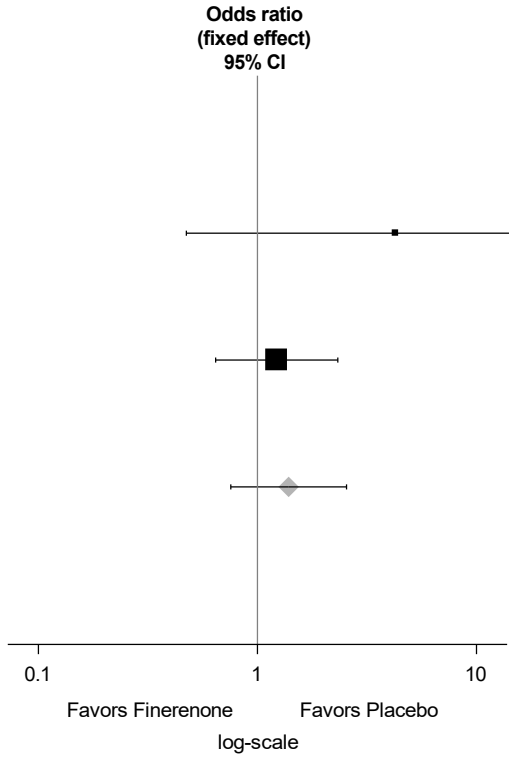
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	6 / 210	2 / 221	8.9	3.22 [0.64,16.14]	
FIGARO-DKD	28 / 2326	34 / 2302	91.1	0.81 [0.49,1.34]	
Total	34 / 2536	36 / 2523		0.94 [0.59,1.51]	Z=-0.25, p=0.7989
Heterogeneity:	Q=2.56 (df=1)	p=0.1093	I^2=61.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.152: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

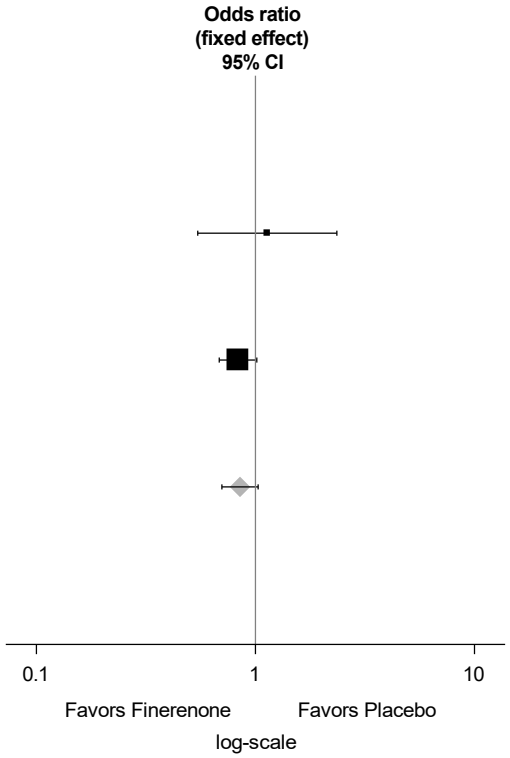
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	1 / 221	7.9	4.27 [0.47,38.54]	
FIGARO-DKD	21 / 2326	17 / 2302	92.1	1.22 [0.64,2.33]	
Total	25 / 2536	18 / 2523		1.39 [0.76,2.55]	Z=1.06, p=0.2906
Heterogeneity:	Q=1.15 (df=1)	p=0.2836	I^2=13.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.153: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

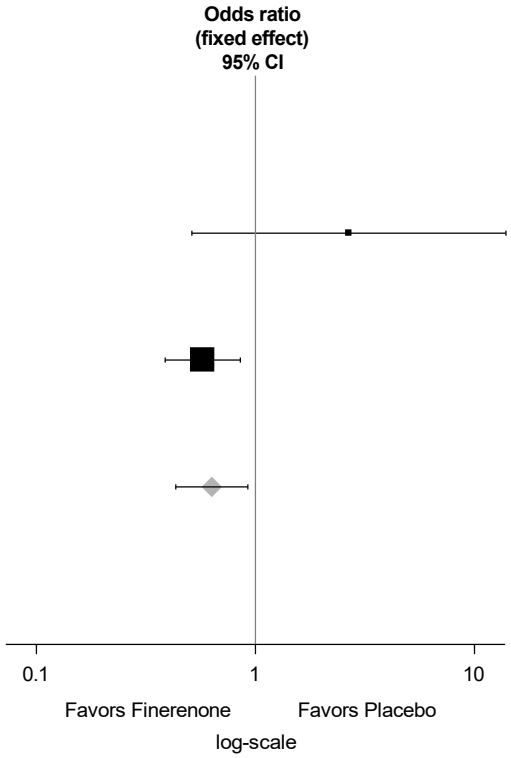
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	16 / 210	15 / 221	6.8	1.13 [0.55,2.35]	
FIGARO-DKD	202 / 2326	236 / 2302	93.2	0.83 [0.68,1.01]	
Total	218 / 2536	251 / 2523		0.85 [0.70,1.03]	Z=-1.67, p=0.0948
Heterogeneity:	Q=0.63 (df=1)	p=0.4257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.154: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

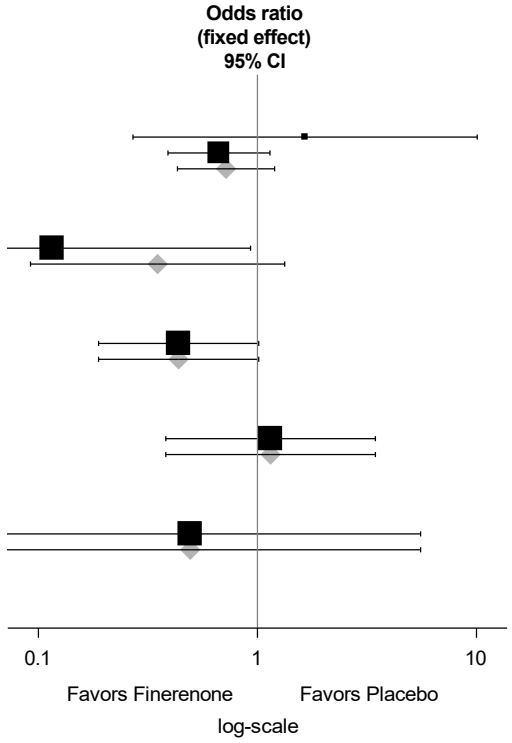
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	2 / 221	5.4	2.67 [0.51,13.92]	
FIGARO-DKD	40 / 2326	68 / 2302	94.6	0.57 [0.39,0.85]	
Total	45 / 2536	70 / 2523		0.63 [0.43,0.92]	Z=-2.37, p=0.0176
Heterogeneity:	Q=3.15 (df=1)	p=0.0760	I^2=68.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.154.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

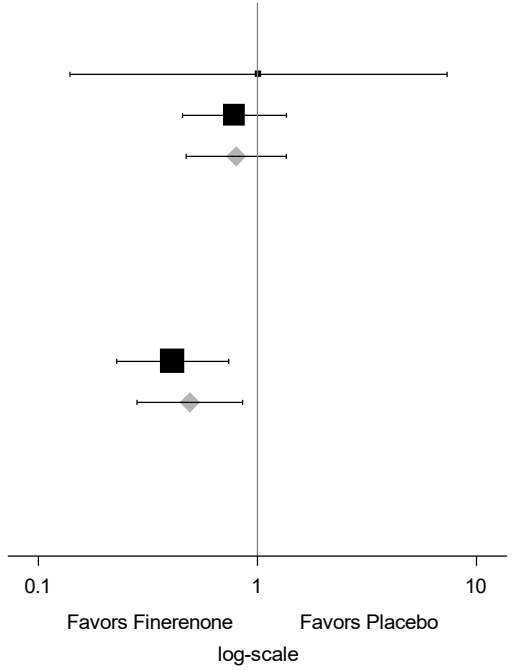
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	3 / 103	2 / 112	8.1	1.65 [0.27,10.08]	
FIGARO-DKD	23 / 1114	34 / 1110	91.9	0.67 [0.39,1.14]	
Total	26 / 1217	36 / 1222		0.72 [0.43,1.20]	Z=-1.27, p=0.2050
Heterogeneity:	Q=0.88 (df=1)	p=0.3470	I^2=0.0%		
North America					
FIDELIO-DKD	2 / 42	0 / 40	0.0	283E9 [283E9,283E9]	
FIGARO-DKD	1 / 292	8 / 277	100.0	0.12 [0.01,0.93]	
Total	3 / 334	8 / 317		0.35 [0.09,1.33]	Z=-1.54, p=0.1236
Heterogeneity:	Q=1.08 (df=1)	p=0.2976	I^2=7.8%		
Asia					
FIDELIO-DKD	0 / 39	0 / 41	0.0	-	
FIGARO-DKD	8 / 522	18 / 523	100.0	0.44 [0.19,1.01]	
Total	8 / 561	18 / 564		0.44 [0.19,1.01]	Z=-1.93, p=0.0537
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 21	0 / 24	0.0	-	
FIGARO-DKD	7 / 322	6 / 316	100.0	1.15 [0.38,3.45]	
Total	7 / 343	6 / 340		1.15 [0.38,3.45]	Z=0.25, p=0.8058
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 5	0 / 4	0.0	-	
FIGARO-DKD	1 / 76	2 / 76	100.0	0.49 [0.04,5.56]	
Total	1 / 81	2 / 80		0.49 [0.04,5.56]	Z=-0.57, p=0.5674
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.90 (df=4)	p=0.5748	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.154.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

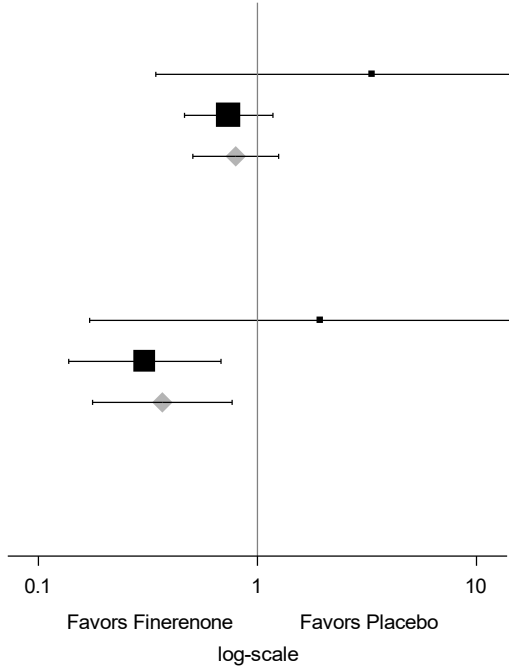
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	2 / 88	2 / 89	7.0	1.01 [0.14,7.35]	
FIGARO-DKD	24 / 811	30 / 803	93.0	0.79 [0.46,1.36]	
Total	26 / 899	32 / 892		0.80 [0.47,1.35]	Z=-0.83, p=0.4053
Heterogeneity:	Q=0.06 (df=1)	p=0.8097	I^2=0.0%		
Absent					
FIDELIO-DKD	3 / 122	0 / 132	0.0	143E9 [143E9,143E9]	
FIGARO-DKD	16 / 1515	38 / 1499	100.0	0.41 [0.23,0.74]	
Total	19 / 1637	38 / 1631		0.49 [0.28,0.86]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.36 (df=1)	p=0.5500	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.56 (df=1)	p=0.2112	I^2=36.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.154.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

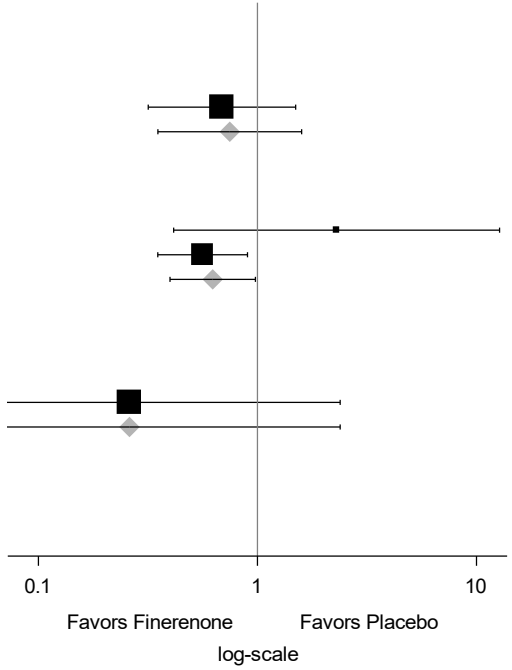
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	3 / 144	1 / 158	4.0	3.34 [0.34,32.48]	
FIGARO-DKD	32 / 1719	42 / 1679	96.0	0.74 [0.46,1.18]	
Total	35 / 1863	43 / 1837		0.80 [0.51,1.25]	Z=-0.99, p=0.3211
Heterogeneity:	Q=1.62 (df=1)	p=0.2025	I^2=38.4%		
> 4.5					
FIDELIO-DKD	2 / 66	1 / 63	9.8	1.94 [0.17,21.91]	
FIGARO-DKD	8 / 607	26 / 622	90.2	0.31 [0.14,0.68]	
Total	10 / 673	27 / 685		0.37 [0.18,0.77]	Z=-2.67, p=0.0075
Heterogeneity:	Q=2.00 (df=1)	p=0.1569	I^2=50.1%		
Subgroup Heterogeneity:	Q=3.08 (df=1)	p=0.0791	I^2=67.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.154.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

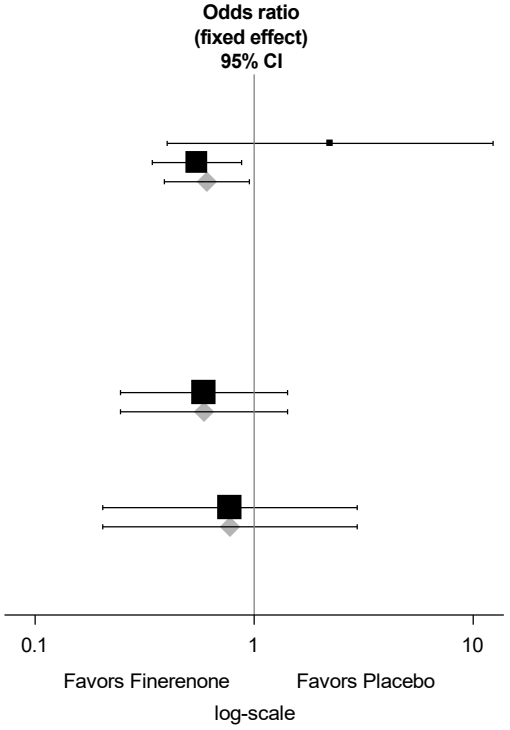
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	1 / 64	0 / 54	0.0	899E8 [899E8,899E8]	
FIGARO-DKD	11 / 693	16 / 699	100.0	0.69 [0.32,1.49]	
Total	12 / 757	16 / 753		0.75 [0.35,1.59]	Z=-0.75, p=0.4504
Heterogeneity:	Q=0.04 (df=1)	p=0.8352	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	4 / 138	2 / 156	7.0	2.30 [0.41,12.75]	
FIGARO-DKD	28 / 1560	48 / 1524	93.0	0.56 [0.35,0.90]	
Total	32 / 1698	50 / 1680		0.62 [0.40,0.98]	Z=-2.05, p=0.0400
Heterogeneity:	Q=2.41 (df=1)	p=0.1202	I^2=58.6%		
>= 160					
FIDELIO-DKD	0 / 8	0 / 11	0.0	-	
FIGARO-DKD	1 / 73	4 / 79	100.0	0.26 [0.03,2.39]	
Total	1 / 81	4 / 90		0.26 [0.03,2.39]	Z=-1.19, p=0.2338
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=2)	p=0.6684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.154.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

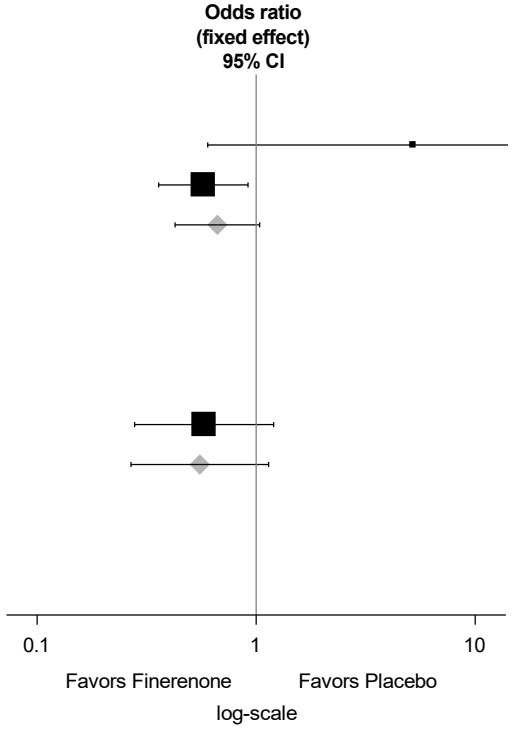
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	4 / 139	2 / 152	7.0	2.22 [0.40,12.33]	
FIGARO-DKD	28 / 1658	49 / 1612	93.0	0.55 [0.34,0.88]	
Total	32 / 1797	51 / 1764		0.61 [0.39,0.95]	Z=-2.18, p=0.0292
Heterogeneity:	Q=2.39 (df=1)	p=0.1223	I^2=58.1%		
Black					
FIDELIO-DKD	1 / 10	0 / 9	0.0	232E9 [232E9,232E9]	
FIGARO-DKD	0 / 70	0 / 74	0.0	-	
Total	1 / 80	0 / 83		338E9 [338E9,338E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 39	0 / 44	0.0	-	
FIGARO-DKD	8 / 464	14 / 485	100.0	0.59 [0.25,1.42]	
Total	8 / 503	14 / 529		0.59 [0.25,1.42]	Z=-1.18, p=0.2393
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 22	0 / 16	0.0	-	
FIGARO-DKD	4 / 134	5 / 131	100.0	0.78 [0.20,2.95]	
Total	4 / 156	5 / 147		0.78 [0.20,2.95]	Z=-0.37, p=0.7093
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=3)	p=0.9886	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.154.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

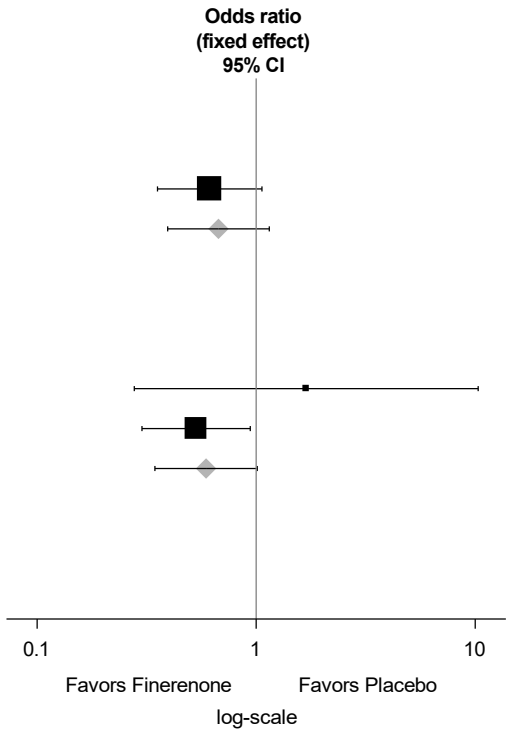
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	5 / 152	1 / 154	4.5	5.20 [0.60,45.08]	
FIGARO-DKD	28 / 1610	49 / 1638	95.5	0.57 [0.36,0.92]	
Total	33 / 1762	50 / 1792		0.66 [0.43,1.04]	Z=-1.80, p=0.0721
Heterogeneity:	Q=3.87 (df=1)	p=0.0493	I^2=74.1%		
Female					
FIDELIO-DKD	0 / 58	1 / 67	0.0	0.00 [0.00,21E296]	
FIGARO-DKD	12 / 716	19 / 664	100.0	0.58 [0.28,1.20]	
Total	12 / 774	20 / 731		0.55 [0.27,1.14]	Z=-1.61, p=0.1085
Heterogeneity:	Q=0.01 (df=1)	p=0.9032	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6703	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.154.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

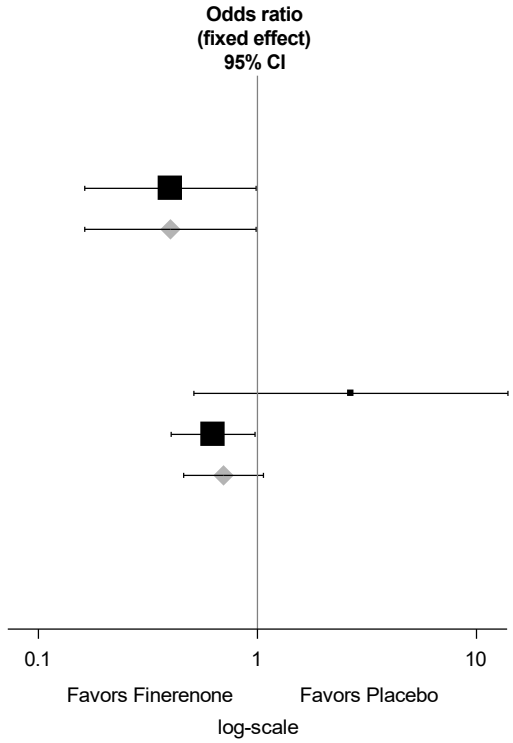
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	2 / 98	0 / 96	0.0	118E9 [118E9,118E9]	
FIGARO-DKD	21 / 1416	34 / 1420	100.0	0.61 [0.35,1.06]	
Total	23 / 1514	34 / 1516		0.67 [0.39,1.15]	Z=-1.45, p=0.1458
Heterogeneity:	Q=0.11 (df=1)	p=0.7427	I^2=0.0%		
>= 65					
FIDELIO-DKD	3 / 112	2 / 125	9.0	1.69 [0.28,10.32]	
FIGARO-DKD	19 / 910	34 / 882	91.0	0.53 [0.30,0.94]	
Total	22 / 1022	36 / 1007		0.59 [0.34,1.01]	Z=-1.92, p=0.0550
Heterogeneity:	Q=1.43 (df=1)	p=0.2312	I^2=30.2%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7360	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure B2.2.154.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

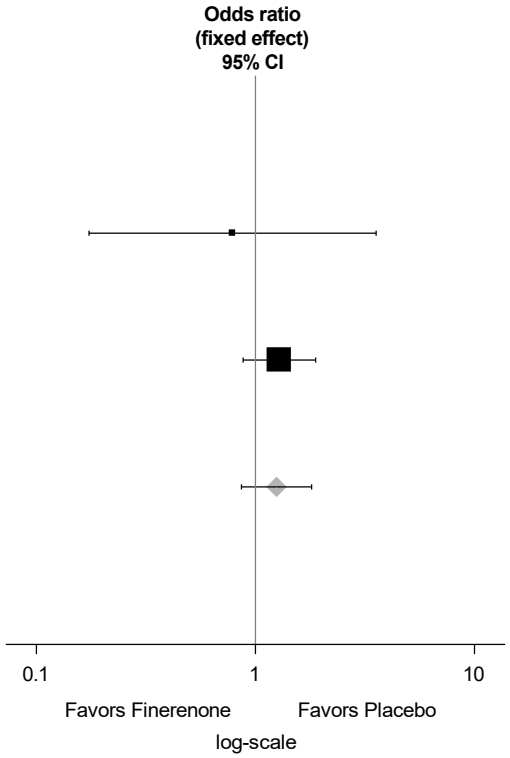
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	0 / 0	0 / 0	0.0	-	
FIGARO-DKD	7 / 363	16 / 342	100.0	0.40 [0.16,0.99]	
Total	7 / 363	16 / 342		0.40 [0.16,0.99]	Z=-1.99, p=0.0466
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Very High					
FIDELIO-DKD	5 / 210	2 / 221	6.7	2.67 [0.51,13.92]	
FIGARO-DKD	33 / 1963	52 / 1960	93.3	0.63 [0.40,0.97]	
Total	38 / 2173	54 / 2181		0.70 [0.46,1.06]	Z=-1.67, p=0.0957
Heterogeneity:	Q=2.76 (df=1)	p=0.0964	I^2=63.8%		
Subgroup Heterogeneity:	Q=1.21 (df=1)	p=0.2708	I^2=17.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure B2.2.155: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

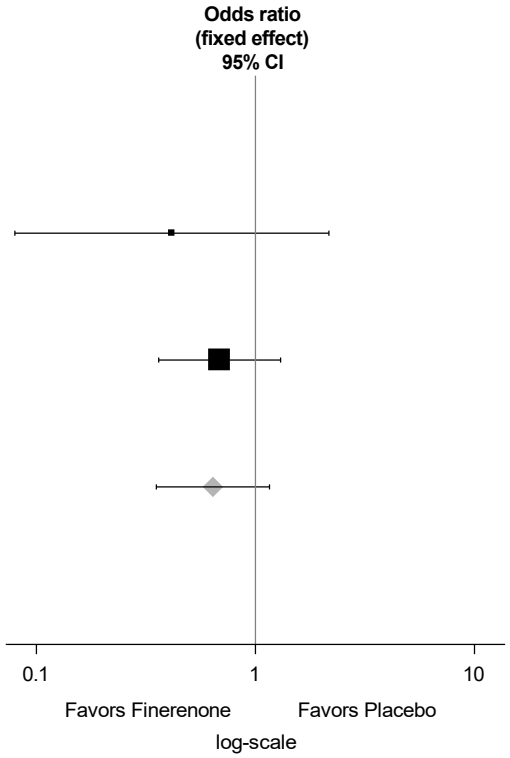
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	4 / 221	6.0	0.79 [0.17,3.56]	
FIGARO-DKD	62 / 2326	48 / 2302	94.0	1.29 [0.88,1.88]	
Total	65 / 2536	52 / 2523		1.25 [0.86,1.80]	Z=1.18, p=0.2391
Heterogeneity:	Q=0.38 (df=1)	p=0.5355	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.156: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

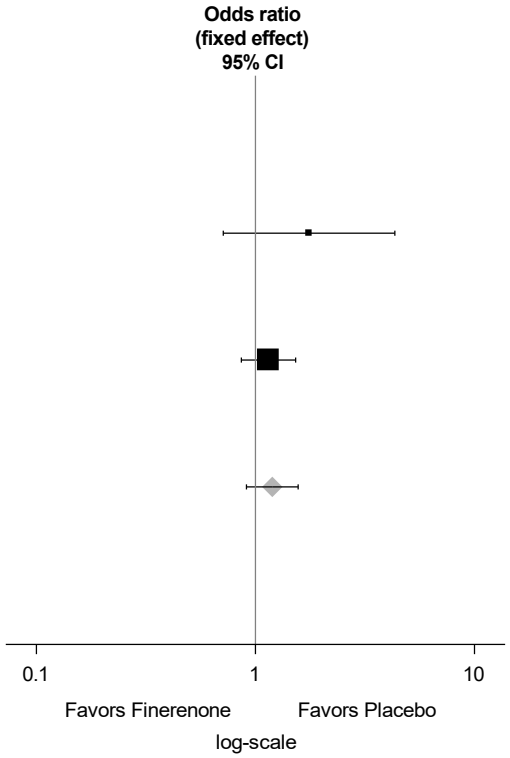
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	5 / 221	13.1	0.42 [0.08,2.16]	
FIGARO-DKD	16 / 2326	23 / 2302	86.9	0.69 [0.36,1.30]	
Total	18 / 2536	28 / 2523		0.64 [0.35,1.16]	Z=-1.47, p=0.1407
Heterogeneity:	Q=0.31 (df=1)	p=0.5782	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.157: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

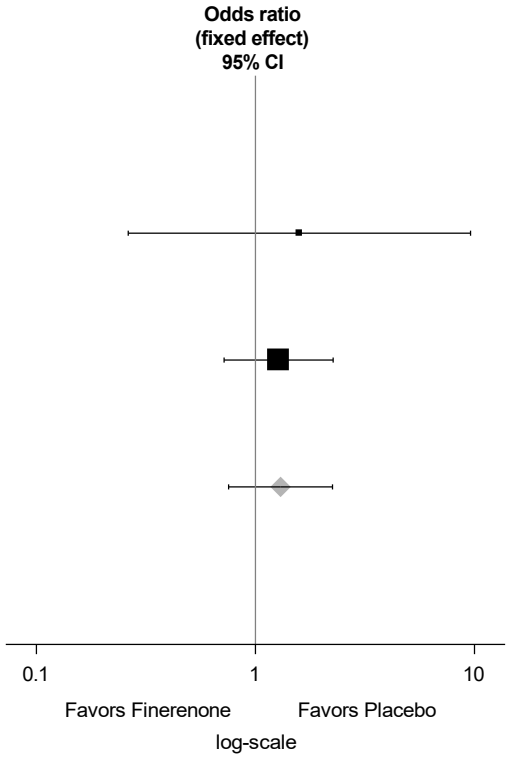
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	13 / 210	8 / 221	9.1	1.76 [0.71,4.33]	
FIGARO-DKD	106 / 2326	92 / 2302	90.9	1.15 [0.86,1.53]	
Total	119 / 2536	100 / 2523		1.19 [0.91,1.57]	Z=1.28, p=0.2015
Heterogeneity:	Q=0.78 (df=1)	p=0.3768	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.158: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

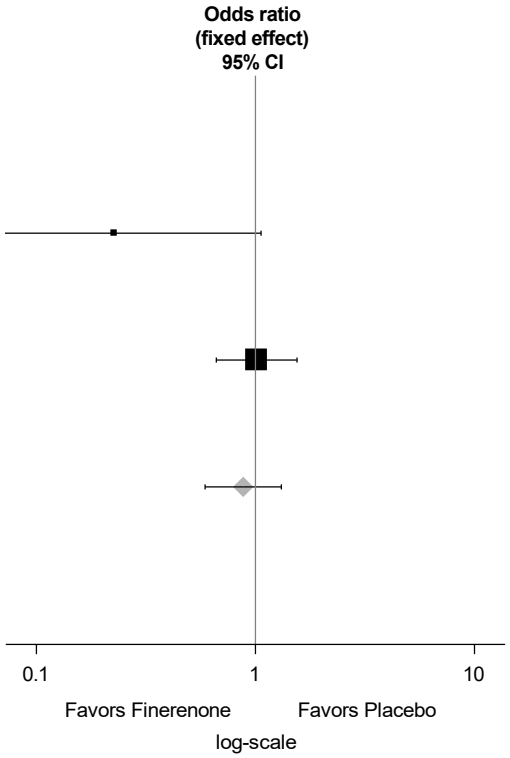
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	9.2	1.59 [0.26,9.59]	
FIGARO-DKD	27 / 2326	21 / 2302	90.8	1.28 [0.72,2.26]	
Total	30 / 2536	23 / 2523		1.30 [0.75,2.25]	Z=0.95, p=0.3435
Heterogeneity:	Q=0.05 (df=1)	p=0.8207	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.159: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

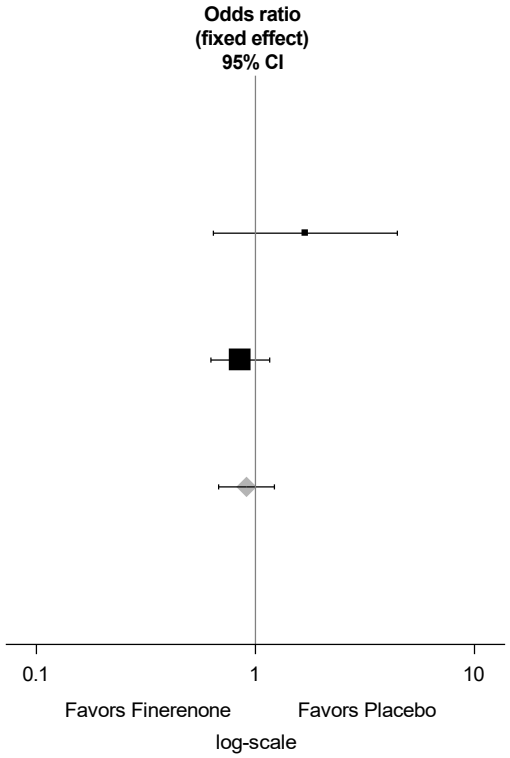
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	9 / 221	7.0	0.23 [0.05,1.06]	
FIGARO-DKD	44 / 2326	43 / 2302	93.0	1.01 [0.66,1.55]	
Total	46 / 2536	52 / 2523		0.88 [0.59,1.31]	Z=-0.63, p=0.5293
Heterogeneity:	Q=3.39 (df=1)	p=0.0655	I^2=70.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.160: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

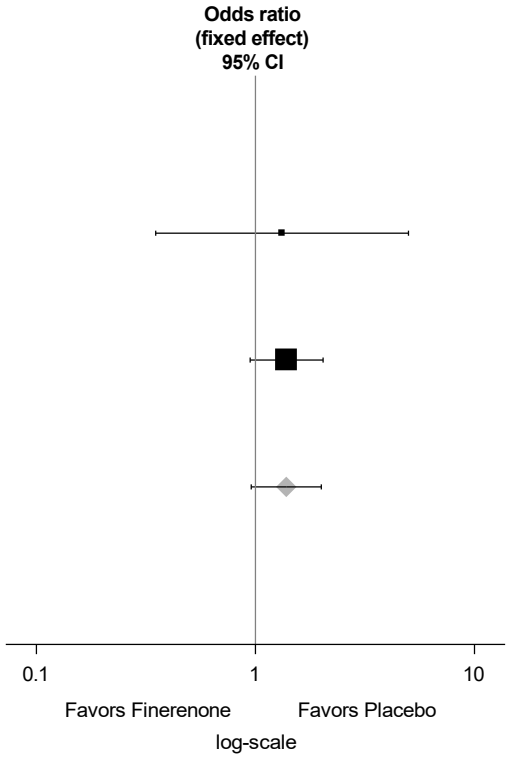
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	11 / 210	7 / 221	9.3	1.69 [0.64,4.44]	
FIGARO-DKD	78 / 2326	90 / 2302	90.7	0.85 [0.63,1.16]	
Total	89 / 2536	97 / 2523		0.91 [0.68,1.22]	Z=-0.63, p=0.5298
Heterogeneity:	Q=1.74 (df=1)	p=0.1867	I^2=42.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.161: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

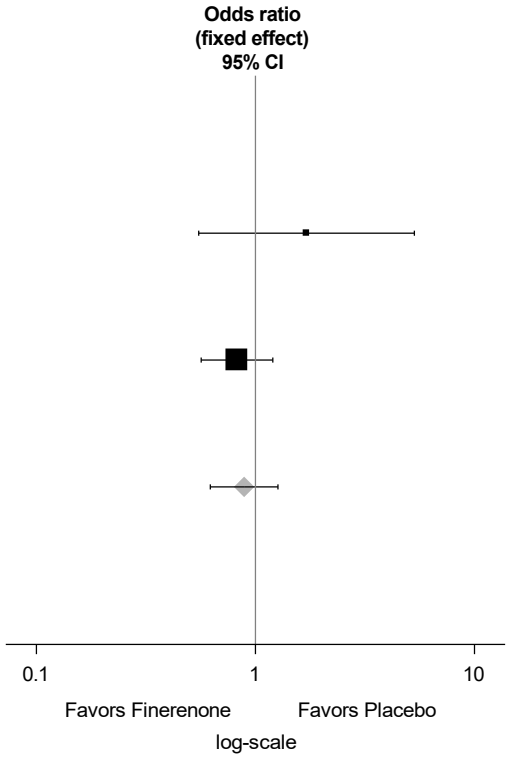
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	4 / 221	7.7	1.32 [0.35,5.00]	
FIGARO-DKD	64 / 2326	46 / 2302	92.3	1.39 [0.95,2.04]	
Total	69 / 2536	50 / 2523		1.38 [0.96,2.00]	Z=1.72, p=0.0847
Heterogeneity:	Q=0.00 (df=1)	p=0.9463	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.162: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

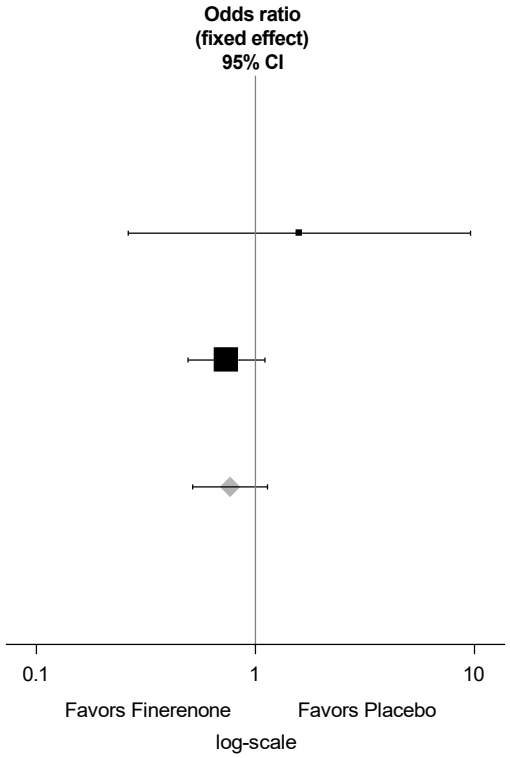
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	5 / 221	9.9	1.71 [0.55,5.32]	
FIGARO-DKD	51 / 2326	61 / 2302	90.1	0.82 [0.57,1.20]	
Total	59 / 2536	66 / 2523		0.89 [0.62,1.27]	Z=-0.66, p=0.5117
Heterogeneity:	Q=1.44 (df=1)	p=0.2303	I^2=30.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.163: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

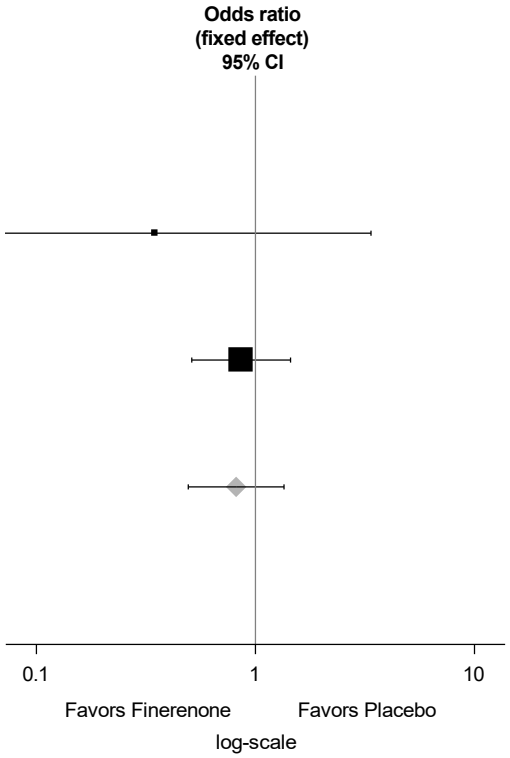
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	4.8	1.59 [0.26,9.59]	
FIGARO-DKD	42 / 2326	56 / 2302	95.2	0.74 [0.49,1.10]	
Total	45 / 2536	58 / 2523		0.77 [0.52,1.14]	Z=-1.33, p=0.1840
Heterogeneity:	Q=0.66 (df=1)	p=0.4154	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.164: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

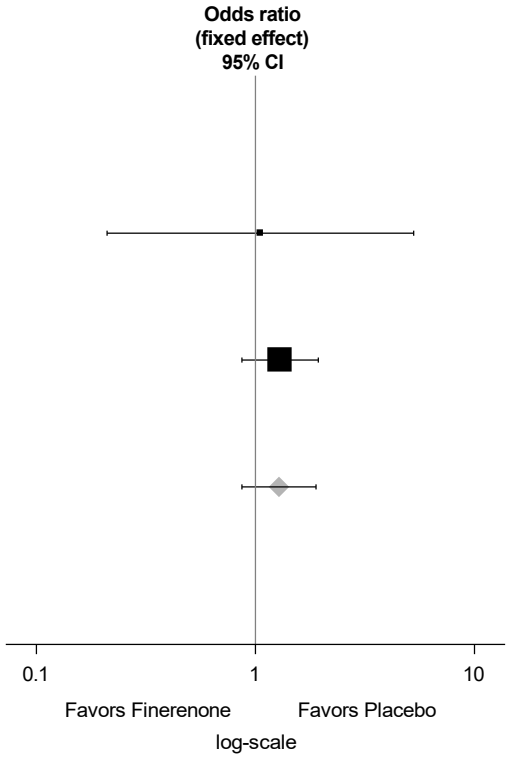
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1 / 210	3 / 221	5.0	0.35 [0.04,3.37]	
FIGARO-DKD	27 / 2326	31 / 2302	95.0	0.86 [0.51,1.45]	
Total	28 / 2536	34 / 2523		0.82 [0.49,1.35]	Z=-0.79, p=0.4290
Heterogeneity:	Q=0.58 (df=1)	p=0.4456	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.165: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

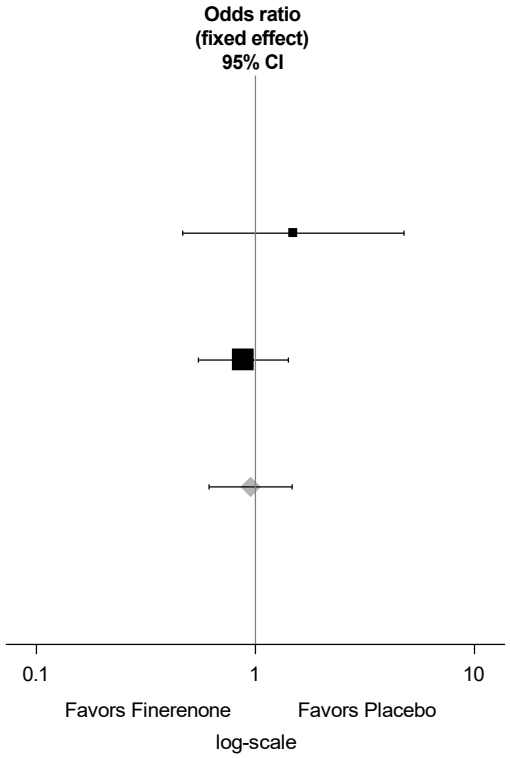
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	3 / 221	5.8	1.05 [0.21,5.28]	
FIGARO-DKD	56 / 2326	43 / 2302	94.2	1.30 [0.87,1.94]	
Total	59 / 2536	46 / 2523		1.28 [0.87,1.89]	Z=1.24, p=0.2136
Heterogeneity:	Q=0.06 (df=1)	p=0.8065	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.166: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

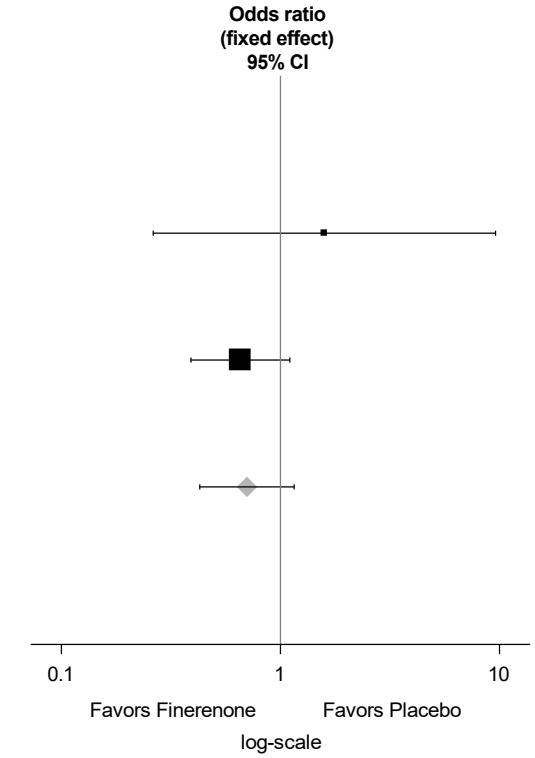
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	5 / 221	14.2	1.49 [0.47,4.77]	
FIGARO-DKD	33 / 2326	37 / 2302	85.8	0.88 [0.55,1.41]	
Total	40 / 2536	42 / 2523		0.95 [0.61,1.47]	Z=-0.23, p=0.8188
Heterogeneity:	Q=0.67 (df=1)	p=0.4124	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.167: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

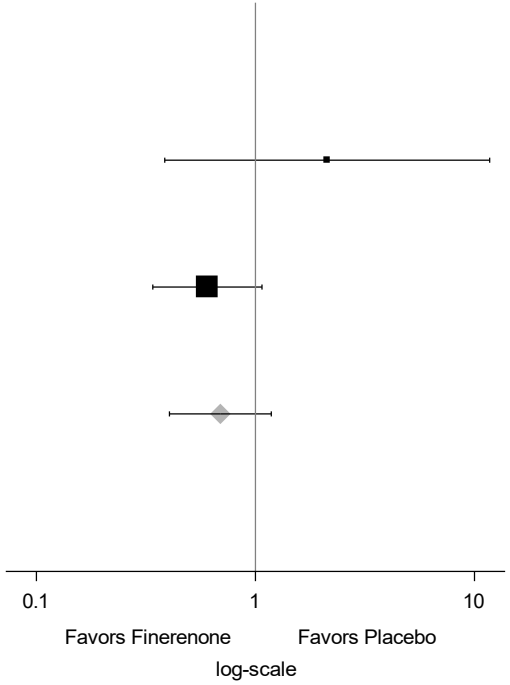
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	2 / 221	7.7	1.59 [0.26,9.59]	
FIGARO-DKD	24 / 2326	36 / 2302	92.3	0.66 [0.39,1.10]	
Total	27 / 2536	38 / 2523		0.70 [0.43,1.16]	Z=-1.39, p=0.1647
Heterogeneity:	Q=0.85 (df=1)	p=0.3554	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.168: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

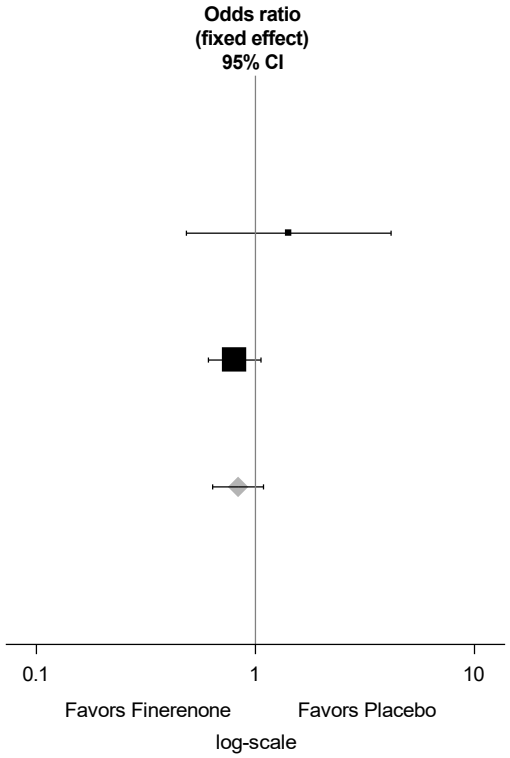
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	2 / 221	10.1	2.13 [0.39,11.73]	
FIGARO-DKD	19 / 2326	31 / 2302	89.9	0.60 [0.34,1.07]	
Total	23 / 2536	33 / 2523		0.69 [0.40,1.18]	Z=-1.35, p=0.1768
Heterogeneity:	Q=1.88 (df=1)	p=0.1705	I^2=46.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.169: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

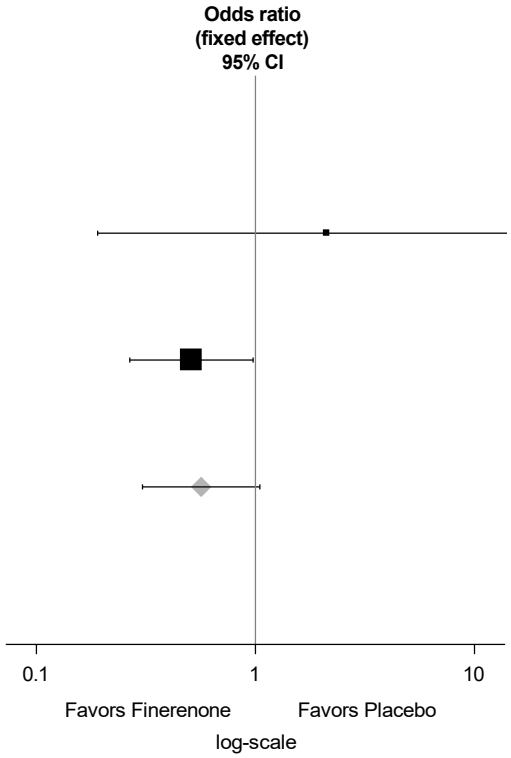
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 210	6 / 221	6.2	1.42 [0.48,4.16]	
FIGARO-DKD	96 / 2326	117 / 2302	93.8	0.80 [0.61,1.06]	
Total	104 / 2536	123 / 2523		0.83 [0.64,1.09]	Z=-1.34, p=0.1803
Heterogeneity:	Q=1.01 (df=1)	p=0.3160	I^2=0.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.170: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

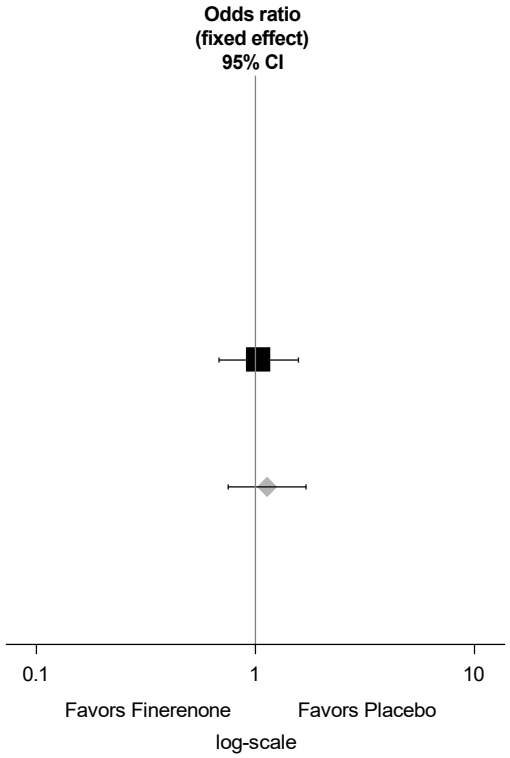
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	1 / 221	6.8	2.12 [0.19,23.50]	
FIGARO-DKD	14 / 2326	27 / 2302	93.2	0.51 [0.27,0.98]	
Total	16 / 2536	28 / 2523		0.57 [0.30,1.05]	Z=-1.81, p=0.0697
Heterogeneity:	Q=1.25 (df=1)	p=0.2636	I^2=20.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.171: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

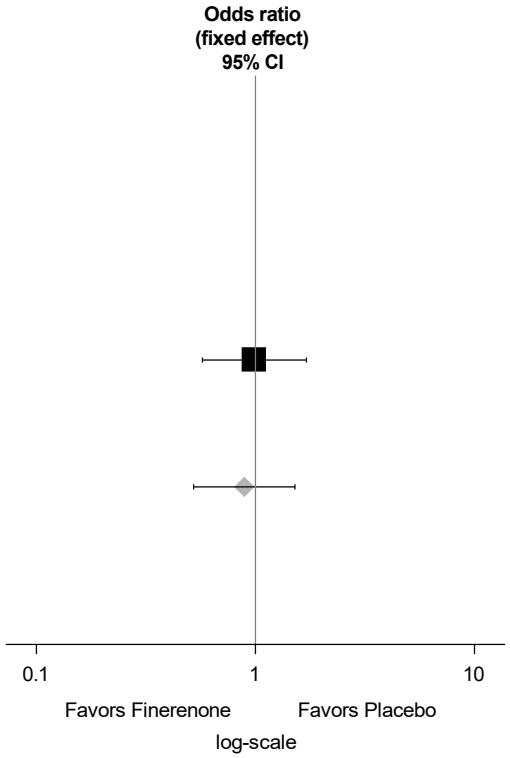
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	4 / 210	0 / 221	0.0	11E10 [11E10,11E10]	
FIGARO-DKD	46 / 2326	44 / 2302	100.0	1.04 [0.68,1.57]	
Total	50 / 2536	44 / 2523		1.13 [0.75,1.70]	Z=0.59, p=0.5575
Heterogeneity:	Q=0.17 (df=1)	p=0.6806	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.172: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	0 / 210	3 / 221	0.0	0.00 [0.00,85E295]	
FIGARO-DKD	26 / 2326	26 / 2302	100.0	0.99 [0.57,1.71]	
Total	26 / 2536	29 / 2523		0.89 [0.52,1.51]	Z=-0.43, p=0.6652
Heterogeneity:	Q=0.15 (df=1)	p=0.7012	I^2=0.0%		

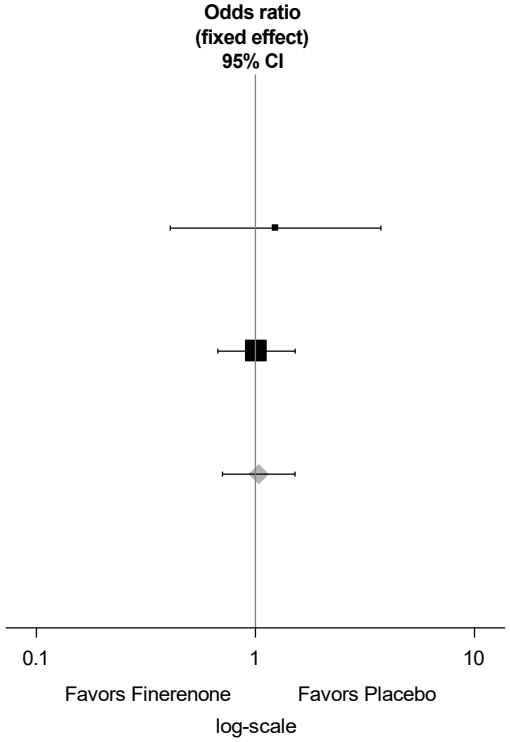


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.173: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

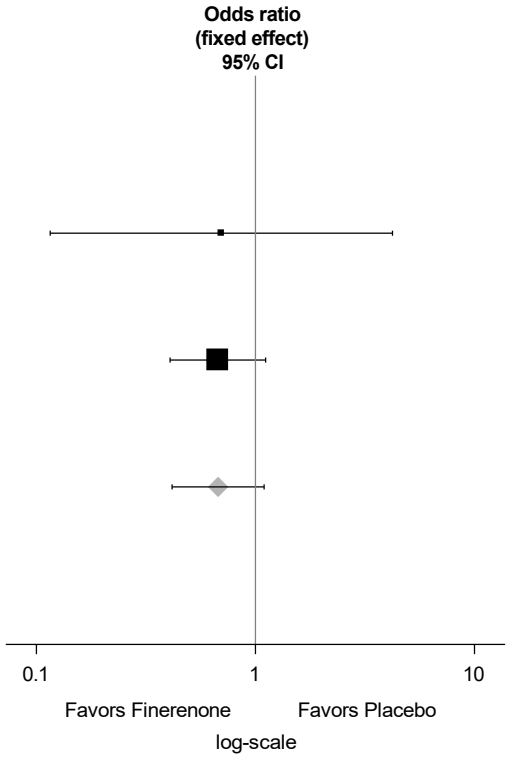
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	7 / 210	6 / 221	11.9	1.24 [0.41,3.74]	
FIGARO-DKD	48 / 2326	47 / 2302	88.1	1.01 [0.67,1.52]	
Total	55 / 2536	53 / 2523		1.04 [0.71,1.52]	Z=0.18, p=0.8580
Heterogeneity:	Q=0.11 (df=1)	p=0.7388	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.174: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

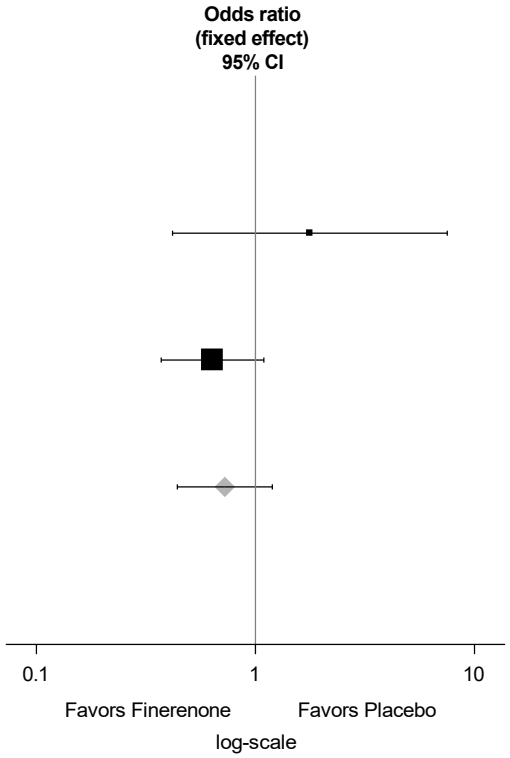
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2 / 210	3 / 221	7.2	0.70 [0.12,4.22]	
FIGARO-DKD	26 / 2326	38 / 2302	92.8	0.67 [0.41,1.11]	
Total	28 / 2536	41 / 2523		0.68 [0.42,1.10]	Z=-1.59, p=0.1117
Heterogeneity:	Q=0.00 (df=1)	p=0.9692	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.175: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

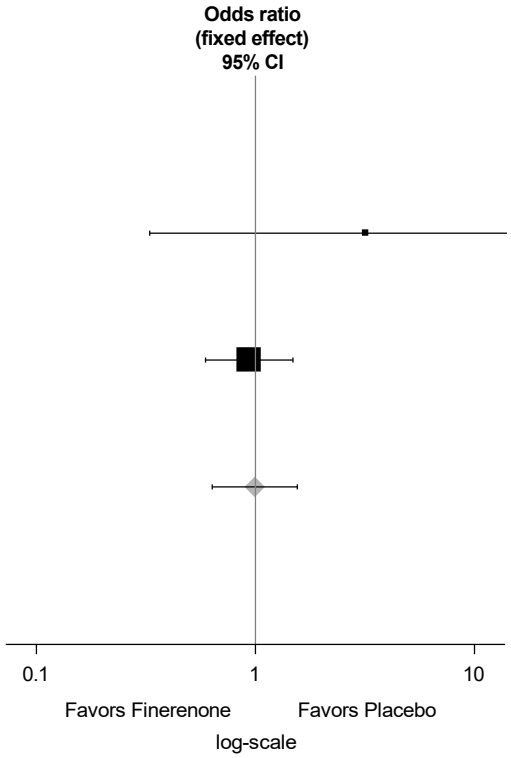
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	5 / 210	3 / 221	12.2	1.77 [0.42,7.51]	
FIGARO-DKD	22 / 2326	34 / 2302	87.8	0.64 [0.37,1.09]	
Total	27 / 2536	37 / 2523		0.72 [0.44,1.19]	Z=-1.26, p=0.2063
Heterogeneity:	Q=1.69 (df=1)	p=0.1932	I^2=40.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.176: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

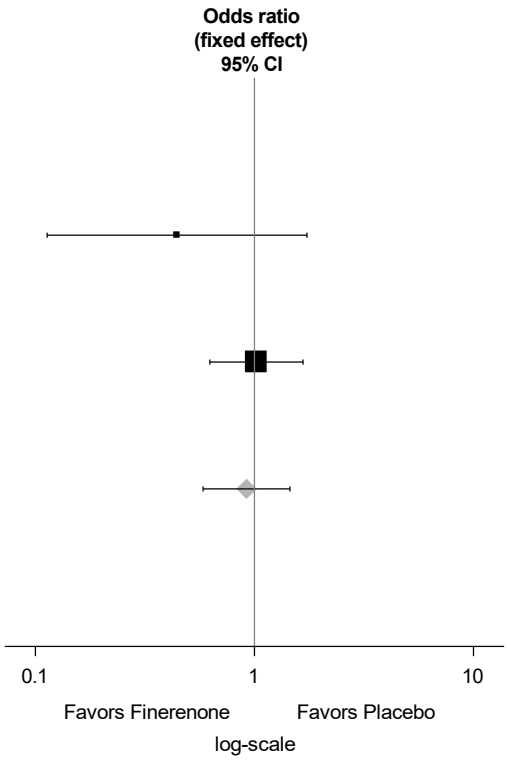
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	1 / 221	3.9	3.19 [0.33,30.90]	
FIGARO-DKD	36 / 2326	38 / 2302	96.1	0.94 [0.59,1.48]	
Total	39 / 2536	39 / 2523		0.99 [0.63,1.55]	Z=-0.03, p=0.9744
Heterogeneity:	Q=1.08 (df=1)	p=0.2997	I^2=7.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure B2.2.177: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR >= 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	3 / 210	7 / 221	11.4	0.44 [0.11,1.74]	
FIGARO-DKD	33 / 2326	32 / 2302	88.6	1.02 [0.63,1.67]	
Total	36 / 2536	39 / 2523		0.92 [0.58,1.45]	Z=-0.36, p=0.7199
Heterogeneity:	Q=1.27 (df=1)	p=0.2593	I^2=21.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

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4.2 Disposition

Table 4.2 / 1: Subject disposition (all enrolled Fidelio)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			13911
Screening failures			8177
Randomized	2866	2868	5734
GCP VIOLATIONS	33	27	60
Full analysis set	2833 (100.0%)	2841 (100.0%)	5674 (100.0%)
Study drug never administered	6 (0.2%)	10 (0.4%)	16 (0.3%)
Treated	2827 (99.8%)	2831 (99.6%)	5658 (99.7%)
Did not complete study	9 (0.3%)	9 (0.3%)	18 (0.3%)
WITHDRAWN CONSENT	4 (0.1%)	6 (0.2%)	10 (0.2%)
LOST TO FOLLOW-UP	5 (0.2%)	3 (0.1%)	8 (0.1%)
Completed study	2824 (99.7%)	2832 (99.7%)	5656 (99.7%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adds.sas 30JAN2023 15:21
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Table 4.2 / 2: Disposition: End of treatment (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Completed epoch	2011 (71.0%)	2040 (71.8%)	4051 (71.4%)
Not completed	822 (29.0%)	801 (28.2%)	1623 (28.6%)
Primary reason			
ADVERSE EVENT	309 (10.9%)	296 (10.4%)	605 (10.7%)
DEATH	130 (4.6%)	157 (5.5%)	287 (5.1%)
WITHDRAWAL BY SUBJECT	158 (5.6%)	169 (5.9%)	327 (5.8%)
LOST TO FOLLOW-UP	5 (0.2%)	4 (0.1%)	9 (0.2%)
PREGNANCY	0	1 (<0.1%)	1 (<0.1%)
PROGRESSIVE DISEASE	0	1 (<0.1%)	1 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	18 (0.6%)	7 (0.2%)	25 (0.4%)
PHYSICIAN DECISION	151 (5.3%)	112 (3.9%)	263 (4.6%)
TECHNICAL PROBLEMS	32 (1.1%)	32 (1.1%)	64 (1.1%)
DETERIORATION OF GENERAL CONDITIONS	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
PROTOCOL DEVIATION	7 (0.2%)	14 (0.5%)	21 (0.4%)
SITE TERMINATED BY SPONSOR	6 (0.2%)	2 (<0.1%)	8 (0.1%)
OTHER	5 (0.2%)	3 (0.1%)	8 (0.1%)

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adds.sas 30JAN2023 15:21
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4.3 Demographic characteristics

Table 4.3 / 1: Demographics (full analysis set Fidelio)

TEXT	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Race (N)			
WHITE	1777 (62.7%)	1815 (63.9%)	3592 (63.3%)
BLACK OR AFRICAN AMERICAN	140 (4.9%)	124 (4.4%)	264 (4.7%)
ASIAN	717 (25.3%)	723 (25.4%)	1440 (25.4%)
AMERICAN INDIAN OR ALASKA NATIVE	78 (2.8%)	76 (2.7%)	154 (2.7%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	11 (0.4%)	7 (0.2%)	18 (0.3%)
NOT REPORTED	9 (0.3%)	10 (0.4%)	19 (0.3%)
MULTIPLE	101 (3.6%)	86 (3.0%)	187 (3.3%)
Sex (N)			
Male	1953 (68.9%)	2030 (71.5%)	3983 (70.2%)
Female	880 (31.1%)	811 (28.5%)	1691 (29.8%)
Age (YEARS)			
n	2833	2841	5674
Mean	65.44	65.67	65.56
SD	8.94	9.16	9.05
Min	32.0	28.0	28.0
Q1	60.00	60.00	60.00
Median	66.00	66.00	66.00
Q3	72.00	72.00	72.00
Max	90.0	97.0	97.0
Run-in age group (years) category (N)			
18 - 44 years	49 (1.7%)	65 (2.3%)	114 (2.0%)
45 - 64 years	1156 (40.8%)	1109 (39.0%)	2265 (39.9%)
65 - 74 years	1197 (42.3%)	1203 (42.3%)	2400 (42.3%)
>= 75 years	431 (15.2%)	464 (16.3%)	895 (15.8%)
Age group (years) category 3 (N)			
< 65 years	1205 (42.5%)	1174 (41.3%)	2379 (41.9%)
>= 65 years	1628 (57.5%)	1667 (58.7%)	3295 (58.1%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	2376 (83.9%)	2397 (84.4%)	4773 (84.1%)
HISPANIC OR LATINO	447 (15.8%)	431 (15.2%)	878 (15.5%)
NOT REPORTED	10 (0.4%)	13 (0.5%)	23 (0.4%)

Table 4.3 / 1: Demographics (full analysis set Fidelio)

TEXT	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Region (N)			
Europe	1182 (41.7%)	1176 (41.4%)	2358 (41.6%)
North America	467 (16.5%)	477 (16.8%)	944 (16.6%)
Asia	790 (27.9%)	789 (27.8%)	1579 (27.8%)
Latin America	295 (10.4%)	298 (10.5%)	593 (10.5%)
Others	99 (3.5%)	101 (3.6%)	200 (3.5%)
Baseline Weight (kg)			
n	2825	2836	5661
Mean	86.79	87.54	87.17
SD	19.80	20.16	19.98
Min	40.0	34.0	34.0
Q1	72.70	73.10	73.00
Median	85.00	85.50	85.20
Q3	98.50	98.80	98.60
Max	182.8	188.9	188.9
Baseline weight (kg) category (N)			
missing	8 (0.3%)	5 (0.2%)	13 (0.2%)
< 60 kg	184 (6.5%)	158 (5.6%)	342 (6.0%)
60 - < 90 kg	1529 (54.0%)	1514 (53.3%)	3043 (53.6%)
>= 90 kg	1112 (39.3%)	1164 (41.0%)	2276 (40.1%)
Baseline Height (cm)			
n	2829	2841	5670
Mean	166.61	167.39	167.00
SD	9.55	9.75	9.66
Min	137.0	136.0	136.0
Q1	160.00	161.00	160.00
Median	167.00	168.00	167.50
Q3	173.00	174.00	174.00
Max	196.0	207.0	207.0

Table 4.3 / 1: Demographics (full analysis set Fidelio)

TEXT	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline Body Mass Index (kg/m2)			
n	2821	2836	5657
Mean	31.13	31.10	31.11
SD	6.03	6.00	6.01
Min	15.5	14.5	14.5
Q1	26.80	26.90	26.90
Median	30.40	30.30	30.40
Q3	34.30	34.50	34.40
Max	63.7	63.2	63.7
Baseline BMI (kg/m2) category 2 (N)			
missing	12 (0.4%)	5 (0.2%)	17 (0.3%)
< 30 kg/m2	1320 (46.6%)	1342 (47.2%)	2662 (46.9%)
>= 30 kg/m2	1501 (53.0%)	1494 (52.6%)	2995 (52.8%)
Baseline BMI (kg/m2) category 3 (N)			
missing	12 (0.4%)	5 (0.2%)	17 (0.3%)
< 20 kg/m2	22 (0.8%)	28 (1.0%)	50 (0.9%)
20 - < 25 kg/m2	348 (12.3%)	348 (12.2%)	696 (12.3%)
25 - < 30 kg/m2	950 (33.5%)	966 (34.0%)	1916 (33.8%)
30 - < 35 kg/m2	866 (30.6%)	846 (29.8%)	1712 (30.2%)
>= 35 kg/m2	635 (22.4%)	648 (22.8%)	1283 (22.6%)
Baseline Hip Circumference (cm)			
n	2822	2828	5650
Mean	107.17	107.19	107.18
SD	13.88	13.82	13.85
Min	42.0	48.3	42.0
Q1	98.00	98.20	98.00
Median	106.00	105.40	105.50
Q3	114.00	114.15	114.00
Max	203.2	170.0	203.2

Table 4.3 / 1: Demographics (full analysis set Fidelio)

TEXT	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline waist circumference (cm)			
n	2823	2832	5655
Mean	106.49	107.00	106.75
SD	15.00	15.41	15.21
Min	41.0	50.0	41.0
Q1	96.40	96.00	96.00
Median	105.60	106.00	106.00
Q3	116.00	117.00	116.00
Max	161.0	200.0	200.0
Baseline waist circumf. (cm) cat. (N)			
missing	10 (0.4%)	9 (0.3%)	19 (0.3%)
normal	335 (11.8%)	362 (12.7%)	697 (12.3%)
increased	547 (19.3%)	528 (18.6%)	1075 (18.9%)
substantially increased	1941 (68.5%)	1942 (68.4%)	3883 (68.4%)
Baseline waist-hip ratio (N)			
n	2821	2827	5648
Mean	1.00	1.00	1.00
SD	0.11	0.12	0.11
Min	0.6	0.5	0.5
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.05	1.05
Max	2.5	2.4	2.5
Smoking History (N)			
NEVER	1375 (48.5%)	1371 (48.3%)	2746 (48.4%)
FORMER	1044 (36.9%)	1078 (37.9%)	2122 (37.4%)
CURRENT	414 (14.6%)	392 (13.8%)	806 (14.2%)

Table 4.3 / 1: Demographics (full analysis set Fidelio)

TEXT	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Alcohol Use (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
ABSTINENT	1733 (61.2%)	1722 (60.6%)	3455 (60.9%)
LIGHT	946 (33.4%)	947 (33.3%)	1893 (33.4%)
MODERATE	143 (5.0%)	155 (5.5%)	298 (5.3%)
HEAVY	11 (0.4%)	16 (0.6%)	27 (0.5%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 30JAN2023 15:21
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4.4 Baseline characteristics

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline potassium (mmol/L)			
n	2832	2840	5672
Arithm. Mean	4.37	4.38	4.37
Arithm. SD	0.46	0.46	0.46
Min	2.6	2.6	2.6
Q1	4.10	4.10	4.10
Median	4.40	4.40	4.40
Q3	4.70	4.70	4.70
Max	6.2	6.9	6.9
Baseline ser. potassium (mmol/L) cat.(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<= 4.5 mmol/L	1881 (66.4%)	1861 (65.5%)	3742 (65.9%)
> 4.5 mmol/L	951 (33.6%)	979 (34.5%)	1930 (34.0%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<=4.8 mmol/L	2444 (86.3%)	2455 (86.4%)	4899 (86.3%)
>4.8 to <=5.0 mmol/L	191 (6.7%)	189 (6.7%)	380 (6.7%)
>5.0 mmol/L	197 (7.0%)	196 (6.9%)	393 (6.9%)
Basel. potass (mmol/L) median FAS (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1381 (48.7%)	1358 (47.8%)	2739 (48.3%)
> 4.30 mmol/L (median in FAS)	1451 (51.2%)	1482 (52.2%)	2933 (51.7%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	860 (30.4%)	851 (30.0%)	1711 (30.2%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	521 (18.4%)	507 (17.8%)	1028 (18.1%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	726 (25.6%)	736 (25.9%)	1462 (25.8%)
>4.6 mmol/L (>Q3 in FAS)	725 (25.6%)	746 (26.3%)	1471 (25.9%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	2830	2839	5669
Arithm. Mean	138.05	138.01	138.03
Arithm. SD	14.32	14.42	14.37
Min	77.0	82.3	77.0
Q1	128.67	128.67	128.67
Median	138.33	138.33	138.33
Q3	147.67	148.33	148.00
Max	197.0	195.3	197.0
Baseline SBP (mmHg) category (N)			
missing	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
< 130 mmHg	788 (27.8%)	778 (27.4%)	1566 (27.6%)
130 - < 160 mmHg	1900 (67.1%)	1922 (67.7%)	3822 (67.4%)
>= 160 mmHg	142 (5.0%)	139 (4.9%)	281 (5.0%)
Baseline SBP (mmHg) median for FAS (N)			
missing	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
<= 137.00 mmHg (median in FAS)	1322 (46.7%)	1324 (46.6%)	2646 (46.6%)
> 137.00 mmHg (median in FAS)	1508 (53.2%)	1515 (53.3%)	3023 (53.3%)
Baseline Diastolic Blood Pressure (mmHg)			
n	2830	2839	5669
Arithm. Mean	75.82	75.83	75.82
Arithm. SD	9.68	9.66	9.67
Min	39.7	44.3	39.7
Q1	69.33	69.67	69.67
Median	76.00	76.67	76.33
Q3	82.33	82.33	82.33
Max	109.3	102.7	109.3
Baseline Heart Rate (BEATS/MIN)			
n	2828	2839	5667
Arithm. Mean	72.30	72.23	72.27
Arithm. SD	11.50	11.32	11.41
Min	37.0	37.7	37.0
Q1	64.50	64.00	64.00
Median	72.00	72.00	72.00
Q3	79.67	79.67	79.67
Max	155.7	117.0	155.7

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	2832	2840	5672
Arithm. Mean	44.36	44.32	44.34
Arithm. SD	12.54	12.57	12.56
Min	15.8	15.8	15.8
Q1	34.55	34.70	34.60
Median	43.00	43.00	43.00
Q3	52.50	52.50	52.50
Max	107.2	104.2	107.2
Baseline eGFR (mL/min/1.73m2) cat.(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
< 25 mL/min/1.73m2	66 (2.3%)	69 (2.4%)	135 (2.4%)
25 - < 45 mL/min/1.73m2	1476 (52.1%)	1505 (53.0%)	2981 (52.5%)
45 - < 60 mL/min/1.73m2	972 (34.3%)	928 (32.7%)	1900 (33.5%)
>= 60 mL/min/1.73m2	318 (11.2%)	338 (11.9%)	656 (11.6%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
< 30 mL/min/1.73m2	342 (12.1%)	354 (12.5%)	696 (12.3%)
30 - < 60 mL/min/1.73m2	2172 (76.7%)	2148 (75.6%)	4320 (76.1%)
60 - < 90 mL/min/1.73m2	313 (11.0%)	332 (11.7%)	645 (11.4%)
>= 90 mL/min/1.73m2	5 (0.2%)	6 (0.2%)	11 (0.2%)
Screening eGFR (mL/min/1.73m2)			
n	2830	2840	5670
Arithm. Mean	44.02	44.22	44.12
Arithm. SD	11.30	11.29	11.30
Min	25.0	21.6	21.6
Q1	35.00	34.90	34.90
Median	43.40	43.65	43.50
Q3	52.30	52.30	52.30
Max	80.8	100.8	100.8
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
< 25 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
25 - < 45 mL/min/1.73m2	1558 (55.0%)	1546 (54.4%)	3104 (54.7%)
45 - < 60 mL/min/1.73m2	1062 (37.5%)	1071 (37.7%)	2133 (37.6%)
>= 60 mL/min/1.73m2	210 (7.4%)	222 (7.8%)	432 (7.6%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
< 30 mL/min/1.73m2	339 (12.0%)	300 (10.6%)	639 (11.3%)
30 - < 60 mL/min/1.73m2	2281 (80.5%)	2318 (81.6%)	4599 (81.1%)
60 - < 90 mL/min/1.73m2	210 (7.4%)	221 (7.8%)	431 (7.6%)
>= 90 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
Baseline UACR (mg/g)			
n	2831	2840	5671
Geom. Mean	798.79	814.73	806.74
Geom. SD	2.65	2.67	2.66
Min	5.6	7.4	5.6
Q1	441.00	453.11	446.24
Median	832.72	867.01	851.87
Q3	1628.14	1644.58	1634.22
Max	7692.3	8806.2	8806.2
Baseline albuminuria (mg/g) cat. (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	11 (0.4%)	12 (0.4%)	23 (0.4%)
High albuminuria (30 mg/g - < 300 mg/g)	350 (12.4%)	335 (11.8%)	685 (12.1%)
Very high albuminuria (>= 300 mg/g)	2470 (87.2%)	2493 (87.8%)	4963 (87.5%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
<= 514.7 mg/g (median in FAS)	863 (30.5%)	842 (29.6%)	1705 (30.0%)
> 514.7 mg/g (median in FAS)	1968 (69.5%)	1998 (70.3%)	3966 (69.9%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
NO	2297 (81.1%)	2307 (81.2%)	4604 (81.1%)
YES	535 (18.9%)	533 (18.8%)	1068 (18.8%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Baseline Creatinine (mg/dL)			
n	2832	2840	5672
Arithm. Mean	1.58	1.59	1.58
Arithm. SD	0.41	0.42	0.41
Min	0.6	0.6	0.6
Q1	1.28	1.28	1.28
Median	1.52	1.54	1.53
Q3	1.84	1.82	1.83
Max	3.2	4.6	4.6
Baseline Albumin (g/dL) in Serum			
n	2832	2840	5672
Arithm. Mean	4.10	4.09	4.10
Arithm. SD	0.34	0.34	0.34
Min	2.1	2.0	2.0
Q1	3.90	3.90	3.90
Median	4.10	4.10	4.10
Q3	4.30	4.30	4.30
Max	5.2	5.3	5.3
Baseline Hemoglobin (g/dL) in Blood			
n	2829	2839	5668
Arithm. Mean	12.96	13.00	12.98
Arithm. SD	1.70	1.72	1.71
Min	6.6	7.7	6.6
Q1	11.80	11.80	11.80
Median	13.00	13.00	13.00
Q3	14.10	14.20	14.10
Max	19.4	19.7	19.7
Baseline Hemoglobin A1C (%)			
n	2826	2837	5663
Arithm. Mean	7.66	7.69	7.68
Arithm. SD	1.33	1.36	1.34
Min	4.3	3.8	3.8
Q1	6.70	6.70	6.70
Median	7.50	7.50	7.50
Q3	8.50	8.50	8.50
Max	12.5	12.9	12.9

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	7 (0.2%)	4 (0.1%)	11 (0.2%)
<= 7.5%	1457 (51.4%)	1491 (52.5%)	2948 (52.0%)
> 7.5%	1369 (48.3%)	1346 (47.4%)	2715 (47.8%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	7 (0.2%)	4 (0.1%)	11 (0.2%)
<=6.7 % (<= Q1 in FAS)	750 (26.5%)	773 (27.2%)	1523 (26.8%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	707 (25.0%)	718 (25.3%)	1425 (25.1%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	703 (24.8%)	673 (23.7%)	1376 (24.3%)
>8.5 % (>Q3 in FAS)	666 (23.5%)	673 (23.7%)	1339 (23.6%)
Baseline C Reactive Protein (mg/L)			
n	2831	2837	5668
Arithm. Mean	4.55	4.60	4.57
Arithm. SD	8.88	9.13	9.01
Min	0.1	0.1	0.1
Q1	0.91	0.94	0.93
Median	2.23	2.26	2.24
Q3	5.16	5.14	5.15
Max	160.0	184.0	184.0
Basel. C Reactive Protein Quartiles (N)			
missing	2 (<0.1%)	4 (0.1%)	6 (0.1%)
<=0.95 % (<= Q1 in FAS)	733 (25.9%)	715 (25.2%)	1448 (25.5%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	679 (24.0%)	686 (24.1%)	1365 (24.1%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	706 (24.9%)	723 (25.4%)	1429 (25.2%)
>5.13 % (>Q3 in FAS)	713 (25.2%)	713 (25.1%)	1426 (25.1%)
Stratification factor 3 (N)			
CVD present	1303 (46.0%)	1302 (45.8%)	2605 (45.9%)
CVD absent	1530 (54.0%)	1539 (54.2%)	3069 (54.1%)
Hyperkalemia (based on MLG) in MH (N)			
NO	2760 (97.4%)	2757 (97.0%)	5517 (97.2%)
YES	73 (2.6%)	84 (3.0%)	157 (2.8%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hepatic impairment in medical history(N)			
NO	2389 (84.3%)	2390 (84.1%)	4779 (84.2%)
YES	444 (15.7%)	451 (15.9%)	895 (15.8%)
Child Pugh (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
likely Child Pugh A	2663 (94.0%)	2671 (94.0%)	5334 (94.0%)
likely Child Pugh B	164 (5.8%)	164 (5.8%)	328 (5.8%)
certain Child Pugh B	4 (0.1%)	5 (0.2%)	9 (0.2%)
Duration of diabetes (in years) (N)			
n	2827	2836	5663
Arithm. Mean	16.58	16.55	16.56
Arithm. SD	8.77	8.77	8.77
Min	0.2	0.2	0.2
Q1	10.16	10.14	10.15
Median	16.12	16.15	16.14
Q3	21.22	21.32	21.25
Max	53.2	62.1	62.1
ACEI use (N)			
NO	1883 (66.5%)	1849 (65.1%)	3732 (65.8%)
YES	950 (33.5%)	992 (34.9%)	1942 (34.2%)
ARB use (N)			
NO	954 (33.7%)	995 (35.0%)	1949 (34.3%)
YES	1879 (66.3%)	1846 (65.0%)	3725 (65.7%)
Beta blocker use at baseline (N)			
NO	1371 (48.4%)	1335 (47.0%)	2706 (47.7%)
YES	1462 (51.6%)	1506 (53.0%)	2968 (52.3%)
Diuretic use at baseline (N)			
NO	1256 (44.3%)	1204 (42.4%)	2460 (43.4%)
YES	1577 (55.7%)	1637 (57.6%)	3214 (56.6%)
Statins use at baseline (N)			
NO	728 (25.7%)	731 (25.7%)	1459 (25.7%)
YES	2105 (74.3%)	2110 (74.3%)	4215 (74.3%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Anti-diabetic use at baseline (N)			
NO	86 (3.0%)	64 (2.3%)	150 (2.6%)
YES	2747 (97.0%)	2777 (97.7%)	5524 (97.4%)
Insul. and analo. use at baseline (N)			
NO	990 (34.9%)	1047 (36.9%)	2037 (35.9%)
YES	1843 (65.1%)	1794 (63.1%)	3637 (64.1%)
Dip pep 4 inhibitors use at baseline (N)			
NO	2069 (73.0%)	2083 (73.3%)	4152 (73.2%)
YES	764 (27.0%)	758 (26.7%)	1522 (26.8%)
GLP1 agonists use at baseline (N)			
NO	2644 (93.3%)	2636 (92.8%)	5280 (93.1%)
YES	189 (6.7%)	205 (7.2%)	394 (6.9%)
SGLT-2 inhib. use at baseline (N)			
NO	2709 (95.6%)	2706 (95.2%)	5415 (95.4%)
YES	124 (4.4%)	135 (4.8%)	259 (4.6%)
Biguanides use at baseline (N)			
NO	1582 (55.8%)	1602 (56.4%)	3184 (56.1%)
YES	1251 (44.2%)	1239 (43.6%)	2490 (43.9%)
Sulfonamides use at baseline (N)			
NO	2179 (76.9%)	2168 (76.3%)	4347 (76.6%)
YES	654 (23.1%)	673 (23.7%)	1327 (23.4%)
Alpha gluc. inhib. use at baseline (N)			
NO	2670 (94.2%)	2680 (94.3%)	5350 (94.3%)
YES	163 (5.8%)	161 (5.7%)	324 (5.7%)
Meglitinides use at baseline (N)			
NO	2665 (94.1%)	2686 (94.5%)	5351 (94.3%)
YES	168 (5.9%)	155 (5.5%)	323 (5.7%)

Table 4.4 / 1: Baseline characteristics (full analysis set Fidelio)

	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Thiazolidinediones use at baseline (N)			
NO	2709 (95.6%)	2736 (96.3%)	5445 (96.0%)
YES	124 (4.4%)	105 (3.7%)	229 (4.0%)
Potassium supplement use at baseline (N)			
NO	2748 (97.0%)	2756 (97.0%)	5504 (97.0%)
YES	85 (3.0%)	85 (3.0%)	170 (3.0%)
Potassium lowering use at baseline (N)			
NO	2763 (97.5%)	2775 (97.7%)	5538 (97.6%)
YES	70 (2.5%)	66 (2.3%)	136 (2.4%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	23 (0.8%)	27 (1.0%)	50 (0.9%)
unclassified	36 (1.3%)	37 (1.3%)	73 (1.3%)
moderate	70 (2.5%)	56 (2.0%)	126 (2.2%)
weak	1776 (62.7%)	1749 (61.6%)	3525 (62.1%)
none	928 (32.8%)	972 (34.2%)	1900 (33.5%)
Potency CYP3A4 inducer at baseline (N)			
strong	6 (0.2%)	4 (0.1%)	10 (0.2%)
unclassified	19 (0.7%)	19 (0.7%)	38 (0.7%)
moderate	11 (0.4%)	10 (0.4%)	21 (0.4%)
weak	110 (3.9%)	113 (4.0%)	223 (3.9%)
none	2687 (94.8%)	2695 (94.9%)	5382 (94.9%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 30JAN2023 15:21
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4.5 Medical History

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Number (%) of subjects with at least one medical history finding	2833 (100.0%)	2841 (100.0%)	5674 (100.0%)
Blood and lymphatic system disorders	557 (19.7%)	527 (18.5%)	1084 (19.1%)
Anaemia	350 (12.4%)	328 (11.5%)	678 (11.9%)
Anaemia folate deficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaemia macrocytic	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Anaemia megaloblastic	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Anaemia of chronic disease	10 (0.4%)	7 (0.2%)	17 (0.3%)
Anaemia vitamin B12 deficiency	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Antiphospholipid syndrome	1 (<0.1%)	0	1 (<0.1%)
Aplastic anaemia	0	1 (<0.1%)	1 (<0.1%)
Blood loss anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone marrow oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coagulopathy	0	2 (<0.1%)	2 (<0.1%)
Cytopenia	0	1 (<0.1%)	1 (<0.1%)
Eosinophilia	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Febrile neutropenia	1 (<0.1%)	0	1 (<0.1%)
Haemolytic uraemic syndrome	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic disorder	1 (<0.1%)	0	1 (<0.1%)
Hyperchromic anaemia	2 (<0.1%)	0	2 (<0.1%)
Hypercoagulation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperfibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Hypergammaglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperviscosity syndrome	1 (<0.1%)	0	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Immune thrombocytopenia	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	66 (2.3%)	51 (1.8%)	117 (2.1%)
Leukocytosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Leukopenia	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lymphadenitis	2 (<0.1%)	0	2 (<0.1%)
Lymphadenopathy	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Lymphadenopathy mediastinal	2 (<0.1%)	0	2 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Lymphoid tissue hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Microcytic anaemia	3 (0.1%)	6 (0.2%)	9 (0.2%)
Microcytosis	0	2 (<0.1%)	2 (<0.1%)
Nephrogenic anaemia	58 (2.0%)	70 (2.5%)	128 (2.3%)
Normochromic anaemia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Normochromic normocytic anaemia	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Normocytic anaemia	7 (0.2%)	10 (0.4%)	17 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Pancytopenia	0	3 (0.1%)	3 (<0.1%)
Pernicious anaemia	9 (0.3%)	3 (0.1%)	12 (0.2%)
Polycythaemia	3 (0.1%)	6 (0.2%)	9 (0.2%)
Spleen disorder	1 (<0.1%)	0	1 (<0.1%)
Splenic calcification	0	1 (<0.1%)	1 (<0.1%)
Splenic granuloma	1 (<0.1%)	0	1 (<0.1%)
Splenomegaly	12 (0.4%)	11 (0.4%)	23 (0.4%)
Thrombocytopenia	17 (0.6%)	24 (0.8%)	41 (0.7%)
Thrombocytosis	4 (0.1%)	4 (0.1%)	8 (0.1%)
Cardiac disorders	1365 (48.2%)	1373 (48.3%)	2738 (48.3%)
Acute coronary syndrome	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Acute left ventricular failure	3 (0.1%)	0	3 (<0.1%)
Acute myocardial infarction	4 (0.1%)	5 (0.2%)	9 (0.2%)
Angina pectoris	121 (4.3%)	116 (4.1%)	237 (4.2%)
Angina unstable	19 (0.7%)	23 (0.8%)	42 (0.7%)
Aortic valve calcification	2 (<0.1%)	0	2 (<0.1%)
Aortic valve disease	5 (0.2%)	5 (0.2%)	10 (0.2%)
Aortic valve incompetence	17 (0.6%)	22 (0.8%)	39 (0.7%)
Aortic valve sclerosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Aortic valve stenosis	11 (0.4%)	11 (0.4%)	22 (0.4%)
Arrhythmia	25 (0.9%)	29 (1.0%)	54 (1.0%)
Arrhythmia supraventricular	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arteriosclerosis coronary artery	31 (1.1%)	36 (1.3%)	67 (1.2%)
Atrial enlargement	0	1 (<0.1%)	1 (<0.1%)
Atrial fibrillation	233 (8.2%)	208 (7.3%)	441 (7.8%)
Atrial flutter	12 (0.4%)	19 (0.7%)	31 (0.5%)
Atrial tachycardia	0	2 (<0.1%)	2 (<0.1%)
Atrial thrombosis	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block	6 (0.2%)	8 (0.3%)	14 (0.2%)
Atrioventricular block complete	3 (0.1%)	9 (0.3%)	12 (0.2%)
Atrioventricular block first degree	50 (1.8%)	50 (1.8%)	100 (1.8%)
Atrioventricular block second degree	10 (0.4%)	5 (0.2%)	15 (0.3%)
Bifascicular block	0	2 (<0.1%)	2 (<0.1%)
Bradyarrhythmia	1 (<0.1%)	0	1 (<0.1%)
Bradycardia	13 (0.5%)	11 (0.4%)	24 (0.4%)
Brugada syndrome	1 (<0.1%)	0	1 (<0.1%)
Bundle branch block	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bundle branch block left	50 (1.8%)	43 (1.5%)	93 (1.6%)
Bundle branch block right	44 (1.6%)	53 (1.9%)	97 (1.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Cardiac aneurysm	0	3 (0.1%)	3 (<0.1%)
Cardiac arrest	2 (<0.1%)	0	2 (<0.1%)
Cardiac discomfort	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac dysfunction	0	3 (0.1%)	3 (<0.1%)
Cardiac failure	43 (1.5%)	76 (2.7%)	119 (2.1%)
Cardiac failure acute	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Cardiac failure chronic	78 (2.8%)	98 (3.4%)	176 (3.1%)
Cardiac failure congestive	52 (1.8%)	42 (1.5%)	94 (1.7%)
Cardiac flutter	2 (<0.1%)	0	2 (<0.1%)
Cardiac hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac septal hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac tamponade	0	2 (<0.1%)	2 (<0.1%)
Cardiac valve disease	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Cardiac valve sclerosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiogenic shock	0	1 (<0.1%)	1 (<0.1%)
Cardiomegaly	10 (0.4%)	8 (0.3%)	18 (0.3%)
Cardiomyopathy	12 (0.4%)	17 (0.6%)	29 (0.5%)
Cardiorenal syndrome	0	2 (<0.1%)	2 (<0.1%)
Cardiovascular disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiovascular insufficiency	2 (<0.1%)	0	2 (<0.1%)
Chronic left ventricular failure	11 (0.4%)	6 (0.2%)	17 (0.3%)
Chronic right ventricular failure	1 (<0.1%)	0	1 (<0.1%)
Chronotropic incompetence	0	1 (<0.1%)	1 (<0.1%)
Conduction disorder	1 (<0.1%)	0	1 (<0.1%)
Congestive cardiomyopathy	11 (0.4%)	4 (0.1%)	15 (0.3%)
Cor pulmonale	0	2 (<0.1%)	2 (<0.1%)
Coronary artery disease	842 (29.7%)	860 (30.3%)	1702 (30.0%)
Coronary artery occlusion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Coronary artery stenosis	5 (0.2%)	4 (0.1%)	9 (0.2%)
Defect conduction intraventricular	3 (0.1%)	4 (0.1%)	7 (0.1%)
Diabetic cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Diastolic dysfunction	15 (0.5%)	18 (0.6%)	33 (0.6%)
Dilatation atrial	1 (<0.1%)	0	1 (<0.1%)
Extrasystoles	3 (0.1%)	6 (0.2%)	9 (0.2%)
Heart valve incompetence	1 (<0.1%)	0	1 (<0.1%)
Hypertensive cardiomyopathy	7 (0.2%)	9 (0.3%)	16 (0.3%)
Hypertensive heart disease	48 (1.7%)	50 (1.8%)	98 (1.7%)
Intracardiac mass	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Ischaemic cardiomyopathy	18 (0.6%)	5 (0.2%)	23 (0.4%)
Left atrial dilatation	8 (0.3%)	6 (0.2%)	14 (0.2%)
Left atrial enlargement	5 (0.2%)	8 (0.3%)	13 (0.2%)
Left atrial hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dysfunction	5 (0.2%)	14 (0.5%)	19 (0.3%)
Left ventricular enlargement	0	3 (0.1%)	3 (<0.1%)
Left ventricular failure	10 (0.4%)	19 (0.7%)	29 (0.5%)
Left ventricular hypertrophy	93 (3.3%)	74 (2.6%)	167 (2.9%)
Metabolic cardiomyopathy	9 (0.3%)	3 (0.1%)	12 (0.2%)
Mitral valve calcification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mitral valve disease	5 (0.2%)	4 (0.1%)	9 (0.2%)
Mitral valve incompetence	49 (1.7%)	73 (2.6%)	122 (2.2%)
Mitral valve prolapse	6 (0.2%)	4 (0.1%)	10 (0.2%)
Mitral valve sclerosis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Mitral valve stenosis	6 (0.2%)	5 (0.2%)	11 (0.2%)
Myocardial fibrosis	8 (0.3%)	8 (0.3%)	16 (0.3%)
Myocardial infarction	378 (13.3%)	388 (13.7%)	766 (13.5%)
Myocardial ischaemia	127 (4.5%)	102 (3.6%)	229 (4.0%)
Myocardial necrosis	0	1 (<0.1%)	1 (<0.1%)
Myocarditis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodal arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Nodal rhythm	0	1 (<0.1%)	1 (<0.1%)
Palpitations	6 (0.2%)	9 (0.3%)	15 (0.3%)
Pericardial effusion	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Pericarditis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pericarditis adhesive	0	2 (<0.1%)	2 (<0.1%)
Pericarditis constrictive	0	1 (<0.1%)	1 (<0.1%)
Pleuropericarditis	1 (<0.1%)	0	1 (<0.1%)
Prinzmetal angina	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Pulmonary valve disease	1 (<0.1%)	0	1 (<0.1%)
Pulmonary valve incompetence	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Restrictive cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Rheumatic heart disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Right atrial dilatation	1 (<0.1%)	0	1 (<0.1%)
Right atrial enlargement	0	1 (<0.1%)	1 (<0.1%)
Right ventricular failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Right ventricular hypertrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Silent myocardial infarction	2 (<0.1%)	0	2 (<0.1%)
Sinoatrial block	2 (<0.1%)	0	2 (<0.1%)
Sinus arrest	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Sinus arrhythmia	6 (0.2%)	4 (0.1%)	10 (0.2%)
Sinus bradycardia	24 (0.8%)	20 (0.7%)	44 (0.8%)
Sinus node dysfunction	11 (0.4%)	7 (0.2%)	18 (0.3%)
Sinus tachycardia	9 (0.3%)	3 (0.1%)	12 (0.2%)
Supraventricular extrasystoles	22 (0.8%)	15 (0.5%)	37 (0.7%)
Supraventricular tachycardia	13 (0.5%)	6 (0.2%)	19 (0.3%)
Systolic dysfunction	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tachyarrhythmia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Tachycardia	4 (0.1%)	8 (0.3%)	12 (0.2%)
Tachycardia paroxysmal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tricuspid valve disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tricuspid valve incompetence	29 (1.0%)	26 (0.9%)	55 (1.0%)
Trifascicular block	1 (<0.1%)	0	1 (<0.1%)
Ventricular arrhythmia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Ventricular extrasystoles	30 (1.1%)	30 (1.1%)	60 (1.1%)
Ventricular fibrillation	2 (<0.1%)	0	2 (<0.1%)
Ventricular hypertrophy	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Ventricular hypokinesia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Ventricular tachycardia	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Wolff-Parkinson-White syndrome	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Congenital, familial and genetic disorders	155 (5.5%)	122 (4.3%)	277 (4.9%)
Accessory kidney	0	1 (<0.1%)	1 (<0.1%)
Accessory spleen	1 (<0.1%)	0	1 (<0.1%)
Adenomatous polyposis coli	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Anomalous arrangement of pancreaticobiliary duct	0	1 (<0.1%)	1 (<0.1%)
Antithrombin III deficiency	0	1 (<0.1%)	1 (<0.1%)
Arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biliary hamartoma	0	1 (<0.1%)	1 (<0.1%)
Cardiac septal defect	1 (<0.1%)	0	1 (<0.1%)
Coarctation of the aorta	1 (<0.1%)	0	1 (<0.1%)
Colour blindness	0	1 (<0.1%)	1 (<0.1%)
Congenital arterial malformation	1 (<0.1%)	0	1 (<0.1%)
Congenital cystic kidney disease	5 (0.2%)	5 (0.2%)	10 (0.2%)
Congenital flat feet	1 (<0.1%)	0	1 (<0.1%)
Congenital myopia	0	1 (<0.1%)	1 (<0.1%)
Congenital neurological disorder	0	1 (<0.1%)	1 (<0.1%)
Congenital neuropathy	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Congenital renal cyst	6 (0.2%)	7 (0.2%)	13 (0.2%)
Corneal dystrophy	0	3 (0.1%)	3 (<0.1%)
Cryptorchism	0	2 (<0.1%)	2 (<0.1%)
Dolichocolon	2 (<0.1%)	0	2 (<0.1%)
Ectopic kidney	0	1 (<0.1%)	1 (<0.1%)
Ectopic thyroid	1 (<0.1%)	0	1 (<0.1%)
Factor V Leiden mutation	0	2 (<0.1%)	2 (<0.1%)
Familial periodic paralysis	0	1 (<0.1%)	1 (<0.1%)
Familial tremor	1 (<0.1%)	0	1 (<0.1%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Fragile X syndrome	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Glycogen storage disease type I	1 (<0.1%)	0	1 (<0.1%)
Haemochromatosis trait	0	1 (<0.1%)	1 (<0.1%)
Haemophilia	0	1 (<0.1%)	1 (<0.1%)
Hamartoma	1 (<0.1%)	0	1 (<0.1%)
Hereditary haemochromatosis	1 (<0.1%)	0	1 (<0.1%)
Hereditary palmoplantar keratoderma	0	1 (<0.1%)	1 (<0.1%)
Hereditary spastic paraplegia	1 (<0.1%)	0	1 (<0.1%)
Hydrocele	10 (0.4%)	3 (0.1%)	13 (0.2%)
Hypertrophic cardiomyopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Hypospadias	3 (0.1%)	0	3 (<0.1%)
Ichthyosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Kidney duplex	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	1 (<0.1%)	1 (<0.1%)
Klippel-Trenaunay syndrome	0	1 (<0.1%)	1 (<0.1%)
Limb malformation	1 (<0.1%)	0	1 (<0.1%)
Muscular dystrophy	3 (0.1%)	0	3 (<0.1%)
Myocardial bridging	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteopetrosis	0	1 (<0.1%)	1 (<0.1%)
Peutz-Jeghers syndrome	1 (<0.1%)	0	1 (<0.1%)
Phimosis	11 (0.4%)	3 (0.1%)	14 (0.2%)
Polycystic liver disease	0	2 (<0.1%)	2 (<0.1%)
Porokeratosis	0	1 (<0.1%)	1 (<0.1%)
Porphyria	1 (<0.1%)	0	1 (<0.1%)
Preauricular cyst	0	1 (<0.1%)	1 (<0.1%)
Primary hypercholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	7 (0.2%)	6 (0.2%)	13 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Renal fusion anomaly	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal hypoplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinitis pigmentosa	1 (<0.1%)	0	1 (<0.1%)
Sacralisation	0	1 (<0.1%)	1 (<0.1%)
Sickle cell anaemia	0	1 (<0.1%)	1 (<0.1%)
Sickle cell trait	0	1 (<0.1%)	1 (<0.1%)
Spina bifida	2 (<0.1%)	0	2 (<0.1%)
Supernumerary rib	0	1 (<0.1%)	1 (<0.1%)
Thalassaemia	4 (0.1%)	3 (0.1%)	7 (0.1%)
Thalassaemia alpha	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thalassaemia beta	2 (<0.1%)	0	2 (<0.1%)
Thalassaemia minor	4 (0.1%)	3 (0.1%)	7 (0.1%)
Tilted disc syndrome	0	1 (<0.1%)	1 (<0.1%)
Type IIa hyperlipidaemia	8 (0.3%)	7 (0.2%)	15 (0.3%)
Type IIb hyperlipidaemia	4 (0.1%)	5 (0.2%)	9 (0.2%)
Type V hyperlipidaemia	48 (1.7%)	34 (1.2%)	82 (1.4%)
Usher's syndrome	0	1 (<0.1%)	1 (<0.1%)
Vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery hypoplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Von Willebrand's disease	1 (<0.1%)	0	1 (<0.1%)
Xeroderma pigmentosum	0	1 (<0.1%)	1 (<0.1%)
Ear and labyrinth disorders	142 (5.0%)	147 (5.2%)	289 (5.1%)
Auditory disorder	7 (0.2%)	3 (0.1%)	10 (0.2%)
Aural polyp	0	1 (<0.1%)	1 (<0.1%)
Cerumen impaction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conductive deafness	0	1 (<0.1%)	1 (<0.1%)
Deafness	33 (1.2%)	25 (0.9%)	58 (1.0%)
Deafness bilateral	6 (0.2%)	7 (0.2%)	13 (0.2%)
Deafness neurosensory	14 (0.5%)	25 (0.9%)	39 (0.7%)
Deafness unilateral	7 (0.2%)	6 (0.2%)	13 (0.2%)
Ear canal stenosis	0	1 (<0.1%)	1 (<0.1%)
Ear pain	0	2 (<0.1%)	2 (<0.1%)
Ear pruritus	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	1 (<0.1%)	0	1 (<0.1%)
Excessive cerumen production	2 (<0.1%)	0	2 (<0.1%)
External ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Hypoacusis	24 (0.8%)	18 (0.6%)	42 (0.7%)
Inner ear disorder	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	4 (0.1%)	2 (<0.1%)	6 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Middle ear adhesions	0	1 (<0.1%)	1 (<0.1%)
Mixed deafness	0	2 (<0.1%)	2 (<0.1%)
Motion sickness	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	1 (<0.1%)	0	1 (<0.1%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	1 (<0.1%)	0	1 (<0.1%)
Presbyacusis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sudden hearing loss	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Tinnitus	18 (0.6%)	15 (0.5%)	33 (0.6%)
Tympanic membrane perforation	3 (0.1%)	0	3 (<0.1%)
Vertigo	31 (1.1%)	33 (1.2%)	64 (1.1%)
Vertigo positional	7 (0.2%)	12 (0.4%)	19 (0.3%)
Vestibular ataxia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vestibular disorder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Endocrine disorders	494 (17.4%)	481 (16.9%)	975 (17.2%)
Acromegaly	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Adrenal disorder	0	1 (<0.1%)	1 (<0.1%)
Adrenal insufficiency	0	1 (<0.1%)	1 (<0.1%)
Adrenal mass	0	3 (0.1%)	3 (<0.1%)
Androgen deficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autoimmune hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	0	1 (<0.1%)
Autoimmune thyroiditis	19 (0.7%)	22 (0.8%)	41 (0.7%)
Basedow's disease	7 (0.2%)	5 (0.2%)	12 (0.2%)
Cushing's syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Empty sella syndrome	0	1 (<0.1%)	1 (<0.1%)
Euthyroid sick syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Goitre	101 (3.6%)	66 (2.3%)	167 (2.9%)
Hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hyperparathyroidism	26 (0.9%)	30 (1.1%)	56 (1.0%)
Hyperparathyroidism primary	4 (0.1%)	0	4 (<0.1%)
Hyperparathyroidism secondary	46 (1.6%)	46 (1.6%)	92 (1.6%)
Hyperpituitarism	0	1 (<0.1%)	1 (<0.1%)
Hyperplasia adrenal	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Hyperprolactinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperthyroidism	18 (0.6%)	19 (0.7%)	37 (0.7%)
Hypogonadism	8 (0.3%)	14 (0.5%)	22 (0.4%)
Hypogonadism male	1 (<0.1%)	4 (0.1%)	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hypoparathyroidism	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Hypopituitarism	0	1 (<0.1%)	1 (<0.1%)
Hypothyroidic goitre	0	2 (<0.1%)	2 (<0.1%)
Hypothyroidism	259 (9.1%)	246 (8.7%)	505 (8.9%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Primary hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary hypogonadism	0	2 (<0.1%)	2 (<0.1%)
Primary hypothyroidism	7 (0.2%)	4 (0.1%)	11 (0.2%)
Secondary hyperthyroidism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Secondary hypogonadism	2 (<0.1%)	0	2 (<0.1%)
Testicular failure	1 (<0.1%)	0	1 (<0.1%)
Thyroid atrophy	1 (<0.1%)	0	1 (<0.1%)
Thyroid cyst	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Thyroid disorder	5 (0.2%)	3 (0.1%)	8 (0.1%)
Thyroid mass	31 (1.1%)	40 (1.4%)	71 (1.3%)
Thyroiditis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Thyroiditis chronic	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	0	1 (<0.1%)
Toxic nodular goitre	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Eye disorders	1663 (58.7%)	1689 (59.5%)	3352 (59.1%)
Age-related macular degeneration	8 (0.3%)	4 (0.1%)	12 (0.2%)
Amaurosis	3 (0.1%)	10 (0.4%)	13 (0.2%)
Amaurosis fugax	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Amblyopia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Amblyopia strabismic	0	1 (<0.1%)	1 (<0.1%)
Angle closure glaucoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Aniseikonia	0	1 (<0.1%)	1 (<0.1%)
Anisometropia	0	1 (<0.1%)	1 (<0.1%)
Aphakia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arcus lipoides	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerotic retinopathy	9 (0.3%)	7 (0.2%)	16 (0.3%)
Asthenopia	5 (0.2%)	6 (0.2%)	11 (0.2%)
Astigmatism	19 (0.7%)	8 (0.3%)	27 (0.5%)
Blepharitis	9 (0.3%)	5 (0.2%)	14 (0.2%)
Blepharochalasis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blindness	6 (0.2%)	9 (0.3%)	15 (0.3%)
Blindness unilateral	14 (0.5%)	11 (0.4%)	25 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Borderline glaucoma	6 (0.2%)	8 (0.3%)	14 (0.2%)
Cataract	453 (16.0%)	500 (17.6%)	953 (16.8%)
Cataract cortical	3 (0.1%)	3 (0.1%)	6 (0.1%)
Cataract diabetic	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Cataract nuclear	9 (0.3%)	4 (0.1%)	13 (0.2%)
Cataract subcapsular	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Central vision loss	0	1 (<0.1%)	1 (<0.1%)
Chalazion	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Chorioretinal atrophy	1 (<0.1%)	0	1 (<0.1%)
Chorioretinopathy	1 (<0.1%)	0	1 (<0.1%)
Choroidal neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Conjunctival haemorrhage	0	4 (0.1%)	4 (<0.1%)
Conjunctival pallor	1 (<0.1%)	0	1 (<0.1%)
Conjunctivitis allergic	20 (0.7%)	14 (0.5%)	34 (0.6%)
Conjunctivochalasis	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	0	1 (<0.1%)	1 (<0.1%)
Corneal erosion	0	2 (<0.1%)	2 (<0.1%)
Corneal infiltrates	0	1 (<0.1%)	1 (<0.1%)
Corneal oedema	0	1 (<0.1%)	1 (<0.1%)
Corneal opacity	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	1 (<0.1%)	0	1 (<0.1%)
Cystoid macular oedema	0	7 (0.2%)	7 (0.1%)
Dacryostenosis acquired	0	3 (0.1%)	3 (<0.1%)
Dermatochalasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic blindness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic eye disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic ophthalmoplegia	1 (<0.1%)	0	1 (<0.1%)
Diabetic retinal oedema	16 (0.6%)	13 (0.5%)	29 (0.5%)
Diabetic retinopathy	1312 (46.3%)	1351 (47.6%)	2663 (46.9%)
Diplopia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dry age-related macular degeneration	4 (0.1%)	4 (0.1%)	8 (0.1%)
Dry eye	48 (1.7%)	54 (1.9%)	102 (1.8%)
Dysmetropsia	1 (<0.1%)	0	1 (<0.1%)
Entropion	1 (<0.1%)	0	1 (<0.1%)
Exfoliation syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exudative retinopathy	1 (<0.1%)	0	1 (<0.1%)
Eye allergy	0	1 (<0.1%)	1 (<0.1%)
Eye disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Eye pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye pruritus	2 (<0.1%)	0	2 (<0.1%)
Eye ulcer	0	1 (<0.1%)	1 (<0.1%)
Eyelid cyst	1 (<0.1%)	0	1 (<0.1%)
Eyelid oedema	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Floppy eyelid syndrome	0	1 (<0.1%)	1 (<0.1%)
Glaucoma	159 (5.6%)	173 (6.1%)	332 (5.9%)
Heerfordt's syndrome	0	1 (<0.1%)	1 (<0.1%)
Hyalosis asteroid	1 (<0.1%)	0	1 (<0.1%)
Hypermetropia	14 (0.5%)	14 (0.5%)	28 (0.5%)
Iridocyclitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Iris neovascularisation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Keratitis	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Keratoconus	0	1 (<0.1%)	1 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Lacrimation increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lagophthalmos	1 (<0.1%)	0	1 (<0.1%)
Lenticular opacities	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	20 (0.7%)	19 (0.7%)	39 (0.7%)
Macular fibrosis	7 (0.2%)	6 (0.2%)	13 (0.2%)
Macular oedema	20 (0.7%)	27 (1.0%)	47 (0.8%)
Macular rupture	0	1 (<0.1%)	1 (<0.1%)
Macular scar	1 (<0.1%)	0	1 (<0.1%)
Macular thickening	0	1 (<0.1%)	1 (<0.1%)
Maculopathy	15 (0.5%)	13 (0.5%)	28 (0.5%)
Meibomian gland dysfunction	1 (<0.1%)	0	1 (<0.1%)
Mydriasis	1 (<0.1%)	0	1 (<0.1%)
Myopia	22 (0.8%)	24 (0.8%)	46 (0.8%)
Myopic chorioretinal degeneration	1 (<0.1%)	0	1 (<0.1%)
Neovascular age-related macular degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Normal tension glaucoma	2 (<0.1%)	0	2 (<0.1%)
Ocular discomfort	0	1 (<0.1%)	1 (<0.1%)
Ocular hypertension	6 (0.2%)	10 (0.4%)	16 (0.3%)
Ocular ischaemic syndrome	2 (<0.1%)	0	2 (<0.1%)
Ocular myasthenia	0	2 (<0.1%)	2 (<0.1%)
Open angle glaucoma	12 (0.4%)	7 (0.2%)	19 (0.3%)
Ophthalmoplegia	1 (<0.1%)	0	1 (<0.1%)
Optic atrophy	5 (0.2%)	0	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Optic disc traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Optic ischaemic neuropathy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Optic nerve cupping	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Papilloedema	0	1 (<0.1%)	1 (<0.1%)
Pathologic myopia	2 (<0.1%)	0	2 (<0.1%)
Periorbital oedema	1 (<0.1%)	0	1 (<0.1%)
Photophobia	0	2 (<0.1%)	2 (<0.1%)
Pinguecula	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Posterior capsule opacification	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Presbyopia	17 (0.6%)	26 (0.9%)	43 (0.8%)
Pseudo-blepharoptosis	0	1 (<0.1%)	1 (<0.1%)
Pseudopapilloedema	1 (<0.1%)	0	1 (<0.1%)
Pterygium	6 (0.2%)	5 (0.2%)	11 (0.2%)
Punctate keratitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pupils unequal	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	4 (0.1%)	5 (0.2%)	9 (0.2%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery embolism	1 (<0.1%)	0	1 (<0.1%)
Retinal artery occlusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinal artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal degeneration	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Retinal depigmentation	1 (<0.1%)	0	1 (<0.1%)
Retinal detachment	15 (0.5%)	13 (0.5%)	28 (0.5%)
Retinal disorder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Retinal drusen	1 (<0.1%)	0	1 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	5 (0.2%)	13 (0.5%)	18 (0.3%)
Retinal neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Retinal oedema	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Retinal pigment epitheliopathy	0	1 (<0.1%)	1 (<0.1%)
Retinal tear	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Retinal vascular disorder	7 (0.2%)	5 (0.2%)	12 (0.2%)
Retinal vascular occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal vascular thrombosis	0	4 (0.1%)	4 (<0.1%)
Retinal vein occlusion	5 (0.2%)	10 (0.4%)	15 (0.3%)
Retinal vein thrombosis	3 (0.1%)	0	3 (<0.1%)
Retinopathy	4 (0.1%)	8 (0.3%)	12 (0.2%)
Retinopathy hypertensive	48 (1.7%)	33 (1.2%)	81 (1.4%)
Retinopathy proliferative	3 (0.1%)	1 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Retinoschisis	1 (<0.1%)	0	1 (<0.1%)
Rhegmatogenous retinal detachment	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scleral haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Scleritis	1 (<0.1%)	0	1 (<0.1%)
Strabismus	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Swelling of eyelid	1 (<0.1%)	0	1 (<0.1%)
Tractional retinal detachment	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Trichiasis	1 (<0.1%)	0	1 (<0.1%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Vision blurred	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Visual acuity reduced	7 (0.2%)	4 (0.1%)	11 (0.2%)
Visual impairment	10 (0.4%)	10 (0.4%)	20 (0.4%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vitreous detachment	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Vitreous floaters	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Vitreous haemorrhage	30 (1.1%)	19 (0.7%)	49 (0.9%)
Vitreous opacities	6 (0.2%)	5 (0.2%)	11 (0.2%)
Vitreous prolapse	1 (<0.1%)	0	1 (<0.1%)
Xerophthalmia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorders	984 (34.7%)	1055 (37.1%)	2039 (35.9%)
Abdominal adhesions	0	2 (<0.1%)	2 (<0.1%)
Abdominal discomfort	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Abdominal distension	7 (0.2%)	5 (0.2%)	12 (0.2%)
Abdominal hernia	19 (0.7%)	25 (0.9%)	44 (0.8%)
Abdominal incarcerated hernia	0	2 (<0.1%)	2 (<0.1%)
Abdominal mass	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	12 (0.4%)	10 (0.4%)	22 (0.4%)
Abdominal pain lower	2 (<0.1%)	0	2 (<0.1%)
Abdominal pain upper	6 (0.2%)	11 (0.4%)	17 (0.3%)
Abdominal symptom	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal wall oedema	0	1 (<0.1%)	1 (<0.1%)
Abnormal faeces	1 (<0.1%)	0	1 (<0.1%)
Acid peptic disease	6 (0.2%)	6 (0.2%)	12 (0.2%)
Alcoholic pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal fistula	4 (0.1%)	3 (0.1%)	7 (0.1%)
Anal haemorrhage	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Anal incontinence	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Anal pruritus	1 (<0.1%)	0	1 (<0.1%)
Anal sphincter atony	1 (<0.1%)	0	1 (<0.1%)
Ascites	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autoimmune pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Barrett's oesophagus	9 (0.3%)	11 (0.4%)	20 (0.4%)
Bowel movement irregularity	1 (<0.1%)	0	1 (<0.1%)
Breath odour	0	1 (<0.1%)	1 (<0.1%)
Change of bowel habit	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic gastritis	85 (3.0%)	106 (3.7%)	191 (3.4%)
Coeliac disease	3 (0.1%)	0	3 (<0.1%)
Colitis	6 (0.2%)	6 (0.2%)	12 (0.2%)
Colitis ischaemic	1 (<0.1%)	0	1 (<0.1%)
Colitis microscopic	1 (<0.1%)	0	1 (<0.1%)
Colitis ulcerative	6 (0.2%)	5 (0.2%)	11 (0.2%)
Constipation	151 (5.3%)	170 (6.0%)	321 (5.7%)
Crohn's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dental caries	8 (0.3%)	8 (0.3%)	16 (0.3%)
Dental cyst	1 (<0.1%)	0	1 (<0.1%)
Diabetic enteropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic gastroparesis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Diaphragmatic hernia	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Diarrhoea	46 (1.6%)	37 (1.3%)	83 (1.5%)
Dieulafoy's vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Diverticular perforation	0	1 (<0.1%)	1 (<0.1%)
Diverticulum	26 (0.9%)	27 (1.0%)	53 (0.9%)
Diverticulum intestinal	35 (1.2%)	27 (1.0%)	62 (1.1%)
Diverticulum intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Diverticulum oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dry mouth	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dumping syndrome	0	1 (<0.1%)	1 (<0.1%)
Duodenal perforation	0	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duodenal ulcer	27 (1.0%)	38 (1.3%)	65 (1.1%)
Duodenal ulcer haemorrhage	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duodenitis	10 (0.4%)	14 (0.5%)	24 (0.4%)
Duodenogastric reflux	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Dysbiosis	0	2 (<0.1%)	2 (<0.1%)
Dyskinesia oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dyspepsia	49 (1.7%)	55 (1.9%)	104 (1.8%)
Dysphagia	5 (0.2%)	5 (0.2%)	10 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Enlarged uvula	1 (<0.1%)	0	1 (<0.1%)
Enteritis	1 (<0.1%)	0	1 (<0.1%)
Enterocele	0	1 (<0.1%)	1 (<0.1%)
Enterocolitis	0	1 (<0.1%)	1 (<0.1%)
Epigastric discomfort	2 (<0.1%)	0	2 (<0.1%)
Epulis	0	1 (<0.1%)	1 (<0.1%)
Erosive duodenitis	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Erosive oesophagitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eructation	1 (<0.1%)	0	1 (<0.1%)
Flatulence	6 (0.2%)	6 (0.2%)	12 (0.2%)
Functional gastrointestinal disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastric disorder	5 (0.2%)	4 (0.1%)	9 (0.2%)
Gastric haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	0	2 (<0.1%)	2 (<0.1%)
Gastric polyps	8 (0.3%)	15 (0.5%)	23 (0.4%)
Gastric ulcer	34 (1.2%)	30 (1.1%)	64 (1.1%)
Gastric ulcer haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastric xanthoma	1 (<0.1%)	0	1 (<0.1%)
Gastritis	110 (3.9%)	95 (3.3%)	205 (3.6%)
Gastritis erosive	13 (0.5%)	14 (0.5%)	27 (0.5%)
Gastritis haemorrhagic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastroduodenal ulcer	4 (0.1%)	3 (0.1%)	7 (0.1%)
Gastrointestinal angiectasia	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal angiodysplasia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastrointestinal disorder	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Gastrointestinal haemorrhage	4 (0.1%)	8 (0.3%)	12 (0.2%)
Gastrointestinal motility disorder	6 (0.2%)	0	6 (0.1%)
Gastrointestinal polyp	0	2 (<0.1%)	2 (<0.1%)
Gastrointestinal scarring	0	2 (<0.1%)	2 (<0.1%)
Gastrointestinal tract mucosal pigmentation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal ulcer	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal ulcer haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	265 (9.4%)	296 (10.4%)	561 (9.9%)
Gastrooesophageal sphincter insufficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haematemesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematochezia	5 (0.2%)	3 (0.1%)	8 (0.1%)
Haemorrhoidal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Haemorrhoids	51 (1.8%)	48 (1.7%)	99 (1.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hiatus hernia	42 (1.5%)	47 (1.7%)	89 (1.6%)
Ileus	4 (0.1%)	0	4 (<0.1%)
Ileus paralytic	0	1 (<0.1%)	1 (<0.1%)
Impaired gastric emptying	7 (0.2%)	9 (0.3%)	16 (0.3%)
Inguinal hernia	29 (1.0%)	31 (1.1%)	60 (1.1%)
Intestinal cyst	0	1 (<0.1%)	1 (<0.1%)
Intestinal metaplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Intestinal mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Intestinal obstruction	4 (0.1%)	11 (0.4%)	15 (0.3%)
Intestinal polyp	5 (0.2%)	5 (0.2%)	10 (0.2%)
Intra-abdominal fluid collection	1 (<0.1%)	0	1 (<0.1%)
Irritable bowel syndrome	24 (0.8%)	33 (1.2%)	57 (1.0%)
Jejunal ulcer	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	0	2 (<0.1%)	2 (<0.1%)
Large intestinal stenosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine perforation	1 (<0.1%)	0	1 (<0.1%)
Large intestine polyp	56 (2.0%)	85 (3.0%)	141 (2.5%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lower gastrointestinal haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Lumbar hernia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Malabsorption	1 (<0.1%)	0	1 (<0.1%)
Mallory-Weiss syndrome	1 (<0.1%)	0	1 (<0.1%)
Mesenteric arteriosclerosis	1 (<0.1%)	0	1 (<0.1%)
Mouth haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nausea	11 (0.4%)	19 (0.7%)	30 (0.5%)
Obstruction gastric	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obstructive defaecation	1 (<0.1%)	0	1 (<0.1%)
Obstructive pancreatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal achalasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal disorder	0	1 (<0.1%)	1 (<0.1%)
Oesophageal spasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophagitis	17 (0.6%)	13 (0.5%)	30 (0.5%)
Oesophagitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Oral discomfort	1 (<0.1%)	0	1 (<0.1%)
Oral disorder	0	2 (<0.1%)	2 (<0.1%)
Pancreatic cyst	7 (0.2%)	6 (0.2%)	13 (0.2%)
Pancreatic disorder	0	1 (<0.1%)	1 (<0.1%)
Pancreatic duct dilatation	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Pancreatic failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	4 (0.1%)	3 (0.1%)	7 (0.1%)
Pancreatitis	9 (0.3%)	15 (0.5%)	24 (0.4%)
Pancreatitis acute	11 (0.4%)	10 (0.4%)	21 (0.4%)
Pancreatitis chronic	32 (1.1%)	22 (0.8%)	54 (1.0%)
Pancreatitis relapsing	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Parotid gland enlargement	0	3 (0.1%)	3 (<0.1%)
Pathological tooth fracture	0	1 (<0.1%)	1 (<0.1%)
Peptic ulcer	25 (0.9%)	18 (0.6%)	43 (0.8%)
Periodontal disease	104 (3.7%)	128 (4.5%)	232 (4.1%)
Portal hypertensive gastropathy	1 (<0.1%)	0	1 (<0.1%)
Proctitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Pyloric sphincter insufficiency	0	1 (<0.1%)	1 (<0.1%)
Rectal haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal polyp	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Rectal prolapse	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Rectal ulcer	1 (<0.1%)	0	1 (<0.1%)
Reflux gastritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Retroperitoneal fibrosis	0	1 (<0.1%)	1 (<0.1%)
Retroperitoneal haematoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland calculus	0	1 (<0.1%)	1 (<0.1%)
Salivary gland disorder	0	1 (<0.1%)	1 (<0.1%)
Salivary gland mass	1 (<0.1%)	0	1 (<0.1%)
Small intestinal obstruction	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Steatorrhoea	1 (<0.1%)	0	1 (<0.1%)
Stomach mass	1 (<0.1%)	0	1 (<0.1%)
Stomatitis	0	3 (0.1%)	3 (<0.1%)
Swollen tongue	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth deposit	0	1 (<0.1%)	1 (<0.1%)
Tooth impacted	1 (<0.1%)	0	1 (<0.1%)
Tooth loss	3 (0.1%)	0	3 (<0.1%)
Toothache	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Trichoglossia	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	38 (1.3%)	31 (1.1%)	69 (1.2%)
Upper gastrointestinal haemorrhage	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Varices oesophageal	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Vomiting	5 (0.2%)	10 (0.4%)	15 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
General disorders and administration site conditions	358 (12.6%)	402 (14.1%)	760 (13.4%)
Adhesion	0	1 (<0.1%)	1 (<0.1%)
Adverse drug reaction	0	1 (<0.1%)	1 (<0.1%)
Asthenia	8 (0.3%)	15 (0.5%)	23 (0.4%)
Chest discomfort	7 (0.2%)	3 (0.1%)	10 (0.2%)
Chest pain	20 (0.7%)	17 (0.6%)	37 (0.7%)
Chills	0	1 (<0.1%)	1 (<0.1%)
Chronic fatigue syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Complication associated with device	0	1 (<0.1%)	1 (<0.1%)
Cyst	9 (0.3%)	8 (0.3%)	17 (0.3%)
Disease susceptibility	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	13 (0.5%)	19 (0.7%)	32 (0.6%)
Fat tissue increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fatigue	31 (1.1%)	33 (1.2%)	64 (1.1%)
Gait disturbance	6 (0.2%)	7 (0.2%)	13 (0.2%)
Generalised oedema	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Granuloma	0	1 (<0.1%)	1 (<0.1%)
Gravitational oedema	0	3 (0.1%)	3 (<0.1%)
Hernia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Impaired healing	1 (<0.1%)	0	1 (<0.1%)
Inflammation	5 (0.2%)	3 (0.1%)	8 (0.1%)
Influenza like illness	1 (<0.1%)	0	1 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Lithiasis	0	1 (<0.1%)	1 (<0.1%)
Localised oedema	0	2 (<0.1%)	2 (<0.1%)
Malaise	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Mass	0	2 (<0.1%)	2 (<0.1%)
Metaplasia	1 (<0.1%)	0	1 (<0.1%)
Multiple organ dysfunction syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodule	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-cardiac chest pain	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Oedema	54 (1.9%)	66 (2.3%)	120 (2.1%)
Oedema due to cardiac disease	0	1 (<0.1%)	1 (<0.1%)
Oedema due to renal disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Oedema peripheral	201 (7.1%)	213 (7.5%)	414 (7.3%)
Pain	15 (0.5%)	14 (0.5%)	29 (0.5%)
Peripheral swelling	12 (0.4%)	16 (0.6%)	28 (0.5%)
Polyp	0	4 (0.1%)	4 (<0.1%)
Pyrexia	3 (0.1%)	5 (0.2%)	8 (0.1%)
Sensation of foreign body	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Systemic inflammatory response syndrome	2 (<0.1%)	0	2 (<0.1%)
Temperature intolerance	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thirst	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular stent thrombosis	1 (<0.1%)	0	1 (<0.1%)
Xerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatobiliary disorders	508 (17.9%)	534 (18.8%)	1042 (18.4%)
Alcoholic liver disease	5 (0.2%)	3 (0.1%)	8 (0.1%)
Bile duct stone	6 (0.2%)	5 (0.2%)	11 (0.2%)
Biliary colic	0	1 (<0.1%)	1 (<0.1%)
Biliary cyst	1 (<0.1%)	0	1 (<0.1%)
Biliary dilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Biliary dyskinesia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Cholangitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholecystitis	16 (0.6%)	20 (0.7%)	36 (0.6%)
Cholecystitis acute	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Cholecystitis chronic	24 (0.8%)	20 (0.7%)	44 (0.8%)
Cholelithiasis	144 (5.1%)	135 (4.8%)	279 (4.9%)
Cholestasis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Chronic hepatitis	6 (0.2%)	8 (0.3%)	14 (0.2%)
Cirrhosis alcoholic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cryptogenic cirrhosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic hepatopathy	4 (0.1%)	6 (0.2%)	10 (0.2%)
Drug-induced liver injury	1 (<0.1%)	0	1 (<0.1%)
Gallbladder cholesterolosis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Gallbladder disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gallbladder enlargement	0	1 (<0.1%)	1 (<0.1%)
Gallbladder polyp	21 (0.7%)	31 (1.1%)	52 (0.9%)
Hepatic cirrhosis	5 (0.2%)	13 (0.5%)	18 (0.3%)
Hepatic cyst	11 (0.4%)	25 (0.9%)	36 (0.6%)
Hepatic failure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic fibrosis	0	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	14 (0.5%)	14 (0.5%)	28 (0.5%)
Hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Hepatic lesion	0	1 (<0.1%)	1 (<0.1%)
Hepatic mass	0	3 (0.1%)	3 (<0.1%)
Hepatic steatosis	312 (11.0%)	310 (10.9%)	622 (11.0%)
Hepatitis	1 (<0.1%)	5 (0.2%)	6 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	0	3 (0.1%)	3 (<0.1%)
Hepatocellular injury	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hepatomegaly	6 (0.2%)	11 (0.4%)	17 (0.3%)
Hepatosplenomegaly	7 (0.2%)	1 (<0.1%)	8 (0.1%)
Hyperplastic cholecystopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Jaundice	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Liver disorder	10 (0.4%)	17 (0.6%)	27 (0.5%)
Liver injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Non-alcoholic steatohepatitis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Nonalcoholic fatty liver disease	15 (0.5%)	13 (0.5%)	28 (0.5%)
Portal hypertension	0	1 (<0.1%)	1 (<0.1%)
Post cholecystectomy syndrome	3 (0.1%)	0	3 (<0.1%)
Primary biliary cholangitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sphincter of Oddi dysfunction	0	1 (<0.1%)	1 (<0.1%)
Steatohepatitis	9 (0.3%)	7 (0.2%)	16 (0.3%)
Immune system disorders	181 (6.4%)	153 (5.4%)	334 (5.9%)
Allergic oedema	1 (<0.1%)	0	1 (<0.1%)
Allergy to animal	2 (<0.1%)	0	2 (<0.1%)
Allergy to arthropod sting	3 (0.1%)	3 (0.1%)	6 (0.1%)
Allergy to chemicals	1 (<0.1%)	0	1 (<0.1%)
Allergy to metals	2 (<0.1%)	0	2 (<0.1%)
Allergy to plants	1 (<0.1%)	0	1 (<0.1%)
Allergy to vaccine	0	1 (<0.1%)	1 (<0.1%)
Amyloidosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Anaphylactic shock	2 (<0.1%)	0	2 (<0.1%)
Contrast media allergy	1 (<0.1%)	0	1 (<0.1%)
Contrast media reaction	0	1 (<0.1%)	1 (<0.1%)
Drug hypersensitivity	72 (2.5%)	68 (2.4%)	140 (2.5%)
Dust allergy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Flour sensitivity	1 (<0.1%)	0	1 (<0.1%)
Food allergy	9 (0.3%)	3 (0.1%)	12 (0.2%)
Hypersensitivity	15 (0.5%)	11 (0.4%)	26 (0.5%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immunodeficiency common variable	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	6 (0.2%)	7 (0.2%)	13 (0.2%)
Milk allergy	0	1 (<0.1%)	1 (<0.1%)
Mite allergy	0	1 (<0.1%)	1 (<0.1%)
Multiple allergies	5 (0.2%)	7 (0.2%)	12 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Mycotic allergy	2 (<0.1%)	0	2 (<0.1%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to colouring	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	2 (<0.1%)	2 (<0.1%)
Rubber sensitivity	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Sarcoidosis	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Seasonal allergy	85 (3.0%)	71 (2.5%)	156 (2.7%)
Selective IgA immunodeficiency	0	1 (<0.1%)	1 (<0.1%)
Infections and infestations	659 (23.3%)	692 (24.4%)	1351 (23.8%)
Abdominal abscess	0	1 (<0.1%)	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abscess	0	1 (<0.1%)	1 (<0.1%)
Abscess limb	5 (0.2%)	5 (0.2%)	10 (0.2%)
Abscess neck	2 (<0.1%)	0	2 (<0.1%)
Abscess soft tissue	0	1 (<0.1%)	1 (<0.1%)
Acarodermatitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acute hepatitis B	0	1 (<0.1%)	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Alveolar osteitis	0	1 (<0.1%)	1 (<0.1%)
American trypanosomiasis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal abscess	3 (0.1%)	6 (0.2%)	9 (0.2%)
Appendicitis	19 (0.7%)	26 (0.9%)	45 (0.8%)
Appendicitis perforated	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Arthritis infective	1 (<0.1%)	0	1 (<0.1%)
Aspergilloma	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic HIV infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)
Bacteraemia	3 (0.1%)	0	3 (<0.1%)
Bacterial disease carrier	1 (<0.1%)	0	1 (<0.1%)
Bacteriuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bartholin's abscess	0	1 (<0.1%)	1 (<0.1%)
Blister infected	0	1 (<0.1%)	1 (<0.1%)
Body tinea	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Bone abscess	0	1 (<0.1%)	1 (<0.1%)
Bone tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Borrelia infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Boutonneuse fever	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Brain abscess	0	1 (<0.1%)	1 (<0.1%)
Bronchiolitis	0	2 (<0.1%)	2 (<0.1%)
Bronchitis	32 (1.1%)	26 (0.9%)	58 (1.0%)
Bursitis infective	1 (<0.1%)	0	1 (<0.1%)
Candida infection	2 (<0.1%)	0	2 (<0.1%)
Carbuncle	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cellulitis	29 (1.0%)	30 (1.1%)	59 (1.0%)
Cervicitis	1 (<0.1%)	0	1 (<0.1%)
Chest wall abscess	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	0	3 (0.1%)	3 (<0.1%)
Cholecystitis infective	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic hepatitis B	6 (0.2%)	4 (0.1%)	10 (0.2%)
Chronic hepatitis C	6 (0.2%)	6 (0.2%)	12 (0.2%)
Chronic sinusitis	10 (0.4%)	12 (0.4%)	22 (0.4%)
Chronic tonsillitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Clostridium difficile colitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coccidioidomycosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conjunctivitis	30 (1.1%)	23 (0.8%)	53 (0.9%)
Cutaneous leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Cystitis	10 (0.4%)	12 (0.4%)	22 (0.4%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	0	2 (<0.1%)	2 (<0.1%)
Dermatophytosis of nail	11 (0.4%)	10 (0.4%)	21 (0.4%)
Device related infection	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Diabetic foot infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic gangrene	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Diverticulitis	10 (0.4%)	13 (0.5%)	23 (0.4%)
Diverticulitis intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Ear infection	4 (0.1%)	3 (0.1%)	7 (0.1%)
Ear infection fungal	0	1 (<0.1%)	1 (<0.1%)
Echinococciasis	3 (0.1%)	0	3 (<0.1%)
Empyema	1 (<0.1%)	0	1 (<0.1%)
Encephalitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	1 (<0.1%)	0	1 (<0.1%)
Endophthalmitis	0	1 (<0.1%)	1 (<0.1%)
Enteritis infectious	1 (<0.1%)	0	1 (<0.1%)
Enterocolitis infectious	1 (<0.1%)	0	1 (<0.1%)
Epididymitis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Erysipelas	6 (0.2%)	11 (0.4%)	17 (0.3%)
Escherichia sepsis	0	1 (<0.1%)	1 (<0.1%)
Eye infection	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Eye infection fungal	0	1 (<0.1%)	1 (<0.1%)
Focal peritonitis	2 (<0.1%)	0	2 (<0.1%)
Folliculitis	8 (0.3%)	4 (0.1%)	12 (0.2%)
Fournier's gangrene	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fungal infection	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Fungal skin infection	6 (0.2%)	6 (0.2%)	12 (0.2%)
Furuncle	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Gangrene	2 (<0.1%)	10 (0.4%)	12 (0.2%)
Gastritis bacterial	0	1 (<0.1%)	1 (<0.1%)
Gastroenteritis	9 (0.3%)	4 (0.1%)	13 (0.2%)
Gastroenteritis salmonella	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis viral	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Genital herpes	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Genitourinary tract infection	0	1 (<0.1%)	1 (<0.1%)
Gingivitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Groin abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
HIV carrier	0	1 (<0.1%)	1 (<0.1%)
HIV infection	2 (<0.1%)	0	2 (<0.1%)
Haemorrhagic fever with renal syndrome	1 (<0.1%)	0	1 (<0.1%)
Helicobacter gastritis	4 (0.1%)	3 (0.1%)	7 (0.1%)
Helicobacter infection	5 (0.2%)	4 (0.1%)	9 (0.2%)
Hepatic echinococciasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis A	4 (0.1%)	4 (0.1%)	8 (0.1%)
Hepatitis B	20 (0.7%)	14 (0.5%)	34 (0.6%)
Hepatitis C	15 (0.5%)	16 (0.6%)	31 (0.5%)
Herpes ophthalmic	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Herpes simplex	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Herpes zoster	17 (0.6%)	17 (0.6%)	34 (0.6%)
Histoplasmosis	0	1 (<0.1%)	1 (<0.1%)
Hordeolum	1 (<0.1%)	0	1 (<0.1%)
Infected dermal cyst	0	1 (<0.1%)	1 (<0.1%)
Infected skin ulcer	1 (<0.1%)	0	1 (<0.1%)
Infection	0	4 (0.1%)	4 (<0.1%)
Infectious pleural effusion	0	1 (<0.1%)	1 (<0.1%)
Infective myositis	0	1 (<0.1%)	1 (<0.1%)
Influenza	8 (0.3%)	12 (0.4%)	20 (0.4%)
Intervertebral discitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint abscess	1 (<0.1%)	0	1 (<0.1%)
Joint tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Kidney infection	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Klebsiella infection	0	1 (<0.1%)	1 (<0.1%)
Labyrinthitis	7 (0.2%)	3 (0.1%)	10 (0.2%)
Laryngitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Latent syphilis	0	1 (<0.1%)	1 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Liver abscess	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Localised infection	9 (0.3%)	6 (0.2%)	15 (0.3%)
Lower respiratory tract infection	1 (<0.1%)	0	1 (<0.1%)
Lung abscess	1 (<0.1%)	0	1 (<0.1%)
Lyme disease	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lymph node tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Malaria	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Mastoiditis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Meningitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Meningitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Meningitis viral	0	1 (<0.1%)	1 (<0.1%)
Molluscum contagiosum	1 (<0.1%)	0	1 (<0.1%)
Mumps	0	2 (<0.1%)	2 (<0.1%)
Myringitis	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	20 (0.7%)	25 (0.9%)	45 (0.8%)
Necrotising fasciitis	0	2 (<0.1%)	2 (<0.1%)
Neuroborreliosis	1 (<0.1%)	0	1 (<0.1%)
Neurocysticercosis	1 (<0.1%)	0	1 (<0.1%)
Neurosyphilis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Onychomycosis	42 (1.5%)	42 (1.5%)	84 (1.5%)
Ophthalmic herpes simplex	2 (<0.1%)	0	2 (<0.1%)
Ophthalmic herpes zoster	0	2 (<0.1%)	2 (<0.1%)
Oral candidiasis	0	1 (<0.1%)	1 (<0.1%)
Oral fungal infection	1 (<0.1%)	0	1 (<0.1%)
Oral herpes	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Orchitis	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Osteomyelitis	23 (0.8%)	20 (0.7%)	43 (0.8%)
Osteomyelitis acute	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis chronic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Otitis externa	5 (0.2%)	5 (0.2%)	10 (0.2%)
Otitis media	4 (0.1%)	3 (0.1%)	7 (0.1%)
Otitis media acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Otitis media chronic	4 (0.1%)	7 (0.2%)	11 (0.2%)
Otitis media fungal	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Paronychia	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Parotid abscess	0	1 (<0.1%)	1 (<0.1%)
Pelvic inflammatory disease	1 (<0.1%)	0	1 (<0.1%)
Perichondritis	0	1 (<0.1%)	1 (<0.1%)
Pericoronitis	0	1 (<0.1%)	1 (<0.1%)
Periodontitis	0	1 (<0.1%)	1 (<0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Peritonsillar abscess	1 (<0.1%)	0	1 (<0.1%)
Periumbilical abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	6 (0.2%)	11 (0.4%)	17 (0.3%)
Pilonidal cyst	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Plasmodium falciparum infection	0	1 (<0.1%)	1 (<0.1%)
Pneumonia	36 (1.3%)	47 (1.7%)	83 (1.5%)
Pneumonia bacterial	1 (<0.1%)	0	1 (<0.1%)
Pneumonia influenzal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia legionella	0	1 (<0.1%)	1 (<0.1%)
Poliomyelitis	3 (0.1%)	0	3 (<0.1%)
Post procedural infection	0	2 (<0.1%)	2 (<0.1%)
Postoperative wound infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prostatic abscess	1 (<0.1%)	0	1 (<0.1%)
Psoas abscess	0	1 (<0.1%)	1 (<0.1%)
Pulmonary echinococciasis	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	16 (0.6%)	21 (0.7%)	37 (0.7%)
Pulpitis dental	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pustule	1 (<0.1%)	0	1 (<0.1%)
Pyelonephritis	5 (0.2%)	9 (0.3%)	14 (0.2%)
Pyelonephritis acute	0	3 (0.1%)	3 (<0.1%)
Pyelonephritis chronic	40 (1.4%)	41 (1.4%)	81 (1.4%)
Pyoderma	0	1 (<0.1%)	1 (<0.1%)
Pyonephrosis	0	1 (<0.1%)	1 (<0.1%)
Pyuria	0	2 (<0.1%)	2 (<0.1%)
Rectal abscess	0	1 (<0.1%)	1 (<0.1%)
Renal abscess	0	2 (<0.1%)	2 (<0.1%)
Renal cyst infection	0	1 (<0.1%)	1 (<0.1%)
Renal tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	3 (0.1%)	8 (0.3%)	11 (0.2%)
Respiratory tract infection viral	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Rhinitis	18 (0.6%)	10 (0.4%)	28 (0.5%)
Salpingo-oophoritis	0	1 (<0.1%)	1 (<0.1%)
Schistosomiasis liver	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Sepsis	3 (0.1%)	7 (0.2%)	10 (0.2%)
Septic shock	1 (<0.1%)	0	1 (<0.1%)
Sinusitis	17 (0.6%)	14 (0.5%)	31 (0.5%)
Skin candida	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin infection	8 (0.3%)	1 (<0.1%)	9 (0.2%)
Soft tissue infection	3 (0.1%)	0	3 (<0.1%)
Staphylococcal bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal infection	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Staphylococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Stoma site abscess	1 (<0.1%)	0	1 (<0.1%)
Streptococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Strongyloidiasis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	4 (0.1%)	4 (0.1%)	8 (0.1%)
Subdiaphragmatic abscess	0	1 (<0.1%)	1 (<0.1%)
Tetanus	0	1 (<0.1%)	1 (<0.1%)
Tick-borne viral encephalitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tinea cruris	4 (0.1%)	0	4 (<0.1%)
Tinea infection	4 (0.1%)	8 (0.3%)	12 (0.2%)
Tinea pedis	27 (1.0%)	30 (1.1%)	57 (1.0%)
Tinea versicolour	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Tonsillitis	7 (0.2%)	4 (0.1%)	11 (0.2%)
Tooth abscess	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tooth infection	1 (<0.1%)	0	1 (<0.1%)
Tracheitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tracheobronchitis	0	1 (<0.1%)	1 (<0.1%)
Trematode infection	0	2 (<0.1%)	2 (<0.1%)
Trichophytosis	1 (<0.1%)	0	1 (<0.1%)
Tuberculosis	13 (0.5%)	8 (0.3%)	21 (0.4%)
Tuberculous laryngitis	1 (<0.1%)	0	1 (<0.1%)
Tuberculous pleurisy	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	37 (1.3%)	41 (1.4%)	78 (1.4%)
Urethritis	1 (<0.1%)	0	1 (<0.1%)
Urinary tract infection	56 (2.0%)	65 (2.3%)	121 (2.1%)
Urinary tract infection bacterial	1 (<0.1%)	0	1 (<0.1%)
Urosepsis	3 (0.1%)	4 (0.1%)	7 (0.1%)
Vaginal infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicella	0	2 (<0.1%)	2 (<0.1%)
Varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Vestibular neuronitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Viral hepatitis carrier	8 (0.3%)	8 (0.3%)	16 (0.3%)
Viral infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Viral myocarditis	1 (<0.1%)	0	1 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	0	2 (<0.1%)
Vulval abscess	0	1 (<0.1%)	1 (<0.1%)
Vulvitis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal mycotic infection	0	2 (<0.1%)	2 (<0.1%)
Wound infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injury, poisoning and procedural complications	237 (8.4%)	229 (8.1%)	466 (8.2%)
Abdominal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Accident	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Airway burns	0	1 (<0.1%)	1 (<0.1%)
Animal scratch	0	1 (<0.1%)	1 (<0.1%)
Ankle fracture	6 (0.2%)	12 (0.4%)	18 (0.3%)
Arterial injury	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Asbestosis	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Back injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blindness traumatic	1 (<0.1%)	0	1 (<0.1%)
Bone contusion	1 (<0.1%)	0	1 (<0.1%)
Bone fissure	0	1 (<0.1%)	1 (<0.1%)
Brain contusion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Burns third degree	0	1 (<0.1%)	1 (<0.1%)
Carotid artery restenosis	1 (<0.1%)	0	1 (<0.1%)
Cartilage injury	0	2 (<0.1%)	2 (<0.1%)
Cataract operation complication	1 (<0.1%)	0	1 (<0.1%)
Cervical vertebral fracture	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Chest injury	0	4 (0.1%)	4 (<0.1%)
Clavicle fracture	5 (0.2%)	6 (0.2%)	11 (0.2%)
Concussion	4 (0.1%)	5 (0.2%)	9 (0.2%)
Contraindicated product administered	1 (<0.1%)	0	1 (<0.1%)
Contusion	5 (0.2%)	4 (0.1%)	9 (0.2%)
Corneal abrasion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary vascular graft occlusion	0	1 (<0.1%)	1 (<0.1%)
Craniocerebral injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Deafness traumatic	0	1 (<0.1%)	1 (<0.1%)
Dislocation of sternum	0	1 (<0.1%)	1 (<0.1%)
Electric shock	0	1 (<0.1%)	1 (<0.1%)
Epicondylitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Exposure to communicable disease	0	3 (0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Exposure to radiation	0	1 (<0.1%)	1 (<0.1%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye injury	4 (0.1%)	0	4 (<0.1%)
Face injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial bones fracture	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Fall	6 (0.2%)	7 (0.2%)	13 (0.2%)
Femoral neck fracture	2 (<0.1%)	0	2 (<0.1%)
Femur fracture	10 (0.4%)	3 (0.1%)	13 (0.2%)
Fibula fracture	7 (0.2%)	4 (0.1%)	11 (0.2%)
Foot fracture	11 (0.4%)	6 (0.2%)	17 (0.3%)
Forearm fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Foreign body	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body in eye	1 (<0.1%)	0	1 (<0.1%)
Fracture	0	1 (<0.1%)	1 (<0.1%)
Fractured sacrum	0	1 (<0.1%)	1 (<0.1%)
Gingival injury	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hand fracture	4 (0.1%)	3 (0.1%)	7 (0.1%)
Head injury	4 (0.1%)	3 (0.1%)	7 (0.1%)
Heart injury	0	1 (<0.1%)	1 (<0.1%)
Heat exhaustion	1 (<0.1%)	0	1 (<0.1%)
Hip fracture	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Humerus fracture	6 (0.2%)	6 (0.2%)	12 (0.2%)
Incision site haematoma	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia	12 (0.4%)	2 (<0.1%)	14 (0.2%)
Injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intervertebral disc injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint dislocation	6 (0.2%)	5 (0.2%)	11 (0.2%)
Joint injury	3 (0.1%)	5 (0.2%)	8 (0.1%)
Kidney contusion	0	1 (<0.1%)	1 (<0.1%)
Kidney rupture	0	1 (<0.1%)	1 (<0.1%)
Laryngeal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament injury	1 (<0.1%)	0	1 (<0.1%)
Ligament rupture	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Ligament sprain	5 (0.2%)	10 (0.4%)	15 (0.3%)
Limb injury	14 (0.5%)	10 (0.4%)	24 (0.4%)
Limb traumatic amputation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lower limb fracture	7 (0.2%)	8 (0.3%)	15 (0.3%)
Lumbar vertebral fracture	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Meniscus injury	10 (0.4%)	10 (0.4%)	20 (0.4%)
Multiple injuries	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Muscle injury	0	1 (<0.1%)	1 (<0.1%)
Muscle rupture	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Muscle strain	3 (0.1%)	4 (0.1%)	7 (0.1%)
Occupational exposure to toxic agent	1 (<0.1%)	0	1 (<0.1%)
Osteochondral fracture	0	1 (<0.1%)	1 (<0.1%)
Palate injury	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	3 (0.1%)	0	3 (<0.1%)
Pelvic fracture	2 (<0.1%)	0	2 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral nerve injury	1 (<0.1%)	0	1 (<0.1%)
Pneumocephalus	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post laminectomy syndrome	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Post procedural haematoma	0	1 (<0.1%)	1 (<0.1%)
Post procedural hypoparathyroidism	0	1 (<0.1%)	1 (<0.1%)
Post procedural hypothyroidism	3 (0.1%)	6 (0.2%)	9 (0.2%)
Post-traumatic neck syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Post-traumatic pain	4 (0.1%)	3 (0.1%)	7 (0.1%)
Procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Radial nerve injury	1 (<0.1%)	0	1 (<0.1%)
Radiation injury	0	1 (<0.1%)	1 (<0.1%)
Radius fracture	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Reactive gastropathy	0	1 (<0.1%)	1 (<0.1%)
Rib fracture	6 (0.2%)	6 (0.2%)	12 (0.2%)
Road traffic accident	7 (0.2%)	4 (0.1%)	11 (0.2%)
Scapula fracture	1 (<0.1%)	0	1 (<0.1%)
Scar	2 (<0.1%)	0	2 (<0.1%)
Skin abrasion	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Skin graft failure	1 (<0.1%)	0	1 (<0.1%)
Skin injury	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin laceration	4 (0.1%)	3 (0.1%)	7 (0.1%)
Skin wound	4 (0.1%)	0	4 (<0.1%)
Skull fracture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Snake bite	0	1 (<0.1%)	1 (<0.1%)
Soft tissue injury	1 (<0.1%)	0	1 (<0.1%)
Spinal compression fracture	0	4 (0.1%)	4 (<0.1%)
Spinal fracture	5 (0.2%)	5 (0.2%)	10 (0.2%)
Stab wound	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sternal fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Stoma complication	1 (<0.1%)	0	1 (<0.1%)
Stomal hernia	1 (<0.1%)	0	1 (<0.1%)
Stress fracture	1 (<0.1%)	0	1 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	0	1 (<0.1%)
Subdural haematoma	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tendon injury	1 (<0.1%)	0	1 (<0.1%)
Tendon rupture	7 (0.2%)	3 (0.1%)	10 (0.2%)
Testicular injury	0	1 (<0.1%)	1 (<0.1%)
Thermal burn	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Thoracic vertebral fracture	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Tibia fracture	6 (0.2%)	6 (0.2%)	12 (0.2%)
Tooth fracture	1 (<0.1%)	0	1 (<0.1%)
Toxicity to various agents	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Traumatic arthritis	0	1 (<0.1%)	1 (<0.1%)
Traumatic fracture	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Traumatic haemothorax	0	1 (<0.1%)	1 (<0.1%)
Traumatic liver injury	0	1 (<0.1%)	1 (<0.1%)
Ulna fracture	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	6 (0.2%)	11 (0.4%)	17 (0.3%)
Vascular pseudoaneurysm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Wound necrosis	0	1 (<0.1%)	1 (<0.1%)
Wrist fracture	6 (0.2%)	4 (0.1%)	10 (0.2%)
Investigations	329 (11.6%)	334 (11.8%)	663 (11.7%)
Activated partial thromboplastin time prolonged	1 (<0.1%)	0	1 (<0.1%)
Alanine aminotransferase increased	5 (0.2%)	3 (0.1%)	8 (0.1%)
Albumin urine present	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amylase increased	0	3 (0.1%)	3 (<0.1%)
Angiocardiogram	23 (0.8%)	10 (0.4%)	33 (0.6%)
Angiogram	9 (0.3%)	5 (0.2%)	14 (0.2%)
Angiogram cerebral	1 (<0.1%)	0	1 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Ankle brachial index	1 (<0.1%)	0	1 (<0.1%)
Aortic bruit	0	1 (<0.1%)	1 (<0.1%)
Aortogram	1 (<0.1%)	0	1 (<0.1%)
Arteriogram	2 (<0.1%)	0	2 (<0.1%)
Arteriogram coronary normal	1 (<0.1%)	0	1 (<0.1%)
Arteriogram renal	1 (<0.1%)	0	1 (<0.1%)
Arthroscopy	6 (0.2%)	4 (0.1%)	10 (0.2%)
Aspartate aminotransferase increased	4 (0.1%)	3 (0.1%)	7 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Aspiration pleural cavity	0	2 (<0.1%)	2 (<0.1%)
Biopsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Biopsy breast	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Biopsy kidney	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Biopsy liver normal	0	1 (<0.1%)	1 (<0.1%)
Biopsy lymph gland	0	1 (<0.1%)	1 (<0.1%)
Biopsy prostate	2 (<0.1%)	0	2 (<0.1%)
Biopsy skin	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	4 (0.1%)	5 (0.2%)	9 (0.2%)
Blood bicarbonate decreased	2 (<0.1%)	0	2 (<0.1%)
Blood cholesterol increased	34 (1.2%)	35 (1.2%)	69 (1.2%)
Blood creatine increased	0	1 (<0.1%)	1 (<0.1%)
Blood creatine phosphokinase increased	41 (1.4%)	50 (1.8%)	91 (1.6%)
Blood creatinine increased	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood glucose abnormal	0	1 (<0.1%)	1 (<0.1%)
Blood homocysteine increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood iron decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood lactate dehydrogenase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood magnesium decreased	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Blood magnesium increased	0	1 (<0.1%)	1 (<0.1%)
Blood parathyroid hormone increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Blood potassium decreased	0	3 (0.1%)	3 (<0.1%)
Blood potassium increased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Blood pressure increased	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Blood sodium decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood testosterone decreased	6 (0.2%)	5 (0.2%)	11 (0.2%)
Blood testosterone increased	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	3 (0.1%)	4 (0.1%)	7 (0.1%)
Blood urea increased	0	2 (<0.1%)	2 (<0.1%)
Blood uric acid increased	10 (0.4%)	15 (0.5%)	25 (0.4%)
Blood urine present	1 (<0.1%)	0	1 (<0.1%)
Blood zinc decreased	1 (<0.1%)	0	1 (<0.1%)
Body mass index increased	7 (0.2%)	2 (<0.1%)	9 (0.2%)
Bone densitometry	1 (<0.1%)	0	1 (<0.1%)
Bone density decreased	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Bronchoscopy normal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	12 (0.4%)	17 (0.6%)	29 (0.5%)
Carbon dioxide decreased	0	2 (<0.1%)	2 (<0.1%)
Cardiac murmur	19 (0.7%)	20 (0.7%)	39 (0.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Cardiac stress test	0	1 (<0.1%)	1 (<0.1%)
Cardiac stress test abnormal	1 (<0.1%)	0	1 (<0.1%)
Cardiac ventriculogram	1 (<0.1%)	0	1 (<0.1%)
Carotid bruit	3 (0.1%)	6 (0.2%)	9 (0.2%)
Carotid intima-media thickness increased	1 (<0.1%)	0	1 (<0.1%)
Catheterisation cardiac	15 (0.5%)	21 (0.7%)	36 (0.6%)
Catheterisation cardiac normal	0	1 (<0.1%)	1 (<0.1%)
Chest X-ray abnormal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Computerised tomogram head abnormal	0	1 (<0.1%)	1 (<0.1%)
Crystal urine present	0	1 (<0.1%)	1 (<0.1%)
Cystoscopy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
ECG signs of myocardial infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
ECG signs of ventricular hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Echocardiogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ejection fraction decreased	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Ejection fraction normal	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QT interval abnormal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Electrocardiogram QT prolonged	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Electrocardiogram ST segment abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram ST-T change	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Electrocardiogram ST-T segment abnormal	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Electrocardiogram T wave abnormal	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Electrocardiogram T wave alternans	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave amplitude decreased	5 (0.2%)	3 (0.1%)	8 (0.1%)
Electrocardiogram T wave inversion	5 (0.2%)	3 (0.1%)	8 (0.1%)
Electrocardiogram U-wave prominent	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram abnormal	6 (0.2%)	4 (0.1%)	10 (0.2%)
Electrocardiogram high voltage	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram repolarisation abnormality	8 (0.3%)	5 (0.2%)	13 (0.2%)
Endoscopic retrograde cholangiopancreatography	0	1 (<0.1%)	1 (<0.1%)
Endoscopy upper gastrointestinal tract	0	1 (<0.1%)	1 (<0.1%)
Eosinophil count increased	0	1 (<0.1%)	1 (<0.1%)
False positive investigation result	0	2 (<0.1%)	2 (<0.1%)
Forced vital capacity decreased	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase increased	17 (0.6%)	17 (0.6%)	34 (0.6%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Gastric pH decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glomerular filtration rate decreased	0	1 (<0.1%)	1 (<0.1%)
Glucose tolerance increased	0	1 (<0.1%)	1 (<0.1%)
Glycosylated haemoglobin increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haemoglobin decreased	0	1 (<0.1%)	1 (<0.1%)
Heart rate increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Heart rate normal	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Helicobacter test positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatic enzyme abnormal	0	1 (<0.1%)	1 (<0.1%)
Hepatic enzyme increased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hepatitis B surface antigen positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis C antibody positive	3 (0.1%)	0	3 (<0.1%)
Hepatitis C virus test positive	0	1 (<0.1%)	1 (<0.1%)
High density lipoprotein increased	1 (<0.1%)	0	1 (<0.1%)
Inflammatory marker increased	1 (<0.1%)	0	1 (<0.1%)
Influenza A virus test positive	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intraocular pressure test abnormal	0	1 (<0.1%)	1 (<0.1%)
Investigation	1 (<0.1%)	0	1 (<0.1%)
Keratometry	1 (<0.1%)	0	1 (<0.1%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)
Light chain analysis increased	0	1 (<0.1%)	1 (<0.1%)
Lipase increased	0	2 (<0.1%)	2 (<0.1%)
Lipids abnormal	1 (<0.1%)	0	1 (<0.1%)
Lipids increased	1 (<0.1%)	0	1 (<0.1%)
Lipoprotein (a) increased	0	2 (<0.1%)	2 (<0.1%)
Liver function test abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Liver function test increased	0	3 (0.1%)	3 (<0.1%)
Mean cell volume increased	1 (<0.1%)	0	1 (<0.1%)
Monocyte count increased	1 (<0.1%)	0	1 (<0.1%)
Muscle enzyme increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial necrosis marker increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial strain	0	3 (0.1%)	3 (<0.1%)
N-terminal prohormone brain natriuretic peptide increased	0	1 (<0.1%)	1 (<0.1%)
Neutrophil count increased	1 (<0.1%)	0	1 (<0.1%)
Ophthalmological examination normal	0	1 (<0.1%)	1 (<0.1%)
Oxygen consumption increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Parasite stool test positive	1 (<0.1%)	0	1 (<0.1%)
Pedal pulse decreased	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Peripheral arteriogram	0	1 (<0.1%)	1 (<0.1%)
Peripheral pulse decreased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Platelet count decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Polymerase chain reaction positive	0	1 (<0.1%)	1 (<0.1%)
Popliteal pulse	0	1 (<0.1%)	1 (<0.1%)
Proctosigmoidoscopy	0	1 (<0.1%)	1 (<0.1%)
Prostatic specific antigen increased	5 (0.2%)	8 (0.3%)	13 (0.2%)
Pulmonary imaging procedure abnormal	1 (<0.1%)	0	1 (<0.1%)
Pulse absent	0	1 (<0.1%)	1 (<0.1%)
QRS axis abnormal	5 (0.2%)	14 (0.5%)	19 (0.3%)
Red blood cell sedimentation rate increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Red cell distribution width increased	0	1 (<0.1%)	1 (<0.1%)
Renal function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Scan myocardial perfusion abnormal	0	1 (<0.1%)	1 (<0.1%)
Smear cervix abnormal	0	1 (<0.1%)	1 (<0.1%)
Stress echocardiogram	0	1 (<0.1%)	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test normal	2 (<0.1%)	0	2 (<0.1%)
Thyroxine abnormal	0	1 (<0.1%)	1 (<0.1%)
Transaminases increased	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Transferrin saturation decreased	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Troponin increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tuberculin test positive	0	1 (<0.1%)	1 (<0.1%)
Ultrasound Doppler	1 (<0.1%)	0	1 (<0.1%)
Ultrasound kidney abnormal	1 (<0.1%)	0	1 (<0.1%)
Ultrasound scan	1 (<0.1%)	0	1 (<0.1%)
Ureteroscopy	0	1 (<0.1%)	1 (<0.1%)
Urinary casts present	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	3 (0.1%)	0	3 (<0.1%)
Vitamin D decreased	7 (0.2%)	11 (0.4%)	18 (0.3%)
Vitamin K decreased	1 (<0.1%)	0	1 (<0.1%)
Weight decreased	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Weight increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
White blood cell count increased	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Metabolism and nutrition disorders	2833 (100.0%)	2841 (100.0%)	5674 (100.0%)
Abnormal loss of weight	0	1 (<0.1%)	1 (<0.1%)
Abnormal weight gain	0	1 (<0.1%)	1 (<0.1%)
Acidosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Calcium deficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Central obesity	15 (0.5%)	17 (0.6%)	32 (0.6%)
Decreased appetite	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Dehydration	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Diabetes mellitus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetes mellitus inadequate control	3 (0.1%)	5 (0.2%)	8 (0.1%)
Diabetic complication	1 (<0.1%)	0	1 (<0.1%)
Diabetic dyslipidaemia	2 (<0.1%)	0	2 (<0.1%)
Diabetic ketoacidosis	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Diabetic ketosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic metabolic decompensation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dyslipidaemia	942 (33.3%)	947 (33.3%)	1889 (33.3%)
Electrolyte imbalance	1 (<0.1%)	0	1 (<0.1%)
Fluid overload	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Fluid retention	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Folate deficiency	7 (0.2%)	7 (0.2%)	14 (0.2%)
Food intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	1 (<0.1%)	0	1 (<0.1%)
Gout	285 (10.1%)	281 (9.9%)	566 (10.0%)
Haemochromatosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haemosiderosis	0	1 (<0.1%)	1 (<0.1%)
Hypercalcaemia	7 (0.2%)	13 (0.5%)	20 (0.4%)
Hyperchloraemia	1 (<0.1%)	0	1 (<0.1%)
Hypercholesterolaemia	344 (12.1%)	331 (11.7%)	675 (11.9%)
Hypercreatininaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperglycaemia	5 (0.2%)	5 (0.2%)	10 (0.2%)
Hyperglycaemic hyperosmolar nonketotic syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperhomocysteinaemia	9 (0.3%)	4 (0.1%)	13 (0.2%)
Hyperkalaemia	70 (2.5%)	82 (2.9%)	152 (2.7%)
Hyperlipidaemia	810 (28.6%)	842 (29.6%)	1652 (29.1%)
Hypernatraemia	1 (<0.1%)	0	1 (<0.1%)
Hyperphagia	1 (<0.1%)	0	1 (<0.1%)
Hyperphosphataemia	6 (0.2%)	8 (0.3%)	14 (0.2%)
Hyperproteinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypertriglyceridaemia	74 (2.6%)	65 (2.3%)	139 (2.4%)
Hyperuricaemia	552 (19.5%)	572 (20.1%)	1124 (19.8%)
Hypo HDL cholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypoalbuminaemia	7 (0.2%)	8 (0.3%)	15 (0.3%)
Hypocalcaemia	6 (0.2%)	11 (0.4%)	17 (0.3%)
Hypocholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypoglycaemia	19 (0.7%)	14 (0.5%)	33 (0.6%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hypokalaemia	27 (1.0%)	32 (1.1%)	59 (1.0%)
Hypolipidaemia	1 (<0.1%)	0	1 (<0.1%)
Hypomagnesaemia	9 (0.3%)	7 (0.2%)	16 (0.3%)
Hypometabolism	0	1 (<0.1%)	1 (<0.1%)
Hyponatraemia	8 (0.3%)	9 (0.3%)	17 (0.3%)
Hypophosphataemia	0	2 (<0.1%)	2 (<0.1%)
Hypoproteinaemia	7 (0.2%)	7 (0.2%)	14 (0.2%)
Hypouricaemia	1 (<0.1%)	0	1 (<0.1%)
Hypovitaminosis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency	22 (0.8%)	26 (0.9%)	48 (0.8%)
Ketoacidosis	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	1 (<0.1%)	0	1 (<0.1%)
Lactose intolerance	3 (0.1%)	3 (0.1%)	6 (0.1%)
Latent autoimmune diabetes in adults	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipid metabolism disorder	7 (0.2%)	16 (0.6%)	23 (0.4%)
Lipoedema	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Metabolic acidosis	9 (0.3%)	15 (0.5%)	24 (0.4%)
Metabolic alkalosis	0	3 (0.1%)	3 (<0.1%)
Metabolic disorder	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Metabolic syndrome	26 (0.9%)	26 (0.9%)	52 (0.9%)
Obesity	1119 (39.5%)	1079 (38.0%)	2198 (38.7%)
Overweight	33 (1.2%)	34 (1.2%)	67 (1.2%)
Pancreatogenous diabetes	0	1 (<0.1%)	1 (<0.1%)
Polydipsia	1 (<0.1%)	0	1 (<0.1%)
Purine metabolism disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tetany	1 (<0.1%)	0	1 (<0.1%)
Type 2 diabetes mellitus	2832 (>99.9%)	2840 (>99.9%)	5672 (>99.9%)
Vitamin B complex deficiency	7 (0.2%)	1 (<0.1%)	8 (0.1%)
Vitamin B1 deficiency	1 (<0.1%)	0	1 (<0.1%)
Vitamin B12 deficiency	50 (1.8%)	50 (1.8%)	100 (1.8%)
Vitamin C deficiency	2 (<0.1%)	0	2 (<0.1%)
Vitamin D deficiency	277 (9.8%)	255 (9.0%)	532 (9.4%)
Zinc deficiency	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal and connective tissue disorders	1061 (37.5%)	1070 (37.7%)	2131 (37.6%)
Acquired claw toe	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle deformity	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Ankle impingement	0	1 (<0.1%)	1 (<0.1%)
Ankylosing spondylitis	4 (0.1%)	5 (0.2%)	9 (0.2%)
Arthralgia	127 (4.5%)	140 (4.9%)	267 (4.7%)
Arthritis	58 (2.0%)	56 (2.0%)	114 (2.0%)
Arthritis reactive	1 (<0.1%)	0	1 (<0.1%)
Arthropathy	7 (0.2%)	11 (0.4%)	18 (0.3%)
Articular calcification	1 (<0.1%)	0	1 (<0.1%)
Axial spondyloarthritis	1 (<0.1%)	0	1 (<0.1%)
Back disorder	2 (<0.1%)	7 (0.2%)	9 (0.2%)
Back pain	189 (6.7%)	210 (7.4%)	399 (7.0%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	0	3 (0.1%)	3 (<0.1%)
Bone formation increased	0	1 (<0.1%)	1 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Bone pain	2 (<0.1%)	0	2 (<0.1%)
Bursitis	8 (0.3%)	10 (0.4%)	18 (0.3%)
Cervical spinal stenosis	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Chondrocalcinosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Chondrocalcinosis pyrophosphate	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic kidney disease-mineral and bone disorder	7 (0.2%)	15 (0.5%)	22 (0.4%)
Costochondritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Crystal arthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deformity thorax	1 (<0.1%)	0	1 (<0.1%)
Destructive spondyloarthropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic amyotrophy	1 (<0.1%)	0	1 (<0.1%)
Diastasis recti abdominis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diffuse idiopathic skeletal hyperostosis	0	2 (<0.1%)	2 (<0.1%)
Dupuytren's contracture	9 (0.3%)	7 (0.2%)	16 (0.3%)
Enthesopathy	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Exostosis	11 (0.4%)	10 (0.4%)	21 (0.4%)
Extremity contracture	1 (<0.1%)	0	1 (<0.1%)
Facet joint syndrome	0	4 (0.1%)	4 (<0.1%)
Fasciitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Fibromyalgia	8 (0.3%)	13 (0.5%)	21 (0.4%)
Flank pain	4 (0.1%)	3 (0.1%)	7 (0.1%)
Foot deformity	20 (0.7%)	22 (0.8%)	42 (0.7%)
Gouty arthritis	46 (1.6%)	39 (1.4%)	85 (1.5%)
Gouty tophus	1 (<0.1%)	0	1 (<0.1%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hand deformity	0	1 (<0.1%)	1 (<0.1%)
Hypercreatinaemia	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc compression	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc degeneration	25 (0.9%)	18 (0.6%)	43 (0.8%)
Intervertebral disc disorder	28 (1.0%)	23 (0.8%)	51 (0.9%)
Intervertebral disc displacement	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Intervertebral disc protrusion	75 (2.6%)	66 (2.3%)	141 (2.5%)
Intervertebral disc space narrowing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Jaw cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint contracture	0	1 (<0.1%)	1 (<0.1%)
Joint deposit	2 (<0.1%)	0	2 (<0.1%)
Joint effusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint instability	0	1 (<0.1%)	1 (<0.1%)
Joint noise	0	1 (<0.1%)	1 (<0.1%)
Joint range of motion decreased	4 (0.1%)	0	4 (<0.1%)
Joint swelling	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Knee deformity	1 (<0.1%)	0	1 (<0.1%)
Kyphosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament disorder	0	1 (<0.1%)	1 (<0.1%)
Limb asymmetry	1 (<0.1%)	0	1 (<0.1%)
Limb discomfort	0	1 (<0.1%)	1 (<0.1%)
Limb mass	0	2 (<0.1%)	2 (<0.1%)
Lumbar spinal stenosis	22 (0.8%)	19 (0.7%)	41 (0.7%)
Meniscal degeneration	2 (<0.1%)	0	2 (<0.1%)
Metatarsalgia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Mobility decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle atrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle contracture	1 (<0.1%)	0	1 (<0.1%)
Muscle disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle spasms	86 (3.0%)	84 (3.0%)	170 (3.0%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	5 (0.2%)	11 (0.4%)	16 (0.3%)
Musculoskeletal chest pain	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Musculoskeletal discomfort	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Musculoskeletal disorder	2 (<0.1%)	0	2 (<0.1%)
Musculoskeletal pain	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Musculoskeletal stiffness	4 (0.1%)	5 (0.2%)	9 (0.2%)
Myalgia	31 (1.1%)	28 (1.0%)	59 (1.0%)
Myofascial pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myopathy	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Myositis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Neck mass	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Neck pain	16 (0.6%)	23 (0.8%)	39 (0.7%)
Neuropathic arthropathy	17 (0.6%)	22 (0.8%)	39 (0.7%)
Nodal osteoarthritis	0	1 (<0.1%)	1 (<0.1%)
Osteitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Osteitis deformans	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteoarthritis	320 (11.3%)	347 (12.2%)	667 (11.8%)
Osteoarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteochondrosis	35 (1.2%)	35 (1.2%)	70 (1.2%)
Osteolysis	0	2 (<0.1%)	2 (<0.1%)
Osteonecrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Osteopenia	17 (0.6%)	28 (1.0%)	45 (0.8%)
Osteoporosis	68 (2.4%)	73 (2.6%)	141 (2.5%)
Osteosclerosis	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	47 (1.7%)	40 (1.4%)	87 (1.5%)
Pain in jaw	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Patellofemoral pain syndrome	0	1 (<0.1%)	1 (<0.1%)
Periarthritis	20 (0.7%)	26 (0.9%)	46 (0.8%)
Plantar fascial fibromatosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Plantar fasciitis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Polyarthritis	2 (<0.1%)	7 (0.2%)	9 (0.2%)
Polymyalgia rheumatica	3 (0.1%)	6 (0.2%)	9 (0.2%)
Polymyositis	1 (<0.1%)	0	1 (<0.1%)
Prognathism	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	1 (<0.1%)	8 (0.3%)	9 (0.2%)
Rhabdomyolysis	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Rheumatic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rheumatic fever	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Rheumatoid arthritis	21 (0.7%)	25 (0.9%)	46 (0.8%)
Rotator cuff syndrome	37 (1.3%)	22 (0.8%)	59 (1.0%)
Sacroiliitis	1 (<0.1%)	0	1 (<0.1%)
Sarcopenia	0	1 (<0.1%)	1 (<0.1%)
Scoliosis	2 (<0.1%)	9 (0.3%)	11 (0.2%)
Senile osteoporosis	0	1 (<0.1%)	1 (<0.1%)
Seronegative arthritis	1 (<0.1%)	0	1 (<0.1%)
Sjogren's syndrome	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Soft tissue disorder	1 (<0.1%)	0	1 (<0.1%)
Soft tissue mass	0	1 (<0.1%)	1 (<0.1%)
Soft tissue swelling	1 (<0.1%)	0	1 (<0.1%)
Spinal deformity	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Spinal ligament ossification	1 (<0.1%)	0	1 (<0.1%)
Spinal osteoarthritis	108 (3.8%)	118 (4.2%)	226 (4.0%)
Spinal pain	11 (0.4%)	8 (0.3%)	19 (0.3%)
Spinal retrolisthesis	0	2 (<0.1%)	2 (<0.1%)
Spinal stenosis	23 (0.8%)	26 (0.9%)	49 (0.9%)
Spondylitis	3 (0.1%)	5 (0.2%)	8 (0.1%)
Spondyloarthropathy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Spondylolisthesis	10 (0.4%)	6 (0.2%)	16 (0.3%)
Spondylolysis	2 (<0.1%)	0	2 (<0.1%)
Still's disease	1 (<0.1%)	0	1 (<0.1%)
Symphysiolysis	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	4 (0.1%)	7 (0.2%)	11 (0.2%)
Synovitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Systemic lupus erythematosus	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Temporomandibular joint syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tendon disorder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tendonitis	7 (0.2%)	11 (0.4%)	18 (0.3%)
Tenosynovitis	5 (0.2%)	3 (0.1%)	8 (0.1%)
Tenosynovitis stenosans	4 (0.1%)	4 (0.1%)	8 (0.1%)
Torticollis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Trigger finger	27 (1.0%)	12 (0.4%)	39 (0.7%)
Vertebral foraminal stenosis	2 (<0.1%)	0	2 (<0.1%)
Vertebral osteophyte	0	2 (<0.1%)	2 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	390 (13.8%)	402 (14.1%)	792 (14.0%)
Acoustic neuroma	0	1 (<0.1%)	1 (<0.1%)
Acrochordon	5 (0.2%)	4 (0.1%)	9 (0.2%)
Acute myeloid leukaemia	0	2 (<0.1%)	2 (<0.1%)
Adenocarcinoma of colon	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Adenoma benign	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Adrenal adenoma	12 (0.4%)	10 (0.4%)	22 (0.4%)
Adrenal gland cancer	0	2 (<0.1%)	2 (<0.1%)
Adrenal neoplasm	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyofibroblastoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyolipoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Appendix adenoma	0	1 (<0.1%)	1 (<0.1%)
B-cell lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal cell carcinoma	31 (1.1%)	23 (0.8%)	54 (1.0%)
Benign breast neoplasm	1 (<0.1%)	3 (0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Benign ear neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign endocrine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign female reproductive tract neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign hepatic neoplasm	2 (<0.1%)	0	2 (<0.1%)
Benign laryngeal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign lung neoplasm	3 (0.1%)	4 (0.1%)	7 (0.1%)
Benign neoplasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Benign neoplasm of adrenal gland	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of choroid	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of prostate	0	2 (<0.1%)	2 (<0.1%)
Benign neoplasm of skin	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Benign neoplasm of thyroid gland	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Benign neoplasm of urethra	0	1 (<0.1%)	1 (<0.1%)
Benign oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign ovarian tumour	0	2 (<0.1%)	2 (<0.1%)
Benign renal neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign salivary gland neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder cancer	5 (0.2%)	10 (0.4%)	15 (0.3%)
Bladder cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Bladder neoplasm	5 (0.2%)	5 (0.2%)	10 (0.2%)
Bladder papilloma	2 (<0.1%)	0	2 (<0.1%)
Bladder transitional cell carcinoma	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Blepharal papilloma	1 (<0.1%)	0	1 (<0.1%)
Bone cancer	0	1 (<0.1%)	1 (<0.1%)
Bone neoplasm	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Bowen's disease	0	1 (<0.1%)	1 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Brain neoplasm benign	0	2 (<0.1%)	2 (<0.1%)
Breast adenoma	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	24 (0.8%)	15 (0.5%)	39 (0.7%)
Breast neoplasm	3 (0.1%)	3 (0.1%)	6 (0.1%)
Carcinoid tumour of the gastrointestinal tract	1 (<0.1%)	0	1 (<0.1%)
Cervix carcinoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholesteatoma	0	2 (<0.1%)	2 (<0.1%)
Chondroma	0	1 (<0.1%)	1 (<0.1%)
Chronic lymphocytic leukaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Chronic lymphocytic leukaemia stage 0	0	1 (<0.1%)	1 (<0.1%)
Chronic myelomonocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Clear cell renal cell carcinoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colon adenoma	11 (0.4%)	9 (0.3%)	20 (0.4%)
Colon cancer	14 (0.5%)	14 (0.5%)	28 (0.5%)
Colon cancer stage 0	1 (<0.1%)	0	1 (<0.1%)
Colon cancer stage I	1 (<0.1%)	0	1 (<0.1%)
Colon neoplasm	3 (0.1%)	0	3 (<0.1%)
Colorectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	0	4 (0.1%)	4 (<0.1%)
Dermatofibrosarcoma protuberans	1 (<0.1%)	0	1 (<0.1%)
Dysplastic naevus	1 (<0.1%)	0	1 (<0.1%)
Ear neoplasm	1 (<0.1%)	0	1 (<0.1%)
Enchondromatosis	1 (<0.1%)	0	1 (<0.1%)
Endobronchial lipoma	1 (<0.1%)	0	1 (<0.1%)
Endometrial cancer	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Essential thrombocythaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Extragonadal primary non-seminoma	0	1 (<0.1%)	1 (<0.1%)
Eye naevus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Female reproductive neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibroadenoma of breast	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fibroma	0	2 (<0.1%)	2 (<0.1%)
Focal nodular hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Gallbladder neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastric adenoma	2 (<0.1%)	0	2 (<0.1%)
Gastric cancer	4 (0.1%)	5 (0.2%)	9 (0.2%)
Gastric sarcoma	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal submucosal tumour	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastrointestinal tract adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gingival cancer	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	2 (<0.1%)	0	2 (<0.1%)
Haemangioma of bone	1 (<0.1%)	0	1 (<0.1%)
Haemangioma of liver	8 (0.3%)	9 (0.3%)	17 (0.3%)
Haemangioma of skin	0	1 (<0.1%)	1 (<0.1%)
Haemangioma of spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic cancer	0	2 (<0.1%)	2 (<0.1%)
Hepatic cancer metastatic	1 (<0.1%)	0	1 (<0.1%)
Hepatic neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hepatocellular carcinoma	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	1 (<0.1%)	0	1 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	3 (0.1%)	3 (0.1%)	6 (0.1%)
Intra-abdominal haemangioma	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Intraductal papillary mucinous neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Intraductal proliferative breast lesion	1 (<0.1%)	0	1 (<0.1%)
Intraocular melanoma	1 (<0.1%)	0	1 (<0.1%)
Invasive ductal breast carcinoma	1 (<0.1%)	0	1 (<0.1%)
Iris melanoma	0	1 (<0.1%)	1 (<0.1%)
Juvenile angiofibroma	0	1 (<0.1%)	1 (<0.1%)
Kaposi's sarcoma	0	1 (<0.1%)	1 (<0.1%)
Langerhans' cell histiocytosis	0	1 (<0.1%)	1 (<0.1%)
Large granular lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine benign neoplasm	3 (0.1%)	11 (0.4%)	14 (0.2%)
Laryngeal cancer	0	1 (<0.1%)	1 (<0.1%)
Laryngeal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Leiomyoma	1 (<0.1%)	0	1 (<0.1%)
Lentigo maligna	1 (<0.1%)	0	1 (<0.1%)
Leukaemia	0	2 (<0.1%)	2 (<0.1%)
Light chain disease	0	1 (<0.1%)	1 (<0.1%)
Lip neoplasm malignant stage unspecified	1 (<0.1%)	0	1 (<0.1%)
Lip squamous cell carcinoma	4 (0.1%)	0	4 (<0.1%)
Lipoma	14 (0.5%)	15 (0.5%)	29 (0.5%)
Liposarcoma	2 (<0.1%)	0	2 (<0.1%)
Lung carcinoma cell type unspecified stage 0	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm malignant	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Lymphoma	1 (<0.1%)	0	1 (<0.1%)
Malignant lymphoid neoplasm	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	6 (0.2%)	9 (0.3%)	15 (0.3%)
Malignant melanoma in situ	0	2 (<0.1%)	2 (<0.1%)
Malignant melanoma stage IV	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eyelid	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Meningioma	3 (0.1%)	4 (0.1%)	7 (0.1%)
Metastases to liver	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metastases to lung	0	2 (<0.1%)	2 (<0.1%)
Monoclonal gammopathy	4 (0.1%)	3 (0.1%)	7 (0.1%)
Myelodysplastic syndrome	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Nasal sinus cancer	0	1 (<0.1%)	1 (<0.1%)
Neoplasm	1 (<0.1%)	0	1 (<0.1%)
Neoplasm malignant	0	1 (<0.1%)	1 (<0.1%)
Neoplasm prostate	5 (0.2%)	5 (0.2%)	10 (0.2%)
Neoplasm skin	2 (<0.1%)	4 (0.1%)	6 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Neuroendocrine tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurofibroma	0	2 (<0.1%)	2 (<0.1%)
Nodular melanoma	0	1 (<0.1%)	1 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Non-secretory adenoma of pituitary	0	1 (<0.1%)	1 (<0.1%)
Non-small cell lung cancer	1 (<0.1%)	0	1 (<0.1%)
Oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal papilloma	0	2 (<0.1%)	2 (<0.1%)
Oral neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oral papilloma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian germ cell teratoma benign	1 (<0.1%)	0	1 (<0.1%)
Ovarian neoplasm	2 (<0.1%)	0	2 (<0.1%)
Papillary cystadenoma lymphomatosum	3 (0.1%)	0	3 (<0.1%)
Papillary thyroid cancer	1 (<0.1%)	0	1 (<0.1%)
Paraproteinaemia	1 (<0.1%)	0	1 (<0.1%)
Parathyroid tumour benign	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Penile squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	5 (0.2%)	4 (0.1%)	9 (0.2%)
Plasma cell myeloma	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pleomorphic adenoma	1 (<0.1%)	0	1 (<0.1%)
Pleomorphic liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Polycythaemia vera	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prolactin-producing pituitary tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prostate cancer	27 (1.0%)	41 (1.4%)	68 (1.2%)
Prostate cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Prostate cancer stage I	1 (<0.1%)	0	1 (<0.1%)
Prostatic adenoma	13 (0.5%)	11 (0.4%)	24 (0.4%)
Rectal adenocarcinoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rectal cancer	8 (0.3%)	4 (0.1%)	12 (0.2%)
Rectal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	11 (0.4%)	4 (0.1%)	15 (0.3%)
Renal cell carcinoma	10 (0.4%)	7 (0.2%)	17 (0.3%)
Renal haemangioma	1 (<0.1%)	0	1 (<0.1%)
Renal hamartoma	5 (0.2%)	3 (0.1%)	8 (0.1%)
Renal neoplasm	3 (0.1%)	5 (0.2%)	8 (0.1%)
Renal oncocytoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cancer	0	1 (<0.1%)	1 (<0.1%)
Salivary gland neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Seborrhoeic keratosis	11 (0.4%)	10 (0.4%)	21 (0.4%)
Seminoma	0	1 (<0.1%)	1 (<0.1%)
Skin cancer	5 (0.2%)	5 (0.2%)	10 (0.2%)
Skin papilloma	4 (0.1%)	5 (0.2%)	9 (0.2%)
Spindle cell sarcoma	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma	3 (0.1%)	4 (0.1%)	7 (0.1%)
Squamous cell carcinoma of lung	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Squamous cell carcinoma of skin	6 (0.2%)	5 (0.2%)	11 (0.2%)
Squamous cell carcinoma of the tongue	1 (<0.1%)	0	1 (<0.1%)
Sweat gland tumour	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testicular neoplasm	1 (<0.1%)	0	1 (<0.1%)
Testis cancer	0	1 (<0.1%)	1 (<0.1%)
Throat cancer	0	1 (<0.1%)	1 (<0.1%)
Thyroid B-cell lymphoma	0	1 (<0.1%)	1 (<0.1%)
Thyroid adenoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroid cancer	4 (0.1%)	4 (0.1%)	8 (0.1%)
Thyroid neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tongue neoplasm	1 (<0.1%)	0	1 (<0.1%)
Tongue neoplasm benign	0	1 (<0.1%)	1 (<0.1%)
Tongue neoplasm malignant stage unspecified	0	2 (<0.1%)	2 (<0.1%)
Tonsil cancer	0	1 (<0.1%)	1 (<0.1%)
Tonsillar neoplasm	0	1 (<0.1%)	1 (<0.1%)
Transitional cell carcinoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ureteric cancer	1 (<0.1%)	0	1 (<0.1%)
Urinary tract neoplasm	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Uterine leiomyoma	30 (1.1%)	28 (1.0%)	58 (1.0%)
Vaginal cancer	0	1 (<0.1%)	1 (<0.1%)
Waldenstrom's macroglobulinaemia	0	2 (<0.1%)	2 (<0.1%)
Nervous system disorders	1454 (51.3%)	1477 (52.0%)	2931 (51.7%)
Amnesia	9 (0.3%)	7 (0.2%)	16 (0.3%)
Amnestic disorder	1 (<0.1%)	0	1 (<0.1%)
Anosmia	0	1 (<0.1%)	1 (<0.1%)
Aphasia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Arachnoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Areflexia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ataxia	4 (0.1%)	0	4 (<0.1%)
Athetosis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Autonomic nervous system imbalance	0	1 (<0.1%)	1 (<0.1%)
Autonomic neuropathy	4 (0.1%)	4 (0.1%)	8 (0.1%)
Axonal neuropathy	2 (<0.1%)	0	2 (<0.1%)
Balance disorder	4 (0.1%)	0	4 (<0.1%)
Basal ganglia haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal ganglia infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basilar artery stenosis	0	1 (<0.1%)	1 (<0.1%)
Bradykinesia	0	1 (<0.1%)	1 (<0.1%)
Brain injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brain oedema	0	1 (<0.1%)	1 (<0.1%)
Brain stem haematoma	0	1 (<0.1%)	1 (<0.1%)
Brain stem haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Brain stem infarction	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Brain stem stroke	1 (<0.1%)	0	1 (<0.1%)
Burning feet syndrome	1 (<0.1%)	0	1 (<0.1%)
Burning sensation	1 (<0.1%)	0	1 (<0.1%)
Cardiac autonomic neuropathy	3 (0.1%)	0	3 (<0.1%)
Carotid arteriosclerosis	63 (2.2%)	67 (2.4%)	130 (2.3%)
Carotid artery disease	5 (0.2%)	12 (0.4%)	17 (0.3%)
Carotid artery insufficiency	1 (<0.1%)	0	1 (<0.1%)
Carotid artery occlusion	7 (0.2%)	3 (0.1%)	10 (0.2%)
Carotid artery stenosis	54 (1.9%)	59 (2.1%)	113 (2.0%)
Carotid artery thrombosis	1 (<0.1%)	0	1 (<0.1%)
Carpal tunnel syndrome	38 (1.3%)	50 (1.8%)	88 (1.6%)
Central nervous system lesion	1 (<0.1%)	0	1 (<0.1%)
Central nervous system necrosis	0	1 (<0.1%)	1 (<0.1%)
Central nervous system vasculitis	0	1 (<0.1%)	1 (<0.1%)
Cerebellar haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Cerebellar ischaemia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar stroke	0	1 (<0.1%)	1 (<0.1%)
Cerebellar syndrome	1 (<0.1%)	0	1 (<0.1%)
Cerebral arteriosclerosis	20 (0.7%)	25 (0.9%)	45 (0.8%)
Cerebral artery embolism	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cerebral artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Cerebral artery stenosis	5 (0.2%)	3 (0.1%)	8 (0.1%)
Cerebral atrophy	9 (0.3%)	8 (0.3%)	17 (0.3%)
Cerebral circulatory failure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Cerebral disorder	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	4 (0.1%)	5 (0.2%)	9 (0.2%)
Cerebral hypoperfusion	3 (0.1%)	0	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Cerebral infarction	20 (0.7%)	14 (0.5%)	34 (0.6%)
Cerebral ischaemia	22 (0.8%)	15 (0.5%)	37 (0.7%)
Cerebral microangiopathy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cerebral small vessel ischaemic disease	0	1 (<0.1%)	1 (<0.1%)
Cerebral thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrosclerosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrospinal fluid circulation disorder	0	1 (<0.1%)	1 (<0.1%)
Cerebrospinal fluid leakage	0	1 (<0.1%)	1 (<0.1%)
Cerebrovascular accident	13 (0.5%)	21 (0.7%)	34 (0.6%)
Cerebrovascular disorder	38 (1.3%)	45 (1.6%)	83 (1.5%)
Cerebrovascular insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cervical cord compression	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Cervicobrachial syndrome	4 (0.1%)	9 (0.3%)	13 (0.2%)
Clonus	0	1 (<0.1%)	1 (<0.1%)
Cluster headache	2 (<0.1%)	0	2 (<0.1%)
Cognitive disorder	5 (0.2%)	4 (0.1%)	9 (0.2%)
Complex regional pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coordination abnormal	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dementia	4 (0.1%)	5 (0.2%)	9 (0.2%)
Dementia Alzheimer's type	6 (0.2%)	3 (0.1%)	9 (0.2%)
Demyelinating polyneuropathy	1 (<0.1%)	0	1 (<0.1%)
Demyelination	2 (<0.1%)	0	2 (<0.1%)
Diabetic autonomic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic coma	0	1 (<0.1%)	1 (<0.1%)
Diabetic encephalopathy	7 (0.2%)	4 (0.1%)	11 (0.2%)
Diabetic mononeuropathy	0	3 (0.1%)	3 (<0.1%)
Diabetic neuropathy	738 (26.1%)	716 (25.2%)	1454 (25.6%)
Disturbance in attention	1 (<0.1%)	0	1 (<0.1%)
Dizziness	44 (1.6%)	43 (1.5%)	87 (1.5%)
Dizziness postural	2 (<0.1%)	0	2 (<0.1%)
Drop attacks	0	1 (<0.1%)	1 (<0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysarthria	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Dysgeusia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Encephalomalacia	0	2 (<0.1%)	2 (<0.1%)
Encephalopathy	16 (0.6%)	14 (0.5%)	30 (0.5%)
Epilepsy	11 (0.4%)	4 (0.1%)	15 (0.3%)
Essential tremor	6 (0.2%)	7 (0.2%)	13 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Extrapyramidal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial paralysis	18 (0.6%)	29 (1.0%)	47 (0.8%)
Facial paresis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Frontal lobe epilepsy	0	1 (<0.1%)	1 (<0.1%)
Frontotemporal dementia	0	1 (<0.1%)	1 (<0.1%)
Gait spastic	1 (<0.1%)	0	1 (<0.1%)
Generalised tonic-clonic seizure	0	2 (<0.1%)	2 (<0.1%)
Guillain-Barre syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Haemorrhage intracranial	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic stroke	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Head discomfort	0	1 (<0.1%)	1 (<0.1%)
Head titubation	1 (<0.1%)	0	1 (<0.1%)
Headache	46 (1.6%)	45 (1.6%)	91 (1.6%)
Hemianaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hemiparesis	12 (0.4%)	14 (0.5%)	26 (0.5%)
Hemiplegia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hydrocephalus	2 (<0.1%)	0	2 (<0.1%)
Hyperaesthesia	0	1 (<0.1%)	1 (<0.1%)
Hyperreflexia	0	1 (<0.1%)	1 (<0.1%)
Hypersomnia	0	2 (<0.1%)	2 (<0.1%)
Hypertensive encephalopathy	4 (0.1%)	6 (0.2%)	10 (0.2%)
Hypertonia	13 (0.5%)	14 (0.5%)	27 (0.5%)
Hypoaesthesia	21 (0.7%)	24 (0.8%)	45 (0.8%)
Hypoxic-ischaemic encephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
IIIrd nerve paralysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Intellectual disability	1 (<0.1%)	0	1 (<0.1%)
Intention tremor	1 (<0.1%)	0	1 (<0.1%)
Intracranial aneurysm	7 (0.2%)	7 (0.2%)	14 (0.2%)
Intracranial pressure increased	0	1 (<0.1%)	1 (<0.1%)
Ischaemic cerebral infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic stroke	329 (11.6%)	360 (12.7%)	689 (12.1%)
Lacunar infarction	22 (0.8%)	14 (0.5%)	36 (0.6%)
Lacunar stroke	1 (<0.1%)	0	1 (<0.1%)
Lateral medullary syndrome	0	1 (<0.1%)	1 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)
Loss of consciousness	0	1 (<0.1%)	1 (<0.1%)
Lumbar radiculopathy	4 (0.1%)	10 (0.4%)	14 (0.2%)
Lumbosacral radiculopathy	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Memory impairment	3 (0.1%)	5 (0.2%)	8 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Meralgia paraesthetica	1 (<0.1%)	0	1 (<0.1%)
Metabolic encephalopathy	3 (0.1%)	6 (0.2%)	9 (0.2%)
Migraine	19 (0.7%)	10 (0.4%)	29 (0.5%)
Migraine with aura	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Migraine without aura	0	1 (<0.1%)	1 (<0.1%)
Mononeuritis	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy	2 (<0.1%)	0	2 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Monoplegia	1 (<0.1%)	0	1 (<0.1%)
Morton's neuralgia	0	1 (<0.1%)	1 (<0.1%)
Movement disorder	0	2 (<0.1%)	2 (<0.1%)
Multiple sclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myasthenia gravis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myelopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Narcolepsy	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neuralgia	27 (1.0%)	16 (0.6%)	43 (0.8%)
Neuralgic amyotrophy	1 (<0.1%)	0	1 (<0.1%)
Neuritis	1 (<0.1%)	0	1 (<0.1%)
Neuritis cranial	0	1 (<0.1%)	1 (<0.1%)
Neuromuscular pain	1 (<0.1%)	0	1 (<0.1%)
Neuropathy peripheral	135 (4.8%)	161 (5.7%)	296 (5.2%)
Normal pressure hydrocephalus	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Occipital neuralgia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Optic neuritis	1 (<0.1%)	0	1 (<0.1%)
Orthostatic intolerance	2 (<0.1%)	0	2 (<0.1%)
Paraesthesia	19 (0.7%)	11 (0.4%)	30 (0.5%)
Paralysis recurrent laryngeal nerve	2 (<0.1%)	0	2 (<0.1%)
Paraparesis	1 (<0.1%)	0	1 (<0.1%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	13 (0.5%)	11 (0.4%)	24 (0.4%)
Parkinsonism	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Parosmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Partial seizures	1 (<0.1%)	0	1 (<0.1%)
Periodic limb movement disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve paresis	0	2 (<0.1%)	2 (<0.1%)
Peripheral sensorimotor neuropathy	2 (<0.1%)	9 (0.3%)	11 (0.2%)
Peripheral sensory neuropathy	5 (0.2%)	3 (0.1%)	8 (0.1%)
Peroneal nerve palsy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Phantom limb syndrome	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Piriformis syndrome	2 (<0.1%)	0	2 (<0.1%)
Polyneuropathy	42 (1.5%)	44 (1.5%)	86 (1.5%)
Poor quality sleep	2 (<0.1%)	0	2 (<0.1%)
Post herpetic neuralgia	4 (0.1%)	3 (0.1%)	7 (0.1%)
Post-traumatic epilepsy	1 (<0.1%)	0	1 (<0.1%)
Posterior reversible encephalopathy syndrome	0	1 (<0.1%)	1 (<0.1%)
Postictal paralysis	1 (<0.1%)	0	1 (<0.1%)
Postural tremor	2 (<0.1%)	0	2 (<0.1%)
Presyncope	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Quadriplegia	0	1 (<0.1%)	1 (<0.1%)
Radicular pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radiculopathy	8 (0.3%)	7 (0.2%)	15 (0.3%)
Resting tremor	1 (<0.1%)	0	1 (<0.1%)
Restless legs syndrome	17 (0.6%)	13 (0.5%)	30 (0.5%)
Reversible ischaemic neurological deficit	1 (<0.1%)	0	1 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	36 (1.3%)	36 (1.3%)	72 (1.3%)
Seizure	6 (0.2%)	4 (0.1%)	10 (0.2%)
Seizure like phenomena	1 (<0.1%)	0	1 (<0.1%)
Senile dementia	2 (<0.1%)	0	2 (<0.1%)
Sleep deficit	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Somnolence	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Spinal claudication	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Spinal cord haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Spinal cord ischaemia	0	1 (<0.1%)	1 (<0.1%)
Spondylitic myelopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subarachnoid haemorrhage	4 (0.1%)	3 (0.1%)	7 (0.1%)
Subdural effusion	1 (<0.1%)	0	1 (<0.1%)
Syncope	19 (0.7%)	8 (0.3%)	27 (0.5%)
Tardive dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Tension headache	7 (0.2%)	4 (0.1%)	11 (0.2%)
Thrombotic cerebral infarction	1 (<0.1%)	0	1 (<0.1%)
Transient global amnesia	0	1 (<0.1%)	1 (<0.1%)
Transient ischaemic attack	50 (1.8%)	38 (1.3%)	88 (1.6%)
Tremor	11 (0.4%)	8 (0.3%)	19 (0.3%)
Trigeminal nerve disorder	0	1 (<0.1%)	1 (<0.1%)
Trigeminal neuralgia	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Ulnar nerve palsy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ulnar tunnel syndrome	0	1 (<0.1%)	1 (<0.1%)
VIth nerve disorder	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
VIth nerve paralysis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
VIth nerve paresis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular dementia	0	2 (<0.1%)	2 (<0.1%)
Vascular encephalopathy	18 (0.6%)	24 (0.8%)	42 (0.7%)
Vertebral artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery stenosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Vertebrobasilar insufficiency	4 (0.1%)	5 (0.2%)	9 (0.2%)
Vertigo CNS origin	0	1 (<0.1%)	1 (<0.1%)
Visual field defect	3 (0.1%)	4 (0.1%)	7 (0.1%)
Vocal cord paralysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vocal cord paresis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
White matter lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	6 (0.2%)	7 (0.2%)	13 (0.2%)
Abortion incomplete	0	1 (<0.1%)	1 (<0.1%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Gestational diabetes	2 (<0.1%)	0	2 (<0.1%)
Postpartum haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Pre-eclampsia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Product issues	0	1 (<0.1%)	1 (<0.1%)
Device breakage	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	443 (15.6%)	493 (17.4%)	936 (16.5%)
Abnormal dreams	1 (<0.1%)	0	1 (<0.1%)
Acute stress disorder	1 (<0.1%)	0	1 (<0.1%)
Adjustment disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adjustment disorder with anxiety	0	1 (<0.1%)	1 (<0.1%)
Adjustment disorder with depressed mood	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Affect lability	0	2 (<0.1%)	2 (<0.1%)
Affective disorder	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Agitation	0	1 (<0.1%)	1 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Alcohol use disorder	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Alcoholism	6 (0.2%)	3 (0.1%)	9 (0.2%)
Anxiety	101 (3.6%)	123 (4.3%)	224 (3.9%)
Anxiety disorder	11 (0.4%)	20 (0.7%)	31 (0.5%)
Attention deficit hyperactivity disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Bipolar I disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bipolar disorder	4 (0.1%)	11 (0.4%)	15 (0.3%)
Bulimia nervosa	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Delirium	0	2 (<0.1%)	2 (<0.1%)
Depressed mood	3 (0.1%)	3 (0.1%)	6 (0.1%)
Depression	184 (6.5%)	211 (7.4%)	395 (7.0%)
Depressive symptom	3 (0.1%)	0	3 (<0.1%)
Dermatillomania	0	1 (<0.1%)	1 (<0.1%)
Dissociative amnesia	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Drug dependence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Generalised anxiety disorder	5 (0.2%)	5 (0.2%)	10 (0.2%)
Hallucination	0	1 (<0.1%)	1 (<0.1%)
Hallucination, visual	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Initial insomnia	0	1 (<0.1%)	1 (<0.1%)
Insomnia	143 (5.0%)	159 (5.6%)	302 (5.3%)
Libido decreased	2 (<0.1%)	0	2 (<0.1%)
Major depression	12 (0.4%)	15 (0.5%)	27 (0.5%)
Mental disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mental disorder due to a general medical condition	0	2 (<0.1%)	2 (<0.1%)
Middle insomnia	0	1 (<0.1%)	1 (<0.1%)
Mixed anxiety and depressive disorder	3 (0.1%)	10 (0.4%)	13 (0.2%)
Mood altered	1 (<0.1%)	0	1 (<0.1%)
Mood swings	1 (<0.1%)	0	1 (<0.1%)
Nervousness	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neurologic somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Neurosis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Nicotine dependence	5 (0.2%)	7 (0.2%)	12 (0.2%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Organic brain syndrome	0	1 (<0.1%)	1 (<0.1%)
Panic attack	0	1 (<0.1%)	1 (<0.1%)
Panic disorder	4 (0.1%)	3 (0.1%)	7 (0.1%)
Panic reaction	1 (<0.1%)	0	1 (<0.1%)
Persistent depressive disorder	3 (0.1%)	5 (0.2%)	8 (0.1%)
Personality disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phobia of driving	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Post-traumatic stress disorder	8 (0.3%)	8 (0.3%)	16 (0.3%)
Psychosexual disorder	0	1 (<0.1%)	1 (<0.1%)
Psychotic disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Schizoid personality disorder	1 (<0.1%)	0	1 (<0.1%)
Schizophrenia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Sleep disorder	24 (0.8%)	17 (0.6%)	41 (0.7%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	0	2 (<0.1%)	2 (<0.1%)
Stress	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Suicide attempt	2 (<0.1%)	0	2 (<0.1%)
Tearfulness	0	1 (<0.1%)	1 (<0.1%)
Tic	0	1 (<0.1%)	1 (<0.1%)
Tobacco abuse	8 (0.3%)	7 (0.2%)	15 (0.3%)
Renal and urinary disorders	2833 (100.0%)	2841 (100.0%)	5674 (100.0%)
Acquired cystic kidney disease	12 (0.4%)	9 (0.3%)	21 (0.4%)
Acute kidney injury	27 (1.0%)	32 (1.1%)	59 (1.0%)
Albuminuria	126 (4.4%)	113 (4.0%)	239 (4.2%)
Azotaemia	3 (0.1%)	4 (0.1%)	7 (0.1%)
Bladder disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bladder diverticulum	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder dysfunction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder leukoplakia	1 (<0.1%)	0	1 (<0.1%)
Bladder mass	1 (<0.1%)	0	1 (<0.1%)
Bladder neck obstruction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder neck sclerosis	1 (<0.1%)	0	1 (<0.1%)
Bladder outlet obstruction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder prolapse	0	4 (0.1%)	4 (<0.1%)
Bladder spasm	0	1 (<0.1%)	1 (<0.1%)
Bladder tamponade	1 (<0.1%)	0	1 (<0.1%)
Bladder trabeculation	1 (<0.1%)	0	1 (<0.1%)
Bladder ulcer	0	1 (<0.1%)	1 (<0.1%)
Calculus bladder	4 (0.1%)	3 (0.1%)	7 (0.1%)
Calculus urethral	1 (<0.1%)	0	1 (<0.1%)
Calculus urinary	34 (1.2%)	28 (1.0%)	62 (1.1%)
Chronic kidney disease	2833 (100.0%)	2841 (100.0%)	5674 (100.0%)
Chyluria	1 (<0.1%)	0	1 (<0.1%)
Costovertebral angle tenderness	1 (<0.1%)	0	1 (<0.1%)
Cystitis interstitial	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	274 (9.7%)	284 (10.0%)	558 (9.8%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Dysuria	7 (0.2%)	9 (0.3%)	16 (0.3%)
End stage renal disease	1 (<0.1%)	0	1 (<0.1%)
Focal segmental glomerulosclerosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Genitourinary symptom	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	12 (0.4%)	14 (0.5%)	26 (0.5%)
Glomerulonephritis membranous	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glomerulonephropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glycosuria	0	1 (<0.1%)	1 (<0.1%)
Haematuria	29 (1.0%)	35 (1.2%)	64 (1.1%)
Hydronephrosis	14 (0.5%)	17 (0.6%)	31 (0.5%)
Hypertensive nephropathy	10 (0.4%)	6 (0.2%)	16 (0.3%)
Hypertonic bladder	11 (0.4%)	13 (0.5%)	24 (0.4%)
Hyperuricosuria	0	2 (<0.1%)	2 (<0.1%)
Hypotonic urinary bladder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
IgA nephropathy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Incontinence	4 (0.1%)	3 (0.1%)	7 (0.1%)
Intercapillary glomerulosclerosis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Ischaemic nephropathy	1 (<0.1%)	0	1 (<0.1%)
Kidney enlargement	3 (0.1%)	0	3 (<0.1%)
Kidney fibrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lower urinary tract symptoms	8 (0.3%)	4 (0.1%)	12 (0.2%)
Lupus nephritis	1 (<0.1%)	0	1 (<0.1%)
Microalbuminuria	60 (2.1%)	52 (1.8%)	112 (2.0%)
Micturition disorder	0	2 (<0.1%)	2 (<0.1%)
Micturition urgency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nephritic syndrome	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Nephritis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Nephroangiosclerosis	5 (0.2%)	9 (0.3%)	14 (0.2%)
Nephrocalcinosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Nephrogenic diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Nephrolithiasis	153 (5.4%)	159 (5.6%)	312 (5.5%)
Nephropathy	20 (0.7%)	13 (0.5%)	33 (0.6%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)
Nephroptosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephrosclerosis	6 (0.2%)	3 (0.1%)	9 (0.2%)
Nephrotic syndrome	5 (0.2%)	14 (0.5%)	19 (0.3%)
Neurogenic bladder	11 (0.4%)	9 (0.3%)	20 (0.4%)
Nocturia	15 (0.5%)	35 (1.2%)	50 (0.9%)
Obstructive nephropathy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Oedematous kidney	3 (0.1%)	0	3 (<0.1%)
Oliguria	1 (<0.1%)	0	1 (<0.1%)
Pelvi-ureteric obstruction	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	8 (0.3%)	10 (0.4%)	18 (0.3%)
Polyuria	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Post infection glomerulonephritis	1 (<0.1%)	0	1 (<0.1%)
Proteinuria	179 (6.3%)	185 (6.5%)	364 (6.4%)
Pyelocaliectasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Reflux nephropathy	0	1 (<0.1%)	1 (<0.1%)
Renal arteriosclerosis	0	2 (<0.1%)	2 (<0.1%)
Renal artery arteriosclerosis	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	6 (0.2%)	8 (0.3%)	14 (0.2%)
Renal atrophy	5 (0.2%)	3 (0.1%)	8 (0.1%)
Renal colic	21 (0.7%)	10 (0.4%)	31 (0.5%)
Renal cyst	133 (4.7%)	147 (5.2%)	280 (4.9%)
Renal disorder	2 (<0.1%)	0	2 (<0.1%)
Renal failure	16 (0.6%)	15 (0.5%)	31 (0.5%)
Renal hypertension	1 (<0.1%)	0	1 (<0.1%)
Renal hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal impairment	6 (0.2%)	3 (0.1%)	9 (0.2%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	1 (<0.1%)	0	1 (<0.1%)
Renal pain	0	1 (<0.1%)	1 (<0.1%)
Renal tubular acidosis	0	1 (<0.1%)	1 (<0.1%)
Renal tubular necrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal vessel disorder	1 (<0.1%)	0	1 (<0.1%)
Single functional kidney	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Stag horn calculus	0	1 (<0.1%)	1 (<0.1%)
Stress urinary incontinence	5 (0.2%)	4 (0.1%)	9 (0.2%)
Subcapsular renal haematoma	2 (<0.1%)	0	2 (<0.1%)
Terminal dribbling	1 (<0.1%)	0	1 (<0.1%)
Trigonitis	1 (<0.1%)	0	1 (<0.1%)
Tubulointerstitial nephritis	0	4 (0.1%)	4 (<0.1%)
Urate nephropathy	3 (0.1%)	0	3 (<0.1%)
Ureteral cyst	0	1 (<0.1%)	1 (<0.1%)
Ureteric stenosis	0	2 (<0.1%)	2 (<0.1%)
Ureterocele	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	14 (0.5%)	17 (0.6%)	31 (0.5%)
Urethral meatus stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral obstruction	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Urethral stenosis	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Urge incontinence	4 (0.1%)	3 (0.1%)	7 (0.1%)
Urinary bladder polyp	3 (0.1%)	0	3 (<0.1%)
Urinary hesitation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Urinary incontinence	34 (1.2%)	35 (1.2%)	69 (1.2%)
Urinary retention	7 (0.2%)	7 (0.2%)	14 (0.2%)
Urinary tract disorder	1 (<0.1%)	0	1 (<0.1%)
Urinary tract obstruction	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Urine abnormality	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Urine flow decreased	0	1 (<0.1%)	1 (<0.1%)
Urine odour abnormal	0	1 (<0.1%)	1 (<0.1%)
Reproductive system and breast disorders	586 (20.7%)	614 (21.6%)	1200 (21.1%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Atrophic vulvovaginitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Balanoposthitis	3 (0.1%)	0	3 (<0.1%)
Benign prostatic hyperplasia	384 (13.6%)	396 (13.9%)	780 (13.7%)
Breast calcifications	0	1 (<0.1%)	1 (<0.1%)
Breast cyst	2 (<0.1%)	0	2 (<0.1%)
Breast disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast fibrosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Breast hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Breast mass	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Calculus prostatic	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Cervical cyst	0	1 (<0.1%)	1 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	0	1 (<0.1%)	1 (<0.1%)
Colpocele	1 (<0.1%)	0	1 (<0.1%)
Cystocele	4 (0.1%)	3 (0.1%)	7 (0.1%)
Dysmenorrhoea	2 (<0.1%)	0	2 (<0.1%)
Endometrial hyperplasia	0	2 (<0.1%)	2 (<0.1%)
Endometrial thickening	0	1 (<0.1%)	1 (<0.1%)
Endometriosis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Epididymal cyst	0	1 (<0.1%)	1 (<0.1%)
Erectile dysfunction	133 (4.7%)	146 (5.1%)	279 (4.9%)
Fibrocystic breast disease	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Genital prolapse	0	2 (<0.1%)	2 (<0.1%)
Gynaecomastia	5 (0.2%)	8 (0.3%)	13 (0.2%)
Haematospermia	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hydrometra	1 (<0.1%)	0	1 (<0.1%)
Infertility	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mammary duct ectasia	0	1 (<0.1%)	1 (<0.1%)
Menometrorrhagia	1 (<0.1%)	0	1 (<0.1%)
Menopausal disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Menorrhagia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metrorrhagia	2 (<0.1%)	0	2 (<0.1%)
Monorchidism	1 (<0.1%)	0	1 (<0.1%)
Organic erectile dysfunction	3 (0.1%)	6 (0.2%)	9 (0.2%)
Ovarian cyst	8 (0.3%)	12 (0.4%)	20 (0.4%)
Ovarian cyst ruptured	1 (<0.1%)	0	1 (<0.1%)
Pelvic adhesions	0	1 (<0.1%)	1 (<0.1%)
Pelvic fluid collection	1 (<0.1%)	0	1 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Perineal pain	1 (<0.1%)	0	1 (<0.1%)
Peyronie's disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Polycystic ovaries	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Prostatic calcification	7 (0.2%)	8 (0.3%)	15 (0.3%)
Prostatic cyst	0	1 (<0.1%)	1 (<0.1%)
Prostatic disorder	6 (0.2%)	6 (0.2%)	12 (0.2%)
Prostatic mass	0	1 (<0.1%)	1 (<0.1%)
Prostatism	5 (0.2%)	9 (0.3%)	14 (0.2%)
Prostatitis	11 (0.4%)	18 (0.6%)	29 (0.5%)
Prostatomegaly	24 (0.8%)	19 (0.7%)	43 (0.8%)
Pruritus genital	0	1 (<0.1%)	1 (<0.1%)
Rectocele	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal mass	0	1 (<0.1%)	1 (<0.1%)
Seminal vesicular disorder	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	1 (<0.1%)	0	1 (<0.1%)
Testicular torsion	1 (<0.1%)	0	1 (<0.1%)
Uterine cervix stenosis	1 (<0.1%)	0	1 (<0.1%)
Uterine enlargement	0	1 (<0.1%)	1 (<0.1%)
Uterine haemorrhage	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Uterine polyp	0	1 (<0.1%)	1 (<0.1%)
Uterine prolapse	0	1 (<0.1%)	1 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal polyp	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Vaginal prolapse	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Varicocele	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Vulvovaginal dryness	2 (<0.1%)	0	2 (<0.1%)
Vulvovaginal pruritus	0	2 (<0.1%)	2 (<0.1%)
Vulvovaginal rash	0	1 (<0.1%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	672 (23.7%)	725 (25.5%)	1397 (24.6%)
Acute pulmonary oedema	0	4 (0.1%)	4 (<0.1%)
Acute respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Adenoidal hypertrophy	0	2 (<0.1%)	2 (<0.1%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic pharyngitis	1 (<0.1%)	0	1 (<0.1%)
Allergic respiratory disease	1 (<0.1%)	0	1 (<0.1%)
Allergic sinusitis	1 (<0.1%)	0	1 (<0.1%)
Apnoea	1 (<0.1%)	0	1 (<0.1%)
Asthma	110 (3.9%)	123 (4.3%)	233 (4.1%)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	1 (<0.1%)	1 (<0.1%)
Atelectasis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Bronchial disorder	0	2 (<0.1%)	2 (<0.1%)
Bronchial hyperreactivity	4 (0.1%)	3 (0.1%)	7 (0.1%)
Bronchial obstruction	1 (<0.1%)	0	1 (<0.1%)
Bronchiectasis	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Bronchitis chronic	27 (1.0%)	44 (1.5%)	71 (1.3%)
Bronchospasm	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Catarrh	0	3 (0.1%)	3 (<0.1%)
Cheyne-Stokes respiration	0	1 (<0.1%)	1 (<0.1%)
Childhood asthma	0	1 (<0.1%)	1 (<0.1%)
Chronic obstructive pulmonary disease	158 (5.6%)	167 (5.9%)	325 (5.7%)
Chronic respiratory disease	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Chronic respiratory failure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cough	30 (1.1%)	40 (1.4%)	70 (1.2%)
Cough variant asthma	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Cystic lung disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Diaphragmatic disorder	0	1 (<0.1%)	1 (<0.1%)
Diaphragmatic paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysphonia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Dyspnoea	30 (1.1%)	31 (1.1%)	61 (1.1%)
Dyspnoea exertional	17 (0.6%)	9 (0.3%)	26 (0.5%)
Emphysema	14 (0.5%)	14 (0.5%)	28 (0.5%)
Epistaxis	7 (0.2%)	12 (0.4%)	19 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Haemoptysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hydrothorax	0	1 (<0.1%)	1 (<0.1%)
Hypercapnia	0	1 (<0.1%)	1 (<0.1%)
Hypersensitivity pneumonitis	1 (<0.1%)	0	1 (<0.1%)
Hypopnoea	0	1 (<0.1%)	1 (<0.1%)
Hypoventilation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Interstitial lung disease	8 (0.3%)	9 (0.3%)	17 (0.3%)
Laryngeal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	1 (<0.1%)
Laryngeal stenosis	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	0	1 (<0.1%)	1 (<0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Lung induration	1 (<0.1%)	0	1 (<0.1%)
Lung infiltration	1 (<0.1%)	0	1 (<0.1%)
Lung opacity	2 (<0.1%)	0	2 (<0.1%)
Nasal congestion	3 (0.1%)	4 (0.1%)	7 (0.1%)
Nasal discomfort	0	1 (<0.1%)	1 (<0.1%)
Nasal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Nasal polyps	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Nasal septum deviation	4 (0.1%)	5 (0.2%)	9 (0.2%)
Nasal septum perforation	1 (<0.1%)	0	1 (<0.1%)
Nasal turbinate hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obliterative bronchiolitis	0	1 (<0.1%)	1 (<0.1%)
Obstructive airways disorder	7 (0.2%)	2 (<0.1%)	9 (0.2%)
Oropharyngeal pain	4 (0.1%)	0	4 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	0	1 (<0.1%)
Paranasal sinus inflammation	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal mass	0	1 (<0.1%)	1 (<0.1%)
Pickwickian syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pleural effusion	7 (0.2%)	11 (0.4%)	18 (0.3%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	1 (<0.1%)	0	1 (<0.1%)
Pleurisy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pneumonitis	5 (0.2%)	0	5 (<0.1%)
Pneumothorax	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Productive cough	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Pulmonary alveolar haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Pulmonary arterial hypertension	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pulmonary calcification	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	16 (0.6%)	18 (0.6%)	34 (0.6%)
Pulmonary fibrosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pulmonary granuloma	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pulmonary hypertension	21 (0.7%)	21 (0.7%)	42 (0.7%)
Pulmonary infarction	0	1 (<0.1%)	1 (<0.1%)
Pulmonary mass	24 (0.8%)	23 (0.8%)	47 (0.8%)
Pulmonary oedema	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Pulmonary sarcoidosis	3 (0.1%)	0	3 (<0.1%)
Respiratory acidosis	0	1 (<0.1%)	1 (<0.1%)
Respiratory alkalosis	1 (<0.1%)	0	1 (<0.1%)
Respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Respiratory disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Respiratory failure	3 (0.1%)	6 (0.2%)	9 (0.2%)
Restrictive pulmonary disease	3 (0.1%)	6 (0.2%)	9 (0.2%)
Rhinitis allergic	67 (2.4%)	67 (2.4%)	134 (2.4%)
Rhinitis hypertrophic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rhinorrhoea	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Sinus congestion	0	1 (<0.1%)	1 (<0.1%)
Sinus disorder	2 (<0.1%)	0	2 (<0.1%)
Sinus perforation	0	1 (<0.1%)	1 (<0.1%)
Sinus polyp	0	1 (<0.1%)	1 (<0.1%)
Sleep apnoea syndrome	250 (8.8%)	248 (8.7%)	498 (8.8%)
Snoring	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Stridor	0	1 (<0.1%)	1 (<0.1%)
Throat irritation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tracheal stenosis	0	1 (<0.1%)	1 (<0.1%)
Upper respiratory tract inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper-airway cough syndrome	0	1 (<0.1%)	1 (<0.1%)
Vasomotor rhinitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vocal cord polyp	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vocal cord thickening	1 (<0.1%)	0	1 (<0.1%)
Wheezing	4 (0.1%)	3 (0.1%)	7 (0.1%)
Skin and subcutaneous tissue disorders	417 (14.7%)	451 (15.9%)	868 (15.3%)
Acanthosis nigricans	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Acne	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Actinic keratosis	27 (1.0%)	24 (0.8%)	51 (0.9%)
Alopecia	3 (0.1%)	4 (0.1%)	7 (0.1%)
Alopecia areata	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Androgenetic alopecia	1 (<0.1%)	0	1 (<0.1%)
Angioedema	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Asteatosis	5 (0.2%)	3 (0.1%)	8 (0.1%)
Blister	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Chronic pigmented purpura	1 (<0.1%)	0	1 (<0.1%)
Chronic spontaneous urticaria	1 (<0.1%)	0	1 (<0.1%)
Dandruff	0	2 (<0.1%)	2 (<0.1%)
Decubitus ulcer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Dermal cyst	1 (<0.1%)	11 (0.4%)	12 (0.2%)
Dermatitis	33 (1.2%)	22 (0.8%)	55 (1.0%)
Dermatitis allergic	6 (0.2%)	9 (0.3%)	15 (0.3%)
Dermatitis atopic	6 (0.2%)	13 (0.5%)	19 (0.3%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	10 (0.4%)	8 (0.3%)	18 (0.3%)
Dermatitis herpetiformis	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Diabetic bullosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic dermopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Diabetic foot	51 (1.8%)	65 (2.3%)	116 (2.0%)
Diabetic neuropathic ulcer	1 (<0.1%)	0	1 (<0.1%)
Diabetic ulcer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Drug eruption	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dry skin	25 (0.9%)	28 (1.0%)	53 (0.9%)
Dyshidrotic eczema	1 (<0.1%)	0	1 (<0.1%)
Eczema	26 (0.9%)	35 (1.2%)	61 (1.1%)
Eczema asteatotic	6 (0.2%)	6 (0.2%)	12 (0.2%)
Eczema nummular	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Erythema	6 (0.2%)	5 (0.2%)	11 (0.2%)
Erythema nodosum	3 (0.1%)	0	3 (<0.1%)
Granuloma annulare	2 (<0.1%)	0	2 (<0.1%)
Granuloma skin	0	1 (<0.1%)	1 (<0.1%)
Hand dermatitis	2 (<0.1%)	0	2 (<0.1%)
Hidradenitis	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Hirsutism	0	1 (<0.1%)	1 (<0.1%)
Hyperhidrosis	0	2 (<0.1%)	2 (<0.1%)
Hyperkeratosis	15 (0.5%)	16 (0.6%)	31 (0.5%)
Hypersensitivity vasculitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Idiopathic urticaria	0	1 (<0.1%)	1 (<0.1%)
Ingrowing nail	5 (0.2%)	6 (0.2%)	11 (0.2%)
Intertrigo	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ischaemic skin ulcer	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Keloid scar	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Leukoderma	0	1 (<0.1%)	1 (<0.1%)
Lichen planus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lichen sclerosus	1 (<0.1%)	0	1 (<0.1%)
Lichenification	2 (<0.1%)	0	2 (<0.1%)
Lipodystrophy acquired	4 (0.1%)	3 (0.1%)	7 (0.1%)
Lipohypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mechanical urticaria	0	1 (<0.1%)	1 (<0.1%)
Melanosis	1 (<0.1%)	0	1 (<0.1%)
Myxoid cyst	1 (<0.1%)	0	1 (<0.1%)
Nail disorder	0	1 (<0.1%)	1 (<0.1%)
Nail dystrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nail hypertrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neurodermatitis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Neuropathic ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neutrophilic dermatosis	0	1 (<0.1%)	1 (<0.1%)
Onychalgia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Onycholysis	1 (<0.1%)	0	1 (<0.1%)
Palmoplantar keratoderma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Panniculitis	1 (<0.1%)	0	1 (<0.1%)
Peau d'orange	1 (<0.1%)	0	1 (<0.1%)
Pemphigoid	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pemphigus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Petechiae	0	1 (<0.1%)	1 (<0.1%)
Pigmentation disorder	2 (<0.1%)	0	2 (<0.1%)
Pityriasis rosea	0	1 (<0.1%)	1 (<0.1%)
Prurigo	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Pruritus	34 (1.2%)	40 (1.4%)	74 (1.3%)
Pruritus allergic	1 (<0.1%)	0	1 (<0.1%)
Pseudofolliculitis	0	1 (<0.1%)	1 (<0.1%)
Psoriasis	42 (1.5%)	53 (1.9%)	95 (1.7%)
Purpura	2 (<0.1%)	0	2 (<0.1%)
Pustular psoriasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rash	12 (0.4%)	20 (0.7%)	32 (0.6%)
Rash erythematous	1 (<0.1%)	0	1 (<0.1%)
Rash pruritic	0	1 (<0.1%)	1 (<0.1%)
Rosacea	8 (0.3%)	5 (0.2%)	13 (0.2%)
Scleroedema	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	13 (0.5%)	10 (0.4%)	23 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Sensitive skin	2 (<0.1%)	0	2 (<0.1%)
Skin atrophy	0	1 (<0.1%)	1 (<0.1%)
Skin discolouration	0	1 (<0.1%)	1 (<0.1%)
Skin disorder	0	2 (<0.1%)	2 (<0.1%)
Skin dystrophy	0	3 (0.1%)	3 (<0.1%)
Skin exfoliation	0	1 (<0.1%)	1 (<0.1%)
Skin fissures	1 (<0.1%)	0	1 (<0.1%)
Skin hyperpigmentation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	4 (0.1%)	7 (0.2%)	11 (0.2%)
Skin mass	0	1 (<0.1%)	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	31 (1.1%)	44 (1.5%)	75 (1.3%)
Skin wrinkling	0	1 (<0.1%)	1 (<0.1%)
Solar dermatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Solar lentigo	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	15 (0.5%)	12 (0.4%)	27 (0.5%)
Stevens-Johnson syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Telangiectasia	2 (<0.1%)	0	2 (<0.1%)
Urticaria	14 (0.5%)	9 (0.3%)	23 (0.4%)
Urticaria chronic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vasculitic rash	0	1 (<0.1%)	1 (<0.1%)
Vasculitic ulcer	0	1 (<0.1%)	1 (<0.1%)
Vitiligo	8 (0.3%)	8 (0.3%)	16 (0.3%)
Xeroderma	4 (0.1%)	3 (0.1%)	7 (0.1%)
Social circumstances	163 (5.8%)	156 (5.5%)	319 (5.6%)
Alcohol use	1 (<0.1%)	0	1 (<0.1%)
Caffeine consumption	1 (<0.1%)	0	1 (<0.1%)
Corrective lens user	0	1 (<0.1%)	1 (<0.1%)
Denture wearer	3 (0.1%)	0	3 (<0.1%)
Diet noncompliance	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	0	1 (<0.1%)	1 (<0.1%)
Edentulous	4 (0.1%)	3 (0.1%)	7 (0.1%)
Ex-tobacco user	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Menopause	109 (3.8%)	89 (3.1%)	198 (3.5%)
Orthosis user	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	35 (1.2%)	47 (1.7%)	82 (1.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Social problem	0	1 (<0.1%)	1 (<0.1%)
Stress at work	0	1 (<0.1%)	1 (<0.1%)
Tobacco user	8 (0.3%)	10 (0.4%)	18 (0.3%)
Wheelchair user	1 (<0.1%)	0	1 (<0.1%)
Surgical and medical procedures	1110 (39.2%)	1122 (39.5%)	2232 (39.3%)
Abdominal hernia repair	3 (0.1%)	8 (0.3%)	11 (0.2%)
Abdominoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Abortion induced	0	1 (<0.1%)	1 (<0.1%)
Abscess drainage	5 (0.2%)	10 (0.4%)	15 (0.3%)
Acoustic neuroma removal	0	2 (<0.1%)	2 (<0.1%)
Adenoidectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenotonsillectomy	2 (<0.1%)	0	2 (<0.1%)
Adrenalectomy	2 (<0.1%)	0	2 (<0.1%)
Amblyopia therapy	0	1 (<0.1%)	1 (<0.1%)
Amputation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal fissure excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Anal fistula repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aneurysm repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angioplasty	9 (0.3%)	8 (0.3%)	17 (0.3%)
Ankle operation	3 (0.1%)	0	3 (<0.1%)
Anticoagulant therapy	0	2 (<0.1%)	2 (<0.1%)
Aortic anastomosis	1 (<0.1%)	0	1 (<0.1%)
Aortic aneurysm repair	2 (<0.1%)	7 (0.2%)	9 (0.2%)
Aortic bypass	7 (0.2%)	4 (0.1%)	11 (0.2%)
Aortic stent insertion	0	4 (0.1%)	4 (<0.1%)
Aortic surgery	0	1 (<0.1%)	1 (<0.1%)
Aortic valve repair	0	4 (0.1%)	4 (<0.1%)
Aortic valve replacement	13 (0.5%)	14 (0.5%)	27 (0.5%)
Apicectomy	1 (<0.1%)	0	1 (<0.1%)
Appendicectomy	83 (2.9%)	118 (4.2%)	201 (3.5%)
Arterial stent insertion	4 (0.1%)	4 (0.1%)	8 (0.1%)
Arthrodesis	0	2 (<0.1%)	2 (<0.1%)
Atrial septal defect repair	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Autonomic ganglionectomy	0	1 (<0.1%)	1 (<0.1%)
Axillary lymphadenectomy	0	1 (<0.1%)	1 (<0.1%)
Baker's cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bariatric gastric balloon insertion	1 (<0.1%)	0	1 (<0.1%)
Benign breast lump removal	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Benign tumour excision	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Bile duct stent insertion	1 (<0.1%)	0	1 (<0.1%)
Biliary tract operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder calculus removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder catheter permanent	1 (<0.1%)	0	1 (<0.1%)
Bladder catheter temporary	1 (<0.1%)	0	1 (<0.1%)
Bladder catheterisation	0	2 (<0.1%)	2 (<0.1%)
Bladder neoplasm surgery	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Bladder operation	2 (<0.1%)	0	2 (<0.1%)
Bladder polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blepharoplasty	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bone cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bone debridement	1 (<0.1%)	0	1 (<0.1%)
Bone graft	2 (<0.1%)	0	2 (<0.1%)
Bone lesion excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bone operation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bone prosthesis insertion	1 (<0.1%)	0	1 (<0.1%)
Bone trimming	0	1 (<0.1%)	1 (<0.1%)
Brachytherapy	1 (<0.1%)	0	1 (<0.1%)
Brachytherapy to prostate	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast conserving surgery	2 (<0.1%)	4 (0.1%)	6 (0.1%)
Breast cyst excision	0	2 (<0.1%)	2 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	0	3 (0.1%)	3 (<0.1%)
Burn operation	0	1 (<0.1%)	1 (<0.1%)
Bursa removal	1 (<0.1%)	0	1 (<0.1%)
CSF shunt operation	0	2 (<0.1%)	2 (<0.1%)
Caesarean section	18 (0.6%)	22 (0.8%)	40 (0.7%)
Cancer surgery	2 (<0.1%)	0	2 (<0.1%)
Cardiac ablation	3 (0.1%)	3 (0.1%)	6 (0.1%)
Cardiac operation	0	1 (<0.1%)	1 (<0.1%)
Cardiac pacemaker insertion	40 (1.4%)	45 (1.6%)	85 (1.5%)
Cardiac pacemaker replacement	1 (<0.1%)	0	1 (<0.1%)
Cardiac resynchronisation therapy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Cardiopulmonary bypass	1 (<0.1%)	0	1 (<0.1%)
Cardiovascular event prophylaxis	0	2 (<0.1%)	2 (<0.1%)
Cardioversion	4 (0.1%)	4 (0.1%)	8 (0.1%)
Carotid artery stent insertion	0	2 (<0.1%)	2 (<0.1%)
Carotid endarterectomy	33 (1.2%)	38 (1.3%)	71 (1.3%)
Carpal tunnel decompression	16 (0.6%)	16 (0.6%)	32 (0.6%)
Cataract operation	166 (5.9%)	156 (5.5%)	322 (5.7%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Catheter placement	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Central venous catheterisation	1 (<0.1%)	0	1 (<0.1%)
Cerebral cyst excision	0	1 (<0.1%)	1 (<0.1%)
Cerebral endovascular aneurysm repair	0	2 (<0.1%)	2 (<0.1%)
Cervical conisation	1 (<0.1%)	0	1 (<0.1%)
Chemotherapy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cholecystectomy	157 (5.5%)	159 (5.6%)	316 (5.6%)
Cholecystostomy	0	1 (<0.1%)	1 (<0.1%)
Cholelithotomy	1 (<0.1%)	0	1 (<0.1%)
Cholelithotripsy	1 (<0.1%)	0	1 (<0.1%)
Cholesteatoma removal	0	1 (<0.1%)	1 (<0.1%)
Circumcision	3 (0.1%)	7 (0.2%)	10 (0.2%)
Colectomy	12 (0.4%)	10 (0.4%)	22 (0.4%)
Colon operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colostomy	0	5 (0.2%)	5 (<0.1%)
Continuous positive airway pressure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Corneal transplant	0	2 (<0.1%)	2 (<0.1%)
Coronary angioplasty	38 (1.3%)	37 (1.3%)	75 (1.3%)
Coronary arterial stent insertion	101 (3.6%)	83 (2.9%)	184 (3.2%)
Coronary artery bypass	112 (4.0%)	114 (4.0%)	226 (4.0%)
Coronary endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Coronary revascularisation	6 (0.2%)	3 (0.1%)	9 (0.2%)
Cox-Maze procedure	0	2 (<0.1%)	2 (<0.1%)
Craniotomy	0	1 (<0.1%)	1 (<0.1%)
Cyst removal	1 (<0.1%)	0	1 (<0.1%)
Cystostomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dacryocystorhinostomy	0	1 (<0.1%)	1 (<0.1%)
Debridement	3 (0.1%)	3 (0.1%)	6 (0.1%)
Dental implantation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dental prosthesis placement	1 (<0.1%)	0	1 (<0.1%)
Dialysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug delivery device placement	0	1 (<0.1%)	1 (<0.1%)
Duodenal sphincterotomy	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer repair	2 (<0.1%)	0	2 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ear tube insertion	1 (<0.1%)	0	1 (<0.1%)
Elbow operation	1 (<0.1%)	0	1 (<0.1%)
Endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Endodontic procedure	1 (<0.1%)	0	1 (<0.1%)
Endometrial ablation	0	1 (<0.1%)	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Enterostomy	1 (<0.1%)	0	1 (<0.1%)
Epidermoid cyst excision	0	2 (<0.1%)	2 (<0.1%)
Epididymal cyst removal	1 (<0.1%)	0	1 (<0.1%)
Ethmoid sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Eustachian tube operation	0	1 (<0.1%)	1 (<0.1%)
Eventration repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Excision of ampulla of Vater	1 (<0.1%)	0	1 (<0.1%)
Explorative laparotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye excision	0	1 (<0.1%)	1 (<0.1%)
Eye laser surgery	17 (0.6%)	12 (0.4%)	29 (0.5%)
Eye operation	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Eye prosthesis insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facetectomy	0	1 (<0.1%)	1 (<0.1%)
Female sterilisation	23 (0.8%)	29 (1.0%)	52 (0.9%)
Finger amputation	5 (0.2%)	4 (0.1%)	9 (0.2%)
Fistula repair	1 (<0.1%)	0	1 (<0.1%)
Foot amputation	10 (0.4%)	12 (0.4%)	22 (0.4%)
Foot operation	0	1 (<0.1%)	1 (<0.1%)
Foraminotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallbladder operation	4 (0.1%)	3 (0.1%)	7 (0.1%)
Gastrectomy	3 (0.1%)	5 (0.2%)	8 (0.1%)
Gastric banding	5 (0.2%)	3 (0.1%)	8 (0.1%)
Gastric bypass	9 (0.3%)	8 (0.3%)	17 (0.3%)
Gastric operation	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal endoscopic therapy	0	1 (<0.1%)	1 (<0.1%)
Gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Glaucoma surgery	7 (0.2%)	4 (0.1%)	11 (0.2%)
Haemodialysis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoid operation	11 (0.4%)	8 (0.3%)	19 (0.3%)
Hearing aid therapy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic embolisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hernia repair	13 (0.5%)	7 (0.2%)	20 (0.4%)
High frequency ablation	1 (<0.1%)	0	1 (<0.1%)
Hip arthroplasty	22 (0.8%)	28 (1.0%)	50 (0.9%)
Hip surgery	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hormone therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Hydrocele operation	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Hysterectomy	80 (2.8%)	82 (2.9%)	162 (2.9%)
Hysterosalpingo-oophorectomy	11 (0.4%)	7 (0.2%)	18 (0.3%)
Ileectomy	1 (<0.1%)	0	1 (<0.1%)
Ileocaecal resection	1 (<0.1%)	0	1 (<0.1%)
Ileocolectomy	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	3 (0.1%)	0	3 (<0.1%)
Ileostomy closure	4 (0.1%)	0	4 (<0.1%)
Implantable defibrillator insertion	7 (0.2%)	6 (0.2%)	13 (0.2%)
Incisional drainage	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Influenza immunisation	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	14 (0.5%)	28 (1.0%)	42 (0.7%)
Internal fixation of fracture	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Intervertebral disc operation	16 (0.6%)	16 (0.6%)	32 (0.6%)
Intestinal anastomosis	1 (<0.1%)	0	1 (<0.1%)
Intestinal operation	0	3 (0.1%)	3 (<0.1%)
Intestinal polypectomy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Intestinal resection	0	1 (<0.1%)	1 (<0.1%)
Intra-cerebral aneurysm operation	3 (0.1%)	0	3 (<0.1%)
Intra-ocular injection	4 (0.1%)	4 (0.1%)	8 (0.1%)
Intra-thoracic aortic aneurysm repair	1 (<0.1%)	0	1 (<0.1%)
Intraocular lens implant	40 (1.4%)	44 (1.5%)	84 (1.5%)
Iridectomy	2 (<0.1%)	0	2 (<0.1%)
Iridotomy	1 (<0.1%)	0	1 (<0.1%)
Jaw operation	1 (<0.1%)	0	1 (<0.1%)
Jejunocolostomy	1 (<0.1%)	0	1 (<0.1%)
Joint arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint injection	0	1 (<0.1%)	1 (<0.1%)
Joint resurfacing surgery	1 (<0.1%)	0	1 (<0.1%)
Keratomileusis	0	1 (<0.1%)	1 (<0.1%)
Knee arthroplasty	24 (0.8%)	46 (1.6%)	70 (1.2%)
Knee operation	15 (0.5%)	14 (0.5%)	29 (0.5%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	11 (0.4%)	16 (0.6%)	27 (0.5%)
Large intestine anastomosis	0	1 (<0.1%)	1 (<0.1%)
Laryngeal operation	1 (<0.1%)	0	1 (<0.1%)
Laryngeal repair	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Leg amputation	18 (0.6%)	26 (0.9%)	44 (0.8%)
Lens capsulotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Lens extraction	9 (0.3%)	5 (0.2%)	14 (0.2%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Limb amputation	1 (<0.1%)	0	1 (<0.1%)
Limb operation	3 (0.1%)	5 (0.2%)	8 (0.1%)
Lip lesion excision	1 (<0.1%)	0	1 (<0.1%)
Lipoma excision	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Lithotripsy	5 (0.2%)	7 (0.2%)	12 (0.2%)
Liver operation	0	1 (<0.1%)	1 (<0.1%)
Liver transplant	0	1 (<0.1%)	1 (<0.1%)
Lung lobectomy	3 (0.1%)	4 (0.1%)	7 (0.1%)
Lung operation	0	1 (<0.1%)	1 (<0.1%)
Lymphadenectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mammoplasty	0	1 (<0.1%)	1 (<0.1%)
Mass excision	0	1 (<0.1%)	1 (<0.1%)
Mastectomy	6 (0.2%)	5 (0.2%)	11 (0.2%)
Mastoidectomy	1 (<0.1%)	0	1 (<0.1%)
Maxillofacial operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Medical device implantation	1 (<0.1%)	0	1 (<0.1%)
Medical device removal	0	1 (<0.1%)	1 (<0.1%)
Meningeal repair	0	1 (<0.1%)	1 (<0.1%)
Meniscus operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Meniscus removal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Metabolic surgery	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Metatarsal excision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mitral commissurotomy	0	1 (<0.1%)	1 (<0.1%)
Mitral valve repair	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Mitral valve replacement	0	3 (0.1%)	3 (<0.1%)
Mole excision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Muscle operation	1 (<0.1%)	0	1 (<0.1%)
Myomectomy	3 (0.1%)	5 (0.2%)	8 (0.1%)
Nail operation	0	1 (<0.1%)	1 (<0.1%)
Nasal polypectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nasal septal operation	6 (0.2%)	4 (0.1%)	10 (0.2%)
Nasopharyngeal surgery	0	1 (<0.1%)	1 (<0.1%)
Neck dissection	1 (<0.1%)	0	1 (<0.1%)
Neck surgery	0	2 (<0.1%)	2 (<0.1%)
Nephrectomy	30 (1.1%)	31 (1.1%)	61 (1.1%)
Nephrostomy	0	1 (<0.1%)	1 (<0.1%)
Nephroureterectomy	2 (<0.1%)	0	2 (<0.1%)
Neurectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Neurolysis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Oesophagoenterostomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	6 (0.2%)	4 (0.1%)	10 (0.2%)
Oophorectomy bilateral	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Orchidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Orchidopexy	0	1 (<0.1%)	1 (<0.1%)
Orthopaedic procedure	1 (<0.1%)	0	1 (<0.1%)
Ostectomy	0	1 (<0.1%)	1 (<0.1%)
Osteotomy	3 (0.1%)	0	3 (<0.1%)
Otorhinolaryngological surgery	1 (<0.1%)	0	1 (<0.1%)
Ovarian cystectomy	3 (0.1%)	4 (0.1%)	7 (0.1%)
Ovarian neoplasm surgery	0	3 (0.1%)	3 (<0.1%)
Ovarian operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreas transplant	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic operation	1 (<0.1%)	0	1 (<0.1%)
Pancreatobiliary sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Papilloma excision	0	1 (<0.1%)	1 (<0.1%)
Parathyroidectomy	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Parotidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Penile prosthesis insertion	5 (0.2%)	4 (0.1%)	9 (0.2%)
Percutaneous coronary intervention	20 (0.7%)	23 (0.8%)	43 (0.8%)
Pericardial drainage	0	2 (<0.1%)	2 (<0.1%)
Perineoplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral artery angioplasty	20 (0.7%)	13 (0.5%)	33 (0.6%)
Peripheral artery bypass	15 (0.5%)	15 (0.5%)	30 (0.5%)
Peripheral artery stent insertion	10 (0.4%)	9 (0.3%)	19 (0.3%)
Peripheral endarterectomy	4 (0.1%)	4 (0.1%)	8 (0.1%)
Peripheral nerve decompression	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral nerve destruction	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve neurostimulation	0	1 (<0.1%)	1 (<0.1%)
Peripheral nerve operation	0	2 (<0.1%)	2 (<0.1%)
Peripheral nerve transposition	1 (<0.1%)	0	1 (<0.1%)
Peripheral revascularisation	0	3 (0.1%)	3 (<0.1%)
Phlebectomy	8 (0.3%)	8 (0.3%)	16 (0.3%)
Phlebotomy	1 (<0.1%)	0	1 (<0.1%)
Photocoagulation	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pituitary tumour removal	0	1 (<0.1%)	1 (<0.1%)
Plastic surgery to the face	0	1 (<0.1%)	1 (<0.1%)
Pleurectomy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Pneumocentesis	0	1 (<0.1%)	1 (<0.1%)
Polypectomy	3 (0.1%)	11 (0.4%)	14 (0.2%)
Posterior lens capsulotomy	1 (<0.1%)	0	1 (<0.1%)
Proctectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Profundaplasty	0	1 (<0.1%)	1 (<0.1%)
Prophylaxis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Prostatectomy	18 (0.6%)	17 (0.6%)	35 (0.6%)
Prostatic operation	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Prosthesis implantation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pterygium operation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ptosis repair	0	1 (<0.1%)	1 (<0.1%)
Pulmonary resection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pyelotomy	1 (<0.1%)	0	1 (<0.1%)
Pyloroplasty	1 (<0.1%)	0	1 (<0.1%)
Radical cystectomy	0	1 (<0.1%)	1 (<0.1%)
Radical hysterectomy	1 (<0.1%)	0	1 (<0.1%)
Radical mastectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Radiotherapy	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Rectal polypectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rectal prolapse repair	1 (<0.1%)	0	1 (<0.1%)
Renal artery angioplasty	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Renal artery stent placement	4 (0.1%)	6 (0.2%)	10 (0.2%)
Renal cyst aspiration	0	1 (<0.1%)	1 (<0.1%)
Renal cyst excision	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	19 (0.7%)	12 (0.4%)	31 (0.5%)
Renal surgery	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Renal sympathetic nerve ablation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Renal transplant	0	1 (<0.1%)	1 (<0.1%)
Renal tumour excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal laser coagulation	24 (0.8%)	20 (0.7%)	44 (0.8%)
Retinal operation	6 (0.2%)	3 (0.1%)	9 (0.2%)
Retinopexy	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Revascularisation procedure	2 (<0.1%)	0	2 (<0.1%)
Rotator cuff repair	5 (0.2%)	6 (0.2%)	11 (0.2%)
Salpingectomy	0	2 (<0.1%)	2 (<0.1%)
Salpingo-oophorectomy	2 (<0.1%)	0	2 (<0.1%)
Salpingo-oophorectomy bilateral	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Salpingo-oophorectomy unilateral	1 (<0.1%)	0	1 (<0.1%)
Scar excision	0	1 (<0.1%)	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Sebaceous cyst excision	0	2 (<0.1%)	2 (<0.1%)
Shoulder arthroplasty	4 (0.1%)	3 (0.1%)	7 (0.1%)
Shoulder operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Sigmoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sinus operation	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Skin graft	4 (0.1%)	2 (<0.1%)	6 (0.1%)
Skin lesion removal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin neoplasm excision	9 (0.3%)	13 (0.5%)	22 (0.4%)
Small intestinal anastomosis	0	1 (<0.1%)	1 (<0.1%)
Small intestinal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Small intestinal resection	0	1 (<0.1%)	1 (<0.1%)
Spinal decompression	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal fusion surgery	7 (0.2%)	3 (0.1%)	10 (0.2%)
Spinal laminectomy	7 (0.2%)	13 (0.5%)	20 (0.4%)
Spinal nerve stimulator implantation	2 (<0.1%)	0	2 (<0.1%)
Spinal operation	9 (0.3%)	11 (0.4%)	20 (0.4%)
Splenectomy	6 (0.2%)	5 (0.2%)	11 (0.2%)
Stent placement	13 (0.5%)	6 (0.2%)	19 (0.3%)
Sterilisation	5 (0.2%)	0	5 (<0.1%)
Steroid therapy	0	1 (<0.1%)	1 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Suprapubic prostatectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Surgery	2 (<0.1%)	0	2 (<0.1%)
Sympathectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Synovectomy	1 (<0.1%)	0	1 (<0.1%)
Synovial cyst removal	0	2 (<0.1%)	2 (<0.1%)
Tendon sheath incision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tenoplasty	0	4 (0.1%)	4 (<0.1%)
Tenotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tetralogy of Fallot repair	0	1 (<0.1%)	1 (<0.1%)
Therapeutic embolisation	1 (<0.1%)	0	1 (<0.1%)
Thoracotomy	0	1 (<0.1%)	1 (<0.1%)
Thromboembolectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid adenoma removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid nodule removal	1 (<0.1%)	0	1 (<0.1%)
Thyroid operation	0	1 (<0.1%)	1 (<0.1%)
Thyroidectomy	28 (1.0%)	34 (1.2%)	62 (1.1%)
Toe amputation	55 (1.9%)	59 (2.1%)	114 (2.0%)
Toe operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Tonsillectomy	34 (1.2%)	43 (1.5%)	77 (1.4%)
Tooth extraction	4 (0.1%)	7 (0.2%)	11 (0.2%)
Tooth repair	1 (<0.1%)	0	1 (<0.1%)
Trabeculectomy	2 (<0.1%)	0	2 (<0.1%)
Tracheostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transcatheter aortic valve implantation	0	1 (<0.1%)	1 (<0.1%)
Transfusion	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Transmyocardial revascularisation	0	1 (<0.1%)	1 (<0.1%)
Transurethral bladder resection	3 (0.1%)	3 (0.1%)	6 (0.1%)
Transurethral prostatectomy	15 (0.5%)	17 (0.6%)	32 (0.6%)
Tricuspid valve repair	0	2 (<0.1%)	2 (<0.1%)
Tumour excision	3 (0.1%)	0	3 (<0.1%)
Turbinectomy	1 (<0.1%)	0	1 (<0.1%)
Turbinoplasty	0	1 (<0.1%)	1 (<0.1%)
Tympanoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia repair	18 (0.6%)	11 (0.4%)	29 (0.5%)
Umbilicoplasty	0	1 (<0.1%)	1 (<0.1%)
Ureter dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Ureteral stent insertion	5 (0.2%)	3 (0.1%)	8 (0.1%)
Ureteric calculus removal	5 (0.2%)	5 (0.2%)	10 (0.2%)
Ureteric operation	1 (<0.1%)	0	1 (<0.1%)
Ureteric repair	0	1 (<0.1%)	1 (<0.1%)
Ureterolithotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral calculus removal	0	1 (<0.1%)	1 (<0.1%)
Urethral dilation procedure	2 (<0.1%)	0	2 (<0.1%)
Urethral meatotomy	0	1 (<0.1%)	1 (<0.1%)
Urethral operation	0	2 (<0.1%)	2 (<0.1%)
Urethral repair	1 (<0.1%)	0	1 (<0.1%)
Urethrotomy	3 (0.1%)	0	3 (<0.1%)
Urinary bladder suspension	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary control neurostimulator implantation	0	1 (<0.1%)	1 (<0.1%)
Urinary cystectomy	1 (<0.1%)	0	1 (<0.1%)
Uterine dilation and curettage	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Uterine operation	0	1 (<0.1%)	1 (<0.1%)
Uterine polypectomy	0	3 (0.1%)	3 (<0.1%)
Uterine repair	1 (<0.1%)	0	1 (<0.1%)
Uterine tumour excision	1 (<0.1%)	0	1 (<0.1%)
Uvulectomy	0	1 (<0.1%)	1 (<0.1%)
Uvulopalatopharyngoplasty	1 (<0.1%)	0	1 (<0.1%)
Uvuloplasty	1 (<0.1%)	0	1 (<0.1%)
Vagotomy	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Varicocele repair	1 (<0.1%)	0	1 (<0.1%)
Varicose vein operation	8 (0.3%)	7 (0.2%)	15 (0.3%)
Vascular graft	7 (0.2%)	5 (0.2%)	12 (0.2%)
Vascular operation	2 (<0.1%)	0	2 (<0.1%)
Vascular stent insertion	6 (0.2%)	7 (0.2%)	13 (0.2%)
Vasectomy	9 (0.3%)	9 (0.3%)	18 (0.3%)
Vena cava filter insertion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Venous angioplasty	0	1 (<0.1%)	1 (<0.1%)
Venous operation	0	1 (<0.1%)	1 (<0.1%)
Venous stent insertion	0	1 (<0.1%)	1 (<0.1%)
Ventriculo-peritoneal shunt	0	1 (<0.1%)	1 (<0.1%)
Vitamin supplementation	0	1 (<0.1%)	1 (<0.1%)
Vitrectomy	31 (1.1%)	33 (1.2%)	64 (1.1%)
Vocal cord operation	1 (<0.1%)	0	1 (<0.1%)
Vocal cord polypectomy	4 (0.1%)	3 (0.1%)	7 (0.1%)
Wisdom teeth removal	0	1 (<0.1%)	1 (<0.1%)
Wrist surgery	1 (<0.1%)	0	1 (<0.1%)
Vascular disorders	2765 (97.6%)	2787 (98.1%)	5552 (97.8%)
Angiopathy	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	20 (0.7%)	23 (0.8%)	43 (0.8%)
Aortic arteriosclerosis	41 (1.4%)	30 (1.1%)	71 (1.3%)
Aortic dilatation	5 (0.2%)	6 (0.2%)	11 (0.2%)
Aortic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic dissection	1 (<0.1%)	0	1 (<0.1%)
Aortic stenosis	30 (1.1%)	17 (0.6%)	47 (0.8%)
Aortic thrombosis	0	1 (<0.1%)	1 (<0.1%)
Arterial insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Arteriosclerosis	44 (1.6%)	60 (2.1%)	104 (1.8%)
Arteriosclerosis Moenckeberg-type	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arteritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atheroembolism	0	1 (<0.1%)	1 (<0.1%)
Brachiocephalic arteriosclerosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Brachiocephalic artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Circulatory collapse	1 (<0.1%)	0	1 (<0.1%)
Cryoglobulinaemia	2 (<0.1%)	0	2 (<0.1%)
Deep vein thrombosis	24 (0.8%)	32 (1.1%)	56 (1.0%)
Diabetic macroangiopathy	11 (0.4%)	10 (0.4%)	21 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Diabetic microangiopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Diabetic vascular disorder	54 (1.9%)	35 (1.2%)	89 (1.6%)
Diastolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Dry gangrene	2 (<0.1%)	0	2 (<0.1%)
Embolism venous	0	1 (<0.1%)	1 (<0.1%)
Essential hypertension	93 (3.3%)	98 (3.4%)	191 (3.4%)
Extremity necrosis	3 (0.1%)	0	3 (<0.1%)
Giant cell arteritis	0	1 (<0.1%)	1 (<0.1%)
Granulomatosis with polyangiitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haematoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hot flush	1 (<0.1%)	0	1 (<0.1%)
Hypertension	2637 (93.1%)	2671 (94.0%)	5308 (93.5%)
Hypertensive angiopathy	9 (0.3%)	6 (0.2%)	15 (0.3%)
Hypertensive crisis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hypertensive end-organ damage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypertensive urgency	2 (<0.1%)	0	2 (<0.1%)
Hypotension	4 (0.1%)	9 (0.3%)	13 (0.2%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Infarction	0	1 (<0.1%)	1 (<0.1%)
Intermittent claudication	23 (0.8%)	33 (1.2%)	56 (1.0%)
Labile hypertension	1 (<0.1%)	0	1 (<0.1%)
Leriche syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphocele	0	1 (<0.1%)	1 (<0.1%)
Lymphoedema	9 (0.3%)	8 (0.3%)	17 (0.3%)
Lymphostasis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Macroangiopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Malignant hypertension	1 (<0.1%)	0	1 (<0.1%)
Microangiopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	4 (0.1%)	8 (0.3%)	12 (0.2%)
Pallor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	470 (16.6%)	453 (15.9%)	923 (16.3%)
Peripheral artery aneurysm	0	2 (<0.1%)	2 (<0.1%)
Peripheral artery occlusion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral artery stenosis	5 (0.2%)	6 (0.2%)	11 (0.2%)
Peripheral artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Peripheral coldness	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Fidelio)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Peripheral ischaemia	4 (0.1%)	3 (0.1%)	7 (0.1%)
Peripheral vascular disorder	19 (0.7%)	27 (1.0%)	46 (0.8%)
Peripheral venous disease	67 (2.4%)	65 (2.3%)	132 (2.3%)
Phlebitis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Poor peripheral circulation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post thrombotic syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Postpartum venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Raynaud's phenomenon	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renovascular hypertension	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Secondary hypertension	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery stenosis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Subclavian steal syndrome	2 (<0.1%)	0	2 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)
Thromboangiitis obliterans	0	2 (<0.1%)	2 (<0.1%)
Thrombophlebitis	6 (0.2%)	8 (0.3%)	14 (0.2%)
Thrombophlebitis superficial	1 (<0.1%)	0	1 (<0.1%)
Thrombosis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Varicose vein	86 (3.0%)	68 (2.4%)	154 (2.7%)
Vasodilatation	0	1 (<0.1%)	1 (<0.1%)
Vein disorder	3 (0.1%)	0	3 (<0.1%)
Venous thrombosis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Venous thrombosis in pregnancy	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis limb	0	4 (0.1%)	4 (<0.1%)
White coat hypertension	5 (0.2%)	7 (0.2%)	12 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 30JAN2023 15:22
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4.6 Concomitant medication

Table 4.6 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set Fidelio)

Drug grouping	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	2314 (81.7%)	2343 (82.5%)	4657 (82.1%)
ACEI	428 (15.1%)	430 (15.1%)	858 (15.1%)
ARB	747 (26.4%)	822 (28.9%)	1569 (27.7%)
RAS-inhibitors	1084 (38.3%)	1120 (39.4%)	2204 (38.8%)
Beta-blocker	767 (27.1%)	855 (30.1%)	1622 (28.6%)
Diuretics	1213 (42.8%)	1288 (45.3%)	2501 (44.1%)
Loop diuretics	921 (32.5%)	989 (34.8%)	1910 (33.7%)
Thiazide diuretics	296 (10.4%)	324 (11.4%)	620 (10.9%)
Potassium supplements	190 (6.7%)	246 (8.7%)	436 (7.7%)
Potassium lowering agents (including binders)	307 (10.8%)	184 (6.5%)	491 (8.7%)
Alpha blocking agents	807 (28.5%)	881 (31.0%)	1688 (29.7%)
Calcium channel blockers	999 (35.3%)	1178 (41.5%)	2177 (38.4%)
Centrally acting antihypertensives	197 (7.0%)	254 (8.9%)	451 (7.9%)
Strong CYP3A4 inhibitors	163 (5.8%)	150 (5.3%)	313 (5.5%)
Moderate CYP3A4 inhibitors	360 (12.7%)	373 (13.1%)	733 (12.9%)
Weak CYP3A4 inhibitors	1144 (40.4%)	1210 (42.6%)	2354 (41.5%)
Unclassified CYP3A4 inhibitors	129 (4.6%)	136 (4.8%)	265 (4.7%)
Strong CYP3A4 inducers	33 (1.2%)	34 (1.2%)	67 (1.2%)
Moderate CYP3A4 inducers	178 (6.3%)	209 (7.4%)	387 (6.8%)
Weak CYP3A4 inducers	192 (6.8%)	206 (7.3%)	398 (7.0%)
Unclassified CYP3A4 inducers	130 (4.6%)	122 (4.3%)	252 (4.4%)
Oral anticoagulants	218 (7.7%)	223 (7.8%)	441 (7.8%)
Acetylsalycylic acid and its salts	448 (15.8%)	482 (17.0%)	930 (16.4%)
Statins	833 (29.4%)	862 (30.3%)	1695 (29.9%)
Erythropoeitin stimulating agents	177 (6.2%)	210 (7.4%)	387 (6.8%)
NSAIDS (excluding acetylsalicylic acid)	719 (25.4%)	759 (26.7%)	1478 (26.0%)
ARNIs	8 (0.3%)	13 (0.5%)	21 (0.4%)
Potassium-sparing diuretics	141 (5.0%)	172 (6.1%)	313 (5.5%)
Platelet aggregation inhibitors (excluding heparin)	670 (23.6%)	693 (24.4%)	1363 (24.0%)
Trimethoprim and derivatives	75 (2.6%)	85 (3.0%)	160 (2.8%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 30JAN2023 15:24
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set Fidelio)

Drug grouping	BAY 94-8862 N=2833 (100%)	Placebo N=2841 (100%)	Total N=5674 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1792 (63.3%)	1841 (64.8%)	3633 (64.0%)
Insulins and analogues	1335 (47.1%)	1384 (48.7%)	2719 (47.9%)
Dipeptidyl peptidase 4 inhibitors	472 (16.7%)	474 (16.7%)	946 (16.7%)
Glucagon-like peptide-1(GLP1) agonists	260 (9.2%)	264 (9.3%)	524 (9.2%)
SGLT-2 inhibitors	186 (6.6%)	216 (7.6%)	402 (7.1%)
Biguanides	516 (18.2%)	495 (17.4%)	1011 (17.8%)
Sulfonylureas	301 (10.6%)	334 (11.8%)	635 (11.2%)
Alpha glucosidase inhibitors	119 (4.2%)	116 (4.1%)	235 (4.1%)
Meglitinides	128 (4.5%)	143 (5.0%)	271 (4.8%)
Thiazolidinediones	80 (2.8%)	82 (2.9%)	162 (2.9%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 30JAN2023 15:24
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4.1 Disposition

Table 4.1 / 1: Subject disposition (all enrolled Figaro)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			19381
Screening failures			11944
Randomized	3723	3714	7437
GCP VIOLATIONS	37	48	85
Full analysis set	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Study drug never administered	4 (0.1%)	7 (0.2%)	11 (0.1%)
Treated	3682 (99.9%)	3659 (99.8%)	7341 (99.9%)
Did not complete treatment due COVID-19	37 (1.0%)	35 (1.0%)	72 (1.0%)
Subject decision: COVID-19 pandemic related	26 (0.7%)	21 (0.6%)	47 (0.6%)
Physician decision: COVID-19 pandemic related	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Logistical reason: COVID-19 pandemic related	4 (0.1%)	11 (0.3%)	15 (0.2%)
Did not complete study	5 (0.1%)	13 (0.4%)	18 (0.2%)
WITHDRAWN CONSENT	1 (<0.1%)	7 (0.2%)	8 (0.1%)
LOST TO FOLLOW-UP	4 (0.1%)	6 (0.2%)	10 (0.1%)
Completed study	3681 (99.9%)	3653 (99.6%)	7334 (99.8%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adds.sas 30JAN2023 15:11
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Table 4.1 / 2: Disposition: End of treatment (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Completed epoch	2677 (72.6%)	2652 (72.3%)	5329 (72.5%)
Not completed	1009 (27.4%)	1014 (27.7%)	2023 (27.5%)
Primary reason			
ADVERSE EVENT	275 (7.5%)	272 (7.4%)	547 (7.4%)
DEATH	214 (5.8%)	251 (6.8%)	465 (6.3%)
WITHDRAWAL BY SUBJECT	244 (6.6%)	218 (5.9%)	462 (6.3%)
LOST TO FOLLOW-UP	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	12 (0.3%)	12 (0.3%)	24 (0.3%)
PHYSICIAN DECISION	150 (4.1%)	130 (3.5%)	280 (3.8%)
TECHNICAL PROBLEMS	42 (1.1%)	59 (1.6%)	101 (1.4%)
DETERIORATION OF GENERAL CONDITIONS	0	2 (<0.1%)	2 (<0.1%)
PROTOCOL DEVIATION	14 (0.4%)	16 (0.4%)	30 (0.4%)
SITE TERMINATED BY SPONSOR	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
LOGISTICAL REASON	1 (<0.1%)	0	1 (<0.1%)
SUBJECT DECISION	6 (0.2%)	4 (0.1%)	10 (0.1%)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	26 (0.7%)	21 (0.6%)	47 (0.6%)
PHYSICIAN DECISION: COVID-19 PANDEMIC RELATED	7 (0.2%)	3 (<0.1%)	10 (0.1%)
LOGISTICAL REASON: COVID-19 PANDEMIC RELATED	4 (0.1%)	11 (0.3%)	15 (0.2%)
OTHER	10 (0.3%)	10 (0.3%)	20 (0.3%)

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adds.sas 30JAN2023 15:11
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4.2 Demographic characteristics

Table 4.2 / 1: Demographics (full analysis set Figaro)

TEXT	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Race (N)			
WHITE	2672 (72.5%)	2605 (71.1%)	5277 (71.8%)
BLACK OR AFRICAN AMERICAN	113 (3.1%)	145 (4.0%)	258 (3.5%)
ASIAN	715 (19.4%)	739 (20.2%)	1454 (19.8%)
AMERICAN INDIAN OR ALASKA NATIVE	73 (2.0%)	70 (1.9%)	143 (1.9%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	17 (0.5%)	14 (0.4%)	31 (0.4%)
NOT REPORTED	9 (0.2%)	7 (0.2%)	16 (0.2%)
MULTIPLE	87 (2.4%)	86 (2.3%)	173 (2.4%)
Sex (N)			
Male	2528 (68.6%)	2577 (70.3%)	5105 (69.4%)
Female	1158 (31.4%)	1089 (29.7%)	2247 (30.6%)
Age (YEARS)			
n	3686	3666	7352
Mean	64.13	64.13	64.13
SD	9.67	10.00	9.84
Min	27.0	23.0	23.0
Q1	58.00	58.00	58.00
Median	65.00	65.00	65.00
Q3	71.00	71.00	71.00
Max	89.0	93.0	93.0
Run-in age group (years) category (N)			
18 - 44 years	127 (3.4%)	123 (3.4%)	250 (3.4%)
45 - 64 years	1626 (44.1%)	1634 (44.6%)	3260 (44.3%)
65 - 74 years	1438 (39.0%)	1383 (37.7%)	2821 (38.4%)
>= 75 years	495 (13.4%)	526 (14.3%)	1021 (13.9%)
Age group (years) category 3 (N)			
< 65 years	1753 (47.6%)	1757 (47.9%)	3510 (47.7%)
>= 65 years	1933 (52.4%)	1909 (52.1%)	3842 (52.3%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	3058 (83.0%)	3057 (83.4%)	6115 (83.2%)
HISPANIC OR LATINO	618 (16.8%)	603 (16.4%)	1221 (16.6%)
NOT REPORTED	10 (0.3%)	6 (0.2%)	16 (0.2%)

Table 4.2 / 1: Demographics (full analysis set Figaro)

TEXT	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Region (N)			
Europe	1754 (47.6%)	1750 (47.7%)	3504 (47.7%)
North America	559 (15.2%)	548 (14.9%)	1107 (15.1%)
Asia	810 (22.0%)	815 (22.2%)	1625 (22.1%)
Latin America	424 (11.5%)	417 (11.4%)	841 (11.4%)
Others	139 (3.8%)	136 (3.7%)	275 (3.7%)
Baseline Weight (kg)			
n	3680	3661	7341
Mean	88.92	88.63	88.77
SD	20.44	19.80	20.12
Min	35.5	37.3	35.5
Q1	74.20	75.00	74.60
Median	86.65	86.90	86.80
Q3	101.00	100.00	100.60
Max	190.4	172.7	190.4
Baseline weight (kg) category (N)			
missing	6 (0.2%)	5 (0.1%)	11 (0.1%)
< 60 kg	178 (4.8%)	185 (5.0%)	363 (4.9%)
60 - < 90 kg	1904 (51.7%)	1878 (51.2%)	3782 (51.4%)
>= 90 kg	1598 (43.4%)	1598 (43.6%)	3196 (43.5%)
Baseline Height (cm)			
n	3680	3662	7342
Mean	167.71	167.67	167.69
SD	9.98	9.71	9.85
Min	118.0	121.0	118.0
Q1	160.85	161.00	161.00
Median	168.00	168.00	168.00
Q3	175.00	174.50	174.60
Max	198.1	206.0	206.0

Table 4.2 / 1: Demographics (full analysis set Figaro)

TEXT	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline Body Mass Index (kg/m2)			
n	3675	3659	7334
Mean	31.46	31.40	31.43
SD	6.04	5.93	5.99
Min	15.8	15.9	15.8
Q1	27.30	27.10	27.20
Median	30.70	30.60	30.70
Q3	34.70	34.80	34.80
Max	83.9	57.2	83.9
Baseline BMI (kg/m2) category 2 (N)			
missing	11 (0.3%)	7 (0.2%)	18 (0.2%)
< 30 kg/m2	1628 (44.2%)	1649 (45.0%)	3277 (44.6%)
>= 30 kg/m2	2047 (55.5%)	2010 (54.8%)	4057 (55.2%)
Baseline BMI (kg/m2) category 3 (N)			
missing	11 (0.3%)	7 (0.2%)	18 (0.2%)
< 20 kg/m2	26 (0.7%)	26 (0.7%)	52 (0.7%)
20 - < 25 kg/m2	400 (10.9%)	406 (11.1%)	806 (11.0%)
25 - < 30 kg/m2	1202 (32.6%)	1217 (33.2%)	2419 (32.9%)
30 - < 35 kg/m2	1160 (31.5%)	1130 (30.8%)	2290 (31.1%)
>= 35 kg/m2	887 (24.1%)	880 (24.0%)	1767 (24.0%)
Baseline Hip Circumference (cm)			
n	3668	3654	7322
Mean	107.69	107.65	107.67
SD	14.10	13.64	13.87
Min	36.0	36.0	36.0
Q1	99.00	99.00	99.00
Median	106.00	106.00	106.00
Q3	115.00	115.00	115.00
Max	199.0	171.0	199.0

Table 4.2 / 1: Demographics (full analysis set Figaro)

TEXT	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline waist circumference (cm)			
n	3674	3657	7331
Mean	107.30	107.16	107.23
SD	15.24	14.81	15.03
Min	34.0	34.0	34.0
Q1	97.00	97.00	97.00
Median	106.00	106.00	106.00
Q3	117.00	116.20	117.00
Max	240.0	173.0	240.0
Baseline waist circumf. (cm) cat. (N)			
missing	12 (0.3%)	9 (0.2%)	21 (0.3%)
normal	433 (11.7%)	401 (10.9%)	834 (11.3%)
increased	619 (16.8%)	661 (18.0%)	1280 (17.4%)
substantially increased	2622 (71.1%)	2595 (70.8%)	5217 (71.0%)
Baseline waist-hip ratio (N)			
n	3668	3652	7320
Mean	1.00	1.00	1.00
SD	0.11	0.11	0.11
Min	0.6	0.4	0.4
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.04	1.05
Max	2.7	2.3	2.7
Smoking History (N)			
NEVER	1760 (47.7%)	1684 (45.9%)	3444 (46.8%)
FORMER	1275 (34.6%)	1346 (36.7%)	2621 (35.7%)
CURRENT	651 (17.7%)	636 (17.3%)	1287 (17.5%)

Table 4.2 / 1: Demographics (full analysis set Figaro)

TEXT	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Alcohol Use (N)			
missing	3 (<0.1%)	0	3 (<0.1%)
ABSTINENT	2197 (59.6%)	2134 (58.2%)	4331 (58.9%)
LIGHT	1253 (34.0%)	1278 (34.9%)	2531 (34.4%)
MODERATE	216 (5.9%)	239 (6.5%)	455 (6.2%)
HEAVY	17 (0.5%)	15 (0.4%)	32 (0.4%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 30JAN2023 15:11
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4.3 Baseline characteristics

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline potassium (mmol/L)			
n	3686	3664	7350
Arithm. Mean	4.33	4.33	4.33
Arithm. SD	0.43	0.43	0.43
Min	2.8	2.6	2.6
Q1	4.10	4.10	4.10
Median	4.30	4.30	4.30
Q3	4.60	4.60	4.60
Max	6.3	6.1	6.3
Baseline ser. potassium (mmol/L) cat.(N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<= 4.5 mmol/L	2643 (71.7%)	2612 (71.2%)	5255 (71.5%)
> 4.5 mmol/L	1043 (28.3%)	1052 (28.7%)	2095 (28.5%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<=4.8 mmol/L	3295 (89.4%)	3288 (89.7%)	6583 (89.5%)
>4.8 to <=5.0 mmol/L	223 (6.0%)	204 (5.6%)	427 (5.8%)
>5.0 mmol/L	168 (4.6%)	172 (4.7%)	340 (4.6%)
Basel. potass (mmol/L) median FAS (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1937 (52.6%)	1926 (52.5%)	3863 (52.5%)
> 4.30 mmol/L (median in FAS)	1749 (47.4%)	1738 (47.4%)	3487 (47.4%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	1188 (32.2%)	1202 (32.8%)	2390 (32.5%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	749 (20.3%)	724 (19.7%)	1473 (20.0%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	969 (26.3%)	962 (26.2%)	1931 (26.3%)
>4.6 mmol/L (>Q3 in FAS)	780 (21.2%)	776 (21.2%)	1556 (21.2%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	3686	3666	7352
Arithm. Mean	135.81	135.70	135.75
Arithm. SD	13.96	14.06	14.01
Min	82.7	85.7	82.7
Q1	126.67	126.33	126.67
Median	135.67	136.00	136.00
Q3	145.33	145.67	145.33
Max	208.0	200.0	208.0
Baseline SBP (mmHg) category (N)			
< 130 mmHg	1187 (32.2%)	1197 (32.7%)	2384 (32.4%)
130 - < 160 mmHg	2392 (64.9%)	2355 (64.2%)	4747 (64.6%)
>= 160 mmHg	107 (2.9%)	114 (3.1%)	221 (3.0%)
Baseline SBP (mmHg) median for FAS (N)			
<= 137.00 mmHg (median in FAS)	1982 (53.8%)	1966 (53.6%)	3948 (53.7%)
> 137.00 mmHg (median in FAS)	1704 (46.2%)	1700 (46.4%)	3404 (46.3%)
Baseline Diastolic Blood Pressure (mmHg)			
n	3686	3666	7352
Arithm. Mean	76.75	76.80	76.77
Arithm. SD	9.54	9.55	9.55
Min	34.7	45.0	34.7
Q1	70.33	70.33	70.33
Median	77.33	77.33	77.33
Q3	83.33	83.00	83.17
Max	112.3	108.0	112.3
Baseline Heart Rate (BEATS/MIN)			
n	3686	3666	7352
Arithm. Mean	73.87	73.56	73.72
Arithm. SD	11.34	11.55	11.44
Min	37.0	35.3	35.3
Q1	66.00	65.00	65.67
Median	73.33	72.67	73.00
Q3	81.00	81.00	81.00
Max	122.7	144.0	144.0

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	3686	3665	7351
Arithm. Mean	67.62	67.99	67.80
Arithm. SD	21.65	21.74	21.69
Min	17.3	17.6	17.3
Q1	50.40	51.00	50.70
Median	67.35	67.80	67.60
Q3	84.60	84.60	84.60
Max	137.1	131.5	137.1
Baseline eGFR (mL/min/1.73m2) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
< 25 mL/min/1.73m2	15 (0.4%)	12 (0.3%)	27 (0.4%)
25 - < 45 mL/min/1.73m2	641 (17.4%)	610 (16.6%)	1251 (17.0%)
45 - < 60 mL/min/1.73m2	745 (20.2%)	789 (21.5%)	1534 (20.9%)
>= 60 mL/min/1.73m2	2285 (62.0%)	2254 (61.5%)	4539 (61.7%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
< 30 mL/min/1.73m2	98 (2.7%)	96 (2.6%)	194 (2.6%)
30 - < 60 mL/min/1.73m2	1303 (35.3%)	1315 (35.9%)	2618 (35.6%)
60 - < 90 mL/min/1.73m2	1631 (44.2%)	1600 (43.6%)	3231 (43.9%)
>= 90 mL/min/1.73m2	654 (17.7%)	654 (17.8%)	1308 (17.8%)
Screening eGFR (mL/min/1.73m2)			
n	3684	3662	7346
Arithm. Mean	68.04	68.11	68.08
Arithm. SD	21.68	21.73	21.71
Min	25.1	22.9	22.9
Q1	50.80	50.80	50.80
Median	68.50	68.15	68.30
Q3	84.50	84.50	84.50
Max	147.0	135.0	147.0
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
< 25 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
25 - < 45 mL/min/1.73m2	641 (17.4%)	629 (17.2%)	1270 (17.3%)
45 - < 60 mL/min/1.73m2	728 (19.8%)	740 (20.2%)	1468 (20.0%)
>= 60 mL/min/1.73m2	2315 (62.8%)	2292 (62.5%)	4607 (62.7%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
< 30 mL/min/1.73m2	99 (2.7%)	86 (2.3%)	185 (2.5%)
30 - < 60 mL/min/1.73m2	1270 (34.5%)	1284 (35.0%)	2554 (34.7%)
60 - < 90 mL/min/1.73m2	1678 (45.5%)	1649 (45.0%)	3327 (45.3%)
>= 90 mL/min/1.73m2	637 (17.3%)	643 (17.5%)	1280 (17.4%)
Baseline UACR (mg/g)			
n	3686	3664	7350
Geom. Mean	284.33	288.87	286.59
Geom. SD	3.58	3.53	3.55
Min	1.8	1.8	1.8
Q1	105.47	111.24	108.09
Median	302.36	315.06	308.18
Q3	749.05	731.01	739.86
Max	7630.5	5642.5	7630.5
Baseline albuminuria (mg/g) cat. (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	109 (3.0%)	98 (2.7%)	207 (2.8%)
High albuminuria (30 mg/g - < 300 mg/g)	1726 (46.8%)	1688 (46.0%)	3414 (46.4%)
Very high albuminuria (>= 300 mg/g)	1851 (50.2%)	1878 (51.2%)	3729 (50.7%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
<= 514.7 mg/g (median in FAS)	2397 (65.0%)	2409 (65.7%)	4806 (65.4%)
> 514.7 mg/g (median in FAS)	1289 (35.0%)	1255 (34.2%)	2544 (34.6%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	0	2 (<0.1%)	2 (<0.1%)
NO	3446 (93.5%)	3450 (94.1%)	6896 (93.8%)
YES	240 (6.5%)	214 (5.8%)	454 (6.2%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Baseline Creatinine (mg/dL)			
n	3686	3665	7351
Arithm. Mean	1.14	1.14	1.14
Arithm. SD	0.37	0.37	0.37
Min	0.4	0.4	0.4
Q1	0.87	0.87	0.87
Median	1.06	1.06	1.06
Q3	1.33	1.32	1.32
Max	3.4	3.4	3.4
Baseline Albumin (g/dL) in Serum			
n	3685	3664	7349
Arithm. Mean	4.26	4.25	4.25
Arithm. SD	0.31	0.32	0.31
Min	2.0	2.4	2.0
Q1	4.10	4.10	4.10
Median	4.30	4.30	4.30
Q3	4.50	4.50	4.50
Max	5.3	5.4	5.4
Baseline Hemoglobin (g/dL) in Blood			
n	3677	3662	7339
Arithm. Mean	13.64	13.60	13.62
Arithm. SD	1.66	1.65	1.65
Min	6.9	5.8	5.8
Q1	12.50	12.50	12.50
Median	13.70	13.65	13.70
Q3	14.80	14.70	14.70
Max	19.4	19.6	19.6
Baseline Hemoglobin A1C (%)			
n	3681	3660	7341
Arithm. Mean	7.74	7.69	7.72
Arithm. SD	1.39	1.35	1.37
Min	4.4	4.5	4.4
Q1	6.70	6.70	6.70
Median	7.50	7.50	7.50
Q3	8.60	8.50	8.50
Max	14.5	12.6	14.5

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	5 (0.1%)	6 (0.2%)	11 (0.1%)
<= 7.5%	1854 (50.3%)	1914 (52.2%)	3768 (51.3%)
> 7.5%	1827 (49.6%)	1746 (47.6%)	3573 (48.6%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	5 (0.1%)	6 (0.2%)	11 (0.1%)
<=6.7 % (<= Q1 in FAS)	943 (25.6%)	1005 (27.4%)	1948 (26.5%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	911 (24.7%)	909 (24.8%)	1820 (24.8%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	886 (24.0%)	856 (23.3%)	1742 (23.7%)
>8.5 % (>Q3 in FAS)	941 (25.5%)	890 (24.3%)	1831 (24.9%)
Baseline C Reactive Protein (mg/L)			
n	3686	3663	7349
Arithm. Mean	5.06	4.67	4.86
Arithm. SD	11.49	9.24	10.43
Min	0.1	0.1	0.1
Q1	0.96	0.98	0.97
Median	2.18	2.19	2.19
Q3	5.18	5.03	5.09
Max	311.0	212.0	311.0
Basel. C Reactive Protein Quartiles (N)			
missing	0	3 (<0.1%)	3 (<0.1%)
<=0.95 % (<= Q1 in FAS)	912 (24.7%)	897 (24.5%)	1809 (24.6%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	949 (25.7%)	947 (25.8%)	1896 (25.8%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	898 (24.4%)	926 (25.3%)	1824 (24.8%)
>5.13 % (>Q3 in FAS)	927 (25.1%)	893 (24.4%)	1820 (24.8%)
Stratification factor 3 (N)			
CVD present	1676 (45.5%)	1654 (45.1%)	3330 (45.3%)
CVD absent	2010 (54.5%)	2012 (54.9%)	4022 (54.7%)
Hyperkalemia (based on MLG) in MH (N)			
NO	3647 (98.9%)	3638 (99.2%)	7285 (99.1%)
YES	39 (1.1%)	28 (0.8%)	67 (0.9%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hepatic impairment in medical history(N)			
NO	3041 (82.5%)	3038 (82.9%)	6079 (82.7%)
YES	645 (17.5%)	628 (17.1%)	1273 (17.3%)
Child Pugh (N)			
missing	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
likely Child Pugh A	3600 (97.7%)	3574 (97.5%)	7174 (97.6%)
likely Child Pugh B	82 (2.2%)	88 (2.4%)	170 (2.3%)
certain Child Pugh B	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Duration of diabetes (in years) (N)			
n	3682	3663	7345
Arithm. Mean	14.53	14.44	14.49
Arithm. SD	8.60	8.44	8.52
Min	0.0	0.1	0.0
Q1	8.14	8.15	8.15
Median	13.18	13.90	13.31
Q3	20.11	19.27	19.83
Max	61.3	54.1	61.3
ACEI use (N)			
NO	2110 (57.2%)	2105 (57.4%)	4215 (57.3%)
YES	1576 (42.8%)	1561 (42.6%)	3137 (42.7%)
ARB use (N)			
NO	1578 (42.8%)	1562 (42.6%)	3140 (42.7%)
YES	2108 (57.2%)	2104 (57.4%)	4212 (57.3%)
Beta blocker use at baseline (N)			
NO	1912 (51.9%)	1904 (51.9%)	3816 (51.9%)
YES	1774 (48.1%)	1762 (48.1%)	3536 (48.1%)
Diuretic use at baseline (N)			
NO	1938 (52.6%)	1918 (52.3%)	3856 (52.4%)
YES	1748 (47.4%)	1748 (47.7%)	3496 (47.6%)
Statins use at baseline (N)			
NO	1134 (30.8%)	1034 (28.2%)	2168 (29.5%)
YES	2552 (69.2%)	2632 (71.8%)	5184 (70.5%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Anti-diabetic use at baseline (N)			
NO	79 (2.1%)	77 (2.1%)	156 (2.1%)
YES	3607 (97.9%)	3589 (97.9%)	7196 (97.9%)
Insul. and analo. use at baseline (N)			
NO	1663 (45.1%)	1696 (46.3%)	3359 (45.7%)
YES	2023 (54.9%)	1970 (53.7%)	3993 (54.3%)
Dip pep 4 inhibitors use at baseline (N)			
NO	2790 (75.7%)	2806 (76.5%)	5596 (76.1%)
YES	896 (24.3%)	860 (23.5%)	1756 (23.9%)
GLP1 agonists use at baseline (N)			
NO	3378 (91.6%)	3424 (93.4%)	6802 (92.5%)
YES	308 (8.4%)	242 (6.6%)	550 (7.5%)
SGLT-2 inhib. use at baseline (N)			
NO	3372 (91.5%)	3362 (91.7%)	6734 (91.6%)
YES	314 (8.5%)	304 (8.3%)	618 (8.4%)
Biguanides use at baseline (N)			
NO	1125 (30.5%)	1160 (31.6%)	2285 (31.1%)
YES	2561 (69.5%)	2506 (68.4%)	5067 (68.9%)
Sulfonamides use at baseline (N)			
NO	2649 (71.9%)	2641 (72.0%)	5290 (72.0%)
YES	1037 (28.1%)	1025 (28.0%)	2062 (28.0%)
Alpha gluc. inhib. use at baseline (N)			
NO	3526 (95.7%)	3494 (95.3%)	7020 (95.5%)
YES	160 (4.3%)	172 (4.7%)	332 (4.5%)
Meglitinides use at baseline (N)			
NO	3581 (97.2%)	3563 (97.2%)	7144 (97.2%)
YES	105 (2.8%)	103 (2.8%)	208 (2.8%)

Table 4.3 / 1: Baseline characteristics (full analysis set Figaro)

	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Thiazolidinediones use at baseline (N)			
NO	3542 (96.1%)	3522 (96.1%)	7064 (96.1%)
YES	144 (3.9%)	144 (3.9%)	288 (3.9%)
Potassium supplement use at baseline (N)			
NO	3575 (97.0%)	3562 (97.2%)	7137 (97.1%)
YES	111 (3.0%)	104 (2.8%)	215 (2.9%)
Potassium lowering use at baseline (N)			
NO	3662 (99.3%)	3644 (99.4%)	7306 (99.4%)
YES	24 (0.7%)	22 (0.6%)	46 (0.6%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	37 (1.0%)	30 (0.8%)	67 (0.9%)
unclassified	48 (1.3%)	56 (1.5%)	104 (1.4%)
moderate	69 (1.9%)	83 (2.3%)	152 (2.1%)
weak	2064 (56.0%)	2088 (57.0%)	4152 (56.5%)
none	1468 (39.8%)	1409 (38.4%)	2877 (39.1%)
Potency CYP3A4 inducer at baseline (N)			
strong	6 (0.2%)	10 (0.3%)	16 (0.2%)
unclassified	13 (0.4%)	12 (0.3%)	25 (0.3%)
moderate	10 (0.3%)	13 (0.4%)	23 (0.3%)
weak	134 (3.6%)	140 (3.8%)	274 (3.7%)
none	3523 (95.6%)	3491 (95.2%)	7014 (95.4%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 30JAN2023 15:11
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4.4 Medical History

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Number (%) of subjects with at least one medical history finding	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Blood and lymphatic system disorders	406 (11.0%)	423 (11.5%)	829 (11.3%)
Anaemia	235 (6.4%)	260 (7.1%)	495 (6.7%)
Anaemia macrocytic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anaemia megaloblastic	0	2 (<0.1%)	2 (<0.1%)
Anaemia of chronic disease	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Aplasia pure red cell	1 (<0.1%)	0	1 (<0.1%)
Blood loss anaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Coagulopathy	1 (<0.1%)	0	1 (<0.1%)
Deficiency anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eosinophilia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Haemolytic anaemia	0	1 (<0.1%)	1 (<0.1%)
Haemolytic uraemic syndrome	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic diathesis	2 (<0.1%)	0	2 (<0.1%)
Heparin-induced thrombocytopenia	1 (<0.1%)	0	1 (<0.1%)
Hypercoagulation	4 (0.1%)	0	4 (<0.1%)
Hyperfibrinogenaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia	0	2 (<0.1%)	2 (<0.1%)
Hypersplenism	0	1 (<0.1%)	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Immune thrombocytopenia	0	3 (<0.1%)	3 (<0.1%)
Increased tendency to bruise	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Iron deficiency anaemia	60 (1.6%)	62 (1.7%)	122 (1.7%)
Leukocytosis	15 (0.4%)	8 (0.2%)	23 (0.3%)
Leukopenia	0	4 (0.1%)	4 (<0.1%)
Lymphadenitis	1 (<0.1%)	0	1 (<0.1%)
Lymphadenopathy	4 (0.1%)	4 (0.1%)	8 (0.1%)
Lymphadenopathy mediastinal	0	1 (<0.1%)	1 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Lymphopenia	0	1 (<0.1%)	1 (<0.1%)
Macrocytosis	0	3 (<0.1%)	3 (<0.1%)
Microcytic anaemia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Microcytosis	0	1 (<0.1%)	1 (<0.1%)
Monoclonal B-cell lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Nephrogenic anaemia	19 (0.5%)	11 (0.3%)	30 (0.4%)
Normochromic anaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Normochromic normocytic anaemia	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Normocytic anaemia	4 (0.1%)	8 (0.2%)	12 (0.2%)
Pancytopenia	2 (<0.1%)	4 (0.1%)	6 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Pernicious anaemia	5 (0.1%)	4 (0.1%)	9 (0.1%)
Polycythaemia	10 (0.3%)	11 (0.3%)	21 (0.3%)
Retroperitoneal lymphadenopathy	0	1 (<0.1%)	1 (<0.1%)
Spleen disorder	0	1 (<0.1%)	1 (<0.1%)
Splenic infarction	1 (<0.1%)	0	1 (<0.1%)
Splenic lesion	1 (<0.1%)	0	1 (<0.1%)
Splenitis	0	1 (<0.1%)	1 (<0.1%)
Splenomegaly	13 (0.4%)	9 (0.2%)	22 (0.3%)
Thrombocytopenia	27 (0.7%)	22 (0.6%)	49 (0.7%)
Thrombocytosis	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Cardiac disorders	1856 (50.4%)	1834 (50.0%)	3690 (50.2%)
Acute coronary syndrome	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Acute myocardial infarction	15 (0.4%)	12 (0.3%)	27 (0.4%)
Angina pectoris	198 (5.4%)	206 (5.6%)	404 (5.5%)
Angina unstable	33 (0.9%)	32 (0.9%)	65 (0.9%)
Aortic valve calcification	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Aortic valve disease	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Aortic valve disease mixed	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic valve incompetence	23 (0.6%)	19 (0.5%)	42 (0.6%)
Aortic valve sclerosis	7 (0.2%)	8 (0.2%)	15 (0.2%)
Aortic valve stenosis	14 (0.4%)	12 (0.3%)	26 (0.4%)
Aortic valve thickening	0	1 (<0.1%)	1 (<0.1%)
Arrhythmia	33 (0.9%)	28 (0.8%)	61 (0.8%)
Arrhythmia supraventricular	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Arteriosclerosis coronary artery	56 (1.5%)	57 (1.6%)	113 (1.5%)
Atrial conduction time prolongation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrial enlargement	2 (<0.1%)	0	2 (<0.1%)
Atrial fibrillation	308 (8.4%)	303 (8.3%)	611 (8.3%)
Atrial flutter	38 (1.0%)	32 (0.9%)	70 (1.0%)
Atrial hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Atrial tachycardia	2 (<0.1%)	0	2 (<0.1%)
Atrial thrombosis	1 (<0.1%)	0	1 (<0.1%)
Atrioventricular block	7 (0.2%)	10 (0.3%)	17 (0.2%)
Atrioventricular block complete	11 (0.3%)	7 (0.2%)	18 (0.2%)
Atrioventricular block first degree	48 (1.3%)	69 (1.9%)	117 (1.6%)
Atrioventricular block second degree	9 (0.2%)	5 (0.1%)	14 (0.2%)
Bifascicular block	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bradyarrhythmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bradycardia	19 (0.5%)	11 (0.3%)	30 (0.4%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Bundle branch block	0	1 (<0.1%)	1 (<0.1%)
Bundle branch block bilateral	0	3 (<0.1%)	3 (<0.1%)
Bundle branch block left	48 (1.3%)	60 (1.6%)	108 (1.5%)
Bundle branch block right	70 (1.9%)	73 (2.0%)	143 (1.9%)
Cardiac aneurysm	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Cardiac arrest	0	2 (<0.1%)	2 (<0.1%)
Cardiac asthma	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Cardiac dysfunction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac failure	61 (1.7%)	71 (1.9%)	132 (1.8%)
Cardiac failure acute	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Cardiac failure chronic	165 (4.5%)	145 (4.0%)	310 (4.2%)
Cardiac failure congestive	43 (1.2%)	44 (1.2%)	87 (1.2%)
Cardiac hypertrophy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Cardiac septal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Cardiac tamponade	1 (<0.1%)	0	1 (<0.1%)
Cardiac valve disease	5 (0.1%)	6 (0.2%)	11 (0.1%)
Cardiac valve sclerosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiogenic shock	0	3 (<0.1%)	3 (<0.1%)
Cardiomegaly	11 (0.3%)	15 (0.4%)	26 (0.4%)
Cardiomyopathy	21 (0.6%)	15 (0.4%)	36 (0.5%)
Cardiovascular disorder	3 (<0.1%)	8 (0.2%)	11 (0.1%)
Cardiovascular insufficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Carditis	0	1 (<0.1%)	1 (<0.1%)
Chronic left ventricular failure	11 (0.3%)	9 (0.2%)	20 (0.3%)
Conduction disorder	1 (<0.1%)	0	1 (<0.1%)
Congestive cardiomyopathy	9 (0.2%)	8 (0.2%)	17 (0.2%)
Cor pulmonale	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Cor pulmonale chronic	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Coronary artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Coronary artery disease	1148 (31.1%)	1147 (31.3%)	2295 (31.2%)
Coronary artery insufficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary artery occlusion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Coronary artery stenosis	10 (0.3%)	14 (0.4%)	24 (0.3%)
Coronary artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Defect conduction intraventricular	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Degenerative aortic valve disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Diastolic dysfunction	16 (0.4%)	20 (0.5%)	36 (0.5%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Dilatation atrial	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dressler's syndrome	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Extrasystoles	6 (0.2%)	9 (0.2%)	15 (0.2%)
Heart valve calcification	0	1 (<0.1%)	1 (<0.1%)
Heart valve incompetence	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypertensive cardiomyopathy	6 (0.2%)	5 (0.1%)	11 (0.1%)
Hypertensive heart disease	46 (1.2%)	49 (1.3%)	95 (1.3%)
Intracardiac thrombus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	10 (0.3%)	15 (0.4%)	25 (0.3%)
Left atrial dilatation	5 (0.1%)	4 (0.1%)	9 (0.1%)
Left atrial enlargement	5 (0.1%)	9 (0.2%)	14 (0.2%)
Left atrial hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Left ventricular dysfunction	13 (0.4%)	11 (0.3%)	24 (0.3%)
Left ventricular enlargement	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Left ventricular failure	13 (0.4%)	15 (0.4%)	28 (0.4%)
Left ventricular hypertrophy	87 (2.4%)	92 (2.5%)	179 (2.4%)
Low cardiac output syndrome	0	1 (<0.1%)	1 (<0.1%)
Malignant hypertensive heart disease	0	1 (<0.1%)	1 (<0.1%)
Metabolic cardiomyopathy	7 (0.2%)	5 (0.1%)	12 (0.2%)
Microvascular coronary artery disease	1 (<0.1%)	0	1 (<0.1%)
Mitral valve calcification	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Mitral valve disease	5 (0.1%)	7 (0.2%)	12 (0.2%)
Mitral valve incompetence	64 (1.7%)	62 (1.7%)	126 (1.7%)
Mitral valve prolapse	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Mitral valve sclerosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mitral valve stenosis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Myocardial fibrosis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Myocardial infarction	640 (17.4%)	616 (16.8%)	1256 (17.1%)
Myocardial ischaemia	170 (4.6%)	158 (4.3%)	328 (4.5%)
Myocardial necrosis	0	2 (<0.1%)	2 (<0.1%)
Myocarditis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nodal rhythm	1 (<0.1%)	0	1 (<0.1%)
Non-obstructive cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Palpitations	12 (0.3%)	13 (0.4%)	25 (0.3%)
Pericardial cyst	2 (<0.1%)	0	2 (<0.1%)
Pericardial effusion	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Pericarditis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Pericarditis constrictive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prinzmetal angina	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Pulmonary valve incompetence	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pulmonary valve stenosis	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Restrictive cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Rheumatic heart disease	2 (<0.1%)	0	2 (<0.1%)
Right atrial dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular dysfunction	0	1 (<0.1%)	1 (<0.1%)
Right ventricular hypertrophy	2 (<0.1%)	0	2 (<0.1%)
Silent myocardial infarction	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sinus arrhythmia	6 (0.2%)	4 (0.1%)	10 (0.1%)
Sinus bradycardia	24 (0.7%)	28 (0.8%)	52 (0.7%)
Sinus node dysfunction	10 (0.3%)	6 (0.2%)	16 (0.2%)
Sinus tachycardia	8 (0.2%)	13 (0.4%)	21 (0.3%)
Stress cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Supraventricular extrasystoles	22 (0.6%)	15 (0.4%)	37 (0.5%)
Supraventricular tachyarrhythmia	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	16 (0.4%)	6 (0.2%)	22 (0.3%)
Systolic dysfunction	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Tachyarrhythmia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tachycardia	13 (0.4%)	6 (0.2%)	19 (0.3%)
Tachycardia induced cardiomyopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tachycardia paroxysmal	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Thyrotoxic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Tricuspid valve disease	0	3 (<0.1%)	3 (<0.1%)
Tricuspid valve incompetence	38 (1.0%)	36 (1.0%)	74 (1.0%)
Tricuspid valve sclerosis	1 (<0.1%)	0	1 (<0.1%)
Trifascicular block	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ventricular arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Ventricular dysfunction	1 (<0.1%)	0	1 (<0.1%)
Ventricular dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Ventricular extrasystoles	28 (0.8%)	26 (0.7%)	54 (0.7%)
Ventricular fibrillation	0	3 (<0.1%)	3 (<0.1%)
Ventricular hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular hypokinesia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ventricular remodelling	2 (<0.1%)	0	2 (<0.1%)
Ventricular tachycardia	5 (0.1%)	7 (0.2%)	12 (0.2%)
Wolff-Parkinson-White syndrome	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Congenital, familial and genetic disorders	181 (4.9%)	151 (4.1%)	332 (4.5%)
Accessory spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adenomatous polyposis coli	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Albinism	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Arnold-Chiari malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	4 (0.1%)	4 (0.1%)	8 (0.1%)
Bicuspid aortic valve	0	2 (<0.1%)	2 (<0.1%)
Birth mark	2 (<0.1%)	0	2 (<0.1%)
Breast malformation	1 (<0.1%)	0	1 (<0.1%)
Cataract congenital	1 (<0.1%)	0	1 (<0.1%)
Cerebrovascular arteriovenous malformation	0	1 (<0.1%)	1 (<0.1%)
Cone dystrophy	0	1 (<0.1%)	1 (<0.1%)
Congenital aortic dilatation	1 (<0.1%)	0	1 (<0.1%)
Congenital cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Congenital cystic kidney disease	0	7 (0.2%)	7 (<0.1%)
Congenital ectopic pancreas	0	1 (<0.1%)	1 (<0.1%)
Congenital hearing disorder	1 (<0.1%)	0	1 (<0.1%)
Congenital hepatobiliary anomaly	0	1 (<0.1%)	1 (<0.1%)
Congenital hydronephrosis	0	1 (<0.1%)	1 (<0.1%)
Congenital hypercoagulation	1 (<0.1%)	0	1 (<0.1%)
Congenital hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Congenital monorchidism	1 (<0.1%)	0	1 (<0.1%)
Congenital musculoskeletal anomaly	1 (<0.1%)	0	1 (<0.1%)
Congenital myopia	1 (<0.1%)	0	1 (<0.1%)
Congenital nose malformation	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	12 (0.3%)	6 (0.2%)	18 (0.2%)
Congenital scoliosis	0	1 (<0.1%)	1 (<0.1%)
Congenital spinal fusion	0	1 (<0.1%)	1 (<0.1%)
Congenital spondylolisthesis	1 (<0.1%)	0	1 (<0.1%)
Congenital ureteric anomaly	2 (<0.1%)	0	2 (<0.1%)
Corneal dystrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Craniofacial deformity	1 (<0.1%)	0	1 (<0.1%)
Cryptorchism	0	1 (<0.1%)	1 (<0.1%)
Cystinuria	0	1 (<0.1%)	1 (<0.1%)
Dermoid cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Developmental hip dysplasia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dolichocolon	0	2 (<0.1%)	2 (<0.1%)
Duane's syndrome	1 (<0.1%)	0	1 (<0.1%)
Ectopic kidney	5 (0.1%)	0	5 (<0.1%)
Exomphalos	2 (<0.1%)	0	2 (<0.1%)
Factor V Leiden carrier	0	1 (<0.1%)	1 (<0.1%)
Factor VIII deficiency	0	1 (<0.1%)	1 (<0.1%)
Factor X deficiency	1 (<0.1%)	0	1 (<0.1%)
Familial high density lipoprotein deficiency	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Familial hypertriglyceridaemia	1 (<0.1%)	0	1 (<0.1%)
Familial mediterranean fever	0	2 (<0.1%)	2 (<0.1%)
Familial tremor	0	2 (<0.1%)	2 (<0.1%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	2 (<0.1%)	0	2 (<0.1%)
Gitelman's syndrome	1 (<0.1%)	0	1 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	0	2 (<0.1%)	2 (<0.1%)
Haemoglobinopathy	1 (<0.1%)	0	1 (<0.1%)
Heart disease congenital	1 (<0.1%)	0	1 (<0.1%)
Hepatic hamartoma	0	1 (<0.1%)	1 (<0.1%)
Hereditary ataxia	1 (<0.1%)	0	1 (<0.1%)
Hereditary motor and sensory neuropathy	1 (<0.1%)	0	1 (<0.1%)
Hereditary neuropathy with liability to pressure palsies	0	1 (<0.1%)	1 (<0.1%)
Heterotaxia	1 (<0.1%)	0	1 (<0.1%)
Homocystinaemia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Homocystinuria	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hydrocele	5 (0.1%)	6 (0.2%)	11 (0.1%)
Hypertrophic cardiomyopathy	5 (0.1%)	13 (0.4%)	18 (0.2%)
Ichthyosis	2 (<0.1%)	0	2 (<0.1%)
Inborn error of bilirubin metabolism	1 (<0.1%)	0	1 (<0.1%)
Intracranial lipoma	1 (<0.1%)	0	1 (<0.1%)
Kidney duplex	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Kimmerle's anomaly	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	2 (<0.1%)	2 (<0.1%)
Klippel-Feil syndrome	1 (<0.1%)	0	1 (<0.1%)
Macroglossia	0	1 (<0.1%)	1 (<0.1%)
Methylenetetrahydrofolate reductase gene mutation	0	1 (<0.1%)	1 (<0.1%)
Multiple endocrine neoplasia Type 1	1 (<0.1%)	0	1 (<0.1%)
Muscular dystrophy	1 (<0.1%)	0	1 (<0.1%)
Myotonic dystrophy	1 (<0.1%)	0	1 (<0.1%)
Patent ductus arteriosus	0	1 (<0.1%)	1 (<0.1%)
Phimosis	13 (0.4%)	6 (0.2%)	19 (0.3%)
Primary hypercholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Protein C deficiency	0	1 (<0.1%)	1 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Renal fusion anomaly	1 (<0.1%)	0	1 (<0.1%)
Renal hypoplasia	2 (<0.1%)	0	2 (<0.1%)
Renal malposition	0	1 (<0.1%)	1 (<0.1%)
Retinitis pigmentosa	0	1 (<0.1%)	1 (<0.1%)
Retinopathy congenital	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Sickle cell trait	3 (<0.1%)	0	3 (<0.1%)
Spinal muscular atrophy	1 (<0.1%)	0	1 (<0.1%)
Spine malformation	1 (<0.1%)	0	1 (<0.1%)
Strabismus congenital	1 (<0.1%)	0	1 (<0.1%)
Synostosis	1 (<0.1%)	0	1 (<0.1%)
Thalassaemia	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Thalassaemia alpha	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Thalassaemia beta	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Thalassaemia minor	4 (0.1%)	4 (0.1%)	8 (0.1%)
Thyroglossal cyst	1 (<0.1%)	0	1 (<0.1%)
Transcobalamin deficiency	1 (<0.1%)	0	1 (<0.1%)
Tuberous sclerosis complex	1 (<0.1%)	0	1 (<0.1%)
Type IIa hyperlipidaemia	6 (0.2%)	7 (0.2%)	13 (0.2%)
Type IIb hyperlipidaemia	5 (0.1%)	5 (0.1%)	10 (0.1%)
Type V hyperlipidaemia	47 (1.3%)	36 (1.0%)	83 (1.1%)
Urethral atresia	1 (<0.1%)	0	1 (<0.1%)
Urinary tract malformation	1 (<0.1%)	0	1 (<0.1%)
Ventricular septal defect	0	1 (<0.1%)	1 (<0.1%)
Vitello-intestinal duct remnant	0	3 (<0.1%)	3 (<0.1%)
Von Willebrand's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Welander distal myopathy	1 (<0.1%)	0	1 (<0.1%)
Ear and labyrinth disorders	235 (6.4%)	203 (5.5%)	438 (6.0%)
Allergic otitis media	0	1 (<0.1%)	1 (<0.1%)
Auditory disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Aural polyp	1 (<0.1%)	0	1 (<0.1%)
Cerumen impaction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conductive deafness	1 (<0.1%)	0	1 (<0.1%)
Deafness	30 (0.8%)	28 (0.8%)	58 (0.8%)
Deafness bilateral	9 (0.2%)	12 (0.3%)	21 (0.3%)
Deafness neurosensory	25 (0.7%)	13 (0.4%)	38 (0.5%)
Deafness unilateral	8 (0.2%)	10 (0.3%)	18 (0.2%)
Ear discomfort	2 (<0.1%)	0	2 (<0.1%)
Ear disorder	1 (<0.1%)	0	1 (<0.1%)
Ear pain	5 (0.1%)	4 (0.1%)	9 (0.1%)
Eustachian tube disorder	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	2 (<0.1%)	0	2 (<0.1%)
Eustachian tube stenosis	0	1 (<0.1%)	1 (<0.1%)
Excessive cerumen production	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exostosis of external ear canal	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hypoacusis	31 (0.8%)	27 (0.7%)	58 (0.8%)
Labyrinthine fistula	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	7 (0.2%)	9 (0.2%)	16 (0.2%)
Middle ear disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Middle ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Motion sickness	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Otosclerosis	5 (0.1%)	0	5 (<0.1%)
Presbyacusis	4 (0.1%)	5 (0.1%)	9 (0.1%)
Sudden hearing loss	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Tinnitus	44 (1.2%)	24 (0.7%)	68 (0.9%)
Tympanic membrane perforation	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Vertigo	55 (1.5%)	53 (1.4%)	108 (1.5%)
Vertigo labyrinthine	1 (<0.1%)	0	1 (<0.1%)
Vertigo positional	13 (0.4%)	9 (0.2%)	22 (0.3%)
Vestibular ataxia	8 (0.2%)	7 (0.2%)	15 (0.2%)
Vestibular disorder	8 (0.2%)	4 (0.1%)	12 (0.2%)
Endocrine disorders	564 (15.3%)	531 (14.5%)	1095 (14.9%)
Acromegaly	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adrenal cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adrenal mass	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Androgen deficiency	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Autoimmune hypothyroidism	2 (<0.1%)	0	2 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Autoimmune thyroiditis	27 (0.7%)	28 (0.8%)	55 (0.7%)
Basedow's disease	8 (0.2%)	5 (0.1%)	13 (0.2%)
Cushing's syndrome	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Cushingoid	0	2 (<0.1%)	2 (<0.1%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Endocrine disorder	0	1 (<0.1%)	1 (<0.1%)
Goitre	124 (3.4%)	116 (3.2%)	240 (3.3%)
Hyperaldosteronism	0	6 (0.2%)	6 (<0.1%)
Hyperparathyroidism	26 (0.7%)	14 (0.4%)	40 (0.5%)
Hyperparathyroidism primary	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Hyperparathyroidism secondary	12 (0.3%)	21 (0.6%)	33 (0.4%)
Hyperplasia adrenal	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Hyperprolactinaemia	2 (<0.1%)	0	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hyperthyroidism	35 (0.9%)	24 (0.7%)	59 (0.8%)
Hypogonadism	10 (0.3%)	14 (0.4%)	24 (0.3%)
Hypogonadism male	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Hypoparathyroidism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoparathyroidism secondary	0	1 (<0.1%)	1 (<0.1%)
Hypopituitarism	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypothalamo-pituitary disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypothyroidism	284 (7.7%)	268 (7.3%)	552 (7.5%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	0	1 (<0.1%)	1 (<0.1%)
Oestrogen deficiency	1 (<0.1%)	0	1 (<0.1%)
Primary hyperaldosteronism	4 (0.1%)	4 (0.1%)	8 (0.1%)
Primary hypogonadism	0	1 (<0.1%)	1 (<0.1%)
Primary hypothyroidism	6 (0.2%)	6 (0.2%)	12 (0.2%)
Secondary hypothyroidism	1 (<0.1%)	0	1 (<0.1%)
Testicular failure	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Thyroid calcification	2 (<0.1%)	0	2 (<0.1%)
Thyroid cyst	6 (0.2%)	5 (0.1%)	11 (0.1%)
Thyroid disorder	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Thyroid mass	46 (1.2%)	33 (0.9%)	79 (1.1%)
Thyroiditis	0	1 (<0.1%)	1 (<0.1%)
Thyroiditis chronic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Toxic nodular goitre	5 (0.1%)	5 (0.1%)	10 (0.1%)
Eye disorders	1716 (46.6%)	1666 (45.4%)	3382 (46.0%)
Age-related macular degeneration	7 (0.2%)	4 (0.1%)	11 (0.1%)
Amaurosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Amaurosis fugax	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Amblyopia	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Amblyopia strabismic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angle closure glaucoma	0	2 (<0.1%)	2 (<0.1%)
Arcus lipoides	1 (<0.1%)	0	1 (<0.1%)
Arteriosclerotic retinopathy	11 (0.3%)	13 (0.4%)	24 (0.3%)
Asthenopia	4 (0.1%)	10 (0.3%)	14 (0.2%)
Astigmatism	16 (0.4%)	17 (0.5%)	33 (0.4%)
Atrophy of globe	1 (<0.1%)	0	1 (<0.1%)
Blepharitis	7 (0.2%)	5 (0.1%)	12 (0.2%)
Blepharitis allergic	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Blepharochalasis	1 (<0.1%)	0	1 (<0.1%)
Blindness	8 (0.2%)	2 (<0.1%)	10 (0.1%)
Blindness transient	0	1 (<0.1%)	1 (<0.1%)
Blindness unilateral	12 (0.3%)	11 (0.3%)	23 (0.3%)
Borderline glaucoma	7 (0.2%)	6 (0.2%)	13 (0.2%)
Cataract	509 (13.8%)	524 (14.3%)	1033 (14.1%)
Cataract cortical	3 (<0.1%)	0	3 (<0.1%)
Cataract diabetic	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cataract nuclear	18 (0.5%)	10 (0.3%)	28 (0.4%)
Cataract subcapsular	5 (0.1%)	0	5 (<0.1%)
Chalazion	1 (<0.1%)	0	1 (<0.1%)
Cholesterolosis bulbi	0	2 (<0.1%)	2 (<0.1%)
Chorioretinal atrophy	2 (<0.1%)	0	2 (<0.1%)
Chorioretinopathy	1 (<0.1%)	0	1 (<0.1%)
Choroidal neovascularisation	2 (<0.1%)	0	2 (<0.1%)
Ciliary body disorder	1 (<0.1%)	0	1 (<0.1%)
Conjunctival haemorrhage	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Conjunctival hyperaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conjunctivitis allergic	25 (0.7%)	13 (0.4%)	38 (0.5%)
Corneal degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Corneal deposits	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	1 (<0.1%)	0	1 (<0.1%)
Corneal erosion	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Corneal leukoma	0	1 (<0.1%)	1 (<0.1%)
Corneal oedema	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	0	1 (<0.1%)	1 (<0.1%)
Cystoid macular oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dacryolith	1 (<0.1%)	0	1 (<0.1%)
Dacryostenosis acquired	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dermatochalasis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Diabetic eye disease	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinal oedema	17 (0.5%)	11 (0.3%)	28 (0.4%)
Diabetic retinopathy	1193 (32.4%)	1098 (30.0%)	2291 (31.2%)
Diplopia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Dry age-related macular degeneration	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dry eye	47 (1.3%)	41 (1.1%)	88 (1.2%)
Eales' disease	0	1 (<0.1%)	1 (<0.1%)
Ectropion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eczema eyelids	1 (<0.1%)	0	1 (<0.1%)
Endocrine ophthalmopathy	0	1 (<0.1%)	1 (<0.1%)
Entropion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Exfoliation glaucoma	1 (<0.1%)	0	1 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Extraocular muscle paresis	1 (<0.1%)	0	1 (<0.1%)
Eye allergy	0	2 (<0.1%)	2 (<0.1%)
Eye disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye irritation	1 (<0.1%)	0	1 (<0.1%)
Eye oedema	1 (<0.1%)	0	1 (<0.1%)
Eye opacity	0	1 (<0.1%)	1 (<0.1%)
Eye pruritus	1 (<0.1%)	0	1 (<0.1%)
Eyelid oedema	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eyelid pain	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	12 (0.3%)	8 (0.2%)	20 (0.3%)
Eyelid skin dryness	1 (<0.1%)	0	1 (<0.1%)
Flat anterior chamber of eye	1 (<0.1%)	0	1 (<0.1%)
Glaucoma	175 (4.7%)	181 (4.9%)	356 (4.8%)
Hypermetropia	24 (0.7%)	33 (0.9%)	57 (0.8%)
Idiopathic orbital inflammation	1 (<0.1%)	0	1 (<0.1%)
Iridocyclitis	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Iris adhesions	0	1 (<0.1%)	1 (<0.1%)
Iris disorder	1 (<0.1%)	0	1 (<0.1%)
Keratitis	5 (0.1%)	0	5 (<0.1%)
Keratoconus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	1 (<0.1%)	0	1 (<0.1%)
Lacrimal disorder	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Lacrimation increased	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Lagophthalmos	1 (<0.1%)	0	1 (<0.1%)
Lenticular opacities	0	2 (<0.1%)	2 (<0.1%)
Macular cyst	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	26 (0.7%)	21 (0.6%)	47 (0.6%)
Macular fibrosis	11 (0.3%)	9 (0.2%)	20 (0.3%)
Macular hole	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Macular ischaemia	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	26 (0.7%)	24 (0.7%)	50 (0.7%)
Macular scar	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Maculopathy	15 (0.4%)	9 (0.2%)	24 (0.3%)
Meibomian gland dysfunction	0	1 (<0.1%)	1 (<0.1%)
Meibomianitis	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Metamorphopsia	0	1 (<0.1%)	1 (<0.1%)
Myopia	47 (1.3%)	41 (1.1%)	88 (1.2%)
Myopic chorioretinal degeneration	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Narrow anterior chamber angle	0	1 (<0.1%)	1 (<0.1%)
Neovascular age-related macular degeneration	0	1 (<0.1%)	1 (<0.1%)
Non-proliferative retinopathy	0	4 (0.1%)	4 (<0.1%)
Normal tension glaucoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ocular discomfort	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Ocular hyperaemia	0	1 (<0.1%)	1 (<0.1%)
Ocular hypertension	7 (0.2%)	12 (0.3%)	19 (0.3%)
Ocular ischaemic syndrome	1 (<0.1%)	0	1 (<0.1%)
Open angle glaucoma	9 (0.2%)	14 (0.4%)	23 (0.3%)
Ophthalmoplegia	4 (0.1%)	0	4 (<0.1%)
Optic atrophy	4 (0.1%)	7 (0.2%)	11 (0.1%)
Optic disc haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Optic ischaemic neuropathy	0	4 (0.1%)	4 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Pathologic myopia	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Periorbital fat herniation	1 (<0.1%)	0	1 (<0.1%)
Posterior capsule opacification	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Presbyopia	41 (1.1%)	52 (1.4%)	93 (1.3%)
Pseudopapilloedema	0	1 (<0.1%)	1 (<0.1%)
Pterygium	6 (0.2%)	16 (0.4%)	22 (0.3%)
Punctate keratitis	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	7 (0.2%)	12 (0.3%)	19 (0.3%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery embolism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal artery occlusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinal artery spasm	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	0	2 (<0.1%)	2 (<0.1%)
Retinal cyst	1 (<0.1%)	0	1 (<0.1%)
Retinal degeneration	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinal detachment	18 (0.5%)	13 (0.4%)	31 (0.4%)
Retinal disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Retinal drusen	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	8 (0.2%)	13 (0.4%)	21 (0.3%)
Retinal infarction	0	1 (<0.1%)	1 (<0.1%)
Retinal oedema	2 (<0.1%)	0	2 (<0.1%)
Retinal pigment epitheliopathy	2 (<0.1%)	0	2 (<0.1%)
Retinal scar	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Retinal tear	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Retinal vascular disorder	14 (0.4%)	17 (0.5%)	31 (0.4%)
Retinal vascular occlusion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Retinal vascular thrombosis	1 (<0.1%)	0	1 (<0.1%)
Retinal vein occlusion	11 (0.3%)	2 (<0.1%)	13 (0.2%)
Retinal vein thrombosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Retinopathy	6 (0.2%)	7 (0.2%)	13 (0.2%)
Retinopathy hypertensive	43 (1.2%)	48 (1.3%)	91 (1.2%)
Retinopathy proliferative	2 (<0.1%)	0	2 (<0.1%)
Retinoschisis	2 (<0.1%)	0	2 (<0.1%)
Rhegmatogenous retinal detachment	1 (<0.1%)	0	1 (<0.1%)
Scintillating scotoma	0	1 (<0.1%)	1 (<0.1%)
Scleritis	0	2 (<0.1%)	2 (<0.1%)
Strabismus	7 (0.2%)	4 (0.1%)	11 (0.1%)
Swelling of eyelid	0	2 (<0.1%)	2 (<0.1%)
Tractional retinal detachment	0	1 (<0.1%)	1 (<0.1%)
Trichiasis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vernal keratoconjunctivitis	0	1 (<0.1%)	1 (<0.1%)
Vision blurred	9 (0.2%)	5 (0.1%)	14 (0.2%)
Visual acuity reduced	3 (<0.1%)	8 (0.2%)	11 (0.1%)
Visual impairment	9 (0.2%)	19 (0.5%)	28 (0.4%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Vitreous detachment	5 (0.1%)	4 (0.1%)	9 (0.1%)
Vitreous disorder	0	1 (<0.1%)	1 (<0.1%)
Vitreous fibrin	0	1 (<0.1%)	1 (<0.1%)
Vitreous floaters	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Vitreous haemorrhage	24 (0.7%)	15 (0.4%)	39 (0.5%)
Vitreous opacities	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Vogt-Koyanagi-Harada disease	0	1 (<0.1%)	1 (<0.1%)
Xanthopsia	0	1 (<0.1%)	1 (<0.1%)
Xerophthalmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal disorders	1340 (36.4%)	1302 (35.5%)	2642 (35.9%)
Abdominal discomfort	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Abdominal distension	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Abdominal hernia	15 (0.4%)	12 (0.3%)	27 (0.4%)
Abdominal mass	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Abdominal pain	14 (0.4%)	12 (0.3%)	26 (0.4%)
Abdominal pain lower	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Abdominal pain upper	14 (0.4%)	14 (0.4%)	28 (0.4%)
Abdominal wall haematoma	1 (<0.1%)	0	1 (<0.1%)
Abnormal faeces	0	1 (<0.1%)	1 (<0.1%)
Acid peptic disease	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Acquired oesophageal web	2 (<0.1%)	0	2 (<0.1%)
Aerophagia	1 (<0.1%)	0	1 (<0.1%)
Alcoholic pancreatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal fissure	5 (0.1%)	8 (0.2%)	13 (0.2%)
Anal fistula	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Anal haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Anal incontinence	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Anal polyp	0	1 (<0.1%)	1 (<0.1%)
Anal pruritus	0	1 (<0.1%)	1 (<0.1%)
Anal skin tags	0	1 (<0.1%)	1 (<0.1%)
Anorectal discomfort	0	1 (<0.1%)	1 (<0.1%)
Aphthous ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Appendicitis noninfective	0	1 (<0.1%)	1 (<0.1%)
Aptyalism	1 (<0.1%)	0	1 (<0.1%)
Ascites	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Barrett's oesophagus	15 (0.4%)	13 (0.4%)	28 (0.4%)
Bowel movement irregularity	0	1 (<0.1%)	1 (<0.1%)
Brunner's gland hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Cardiospasm	0	1 (<0.1%)	1 (<0.1%)
Change of bowel habit	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	127 (3.4%)	109 (3.0%)	236 (3.2%)
Coeliac artery aneurysm	1 (<0.1%)	0	1 (<0.1%)
Coeliac disease	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Colitis	13 (0.4%)	11 (0.3%)	24 (0.3%)
Colitis erosive	0	1 (<0.1%)	1 (<0.1%)
Colitis ischaemic	2 (<0.1%)	0	2 (<0.1%)
Colitis microscopic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Colitis ulcerative	8 (0.2%)	11 (0.3%)	19 (0.3%)
Colon dysplasia	2 (<0.1%)	0	2 (<0.1%)
Constipation	172 (4.7%)	144 (3.9%)	316 (4.3%)
Crohn's disease	4 (0.1%)	6 (0.2%)	10 (0.1%)
Cyclic vomiting syndrome	0	1 (<0.1%)	1 (<0.1%)
Dental caries	4 (0.1%)	7 (0.2%)	11 (0.1%)
Dental cyst	0	1 (<0.1%)	1 (<0.1%)
Diabetic enteropathy	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Diabetic gastroparesis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Diabetic gastropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic hernia	6 (0.2%)	5 (0.1%)	11 (0.1%)
Diarrhoea	43 (1.2%)	61 (1.7%)	104 (1.4%)
Diverticular perforation	0	1 (<0.1%)	1 (<0.1%)
Diverticulum	33 (0.9%)	41 (1.1%)	74 (1.0%)
Diverticulum gastric	1 (<0.1%)	0	1 (<0.1%)
Diverticulum intestinal	48 (1.3%)	38 (1.0%)	86 (1.2%)
Diverticulum intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Diverticulum oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dry mouth	6 (0.2%)	4 (0.1%)	10 (0.1%)
Dumping syndrome	0	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Duodenal ulcer	29 (0.8%)	30 (0.8%)	59 (0.8%)
Duodenal ulcer haemorrhage	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Duodenitis	12 (0.3%)	8 (0.2%)	20 (0.3%)
Duodenogastric reflux	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Dyspepsia	77 (2.1%)	60 (1.6%)	137 (1.9%)
Dysphagia	11 (0.3%)	10 (0.3%)	21 (0.3%)
Ectopic gastric mucosa	0	1 (<0.1%)	1 (<0.1%)
Enteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterocolitis	2 (<0.1%)	0	2 (<0.1%)
Enterovesical fistula	1 (<0.1%)	0	1 (<0.1%)
Epigastric discomfort	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Epiploic appendagitis	1 (<0.1%)	0	1 (<0.1%)
Erosive duodenitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Erosive oesophagitis	3 (<0.1%)	0	3 (<0.1%)
Faeces soft	0	1 (<0.1%)	1 (<0.1%)
Fistula of small intestine	0	1 (<0.1%)	1 (<0.1%)
Flatulence	5 (0.1%)	5 (0.1%)	10 (0.1%)
Food poisoning	0	1 (<0.1%)	1 (<0.1%)
Functional gastrointestinal disorder	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gallstone ileus	1 (<0.1%)	0	1 (<0.1%)
Gastric disorder	7 (0.2%)	1 (<0.1%)	8 (0.1%)
Gastric haemorrhage	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gastric hypermotility	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastric mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	2 (<0.1%)	0	2 (<0.1%)
Gastric polyps	18 (0.5%)	20 (0.5%)	38 (0.5%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Gastric ulcer	47 (1.3%)	45 (1.2%)	92 (1.3%)
Gastric ulcer haemorrhage	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastric ulcer perforation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastritis	125 (3.4%)	114 (3.1%)	239 (3.3%)
Gastritis erosive	20 (0.5%)	15 (0.4%)	35 (0.5%)
Gastritis haemorrhagic	0	2 (<0.1%)	2 (<0.1%)
Gastritis hypertrophic	0	1 (<0.1%)	1 (<0.1%)
Gastroduodenal ulcer	0	3 (<0.1%)	3 (<0.1%)
Gastrointestinal angiectasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal angiodysplasia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastrointestinal disorder	8 (0.2%)	7 (0.2%)	15 (0.2%)
Gastrointestinal dysplasia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal haemorrhage	10 (0.3%)	7 (0.2%)	17 (0.2%)
Gastrointestinal hypomotility	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastrointestinal inflammation	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal motility disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastrointestinal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal polyp	2 (<0.1%)	0	2 (<0.1%)
Gastrointestinal polyp haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal scarring	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal tract mucosal pigmentation	2 (<0.1%)	0	2 (<0.1%)
Gastrooesophageal reflux disease	376 (10.2%)	382 (10.4%)	758 (10.3%)
Gingival bleeding	2 (<0.1%)	0	2 (<0.1%)
Gingival hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gingival pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gingival recession	1 (<0.1%)	0	1 (<0.1%)
Gingival swelling	0	2 (<0.1%)	2 (<0.1%)
Haematochezia	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Haemorrhagic erosive gastritis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic necrotic pancreatitis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoidal haemorrhage	3 (<0.1%)	0	3 (<0.1%)
Haemorrhoids	80 (2.2%)	85 (2.3%)	165 (2.2%)
Hernial eventration	0	3 (<0.1%)	3 (<0.1%)
Hiatus hernia	60 (1.6%)	56 (1.5%)	116 (1.6%)
Hyperchlorhydria	1 (<0.1%)	0	1 (<0.1%)
Ileus	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Impaired gastric emptying	5 (0.1%)	9 (0.2%)	14 (0.2%)
Incarcerated umbilical hernia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Inflammatory bowel disease	0	2 (<0.1%)	2 (<0.1%)
Inguinal hernia	26 (0.7%)	52 (1.4%)	78 (1.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Internal hernia	0	1 (<0.1%)	1 (<0.1%)
Intestinal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Intestinal ischaemia	2 (<0.1%)	0	2 (<0.1%)
Intestinal metaplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intestinal obstruction	0	5 (0.1%)	5 (<0.1%)
Intestinal perforation	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intestinal polyp	6 (0.2%)	5 (0.1%)	11 (0.1%)
Irritable bowel syndrome	33 (0.9%)	26 (0.7%)	59 (0.8%)
Large intestinal haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	1 (<0.1%)	0	1 (<0.1%)
Large intestinal stenosis	0	1 (<0.1%)	1 (<0.1%)
Large intestine polyp	69 (1.9%)	65 (1.8%)	134 (1.8%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lip disorder	2 (<0.1%)	0	2 (<0.1%)
Lip erosion	1 (<0.1%)	0	1 (<0.1%)
Lip oedema	1 (<0.1%)	0	1 (<0.1%)
Lip swelling	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Lumbar hernia	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Melaena	0	3 (<0.1%)	3 (<0.1%)
Mesenteric panniculitis	0	1 (<0.1%)	1 (<0.1%)
Mouth cyst	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	0	1 (<0.1%)
Nausea	20 (0.5%)	22 (0.6%)	42 (0.6%)
Obstructive pancreatitis	0	2 (<0.1%)	2 (<0.1%)
Odynophagia	0	1 (<0.1%)	1 (<0.1%)
Oesophageal achalasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal dilatation	0	1 (<0.1%)	1 (<0.1%)
Oesophageal disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oesophageal dysplasia	1 (<0.1%)	0	1 (<0.1%)
Oesophageal obstruction	0	1 (<0.1%)	1 (<0.1%)
Oesophageal spasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oesophageal ulcer	0	2 (<0.1%)	2 (<0.1%)
Oesophagitis	12 (0.3%)	14 (0.4%)	26 (0.4%)
Oesophagitis ulcerative	0	1 (<0.1%)	1 (<0.1%)
Oral disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic atrophy	0	2 (<0.1%)	2 (<0.1%)
Pancreatic calcification	0	1 (<0.1%)	1 (<0.1%)
Pancreatic cyst	9 (0.2%)	5 (0.1%)	14 (0.2%)
Pancreatic failure	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Pancreatic mass	1 (<0.1%)	0	1 (<0.1%)
Pancreatic necrosis	0	1 (<0.1%)	1 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	4 (0.1%)	0	4 (<0.1%)
Pancreatitis	19 (0.5%)	15 (0.4%)	34 (0.5%)
Pancreatitis acute	21 (0.6%)	23 (0.6%)	44 (0.6%)
Pancreatitis chronic	57 (1.5%)	47 (1.3%)	104 (1.4%)
Pancreatitis necrotising	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatitis relapsing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatolithiasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer	24 (0.7%)	20 (0.5%)	44 (0.6%)
Peptic ulcer haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Periodontal disease	195 (5.3%)	174 (4.7%)	369 (5.0%)
Peristalsis visible	1 (<0.1%)	0	1 (<0.1%)
Pharyngo-oesophageal diverticulum	2 (<0.1%)	0	2 (<0.1%)
Poor dental condition	2 (<0.1%)	0	2 (<0.1%)
Portal hypertensive gastropathy	1 (<0.1%)	0	1 (<0.1%)
Pouchitis	1 (<0.1%)	0	1 (<0.1%)
Presbyoesophagus	1 (<0.1%)	0	1 (<0.1%)
Proctalgia	1 (<0.1%)	0	1 (<0.1%)
Proctitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal fissure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal haemorrhage	7 (0.2%)	7 (0.2%)	14 (0.2%)
Rectal polyp	4 (0.1%)	6 (0.2%)	10 (0.1%)
Rectal prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Reflux gastritis	0	5 (0.1%)	5 (<0.1%)
Retching	0	1 (<0.1%)	1 (<0.1%)
Salivary gland calculus	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cyst	0	1 (<0.1%)	1 (<0.1%)
Salivary gland disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Segmental diverticular colitis	0	1 (<0.1%)	1 (<0.1%)
Short-bowel syndrome	1 (<0.1%)	0	1 (<0.1%)
Small intestinal obstruction	0	1 (<0.1%)	1 (<0.1%)
Spigelian hernia	1 (<0.1%)	0	1 (<0.1%)
Splenic artery aneurysm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Stomatitis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Tongue dry	0	1 (<0.1%)	1 (<0.1%)
Tongue dysplasia	0	1 (<0.1%)	1 (<0.1%)
Tongue oedema	0	1 (<0.1%)	1 (<0.1%)
Tooth disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Tooth loss	4 (0.1%)	0	4 (<0.1%)
Toothache	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Ulcerative gastritis	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	42 (1.1%)	47 (1.3%)	89 (1.2%)
Upper gastrointestinal haemorrhage	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Varices oesophageal	4 (0.1%)	4 (0.1%)	8 (0.1%)
Vomiting	9 (0.2%)	9 (0.2%)	18 (0.2%)
General disorders and administration site conditions	350 (9.5%)	322 (8.8%)	672 (9.1%)
Application site hypersensitivity	1 (<0.1%)	0	1 (<0.1%)
Asthenia	7 (0.2%)	11 (0.3%)	18 (0.2%)
Axillary pain	1 (<0.1%)	0	1 (<0.1%)
Calcinosis	2 (<0.1%)	0	2 (<0.1%)
Chest discomfort	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Chest pain	34 (0.9%)	28 (0.8%)	62 (0.8%)
Chills	1 (<0.1%)	0	1 (<0.1%)
Chronic fatigue syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cyst	12 (0.3%)	10 (0.3%)	22 (0.3%)
Disease susceptibility	0	1 (<0.1%)	1 (<0.1%)
Drug ineffective	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	17 (0.5%)	16 (0.4%)	33 (0.4%)
Face oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial discomfort	0	1 (<0.1%)	1 (<0.1%)
Facial pain	2 (<0.1%)	0	2 (<0.1%)
Fatigue	26 (0.7%)	24 (0.7%)	50 (0.7%)
Feeling cold	0	1 (<0.1%)	1 (<0.1%)
Fibrosis	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	11 (0.3%)	7 (0.2%)	18 (0.2%)
Generalised oedema	2 (<0.1%)	0	2 (<0.1%)
Granuloma	1 (<0.1%)	0	1 (<0.1%)
Gravitational oedema	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Hernia	4 (0.1%)	6 (0.2%)	10 (0.1%)
Hypothermia	0	1 (<0.1%)	1 (<0.1%)
Illness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Impaired healing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Impaired self-care	0	1 (<0.1%)	1 (<0.1%)
Inflammation	9 (0.2%)	3 (<0.1%)	12 (0.2%)
Influenza like illness	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Injury associated with device	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Localised oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malaise	3 (<0.1%)	0	3 (<0.1%)
Mass	0	1 (<0.1%)	1 (<0.1%)
Medical device pain	1 (<0.1%)	0	1 (<0.1%)
Nodule	0	1 (<0.1%)	1 (<0.1%)
Non-cardiac chest pain	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oedema	35 (0.9%)	31 (0.8%)	66 (0.9%)
Oedema due to renal disease	1 (<0.1%)	0	1 (<0.1%)
Oedema peripheral	153 (4.2%)	155 (4.2%)	308 (4.2%)
Pain	21 (0.6%)	20 (0.5%)	41 (0.6%)
Peripheral swelling	11 (0.3%)	7 (0.2%)	18 (0.2%)
Polyp	5 (0.1%)	5 (0.1%)	10 (0.1%)
Pseudocyst	0	1 (<0.1%)	1 (<0.1%)
Pyrexia	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Secretion discharge	1 (<0.1%)	0	1 (<0.1%)
Sensation of foreign body	1 (<0.1%)	0	1 (<0.1%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Temperature intolerance	1 (<0.1%)	0	1 (<0.1%)
Tissue infiltration	0	1 (<0.1%)	1 (<0.1%)
Treatment noncompliance	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vascular stent stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Xerosis	0	1 (<0.1%)	1 (<0.1%)
Hepatobiliary disorders	758 (20.6%)	729 (19.9%)	1487 (20.2%)
Acute hepatic failure	1 (<0.1%)	0	1 (<0.1%)
Alcoholic liver disease	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Autoimmune hepatitis	0	2 (<0.1%)	2 (<0.1%)
Bile duct stone	5 (0.1%)	5 (0.1%)	10 (0.1%)
Biliary colic	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Biliary dilatation	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Biliary dyskinesia	9 (0.2%)	0	9 (0.1%)
Cholangitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholangitis acute	2 (<0.1%)	0	2 (<0.1%)
Cholangitis chronic	1 (<0.1%)	0	1 (<0.1%)
Cholangitis sclerosing	2 (<0.1%)	0	2 (<0.1%)
Cholecystitis	28 (0.8%)	22 (0.6%)	50 (0.7%)
Cholecystitis acute	6 (0.2%)	5 (0.1%)	11 (0.1%)
Cholecystitis chronic	33 (0.9%)	37 (1.0%)	70 (1.0%)
Cholelithiasis	179 (4.9%)	166 (4.5%)	345 (4.7%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Cholestasis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Chronic hepatitis	15 (0.4%)	6 (0.2%)	21 (0.3%)
Cirrhosis alcoholic	0	1 (<0.1%)	1 (<0.1%)
Diabetic hepatopathy	17 (0.5%)	9 (0.2%)	26 (0.4%)
Dilatation intrahepatic duct acquired	1 (<0.1%)	0	1 (<0.1%)
Drug-induced liver injury	0	2 (<0.1%)	2 (<0.1%)
Fatty liver alcoholic	0	3 (<0.1%)	3 (<0.1%)
Gallbladder cholesterolosis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Gallbladder disorder	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Gallbladder enlargement	3 (<0.1%)	0	3 (<0.1%)
Gallbladder hypofunction	1 (<0.1%)	0	1 (<0.1%)
Gallbladder polyp	15 (0.4%)	29 (0.8%)	44 (0.6%)
Granulomatous liver disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic calcification	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hepatic cirrhosis	12 (0.3%)	13 (0.4%)	25 (0.3%)
Hepatic cyst	18 (0.5%)	16 (0.4%)	34 (0.5%)
Hepatic failure	1 (<0.1%)	0	1 (<0.1%)
Hepatic fibrosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hepatic function abnormal	10 (0.3%)	11 (0.3%)	21 (0.3%)
Hepatic lesion	0	5 (0.1%)	5 (<0.1%)
Hepatic mass	0	1 (<0.1%)	1 (<0.1%)
Hepatic steato-fibrosis	2 (<0.1%)	0	2 (<0.1%)
Hepatic steatosis	462 (12.5%)	462 (12.6%)	924 (12.6%)
Hepatitis	4 (0.1%)	14 (0.4%)	18 (0.2%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Hepatocellular injury	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Hepatomegaly	14 (0.4%)	15 (0.4%)	29 (0.4%)
Hepatosplenomegaly	0	3 (<0.1%)	3 (<0.1%)
Hepatotoxicity	1 (<0.1%)	0	1 (<0.1%)
Hydrocholecystis	0	1 (<0.1%)	1 (<0.1%)
Hyperbilirubinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperplastic cholecystopathy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Hypertransaminasaemia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Ischaemic hepatitis	1 (<0.1%)	0	1 (<0.1%)
Jaundice	0	2 (<0.1%)	2 (<0.1%)
Liver disorder	22 (0.6%)	22 (0.6%)	44 (0.6%)
Liver injury	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Non-alcoholic steatohepatitis	14 (0.4%)	12 (0.3%)	26 (0.4%)
Nonalcoholic fatty liver disease	36 (1.0%)	26 (0.7%)	62 (0.8%)
Porcelain gallbladder	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Portal hypertension	0	1 (<0.1%)	1 (<0.1%)
Post cholecystectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Sphincter of Oddi dysfunction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Steatohepatitis	8 (0.2%)	11 (0.3%)	19 (0.3%)
Subcapsular hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Immune system disorders	202 (5.5%)	221 (6.0%)	423 (5.8%)
Allergy to animal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Allergy to arthropod bite	1 (<0.1%)	0	1 (<0.1%)
Allergy to arthropod sting	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Allergy to chemicals	4 (0.1%)	0	4 (<0.1%)
Allergy to metals	0	2 (<0.1%)	2 (<0.1%)
Alloimmunisation	0	1 (<0.1%)	1 (<0.1%)
Anaphylactic reaction	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Anaphylactic shock	0	1 (<0.1%)	1 (<0.1%)
Autoimmune disorder	0	1 (<0.1%)	1 (<0.1%)
Contrast media allergy	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Cryofibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Drug hypersensitivity	79 (2.1%)	90 (2.5%)	169 (2.3%)
Dust allergy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Food allergy	7 (0.2%)	9 (0.2%)	16 (0.2%)
Graft versus host disease	0	1 (<0.1%)	1 (<0.1%)
Hypersensitivity	8 (0.2%)	13 (0.4%)	21 (0.3%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immune system disorder	1 (<0.1%)	0	1 (<0.1%)
Immunodeficiency	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Mite allergy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Multiple allergies	8 (0.2%)	8 (0.2%)	16 (0.2%)
Perennial allergy	0	1 (<0.1%)	1 (<0.1%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	1 (<0.1%)	1 (<0.1%)
Rubber sensitivity	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sarcoidosis	4 (0.1%)	4 (0.1%)	8 (0.1%)
Seasonal allergy	91 (2.5%)	92 (2.5%)	183 (2.5%)
Infections and infestations	854 (23.2%)	795 (21.7%)	1649 (22.4%)
Abdominal abscess	1 (<0.1%)	0	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	0	1 (<0.1%)
Abscess	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Abscess limb	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Abscess neck	0	1 (<0.1%)	1 (<0.1%)
Abscess oral	1 (<0.1%)	0	1 (<0.1%)
Acquired immunodeficiency syndrome	0	1 (<0.1%)	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	0	2 (<0.1%)
American trypanosomiasis	0	3 (<0.1%)	3 (<0.1%)
Anal abscess	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Antibiotic associated colitis	0	1 (<0.1%)	1 (<0.1%)
Appendicitis	22 (0.6%)	21 (0.6%)	43 (0.6%)
Appendicitis perforated	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arthritis bacterial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arthritis infective	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aspergilloma	1 (<0.1%)	0	1 (<0.1%)
Aspergillus infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	0	1 (<0.1%)	1 (<0.1%)
Atypical mycobacterial pneumonia	1 (<0.1%)	0	1 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)
Bacteraemia	0	1 (<0.1%)	1 (<0.1%)
Bacterial disease carrier	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Bacterial infection	1 (<0.1%)	0	1 (<0.1%)
Bacterial sepsis	1 (<0.1%)	0	1 (<0.1%)
Bacteriuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Balanitis candida	2 (<0.1%)	0	2 (<0.1%)
Balanoposthitis infective	1 (<0.1%)	0	1 (<0.1%)
Body tinea	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Bone tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Borrelia infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bronchiolitis	1 (<0.1%)	0	1 (<0.1%)
Bronchitis	29 (0.8%)	48 (1.3%)	77 (1.0%)
Bronchitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Brucellosis	0	3 (<0.1%)	3 (<0.1%)
Campylobacter colitis	0	1 (<0.1%)	1 (<0.1%)
Candida infection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Carbuncle	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Catheter site infection	1 (<0.1%)	0	1 (<0.1%)
Cellulitis	47 (1.3%)	23 (0.6%)	70 (1.0%)
Cellulitis of male external genital organ	1 (<0.1%)	0	1 (<0.1%)
Cervicitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chancroid	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis infective	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Chorioretinitis	1 (<0.1%)	0	1 (<0.1%)
Chronic hepatitis B	6 (0.2%)	7 (0.2%)	13 (0.2%)
Chronic hepatitis C	2 (<0.1%)	10 (0.3%)	12 (0.2%)
Chronic sinusitis	27 (0.7%)	20 (0.5%)	47 (0.6%)
Chronic tonsillitis	4 (0.1%)	5 (0.1%)	9 (0.1%)
Clostridium difficile colitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coccidioidomycosis	0	1 (<0.1%)	1 (<0.1%)
Conjunctivitis	29 (0.8%)	13 (0.4%)	42 (0.6%)
Conjunctivitis viral	1 (<0.1%)	0	1 (<0.1%)
Coxsackie viral infection	0	1 (<0.1%)	1 (<0.1%)
Cystitis	9 (0.2%)	9 (0.2%)	18 (0.2%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dengue fever	0	1 (<0.1%)	1 (<0.1%)
Dental fistula	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Dermatophytosis of nail	15 (0.4%)	20 (0.5%)	35 (0.5%)
Diabetic foot infection	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Diabetic gangrene	4 (0.1%)	5 (0.1%)	9 (0.1%)
Diarrhoea infectious	1 (<0.1%)	0	1 (<0.1%)
Disseminated tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Disseminated varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Diverticulitis	24 (0.7%)	26 (0.7%)	50 (0.7%)
Ear infection	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Eczema impetiginous	0	1 (<0.1%)	1 (<0.1%)
Eczema infected	0	2 (<0.1%)	2 (<0.1%)
Emphysematous cystitis	0	1 (<0.1%)	1 (<0.1%)
Encephalitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Endocarditis bacterial	0	1 (<0.1%)	1 (<0.1%)
Enterococcal bacteraemia	0	1 (<0.1%)	1 (<0.1%)
Epididymitis	4 (0.1%)	0	4 (<0.1%)
Epiglottitis	0	1 (<0.1%)	1 (<0.1%)
Epstein-Barr virus infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Erysipelas	19 (0.5%)	14 (0.4%)	33 (0.4%)
Escherichia urinary tract infection	0	2 (<0.1%)	2 (<0.1%)
External ear cellulitis	0	1 (<0.1%)	1 (<0.1%)
Eye infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye infection toxoplasmal	1 (<0.1%)	0	1 (<0.1%)
Folliculitis	5 (0.1%)	5 (0.1%)	10 (0.1%)
Fournier's gangrene	1 (<0.1%)	0	1 (<0.1%)
Fungal infection	5 (0.1%)	1 (<0.1%)	6 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Fungal skin infection	14 (0.4%)	4 (0.1%)	18 (0.2%)
Furuncle	6 (0.2%)	4 (0.1%)	10 (0.1%)
Gallbladder abscess	1 (<0.1%)	0	1 (<0.1%)
Gangrene	3 (<0.1%)	9 (0.2%)	12 (0.2%)
Gastritis viral	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis	6 (0.2%)	9 (0.2%)	15 (0.2%)
Gastroenteritis norovirus	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis viral	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Genital herpes	0	3 (<0.1%)	3 (<0.1%)
Genital infection fungal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Genitourinary tract infection	0	1 (<0.1%)	1 (<0.1%)
Gingivitis	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Groin abscess	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
HIV infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Helicobacter gastritis	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Helicobacter infection	5 (0.1%)	7 (0.2%)	12 (0.2%)
Hepatic echinococciasis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis A	12 (0.3%)	7 (0.2%)	19 (0.3%)
Hepatitis B	21 (0.6%)	11 (0.3%)	32 (0.4%)
Hepatitis C	15 (0.4%)	17 (0.5%)	32 (0.4%)
Hepatitis infectious mononucleosis	0	1 (<0.1%)	1 (<0.1%)
Hepatitis viral	1 (<0.1%)	0	1 (<0.1%)
Herpes dermatitis	0	1 (<0.1%)	1 (<0.1%)
Herpes ophthalmic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Herpes simplex	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Herpes virus infection	0	1 (<0.1%)	1 (<0.1%)
Herpes zoster	26 (0.7%)	19 (0.5%)	45 (0.6%)
Herpes zoster reactivation	1 (<0.1%)	0	1 (<0.1%)
Hordeolum	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Human T-cell lymphocytic virus type II infection	0	1 (<0.1%)	1 (<0.1%)
Human T-cell lymphotropic virus type I infection	0	1 (<0.1%)	1 (<0.1%)
Infected bite	2 (<0.1%)	0	2 (<0.1%)
Infected skin ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infection	1 (<0.1%)	0	1 (<0.1%)
Infectious mononucleosis	1 (<0.1%)	0	1 (<0.1%)
Infectious pleural effusion	1 (<0.1%)	0	1 (<0.1%)
Infective keratitis	0	1 (<0.1%)	1 (<0.1%)
Infective spondylitis	0	1 (<0.1%)	1 (<0.1%)
Influenza	16 (0.4%)	11 (0.3%)	27 (0.4%)
Intervertebral discitis	0	2 (<0.1%)	2 (<0.1%)
Intestinal tuberculosis	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Kidney infection	1 (<0.1%)	0	1 (<0.1%)
Klebsiella bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Labyrinthitis	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Laryngitis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Legionella infection	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Leprosy	3 (<0.1%)	0	3 (<0.1%)
Lice infestation	0	1 (<0.1%)	1 (<0.1%)
Liver abscess	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Localised infection	5 (0.1%)	6 (0.2%)	11 (0.1%)
Lower respiratory tract infection	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Lower respiratory tract infection viral	0	1 (<0.1%)	1 (<0.1%)
Lung abscess	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Lyme disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lymphangitis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Malaria	1 (<0.1%)	0	1 (<0.1%)
Mastitis	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Mediastinal abscess	0	1 (<0.1%)	1 (<0.1%)
Mediastinitis	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	1 (<0.1%)	0	1 (<0.1%)
Meningitis	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Meningitis aseptic	0	1 (<0.1%)	1 (<0.1%)
Meningitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Meningitis tuberculous	1 (<0.1%)	0	1 (<0.1%)
Mumps	0	1 (<0.1%)	1 (<0.1%)
Muscle abscess	0	1 (<0.1%)	1 (<0.1%)
Myocarditis infectious	0	1 (<0.1%)	1 (<0.1%)
Myringitis	1 (<0.1%)	0	1 (<0.1%)
Nail candida	0	2 (<0.1%)	2 (<0.1%)
Nasal abscess	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	29 (0.8%)	22 (0.6%)	51 (0.7%)
Necrotising fasciitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Onychomycosis	64 (1.7%)	52 (1.4%)	116 (1.6%)
Oophoritis	0	1 (<0.1%)	1 (<0.1%)
Opisthorchiasis	0	1 (<0.1%)	1 (<0.1%)
Oral candidiasis	0	3 (<0.1%)	3 (<0.1%)
Oral fungal infection	0	1 (<0.1%)	1 (<0.1%)
Oral herpes	1 (<0.1%)	4 (0.1%)	5 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Osteomyelitis	11 (0.3%)	17 (0.5%)	28 (0.4%)
Osteomyelitis chronic	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Otitis externa	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Otitis media	7 (0.2%)	6 (0.2%)	13 (0.2%)
Otitis media chronic	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Otosalpingitis	0	1 (<0.1%)	1 (<0.1%)
Pancreas infection	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	0	2 (<0.1%)	2 (<0.1%)
Paronychia	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Parotitis	6 (0.2%)	0	6 (<0.1%)
Penile infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Periodontitis	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Peritonsillar abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal abscess	0	2 (<0.1%)	2 (<0.1%)
Pharyngitis	7 (0.2%)	13 (0.4%)	20 (0.3%)
Pharyngotonsillitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pilonidal cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pleurisy viral	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	51 (1.4%)	43 (1.2%)	94 (1.3%)
Pneumonia bacterial	0	2 (<0.1%)	2 (<0.1%)
Pneumonia legionella	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonia moraxella	0	1 (<0.1%)	1 (<0.1%)
Pneumonia pseudomonal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia viral	1 (<0.1%)	0	1 (<0.1%)
Poliomyelitis	5 (0.1%)	5 (0.1%)	10 (0.1%)
Post procedural infection	2 (<0.1%)	0	2 (<0.1%)
Postoperative wound infection	2 (<0.1%)	0	2 (<0.1%)
Pulmonary sepsis	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculoma	0	2 (<0.1%)	2 (<0.1%)
Pulmonary tuberculosis	11 (0.3%)	13 (0.4%)	24 (0.3%)
Pulpitis dental	0	1 (<0.1%)	1 (<0.1%)
Pustule	0	2 (<0.1%)	2 (<0.1%)
Pyelonephritis	10 (0.3%)	13 (0.4%)	23 (0.3%)
Pyelonephritis acute	4 (0.1%)	8 (0.2%)	12 (0.2%)
Pyelonephritis chronic	69 (1.9%)	55 (1.5%)	124 (1.7%)
Pyoderma	1 (<0.1%)	0	1 (<0.1%)
Pyuria	1 (<0.1%)	0	1 (<0.1%)
Rectal abscess	1 (<0.1%)	0	1 (<0.1%)
Renal abscess	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Respiratory tract infection	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Respiratory tract infection viral	2 (<0.1%)	0	2 (<0.1%)
Retroperitoneal abscess	0	1 (<0.1%)	1 (<0.1%)
Rhinitis	19 (0.5%)	19 (0.5%)	38 (0.5%)
Salpingo-oophoritis	2 (<0.1%)	0	2 (<0.1%)
Scrotal abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scrotal infection	0	1 (<0.1%)	1 (<0.1%)
Sepsis	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Septic arthritis staphylococcal	1 (<0.1%)	0	1 (<0.1%)
Septic embolus	0	1 (<0.1%)	1 (<0.1%)
Septic shock	2 (<0.1%)	0	2 (<0.1%)
Sialoadenitis	0	1 (<0.1%)	1 (<0.1%)
Sinusitis	21 (0.6%)	24 (0.7%)	45 (0.6%)
Skin candida	0	2 (<0.1%)	2 (<0.1%)
Skin infection	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Staphylococcal infection	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal sepsis	0	1 (<0.1%)	1 (<0.1%)
Sternitis	0	2 (<0.1%)	2 (<0.1%)
Streptococcal endocarditis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	5 (0.1%)	4 (0.1%)	9 (0.1%)
Syphilis	2 (<0.1%)	0	2 (<0.1%)
Systemic candida	1 (<0.1%)	0	1 (<0.1%)
Taeniasis	1 (<0.1%)	0	1 (<0.1%)
Tinea capitis	0	2 (<0.1%)	2 (<0.1%)
Tinea cruris	11 (0.3%)	4 (0.1%)	15 (0.2%)
Tinea infection	9 (0.2%)	11 (0.3%)	20 (0.3%)
Tinea manuum	0	1 (<0.1%)	1 (<0.1%)
Tinea pedis	38 (1.0%)	42 (1.1%)	80 (1.1%)
Tinea versicolour	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Tonsillitis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Tonsillitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Tooth abscess	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Tooth infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tracheitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Trichuriasis	0	1 (<0.1%)	1 (<0.1%)
Tuberculosis	19 (0.5%)	12 (0.3%)	31 (0.4%)
Tuberculous pleurisy	2 (<0.1%)	0	2 (<0.1%)
Tubo-ovarian abscess	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	33 (0.9%)	34 (0.9%)	67 (0.9%)
Urethritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary tract infection	58 (1.6%)	77 (2.1%)	135 (1.8%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Urinary tract infection bacterial	0	2 (<0.1%)	2 (<0.1%)
Urosepsis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Vaginal infection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Varicella	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular device infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vestibular neuronitis	0	2 (<0.1%)	2 (<0.1%)
Viral diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Viral hepatitis carrier	4 (0.1%)	6 (0.2%)	10 (0.1%)
Viral infection	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Viral pericarditis	0	1 (<0.1%)	1 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vulval abscess	1 (<0.1%)	0	1 (<0.1%)
Vulvitis	0	1 (<0.1%)	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginitis	0	2 (<0.1%)	2 (<0.1%)
Wound infection	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Zika virus infection	1 (<0.1%)	0	1 (<0.1%)
Injury, poisoning and procedural complications	329 (8.9%)	309 (8.4%)	638 (8.7%)
Abdominal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Accident	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Acetabulum fracture	1 (<0.1%)	0	1 (<0.1%)
Anastomotic ulcer	0	1 (<0.1%)	1 (<0.1%)
Animal bite	1 (<0.1%)	0	1 (<0.1%)
Ankle fracture	22 (0.6%)	16 (0.4%)	38 (0.5%)
Aortic injury	1 (<0.1%)	0	1 (<0.1%)
Arterial bypass occlusion	0	1 (<0.1%)	1 (<0.1%)
Arterial bypass thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arthropod sting	1 (<0.1%)	0	1 (<0.1%)
Asbestosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Auricular haematoma	1 (<0.1%)	0	1 (<0.1%)
Back injury	1 (<0.1%)	0	1 (<0.1%)
Blindness traumatic	2 (<0.1%)	0	2 (<0.1%)
Bone contusion	0	1 (<0.1%)	1 (<0.1%)
Brain contusion	1 (<0.1%)	0	1 (<0.1%)
Breast injury	1 (<0.1%)	0	1 (<0.1%)
Burns second degree	1 (<0.1%)	0	1 (<0.1%)
Burns third degree	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cartilage injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Cervical vertebral fracture	1 (<0.1%)	0	1 (<0.1%)
Chest injury	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Chillblains	0	1 (<0.1%)	1 (<0.1%)
Clavicle fracture	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Compression fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Concussion	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Contusion	12 (0.3%)	5 (0.1%)	17 (0.2%)
Corneal abrasion	0	2 (<0.1%)	2 (<0.1%)
Coronary bypass stenosis	0	1 (<0.1%)	1 (<0.1%)
Coronary vascular graft occlusion	1 (<0.1%)	0	1 (<0.1%)
Craniocerebral injury	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Electric injury	1 (<0.1%)	0	1 (<0.1%)
Endotracheal intubation complication	1 (<0.1%)	0	1 (<0.1%)
Epicondylitis	13 (0.4%)	9 (0.2%)	22 (0.3%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye contusion	1 (<0.1%)	0	1 (<0.1%)
Eye injury	0	2 (<0.1%)	2 (<0.1%)
Eye laser scar	1 (<0.1%)	0	1 (<0.1%)
Eyeball avulsion	0	1 (<0.1%)	1 (<0.1%)
Face injury	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Facial bones fracture	2 (<0.1%)	0	2 (<0.1%)
Fall	7 (0.2%)	5 (0.1%)	12 (0.2%)
Femoral neck fracture	2 (<0.1%)	0	2 (<0.1%)
Femur fracture	10 (0.3%)	9 (0.2%)	19 (0.3%)
Fibula fracture	8 (0.2%)	8 (0.2%)	16 (0.2%)
Foot fracture	9 (0.2%)	8 (0.2%)	17 (0.2%)
Forearm fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body	0	1 (<0.1%)	1 (<0.1%)
Foreign body in eye	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fracture of penis	1 (<0.1%)	0	1 (<0.1%)
Fractured coccyx	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Fractured sacrum	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal anastomotic leak	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hand fracture	6 (0.2%)	4 (0.1%)	10 (0.1%)
Head injury	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Hip fracture	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Humerus fracture	7 (0.2%)	10 (0.3%)	17 (0.2%)
Iliotibial band syndrome	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia	12 (0.3%)	8 (0.2%)	20 (0.3%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injury corneal	0	2 (<0.1%)	2 (<0.1%)
Injury to brachial plexus due to birth trauma	1 (<0.1%)	0	1 (<0.1%)
Intentional overdose	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc injury	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Iris injury	1 (<0.1%)	0	1 (<0.1%)
Jaw fracture	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Joint dislocation	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Joint injury	4 (0.1%)	7 (0.2%)	11 (0.1%)
Ligament injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ligament rupture	8 (0.2%)	10 (0.3%)	18 (0.2%)
Ligament sprain	7 (0.2%)	10 (0.3%)	17 (0.2%)
Limb crushing injury	1 (<0.1%)	0	1 (<0.1%)
Limb injury	20 (0.5%)	21 (0.6%)	41 (0.6%)
Limb traumatic amputation	4 (0.1%)	7 (0.2%)	11 (0.1%)
Lower limb fracture	2 (<0.1%)	11 (0.3%)	13 (0.2%)
Lumbar vertebral fracture	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Median nerve injury	0	1 (<0.1%)	1 (<0.1%)
Meniscus injury	23 (0.6%)	20 (0.5%)	43 (0.6%)
Mouth injury	0	1 (<0.1%)	1 (<0.1%)
Multiple fractures	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Multiple injuries	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Muscle injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Muscle rupture	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Muscle strain	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Nerve injury	0	1 (<0.1%)	1 (<0.1%)
Optic nerve injury	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Pelvic bone injury	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penis injury	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve injury	0	1 (<0.1%)	1 (<0.1%)
Persistent corneal epithelial defect	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	2 (<0.1%)	0	2 (<0.1%)
Pneumonitis chemical	1 (<0.1%)	0	1 (<0.1%)
Post concussion syndrome	1 (<0.1%)	0	1 (<0.1%)
Post laminectomy syndrome	0	2 (<0.1%)	2 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural fistula	0	1 (<0.1%)	1 (<0.1%)
Post procedural haematoma	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Post procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypotension	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypothyroidism	12 (0.3%)	10 (0.3%)	22 (0.3%)
Post procedural swelling	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic neck syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post-traumatic pain	5 (0.1%)	4 (0.1%)	9 (0.1%)
Postoperative adhesion	1 (<0.1%)	0	1 (<0.1%)
Postoperative renal failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative thoracic procedure complication	1 (<0.1%)	0	1 (<0.1%)
Procedural intestinal perforation	1 (<0.1%)	0	1 (<0.1%)
Procedural pain	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Pulmonary contusion	1 (<0.1%)	0	1 (<0.1%)
Radial nerve injury	1 (<0.1%)	0	1 (<0.1%)
Radiation skin injury	1 (<0.1%)	0	1 (<0.1%)
Radius fracture	8 (0.2%)	4 (0.1%)	12 (0.2%)
Rib fracture	13 (0.4%)	5 (0.1%)	18 (0.2%)
Road traffic accident	6 (0.2%)	6 (0.2%)	12 (0.2%)
Sacroiliac fracture	0	1 (<0.1%)	1 (<0.1%)
Scar	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Silicosis	2 (<0.1%)	0	2 (<0.1%)
Skin abrasion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin injury	0	1 (<0.1%)	1 (<0.1%)
Skin laceration	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Skin wound	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skull fracture	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Soft tissue injury	2 (<0.1%)	0	2 (<0.1%)
Spinal column injury	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Spinal compression fracture	6 (0.2%)	4 (0.1%)	10 (0.1%)
Spinal cord injury	0	1 (<0.1%)	1 (<0.1%)
Spinal cord injury thoracic	0	1 (<0.1%)	1 (<0.1%)
Spinal fracture	0	3 (<0.1%)	3 (<0.1%)
Spleen contusion	1 (<0.1%)	0	1 (<0.1%)
Splenic rupture	0	2 (<0.1%)	2 (<0.1%)
Stoma site irritation	0	1 (<0.1%)	1 (<0.1%)
Stomal hernia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Stress fracture	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma	4 (0.1%)	4 (0.1%)	8 (0.1%)
Subdural haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Synovial rupture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Tendon injury	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tendon rupture	11 (0.3%)	7 (0.2%)	18 (0.2%)
Thermal burn	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Thermal burns of eye	0	1 (<0.1%)	1 (<0.1%)
Thoracic vertebral fracture	2 (<0.1%)	0	2 (<0.1%)
Tibia fracture	5 (0.1%)	8 (0.2%)	13 (0.2%)
Tobacco poisoning	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth fracture	0	4 (0.1%)	4 (<0.1%)
Toxicity to various agents	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Traumatic arthritis	0	2 (<0.1%)	2 (<0.1%)
Traumatic arthropathy	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthrosis	2 (<0.1%)	0	2 (<0.1%)
Traumatic fracture	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Traumatic haemothorax	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Traumatic renal injury	1 (<0.1%)	0	1 (<0.1%)
Traumatic shock	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ulna fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ulnar nerve injury	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	7 (0.2%)	13 (0.4%)	20 (0.3%)
Ureteric injury	0	1 (<0.1%)	1 (<0.1%)
Urethral stricture traumatic	0	1 (<0.1%)	1 (<0.1%)
Urinary retention postoperative	0	1 (<0.1%)	1 (<0.1%)
Vascular graft complication	0	1 (<0.1%)	1 (<0.1%)
Vascular pseudoaneurysm	1 (<0.1%)	0	1 (<0.1%)
Wound complication	1 (<0.1%)	0	1 (<0.1%)
Wound dehiscence	0	3 (<0.1%)	3 (<0.1%)
Wound necrosis	2 (<0.1%)	0	2 (<0.1%)
Wrist fracture	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Investigations	411 (11.2%)	419 (11.4%)	830 (11.3%)
Alanine aminotransferase increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Albumin urine present	0	2 (<0.1%)	2 (<0.1%)
Amylase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angiocardiogram	33 (0.9%)	30 (0.8%)	63 (0.9%)
Angiogram	12 (0.3%)	6 (0.2%)	18 (0.2%)
Angiogram cerebral	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Ankle brachial index decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anti factor VIII antibody positive	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Anti factor XI antibody positive	0	1 (<0.1%)	1 (<0.1%)
Antinuclear antibody positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic bruit	0	2 (<0.1%)	2 (<0.1%)
Aortogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arterial bruit	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arteriogram abnormal	1 (<0.1%)	0	1 (<0.1%)
Arteriogram carotid	1 (<0.1%)	0	1 (<0.1%)
Arthroscopy	12 (0.3%)	11 (0.3%)	23 (0.3%)
Aspartate aminotransferase increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aspiration pleural cavity	1 (<0.1%)	0	1 (<0.1%)
Autoantibody positive	0	1 (<0.1%)	1 (<0.1%)
Biopsy	1 (<0.1%)	0	1 (<0.1%)
Biopsy breast	2 (<0.1%)	0	2 (<0.1%)
Biopsy bronchus	0	1 (<0.1%)	1 (<0.1%)
Biopsy colon	1 (<0.1%)	0	1 (<0.1%)
Biopsy kidney	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Biopsy prostate	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Biopsy thyroid gland	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Blood bicarbonate decreased	1 (<0.1%)	0	1 (<0.1%)
Blood calcium decreased	1 (<0.1%)	0	1 (<0.1%)
Blood calcium increased	0	1 (<0.1%)	1 (<0.1%)
Blood chloride increased	1 (<0.1%)	0	1 (<0.1%)
Blood cholesterol increased	47 (1.3%)	69 (1.9%)	116 (1.6%)
Blood creatine phosphokinase abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood creatine phosphokinase increased	39 (1.1%)	57 (1.6%)	96 (1.3%)
Blood creatinine increased	0	4 (0.1%)	4 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood folate increased	0	1 (<0.1%)	1 (<0.1%)
Blood glucose increased	0	1 (<0.1%)	1 (<0.1%)
Blood iron decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood lactate dehydrogenase increased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Blood magnesium decreased	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Blood parathyroid hormone increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood potassium decreased	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Blood pressure increased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Blood sodium decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Blood testosterone decreased	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Blood thyroid stimulating hormone normal	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	9 (0.2%)	7 (0.2%)	16 (0.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Blood urea increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Blood uric acid abnormal	2 (<0.1%)	0	2 (<0.1%)
Blood uric acid increased	8 (0.2%)	11 (0.3%)	19 (0.3%)
Blood urine present	1 (<0.1%)	0	1 (<0.1%)
Body mass index increased	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Bone densitometry	1 (<0.1%)	0	1 (<0.1%)
Bone density decreased	0	1 (<0.1%)	1 (<0.1%)
Borrelia test positive	0	1 (<0.1%)	1 (<0.1%)
Brain scan abnormal	0	1 (<0.1%)	1 (<0.1%)
Breath sounds abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	22 (0.6%)	13 (0.4%)	35 (0.5%)
Carbon dioxide decreased	1 (<0.1%)	0	1 (<0.1%)
Carcinoembryonic antigen increased	1 (<0.1%)	0	1 (<0.1%)
Cardiac function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Cardiac murmur	29 (0.8%)	24 (0.7%)	53 (0.7%)
Cardiac stress test	1 (<0.1%)	0	1 (<0.1%)
Cardiac stress test abnormal	2 (<0.1%)	0	2 (<0.1%)
Cardiac stress test normal	0	1 (<0.1%)	1 (<0.1%)
Cardiac ventriculogram	1 (<0.1%)	0	1 (<0.1%)
Cardiac ventriculogram left normal	1 (<0.1%)	0	1 (<0.1%)
Carotid bruit	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Carotid intima-media thickness increased	0	1 (<0.1%)	1 (<0.1%)
Catheterisation cardiac	16 (0.4%)	13 (0.4%)	29 (0.4%)
Catheterisation cardiac normal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	5 (0.1%)	6 (0.2%)	11 (0.1%)
Computerised tomogram abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram coronary artery	0	1 (<0.1%)	1 (<0.1%)
Computerised tomogram head	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram pelvis abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram thorax abnormal	0	1 (<0.1%)	1 (<0.1%)
Culture urine positive	1 (<0.1%)	0	1 (<0.1%)
Cystoscopy	3 (<0.1%)	0	3 (<0.1%)
ECG electrically inactive area	2 (<0.1%)	0	2 (<0.1%)
ECG signs of myocardial infarction	1 (<0.1%)	0	1 (<0.1%)
ECG signs of myocardial ischaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Echocardiogram	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ejection fraction decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ejection fraction normal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Electrocardiogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Electrocardiogram PR shortened	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QRS complex abnormal	3 (<0.1%)	0	3 (<0.1%)
Electrocardiogram QT interval abnormal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Electrocardiogram QT prolonged	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Electrocardiogram ST segment abnormal	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Electrocardiogram ST segment depression	0	4 (0.1%)	4 (<0.1%)
Electrocardiogram ST segment elevation	0	2 (<0.1%)	2 (<0.1%)
Electrocardiogram ST-T change	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram ST-T segment abnormal	0	2 (<0.1%)	2 (<0.1%)
Electrocardiogram T wave abnormal	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Electrocardiogram T wave amplitude decreased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Electrocardiogram T wave biphasic	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave inversion	6 (0.2%)	6 (0.2%)	12 (0.2%)
Electrocardiogram abnormal	4 (0.1%)	6 (0.2%)	10 (0.1%)
Electrocardiogram repolarisation abnormality	8 (0.2%)	7 (0.2%)	15 (0.2%)
Endoscopic retrograde cholangiopancreatography	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Endoscopy	1 (<0.1%)	0	1 (<0.1%)
Enzyme activity abnormal	1 (<0.1%)	0	1 (<0.1%)
False positive investigation result	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Femoral bruit	1 (<0.1%)	0	1 (<0.1%)
Forced expiratory volume decreased	0	1 (<0.1%)	1 (<0.1%)
Gamma-glutamyltransferase abnormal	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase increased	16 (0.4%)	25 (0.7%)	41 (0.6%)
Gastric pH decreased	4 (0.1%)	5 (0.1%)	9 (0.1%)
Globulin abnormal	0	1 (<0.1%)	1 (<0.1%)
Glomerular filtration rate decreased	2 (<0.1%)	0	2 (<0.1%)
Glycosylated haemoglobin increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
HLA-B*5801 assay positive	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haemoglobin increased	0	2 (<0.1%)	2 (<0.1%)
Heart rate decreased	0	1 (<0.1%)	1 (<0.1%)
Heart rate irregular	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Helicobacter test positive	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Hepatic enzyme abnormal	0	2 (<0.1%)	2 (<0.1%)
Hepatic enzyme increased	13 (0.4%)	6 (0.2%)	19 (0.3%)
Hepatitis B antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B core antibody positive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis B surface antibody positive	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hepatitis B surface antigen positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	0	2 (<0.1%)
Hepatitis C antibody positive	0	1 (<0.1%)	1 (<0.1%)
Hepatitis C virus test positive	1 (<0.1%)	0	1 (<0.1%)
Human papilloma virus test negative	1 (<0.1%)	0	1 (<0.1%)
Hysteroscopy	0	1 (<0.1%)	1 (<0.1%)
Intraocular pressure decreased	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure increased	4 (0.1%)	5 (0.1%)	9 (0.1%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)
Left ventricular end-diastolic pressure increased	0	1 (<0.1%)	1 (<0.1%)
Light chain analysis decreased	1 (<0.1%)	0	1 (<0.1%)
Lipase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipids abnormal	0	3 (<0.1%)	3 (<0.1%)
Lipids increased	1 (<0.1%)	0	1 (<0.1%)
Lipoprotein (a) increased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Lipoprotein abnormal	0	1 (<0.1%)	1 (<0.1%)
Liver function test abnormal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Liver function test increased	5 (0.1%)	9 (0.2%)	14 (0.2%)
Liver scan abnormal	1 (<0.1%)	0	1 (<0.1%)
Low density lipoprotein increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Macroenzyme creatine kinase	1 (<0.1%)	0	1 (<0.1%)
Magnetic resonance imaging brain	1 (<0.1%)	0	1 (<0.1%)
Mammogram	1 (<0.1%)	0	1 (<0.1%)
Mammogram abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mean cell volume increased	0	1 (<0.1%)	1 (<0.1%)
Muscle enzyme increased	0	1 (<0.1%)	1 (<0.1%)
Occult blood positive	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Oxygen consumption increased	2 (<0.1%)	0	2 (<0.1%)
Pedal pulse decreased	1 (<0.1%)	0	1 (<0.1%)
Peripheral arteriogram	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Physical examination	0	1 (<0.1%)	1 (<0.1%)
Platelet aggregation decreased	1 (<0.1%)	0	1 (<0.1%)
Platelet count decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prostatic specific antigen increased	9 (0.2%)	4 (0.1%)	13 (0.2%)
Protein urine present	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary function test decreased	1 (<0.1%)	0	1 (<0.1%)
Pulmonary imaging procedure abnormal	2 (<0.1%)	0	2 (<0.1%)
Pulse absent	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pyeloscopy	1 (<0.1%)	0	1 (<0.1%)
QRS axis abnormal	20 (0.5%)	15 (0.4%)	35 (0.5%)
Red blood cell count increased	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Red blood cell sedimentation rate increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Scan myocardial perfusion	1 (<0.1%)	0	1 (<0.1%)
Scan myocardial perfusion abnormal	0	1 (<0.1%)	1 (<0.1%)
Serum ferritin increased	1 (<0.1%)	0	1 (<0.1%)
Spinal X-ray	0	1 (<0.1%)	1 (<0.1%)
Staphylococcus test positive	0	1 (<0.1%)	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test normal	2 (<0.1%)	0	2 (<0.1%)
Thyroid gland scan abnormal	0	1 (<0.1%)	1 (<0.1%)
Thyroid hormones decreased	0	1 (<0.1%)	1 (<0.1%)
Total lung capacity decreased	0	1 (<0.1%)	1 (<0.1%)
Transaminases increased	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Treponema test positive	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Troponin increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tuberculin test positive	0	1 (<0.1%)	1 (<0.1%)
Ultrasound Doppler abnormal	0	1 (<0.1%)	1 (<0.1%)
Ultrasound abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)
Ultrasound kidney	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ultrasound kidney abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ultrasound thyroid	1 (<0.1%)	0	1 (<0.1%)
Ultrasound thyroid abnormal	0	1 (<0.1%)	1 (<0.1%)
Ureteroscopy	2 (<0.1%)	0	2 (<0.1%)
Urinary occult blood positive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urine albumin/creatinine ratio increased	0	2 (<0.1%)	2 (<0.1%)
Urine analysis abnormal	0	1 (<0.1%)	1 (<0.1%)
Urogram	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Vitamin B12 increased	1 (<0.1%)	0	1 (<0.1%)
Vitamin D decreased	5 (0.1%)	8 (0.2%)	13 (0.2%)
Vitamin E decreased	0	1 (<0.1%)	1 (<0.1%)
Weight decreased	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Weight increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
White blood cell count increased	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
X-ray limb	0	1 (<0.1%)	1 (<0.1%)
X-ray of pelvis and hip	0	1 (<0.1%)	1 (<0.1%)
Metabolism and nutrition disorders	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Abnormal loss of weight	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acidosis	2 (<0.1%)	0	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Acquired mixed hyperlipidaemia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Calcium deficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Central obesity	33 (0.9%)	26 (0.7%)	59 (0.8%)
Decreased appetite	6 (0.2%)	6 (0.2%)	12 (0.2%)
Dehydration	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetes mellitus	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Diabetes mellitus inadequate control	11 (0.3%)	8 (0.2%)	19 (0.3%)
Diabetic dyslipidaemia	0	3 (<0.1%)	3 (<0.1%)
Diabetic ketoacidosis	0	6 (0.2%)	6 (<0.1%)
Diabetic ketosis	0	5 (0.1%)	5 (<0.1%)
Diabetic metabolic decompensation	0	1 (<0.1%)	1 (<0.1%)
Disaccharidase deficiency	0	1 (<0.1%)	1 (<0.1%)
Dyslipidaemia	1245 (33.8%)	1249 (34.1%)	2494 (33.9%)
Electrolyte imbalance	1 (<0.1%)	0	1 (<0.1%)
Fluid overload	0	2 (<0.1%)	2 (<0.1%)
Fluid retention	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Folate deficiency	5 (0.1%)	7 (0.2%)	12 (0.2%)
Fructose intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Gout	248 (6.7%)	276 (7.5%)	524 (7.1%)
Haemochromatosis	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Hyper HDL cholesterolaemia	1 (<0.1%)	0	1 (<0.1%)
Hypercalcaemia	16 (0.4%)	13 (0.4%)	29 (0.4%)
Hypercholesterolaemia	450 (12.2%)	461 (12.6%)	911 (12.4%)
Hyperferritinaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyperglycaemia	5 (0.1%)	7 (0.2%)	12 (0.2%)
Hyperhomocysteinaemia	8 (0.2%)	4 (0.1%)	12 (0.2%)
Hyperinsulinaemic hypoglycaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperkalaemia	37 (1.0%)	26 (0.7%)	63 (0.9%)
Hyperlipidaemia	928 (25.2%)	933 (25.5%)	1861 (25.3%)
Hyperphosphataemia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hypertriglyceridaemia	84 (2.3%)	81 (2.2%)	165 (2.2%)
Hyperuricaemia	410 (11.1%)	411 (11.2%)	821 (11.2%)
Hypervolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypo HDL cholesterolaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hypoalbuminaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypocalcaemia	6 (0.2%)	5 (0.1%)	11 (0.1%)
Hypoglycaemia	22 (0.6%)	20 (0.5%)	42 (0.6%)
Hypokalaemia	38 (1.0%)	29 (0.8%)	67 (0.9%)
Hypomagnesaemia	19 (0.5%)	13 (0.4%)	32 (0.4%)
Hyponatraemia	17 (0.5%)	14 (0.4%)	31 (0.4%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hypophosphataemia	0	2 (<0.1%)	2 (<0.1%)
Hypoproteinaemia	5 (0.1%)	6 (0.2%)	11 (0.1%)
Hypouricaemia	1 (<0.1%)	0	1 (<0.1%)
Hypovitaminosis	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Impaired fasting glucose	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iodine deficiency	0	1 (<0.1%)	1 (<0.1%)
Iron deficiency	30 (0.8%)	24 (0.7%)	54 (0.7%)
Iron overload	0	1 (<0.1%)	1 (<0.1%)
Ketosis	0	1 (<0.1%)	1 (<0.1%)
Lactic acidosis	0	1 (<0.1%)	1 (<0.1%)
Lactose intolerance	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Lipid metabolism disorder	14 (0.4%)	14 (0.4%)	28 (0.4%)
Lipomatosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lipoprotein deficiency	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Magnesium metabolism disorder	0	1 (<0.1%)	1 (<0.1%)
Malnutrition	0	1 (<0.1%)	1 (<0.1%)
Metabolic acidosis	5 (0.1%)	8 (0.2%)	13 (0.2%)
Metabolic alkalosis	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metabolic syndrome	25 (0.7%)	23 (0.6%)	48 (0.7%)
Obesity	1591 (43.2%)	1577 (43.0%)	3168 (43.1%)
Overweight	36 (1.0%)	35 (1.0%)	71 (1.0%)
Purine metabolism disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Type 2 diabetes mellitus	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Vitamin B complex deficiency	5 (0.1%)	10 (0.3%)	15 (0.2%)
Vitamin B1 deficiency	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 deficiency	65 (1.8%)	52 (1.4%)	117 (1.6%)
Vitamin D deficiency	240 (6.5%)	231 (6.3%)	471 (6.4%)
Zinc deficiency	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal and connective tissue disorders	1353 (36.7%)	1351 (36.9%)	2704 (36.8%)
Acquired claw toe	1 (<0.1%)	0	1 (<0.1%)
Ankle deformity	0	1 (<0.1%)	1 (<0.1%)
Ankylosing spondylitis	7 (0.2%)	9 (0.2%)	16 (0.2%)
Arthralgia	143 (3.9%)	142 (3.9%)	285 (3.9%)
Arthritis	55 (1.5%)	68 (1.9%)	123 (1.7%)
Arthritis reactive	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Arthropathy	9 (0.2%)	5 (0.1%)	14 (0.2%)
Articular calcification	1 (<0.1%)	0	1 (<0.1%)
Autoimmune arthritis	1 (<0.1%)	0	1 (<0.1%)
Axillary mass	1 (<0.1%)	0	1 (<0.1%)
Back disorder	6 (0.2%)	15 (0.4%)	21 (0.3%)
Back pain	235 (6.4%)	262 (7.1%)	497 (6.8%)
Bone atrophy	1 (<0.1%)	0	1 (<0.1%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone infarction	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	1 (<0.1%)	0	1 (<0.1%)
Bone loss	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	3 (<0.1%)	0	3 (<0.1%)
Bone pain	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bone swelling	1 (<0.1%)	0	1 (<0.1%)
Bursa disorder	0	1 (<0.1%)	1 (<0.1%)
Bursitis	23 (0.6%)	17 (0.5%)	40 (0.5%)
Calcification of muscle	1 (<0.1%)	0	1 (<0.1%)
Cervical spinal stenosis	9 (0.2%)	12 (0.3%)	21 (0.3%)
Chondrocalcinosis	0	2 (<0.1%)	2 (<0.1%)
Chondrocalcinosis pyrophosphate	2 (<0.1%)	0	2 (<0.1%)
Chondromalacia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chondropathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Chronic kidney disease-mineral and bone disorder	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Clubbing	0	1 (<0.1%)	1 (<0.1%)
Coccydynia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Collagen disorder	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Connective tissue inflammation	0	1 (<0.1%)	1 (<0.1%)
Costochondritis	1 (<0.1%)	0	1 (<0.1%)
Crowned dens syndrome	1 (<0.1%)	0	1 (<0.1%)
Crystal arthropathy	1 (<0.1%)	0	1 (<0.1%)
Dactylitis	0	1 (<0.1%)	1 (<0.1%)
Diabetic amyotrophy	0	2 (<0.1%)	2 (<0.1%)
Diastasis recti abdominis	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Diffuse idiopathic skeletal hyperostosis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Dupuytren's contracture	19 (0.5%)	11 (0.3%)	30 (0.4%)
Enthesopathy	5 (0.1%)	0	5 (<0.1%)
Exostosis	9 (0.2%)	17 (0.5%)	26 (0.4%)
Facet joint syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Fasciitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fibromyalgia	13 (0.4%)	9 (0.2%)	22 (0.3%)
Finger deformity	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fistula	1 (<0.1%)	0	1 (<0.1%)
Flank pain	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Foot deformity	19 (0.5%)	22 (0.6%)	41 (0.6%)
Gouty arthritis	34 (0.9%)	20 (0.5%)	54 (0.7%)
Gouty tophus	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)
Haemarthrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Inclusion body myositis	1 (<0.1%)	0	1 (<0.1%)
Inguinal mass	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc compression	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc degeneration	35 (0.9%)	30 (0.8%)	65 (0.9%)
Intervertebral disc disorder	48 (1.3%)	32 (0.9%)	80 (1.1%)
Intervertebral disc displacement	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Intervertebral disc protrusion	92 (2.5%)	111 (3.0%)	203 (2.8%)
Intervertebral disc space narrowing	1 (<0.1%)	0	1 (<0.1%)
Jaw cyst	1 (<0.1%)	0	1 (<0.1%)
Joint contracture	0	1 (<0.1%)	1 (<0.1%)
Joint deposit	1 (<0.1%)	0	1 (<0.1%)
Joint effusion	0	3 (<0.1%)	3 (<0.1%)
Joint range of motion decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Joint stiffness	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Joint swelling	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Knee deformity	2 (<0.1%)	0	2 (<0.1%)
Kyphosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Limb asymmetry	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Limb deformity	0	1 (<0.1%)	1 (<0.1%)
Limb discomfort	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lumbar spinal stenosis	27 (0.7%)	25 (0.7%)	52 (0.7%)
Meniscal degeneration	0	1 (<0.1%)	1 (<0.1%)
Metatarsalgia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle atrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle contracture	2 (<0.1%)	0	2 (<0.1%)
Muscle fatigue	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	80 (2.2%)	75 (2.0%)	155 (2.1%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscle twitching	0	1 (<0.1%)	1 (<0.1%)
Muscular weakness	4 (0.1%)	8 (0.2%)	12 (0.2%)
Musculoskeletal chest pain	3 (<0.1%)	0	3 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Musculoskeletal discomfort	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Musculoskeletal pain	1 (<0.1%)	6 (0.2%)	7 (<0.1%)
Musculoskeletal stiffness	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Myalgia	51 (1.4%)	49 (1.3%)	100 (1.4%)
Myofascial pain syndrome	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Myopathy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Myositis	3 (<0.1%)	0	3 (<0.1%)
Neck mass	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neck pain	32 (0.9%)	31 (0.8%)	63 (0.9%)
Neuropathic arthropathy	14 (0.4%)	15 (0.4%)	29 (0.4%)
Oligoarthritis	2 (<0.1%)	0	2 (<0.1%)
Osteitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Osteitis deformans	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Osteoarthritis	487 (13.2%)	462 (12.6%)	949 (12.9%)
Osteoarthropathy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Osteochondritis	1 (<0.1%)	0	1 (<0.1%)
Osteochondrosis	48 (1.3%)	57 (1.6%)	105 (1.4%)
Osteomalacia	1 (<0.1%)	0	1 (<0.1%)
Osteonecrosis	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Osteopenia	42 (1.1%)	21 (0.6%)	63 (0.9%)
Osteoporosis	106 (2.9%)	103 (2.8%)	209 (2.8%)
Osteoporosis postmenopausal	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Osteoporotic fracture	1 (<0.1%)	0	1 (<0.1%)
Osteosclerosis	3 (<0.1%)	0	3 (<0.1%)
Pain in extremity	51 (1.4%)	57 (1.6%)	108 (1.5%)
Patellofemoral pain syndrome	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Pathological fracture	2 (<0.1%)	0	2 (<0.1%)
Periarthritis	39 (1.1%)	16 (0.4%)	55 (0.7%)
Perthes disease	1 (<0.1%)	0	1 (<0.1%)
Plantar fascial fibromatosis	0	2 (<0.1%)	2 (<0.1%)
Plantar fasciitis	9 (0.2%)	11 (0.3%)	20 (0.3%)
Plica syndrome	1 (<0.1%)	0	1 (<0.1%)
Polyarthritis	7 (0.2%)	9 (0.2%)	16 (0.2%)
Polymyalgia rheumatica	6 (0.2%)	6 (0.2%)	12 (0.2%)
Pseudarthrosis	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	8 (0.2%)	7 (0.2%)	15 (0.2%)
Rhabdomyolysis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Rheumatic disorder	5 (0.1%)	8 (0.2%)	13 (0.2%)
Rheumatic fever	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Rheumatoid arthritis	30 (0.8%)	23 (0.6%)	53 (0.7%)
Rotator cuff syndrome	44 (1.2%)	41 (1.1%)	85 (1.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Sacroiliitis	4 (0.1%)	0	4 (<0.1%)
Scleroderma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scoliosis	8 (0.2%)	7 (0.2%)	15 (0.2%)
Senile osteoporosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Seronegative arthritis	0	1 (<0.1%)	1 (<0.1%)
Sjogren's syndrome	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Soft tissue disorder	2 (<0.1%)	0	2 (<0.1%)
Soft tissue mass	0	1 (<0.1%)	1 (<0.1%)
Spinal deformity	4 (0.1%)	0	4 (<0.1%)
Spinal disorder	4 (0.1%)	4 (0.1%)	8 (0.1%)
Spinal fusion acquired	1 (<0.1%)	0	1 (<0.1%)
Spinal instability	1 (<0.1%)	0	1 (<0.1%)
Spinal ligament ossification	0	3 (<0.1%)	3 (<0.1%)
Spinal osteoarthritis	158 (4.3%)	142 (3.9%)	300 (4.1%)
Spinal pain	22 (0.6%)	23 (0.6%)	45 (0.6%)
Spinal retrolisthesis	2 (<0.1%)	0	2 (<0.1%)
Spinal stenosis	35 (0.9%)	31 (0.8%)	66 (0.9%)
Spondylitis	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Spondyloarthropathy	4 (0.1%)	5 (0.1%)	9 (0.1%)
Spondylolisthesis	12 (0.3%)	11 (0.3%)	23 (0.3%)
Sympathetic posterior cervical syndrome	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	11 (0.3%)	4 (0.1%)	15 (0.2%)
Synovitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Systemic lupus erythematosus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Temporomandibular joint syndrome	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Tendon calcification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tendon disorder	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Tendon pain	1 (<0.1%)	0	1 (<0.1%)
Tendonitis	15 (0.4%)	10 (0.3%)	25 (0.3%)
Tenosynovitis	10 (0.3%)	9 (0.2%)	19 (0.3%)
Tenosynovitis stenosans	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Torticollis	1 (<0.1%)	0	1 (<0.1%)
Trigger finger	16 (0.4%)	16 (0.4%)	32 (0.4%)
Vertebral foraminal stenosis	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Vertebral lesion	1 (<0.1%)	0	1 (<0.1%)
Vertebral osteophyte	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	434 (11.8%)	435 (11.9%)	869 (11.8%)
Acoustic neuroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acrochordon	7 (0.2%)	2 (<0.1%)	9 (0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Acute myeloid leukaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adenocarcinoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adenocarcinoma gastric	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma of colon	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Adenoma benign	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Adrenal adenoma	13 (0.4%)	12 (0.3%)	25 (0.3%)
Adrenal neoplasm	8 (0.2%)	5 (0.1%)	13 (0.2%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyolipoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anogenital warts	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
B-cell lymphoma	1 (<0.1%)	0	1 (<0.1%)
Basal cell carcinoma	27 (0.7%)	29 (0.8%)	56 (0.8%)
Basosquamous carcinoma	1 (<0.1%)	0	1 (<0.1%)
Benign abdominal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign breast neoplasm	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Benign duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Benign gastrointestinal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign hepatic neoplasm	2 (<0.1%)	0	2 (<0.1%)
Benign hepatobiliary neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign laryngeal neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign lung neoplasm	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Benign mediastinal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm	2 (<0.1%)	0	2 (<0.1%)
Benign neoplasm of adrenal gland	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of cornea	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of eyelid	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of orbit	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of prostate	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Benign neoplasm of skin	0	3 (<0.1%)	3 (<0.1%)
Benign neoplasm of thyroid gland	8 (0.2%)	2 (<0.1%)	10 (0.1%)
Benign nipple neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign ovarian tumour	0	1 (<0.1%)	1 (<0.1%)
Benign pancreatic neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign penile neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign salivary gland neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign soft tissue neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Bladder cancer	14 (0.4%)	16 (0.4%)	30 (0.4%)
Bladder cancer recurrent	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Bladder neoplasm	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Bladder papilloma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bladder transitional cell carcinoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blepharal papilloma	0	1 (<0.1%)	1 (<0.1%)
Bowen's disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Breast adenoma	1 (<0.1%)	0	1 (<0.1%)
Breast cancer	20 (0.5%)	19 (0.5%)	39 (0.5%)
Breast cancer in situ	0	1 (<0.1%)	1 (<0.1%)
Breast cancer metastatic	0	1 (<0.1%)	1 (<0.1%)
Breast fibroma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Breast neoplasm	0	1 (<0.1%)	1 (<0.1%)
Bronchioloalveolar carcinoma	1 (<0.1%)	0	1 (<0.1%)
Carcinoid tumour of the stomach	1 (<0.1%)	0	1 (<0.1%)
Carcinoma in situ	0	1 (<0.1%)	1 (<0.1%)
Cerebellopontine angle tumour	1 (<0.1%)	0	1 (<0.1%)
Cerebral haemangioma	0	1 (<0.1%)	1 (<0.1%)
Cervix carcinoma	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cholesteatoma	1 (<0.1%)	0	1 (<0.1%)
Chronic lymphocytic leukaemia	2 (<0.1%)	0	2 (<0.1%)
Chronic myeloid leukaemia	0	1 (<0.1%)	1 (<0.1%)
Clear cell renal cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Colon adenoma	17 (0.5%)	8 (0.2%)	25 (0.3%)
Colon cancer	13 (0.4%)	18 (0.5%)	31 (0.4%)
Colon cancer stage 0	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colon neoplasm	0	2 (<0.1%)	2 (<0.1%)
Colorectal cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cutaneous lymphoma	1 (<0.1%)	0	1 (<0.1%)
Dermatofibrosarcoma protuberans	0	1 (<0.1%)	1 (<0.1%)
Duodenal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Dysplastic naevus	0	1 (<0.1%)	1 (<0.1%)
Ear neoplasm	0	1 (<0.1%)	1 (<0.1%)
Enchondromatosis	2 (<0.1%)	0	2 (<0.1%)
Endometrial cancer	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Epiglottic cancer	1 (<0.1%)	0	1 (<0.1%)
Erythroplasia	1 (<0.1%)	0	1 (<0.1%)
Essential thrombocythaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Extranodal marginal zone B-cell lymphoma (MALT type)	0	1 (<0.1%)	1 (<0.1%)
Eye naevus	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Fibroadenoma of breast	1 (<0.1%)	0	1 (<0.1%)
Fibroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Fibromatosis	1 (<0.1%)	0	1 (<0.1%)
Fibrous histiocytoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Focal nodular hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Gallbladder adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallbladder cancer	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastric cancer	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal carcinoma	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal stromal tumour	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal submucosal tumour	2 (<0.1%)	0	2 (<0.1%)
Gastrointestinal tract adenoma	0	1 (<0.1%)	1 (<0.1%)
Germ cell neoplasm	1 (<0.1%)	0	1 (<0.1%)
Glomus tumour	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	4 (0.1%)	0	4 (<0.1%)
Haemangioma of bone	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Haemangioma of liver	7 (0.2%)	10 (0.3%)	17 (0.2%)
Haemangioma of skin	1 (<0.1%)	0	1 (<0.1%)
Haemangioma of spleen	1 (<0.1%)	0	1 (<0.1%)
Hair follicle tumour benign	1 (<0.1%)	0	1 (<0.1%)
Hepatic adenoma	0	1 (<0.1%)	1 (<0.1%)
Hepatic cancer	0	1 (<0.1%)	1 (<0.1%)
Hepatic neoplasm	0	2 (<0.1%)	2 (<0.1%)
Hepatocellular carcinoma	0	2 (<0.1%)	2 (<0.1%)
Hodgkin's disease	0	1 (<0.1%)	1 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	2 (<0.1%)	0	2 (<0.1%)
Intraductal papillary mucinous neoplasm	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Invasive ductal breast carcinoma	1 (<0.1%)	0	1 (<0.1%)
Iris neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine benign neoplasm	3 (<0.1%)	0	3 (<0.1%)
Laryngeal cancer	0	3 (<0.1%)	3 (<0.1%)
Laryngeal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Laryngeal papilloma	1 (<0.1%)	0	1 (<0.1%)
Leiomyosarcoma	0	1 (<0.1%)	1 (<0.1%)
Leukaemia	0	1 (<0.1%)	1 (<0.1%)
Lip squamous cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Lipoma	16 (0.4%)	14 (0.4%)	30 (0.4%)
Lipoma of breast	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lung adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Lung neoplasm malignant	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lymphangioma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Malignant melanoma	10 (0.3%)	6 (0.2%)	16 (0.2%)
Malignant melanoma in situ	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of conjunctiva	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eye	1 (<0.1%)	0	1 (<0.1%)
Malignant palate neoplasm	1 (<0.1%)	0	1 (<0.1%)
Malignant urinary tract neoplasm	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	7 (0.2%)	8 (0.2%)	15 (0.2%)
Meningioma	8 (0.2%)	4 (0.1%)	12 (0.2%)
Meningioma benign	2 (<0.1%)	0	2 (<0.1%)
Metastases to liver	0	3 (<0.1%)	3 (<0.1%)
Metastases to lung	0	2 (<0.1%)	2 (<0.1%)
Metastases to lymph nodes	1 (<0.1%)	0	1 (<0.1%)
Metastatic malignant melanoma	1 (<0.1%)	0	1 (<0.1%)
Monoclonal gammopathy	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Myelodysplastic syndrome	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Myeloid leukaemia	1 (<0.1%)	0	1 (<0.1%)
Nasopharyngeal neoplasm benign	1 (<0.1%)	0	1 (<0.1%)
Neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Neoplasm prostate	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Neoplasm skin	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-secretory adenoma of pituitary	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ocular lymphoma	2 (<0.1%)	0	2 (<0.1%)
Oesophageal papilloma	1 (<0.1%)	0	1 (<0.1%)
Oral haemangioma	1 (<0.1%)	0	1 (<0.1%)
Osteochondroma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian adenoma	2 (<0.1%)	0	2 (<0.1%)
Ovarian cancer	0	4 (0.1%)	4 (<0.1%)
Ovarian epithelial cancer	1 (<0.1%)	0	1 (<0.1%)
Ovarian neoplasm	1 (<0.1%)	0	1 (<0.1%)
Paget's disease of nipple	1 (<0.1%)	0	1 (<0.1%)
Pancreatic neoplasm	2 (<0.1%)	0	2 (<0.1%)
Pancreatic neuroendocrine tumour	0	1 (<0.1%)	1 (<0.1%)
Papillary cystadenoma lymphomatosum	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Papillary thyroid cancer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Paraproteinaemia	0	1 (<0.1%)	1 (<0.1%)
Parathyroid tumour benign	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	7 (0.2%)	7 (0.2%)	14 (0.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Plasma cell myeloma	0	1 (<0.1%)	1 (<0.1%)
Plasma cell myeloma in remission	0	1 (<0.1%)	1 (<0.1%)
Pleomorphic adenoma	0	2 (<0.1%)	2 (<0.1%)
Polycythaemia vera	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Primary myelofibrosis	1 (<0.1%)	0	1 (<0.1%)
Prolactin-producing pituitary tumour	0	1 (<0.1%)	1 (<0.1%)
Prostate cancer	42 (1.1%)	49 (1.3%)	91 (1.2%)
Prostate cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Prostatic adenoma	13 (0.4%)	14 (0.4%)	27 (0.4%)
Rectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer	5 (0.1%)	4 (0.1%)	9 (0.1%)
Rectal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Rectosigmoid cancer	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	6 (0.2%)	4 (0.1%)	10 (0.1%)
Renal cell carcinoma	7 (0.2%)	7 (0.2%)	14 (0.2%)
Renal hamartoma	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Renal neoplasm	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Renal oncocytoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland adenoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland neoplasm	2 (<0.1%)	0	2 (<0.1%)
Schwannoma	0	1 (<0.1%)	1 (<0.1%)
Seborrhoeic keratosis	16 (0.4%)	20 (0.5%)	36 (0.5%)
Seminoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin cancer	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Skin papilloma	8 (0.2%)	6 (0.2%)	14 (0.2%)
Small cell lung cancer	0	1 (<0.1%)	1 (<0.1%)
Small intestine carcinoma	0	1 (<0.1%)	1 (<0.1%)
Spinal meningioma benign	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma	2 (<0.1%)	10 (0.3%)	12 (0.2%)
Squamous cell carcinoma of pharynx	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma of skin	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Squamous cell carcinoma of the tongue	0	1 (<0.1%)	1 (<0.1%)
Superficial spreading melanoma stage unspecified	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testis cancer	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Throat cancer	0	1 (<0.1%)	1 (<0.1%)
Thyroid adenoma	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Thyroid cancer	6 (0.2%)	7 (0.2%)	13 (0.2%)
Tongue neoplasm benign	1 (<0.1%)	0	1 (<0.1%)
Tongue neoplasm malignant stage unspecified	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Tonsil cancer	1 (<0.1%)	0	1 (<0.1%)
Transitional cell cancer of the renal pelvis and ureter	2 (<0.1%)	0	2 (<0.1%)
Transitional cell carcinoma	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Transitional cell carcinoma urethra	1 (<0.1%)	0	1 (<0.1%)
Urinary bladder adenoma	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Uterine leiomyoma	40 (1.1%)	41 (1.1%)	81 (1.1%)
Vulvovaginal warts	1 (<0.1%)	0	1 (<0.1%)
Waldenstrom's macroglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Nervous system disorders	1930 (52.4%)	1880 (51.3%)	3810 (51.8%)
Acoustic neuritis	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Akinesia	1 (<0.1%)	0	1 (<0.1%)
Allodynia	0	3 (<0.1%)	3 (<0.1%)
Amnesia	11 (0.3%)	10 (0.3%)	21 (0.3%)
Anaesthesia	1 (<0.1%)	0	1 (<0.1%)
Anosmia	1 (<0.1%)	0	1 (<0.1%)
Aphasia	0	1 (<0.1%)	1 (<0.1%)
Arachnoid cyst	3 (<0.1%)	0	3 (<0.1%)
Arachnoiditis	1 (<0.1%)	0	1 (<0.1%)
Areflexia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Ataxia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Autoimmune neuropathy	0	1 (<0.1%)	1 (<0.1%)
Autonomic nervous system imbalance	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Autonomic neuropathy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Axonal neuropathy	0	1 (<0.1%)	1 (<0.1%)
Balance disorder	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Basal ganglia infarction	2 (<0.1%)	0	2 (<0.1%)
Basilar artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Basilar artery stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brain stem infarction	0	3 (<0.1%)	3 (<0.1%)
Burning sensation	0	2 (<0.1%)	2 (<0.1%)
Cardiac autonomic neuropathy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Carotid arteriosclerosis	83 (2.3%)	73 (2.0%)	156 (2.1%)
Carotid artery aneurysm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Carotid artery disease	6 (0.2%)	12 (0.3%)	18 (0.2%)
Carotid artery occlusion	8 (0.2%)	7 (0.2%)	15 (0.2%)
Carotid artery stenosis	68 (1.8%)	61 (1.7%)	129 (1.8%)
Carotid artery thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carpal tunnel syndrome	74 (2.0%)	52 (1.4%)	126 (1.7%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Central nervous system lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cerebellar ataxia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar atrophy	0	1 (<0.1%)	1 (<0.1%)
Cerebellar stroke	1 (<0.1%)	0	1 (<0.1%)
Cerebellar syndrome	0	1 (<0.1%)	1 (<0.1%)
Cerebral arteriosclerosis	33 (0.9%)	44 (1.2%)	77 (1.0%)
Cerebral artery embolism	1 (<0.1%)	0	1 (<0.1%)
Cerebral artery occlusion	0	5 (0.1%)	5 (<0.1%)
Cerebral artery stenosis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cerebral artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebral atrophy	11 (0.3%)	10 (0.3%)	21 (0.3%)
Cerebral circulatory failure	0	2 (<0.1%)	2 (<0.1%)
Cerebral disorder	1 (<0.1%)	0	1 (<0.1%)
Cerebral haematoma	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	7 (0.2%)	7 (0.2%)	14 (0.2%)
Cerebral infarction	26 (0.7%)	17 (0.5%)	43 (0.6%)
Cerebral ischaemia	37 (1.0%)	31 (0.8%)	68 (0.9%)
Cerebral microangiopathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cerebral small vessel ischaemic disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cerebral ventricle dilatation	1 (<0.1%)	0	1 (<0.1%)
Cerebrovascular accident	24 (0.7%)	19 (0.5%)	43 (0.6%)
Cerebrovascular disorder	57 (1.5%)	50 (1.4%)	107 (1.5%)
Cerebrovascular insufficiency	2 (<0.1%)	0	2 (<0.1%)
Cerebrovascular stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cervical radiculopathy	10 (0.3%)	9 (0.2%)	19 (0.3%)
Cervicobrachial syndrome	10 (0.3%)	9 (0.2%)	19 (0.3%)
Cervicogenic headache	1 (<0.1%)	0	1 (<0.1%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1 (<0.1%)	1 (<0.1%)
Circadian rhythm sleep disorder	0	1 (<0.1%)	1 (<0.1%)
Clonus	1 (<0.1%)	0	1 (<0.1%)
Cluster headache	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Cognitive disorder	9 (0.2%)	4 (0.1%)	13 (0.2%)
Cogwheel rigidity	1 (<0.1%)	0	1 (<0.1%)
Coma	1 (<0.1%)	0	1 (<0.1%)
Complex regional pain syndrome	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Decreased vibratory sense	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Dementia	4 (0.1%)	5 (0.1%)	9 (0.1%)
Dementia Alzheimer's type	5 (0.1%)	4 (0.1%)	9 (0.1%)
Demyelination	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic autonomic neuropathy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Diabetic coma	0	2 (<0.1%)	2 (<0.1%)
Diabetic encephalopathy	8 (0.2%)	11 (0.3%)	19 (0.3%)
Diabetic mononeuropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic neuropathy	1040 (28.2%)	984 (26.8%)	2024 (27.5%)
Diplegia	0	1 (<0.1%)	1 (<0.1%)
Disturbance in attention	0	1 (<0.1%)	1 (<0.1%)
Dizziness	52 (1.4%)	40 (1.1%)	92 (1.3%)
Dizziness postural	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	0	2 (<0.1%)	2 (<0.1%)
Dysarthria	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Dyslalia	0	1 (<0.1%)	1 (<0.1%)
Dysmetria	1 (<0.1%)	0	1 (<0.1%)
Embolic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Encephalopathy	40 (1.1%)	28 (0.8%)	68 (0.9%)
Epilepsy	14 (0.4%)	11 (0.3%)	25 (0.3%)
Essential tremor	11 (0.3%)	16 (0.4%)	27 (0.4%)
Facial nerve disorder	2 (<0.1%)	0	2 (<0.1%)
Facial paralysis	20 (0.5%)	25 (0.7%)	45 (0.6%)
Facial paresis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Fine motor skill dysfunction	1 (<0.1%)	0	1 (<0.1%)
Focal dyscognitive seizures	0	1 (<0.1%)	1 (<0.1%)
Generalised tonic-clonic seizure	1 (<0.1%)	0	1 (<0.1%)
Glossopharyngeal neuralgia	0	1 (<0.1%)	1 (<0.1%)
Guillain-Barre syndrome	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Haemorrhage intracranial	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic stroke	5 (0.1%)	5 (0.1%)	10 (0.1%)
Headache	66 (1.8%)	48 (1.3%)	114 (1.6%)
Hemianaesthesia	2 (<0.1%)	0	2 (<0.1%)
Hemianopia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	0	3 (<0.1%)	3 (<0.1%)
Hemiparaesthesia	2 (<0.1%)	0	2 (<0.1%)
Hemiparesis	17 (0.5%)	21 (0.6%)	38 (0.5%)
Hemiplegia	6 (0.2%)	4 (0.1%)	10 (0.1%)
Hippocampal sclerosis	1 (<0.1%)	0	1 (<0.1%)
Horner's syndrome	1 (<0.1%)	0	1 (<0.1%)
Hydrocephalus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyperaesthesia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperreflexia	0	1 (<0.1%)	1 (<0.1%)
Hypersomnia	0	3 (<0.1%)	3 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Hypertensive encephalopathy	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Hypertonia	25 (0.7%)	23 (0.6%)	48 (0.7%)
Hypoaesthesia	26 (0.7%)	24 (0.7%)	50 (0.7%)
Hyporeflexia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyposmia	1 (<0.1%)	0	1 (<0.1%)
Hypoxic-ischaemic encephalopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
IIIrd nerve paralysis	0	1 (<0.1%)	1 (<0.1%)
IIIrd nerve paresis	1 (<0.1%)	0	1 (<0.1%)
Intellectual disability	0	1 (<0.1%)	1 (<0.1%)
Intention tremor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intercostal neuralgia	2 (<0.1%)	0	2 (<0.1%)
Internal capsule infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intracranial aneurysm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Intraventricular haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Ischaemic cerebral infarction	1 (<0.1%)	0	1 (<0.1%)
Ischaemic stroke	442 (12.0%)	425 (11.6%)	867 (11.8%)
Lacunar infarction	22 (0.6%)	8 (0.2%)	30 (0.4%)
Lacunar stroke	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)
Leukoencephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Loss of consciousness	0	3 (<0.1%)	3 (<0.1%)
Lumbar radiculopathy	10 (0.3%)	7 (0.2%)	17 (0.2%)
Lumbosacral plexopathy	1 (<0.1%)	0	1 (<0.1%)
Lumbosacral plexus lesion	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Lumbosacral radiculopathy	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Memory impairment	8 (0.2%)	8 (0.2%)	16 (0.2%)
Meralgia paraesthetica	0	2 (<0.1%)	2 (<0.1%)
Metabolic encephalopathy	4 (0.1%)	9 (0.2%)	13 (0.2%)
Migraine	15 (0.4%)	28 (0.8%)	43 (0.6%)
Migraine with aura	0	2 (<0.1%)	2 (<0.1%)
Migraine without aura	0	1 (<0.1%)	1 (<0.1%)
Mononeuropathy	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Monoplegia	0	3 (<0.1%)	3 (<0.1%)
Morton's neuralgia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Multiple sclerosis	1 (<0.1%)	6 (0.2%)	7 (<0.1%)
Muscle contractions involuntary	2 (<0.1%)	0	2 (<0.1%)
Muscle spasticity	0	1 (<0.1%)	1 (<0.1%)
Muscle tone disorder	1 (<0.1%)	0	1 (<0.1%)
Myasthenia gravis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Myelomalacia	1 (<0.1%)	0	1 (<0.1%)
Myelopathy	8 (0.2%)	4 (0.1%)	12 (0.2%)
Myoclonus	0	1 (<0.1%)	1 (<0.1%)
Myotonia	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	5 (0.1%)	4 (0.1%)	9 (0.1%)
Nervous system disorder	3 (<0.1%)	0	3 (<0.1%)
Neuralgia	22 (0.6%)	13 (0.4%)	35 (0.5%)
Neuralgic amyotrophy	3 (<0.1%)	0	3 (<0.1%)
Neuritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neuritis cranial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurodegenerative disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neurological symptom	1 (<0.1%)	0	1 (<0.1%)
Neuropathy peripheral	168 (4.6%)	152 (4.1%)	320 (4.4%)
Normal pressure hydrocephalus	1 (<0.1%)	0	1 (<0.1%)
Nystagmus	1 (<0.1%)	0	1 (<0.1%)
Occipital neuralgia	0	1 (<0.1%)	1 (<0.1%)
Optic neuritis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Orthostatic intolerance	0	2 (<0.1%)	2 (<0.1%)
Paraesthesia	19 (0.5%)	23 (0.6%)	42 (0.6%)
Paralysis	1 (<0.1%)	0	1 (<0.1%)
Paralysis recurrent laryngeal nerve	0	1 (<0.1%)	1 (<0.1%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	9 (0.2%)	14 (0.4%)	23 (0.3%)
Parkinsonian rest tremor	0	1 (<0.1%)	1 (<0.1%)
Parkinsonism	0	3 (<0.1%)	3 (<0.1%)
Parosmia	1 (<0.1%)	0	1 (<0.1%)
Partial seizures	0	3 (<0.1%)	3 (<0.1%)
Perineurial cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Periodic limb movement disorder	2 (<0.1%)	0	2 (<0.1%)
Peripheral nerve lesion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral nerve paresis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral sensorimotor neuropathy	8 (0.2%)	6 (0.2%)	14 (0.2%)
Peripheral sensory neuropathy	11 (0.3%)	13 (0.4%)	24 (0.3%)
Peroneal nerve palsy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Petit mal epilepsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phantom limb syndrome	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Pineal gland cyst	0	1 (<0.1%)	1 (<0.1%)
Piriformis syndrome	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	54 (1.5%)	71 (1.9%)	125 (1.7%)
Polyneuropathy chronic	1 (<0.1%)	0	1 (<0.1%)
Poor quality sleep	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Post herpetic neuralgia	5 (0.1%)	5 (0.1%)	10 (0.1%)
Post polio syndrome	3 (<0.1%)	0	3 (<0.1%)
Post stroke epilepsy	1 (<0.1%)	0	1 (<0.1%)
Posterior cortical atrophy	0	1 (<0.1%)	1 (<0.1%)
Precerebral arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Precerebral artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Presyncope	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Quadriplegia	1 (<0.1%)	0	1 (<0.1%)
Radial nerve palsy	1 (<0.1%)	0	1 (<0.1%)
Radicular pain	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Radiculopathy	11 (0.3%)	9 (0.2%)	20 (0.3%)
Resting tremor	0	2 (<0.1%)	2 (<0.1%)
Restless legs syndrome	21 (0.6%)	19 (0.5%)	40 (0.5%)
Right hemisphere deficit syndrome	0	1 (<0.1%)	1 (<0.1%)
Sacral radiculopathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	44 (1.2%)	55 (1.5%)	99 (1.3%)
Seizure	8 (0.2%)	6 (0.2%)	14 (0.2%)
Sensorimotor disorder	0	1 (<0.1%)	1 (<0.1%)
Sensory disturbance	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Simple partial seizures	0	1 (<0.1%)	1 (<0.1%)
Somnolence	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Spinal claudication	0	2 (<0.1%)	2 (<0.1%)
Spinal cord compression	1 (<0.1%)	0	1 (<0.1%)
Spinal cord disorder	1 (<0.1%)	0	1 (<0.1%)
Spinal cord herniation	1 (<0.1%)	0	1 (<0.1%)
Spinal stroke	1 (<0.1%)	0	1 (<0.1%)
Spondylitic myelopathy	0	2 (<0.1%)	2 (<0.1%)
Stupor	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Syncope	19 (0.5%)	17 (0.5%)	36 (0.5%)
Tardive dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Taste disorder	1 (<0.1%)	0	1 (<0.1%)
Tension headache	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Thalamic infarction	2 (<0.1%)	0	2 (<0.1%)
Thoracic outlet syndrome	2 (<0.1%)	0	2 (<0.1%)
Tongue biting	1 (<0.1%)	0	1 (<0.1%)
Toxic encephalopathy	1 (<0.1%)	0	1 (<0.1%)
Transient ischaemic attack	73 (2.0%)	56 (1.5%)	129 (1.8%)
Transverse sinus thrombosis	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Tremor	13 (0.4%)	11 (0.3%)	24 (0.3%)
Trigeminal neuralgia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Upper motor neurone lesion	1 (<0.1%)	0	1 (<0.1%)
VIth nerve disorder	1 (<0.1%)	0	1 (<0.1%)
VIth nerve paralysis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Vascular dementia	0	1 (<0.1%)	1 (<0.1%)
Vascular encephalopathy	41 (1.1%)	37 (1.0%)	78 (1.1%)
Vascular headache	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery stenosis	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Vertebrobasilar dolichoectasia	0	1 (<0.1%)	1 (<0.1%)
Vertebrobasilar insufficiency	8 (0.2%)	10 (0.3%)	18 (0.2%)
Vertigo CNS origin	2 (<0.1%)	0	2 (<0.1%)
Visual field defect	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Vocal cord paralysis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Vocal cord paresis	1 (<0.1%)	0	1 (<0.1%)
White matter lesion	2 (<0.1%)	0	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	9 (0.2%)	14 (0.4%)	23 (0.3%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Cephalo-pelvic disproportion	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	4 (0.1%)	4 (0.1%)	8 (0.1%)
Gestational diabetes	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Pre-eclampsia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Ruptured ectopic pregnancy	1 (<0.1%)	0	1 (<0.1%)
Product issues	0	3 (<0.1%)	3 (<0.1%)
Device dislocation	0	2 (<0.1%)	2 (<0.1%)
Thrombosis in device	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	564 (15.3%)	574 (15.7%)	1138 (15.5%)
Adjustment disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Adjustment disorder with depressed mood	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	1 (<0.1%)	0	1 (<0.1%)
Affective disorder	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	5 (0.1%)	5 (0.1%)	10 (0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Alcohol use disorder	0	1 (<0.1%)	1 (<0.1%)
Alcoholism	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Antisocial personality disorder	0	1 (<0.1%)	1 (<0.1%)
Anxiety	109 (3.0%)	132 (3.6%)	241 (3.3%)
Anxiety disorder	25 (0.7%)	19 (0.5%)	44 (0.6%)
Attention deficit hyperactivity disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Behaviour disorder	1 (<0.1%)	0	1 (<0.1%)
Bipolar disorder	10 (0.3%)	8 (0.2%)	18 (0.2%)
Borderline personality disorder	0	1 (<0.1%)	1 (<0.1%)
Breathing-related sleep disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bruxism	0	1 (<0.1%)	1 (<0.1%)
Claustrophobia	2 (<0.1%)	0	2 (<0.1%)
Conversion disorder	1 (<0.1%)	0	1 (<0.1%)
Delirium	0	1 (<0.1%)	1 (<0.1%)
Depressed mood	4 (0.1%)	5 (0.1%)	9 (0.1%)
Depression	251 (6.8%)	246 (6.7%)	497 (6.8%)
Depressive symptom	0	1 (<0.1%)	1 (<0.1%)
Disorientation	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug dependence	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dyssomnia	1 (<0.1%)	0	1 (<0.1%)
Enuresis	0	1 (<0.1%)	1 (<0.1%)
Epileptic psychosis	0	1 (<0.1%)	1 (<0.1%)
Factitious disorder	0	1 (<0.1%)	1 (<0.1%)
Generalised anxiety disorder	8 (0.2%)	4 (0.1%)	12 (0.2%)
Genito-pelvic pain/penetration disorder	1 (<0.1%)	0	1 (<0.1%)
Hallucination	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Illness anxiety disorder	1 (<0.1%)	0	1 (<0.1%)
Initial insomnia	0	2 (<0.1%)	2 (<0.1%)
Insomnia	189 (5.1%)	171 (4.7%)	360 (4.9%)
Libido decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Major depression	19 (0.5%)	19 (0.5%)	38 (0.5%)
Mental disorder	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Mixed anxiety and depressive disorder	9 (0.2%)	5 (0.1%)	14 (0.2%)
Mood disorder due to a general medical condition	0	2 (<0.1%)	2 (<0.1%)
Neurosis	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Nicotine dependence	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Obsessive-compulsive disorder	0	1 (<0.1%)	1 (<0.1%)
Panic attack	1 (<0.1%)	0	1 (<0.1%)
Panic disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Persistent depressive disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Personality disorder	1 (<0.1%)	0	1 (<0.1%)
Polydipsia psychogenic	1 (<0.1%)	0	1 (<0.1%)
Post-traumatic stress disorder	16 (0.4%)	14 (0.4%)	30 (0.4%)
Premature ejaculation	1 (<0.1%)	0	1 (<0.1%)
Pseudodementia	0	1 (<0.1%)	1 (<0.1%)
Schizophrenia	5 (0.1%)	5 (0.1%)	10 (0.1%)
Schizophreniform disorder	0	1 (<0.1%)	1 (<0.1%)
Sleep disorder	28 (0.8%)	34 (0.9%)	62 (0.8%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Stress	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Substance abuse	2 (<0.1%)	0	2 (<0.1%)
Suicide attempt	1 (<0.1%)	0	1 (<0.1%)
Tic	1 (<0.1%)	0	1 (<0.1%)
Tobacco abuse	11 (0.3%)	9 (0.2%)	20 (0.3%)
Renal and urinary disorders	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Acquired cystic kidney disease	5 (0.1%)	5 (0.1%)	10 (0.1%)
Acute kidney injury	27 (0.7%)	23 (0.6%)	50 (0.7%)
Albuminuria	202 (5.5%)	194 (5.3%)	396 (5.4%)
Azotaemia	0	4 (0.1%)	4 (<0.1%)
Bladder discomfort	1 (<0.1%)	0	1 (<0.1%)
Bladder dysfunction	0	2 (<0.1%)	2 (<0.1%)
Bladder mass	1 (<0.1%)	0	1 (<0.1%)
Bladder outlet obstruction	0	1 (<0.1%)	1 (<0.1%)
Bladder prolapse	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
C3 glomerulopathy	0	1 (<0.1%)	1 (<0.1%)
Calculus bladder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Calculus urethral	0	1 (<0.1%)	1 (<0.1%)
Calculus urinary	45 (1.2%)	31 (0.8%)	76 (1.0%)
Chronic kidney disease	3686 (100.0%)	3666 (100.0%)	7352 (100.0%)
Crystalluria	0	1 (<0.1%)	1 (<0.1%)
Cystitis interstitial	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Detrusor sphincter dyssynergia	0	2 (<0.1%)	2 (<0.1%)
Diabetic nephropathy	241 (6.5%)	273 (7.4%)	514 (7.0%)
Dysuria	8 (0.2%)	10 (0.3%)	18 (0.2%)
End stage renal disease	0	1 (<0.1%)	1 (<0.1%)
Focal segmental glomerulosclerosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Follicular cystitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Glomerulonephritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	12 (0.3%)	6 (0.2%)	18 (0.2%)
Glomerulonephritis membranoproliferative	1 (<0.1%)	0	1 (<0.1%)
Glomerulonephritis membranous	2 (<0.1%)	0	2 (<0.1%)
Glomerulonephritis proliferative	0	1 (<0.1%)	1 (<0.1%)
Glomerulosclerosis	0	1 (<0.1%)	1 (<0.1%)
Glycosuria	1 (<0.1%)	0	1 (<0.1%)
Haematuria	30 (0.8%)	31 (0.8%)	61 (0.8%)
Hydronephrosis	25 (0.7%)	11 (0.3%)	36 (0.5%)
Hypercalciuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypertensive nephropathy	12 (0.3%)	10 (0.3%)	22 (0.3%)
Hypertonic bladder	17 (0.5%)	18 (0.5%)	35 (0.5%)
Hyperuricosuria	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypocitraturia	0	2 (<0.1%)	2 (<0.1%)
IgA nephropathy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Incontinence	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Intercapillary glomerulosclerosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Ketonuria	0	1 (<0.1%)	1 (<0.1%)
Kidney congestion	1 (<0.1%)	0	1 (<0.1%)
Kidney small	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Leukocyturia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lower urinary tract symptoms	4 (0.1%)	4 (0.1%)	8 (0.1%)
Mesangioproliferative glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Microalbuminuria	120 (3.3%)	133 (3.6%)	253 (3.4%)
Micturition disorder	0	1 (<0.1%)	1 (<0.1%)
Micturition urgency	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Nephritic syndrome	0	1 (<0.1%)	1 (<0.1%)
Nephritis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Nephroangiosclerosis	6 (0.2%)	0	6 (<0.1%)
Nephrocalcinosis	3 (<0.1%)	0	3 (<0.1%)
Nephrolithiasis	221 (6.0%)	221 (6.0%)	442 (6.0%)
Nephropathy	19 (0.5%)	11 (0.3%)	30 (0.4%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)
Nephroptosis	4 (0.1%)	4 (0.1%)	8 (0.1%)
Nephrosclerosis	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Nephrotic syndrome	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Neurogenic bladder	7 (0.2%)	8 (0.2%)	15 (0.2%)
Nocturia	30 (0.8%)	26 (0.7%)	56 (0.8%)
Obstructive nephropathy	1 (<0.1%)	0	1 (<0.1%)
Oedematous kidney	2 (<0.1%)	0	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Pollakiuria	6 (0.2%)	11 (0.3%)	17 (0.2%)
Polyuria	0	8 (0.2%)	8 (0.1%)
Post streptococcal glomerulonephritis	0	1 (<0.1%)	1 (<0.1%)
Proteinuria	136 (3.7%)	158 (4.3%)	294 (4.0%)
Pyelocaliectasis	0	1 (<0.1%)	1 (<0.1%)
Reduced bladder capacity	2 (<0.1%)	0	2 (<0.1%)
Renal artery arteriosclerosis	0	2 (<0.1%)	2 (<0.1%)
Renal artery fibromuscular dysplasia	0	1 (<0.1%)	1 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	7 (0.2%)	7 (0.2%)	14 (0.2%)
Renal atrophy	8 (0.2%)	6 (0.2%)	14 (0.2%)
Renal colic	24 (0.7%)	18 (0.5%)	42 (0.6%)
Renal cyst	172 (4.7%)	158 (4.3%)	330 (4.5%)
Renal disorder	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Renal failure	11 (0.3%)	13 (0.4%)	24 (0.3%)
Renal hypertension	0	1 (<0.1%)	1 (<0.1%)
Renal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Renal impairment	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Renal tubular acidosis	1 (<0.1%)	0	1 (<0.1%)
Renal tubular necrosis	2 (<0.1%)	0	2 (<0.1%)
Renal vessel disorder	1 (<0.1%)	0	1 (<0.1%)
Single functional kidney	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Stag horn calculus	0	1 (<0.1%)	1 (<0.1%)
Stress urinary incontinence	7 (0.2%)	6 (0.2%)	13 (0.2%)
Subcapsular renal haematoma	1 (<0.1%)	0	1 (<0.1%)
Trigonitis	0	1 (<0.1%)	1 (<0.1%)
Tubulointerstitial nephritis	3 (<0.1%)	0	3 (<0.1%)
Urate nephropathy	0	1 (<0.1%)	1 (<0.1%)
Ureteric stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ureterocele	0	1 (<0.1%)	1 (<0.1%)
Ureterolithiasis	22 (0.6%)	8 (0.2%)	30 (0.4%)
Urethral disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral stenosis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Urge incontinence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary bladder polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary bladder varices	0	1 (<0.1%)	1 (<0.1%)
Urinary hesitation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Urinary incontinence	42 (1.1%)	39 (1.1%)	81 (1.1%)
Urinary retention	2 (<0.1%)	10 (0.3%)	12 (0.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Urinary tract disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Urinary tract obstruction	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Urine abnormality	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Urine flow decreased	0	1 (<0.1%)	1 (<0.1%)
Urine odour abnormal	1 (<0.1%)	0	1 (<0.1%)
Reproductive system and breast disorders	725 (19.7%)	709 (19.3%)	1434 (19.5%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Adenomyosis	0	1 (<0.1%)	1 (<0.1%)
Adnexa uteri cyst	0	1 (<0.1%)	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Artificial menopause	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atrophic vulvovaginitis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Azoospermia	1 (<0.1%)	0	1 (<0.1%)
Balanoposthitis	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Bartholin's cyst	0	1 (<0.1%)	1 (<0.1%)
Benign prostatic hyperplasia	437 (11.9%)	427 (11.6%)	864 (11.8%)
Breast calcifications	2 (<0.1%)	0	2 (<0.1%)
Breast cyst	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Breast disorder	4 (0.1%)	0	4 (<0.1%)
Breast enlargement	1 (<0.1%)	0	1 (<0.1%)
Breast fibrosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Breast haematoma	0	1 (<0.1%)	1 (<0.1%)
Breast hyperplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast mass	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Breast pain	1 (<0.1%)	0	1 (<0.1%)
Calculus prostatic	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	4 (0.1%)	0	4 (<0.1%)
Cystocele	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Dysfunctional uterine bleeding	1 (<0.1%)	0	1 (<0.1%)
Dysmenorrhoea	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Endocervicosis	0	1 (<0.1%)	1 (<0.1%)
Endometrial atrophy	1 (<0.1%)	0	1 (<0.1%)
Endometrial hyperplasia	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Endometriosis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Epididymal cyst	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Erectile dysfunction	172 (4.7%)	195 (5.3%)	367 (5.0%)
Female genital tract fistula	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Fibrocystic breast disease	0	2 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Genital prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gynaecomastia	4 (0.1%)	4 (0.1%)	8 (0.1%)
Hydrometra	0	1 (<0.1%)	1 (<0.1%)
Hydrosalpinx	3 (<0.1%)	0	3 (<0.1%)
Infertility	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Infertility male	0	1 (<0.1%)	1 (<0.1%)
Male reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Menorrhagia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Menstruation irregular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metrorrhagia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Organic erectile dysfunction	9 (0.2%)	5 (0.1%)	14 (0.2%)
Ovarian cyst	5 (0.1%)	5 (0.1%)	10 (0.1%)
Ovarian hyperfunction	0	1 (<0.1%)	1 (<0.1%)
Ovarian mass	0	1 (<0.1%)	1 (<0.1%)
Pelvic adhesions	2 (<0.1%)	0	2 (<0.1%)
Pelvic cyst	1 (<0.1%)	0	1 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penile oedema	1 (<0.1%)	0	1 (<0.1%)
Penile rash	0	1 (<0.1%)	1 (<0.1%)
Perineal pain	0	1 (<0.1%)	1 (<0.1%)
Peyronie's disease	0	3 (<0.1%)	3 (<0.1%)
Polycystic ovaries	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Postmenopausal haemorrhage	4 (0.1%)	0	4 (<0.1%)
Premature menopause	0	1 (<0.1%)	1 (<0.1%)
Prostatic calcification	10 (0.3%)	4 (0.1%)	14 (0.2%)
Prostatic cyst	2 (<0.1%)	0	2 (<0.1%)
Prostatic disorder	5 (0.1%)	5 (0.1%)	10 (0.1%)
Prostatic dysplasia	1 (<0.1%)	0	1 (<0.1%)
Prostatic mass	1 (<0.1%)	0	1 (<0.1%)
Prostatic obstruction	0	1 (<0.1%)	1 (<0.1%)
Prostatism	11 (0.3%)	10 (0.3%)	21 (0.3%)
Prostatitis	21 (0.6%)	24 (0.7%)	45 (0.6%)
Prostatomegaly	29 (0.8%)	27 (0.7%)	56 (0.8%)
Pruritus genital	1 (<0.1%)	0	1 (<0.1%)
Rectocele	0	1 (<0.1%)	1 (<0.1%)
Reproductive tract disorder	1 (<0.1%)	0	1 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal cyst	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Scrotal swelling	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Spermatocele	0	1 (<0.1%)	1 (<0.1%)
Testicular atrophy	0	1 (<0.1%)	1 (<0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	0	2 (<0.1%)	2 (<0.1%)
Uterine disorder	1 (<0.1%)	0	1 (<0.1%)
Uterine fibrosis	1 (<0.1%)	0	1 (<0.1%)
Uterine haemorrhage	4 (0.1%)	0	4 (<0.1%)
Uterine mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine polyp	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Uterine prolapse	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal prolapse	3 (<0.1%)	9 (0.2%)	12 (0.2%)
Varicocele	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Vulval disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vulval polyp	1 (<0.1%)	0	1 (<0.1%)
Vulvar squamous cell hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal dryness	3 (<0.1%)	0	3 (<0.1%)
Vulvovaginal pruritus	3 (<0.1%)	0	3 (<0.1%)
Respiratory, thoracic and mediastinal disorders	895 (24.3%)	843 (23.0%)	1738 (23.6%)
Acquired diaphragmatic eventration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Acute interstitial pneumonitis	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Acute respiratory failure	0	2 (<0.1%)	2 (<0.1%)
Adenoidal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic cough	0	2 (<0.1%)	2 (<0.1%)
Allergic sinusitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Apnoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aspirin-exacerbated respiratory disease	0	1 (<0.1%)	1 (<0.1%)
Asthma	166 (4.5%)	165 (4.5%)	331 (4.5%)
Asthma late onset	1 (<0.1%)	0	1 (<0.1%)
Asthma-chronic obstructive pulmonary disease overlap syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atelectasis	4 (0.1%)	0	4 (<0.1%)
Atopic cough	0	1 (<0.1%)	1 (<0.1%)
Atrophic pharyngitis	0	1 (<0.1%)	1 (<0.1%)
Bronchial disorder	0	1 (<0.1%)	1 (<0.1%)
Bronchial dysplasia	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Bronchial hyperreactivity	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Bronchiectasis	9 (0.2%)	5 (0.1%)	14 (0.2%)
Bronchitis chronic	52 (1.4%)	38 (1.0%)	90 (1.2%)
Bronchopneumopathy	1 (<0.1%)	0	1 (<0.1%)
Bronchospasm	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Childhood asthma	1 (<0.1%)	0	1 (<0.1%)
Chronic obstructive pulmonary disease	228 (6.2%)	237 (6.5%)	465 (6.3%)
Chronic respiratory failure	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cough	47 (1.3%)	33 (0.9%)	80 (1.1%)
Cough variant asthma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cystic lung disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic disorder	1 (<0.1%)	0	1 (<0.1%)
Dysphonia	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Dyspnoea	37 (1.0%)	37 (1.0%)	74 (1.0%)
Dyspnoea exertional	25 (0.7%)	15 (0.4%)	40 (0.5%)
Emphysema	17 (0.5%)	20 (0.5%)	37 (0.5%)
Epiglottic cyst	1 (<0.1%)	0	1 (<0.1%)
Epistaxis	7 (0.2%)	9 (0.2%)	16 (0.2%)
Fibrinous bronchitis	0	1 (<0.1%)	1 (<0.1%)
Haemoptysis	0	1 (<0.1%)	1 (<0.1%)
Haemothorax	0	1 (<0.1%)	1 (<0.1%)
Hiccups	1 (<0.1%)	0	1 (<0.1%)
Hypercapnia	2 (<0.1%)	0	2 (<0.1%)
Hyperventilation	2 (<0.1%)	0	2 (<0.1%)
Hypoventilation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypoxia	0	1 (<0.1%)	1 (<0.1%)
Increased upper airway secretion	0	3 (<0.1%)	3 (<0.1%)
Interstitial lung disease	11 (0.3%)	4 (0.1%)	15 (0.2%)
Laryngeal disorder	0	1 (<0.1%)	1 (<0.1%)
Laryngeal leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Laryngeal oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal polyp	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Lung infiltration	0	1 (<0.1%)	1 (<0.1%)
Nasal congestion	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Nasal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nasal inflammation	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	0	1 (<0.1%)	1 (<0.1%)
Nasal oedema	1 (<0.1%)	0	1 (<0.1%)
Nasal polyps	6 (0.2%)	7 (0.2%)	13 (0.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Nasal pruritus	1 (<0.1%)	0	1 (<0.1%)
Nasal septum deviation	12 (0.3%)	12 (0.3%)	24 (0.3%)
Nasal turbinate hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nocturnal dyspnoea	0	1 (<0.1%)	1 (<0.1%)
Obliterative bronchiolitis	1 (<0.1%)	0	1 (<0.1%)
Obstructive airways disorder	4 (0.1%)	4 (0.1%)	8 (0.1%)
Oropharyngeal pain	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Orthopnoea	0	1 (<0.1%)	1 (<0.1%)
Paranasal cyst	3 (<0.1%)	0	3 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Paranasal sinus inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pharyngeal fistula	1 (<0.1%)	0	1 (<0.1%)
Pharyngeal polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pickwickian syndrome	0	1 (<0.1%)	1 (<0.1%)
Pleural calcification	0	1 (<0.1%)	1 (<0.1%)
Pleural disorder	1 (<0.1%)	0	1 (<0.1%)
Pleural effusion	7 (0.2%)	6 (0.2%)	13 (0.2%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	0	1 (<0.1%)	1 (<0.1%)
Pleurisy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pneumonitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pneumothorax	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Pneumothorax spontaneous	2 (<0.1%)	0	2 (<0.1%)
Productive cough	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pulmonary arterial hypertension	0	2 (<0.1%)	2 (<0.1%)
Pulmonary calcification	0	1 (<0.1%)	1 (<0.1%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	20 (0.5%)	13 (0.4%)	33 (0.4%)
Pulmonary fibrosis	6 (0.2%)	9 (0.2%)	15 (0.2%)
Pulmonary granuloma	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Pulmonary hypertension	20 (0.5%)	15 (0.4%)	35 (0.5%)
Pulmonary mass	26 (0.7%)	18 (0.5%)	44 (0.6%)
Pulmonary oedema	4 (0.1%)	4 (0.1%)	8 (0.1%)
Pulmonary sarcoidosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary thrombosis	1 (<0.1%)	0	1 (<0.1%)
Rales	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory disorder	2 (<0.1%)	0	2 (<0.1%)
Respiratory failure	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Restrictive pulmonary disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rhinitis allergic	72 (2.0%)	74 (2.0%)	146 (2.0%)
Rhinitis hypertrophic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Rhinitis perennial	0	3 (<0.1%)	3 (<0.1%)
Rhinorrhoea	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Sinus congestion	2 (<0.1%)	0	2 (<0.1%)
Sinus disorder	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Sinus polyp	2 (<0.1%)	0	2 (<0.1%)
Sleep apnoea syndrome	306 (8.3%)	304 (8.3%)	610 (8.3%)
Snoring	5 (0.1%)	4 (0.1%)	9 (0.1%)
Throat irritation	1 (<0.1%)	0	1 (<0.1%)
Tonsillar hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Upper respiratory tract inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper-airway cough syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vasomotor rhinitis	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Vocal cord cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polyp	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vocal cord thickening	0	1 (<0.1%)	1 (<0.1%)
Wheezing	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Skin and subcutaneous tissue disorders	522 (14.2%)	477 (13.0%)	999 (13.6%)
Acanthosis	0	2 (<0.1%)	2 (<0.1%)
Acanthosis nigricans	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Acne	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Acquired digital fibrokeratoma	1 (<0.1%)	0	1 (<0.1%)
Actinic cheilitis	1 (<0.1%)	0	1 (<0.1%)
Actinic keratosis	17 (0.5%)	12 (0.3%)	29 (0.4%)
Alopecia	6 (0.2%)	4 (0.1%)	10 (0.1%)
Alopecia areata	0	2 (<0.1%)	2 (<0.1%)
Alopecia scarring	0	1 (<0.1%)	1 (<0.1%)
Androgenetic alopecia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Angioedema	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Asteatosis	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Blister	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Blood blister	0	1 (<0.1%)	1 (<0.1%)
Brow ptosis	1 (<0.1%)	0	1 (<0.1%)
Chloasma	0	1 (<0.1%)	1 (<0.1%)
Chronic pigmented purpura	0	2 (<0.1%)	2 (<0.1%)
Cutaneous amyloidosis	1 (<0.1%)	0	1 (<0.1%)
Cutaneous lupus erythematosus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Decubitus ulcer	2 (<0.1%)	0	2 (<0.1%)
Dermal cyst	10 (0.3%)	5 (0.1%)	15 (0.2%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Dermatitis	22 (0.6%)	22 (0.6%)	44 (0.6%)
Dermatitis allergic	5 (0.1%)	8 (0.2%)	13 (0.2%)
Dermatitis atopic	10 (0.3%)	5 (0.1%)	15 (0.2%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	12 (0.3%)	13 (0.4%)	25 (0.3%)
Dermatitis diaper	0	1 (<0.1%)	1 (<0.1%)
Dermatitis exfoliative	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Dermatosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic cheiroarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic dermopathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic foot	80 (2.2%)	76 (2.1%)	156 (2.1%)
Diabetic ulcer	0	2 (<0.1%)	2 (<0.1%)
Drug eruption	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	1 (<0.1%)	0	1 (<0.1%)
Dry skin	32 (0.9%)	38 (1.0%)	70 (1.0%)
Dyshidrotic eczema	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eczema	58 (1.6%)	45 (1.2%)	103 (1.4%)
Eczema asteatotic	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Eczema nummular	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Eosinophilic cellulitis	0	1 (<0.1%)	1 (<0.1%)
Erythema	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Erythematotelangiectatic rosacea	1 (<0.1%)	0	1 (<0.1%)
Excessive skin	1 (<0.1%)	0	1 (<0.1%)
Granuloma annulare	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hair disorder	1 (<0.1%)	0	1 (<0.1%)
Hand dermatitis	1 (<0.1%)	0	1 (<0.1%)
Hidradenitis	8 (0.2%)	2 (<0.1%)	10 (0.1%)
Hirsutism	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Hyperhidrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperkeratosis	20 (0.5%)	18 (0.5%)	38 (0.5%)
Hypersensitivity vasculitis	1 (<0.1%)	0	1 (<0.1%)
Idiopathic urticaria	1 (<0.1%)	0	1 (<0.1%)
Ingrowing nail	10 (0.3%)	4 (0.1%)	14 (0.2%)
Intertrigo	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic skin ulcer	2 (<0.1%)	0	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Leukoderma	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Lichen planus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lichen sclerosus	2 (<0.1%)	0	2 (<0.1%)
Lichenoid keratosis	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Linear IgA disease	0	1 (<0.1%)	1 (<0.1%)
Lipodystrophy acquired	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Lipohypertrophy	3 (<0.1%)	0	3 (<0.1%)
Miliaria	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myxoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nail disorder	1 (<0.1%)	0	1 (<0.1%)
Nail hypertrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nail pigmentation	1 (<0.1%)	0	1 (<0.1%)
Necrobiosis lipoidica diabeticorum	0	2 (<0.1%)	2 (<0.1%)
Neurodermatitis	11 (0.3%)	9 (0.2%)	20 (0.3%)
Neuropathic ulcer	1 (<0.1%)	0	1 (<0.1%)
Night sweats	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Onychogryphosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Palmoplantar keratoderma	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Palmoplantar pustulosis	1 (<0.1%)	0	1 (<0.1%)
Papule	0	1 (<0.1%)	1 (<0.1%)
Parapsoriasis	2 (<0.1%)	0	2 (<0.1%)
Pemphigoid	0	1 (<0.1%)	1 (<0.1%)
Photosensitivity reaction	0	1 (<0.1%)	1 (<0.1%)
Pigmentation disorder	1 (<0.1%)	0	1 (<0.1%)
Prurigo	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pruritus	36 (1.0%)	32 (0.9%)	68 (0.9%)
Pseudofolliculitis	0	1 (<0.1%)	1 (<0.1%)
Psoriasis	62 (1.7%)	66 (1.8%)	128 (1.7%)
Purpura	1 (<0.1%)	0	1 (<0.1%)
Purpura senile	0	1 (<0.1%)	1 (<0.1%)
Pyoderma gangrenosum	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rash	16 (0.4%)	17 (0.5%)	33 (0.4%)
Rash erythematous	0	1 (<0.1%)	1 (<0.1%)
Rash papular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rash pruritic	2 (<0.1%)	0	2 (<0.1%)
Rosacea	5 (0.1%)	8 (0.2%)	13 (0.2%)
Scab	0	1 (<0.1%)	1 (<0.1%)
Sebaceous hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	0	2 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	26 (0.7%)	14 (0.4%)	40 (0.5%)
Segmented hyalinising vasculitis	1 (<0.1%)	0	1 (<0.1%)
Senile xerosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin atrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin discolouration	0	2 (<0.1%)	2 (<0.1%)
Skin disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Skin exfoliation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin hyperpigmentation	3 (<0.1%)	0	3 (<0.1%)
Skin hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	4 (0.1%)	7 (0.2%)	11 (0.1%)
Skin maceration	1 (<0.1%)	0	1 (<0.1%)
Skin mass	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin necrosis	0	1 (<0.1%)	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	47 (1.3%)	35 (1.0%)	82 (1.1%)
Skin warm	1 (<0.1%)	0	1 (<0.1%)
Solar dermatitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Solar lentigo	2 (<0.1%)	0	2 (<0.1%)
Stasis dermatitis	10 (0.3%)	14 (0.4%)	24 (0.3%)
Telangiectasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urticaria	23 (0.6%)	11 (0.3%)	34 (0.5%)
Urticaria chronic	2 (<0.1%)	0	2 (<0.1%)
Urticarial vasculitis	0	1 (<0.1%)	1 (<0.1%)
Vascular purpura	0	1 (<0.1%)	1 (<0.1%)
Vascular skin disorder	1 (<0.1%)	0	1 (<0.1%)
Vitiligo	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Xanthelasma	1 (<0.1%)	0	1 (<0.1%)
Xeroderma	5 (0.1%)	5 (0.1%)	10 (0.1%)
Social circumstances	213 (5.8%)	194 (5.3%)	407 (5.5%)
Alcohol use	0	1 (<0.1%)	1 (<0.1%)
Cardiac assistance device user	0	1 (<0.1%)	1 (<0.1%)
Corrective lens user	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Disease risk factor	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Drug abuser	1 (<0.1%)	0	1 (<0.1%)
Edentulous	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Ex-alcoholic	1 (<0.1%)	0	1 (<0.1%)
Ex-tobacco user	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Exercise lack of	1 (<0.1%)	0	1 (<0.1%)
Familial risk factor	1 (<0.1%)	0	1 (<0.1%)
Limb prosthesis user	0	1 (<0.1%)	1 (<0.1%)
Loss of personal independence in daily activities	0	1 (<0.1%)	1 (<0.1%)
Menopause	140 (3.8%)	125 (3.4%)	265 (3.6%)
Organ donor	2 (<0.1%)	0	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Parity	1 (<0.1%)	0	1 (<0.1%)
Passive smoking	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	42 (1.1%)	48 (1.3%)	90 (1.2%)
Tobacco user	15 (0.4%)	14 (0.4%)	29 (0.4%)
Surgical and medical procedures	1421 (38.6%)	1377 (37.6%)	2798 (38.1%)
Abdominal hernia repair	8 (0.2%)	7 (0.2%)	15 (0.2%)
Abdominal wall operation	1 (<0.1%)	0	1 (<0.1%)
Abdominoplasty	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Abscess drainage	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Acrochordon excision	1 (<0.1%)	0	1 (<0.1%)
Adenoidectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenotonsillectomy	2 (<0.1%)	0	2 (<0.1%)
Adrenalectomy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Amputation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal fissure excision	0	1 (<0.1%)	1 (<0.1%)
Anal fistula repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Androgen replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Angioplasty	29 (0.8%)	25 (0.7%)	54 (0.7%)
Ankle arthroplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ankle operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anorectal operation	2 (<0.1%)	0	2 (<0.1%)
Antibiotic therapy	0	1 (<0.1%)	1 (<0.1%)
Anticoagulant therapy	0	1 (<0.1%)	1 (<0.1%)
Aorta coarctation repair	0	1 (<0.1%)	1 (<0.1%)
Aortic anastomosis	0	2 (<0.1%)	2 (<0.1%)
Aortic aneurysm repair	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Aortic bypass	5 (0.1%)	7 (0.2%)	12 (0.2%)
Aortic stent insertion	1 (<0.1%)	0	1 (<0.1%)
Aortic valve repair	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Aortic valve replacement	25 (0.7%)	22 (0.6%)	47 (0.6%)
Appendicectomy	123 (3.3%)	164 (4.5%)	287 (3.9%)
Arterial repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arterial stent insertion	5 (0.1%)	5 (0.1%)	10 (0.1%)
Arterial therapeutic procedure	1 (<0.1%)	0	1 (<0.1%)
Arteriovenous fistula operation	0	1 (<0.1%)	1 (<0.1%)
Arthrectomy	0	1 (<0.1%)	1 (<0.1%)
Arthrodesis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Atrial appendage closure	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Atrial septal defect repair	1 (<0.1%)	0	1 (<0.1%)
Benign breast lump removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bentall procedure	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Bladder catheter permanent	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm surgery	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder operation	1 (<0.1%)	0	1 (<0.1%)
Bladder repair	1 (<0.1%)	0	1 (<0.1%)
Blepharoplasty	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Bone graft	1 (<0.1%)	0	1 (<0.1%)
Bone lesion excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone marrow transplant	0	1 (<0.1%)	1 (<0.1%)
Bone operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Brachytherapy	0	1 (<0.1%)	1 (<0.1%)
Breast conserving surgery	5 (0.1%)	10 (0.3%)	15 (0.2%)
Breast cyst excision	2 (<0.1%)	0	2 (<0.1%)
Breast reconstruction	2 (<0.1%)	0	2 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
CSF shunt operation	1 (<0.1%)	0	1 (<0.1%)
Caesarean section	29 (0.8%)	21 (0.6%)	50 (0.7%)
Cancer surgery	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Cardiac ablation	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Cardiac aneurysm repair	0	1 (<0.1%)	1 (<0.1%)
Cardiac operation	2 (<0.1%)	0	2 (<0.1%)
Cardiac pacemaker insertion	50 (1.4%)	45 (1.2%)	95 (1.3%)
Cardiac pacemaker replacement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac resynchronisation therapy	2 (<0.1%)	0	2 (<0.1%)
Cardiopulmonary bypass	1 (<0.1%)	0	1 (<0.1%)
Cardiovascular event prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Cardioversion	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Carotid angioplasty	1 (<0.1%)	0	1 (<0.1%)
Carotid artery bypass	0	2 (<0.1%)	2 (<0.1%)
Carotid artery stent insertion	3 (<0.1%)	0	3 (<0.1%)
Carotid endarterectomy	43 (1.2%)	50 (1.4%)	93 (1.3%)
Carpal tunnel decompression	26 (0.7%)	17 (0.5%)	43 (0.6%)
Cartilage operation	1 (<0.1%)	0	1 (<0.1%)
Cataract operation	136 (3.7%)	168 (4.6%)	304 (4.1%)
Catheter placement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cervical conisation	1 (<0.1%)	0	1 (<0.1%)
Cervical laser therapy	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Cervical polypectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Chemonucleolysis	1 (<0.1%)	0	1 (<0.1%)
Chest wall operation	0	1 (<0.1%)	1 (<0.1%)
Cholangiostomy	1 (<0.1%)	0	1 (<0.1%)
Cholecystectomy	210 (5.7%)	199 (5.4%)	409 (5.6%)
Cholecystostomy	1 (<0.1%)	0	1 (<0.1%)
Cholelithotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Circumcision	8 (0.2%)	4 (0.1%)	12 (0.2%)
Closed fracture manipulation	0	1 (<0.1%)	1 (<0.1%)
Colectomy	11 (0.3%)	9 (0.2%)	20 (0.3%)
Colectomy total	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colon operation	0	2 (<0.1%)	2 (<0.1%)
Colorectostomy	1 (<0.1%)	0	1 (<0.1%)
Colostomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Colostomy closure	1 (<0.1%)	0	1 (<0.1%)
Colporrhaphy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Continuous positive airway pressure	1 (<0.1%)	0	1 (<0.1%)
Corneal lesion removal	0	1 (<0.1%)	1 (<0.1%)
Corneal operation	0	1 (<0.1%)	1 (<0.1%)
Corneal transplant	1 (<0.1%)	0	1 (<0.1%)
Coronary angioplasty	52 (1.4%)	62 (1.7%)	114 (1.6%)
Coronary arterial stent insertion	142 (3.9%)	106 (2.9%)	248 (3.4%)
Coronary artery bypass	154 (4.2%)	144 (3.9%)	298 (4.1%)
Coronary revascularisation	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Cranial nerve decompression	1 (<0.1%)	0	1 (<0.1%)
Cranial operation	1 (<0.1%)	0	1 (<0.1%)
Craniotomy	0	1 (<0.1%)	1 (<0.1%)
Cyst removal	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Cystocele repair	0	1 (<0.1%)	1 (<0.1%)
Cystoprostatectomy	0	1 (<0.1%)	1 (<0.1%)
Cystostomy	1 (<0.1%)	0	1 (<0.1%)
Dacryocystorhinostomy	0	1 (<0.1%)	1 (<0.1%)
Debridement	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Dental implantation	0	2 (<0.1%)	2 (<0.1%)
Dental prosthesis placement	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Dermatofibroma removal	1 (<0.1%)	0	1 (<0.1%)
Diabetes mellitus management	0	1 (<0.1%)	1 (<0.1%)
Dialysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Duodenal ulcer repair	1 (<0.1%)	0	1 (<0.1%)
Duodeno-jejunal bypass sleeve therapy	1 (<0.1%)	0	1 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Ear operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Elbow operation	0	2 (<0.1%)	2 (<0.1%)
Endarterectomy	1 (<0.1%)	0	1 (<0.1%)
Endarterectomy of aorta	1 (<0.1%)	0	1 (<0.1%)
Endocarditis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Endoscopic sleeve gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterostomy	1 (<0.1%)	0	1 (<0.1%)
Epidermoid cyst excision	1 (<0.1%)	0	1 (<0.1%)
Eventration repair	1 (<0.1%)	0	1 (<0.1%)
Exeresis	0	1 (<0.1%)	1 (<0.1%)
Explorative laparotomy	0	2 (<0.1%)	2 (<0.1%)
Eye excision	0	2 (<0.1%)	2 (<0.1%)
Eye laser surgery	12 (0.3%)	12 (0.3%)	24 (0.3%)
Eye operation	4 (0.1%)	6 (0.2%)	10 (0.1%)
Eye prosthesis insertion	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Eyelid operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facetectomy	0	2 (<0.1%)	2 (<0.1%)
Fallopian tube operation	0	1 (<0.1%)	1 (<0.1%)
Fasciectomy	0	1 (<0.1%)	1 (<0.1%)
Fasciotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Female genital operation	1 (<0.1%)	0	1 (<0.1%)
Female sterilisation	32 (0.9%)	27 (0.7%)	59 (0.8%)
Finger amputation	8 (0.2%)	7 (0.2%)	15 (0.2%)
Finger repair operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fistula repair	0	2 (<0.1%)	2 (<0.1%)
Foot amputation	12 (0.3%)	12 (0.3%)	24 (0.3%)
Foot operation	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Functional endoscopic sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Gallbladder operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Gastrectomy	5 (0.1%)	5 (0.1%)	10 (0.1%)
Gastric banding	8 (0.2%)	5 (0.1%)	13 (0.2%)
Gastric bypass	7 (0.2%)	9 (0.2%)	16 (0.2%)
Gastric electrical stimulation	1 (<0.1%)	0	1 (<0.1%)
Gastric operation	1 (<0.1%)	0	1 (<0.1%)
Gastric polypectomy	0	1 (<0.1%)	1 (<0.1%)
Gastric stapling	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastric ulcer surgery	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastroenterostomy	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorder prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal endoscopic therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Gastrointestinal surgery	1 (<0.1%)	0	1 (<0.1%)
Gastrostomy	1 (<0.1%)	0	1 (<0.1%)
Glaucoma surgery	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Haemangioma removal	0	1 (<0.1%)	1 (<0.1%)
Haemodialysis	0	2 (<0.1%)	2 (<0.1%)
Haemorrhoid operation	10 (0.3%)	12 (0.3%)	22 (0.3%)
Haemostasis	0	1 (<0.1%)	1 (<0.1%)
Hand amputation	1 (<0.1%)	0	1 (<0.1%)
Hand repair operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hearing aid therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Hepatectomy	0	2 (<0.1%)	2 (<0.1%)
Hepatitis B immunisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	0	1 (<0.1%)
Hernia repair	12 (0.3%)	21 (0.6%)	33 (0.4%)
High frequency ablation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hip arthroplasty	36 (1.0%)	33 (0.9%)	69 (0.9%)
Hip surgery	0	4 (0.1%)	4 (<0.1%)
Hydrocele operation	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Hysterectomy	106 (2.9%)	115 (3.1%)	221 (3.0%)
Hysterosalpingo-oophorectomy	11 (0.3%)	8 (0.2%)	19 (0.3%)
Hysterotomy	1 (<0.1%)	0	1 (<0.1%)
Ileocolostomy	1 (<0.1%)	0	1 (<0.1%)
Ileojejunal bypass	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Implantable cardiac monitor insertion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Implantable defibrillator insertion	10 (0.3%)	10 (0.3%)	20 (0.3%)
Implantable defibrillator replacement	0	1 (<0.1%)	1 (<0.1%)
Incisional drainage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Incisional hernia repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infection prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	34 (0.9%)	35 (1.0%)	69 (0.9%)
Internal fixation of fracture	6 (0.2%)	5 (0.1%)	11 (0.1%)
Internal fixation of spine	2 (<0.1%)	0	2 (<0.1%)
Internal limiting membrane peeling	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intervertebral disc operation	26 (0.7%)	17 (0.5%)	43 (0.6%)
Intestinal polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intestinal resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intra-aortic balloon placement	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Intra-cerebral aneurysm operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intra-ocular injection	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Intra-uterine contraceptive device insertion	1 (<0.1%)	0	1 (<0.1%)
Intraocular lens implant	30 (0.8%)	30 (0.8%)	60 (0.8%)
Intravitreal implant	1 (<0.1%)	0	1 (<0.1%)
Iridotomy	2 (<0.1%)	0	2 (<0.1%)
Jaw operation	0	1 (<0.1%)	1 (<0.1%)
Joint arthroplasty	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Knee arthroplasty	53 (1.4%)	52 (1.4%)	105 (1.4%)
Knee operation	8 (0.2%)	18 (0.5%)	26 (0.4%)
Lacrimal duct procedure	0	2 (<0.1%)	2 (<0.1%)
Lacrimal gland operation	0	1 (<0.1%)	1 (<0.1%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	24 (0.7%)	18 (0.5%)	42 (0.6%)
Large intestine anastomosis	0	1 (<0.1%)	1 (<0.1%)
Laryngeal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Laryngectomy	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	0	3 (<0.1%)	3 (<0.1%)
Leg amputation	23 (0.6%)	27 (0.7%)	50 (0.7%)
Lens capsulotomy	1 (<0.1%)	0	1 (<0.1%)
Lens extraction	5 (0.1%)	5 (0.1%)	10 (0.1%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Limb amputation	1 (<0.1%)	0	1 (<0.1%)
Limb operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lipectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lipoma excision	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Liposuction	0	2 (<0.1%)	2 (<0.1%)
Lithotripsy	13 (0.4%)	7 (0.2%)	20 (0.3%)
Liver transplant	0	1 (<0.1%)	1 (<0.1%)
Lung lobectomy	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Lymphadenectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mammoplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Manual lymphatic drainage	0	1 (<0.1%)	1 (<0.1%)
Mass excision	0	1 (<0.1%)	1 (<0.1%)
Mastectomy	12 (0.3%)	5 (0.1%)	17 (0.2%)
Mastoidectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Maxillary antrum operation	2 (<0.1%)	0	2 (<0.1%)
Medical device removal	1 (<0.1%)	0	1 (<0.1%)
Medical diet	1 (<0.1%)	0	1 (<0.1%)
Meningioma surgery	0	3 (<0.1%)	3 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Meniscus operation	9 (0.2%)	6 (0.2%)	15 (0.2%)
Meniscus removal	6 (0.2%)	6 (0.2%)	12 (0.2%)
Metabolic surgery	0	2 (<0.1%)	2 (<0.1%)
Metatarsal excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mitral valve repair	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Mitral valve replacement	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Mole excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Multiple drug therapy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Muscle operation	1 (<0.1%)	0	1 (<0.1%)
Myomectomy	4 (0.1%)	7 (0.2%)	11 (0.1%)
Nail operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nasal polypectomy	4 (0.1%)	0	4 (<0.1%)
Nasal septal operation	8 (0.2%)	4 (0.1%)	12 (0.2%)
Neobladder surgery	1 (<0.1%)	0	1 (<0.1%)
Nephrectomy	25 (0.7%)	22 (0.6%)	47 (0.6%)
Nephrostomy	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Nephroureterectomy	1 (<0.1%)	0	1 (<0.1%)
Nerve block	0	1 (<0.1%)	1 (<0.1%)
Neurectomy	1 (<0.1%)	0	1 (<0.1%)
Neurolysis	1 (<0.1%)	0	1 (<0.1%)
Oesophageal dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Oesophageal operation	1 (<0.1%)	0	1 (<0.1%)
Oesophagogastric fundoplasty	0	1 (<0.1%)	1 (<0.1%)
Omentectomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	14 (0.4%)	5 (0.1%)	19 (0.3%)
Oophorectomy bilateral	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Ophthalmic fluid-air exchange procedure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Orchidectomy	4 (0.1%)	0	4 (<0.1%)
Ostectomy	1 (<0.1%)	0	1 (<0.1%)
Osteotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian cystectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ovarian operation	1 (<0.1%)	0	1 (<0.1%)
Palatoplasty	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Pancreatic cyst drainage	1 (<0.1%)	0	1 (<0.1%)
Pancreatic stent placement	0	1 (<0.1%)	1 (<0.1%)
Pancreaticoduodenectomy	0	1 (<0.1%)	1 (<0.1%)
Pancreaticogastrostomy	1 (<0.1%)	0	1 (<0.1%)
Papilloma excision	0	2 (<0.1%)	2 (<0.1%)
Parathyroidectomy	11 (0.3%)	3 (<0.1%)	14 (0.2%)
Parotidectomy	0	2 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Partial cystectomy	1 (<0.1%)	0	1 (<0.1%)
Pelvic operation	1 (<0.1%)	0	1 (<0.1%)
Penile prosthesis insertion	4 (0.1%)	4 (0.1%)	8 (0.1%)
Percutaneous coronary intervention	36 (1.0%)	43 (1.2%)	79 (1.1%)
Pericardial drainage	0	1 (<0.1%)	1 (<0.1%)
Perineoplasty	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Peripheral artery angioplasty	21 (0.6%)	21 (0.6%)	42 (0.6%)
Peripheral artery bypass	17 (0.5%)	21 (0.6%)	38 (0.5%)
Peripheral artery stent insertion	22 (0.6%)	15 (0.4%)	37 (0.5%)
Peripheral endarterectomy	9 (0.2%)	4 (0.1%)	13 (0.2%)
Peripheral nerve decompression	2 (<0.1%)	0	2 (<0.1%)
Peripheral nerve operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral revascularisation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Permanent cosmetic dermapigmentation	1 (<0.1%)	0	1 (<0.1%)
Pharyngeal operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pharyngectomy	1 (<0.1%)	0	1 (<0.1%)
Phlebectomy	14 (0.4%)	10 (0.3%)	24 (0.3%)
Phlebotomy	1 (<0.1%)	0	1 (<0.1%)
Photorefractive keratectomy	1 (<0.1%)	0	1 (<0.1%)
Pilonidal sinus repair	2 (<0.1%)	0	2 (<0.1%)
Polypectomy	9 (0.2%)	9 (0.2%)	18 (0.2%)
Proctectomy	2 (<0.1%)	0	2 (<0.1%)
Proctocolectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Profundaplasty	1 (<0.1%)	0	1 (<0.1%)
Prolapse repair	1 (<0.1%)	0	1 (<0.1%)
Prostate ablation	0	1 (<0.1%)	1 (<0.1%)
Prostatectomy	11 (0.3%)	22 (0.6%)	33 (0.4%)
Prostatic operation	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Prosthesis implantation	0	1 (<0.1%)	1 (<0.1%)
Prosthetic vessel implantation	1 (<0.1%)	0	1 (<0.1%)
Pterygium operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary resection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Radical cystectomy	1 (<0.1%)	0	1 (<0.1%)
Radical hysterectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	5 (0.1%)	4 (0.1%)	9 (0.1%)
Radioactive iodine therapy	0	1 (<0.1%)	1 (<0.1%)
Radiotherapy	2 (<0.1%)	0	2 (<0.1%)
Radiotherapy to pharynx	1 (<0.1%)	0	1 (<0.1%)
Rectal polypectomy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Rectal prolapse repair	0	1 (<0.1%)	1 (<0.1%)
Removal of foreign body from eyelids	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Renal artery stent placement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Renal replacement therapy	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	18 (0.5%)	18 (0.5%)	36 (0.5%)
Renal surgery	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Renal sympathetic nerve ablation	1 (<0.1%)	0	1 (<0.1%)
Renal transplant	1 (<0.1%)	0	1 (<0.1%)
Renal tumour excision	0	1 (<0.1%)	1 (<0.1%)
Retinal cryoablation	1 (<0.1%)	0	1 (<0.1%)
Retinal laser coagulation	15 (0.4%)	15 (0.4%)	30 (0.4%)
Retinal operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinopexy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retro-pubic prostatectomy	1 (<0.1%)	0	1 (<0.1%)
Revascularisation procedure	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Rhinoplasty	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Rotator cuff repair	4 (0.1%)	11 (0.3%)	15 (0.2%)
Routine health maintenance	1 (<0.1%)	0	1 (<0.1%)
Roux loop conversion	2 (<0.1%)	0	2 (<0.1%)
Salivary gland resection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salpingectomy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Salpingo-oophorectomy	0	2 (<0.1%)	2 (<0.1%)
Salpingo-oophorectomy bilateral	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Salpingo-oophorectomy unilateral	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Scar excision	1 (<0.1%)	0	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)
Scrotal cystectomy	0	1 (<0.1%)	1 (<0.1%)
Scrotal operation	1 (<0.1%)	0	1 (<0.1%)
Sebaceous cyst excision	2 (<0.1%)	0	2 (<0.1%)
Shoulder arthroplasty	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Shoulder operation	7 (0.2%)	8 (0.2%)	15 (0.2%)
Sigmoidectomy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Sinuplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus operation	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Skin cryotherapy	1 (<0.1%)	0	1 (<0.1%)
Skin cyst excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin graft	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Skin lesion removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin neoplasm excision	11 (0.3%)	13 (0.4%)	24 (0.3%)
Skin operation	1 (<0.1%)	0	1 (<0.1%)
Spinal corpectomy	1 (<0.1%)	0	1 (<0.1%)
Spinal decompression	2 (<0.1%)	4 (0.1%)	6 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Spinal fusion surgery	6 (0.2%)	6 (0.2%)	12 (0.2%)
Spinal laminectomy	12 (0.3%)	6 (0.2%)	18 (0.2%)
Spinal operation	12 (0.3%)	10 (0.3%)	22 (0.3%)
Spinal rod insertion	0	1 (<0.1%)	1 (<0.1%)
Splenectomy	4 (0.1%)	7 (0.2%)	11 (0.1%)
Stent placement	28 (0.8%)	28 (0.8%)	56 (0.8%)
Stent removal	1 (<0.1%)	0	1 (<0.1%)
Sterilisation	3 (<0.1%)	0	3 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma evacuation	2 (<0.1%)	0	2 (<0.1%)
Surgery	0	1 (<0.1%)	1 (<0.1%)
Sympathectomy	1 (<0.1%)	0	1 (<0.1%)
Synovectomy	1 (<0.1%)	0	1 (<0.1%)
Synovial cyst removal	0	1 (<0.1%)	1 (<0.1%)
Tendon sheath incision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tenoplasty	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Testicular operation	0	2 (<0.1%)	2 (<0.1%)
Testicular prosthesis insertion	0	1 (<0.1%)	1 (<0.1%)
Therapeutic embolisation	0	1 (<0.1%)	1 (<0.1%)
Thoracic cavity drainage	0	1 (<0.1%)	1 (<0.1%)
Thoracotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thrombectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thromboembolectomy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thrombosis prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid adenoma removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid nodule removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroid operation	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Thyroidectomy	30 (0.8%)	38 (1.0%)	68 (0.9%)
Toe amputation	68 (1.8%)	43 (1.2%)	111 (1.5%)
Toe operation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tongue operation	1 (<0.1%)	0	1 (<0.1%)
Tonsillectomy	42 (1.1%)	52 (1.4%)	94 (1.3%)
Tooth extraction	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Trabeculectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transfusion	1 (<0.1%)	0	1 (<0.1%)
Transurethral bladder resection	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Transurethral incision of prostate	1 (<0.1%)	0	1 (<0.1%)
Transurethral prostatectomy	17 (0.5%)	15 (0.4%)	32 (0.4%)
Tricuspid valve repair	0	2 (<0.1%)	2 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Tricuspid valve replacement	1 (<0.1%)	0	1 (<0.1%)
Tumour excision	0	1 (<0.1%)	1 (<0.1%)
Turbinectomy	0	1 (<0.1%)	1 (<0.1%)
Turbinoplasty	2 (<0.1%)	0	2 (<0.1%)
Tympanoplasty	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Umbilical hernia repair	14 (0.4%)	19 (0.5%)	33 (0.4%)
Ureteral stent insertion	8 (0.2%)	3 (<0.1%)	11 (0.1%)
Ureteric calculus removal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ureterocelectomy	0	1 (<0.1%)	1 (<0.1%)
Ureterolithotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ureteroneocystostomy	1 (<0.1%)	0	1 (<0.1%)
Urethral operation	0	1 (<0.1%)	1 (<0.1%)
Urethral repair	1 (<0.1%)	0	1 (<0.1%)
Urethral stent insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethrotomy	1 (<0.1%)	0	1 (<0.1%)
Urinary bladder suspension	7 (0.2%)	4 (0.1%)	11 (0.1%)
Urinary cystectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary tract operation	0	2 (<0.1%)	2 (<0.1%)
Urostomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Uterine cystectomy	0	1 (<0.1%)	1 (<0.1%)
Uterine dilation and curettage	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Uterine operation	1 (<0.1%)	0	1 (<0.1%)
Uterine polypectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Uvulopalatopharyngoplasty	0	2 (<0.1%)	2 (<0.1%)
Uvuloplasty	0	1 (<0.1%)	1 (<0.1%)
Vaginal cyst excision	1 (<0.1%)	0	1 (<0.1%)
Vaginoperineoplasty	1 (<0.1%)	0	1 (<0.1%)
Vagotomy	1 (<0.1%)	0	1 (<0.1%)
Varicocele repair	0	3 (<0.1%)	3 (<0.1%)
Varicose vein operation	6 (0.2%)	5 (0.1%)	11 (0.1%)
Vascular anastomosis	1 (<0.1%)	0	1 (<0.1%)
Vascular graft	16 (0.4%)	7 (0.2%)	23 (0.3%)
Vascular operation	0	2 (<0.1%)	2 (<0.1%)
Vascular stent insertion	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Vasectomy	11 (0.3%)	16 (0.4%)	27 (0.4%)
Vasodilation procedure	0	1 (<0.1%)	1 (<0.1%)
Vena cava filter insertion	0	2 (<0.1%)	2 (<0.1%)
Venous angioplasty	2 (<0.1%)	0	2 (<0.1%)
Ventriculo-peritoneal shunt	0	2 (<0.1%)	2 (<0.1%)
Vertebroplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vision correction operation	1 (<0.1%)	0	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Vitamin supplementation	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	22 (0.6%)	20 (0.5%)	42 (0.6%)
Vocal cord operation	0	3 (<0.1%)	3 (<0.1%)
Vocal cord polypectomy	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Volvulus repair	0	1 (<0.1%)	1 (<0.1%)
Wisdom teeth removal	0	1 (<0.1%)	1 (<0.1%)
Wound treatment	0	1 (<0.1%)	1 (<0.1%)
Wrist surgery	3 (<0.1%)	0	3 (<0.1%)
Vascular disorders	3581 (97.2%)	3559 (97.1%)	7140 (97.1%)
Accelerated hypertension	0	1 (<0.1%)	1 (<0.1%)
Aneurysm	2 (<0.1%)	0	2 (<0.1%)
Angiopathy	6 (0.2%)	5 (0.1%)	11 (0.1%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	20 (0.5%)	30 (0.8%)	50 (0.7%)
Aortic arteriosclerosis	65 (1.8%)	64 (1.7%)	129 (1.8%)
Aortic dilatation	4 (0.1%)	9 (0.2%)	13 (0.2%)
Aortic disorder	0	2 (<0.1%)	2 (<0.1%)
Aortic dissection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic stenosis	32 (0.9%)	29 (0.8%)	61 (0.8%)
Aortic thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arterial disorder	4 (0.1%)	0	4 (<0.1%)
Arterial insufficiency	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Arterial stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial wall hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriosclerosis	76 (2.1%)	57 (1.6%)	133 (1.8%)
Arteriosclerosis Moenckeberg-type	3 (<0.1%)	0	3 (<0.1%)
Arteriovenous fistula	0	2 (<0.1%)	2 (<0.1%)
Arteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brachiocephalic arteriosclerosis	5 (0.1%)	10 (0.3%)	15 (0.2%)
Brachiocephalic artery stenosis	2 (<0.1%)	0	2 (<0.1%)
Cyanosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deep vein thrombosis	27 (0.7%)	28 (0.8%)	55 (0.7%)
Diabetic macroangiopathy	10 (0.3%)	11 (0.3%)	21 (0.3%)
Diabetic microangiopathy	9 (0.2%)	3 (<0.1%)	12 (0.2%)
Diabetic vascular disorder	102 (2.8%)	95 (2.6%)	197 (2.7%)
Dry gangrene	1 (<0.1%)	0	1 (<0.1%)
Embolism	0	2 (<0.1%)	2 (<0.1%)
Embolism venous	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Essential hypertension	107 (2.9%)	120 (3.3%)	227 (3.1%)
Extremity necrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Granulomatosis with polyangiitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Haemorrhagic vasculitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hot flush	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Hyperaemia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hypertension	3436 (93.2%)	3398 (92.7%)	6834 (93.0%)
Hypertensive angiopathy	7 (0.2%)	5 (0.1%)	12 (0.2%)
Hypertensive crisis	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Hypertensive emergency	1 (<0.1%)	0	1 (<0.1%)
Hypertensive end-organ damage	1 (<0.1%)	0	1 (<0.1%)
Hypotension	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infarction	0	1 (<0.1%)	1 (<0.1%)
Intermittent claudication	37 (1.0%)	46 (1.3%)	83 (1.1%)
Labile hypertension	1 (<0.1%)	0	1 (<0.1%)
Lymphangiectasia	0	1 (<0.1%)	1 (<0.1%)
Lymphocele	1 (<0.1%)	0	1 (<0.1%)
Lymphoedema	6 (0.2%)	9 (0.2%)	15 (0.2%)
Macroangiopathy	5 (0.1%)	6 (0.2%)	11 (0.1%)
Microangiopathy	7 (0.2%)	6 (0.2%)	13 (0.2%)
Obstructive shock	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	11 (0.3%)	5 (0.1%)	16 (0.2%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	587 (15.9%)	575 (15.7%)	1162 (15.8%)
Peripheral artery aneurysm	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Peripheral artery occlusion	6 (0.2%)	8 (0.2%)	14 (0.2%)
Peripheral artery stenosis	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Peripheral artery thrombosis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Peripheral coldness	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	0	2 (<0.1%)	2 (<0.1%)
Peripheral ischaemia	10 (0.3%)	9 (0.2%)	19 (0.3%)
Peripheral vascular disorder	38 (1.0%)	36 (1.0%)	74 (1.0%)
Peripheral venous disease	83 (2.3%)	62 (1.7%)	145 (2.0%)
Phlebitis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Phlebitis deep	1 (<0.1%)	0	1 (<0.1%)
Poor peripheral circulation	0	1 (<0.1%)	1 (<0.1%)
Post thrombotic syndrome	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)

Table 4.4 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set Figaro)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Raynaud's phenomenon	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Renovascular hypertension	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subclavian artery stenosis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Subgaleal haematoma	0	1 (<0.1%)	1 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)
Systolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Takayasu's arteritis	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis	7 (0.2%)	11 (0.3%)	18 (0.2%)
Thrombosis	5 (0.1%)	6 (0.2%)	11 (0.1%)
Varicophlebitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicose ulceration	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Varicose vein	114 (3.1%)	109 (3.0%)	223 (3.0%)
Vascular stenosis	1 (<0.1%)	0	1 (<0.1%)
Vasoconstriction	0	2 (<0.1%)	2 (<0.1%)
Vasodilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vein disorder	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vena cava thrombosis	0	1 (<0.1%)	1 (<0.1%)
Venous hypertension	1 (<0.1%)	0	1 (<0.1%)
Venous occlusion	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis	2 (<0.1%)	0	2 (<0.1%)
Venous thrombosis limb	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
White coat hypertension	7 (0.2%)	10 (0.3%)	17 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 30JAN2023 15:12
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4.5 Concomitant medication

Table 4.5 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set Figaro)

Drug grouping	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	2796 (75.9%)	2834 (77.3%)	5630 (76.6%)
ACEI	531 (14.4%)	567 (15.5%)	1098 (14.9%)
ARB	850 (23.1%)	889 (24.2%)	1739 (23.7%)
RAS-inhibitors	1257 (34.1%)	1312 (35.8%)	2569 (34.9%)
Beta-blocker	895 (24.3%)	920 (25.1%)	1815 (24.7%)
Diuretics	1243 (33.7%)	1325 (36.1%)	2568 (34.9%)
Loop diuretics	783 (21.2%)	866 (23.6%)	1649 (22.4%)
Thiazide diuretics	363 (9.8%)	423 (11.5%)	786 (10.7%)
Potassium supplements	245 (6.6%)	298 (8.1%)	543 (7.4%)
Potassium lowering agents (including binders)	167 (4.5%)	101 (2.8%)	268 (3.6%)
Alpha blocking agents	895 (24.3%)	926 (25.3%)	1821 (24.8%)
Calcium channel blockers	1015 (27.5%)	1132 (30.9%)	2147 (29.2%)
Centrally acting antihypertensives	159 (4.3%)	187 (5.1%)	346 (4.7%)
Strong CYP3A4 inhibitors	186 (5.0%)	186 (5.1%)	372 (5.1%)
Moderate CYP3A4 inhibitors	497 (13.5%)	497 (13.6%)	994 (13.5%)
Weak CYP3A4 inhibitors	1339 (36.3%)	1355 (37.0%)	2694 (36.6%)
Unclassified CYP3A4 inhibitors	166 (4.5%)	171 (4.7%)	337 (4.6%)
Strong CYP3A4 inducers	48 (1.3%)	50 (1.4%)	98 (1.3%)
Moderate CYP3A4 inducers	269 (7.3%)	275 (7.5%)	544 (7.4%)
Weak CYP3A4 inducers	245 (6.6%)	240 (6.5%)	485 (6.6%)
Unclassified CYP3A4 inducers	146 (4.0%)	138 (3.8%)	284 (3.9%)
Oral anticoagulants	324 (8.8%)	322 (8.8%)	646 (8.8%)
Acetylsalycylic acid and its salts	572 (15.5%)	582 (15.9%)	1154 (15.7%)
Statins	1058 (28.7%)	1010 (27.6%)	2068 (28.1%)
Erythropoeitin stimulating agents	58 (1.6%)	53 (1.4%)	111 (1.5%)
NSAIDS (excluding acetylsalicylic acid)	1125 (30.5%)	1106 (30.2%)	2231 (30.3%)
ARNIs	7 (0.2%)	6 (0.2%)	13 (0.2%)
Potassium-sparing diuretics	199 (5.4%)	225 (6.1%)	424 (5.8%)
Platelet aggregation inhibitors (excluding heparin)	858 (23.3%)	846 (23.1%)	1704 (23.2%)
Trimethoprim and derivatives	114 (3.1%)	108 (2.9%)	222 (3.0%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 30JAN2023 15:15
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Table 4.5 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set Figaro)

Drug grouping	BAY 94-8862 N=3686 (100%)	Placebo N=3666 (100%)	Total N=7352 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	2259 (61.3%)	2302 (62.8%)	4561 (62.0%)
Insulins and analogues	1527 (41.4%)	1509 (41.2%)	3036 (41.3%)
Dipeptidyl peptidase 4 inhibitors	603 (16.4%)	570 (15.5%)	1173 (16.0%)
Glucagon-like peptide-1(GLP1) agonists	419 (11.4%)	413 (11.3%)	832 (11.3%)
SGLT-2 inhibitors	580 (15.7%)	578 (15.8%)	1158 (15.8%)
Biguanides	969 (26.3%)	944 (25.8%)	1913 (26.0%)
Sulfonylureas	479 (13.0%)	480 (13.1%)	959 (13.0%)
Alpha glucosidase inhibitors	137 (3.7%)	123 (3.4%)	260 (3.5%)
Meglitinides	100 (2.7%)	95 (2.6%)	195 (2.7%)
Thiazolidinediones	118 (3.2%)	115 (3.1%)	233 (3.2%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 30JAN2023 15:15
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1.3.1 Time-to-event analyses

Table 1.3.1 / 1: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	552 (8.5%)	614 (9.4%)
Number (%) of subjects censored	5967 (91.5%)	5893 (90.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.79; >1.00]	
two-sided p-value from stratified logrank test	0.0510	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	289 (9.8%)	319 (10.9%)
Number (%) of subjects censored	2647 (90.2%)	2607 (89.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.77; 1.06]	
two-sided p-value from stratified logrank test	0.1927	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	103 (10.0%)	87 (8.5%)
Number (%) of subjects censored	923 (90.0%)	938 (91.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.21 [0.91; 1.61]	
two-sided p-value from stratified logrank test	0.1935	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	68 (4.3%)	101 (6.3%)
Number (%) of subjects censored	1532 (95.8%)	1503 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.48; 0.89]	
two-sided p-value from stratified logrank test	0.0069	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	60 (8.3%)	87 (12.2%)
Number (%) of subjects censored	659 (91.7%)	628 (87.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.49; 0.94]	
two-sided p-value from stratified logrank test	0.0192	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	32 (13.4%)	20 (8.4%)
Number (%) of subjects censored	206 (86.6%)	217 (91.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.55 [0.89; 2.73]	
two-sided p-value from stratified logrank test	0.1217	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 3: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0055

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	235 (10.7%)	227 (10.4%)
Number (%) of subjects censored	1964 (89.3%)	1948 (89.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.85; 1.22]	
two-sided p-value from stratified logrank test	0.8661	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	134 (7.5%)	162 (8.9%)
Number (%) of subjects censored	1656 (92.5%)	1649 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.67; 1.06]	
two-sided p-value from stratified logrank test	0.1478	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	182 (7.2%)	224 (8.9%)
Number (%) of subjects censored	2343 (92.8%)	2290 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.66; 0.98]	
two-sided p-value from stratified logrank test	0.0278	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 5: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.1938

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	207 (10.7%)	215 (11.3%)
Number (%) of subjects censored	1727 (89.3%)	1694 (88.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.80; 1.17]	
two-sided p-value from stratified logrank test	0.7351	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	344 (7.5%)	397 (8.7%)
Number (%) of subjects censored	4227 (92.5%)	4187 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.74; 0.99]	
two-sided p-value from stratified logrank test	0.0376	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 7: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.4074

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	323 (10.8%)	372 (12.6%)
Number (%) of subjects censored	2656 (89.2%)	2584 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.74; 0.99]	
two-sided p-value from stratified logrank test	0.0384	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	229 (6.5%)	242 (6.8%)
Number (%) of subjects censored	3311 (93.5%)	3309 (93.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.79; 1.14]	
two-sided p-value from stratified logrank test	0.5791	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 9: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3752

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	364 (8.0%)	403 (9.0%)
Number (%) of subjects censored	4160 (92.0%)	4070 (91.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.77; 1.02]	
two-sided p-value from stratified logrank test	0.0914	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	187 (9.4%)	210 (10.3%)
Number (%) of subjects censored	1807 (90.6%)	1821 (89.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.76; 1.13]	
two-sided p-value from stratified logrank test	0.4644	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 11: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.7395

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	150 (7.6%)	173 (8.8%)
Number (%) of subjects censored	1825 (92.4%)	1802 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.69; 1.07]	
two-sided p-value from stratified logrank test	0.1678	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	373 (8.7%)	418 (9.8%)
Number (%) of subjects censored	3919 (91.3%)	3859 (90.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.77; 1.02]	
two-sided p-value from stratified logrank test	0.0862	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	27 (10.8%)	23 (9.1%)
Number (%) of subjects censored	222 (89.2%)	230 (90.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.62; 2.13]	
two-sided p-value from stratified logrank test	0.6512	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 13: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.5567

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	433 (9.7%)	474 (10.7%)
Number (%) of subjects censored	4016 (90.3%)	3946 (89.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.79; 1.03]	
two-sided p-value from stratified logrank test	0.1303	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	27 (10.7%)	25 (9.3%)
Number (%) of subjects censored	226 (89.3%)	244 (90.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.59; 1.97]	
two-sided p-value from stratified logrank test	0.8148	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	59 (4.1%)	81 (5.5%)
Number (%) of subjects censored	1373 (95.9%)	1381 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.50; 0.99]	
two-sided p-value from stratified logrank test	0.0416	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	33 (8.6%)	34 (9.6%)
Number (%) of subjects censored	352 (91.4%)	322 (90.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.54; 1.47]	
two-sided p-value from stratified logrank test	0.6574	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 15: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.4893

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	374 (8.3%)	448 (9.7%)
Number (%) of subjects censored	4107 (91.7%)	4159 (90.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.74; 0.97]	
two-sided p-value from stratified logrank test	0.0181	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	178 (8.7%)	166 (8.7%)
Number (%) of subjects censored	1860 (91.3%)	1734 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.81; 1.25]	
two-sided p-value from stratified logrank test	0.9366	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 17: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1693

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 18: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	187 (6.3%)	197 (6.7%)
Number (%) of subjects censored	2771 (93.7%)	2734 (93.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.76; 1.15]	
two-sided p-value from stratified logrank test	0.5218	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 18: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	365 (10.2%)	417 (11.7%)
Number (%) of subjects censored	3196 (89.8%)	3159 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.76; >1.00]	
two-sided p-value from stratified logrank test	0.0554	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 19: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.5623

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 20: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	552 (8.5%)	614 (9.4%)
Number (%) of subjects censored	5967 (91.5%)	5893 (90.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.80; >1.00]	
two-sided p-value from unstratified logrank test	0.0523	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	854 (13.1%)	995 (15.3%)
Number (%) of subjects censored	5665 (86.9%)	5512 (84.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.77; 0.93]	
two-sided p-value from stratified logrank test	0.0004	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 22: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	360 (5.5%)	465 (7.1%)
Number (%) of subjects censored	6159 (94.5%)	6042 (92.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.67; 0.88]	
two-sided p-value from stratified logrank test	0.0002	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	105 (3.6%)	147 (5.0%)
Number (%) of subjects censored	2831 (96.4%)	2779 (95.0%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.55; 0.92]	
two-sided p-value from stratified logrank test	0.0078	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	69 (6.7%)	82 (8.0%)
Number (%) of subjects censored	957 (93.3%)	943 (92.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.61; 1.16]	
two-sided p-value from stratified logrank test	0.2913	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	116 (7.3%)	175 (10.9%)
Number (%) of subjects censored	1484 (92.8%)	1429 (89.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.51; 0.82]	
two-sided p-value from stratified logrank test	0.0003	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	53 (7.4%)	49 (6.9%)
Number (%) of subjects censored	666 (92.6%)	666 (93.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.73; 1.58]	
two-sided p-value from stratified logrank test	0.7300	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	17 (7.1%)	12 (5.1%)
Number (%) of subjects censored	221 (92.9%)	225 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.57 [0.73; 3.39]	
two-sided p-value from stratified logrank test	0.2428	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 24: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0692

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	209 (9.5%)	252 (11.6%)
Number (%) of subjects censored	1990 (90.5%)	1923 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.97]	
two-sided p-value from stratified logrank test	0.0237	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	71 (4.0%)	90 (5.0%)
Number (%) of subjects censored	1719 (96.0%)	1721 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.62; 1.17]	
two-sided p-value from stratified logrank test	0.3146	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	80 (3.2%)	122 (4.9%)
Number (%) of subjects censored	2445 (96.8%)	2392 (95.1%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.49; 0.86]	
two-sided p-value from stratified logrank test	0.0022	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 26: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.3458

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	41 (2.1%)	41 (2.1%)
Number (%) of subjects censored	1893 (97.9%)	1868 (97.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.65; 1.56]	
two-sided p-value from stratified logrank test	0.9616	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	319 (7.0%)	424 (9.2%)
Number (%) of subjects censored	4252 (93.0%)	4160 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.65; 0.87]	
two-sided p-value from stratified logrank test	0.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 28: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.2074

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	139 (4.7%)	189 (6.4%)
Number (%) of subjects censored	2840 (95.3%)	2767 (93.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.57; 0.88]	
two-sided p-value from stratified logrank test	0.0019	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	221 (6.2%)	276 (7.8%)
Number (%) of subjects censored	3319 (93.8%)	3275 (92.2%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.68; 0.97]	
two-sided p-value from stratified logrank test	0.0227	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 30: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3251

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	251 (5.5%)	326 (7.3%)
Number (%) of subjects censored	4273 (94.5%)	4147 (92.7%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.63; 0.88]	
two-sided p-value from stratified logrank test	0.0006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	109 (5.5%)	139 (6.8%)
Number (%) of subjects censored	1885 (94.5%)	1892 (93.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.65; 1.08]	
two-sided p-value from stratified logrank test	0.1793	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 32: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5811

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	72 (3.6%)	86 (4.4%)
Number (%) of subjects censored	1903 (96.4%)	1889 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.61; 1.15]	
two-sided p-value from stratified logrank test	0.2597	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	261 (6.1%)	339 (7.9%)
Number (%) of subjects censored	4031 (93.9%)	3938 (92.1%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.65; 0.90]	
two-sided p-value from stratified logrank test	0.0012	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	26 (10.4%)	40 (15.8%)
Number (%) of subjects censored	223 (89.6%)	213 (84.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.57 [0.32; <1.00]	
two-sided p-value from stratified logrank test	0.0465	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 34: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.3301

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	173 (3.9%)	219 (5.0%)
Number (%) of subjects censored	4276 (96.1%)	4201 (95.0%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.65; 0.97]	
two-sided p-value from stratified logrank test	0.0213	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	35 (13.8%)	39 (14.5%)
Number (%) of subjects censored	218 (86.2%)	230 (85.5%)
Median Time to event (month) [95 % CI]	n.c.	57.833 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.43; 1.16]	
two-sided p-value from stratified logrank test	0.1652	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	109 (7.6%)	170 (11.6%)
Number (%) of subjects censored	1323 (92.4%)	1292 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.52; 0.84]	
two-sided p-value from stratified logrank test	0.0007	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	43 (11.2%)	37 (10.4%)
Number (%) of subjects censored	342 (88.8%)	319 (89.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.16 [0.73; 1.84]	
two-sided p-value from stratified logrank test	0.5259	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 36: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.1362

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 37: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	257 (5.7%)	341 (7.4%)
Number (%) of subjects censored	4224 (94.3%)	4266 (92.6%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.64; 0.89]	
two-sided p-value from stratified logrank test	0.0006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 37: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	103 (5.1%)	124 (6.5%)
Number (%) of subjects censored	1935 (94.9%)	1776 (93.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.62; 1.06]	
two-sided p-value from stratified logrank test	0.1266	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 38: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.6256

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 39: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	202 (6.8%)	266 (9.1%)
Number (%) of subjects censored	2756 (93.2%)	2665 (90.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.63; 0.92]	
two-sided p-value from stratified logrank test	0.0038	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 39: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	158 (4.4%)	199 (5.6%)
Number (%) of subjects censored	3403 (95.6%)	3377 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.64; 0.98]	
two-sided p-value from stratified logrank test	0.0305	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 40: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.7796

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 41: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	360 (5.5%)	465 (7.1%)
Number (%) of subjects censored	6159 (94.5%)	6042 (92.9%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.67; 0.88]	
two-sided p-value from unstratified logrank test	0.0002	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 42: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	224 (3.4%)	325 (5.0%)
Number (%) of subjects censored	6295 (96.6%)	6182 (95.0%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.69 [0.58; 0.82]	
two-sided p-value from stratified logrank test	<.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 43: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	254 (3.9%)	297 (4.6%)
Number (%) of subjects censored	6265 (96.1%)	6210 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.71; 0.99]	
two-sided p-value from stratified logrank test	0.0392	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	65 (2.2%)	93 (3.2%)
Number (%) of subjects censored	2871 (97.8%)	2833 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.51; 0.96]	
two-sided p-value from stratified logrank test	0.0244	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	57 (5.6%)	52 (5.1%)
Number (%) of subjects censored	969 (94.4%)	973 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.73; 1.56]	
two-sided p-value from stratified logrank test	0.7267	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	83 (5.2%)	118 (7.4%)
Number (%) of subjects censored	1517 (94.8%)	1486 (92.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.51; 0.90]	
two-sided p-value from stratified logrank test	0.0067	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	36 (5.0%)	27 (3.8%)
Number (%) of subjects censored	683 (95.0%)	688 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.29 [0.79; 2.13]	
two-sided p-value from stratified logrank test	0.3095	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	13 (5.5%)	7 (3.0%)
Number (%) of subjects censored	225 (94.5%)	230 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	2.01 [0.80; 5.08]	
two-sided p-value from stratified logrank test	0.1319	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 45: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0225

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	199 (9.0%)	218 (10.0%)
Number (%) of subjects censored	2000 (91.0%)	1957 (90.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.73; 1.08]	
two-sided p-value from stratified logrank test	0.2319	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	31 (1.7%)	33 (1.8%)
Number (%) of subjects censored	1759 (98.3%)	1778 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.57; 1.54]	
two-sided p-value from stratified logrank test	0.7964	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	24 (1.0%)	46 (1.8%)
Number (%) of subjects censored	2501 (99.0%)	2468 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.52 [0.32; 0.85]	
two-sided p-value from stratified logrank test	0.0079	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 47: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.1222

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	25 (1.3%)	28 (1.5%)
Number (%) of subjects censored	1909 (98.7%)	1881 (98.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.49; 1.46]	
two-sided p-value from stratified logrank test	0.5472	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	229 (5.0%)	269 (5.9%)
Number (%) of subjects censored	4342 (95.0%)	4315 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.70; <1.00]	
two-sided p-value from stratified logrank test	0.0473	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 49: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9783

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	97 (3.3%)	128 (4.3%)
Number (%) of subjects censored	2882 (96.7%)	2828 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.55; 0.93]	
two-sided p-value from stratified logrank test	0.0117	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	157 (4.4%)	169 (4.8%)
Number (%) of subjects censored	3383 (95.6%)	3382 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.75; 1.17]	
two-sided p-value from stratified logrank test	0.5579	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 51: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.1175

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	170 (3.8%)	196 (4.4%)
Number (%) of subjects censored	4354 (96.2%)	4277 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.68; 1.02]	
two-sided p-value from stratified logrank test	0.0796	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	84 (4.2%)	101 (5.0%)
Number (%) of subjects censored	1910 (95.8%)	1930 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.63; 1.14]	
two-sided p-value from stratified logrank test	0.2659	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 53: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.9894

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	56 (2.8%)	56 (2.8%)
Number (%) of subjects censored	1919 (97.2%)	1919 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.66; 1.39]	
two-sided p-value from stratified logrank test	0.8173	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	181 (4.2%)	213 (5.0%)
Number (%) of subjects censored	4111 (95.8%)	4064 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.68; 1.02]	
two-sided p-value from stratified logrank test	0.0724	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	16 (6.4%)	28 (11.1%)
Number (%) of subjects censored	233 (93.6%)	225 (88.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.48 [0.24; 0.93]	
two-sided p-value from stratified logrank test	0.0276	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 55: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.0777

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	121 (2.7%)	138 (3.1%)
Number (%) of subjects censored	4328 (97.3%)	4282 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.68; 1.11]	
two-sided p-value from stratified logrank test	0.2514	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	29 (11.5%)	22 (8.2%)
Number (%) of subjects censored	224 (88.5%)	247 (91.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.50; 1.68]	
two-sided p-value from stratified logrank test	0.7801	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	77 (5.4%)	118 (8.1%)
Number (%) of subjects censored	1355 (94.6%)	1344 (91.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.49; 0.87]	
two-sided p-value from stratified logrank test	0.0037	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	27 (7.0%)	19 (5.3%)
Number (%) of subjects censored	358 (93.0%)	337 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.48 [0.81; 2.72]	
two-sided p-value from stratified logrank test	0.2027	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 57: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.0699

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 58: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	171 (3.8%)	224 (4.9%)
Number (%) of subjects censored	4310 (96.2%)	4383 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.61; 0.91]	
two-sided p-value from stratified logrank test	0.0043	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 58: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	83 (4.1%)	73 (3.8%)
Number (%) of subjects censored	1955 (95.9%)	1827 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.80; 1.52]	
two-sided p-value from stratified logrank test	0.5438	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 59: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.0400

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 60: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	141 (4.8%)	160 (5.5%)
Number (%) of subjects censored	2817 (95.2%)	2771 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.69; 1.09]	
two-sided p-value from stratified logrank test	0.2170	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 60: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	113 (3.2%)	137 (3.8%)
Number (%) of subjects censored	3448 (96.8%)	3439 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.62; 1.03]	
two-sided p-value from stratified logrank test	0.0801	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 61: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.6882

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 62: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	254 (3.9%)	297 (4.6%)
Number (%) of subjects censored	6265 (96.1%)	6210 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.72; 1.01]	
two-sided p-value from unstratified logrank test	0.0601	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 63: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	137 (2.1%)	182 (2.8%)
Number (%) of subjects censored	6382 (97.9%)	6325 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.60; 0.94]	
two-sided p-value from stratified logrank test	0.0130	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 64: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	151 (2.3%)	188 (2.9%)
Number (%) of subjects censored	6368 (97.7%)	6319 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.64; 0.99]	
two-sided p-value from stratified logrank test	0.0403	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 65: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	195 (3.0%)	237 (3.6%)
Number (%) of subjects censored	6324 (97.0%)	6270 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.98]	
two-sided p-value from stratified logrank test	0.0263	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 66: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	257 (3.9%)	361 (5.5%)
Number (%) of subjects censored	6262 (96.1%)	6146 (94.5%)
Median Time to event (month) [95 % CI]	61.900 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.60; 0.83]	
two-sided p-value from stratified logrank test	<.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 67: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	2 (<0.1%)	4 (<0.1%)
Number (%) of subjects censored	6517 (>99.9%)	6503 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.53 [0.10; 2.91]	
two-sided p-value from stratified logrank test	0.4599	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 68: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	557 (8.5%)	623 (9.6%)
Number (%) of subjects censored	5962 (91.5%)	5884 (90.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.79; 0.99]	
two-sided p-value from stratified logrank test	0.0360	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 69: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	825 (12.7%)	939 (14.4%)
Number (%) of subjects censored	5694 (87.3%)	5568 (85.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.78; 0.95]	
two-sided p-value from stratified logrank test	0.0018	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	405 (13.8%)	442 (15.1%)
Number (%) of subjects censored	2531 (86.2%)	2484 (84.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.79; 1.03]	
two-sided p-value from stratified logrank test	0.1264	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	154 (15.0%)	185 (18.0%)
Number (%) of subjects censored	872 (85.0%)	840 (82.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.68; 1.04]	
two-sided p-value from stratified logrank test	0.1044	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	157 (9.8%)	187 (11.7%)
Number (%) of subjects censored	1443 (90.2%)	1417 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.65; 0.99]	
two-sided p-value from stratified logrank test	0.0419	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	69 (9.6%)	93 (13.0%)
Number (%) of subjects censored	650 (90.4%)	622 (87.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.53; 0.99]	
two-sided p-value from stratified logrank test	0.0419	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	40 (16.8%)	32 (13.5%)
Number (%) of subjects censored	198 (83.2%)	205 (86.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.22 [0.76; 1.94]	
two-sided p-value from stratified logrank test	0.4113	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 71: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.3822

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	325 (14.8%)	359 (16.5%)
Number (%) of subjects censored	1874 (85.2%)	1816 (83.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.75; 1.01]	
two-sided p-value from stratified logrank test	0.0686	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	204 (11.4%)	256 (14.1%)
Number (%) of subjects censored	1586 (88.6%)	1555 (85.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.66; 0.95]	
two-sided p-value from stratified logrank test	0.0122	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	295 (11.7%)	323 (12.8%)
Number (%) of subjects censored	2230 (88.3%)	2191 (87.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.77; 1.06]	
two-sided p-value from stratified logrank test	0.2231	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 73: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.5506

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	261 (13.5%)	295 (15.5%)
Number (%) of subjects censored	1673 (86.5%)	1614 (84.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.73; 1.02]	
two-sided p-value from stratified logrank test	0.0922	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	562 (12.3%)	642 (14.0%)
Number (%) of subjects censored	4009 (87.7%)	3942 (86.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.77; 0.97]	
two-sided p-value from stratified logrank test	0.0124	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 75: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9499

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	511 (17.2%)	595 (20.1%)
Number (%) of subjects censored	2468 (82.8%)	2361 (79.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.74; 0.94]	
two-sided p-value from stratified logrank test	0.0026	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	314 (8.9%)	344 (9.7%)
Number (%) of subjects censored	3226 (91.1%)	3207 (90.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.78; 1.06]	
two-sided p-value from stratified logrank test	0.2288	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 77: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3750

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	569 (12.6%)	627 (14.0%)
Number (%) of subjects censored	3955 (87.4%)	3846 (86.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.78; 0.98]	
two-sided p-value from stratified logrank test	0.0203	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	255 (12.8%)	311 (15.3%)
Number (%) of subjects censored	1739 (87.2%)	1720 (84.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.70; 0.98]	
two-sided p-value from stratified logrank test	0.0262	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 79: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5782

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	210 (10.6%)	230 (11.6%)
Number (%) of subjects censored	1765 (89.4%)	1745 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.74; 1.08]	
two-sided p-value from stratified logrank test	0.2421	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	568 (13.2%)	662 (15.5%)
Number (%) of subjects censored	3724 (86.8%)	3615 (84.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.75; 0.93]	
two-sided p-value from stratified logrank test	0.0016	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	45 (18.1%)	46 (18.2%)
Number (%) of subjects censored	204 (81.9%)	207 (81.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.60; 1.48]	
two-sided p-value from stratified logrank test	0.8013	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 81: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.5596

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	621 (14.0%)	699 (15.8%)
Number (%) of subjects censored	3828 (86.0%)	3721 (84.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.78; 0.96]	
two-sided p-value from stratified logrank test	0.0083	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	39 (15.4%)	53 (19.7%)
Number (%) of subjects censored	214 (84.6%)	216 (80.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.51; 1.24]	
two-sided p-value from stratified logrank test	0.3106	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	122 (8.5%)	139 (9.5%)
Number (%) of subjects censored	1310 (91.5%)	1323 (90.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.70; 1.15]	
two-sided p-value from stratified logrank test	0.3878	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	43 (11.2%)	48 (13.5%)
Number (%) of subjects censored	342 (88.8%)	308 (86.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.51; 1.22]	
two-sided p-value from stratified logrank test	0.2895	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 83: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.9114

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 84: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	579 (12.9%)	675 (14.7%)
Number (%) of subjects censored	3902 (87.1%)	3932 (85.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.77; 0.96]	
two-sided p-value from stratified logrank test	0.0064	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 84: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	246 (12.1%)	264 (13.9%)
Number (%) of subjects censored	1792 (87.9%)	1636 (86.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.73; 1.04]	
two-sided p-value from stratified logrank test	0.1369	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 85: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.9165

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 86: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	323 (10.9%)	337 (11.5%)
Number (%) of subjects censored	2635 (89.1%)	2594 (88.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.81; 1.10]	
two-sided p-value from stratified logrank test	0.4395	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 86: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	502 (14.1%)	602 (16.8%)
Number (%) of subjects censored	3059 (85.9%)	2974 (83.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.73; 0.93]	
two-sided p-value from stratified logrank test	0.0014	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 87: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.2018

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 88: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	825 (12.7%)	939 (14.4%)
Number (%) of subjects censored	5694 (87.3%)	5568 (85.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.79; 0.95]	
two-sided p-value from unstratified logrank test	0.0025	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
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Table 1.3.1 / 89: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	620 (9.5%)	758 (11.6%)
Number (%) of subjects censored	5899 (90.5%)	5749 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.73; 0.90]	
two-sided p-value from stratified logrank test	0.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 90: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	322 (4.9%)	364 (5.6%)
Number (%) of subjects censored	6197 (95.1%)	6143 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.76; 1.02]	
two-sided p-value from stratified logrank test	0.0922	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 91: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	173 (2.7%)	189 (2.9%)
Number (%) of subjects censored	6346 (97.3%)	6318 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.74; 1.12]	
two-sided p-value from stratified logrank test	0.3601	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 92: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	198 (3.0%)	198 (3.0%)
Number (%) of subjects censored	6321 (97.0%)	6309 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.82; 1.21]	
two-sided p-value from stratified logrank test	0.9460	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 93: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	256 (3.9%)	325 (5.0%)
Number (%) of subjects censored	6263 (96.1%)	6182 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.66; 0.92]	
two-sided p-value from stratified logrank test	0.0030	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 94: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	195 (3.0%)	204 (3.1%)
Number (%) of subjects censored	6324 (97.0%)	6303 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.78; 1.15]	
two-sided p-value from stratified logrank test	0.5861	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	96 (3.3%)	89 (3.0%)
Number (%) of subjects censored	2840 (96.7%)	2837 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.80; 1.42]	
two-sided p-value from stratified logrank test	0.6770	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	29 (2.8%)	48 (4.7%)
Number (%) of subjects censored	997 (97.2%)	977 (95.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.39; 0.97]	
two-sided p-value from stratified logrank test	0.0353	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	44 (2.8%)	43 (2.7%)
Number (%) of subjects censored	1556 (97.3%)	1561 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.67; 1.56]	
two-sided p-value from stratified logrank test	0.9316	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	12 (1.7%)	14 (2.0%)
Number (%) of subjects censored	707 (98.3%)	701 (98.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.40; 1.87]	
two-sided p-value from stratified logrank test	0.7094	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	14 (5.9%)	10 (4.2%)
Number (%) of subjects censored	224 (94.1%)	227 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.30 [0.57; 2.94]	
two-sided p-value from stratified logrank test	0.5314	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 96: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.3099

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	63 (2.9%)	92 (4.2%)
Number (%) of subjects censored	2136 (97.1%)	2083 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.48; 0.91]	
two-sided p-value from stratified logrank test	0.0118	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	58 (3.2%)	49 (2.7%)
Number (%) of subjects censored	1732 (96.8%)	1762 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.16 [0.79; 1.71]	
two-sided p-value from stratified logrank test	0.4366	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	73 (2.9%)	63 (2.5%)
Number (%) of subjects censored	2452 (97.1%)	2451 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.17 [0.83; 1.64]	
two-sided p-value from stratified logrank test	0.3745	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 98: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.0226

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	65 (3.4%)	71 (3.7%)
Number (%) of subjects censored	1869 (96.6%)	1838 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.63; 1.23]	
two-sided p-value from stratified logrank test	0.4468	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	129 (2.8%)	133 (2.9%)
Number (%) of subjects censored	4442 (97.2%)	4451 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.77; 1.25]	
two-sided p-value from stratified logrank test	0.8569	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 100: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.6494

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	138 (4.6%)	135 (4.6%)
Number (%) of subjects censored	2841 (95.4%)	2821 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.80; 1.29]	
two-sided p-value from stratified logrank test	0.8919	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	57 (1.6%)	69 (1.9%)
Number (%) of subjects censored	3483 (98.4%)	3482 (98.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.57; 1.15]	
two-sided p-value from stratified logrank test	0.2435	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 102: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.2997

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 103: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	138 (3.1%)	134 (3.0%)
Number (%) of subjects censored	4386 (96.9%)	4339 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.78; 1.26]	
two-sided p-value from stratified logrank test	0.9322	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 103: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	56 (2.8%)	70 (3.4%)
Number (%) of subjects censored	1938 (97.2%)	1961 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.57; 1.16]	
two-sided p-value from stratified logrank test	0.2558	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 104: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.3410

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	41 (2.1%)	53 (2.7%)
Number (%) of subjects censored	1934 (97.9%)	1922 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.50; 1.15]	
two-sided p-value from stratified logrank test	0.1882	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	149 (3.5%)	140 (3.3%)
Number (%) of subjects censored	4143 (96.5%)	4137 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.84; 1.34]	
two-sided p-value from stratified logrank test	0.6022	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	4 (1.6%)	11 (4.3%)
Number (%) of subjects censored	245 (98.4%)	242 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.41 [0.13; 1.29]	
two-sided p-value from stratified logrank test	0.1157	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 106: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.1010

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	154 (3.5%)	158 (3.6%)
Number (%) of subjects censored	4295 (96.5%)	4262 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.77; 1.20]	
two-sided p-value from stratified logrank test	0.7056	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	4 (1.6%)	9 (3.3%)
Number (%) of subjects censored	249 (98.4%)	260 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.47 [0.14; 1.61]	
two-sided p-value from stratified logrank test	0.2226	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	28 (2.0%)	27 (1.8%)
Number (%) of subjects censored	1404 (98.0%)	1435 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.26 [0.72; 2.21]	
two-sided p-value from stratified logrank test	0.4205	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	9 (2.3%)	10 (2.8%)
Number (%) of subjects censored	376 (97.7%)	346 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.32; 2.22]	
two-sided p-value from stratified logrank test	0.7298	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 108: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.5999

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 109: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	151 (3.4%)	163 (3.5%)
Number (%) of subjects censored	4330 (96.6%)	4444 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.75; 1.16]	
two-sided p-value from stratified logrank test	0.5390	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 109: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	44 (2.2%)	41 (2.2%)
Number (%) of subjects censored	1994 (97.8%)	1859 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.05 [0.68; 1.63]	
two-sided p-value from stratified logrank test	0.8188	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 110: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.7748

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 111: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	72 (2.4%)	72 (2.5%)
Number (%) of subjects censored	2886 (97.6%)	2859 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.72; 1.40]	
two-sided p-value from stratified logrank test	0.9596	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 111: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	123 (3.5%)	132 (3.7%)
Number (%) of subjects censored	3438 (96.5%)	3444 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.73; 1.20]	
two-sided p-value from stratified logrank test	0.5863	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 112: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.8208

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 113: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	195 (3.0%)	204 (3.1%)
Number (%) of subjects censored	6324 (97.0%)	6303 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.78; 1.15]	
two-sided p-value from unstratified logrank test	0.5949	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 114: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	160 (2.5%)	171 (2.6%)
Number (%) of subjects censored	6359 (97.5%)	6336 (97.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.75; 1.15]	
two-sided p-value from stratified logrank test	0.4974	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 115: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	221 (3.4%)	228 (3.5%)
Number (%) of subjects censored	6298 (96.6%)	6279 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.80; 1.16]	
two-sided p-value from stratified logrank test	0.6742	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	108 (3.7%)	101 (3.5%)
Number (%) of subjects censored	2828 (96.3%)	2825 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.81; 1.39]	
two-sided p-value from stratified logrank test	0.6695	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	26 (2.5%)	44 (4.3%)
Number (%) of subjects censored	1000 (97.5%)	981 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.37; 0.99]	
two-sided p-value from stratified logrank test	0.0433	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	55 (3.4%)	56 (3.5%)
Number (%) of subjects censored	1545 (96.6%)	1548 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.66; 1.40]	
two-sided p-value from stratified logrank test	0.8346	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	19 (2.6%)	20 (2.8%)
Number (%) of subjects censored	700 (97.4%)	695 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.49; 1.74]	
two-sided p-value from stratified logrank test	0.8144	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	13 (5.5%)	7 (3.0%)
Number (%) of subjects censored	225 (94.5%)	230 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.76 [0.70; 4.43]	
two-sided p-value from stratified logrank test	0.2206	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 117: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.2328

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	72 (3.3%)	70 (3.2%)
Number (%) of subjects censored	2127 (96.7%)	2105 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.71; 1.38]	
two-sided p-value from stratified logrank test	0.9705	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	56 (3.1%)	71 (3.9%)
Number (%) of subjects censored	1734 (96.9%)	1740 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.56; 1.12]	
two-sided p-value from stratified logrank test	0.1893	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	93 (3.7%)	87 (3.5%)
Number (%) of subjects censored	2432 (96.3%)	2427 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.07 [0.80; 1.44]	
two-sided p-value from stratified logrank test	0.6441	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 119: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.4150

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	64 (3.3%)	73 (3.8%)
Number (%) of subjects censored	1870 (96.7%)	1836 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.64; 1.25]	
two-sided p-value from stratified logrank test	0.5132	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	157 (3.4%)	155 (3.4%)
Number (%) of subjects censored	4414 (96.6%)	4429 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.81; 1.26]	
two-sided p-value from stratified logrank test	0.9391	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 121: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.4389

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 122: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	124 (4.2%)	146 (4.9%)
Number (%) of subjects censored	2855 (95.8%)	2810 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.66; 1.07]	
two-sided p-value from stratified logrank test	0.1520	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 122: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	97 (2.7%)	82 (2.3%)
Number (%) of subjects censored	3443 (97.3%)	3469 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.18 [0.88; 1.58]	
two-sided p-value from stratified logrank test	0.2751	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 123: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.0810

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 124: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	159 (3.5%)	153 (3.4%)
Number (%) of subjects censored	4365 (96.5%)	4320 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.81; 1.27]	
two-sided p-value from stratified logrank test	0.9057	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 124: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	62 (3.1%)	75 (3.7%)
Number (%) of subjects censored	1932 (96.9%)	1956 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.61; 1.21]	
two-sided p-value from stratified logrank test	0.3818	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 125: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.3819

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	50 (2.5%)	43 (2.2%)
Number (%) of subjects censored	1925 (97.5%)	1932 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.76; 1.74]	
two-sided p-value from stratified logrank test	0.4996	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	160 (3.7%)	172 (4.0%)
Number (%) of subjects censored	4132 (96.3%)	4105 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.73; 1.13]	
two-sided p-value from stratified logrank test	0.3938	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	11 (4.4%)	12 (4.7%)
Number (%) of subjects censored	238 (95.6%)	241 (95.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.35; 2.03]	
two-sided p-value from stratified logrank test	0.6985	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 127: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.5681

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	155 (3.5%)	159 (3.6%)
Number (%) of subjects censored	4294 (96.5%)	4261 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.77; 1.20]	
two-sided p-value from stratified logrank test	0.7327	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	7 (2.8%)	16 (5.9%)
Number (%) of subjects censored	246 (97.2%)	253 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.62 [0.24; 1.58]	
two-sided p-value from stratified logrank test	0.3140	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	47 (3.3%)	45 (3.1%)
Number (%) of subjects censored	1385 (96.7%)	1417 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.05 [0.70; 1.59]	
two-sided p-value from stratified logrank test	0.8067	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	12 (3.1%)	8 (2.2%)
Number (%) of subjects censored	373 (96.9%)	348 (97.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.25 [0.50; 3.13]	
two-sided p-value from stratified logrank test	0.6322	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 129: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.3671

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 130: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	163 (3.6%)	157 (3.4%)
Number (%) of subjects censored	4318 (96.4%)	4450 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.85; 1.32]	
two-sided p-value from stratified logrank test	0.5868	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 130: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	58 (2.8%)	71 (3.7%)
Number (%) of subjects censored	1980 (97.2%)	1829 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.54; 1.09]	
two-sided p-value from stratified logrank test	0.1334	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 131: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1069

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 132: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	90 (3.0%)	89 (3.0%)
Number (%) of subjects censored	2868 (97.0%)	2842 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.75; 1.35]	
two-sided p-value from stratified logrank test	0.9714	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 132: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	131 (3.7%)	139 (3.9%)
Number (%) of subjects censored	3430 (96.3%)	3437 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.74; 1.19]	
two-sided p-value from stratified logrank test	0.6027	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 133: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.8170

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 134: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	221 (3.4%)	228 (3.5%)
Number (%) of subjects censored	6298 (96.6%)	6279 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.80; 1.16]	
two-sided p-value from unstratified logrank test	0.6715	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 135: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	178 (2.7%)	190 (2.9%)
Number (%) of subjects censored	6341 (97.3%)	6317 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.77; 1.17]	
two-sided p-value from stratified logrank test	0.6251	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 136: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	261 (4.0%)	343 (5.3%)
Number (%) of subjects censored	6258 (96.0%)	6164 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.64; 0.89]	
two-sided p-value from stratified logrank test	0.0006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	118 (4.0%)	161 (5.5%)
Number (%) of subjects censored	2818 (96.0%)	2765 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.57; 0.92]	
two-sided p-value from stratified logrank test	0.0078	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	68 (6.6%)	74 (7.2%)
Number (%) of subjects censored	958 (93.4%)	951 (92.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.69; 1.33]	
two-sided p-value from stratified logrank test	0.7904	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	45 (2.8%)	70 (4.4%)
Number (%) of subjects censored	1555 (97.2%)	1534 (95.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.60 [0.41; 0.87]	
two-sided p-value from stratified logrank test	0.0071	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	20 (2.8%)	25 (3.5%)
Number (%) of subjects censored	699 (97.2%)	690 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.45; 1.45]	
two-sided p-value from stratified logrank test	0.4661	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	10 (4.2%)	13 (5.5%)
Number (%) of subjects censored	228 (95.8%)	224 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.33; 1.76]	
two-sided p-value from stratified logrank test	0.5286	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 138: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.4693

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	123 (5.6%)	132 (6.1%)
Number (%) of subjects censored	2076 (94.4%)	2043 (93.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.71; 1.17]	
two-sided p-value from stratified logrank test	0.4585	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	68 (3.8%)	102 (5.6%)
Number (%) of subjects censored	1722 (96.2%)	1709 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.50; 0.93]	
two-sided p-value from stratified logrank test	0.0136	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	70 (2.8%)	109 (4.3%)
Number (%) of subjects censored	2455 (97.2%)	2405 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.47; 0.86]	
two-sided p-value from stratified logrank test	0.0030	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 140: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.1416

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 141: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	70 (3.6%)	93 (4.9%)
Number (%) of subjects censored	1864 (96.4%)	1816 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.53; <1.00]	
two-sided p-value from stratified logrank test	0.0460	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 141: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	190 (4.2%)	249 (5.4%)
Number (%) of subjects censored	4381 (95.8%)	4335 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.64; 0.93]	
two-sided p-value from stratified logrank test	0.0062	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 142: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.7828

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 143: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	166 (5.6%)	228 (7.7%)
Number (%) of subjects censored	2813 (94.4%)	2728 (92.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.59; 0.88]	
two-sided p-value from stratified logrank test	0.0012	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 143: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	95 (2.7%)	115 (3.2%)
Number (%) of subjects censored	3445 (97.3%)	3436 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.63; 1.08]	
two-sided p-value from stratified logrank test	0.1632	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 144: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.4303

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 145: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	182 (4.0%)	241 (5.4%)
Number (%) of subjects censored	4342 (96.0%)	4232 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.60; 0.88]	
two-sided p-value from stratified logrank test	0.0011	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 145: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	79 (4.0%)	102 (5.0%)
Number (%) of subjects censored	1915 (96.0%)	1929 (95.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.58; 1.05]	
two-sided p-value from stratified logrank test	0.1003	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 146: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5844

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	68 (3.4%)	83 (4.2%)
Number (%) of subjects censored	1907 (96.6%)	1892 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.58; 1.12]	
two-sided p-value from stratified logrank test	0.2001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	174 (4.1%)	245 (5.7%)
Number (%) of subjects censored	4118 (95.9%)	4032 (94.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.57; 0.85]	
two-sided p-value from stratified logrank test	0.0003	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	18 (7.2%)	15 (5.9%)
Number (%) of subjects censored	231 (92.8%)	238 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.51; 2.38]	
two-sided p-value from stratified logrank test	0.7954	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 148: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.2081

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	194 (4.4%)	257 (5.8%)
Number (%) of subjects censored	4255 (95.6%)	4163 (94.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.62; 0.90]	
two-sided p-value from stratified logrank test	0.0020	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	18 (7.1%)	18 (6.7%)
Number (%) of subjects censored	235 (92.9%)	251 (93.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.12 [0.56; 2.26]	
two-sided p-value from stratified logrank test	0.7457	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	33 (2.3%)	50 (3.4%)
Number (%) of subjects censored	1399 (97.7%)	1412 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.41; >1.00]	
two-sided p-value from stratified logrank test	0.0487	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	16 (4.2%)	18 (5.1%)
Number (%) of subjects censored	369 (95.8%)	338 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.37; 1.57]	
two-sided p-value from stratified logrank test	0.4534	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 150: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.7409

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 151: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	167 (3.7%)	253 (5.5%)
Number (%) of subjects censored	4314 (96.3%)	4354 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.65 [0.54; 0.79]	
two-sided p-value from stratified logrank test	<.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 151: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	94 (4.6%)	90 (4.7%)
Number (%) of subjects censored	1944 (95.4%)	1810 (95.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.72; 1.29]	
two-sided p-value from stratified logrank test	0.8101	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 152: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.0197

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 153: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	95 (3.2%)	114 (3.9%)
Number (%) of subjects censored	2863 (96.8%)	2817 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.63; 1.09]	
two-sided p-value from stratified logrank test	0.1720	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 153: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	166 (4.7%)	229 (6.4%)
Number (%) of subjects censored	3395 (95.3%)	3347 (93.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.60; 0.89]	
two-sided p-value from stratified logrank test	0.0020	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 154: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.4885

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 155: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	261 (4.0%)	343 (5.3%)
Number (%) of subjects censored	6258 (96.0%)	6164 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.64; 0.88]	
two-sided p-value from unstratified logrank test	0.0005	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 156: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	182 (2.8%)	283 (4.3%)
Number (%) of subjects censored	6337 (97.2%)	6224 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.53; 0.78]	
two-sided p-value from stratified logrank test	<.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 157: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	2836 (43.5%)	2926 (45.0%)
Number (%) of subjects censored	3683 (56.5%)	3581 (55.0%)
Median Time to event (month) [95 % CI]	48.333 [45.000;50.867]	44.867 [42.967;47.133]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.91; 1.01]	
two-sided p-value from stratified logrank test	0.0870	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	2936 (100.0%)	2926 (100.0%)
Number (%) of subjects with event	1288 (43.9%)	1293 (44.2%)
Number (%) of subjects censored	1648 (56.1%)	1633 (55.8%)
Median Time to event (month) [95 % CI]	47.867 [43.000;52.933]	47.133 [43.600;51.333]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.90; 1.06]	
two-sided p-value from stratified logrank test	0.5664	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	1026 (100.0%)	1025 (100.0%)
Number (%) of subjects with event	441 (43.0%)	445 (43.4%)
Number (%) of subjects censored	585 (57.0%)	580 (56.6%)
Median Time to event (month) [95 % CI]	50.100 [n.c.]	49.467 [43.833;54.900]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.03 [0.90; 1.17]	
two-sided p-value from stratified logrank test	0.6964	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1600 (100.0%)	1604 (100.0%)
Number (%) of subjects with event	779 (48.7%)	827 (51.6%)
Number (%) of subjects censored	821 (51.3%)	777 (48.4%)
Median Time to event (month) [95 % CI]	40.100 [35.200;45.533]	36.767 [32.933;40.767]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.83; 1.01]	
two-sided p-value from stratified logrank test	0.0764	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	719 (100.0%)	715 (100.0%)
Number (%) of subjects with event	202 (28.1%)	233 (32.6%)
Number (%) of subjects censored	517 (71.9%)	482 (67.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.70; 1.02]	
two-sided p-value from stratified logrank test	0.0826	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	238 (100.0%)	237 (100.0%)
Number (%) of subjects with event	126 (52.9%)	128 (54.0%)
Number (%) of subjects censored	112 (47.1%)	109 (46.0%)
Median Time to event (month) [95 % CI]	31.500 [24.033;46.833]	29.967 [26.300;39.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.75; 1.23]	
two-sided p-value from stratified logrank test	0.7470	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 159: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.4332

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2199 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	1061 (48.2%)	1079 (49.6%)
Number (%) of subjects censored	1138 (51.8%)	1096 (50.4%)
Median Time to event (month) [95 % CI]	37.933 [34.900;40.067]	35.000 [32.233;38.033]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.88; 1.05]	
two-sided p-value from stratified logrank test	0.3816	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1790 (100.0%)	1811 (100.0%)
Number (%) of subjects with event	788 (44.0%)	838 (46.3%)
Number (%) of subjects censored	1002 (56.0%)	973 (53.7%)
Median Time to event (month) [95 % CI]	45.133 [41.500;50.100]	40.333 [36.833;44.667]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.85; 1.03]	
two-sided p-value from stratified logrank test	0.1798	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2525 (100.0%)	2514 (100.0%)
Number (%) of subjects with event	986 (39.0%)	1006 (40.0%)
Number (%) of subjects censored	1539 (61.0%)	1508 (60.0%)
Median Time to event (month) [95 % CI]	n.c.	56.133 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.89; 1.06]	
two-sided p-value from stratified logrank test	0.5039	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 161: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.8008

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 162: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1934 (100.0%)	1909 (100.0%)
Number (%) of subjects with event	941 (48.7%)	952 (49.9%)
Number (%) of subjects censored	993 (51.3%)	957 (50.1%)
Median Time to event (month) [95 % CI]	47.600 [42.700;50.867]	43.900 [39.767;47.833]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.88; 1.05]	
two-sided p-value from stratified logrank test	0.3971	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 162: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	4571 (100.0%)	4584 (100.0%)
Number (%) of subjects with event	1888 (41.3%)	1967 (42.9%)
Number (%) of subjects censored	2683 (58.7%)	2617 (57.1%)
Median Time to event (month) [95 % CI]	49.333 [n.c.]	45.000 [42.967;47.733]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.90; 1.02]	
two-sided p-value from stratified logrank test	0.1457	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 163: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.8881

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 164: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2979 (100.0%)	2956 (100.0%)
Number (%) of subjects with event	1475 (49.5%)	1513 (51.2%)
Number (%) of subjects censored	1504 (50.5%)	1443 (48.8%)
Median Time to event (month) [95 % CI]	36.833 [34.267;39.667]	32.933 [31.000;35.967]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.88; 1.01]	
two-sided p-value from stratified logrank test	0.1044	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 164: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	3540 (100.0%)	3551 (100.0%)
Number (%) of subjects with event	1361 (38.4%)	1413 (39.8%)
Number (%) of subjects censored	2179 (61.6%)	2138 (60.2%)
Median Time to event (month) [95 % CI]	58.933 [n.c.]	54.100 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.90; 1.05]	
two-sided p-value from stratified logrank test	0.4340	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 165: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.5713

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 166: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	4524 (100.0%)	4473 (100.0%)
Number (%) of subjects with event	1981 (43.8%)	1999 (44.7%)
Number (%) of subjects censored	2543 (56.2%)	2474 (55.3%)
Median Time to event (month) [95 % CI]	48.333 [43.933;51.467]	45.300 [43.033;47.733]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.91; 1.03]	
two-sided p-value from stratified logrank test	0.3632	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 166: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1994 (100.0%)	2031 (100.0%)
Number (%) of subjects with event	854 (42.8%)	926 (45.6%)
Number (%) of subjects censored	1140 (57.2%)	1105 (54.4%)
Median Time to event (month) [95 % CI]	48.600 [43.300;54.633]	43.900 [39.100;49.467]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.84; 1.02]	
two-sided p-value from stratified logrank test	0.1219	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
End of table

Table 1.3.1 / 167: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.3614

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1975 (100.0%)	1975 (100.0%)
Number (%) of subjects with event	799 (40.5%)	823 (41.7%)
Number (%) of subjects censored	1176 (59.5%)	1152 (58.3%)
Median Time to event (month) [95 % CI]	54.333 [n.c.]	51.300 [47.567;54.900]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.89; 1.08]	
two-sided p-value from stratified logrank test	0.6870	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	4292 (100.0%)	4277 (100.0%)
Number (%) of subjects with event	1921 (44.8%)	1974 (46.2%)
Number (%) of subjects censored	2371 (55.2%)	2303 (53.8%)
Median Time to event (month) [95 % CI]	44.700 [41.733;48.633]	42.967 [39.800;45.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.89; 1.01]	
two-sided p-value from stratified logrank test	0.0997	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	249 (100.0%)	253 (100.0%)
Number (%) of subjects with event	114 (45.8%)	127 (50.2%)
Number (%) of subjects censored	135 (54.2%)	126 (49.8%)
Median Time to event (month) [95 % CI]	39.033 [n.c.]	38.367 [29.433;41.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.08 [0.82; 1.44]	
two-sided p-value from stratified logrank test	0.5717	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
End of table

Table 1.3.1 / 169: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.7680

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	4449 (100.0%)	4420 (100.0%)
Number (%) of subjects with event	1918 (43.1%)	1950 (44.1%)
Number (%) of subjects censored	2531 (56.9%)	2470 (55.9%)
Median Time to event (month) [95 % CI]	48.600 [44.700;52.767]	46.400 [43.033;48.967]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.91; 1.04]	
two-sided p-value from stratified logrank test	0.3722	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	253 (100.0%)	269 (100.0%)
Number (%) of subjects with event	104 (41.1%)	121 (45.0%)
Number (%) of subjects censored	149 (58.9%)	148 (55.0%)
Median Time to event (month) [95 % CI]	47.600 [n.c.]	41.767 [31.600;53.933]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.67; 1.18]	
two-sided p-value from stratified logrank test	0.4004	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	1432 (100.0%)	1462 (100.0%)
Number (%) of subjects with event	674 (47.1%)	722 (49.4%)
Number (%) of subjects censored	758 (52.9%)	740 (50.6%)
Median Time to event (month) [95 % CI]	44.267 [38.967;49.767]	42.300 [36.567;45.233]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.84; 1.04]	
two-sided p-value from stratified logrank test	0.1968	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	385 (100.0%)	356 (100.0%)
Number (%) of subjects with event	140 (36.4%)	133 (37.4%)
Number (%) of subjects censored	245 (63.6%)	223 (62.6%)
Median Time to event (month) [95 % CI]	n.c.	47.567 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.73; 1.23]	
two-sided p-value from stratified logrank test	0.7010	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 171: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8190

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 172: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	4481 (100.0%)	4607 (100.0%)
Number (%) of subjects with event	2037 (45.5%)	2132 (46.3%)
Number (%) of subjects censored	2444 (54.5%)	2475 (53.7%)
Median Time to event (month) [95 % CI]	43.700 [41.500;47.600]	42.967 [40.300;45.700]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.91; 1.03]	
two-sided p-value from stratified logrank test	0.2927	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 172: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	2038 (100.0%)	1900 (100.0%)
Number (%) of subjects with event	799 (39.2%)	794 (41.8%)
Number (%) of subjects censored	1239 (60.8%)	1106 (58.2%)
Median Time to event (month) [95 % CI]	n.c.	50.200 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.85; 1.04]	
two-sided p-value from stratified logrank test	0.2634	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 173: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.5212

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 174: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	2958 (100.0%)	2931 (100.0%)
Number (%) of subjects with event	1170 (39.6%)	1194 (40.7%)
Number (%) of subjects censored	1788 (60.4%)	1737 (59.3%)
Median Time to event (month) [95 % CI]	n.c.	52.933 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.89; 1.05]	
two-sided p-value from stratified logrank test	0.3678	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30

Table 1.3.1 / 174: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	3561 (100.0%)	3576 (100.0%)
Number (%) of subjects with event	1666 (46.8%)	1732 (48.4%)
Number (%) of subjects censored	1895 (53.2%)	1844 (51.6%)
Median Time to event (month) [95 % CI]	41.567 [39.433;44.800]	39.333 [37.267;41.467]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.90; 1.02]	
two-sided p-value from stratified logrank test	0.2125	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 175: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9866

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.3.1 / 176: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	2836 (43.5%)	2926 (45.0%)
Number (%) of subjects censored	3683 (56.5%)	3581 (55.0%)
Median Time to event (month) [95 % CI]	48.333 [45.000;50.867]	44.867 [42.967;47.133]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.91; 1.01]	
two-sided p-value from unstratified logrank test	0.0946	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 177: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set)

Statistics	BAY 94-8862	Placebo
N	6519 (100.0%)	6507 (100.0%)
Number (%) of subjects with event	2554 (39.2%)	2667 (41.0%)
Number (%) of subjects censored	3965 (60.8%)	3840 (59.0%)
Median Time to event (month) [95 % CI]	49.533 [46.067;52.767]	46.400 [44.067;48.833]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.91; 1.01]	
two-sided p-value from stratified logrank test	0.1230	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz.sas 06FEB2023 11:30
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Table 1.3.1 / 178: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.87; 1.02]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.1506

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
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Figure 1.3.1 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set)

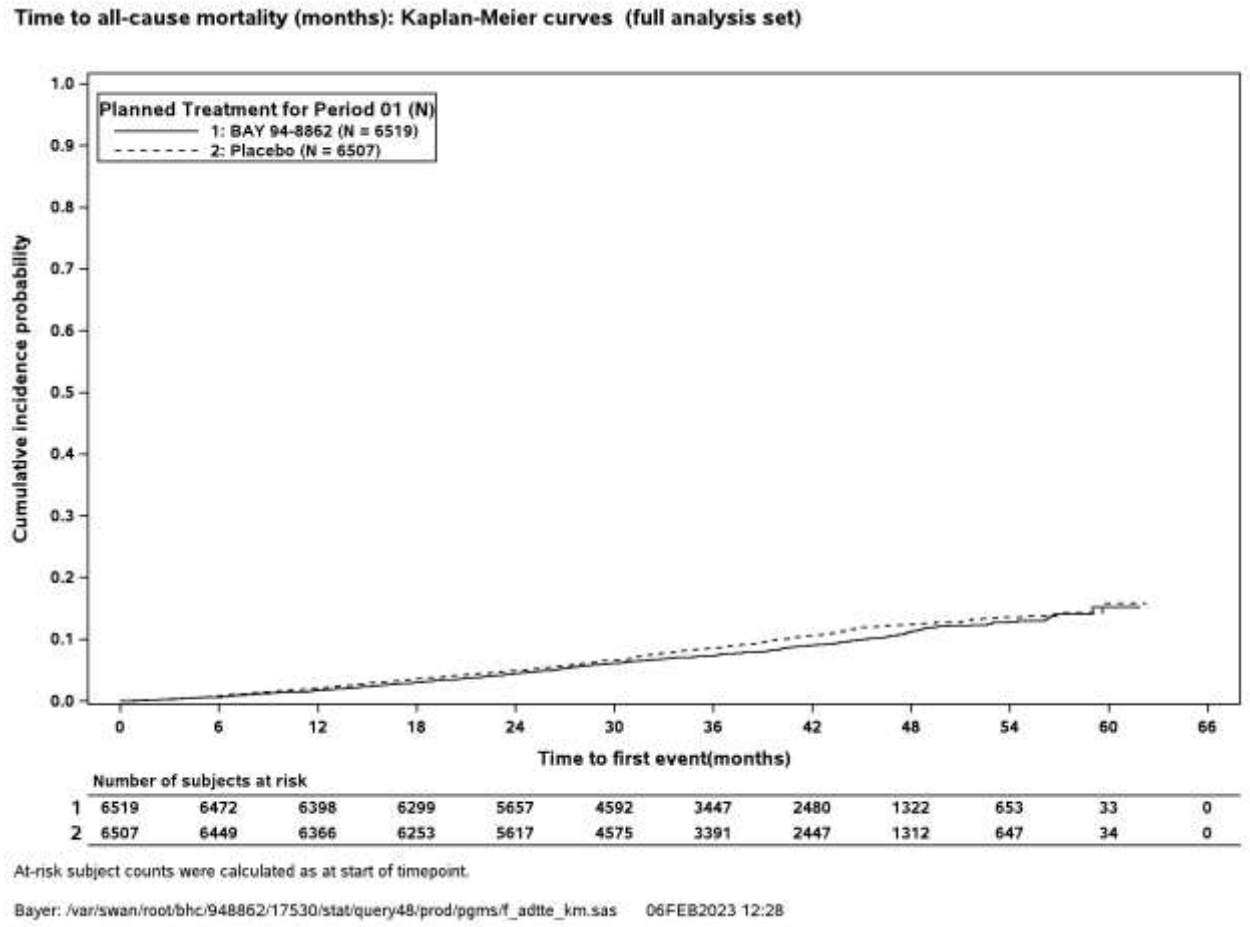


Figure 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

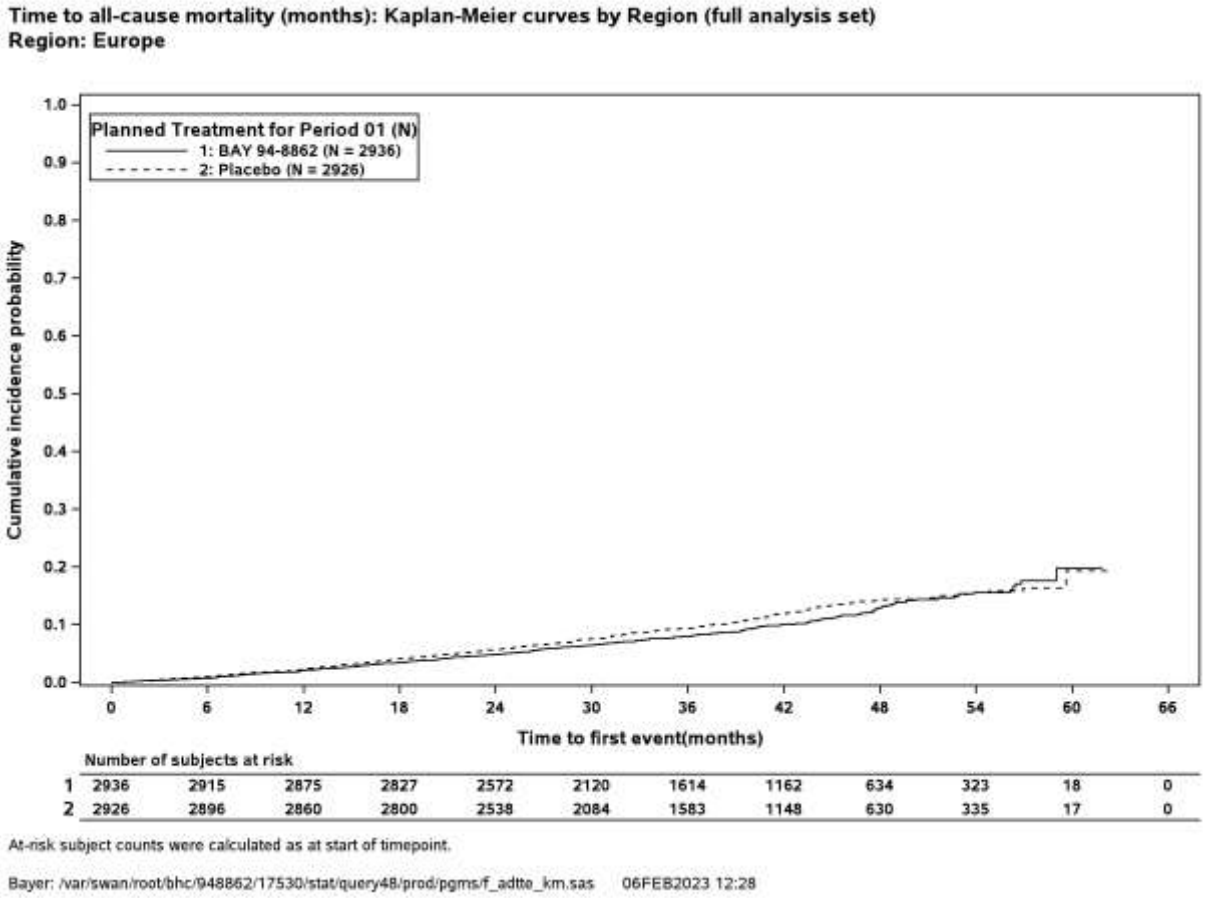


Figure 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

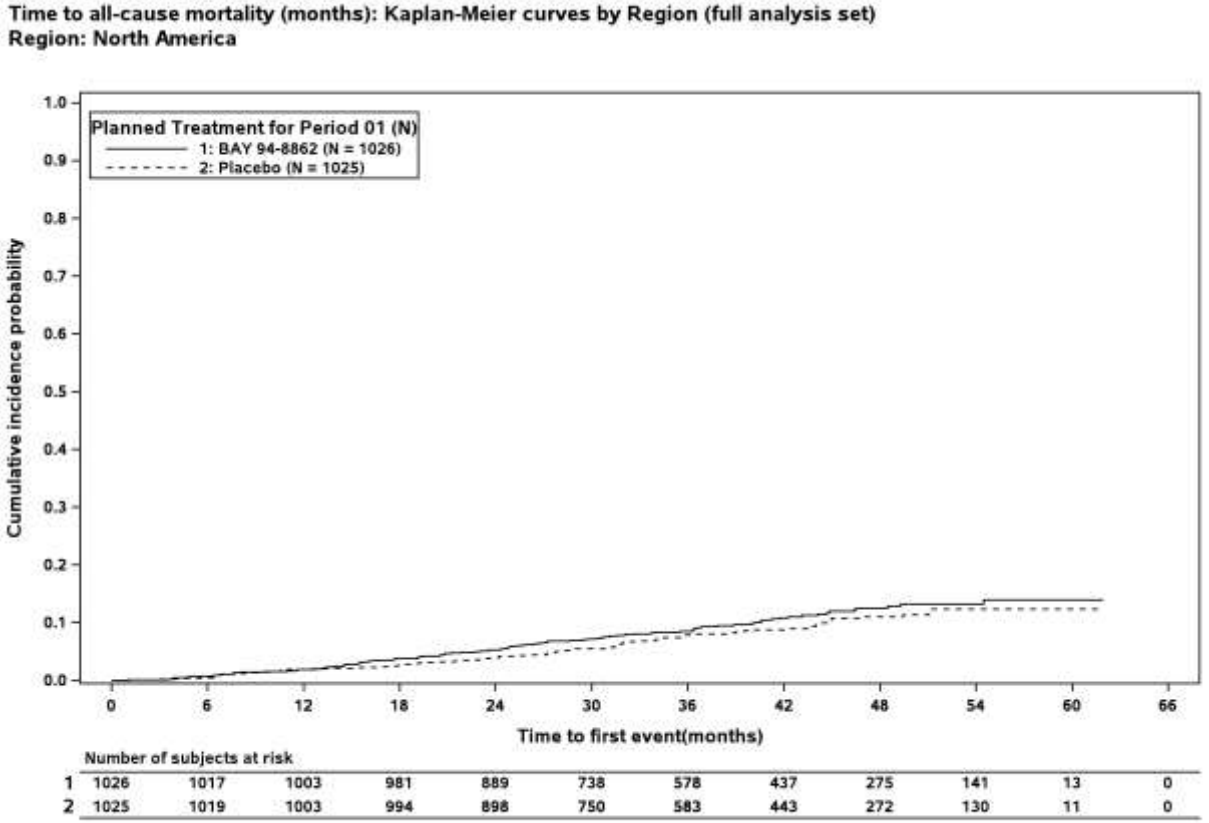


Figure 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

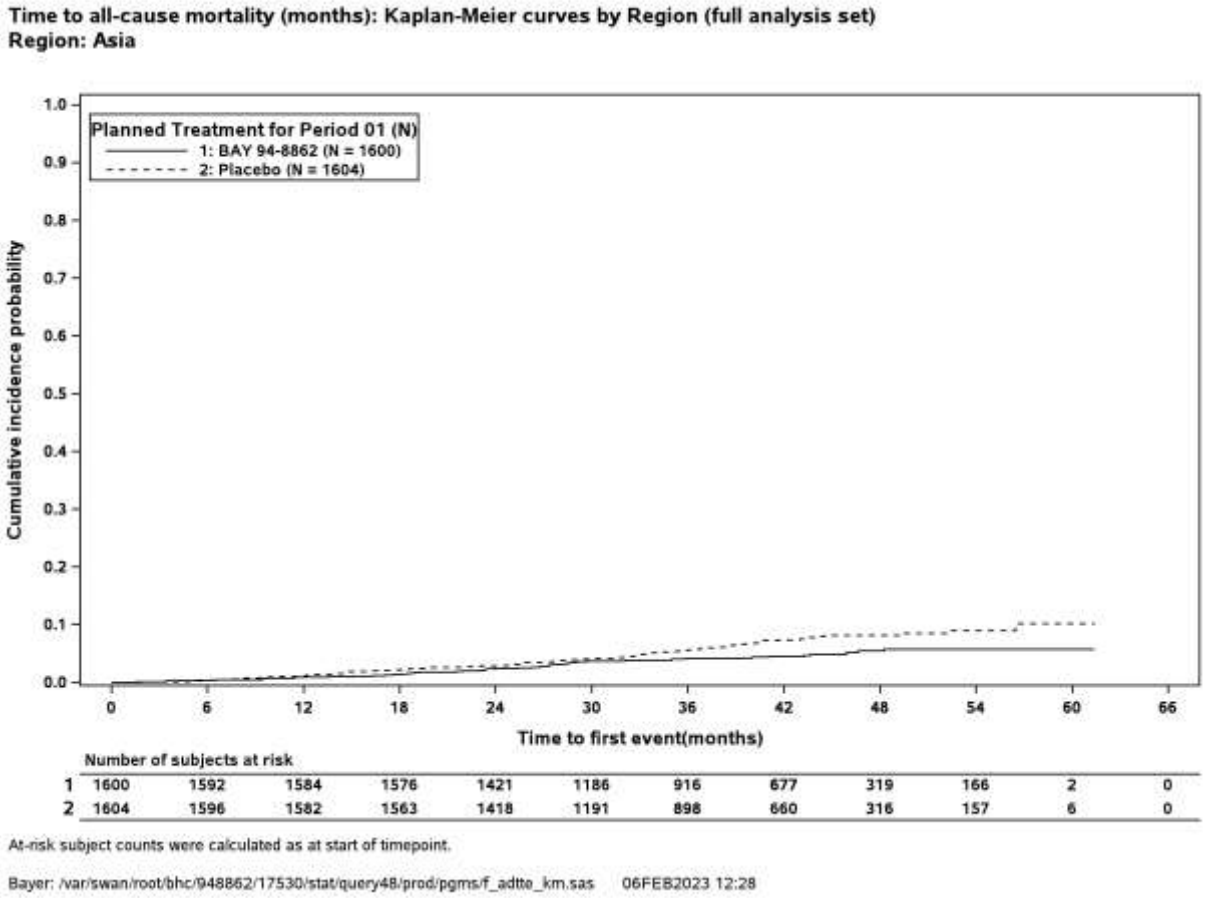


Figure 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

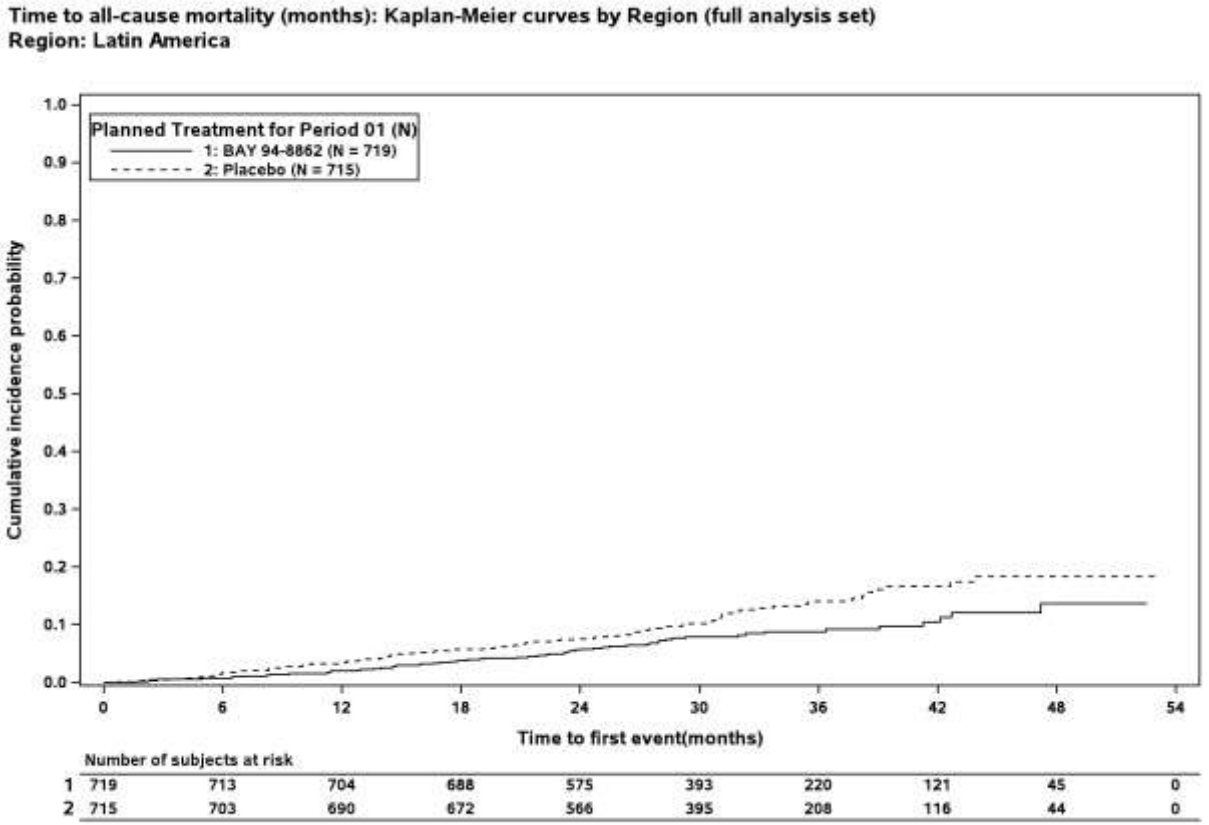


Figure 1.3.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

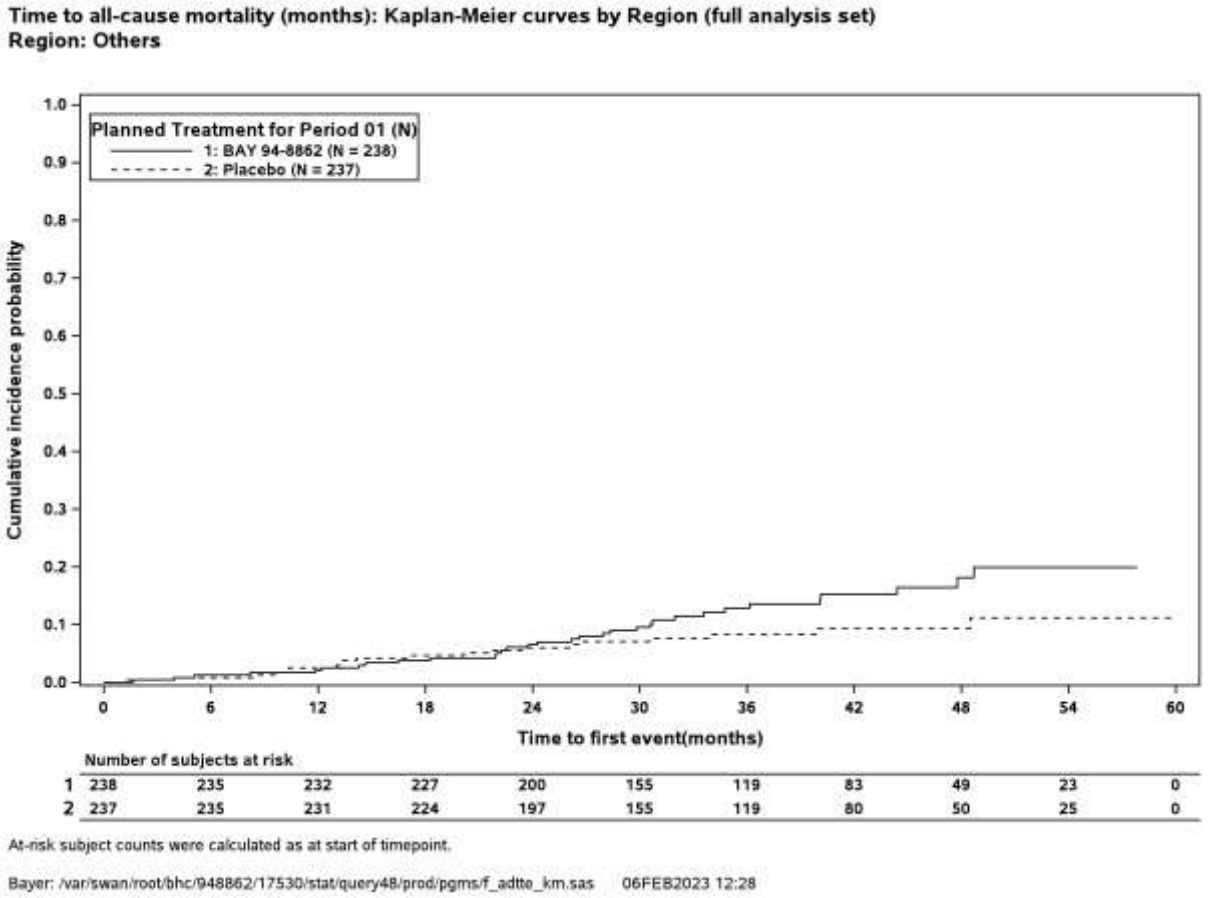


Figure 1.3.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

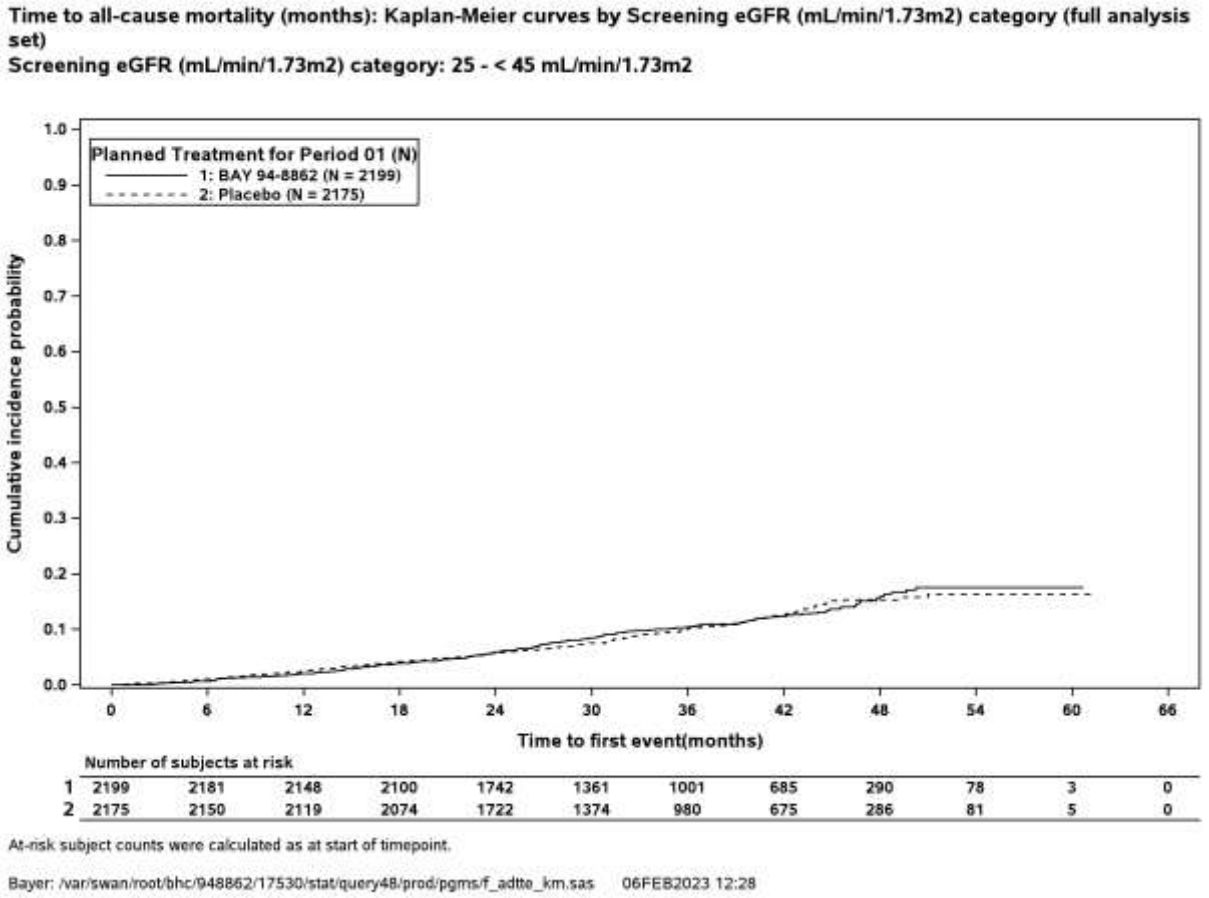


Figure 1.3.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

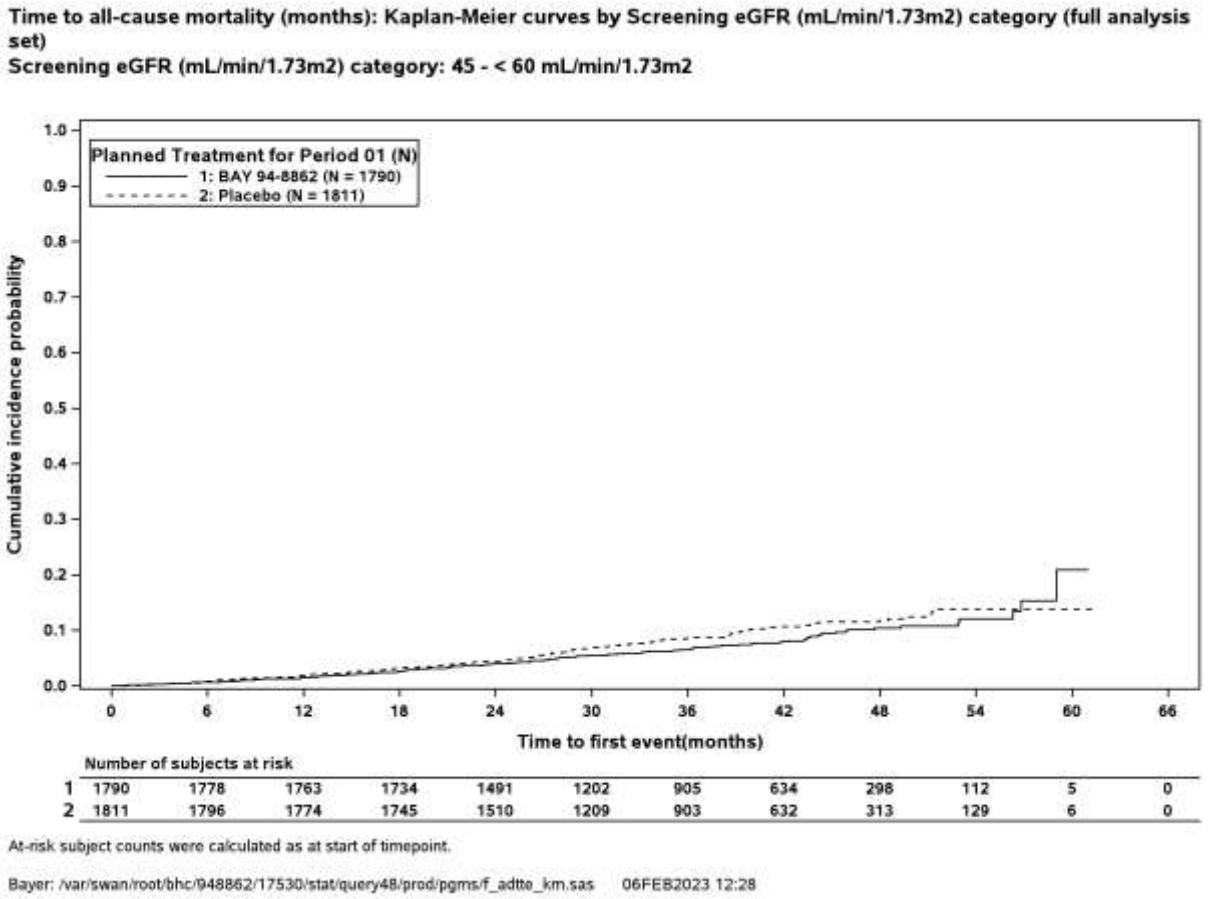


Figure 1.3.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

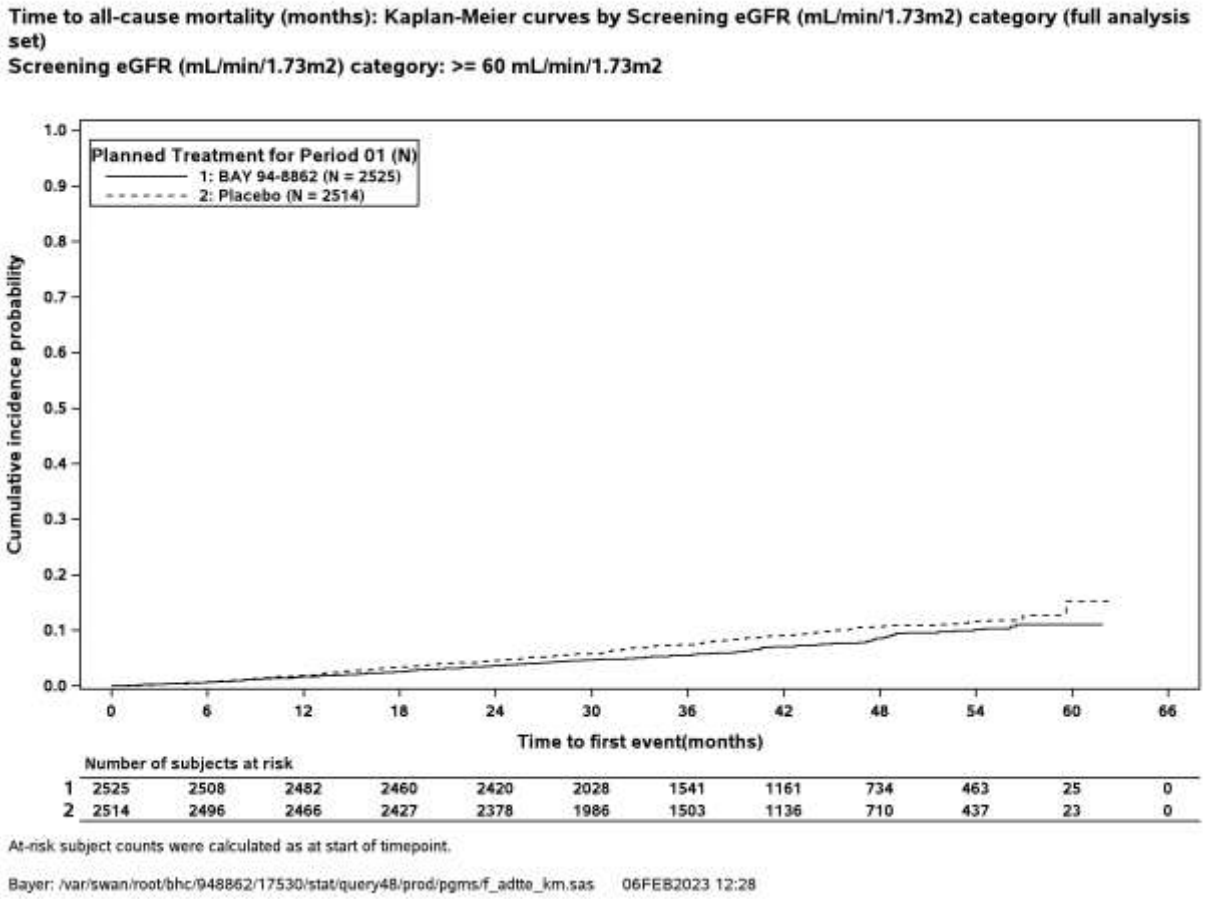


Figure 1.3.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

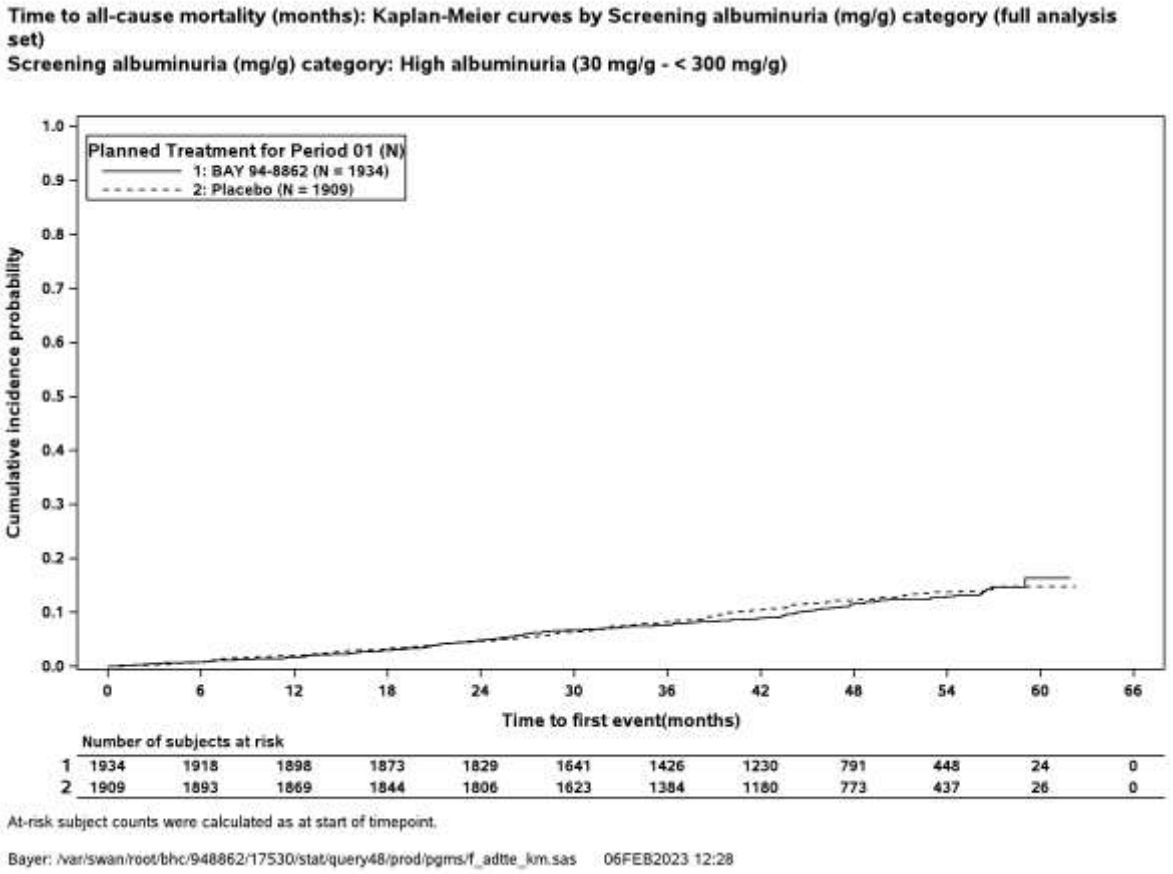


Figure 1.3.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

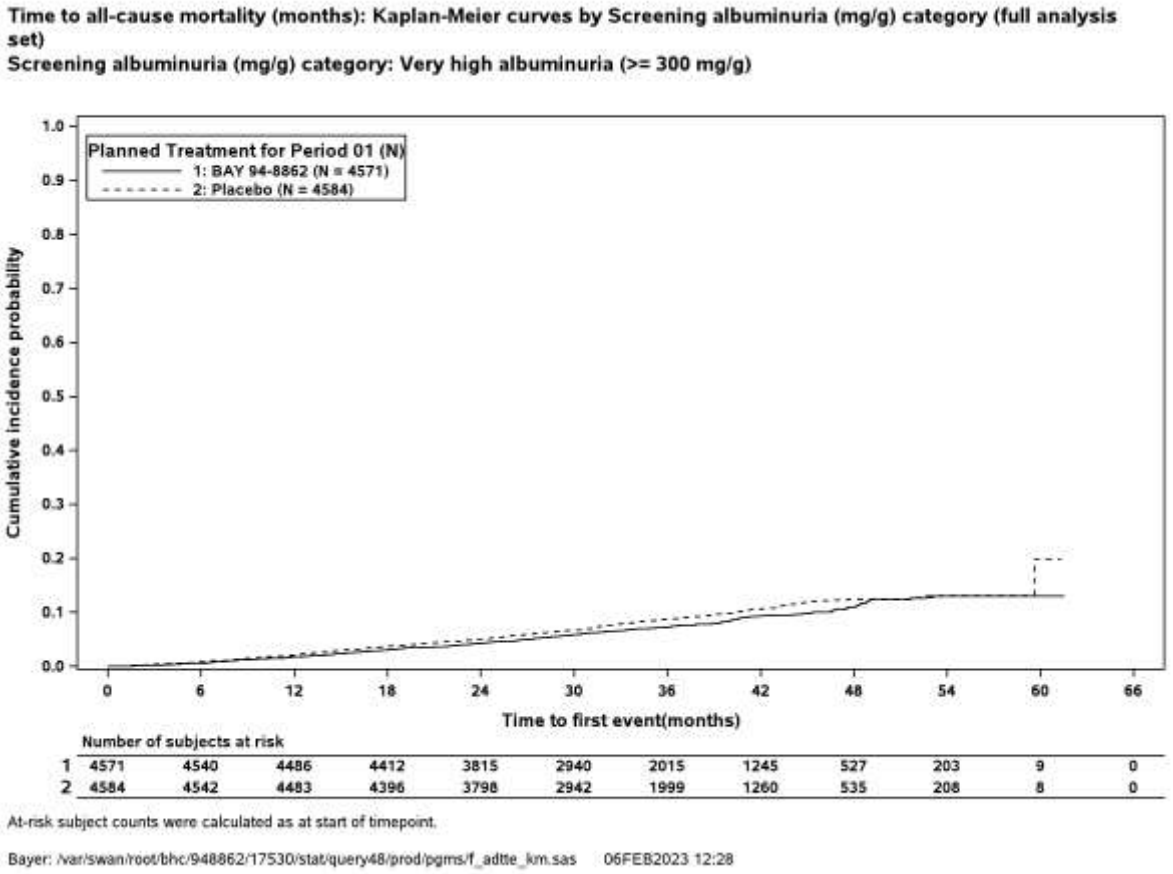


Figure 1.3.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

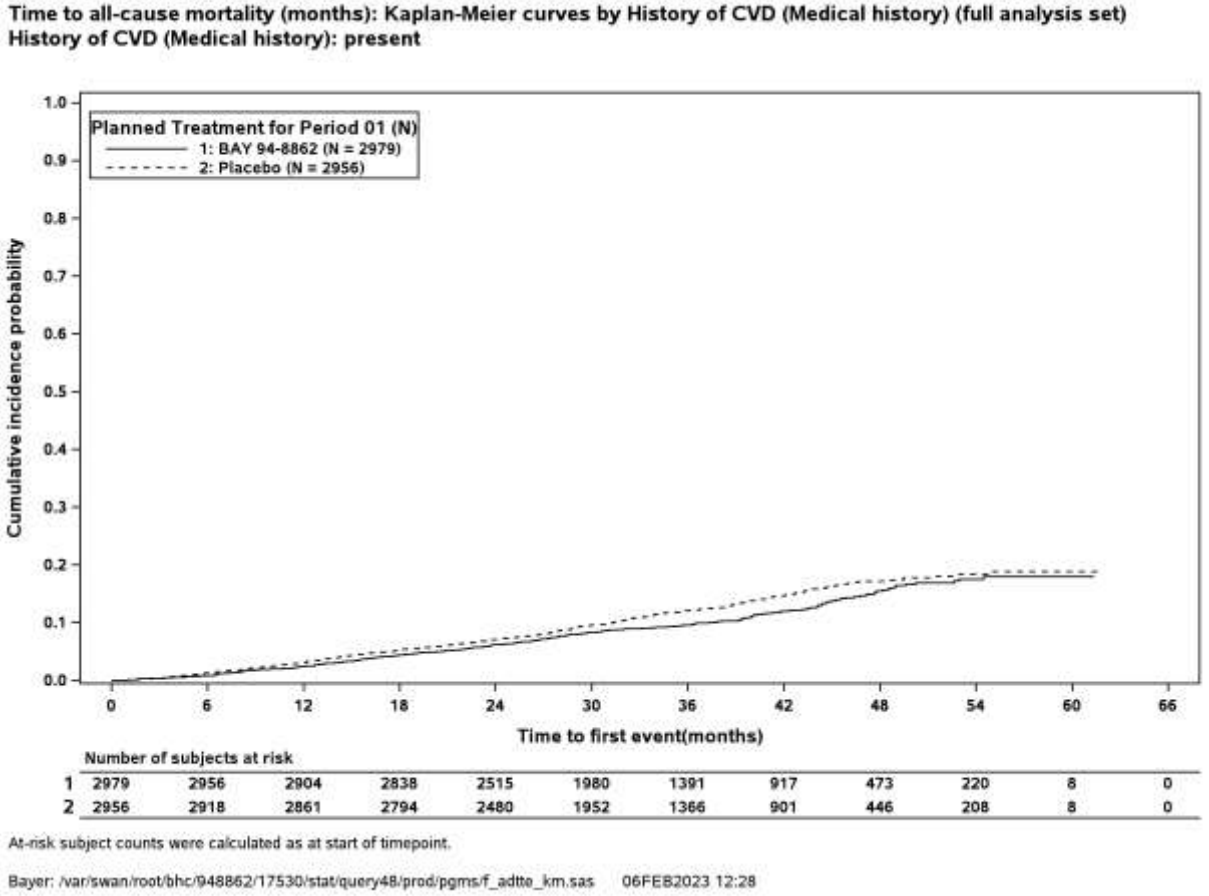


Figure 1.3.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

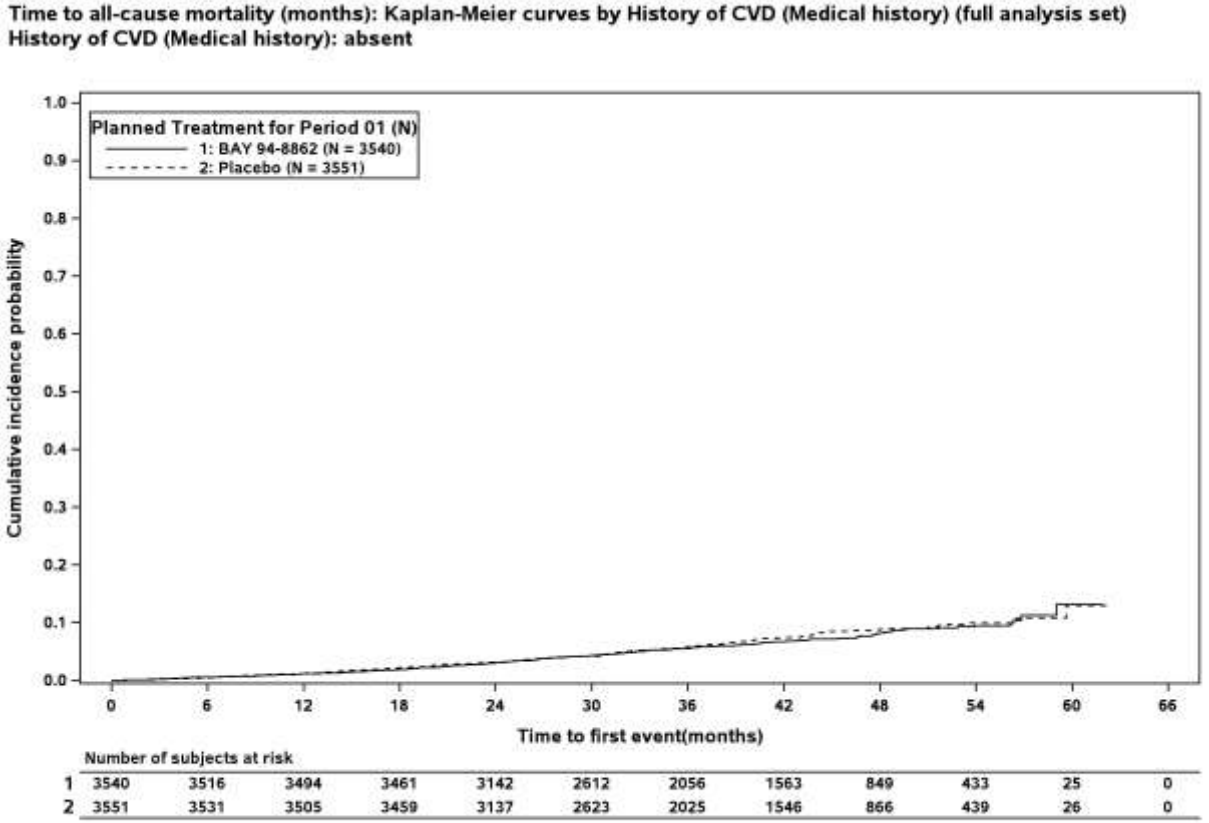


Figure 1.3.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

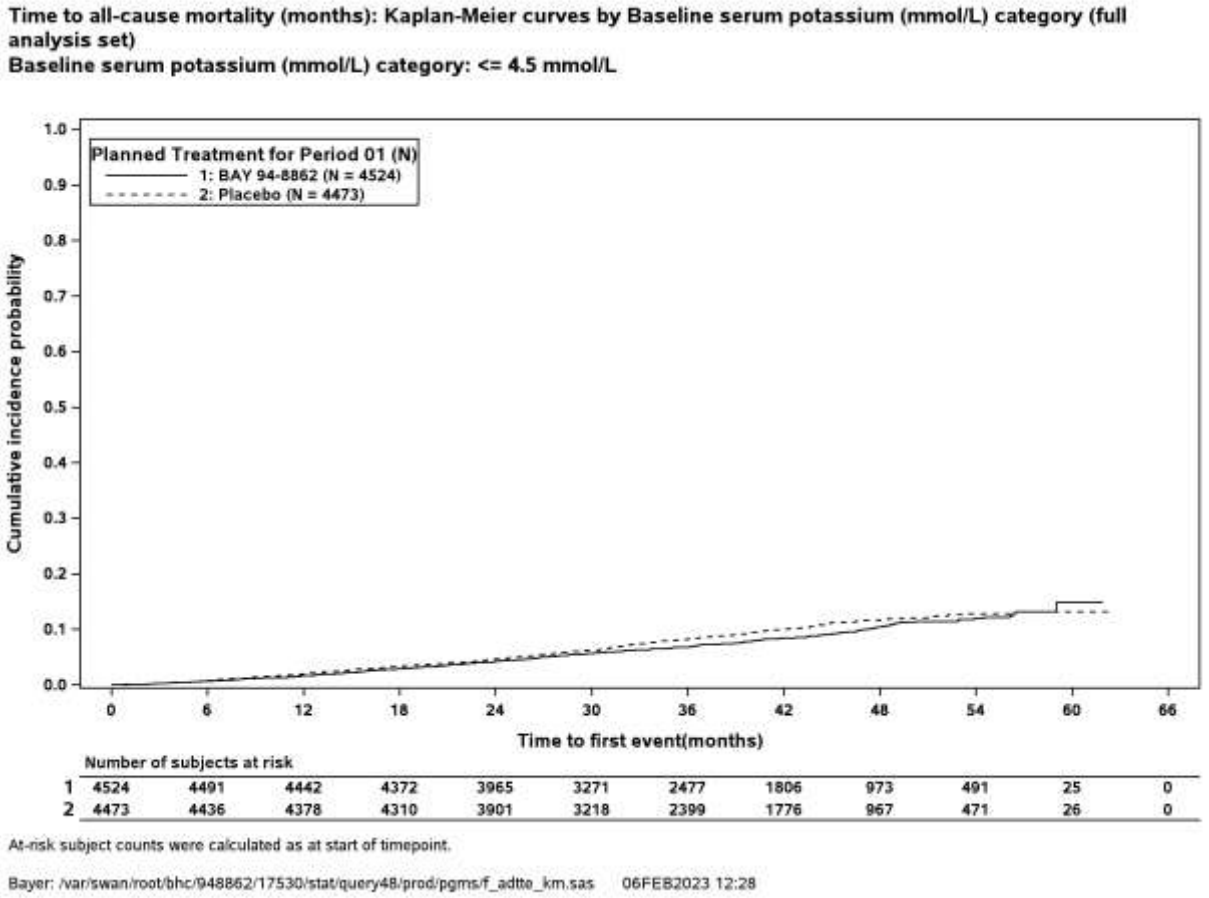
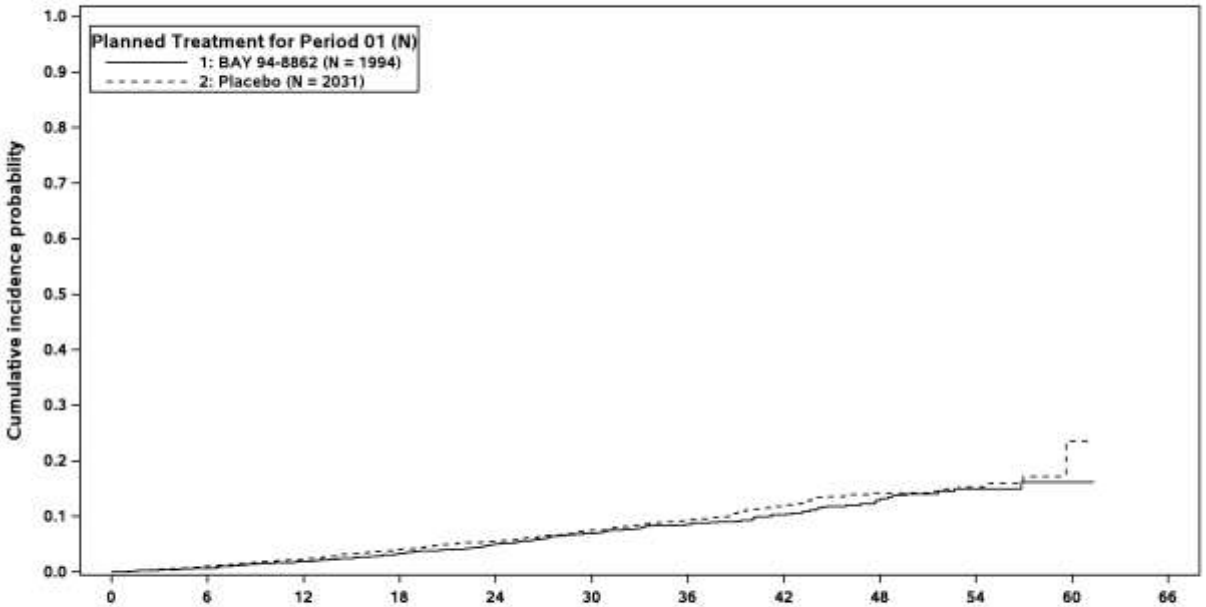


Figure 1.3.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1994	1980	1955	1926	1691	1321	970	674	349	162	8	0
2	2031	2010	1985	1940	1713	1355	991	670	344	175	8	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

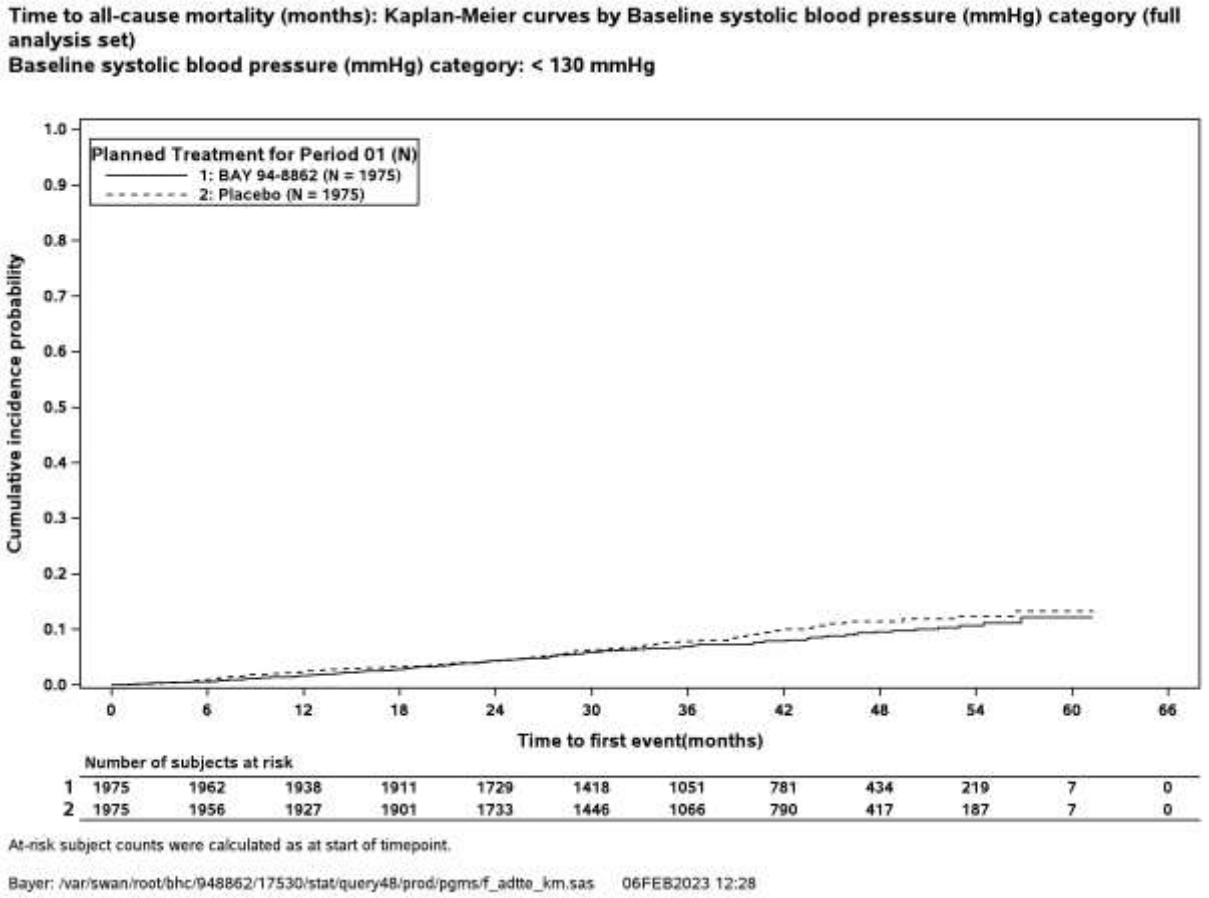


Figure 1.3.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

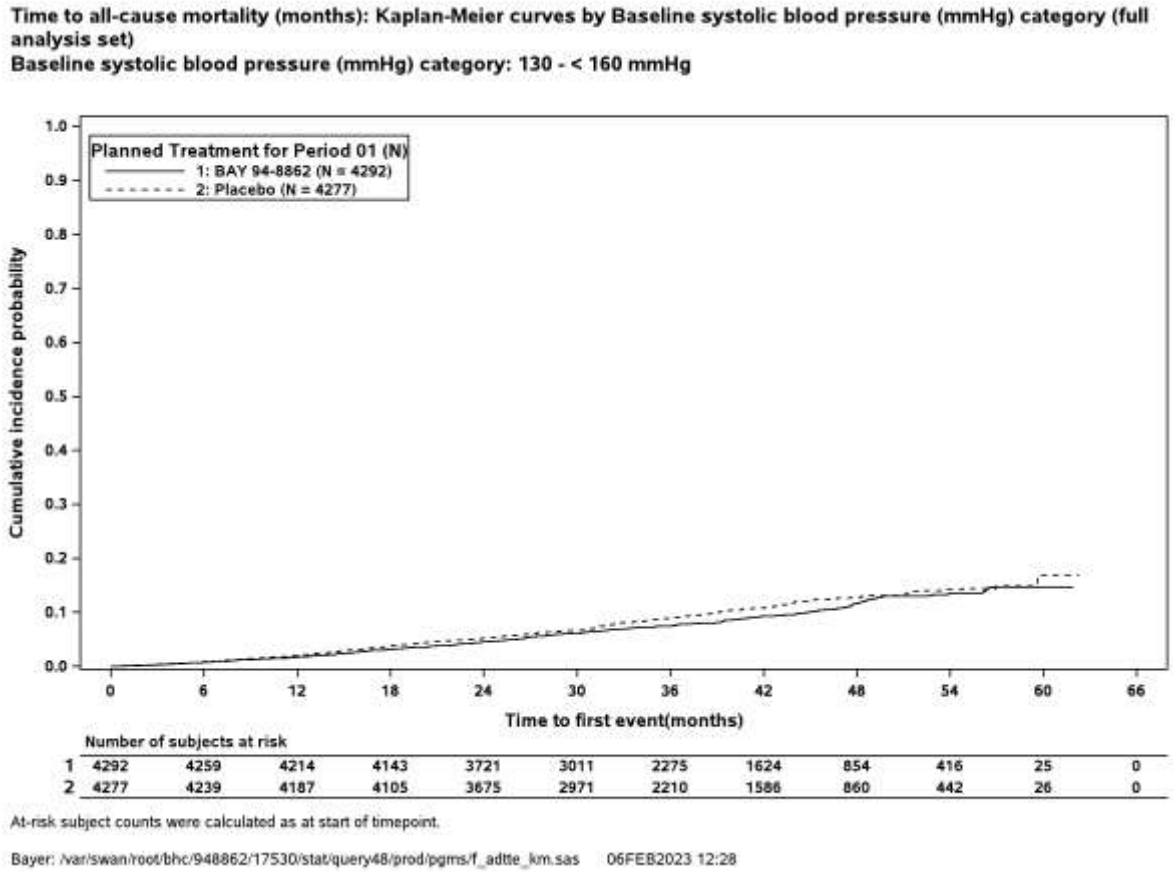


Figure 1.3.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

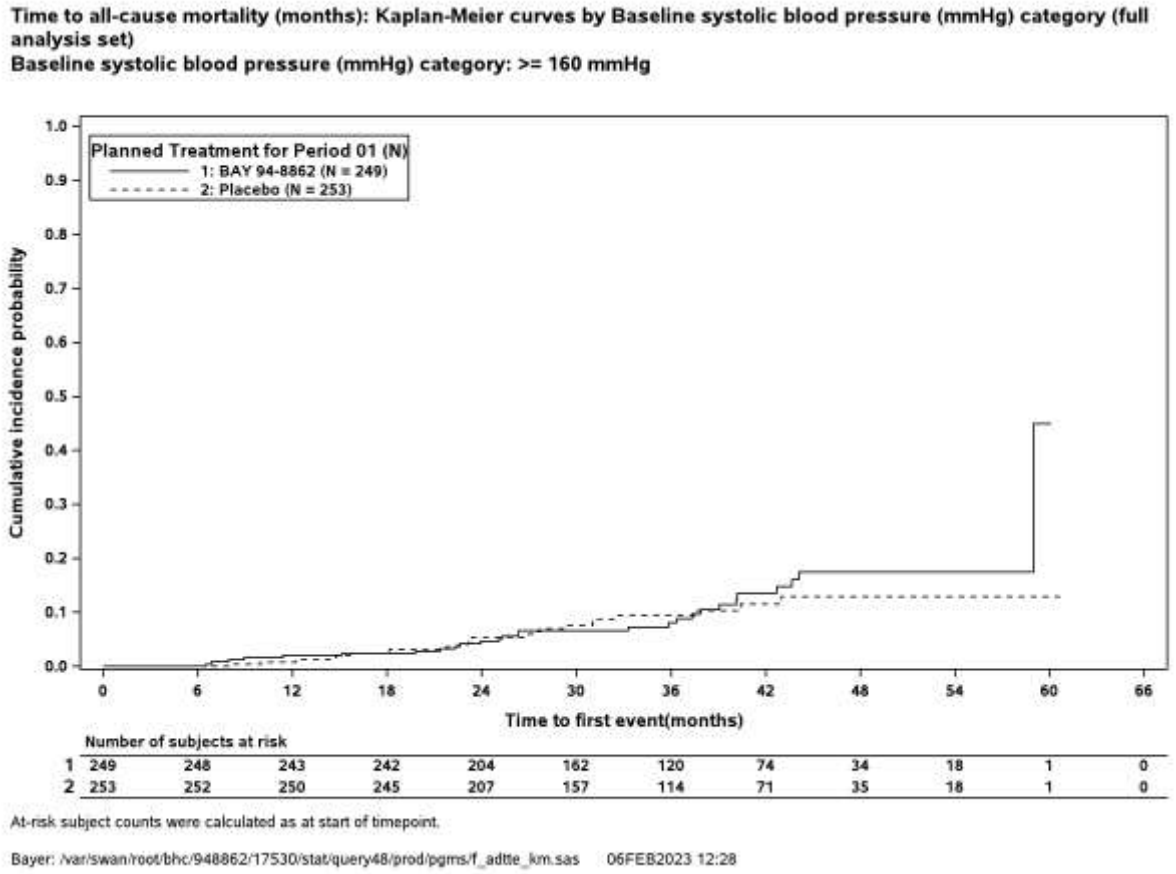


Figure 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

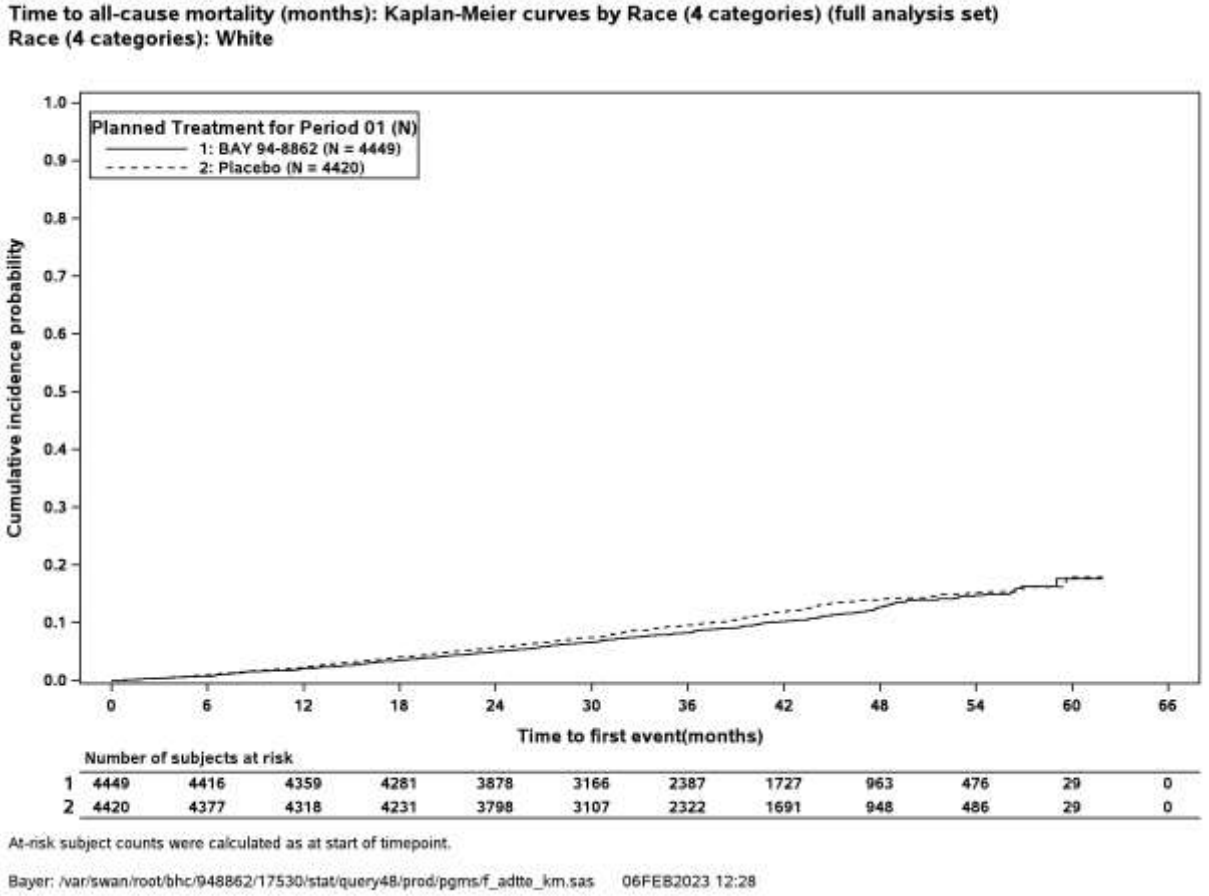


Figure 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

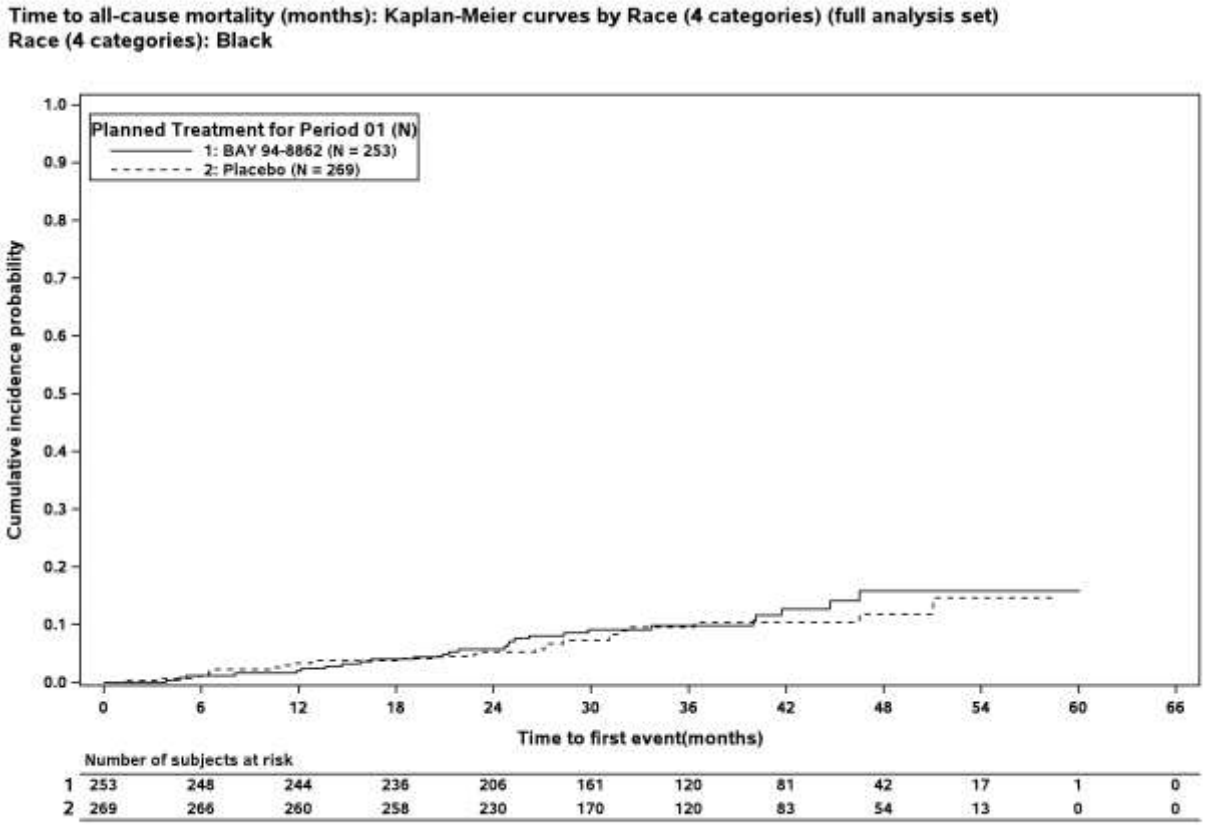


Figure 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

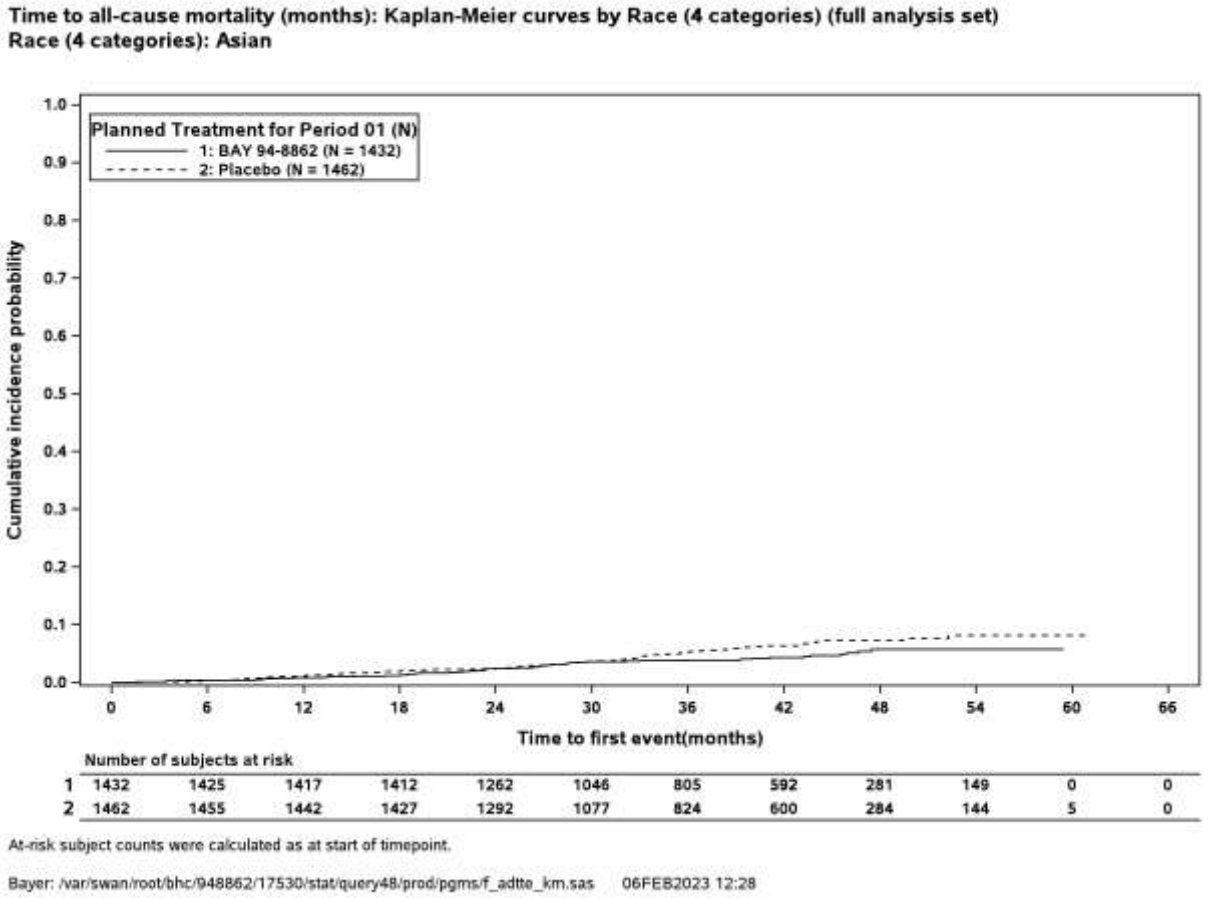


Figure 1.3.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

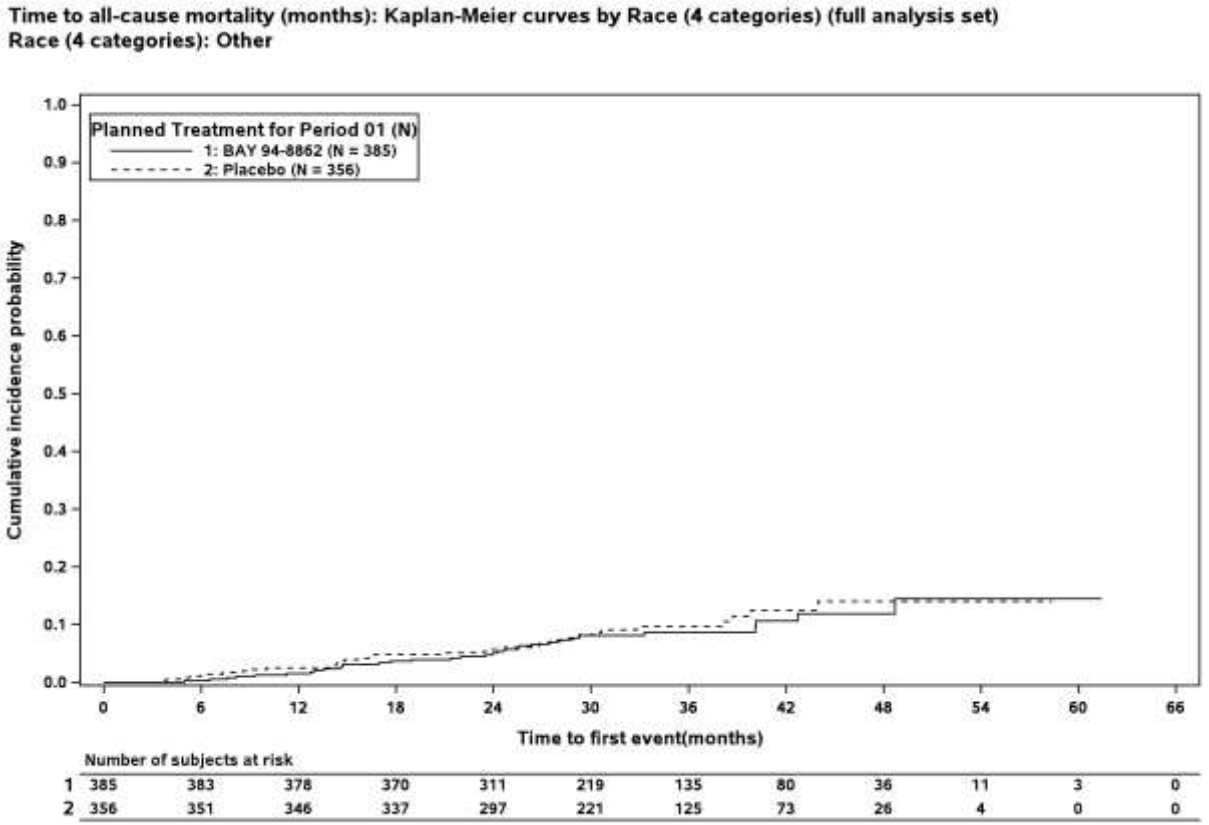


Figure 1.3.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

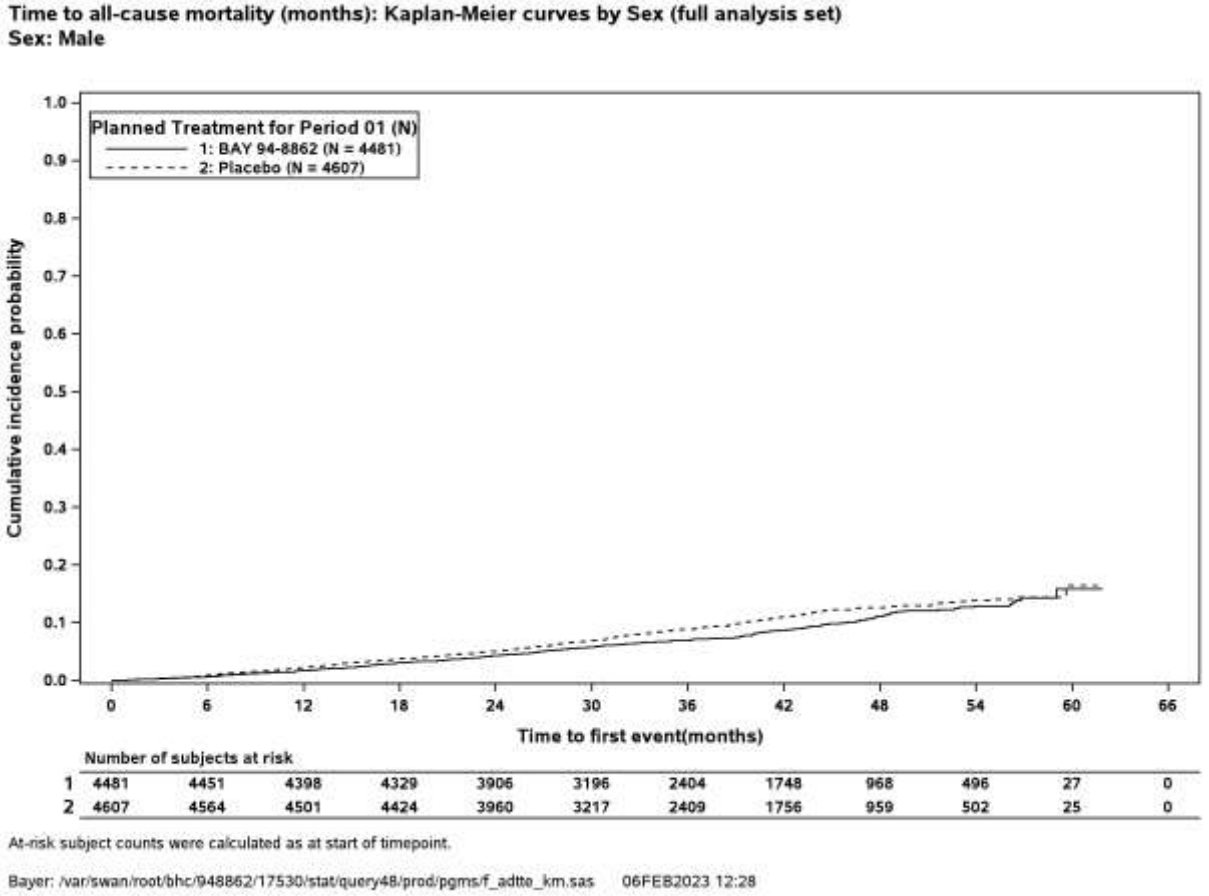


Figure 1.3.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

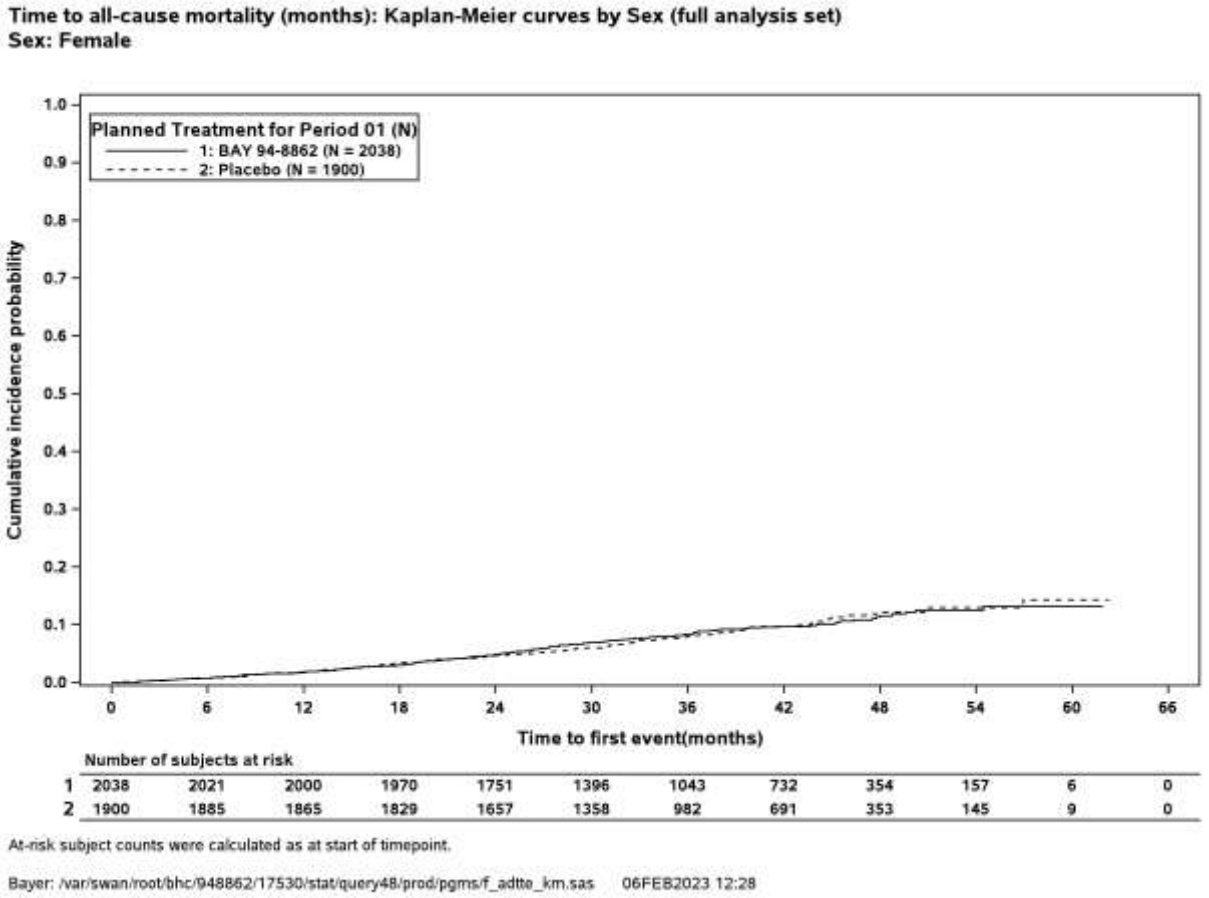


Figure 1.3.1 / 10: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

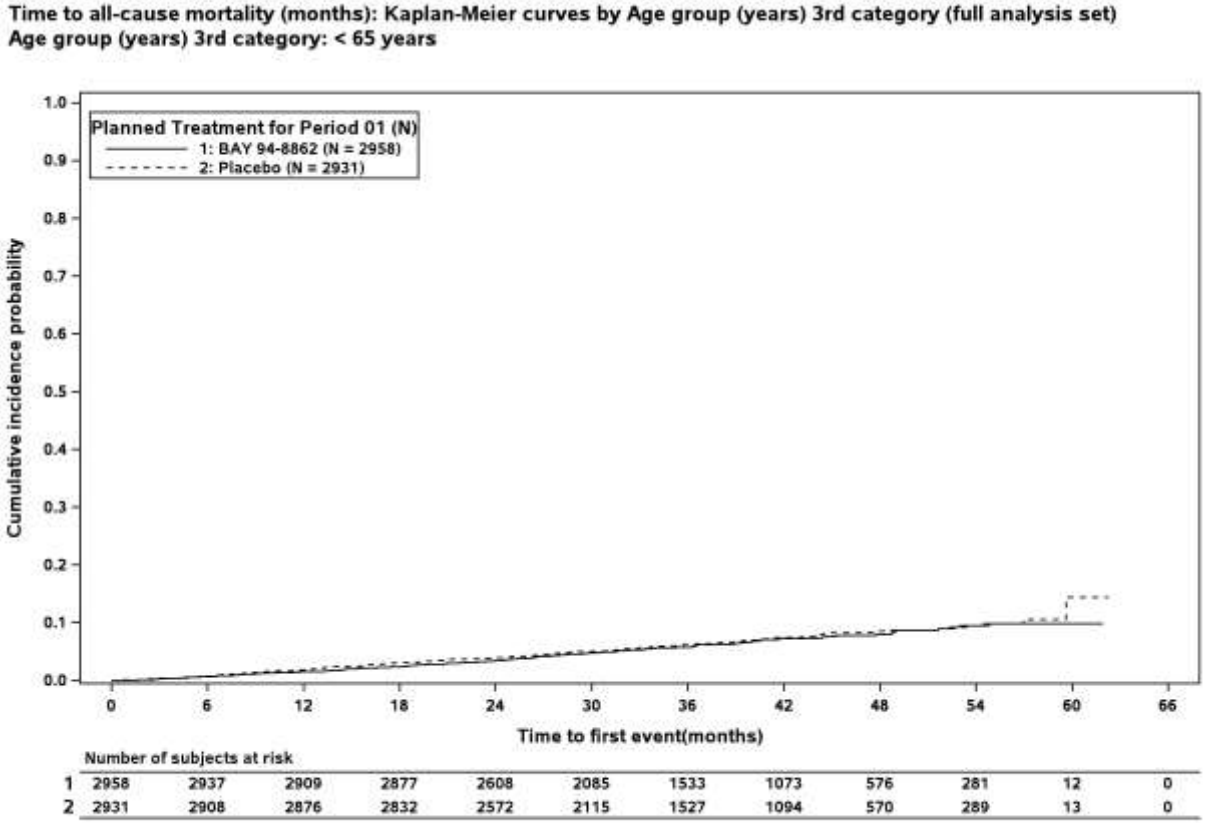


Figure 1.3.1 / 10: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

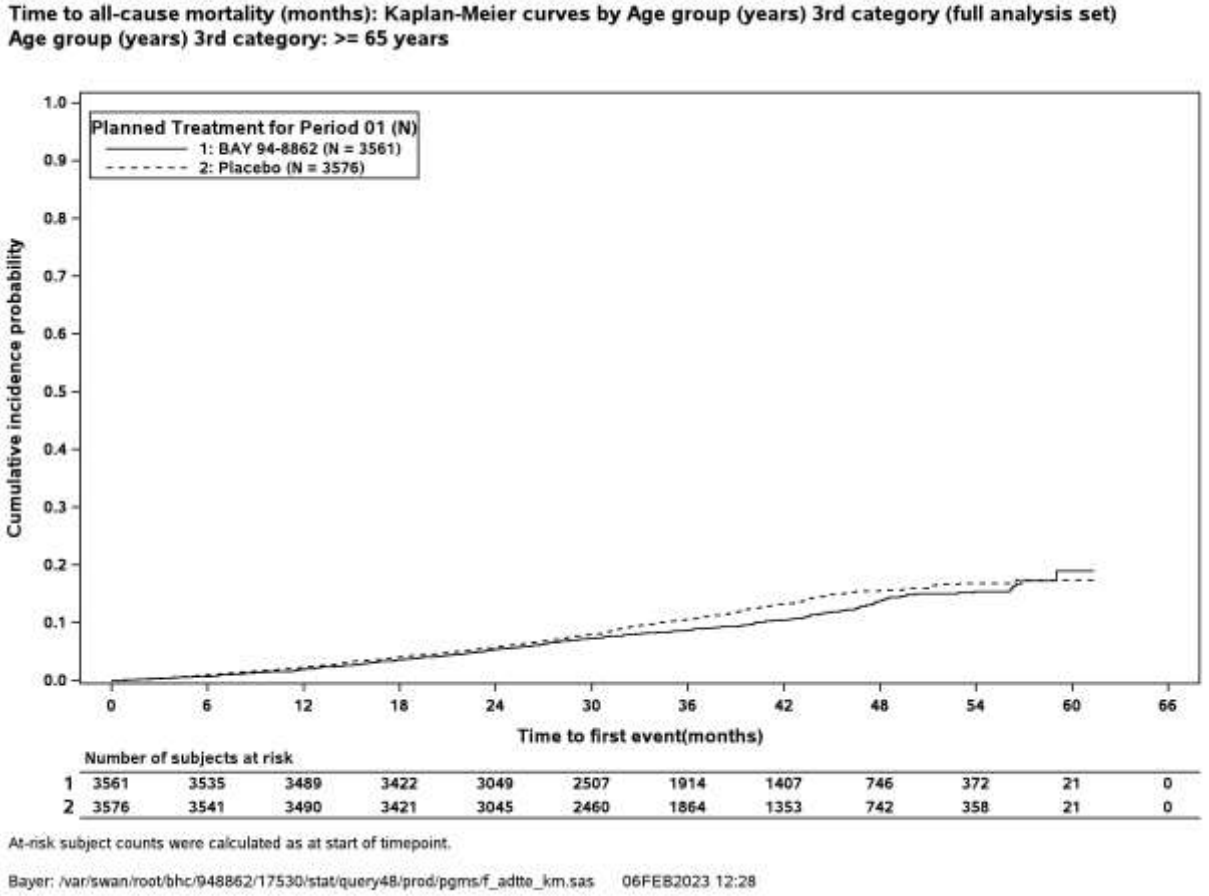


Figure 1.3.1 / 11: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set)

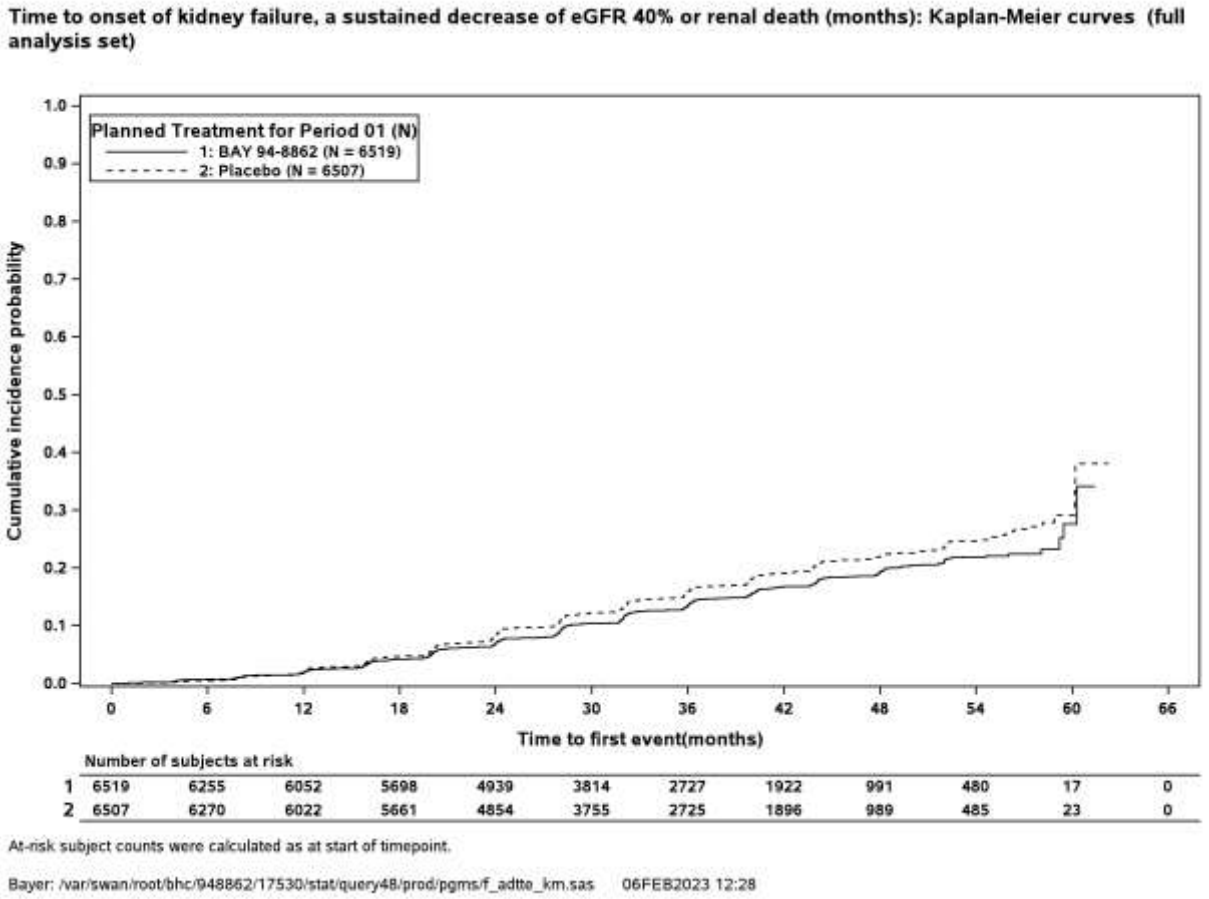


Figure 1.3.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set)

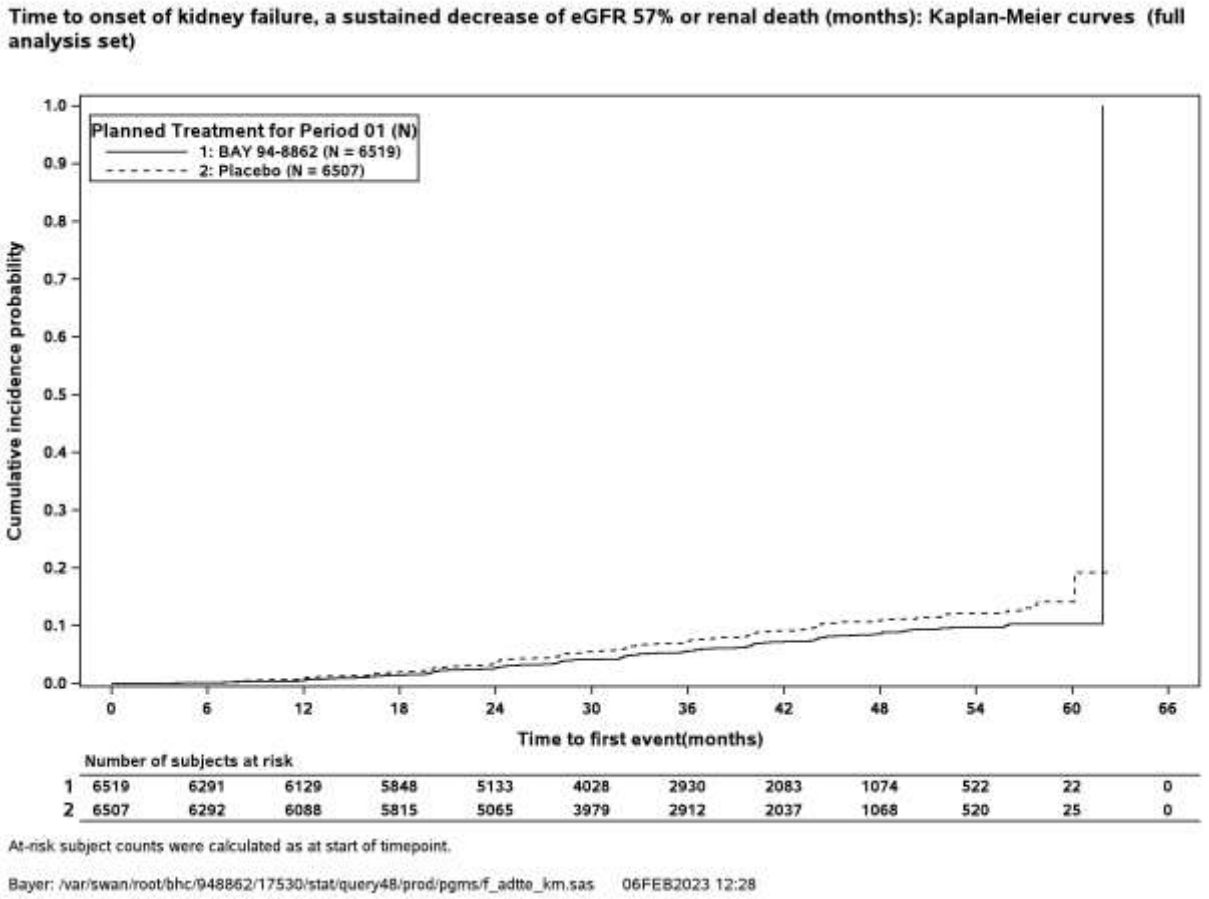


Figure 1.3.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

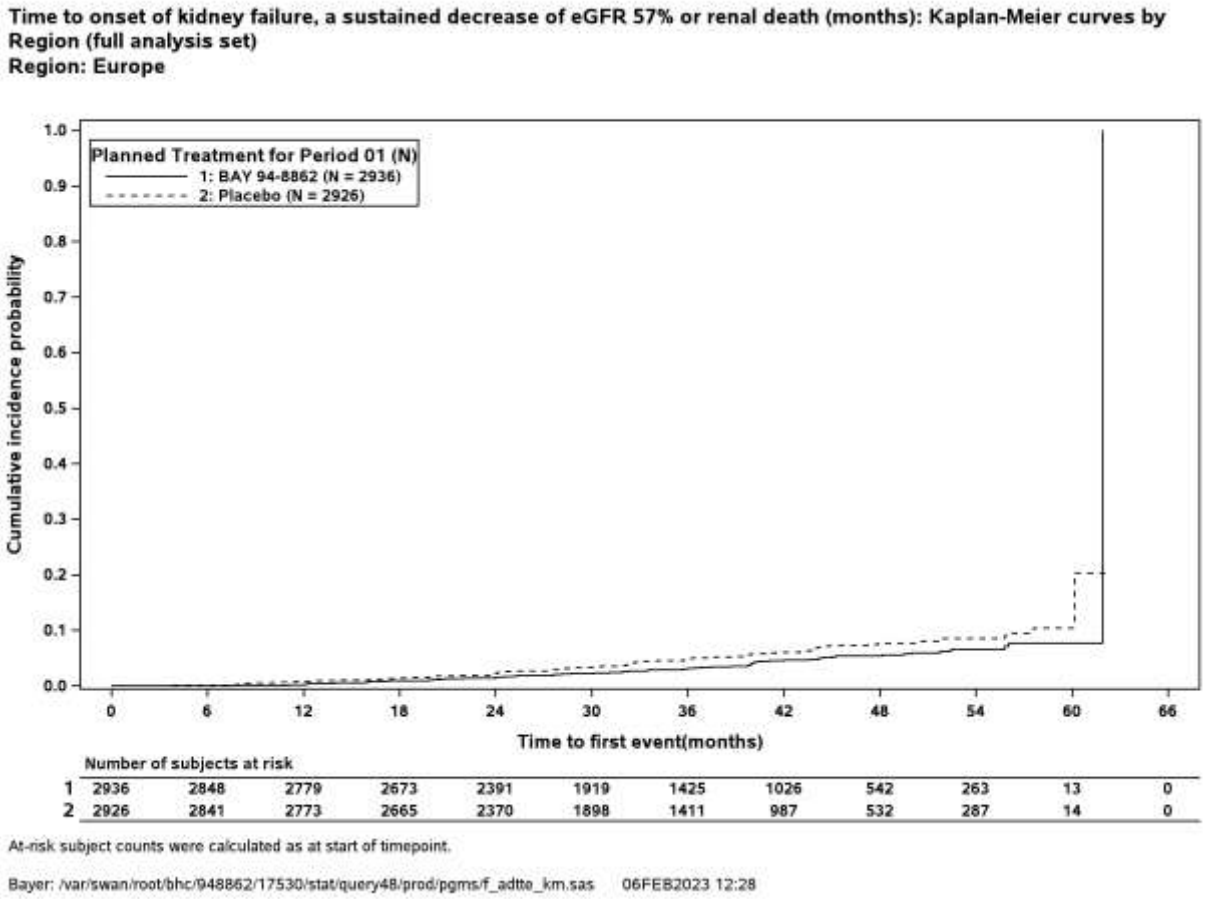


Figure 1.3.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

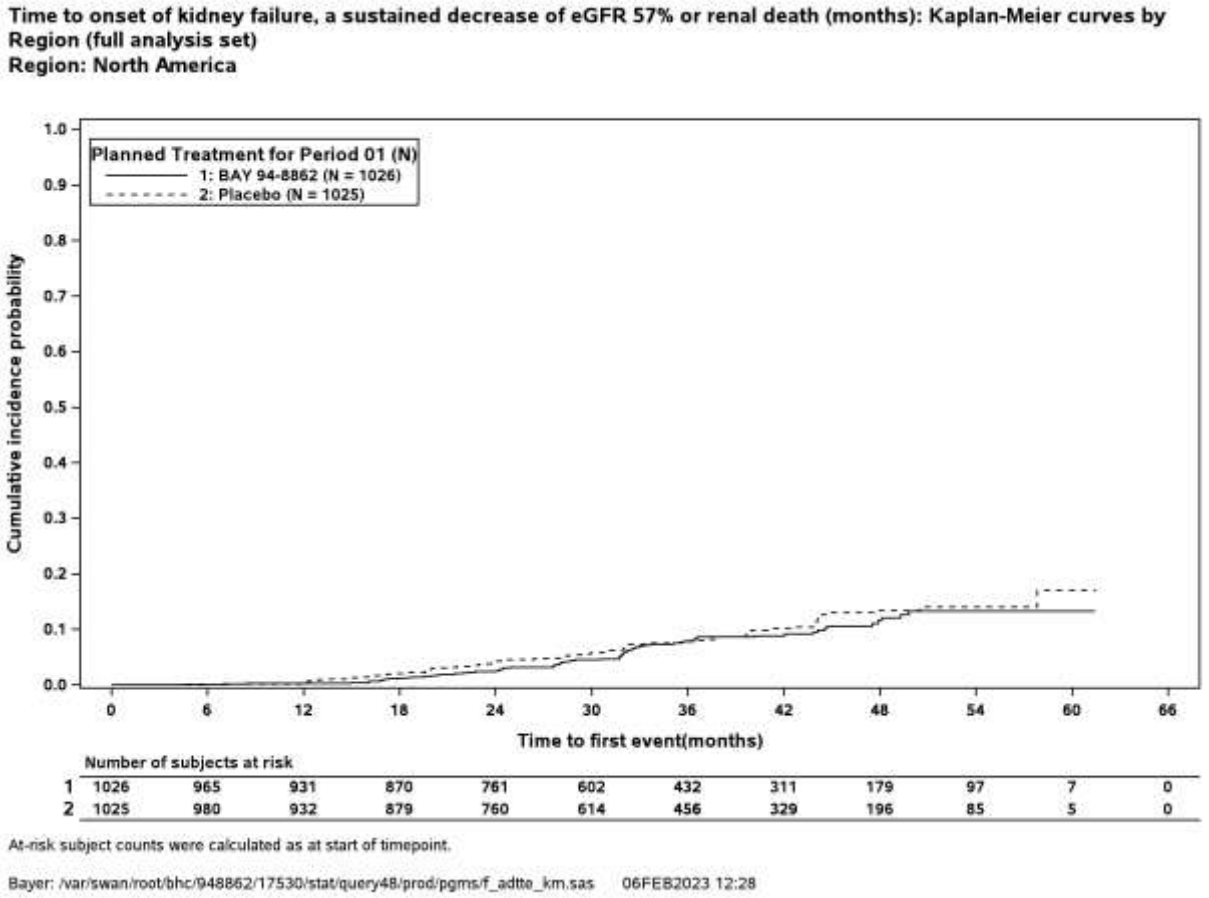


Figure 1.3.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

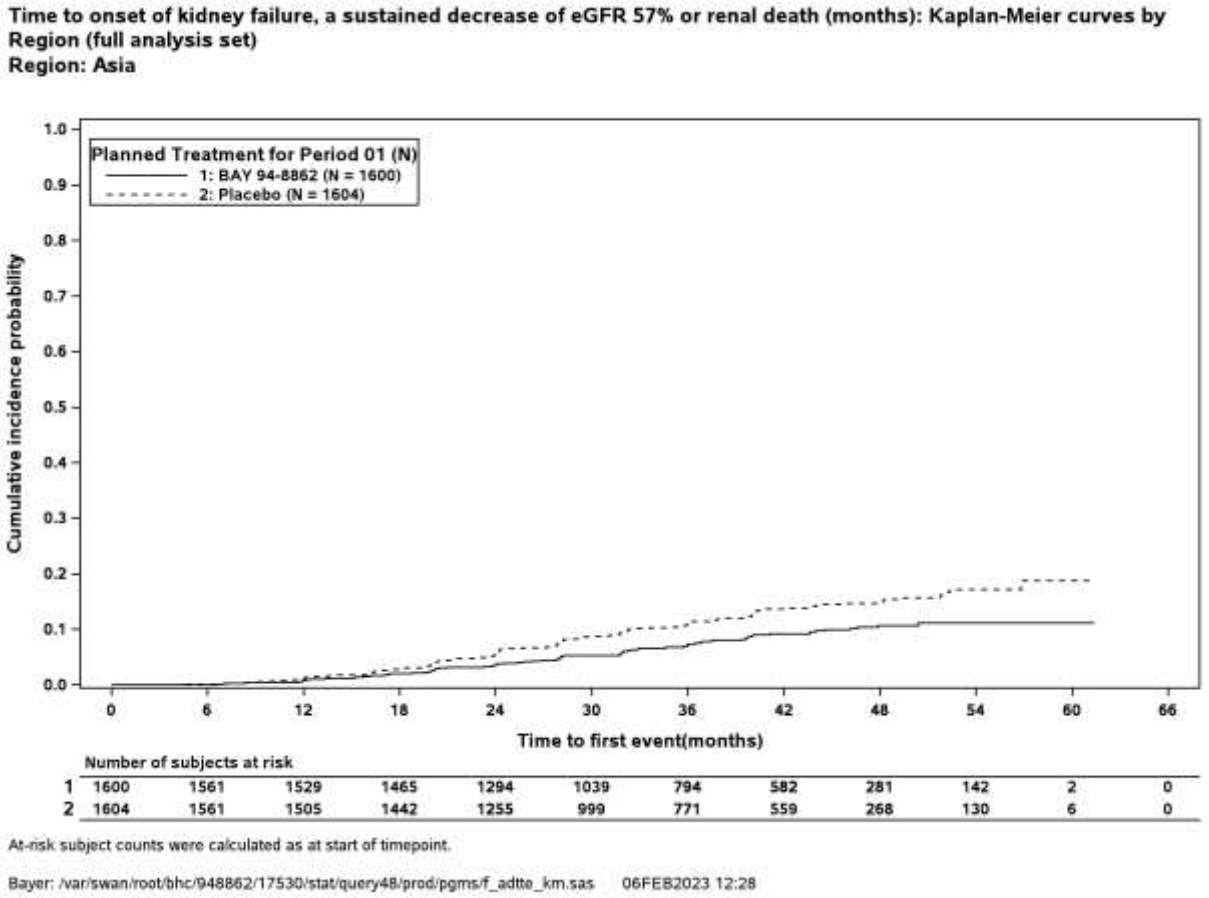


Figure 1.3.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

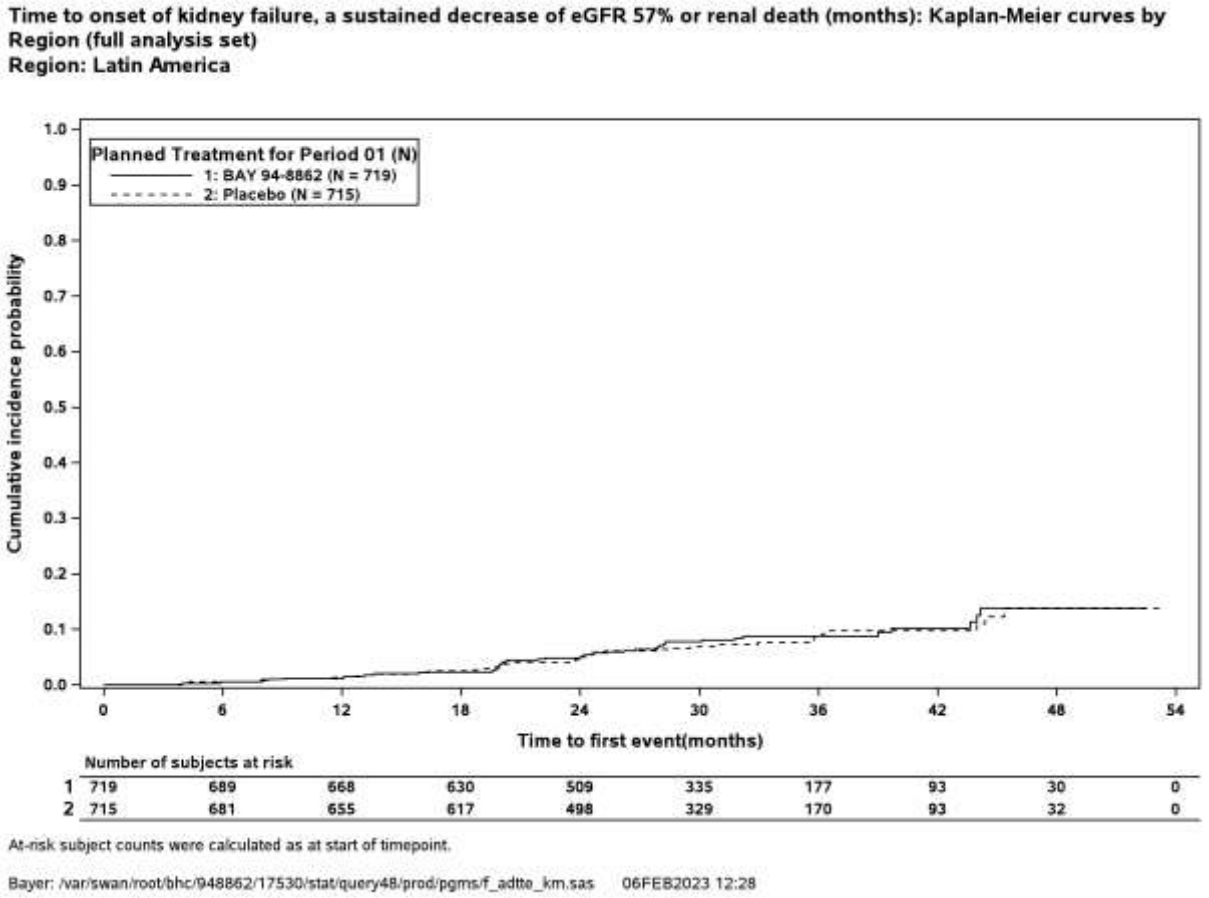


Figure 1.3.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

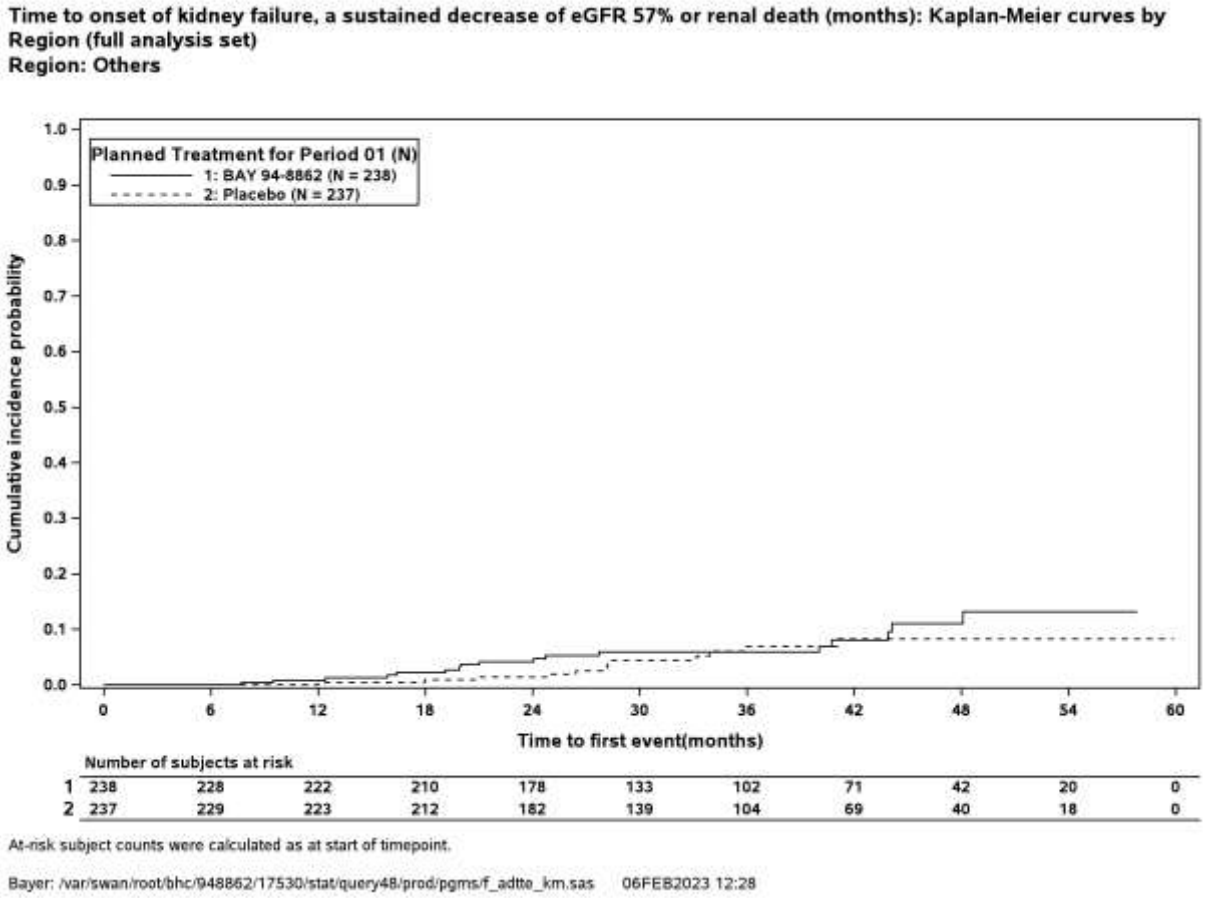


Figure 1.3.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

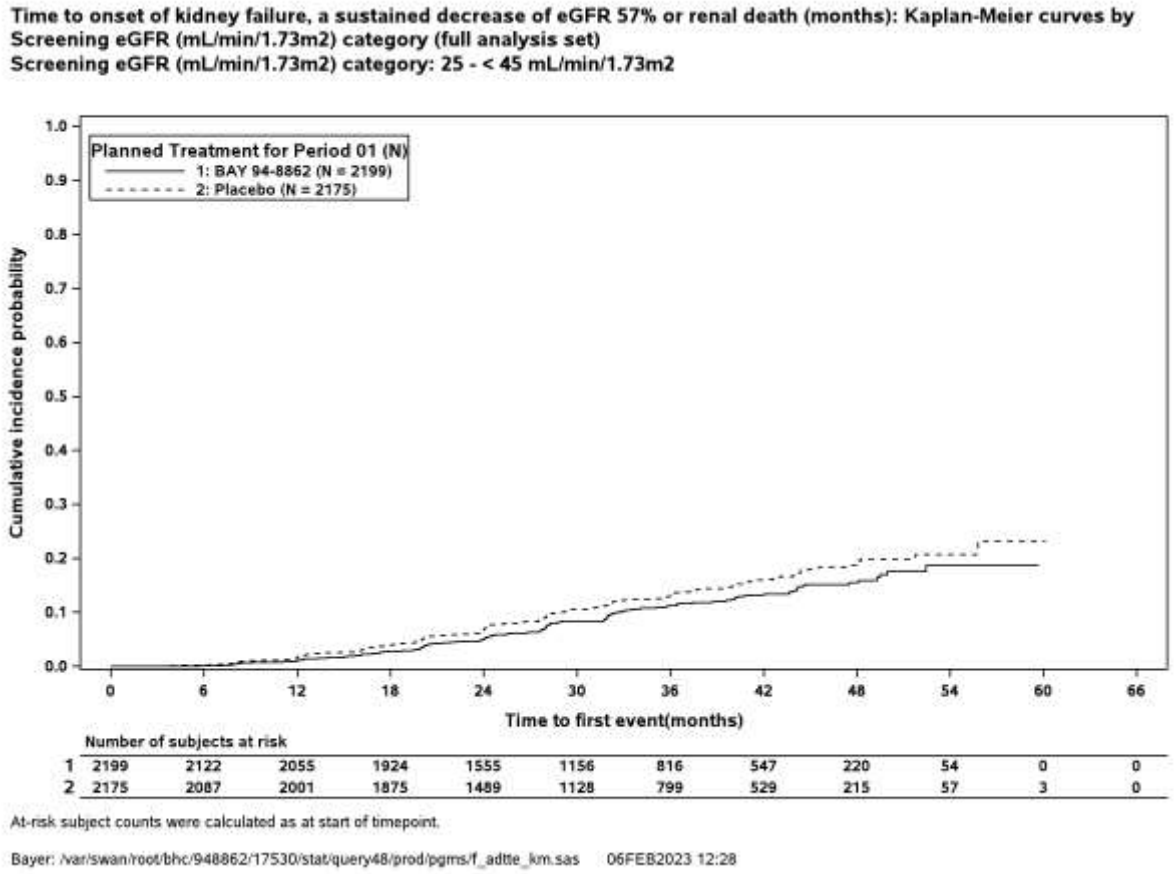


Figure 1.3.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

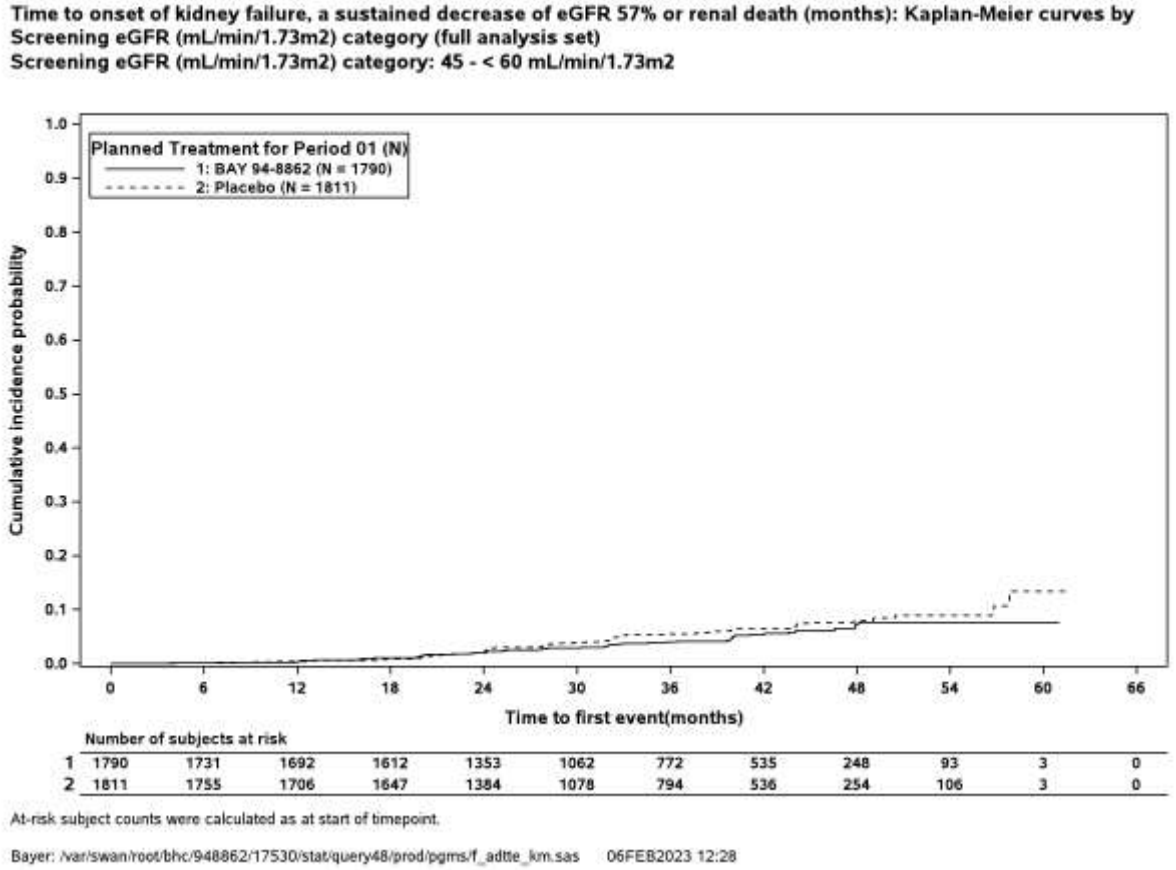


Figure 1.3.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

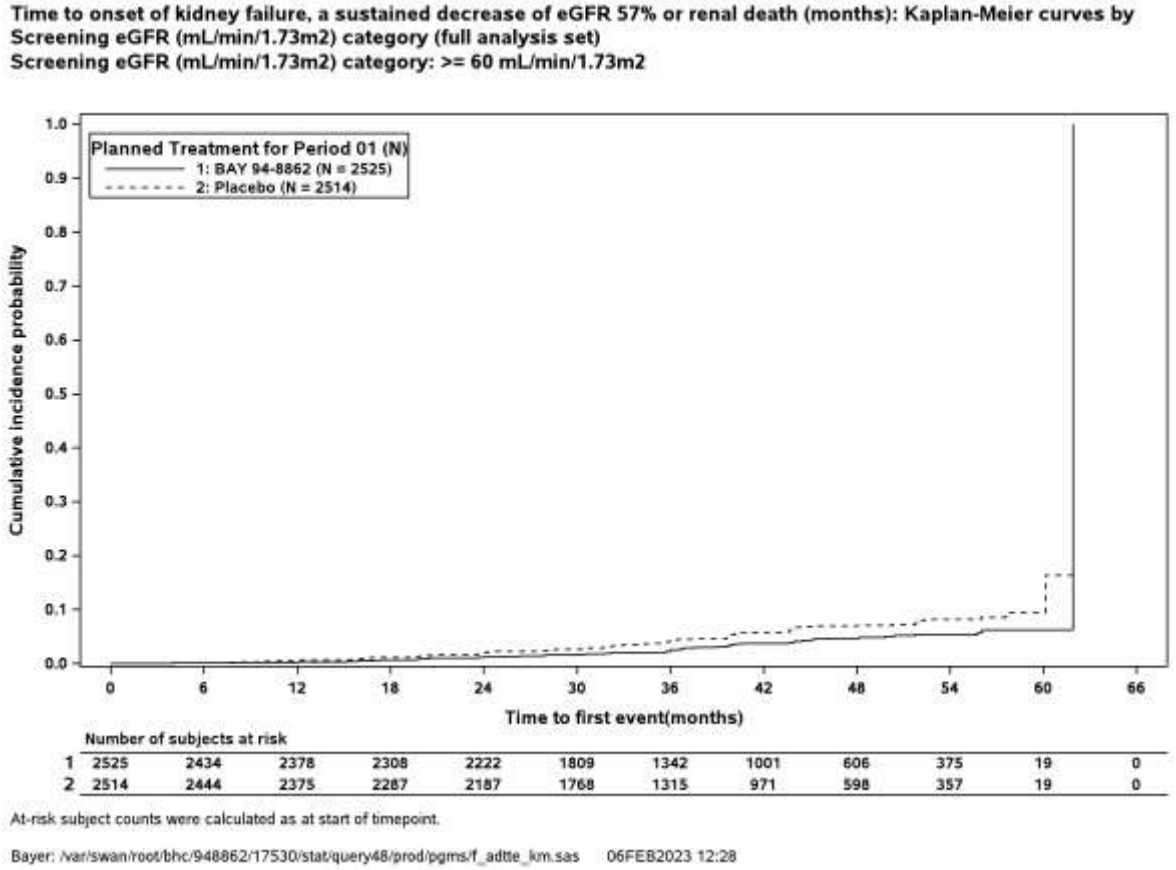


Figure 1.3.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

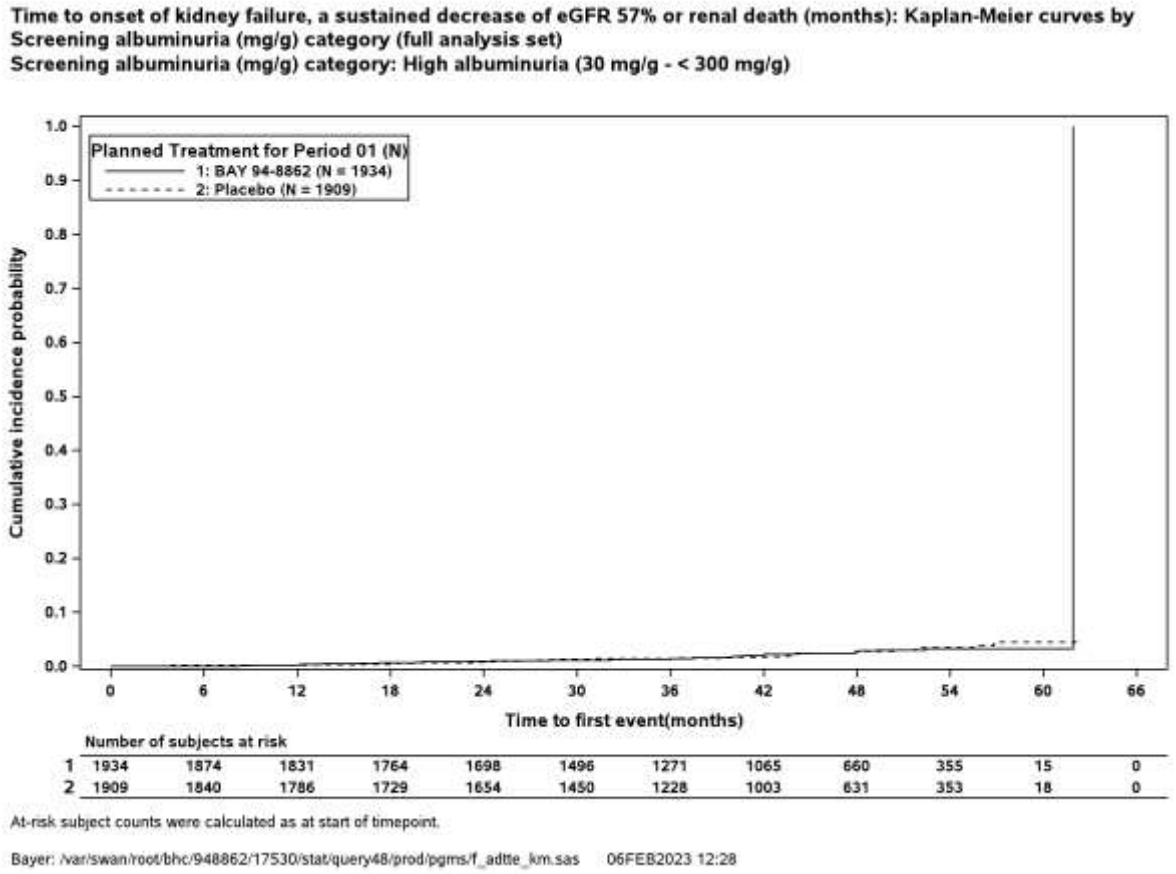
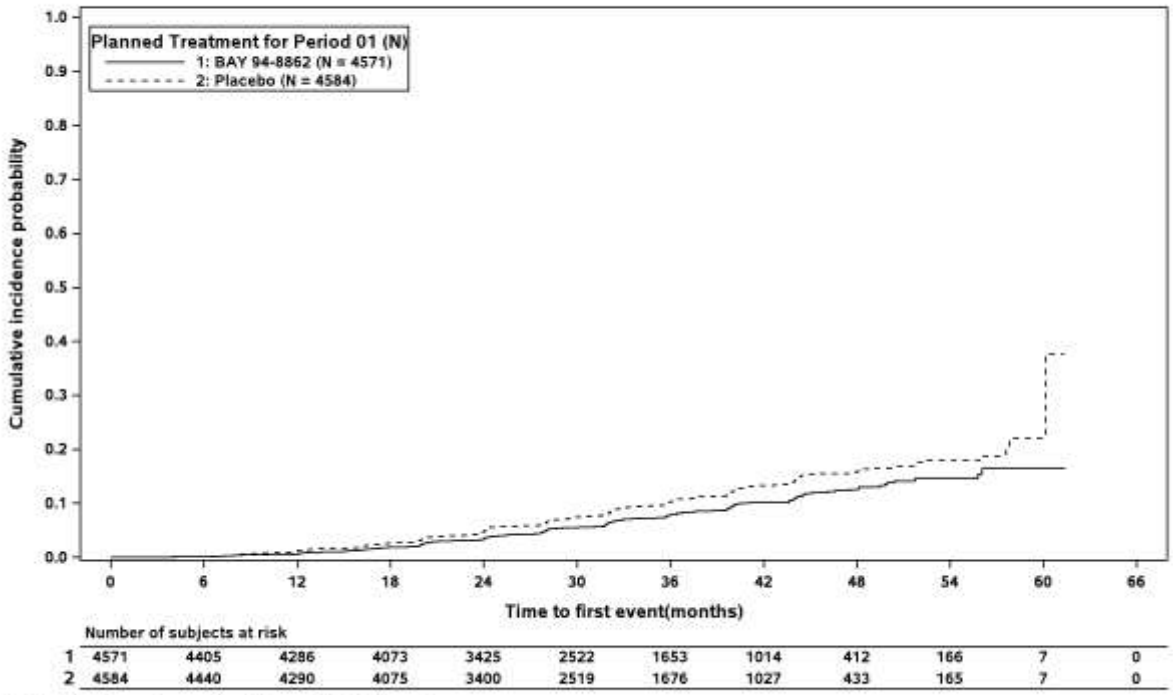


Figure 1.3.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4405	4286	4073	3425	2522	1653	1014	412	166	7	0
2	4584	4440	4290	4075	3400	2519	1676	1027	433	165	7	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

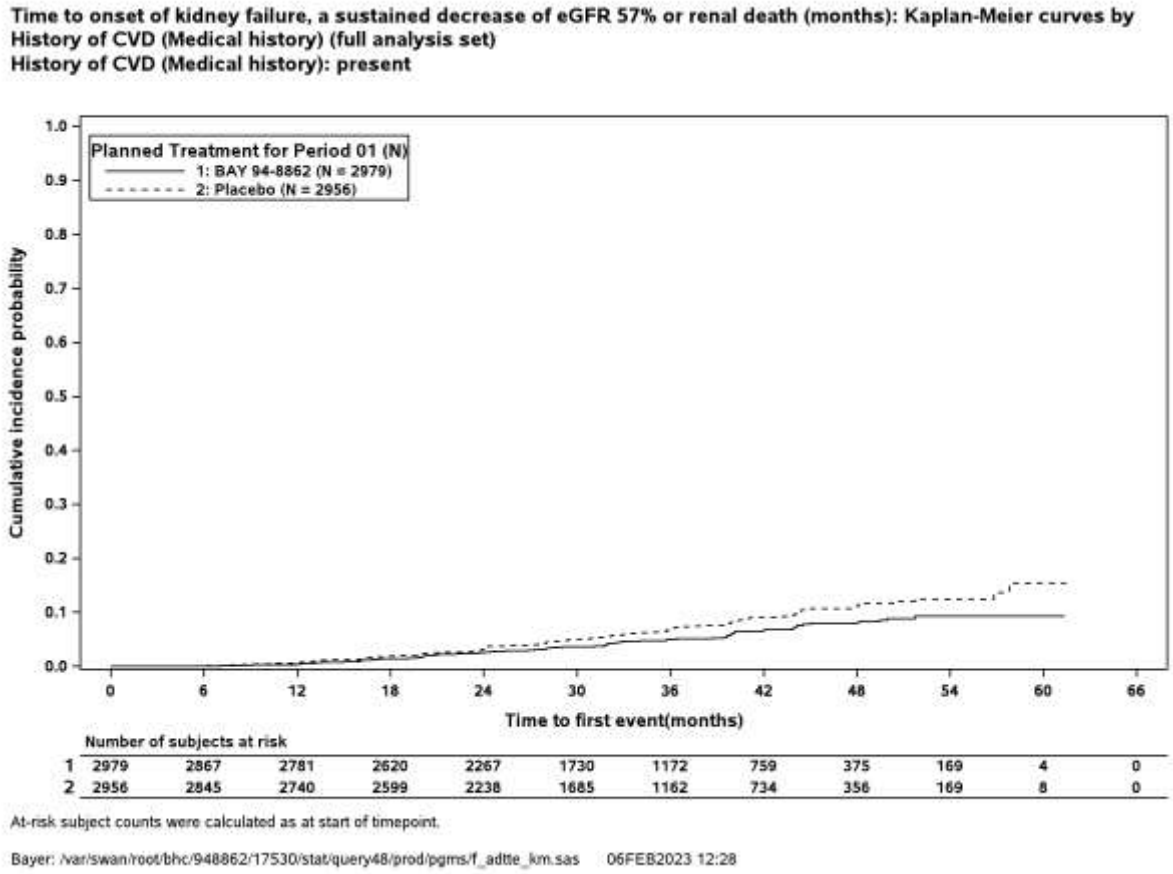
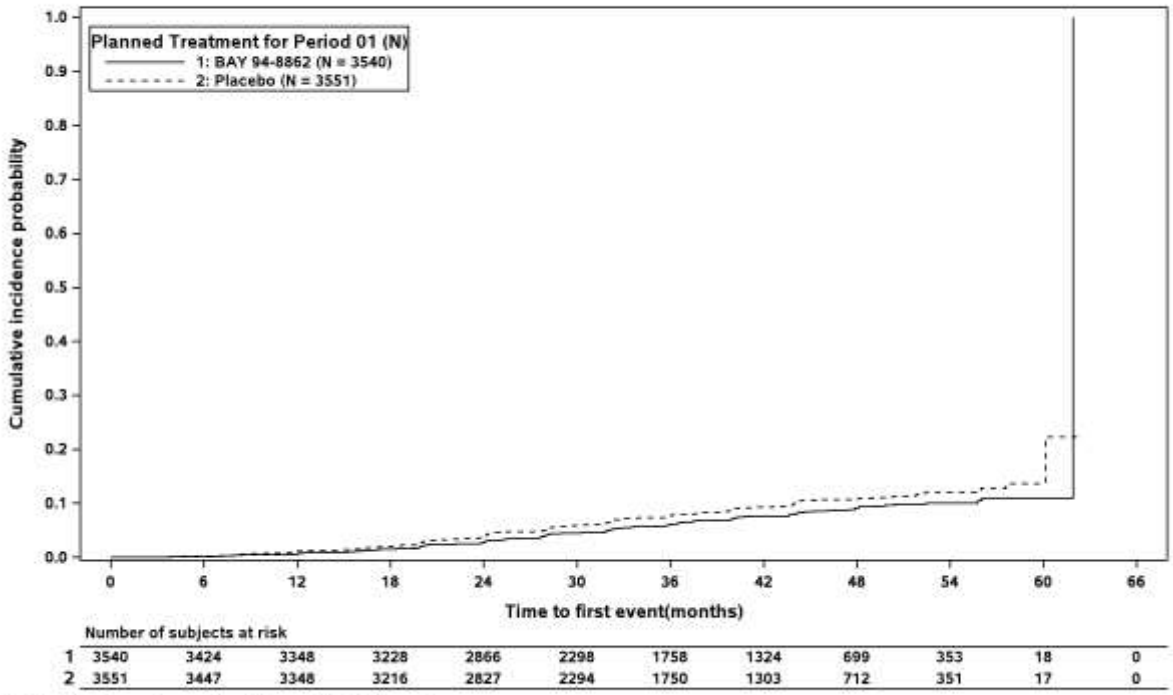


Figure 1.3.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)
History of CVD (Medical history): absent



Number of subjects at risk

1	3540	3424	3348	3228	2866	2298	1758	1324	699	353	18	0
2	3551	3447	3348	3216	2827	2294	1750	1303	712	351	17	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

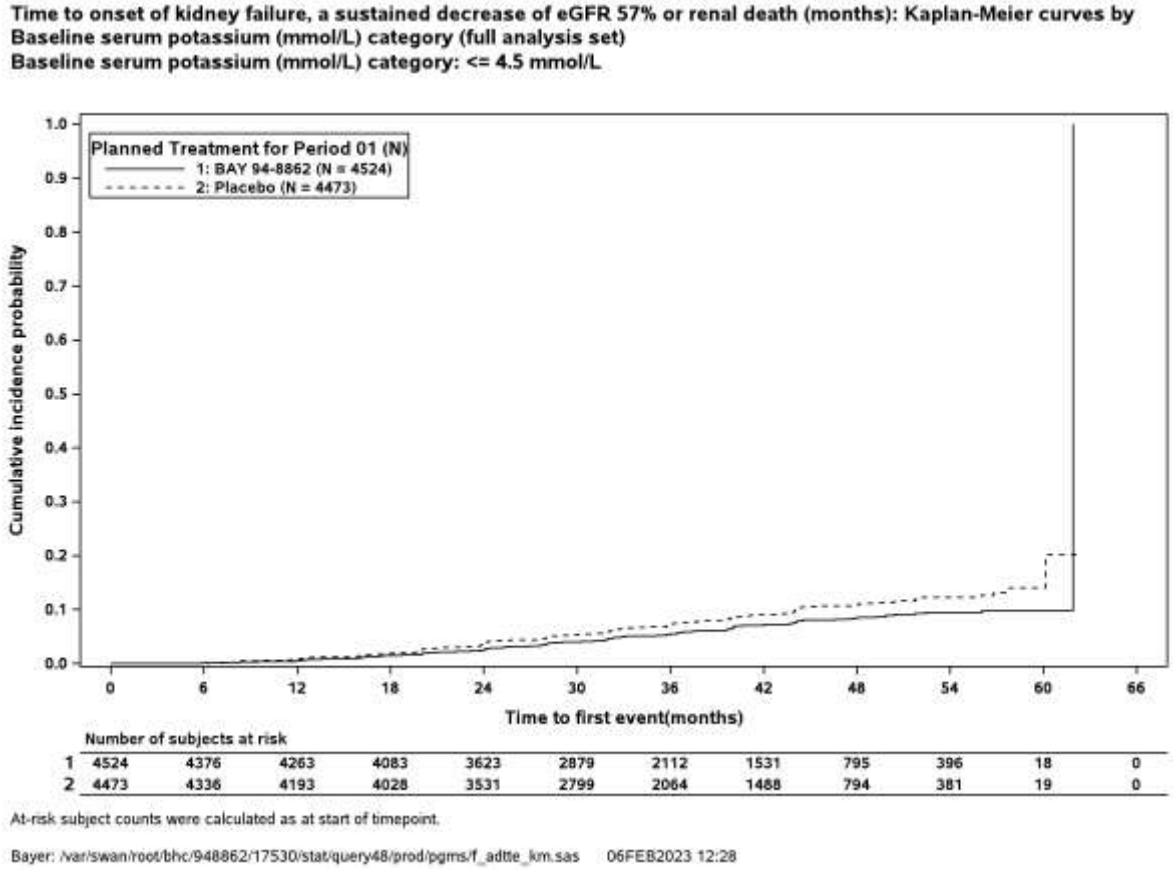
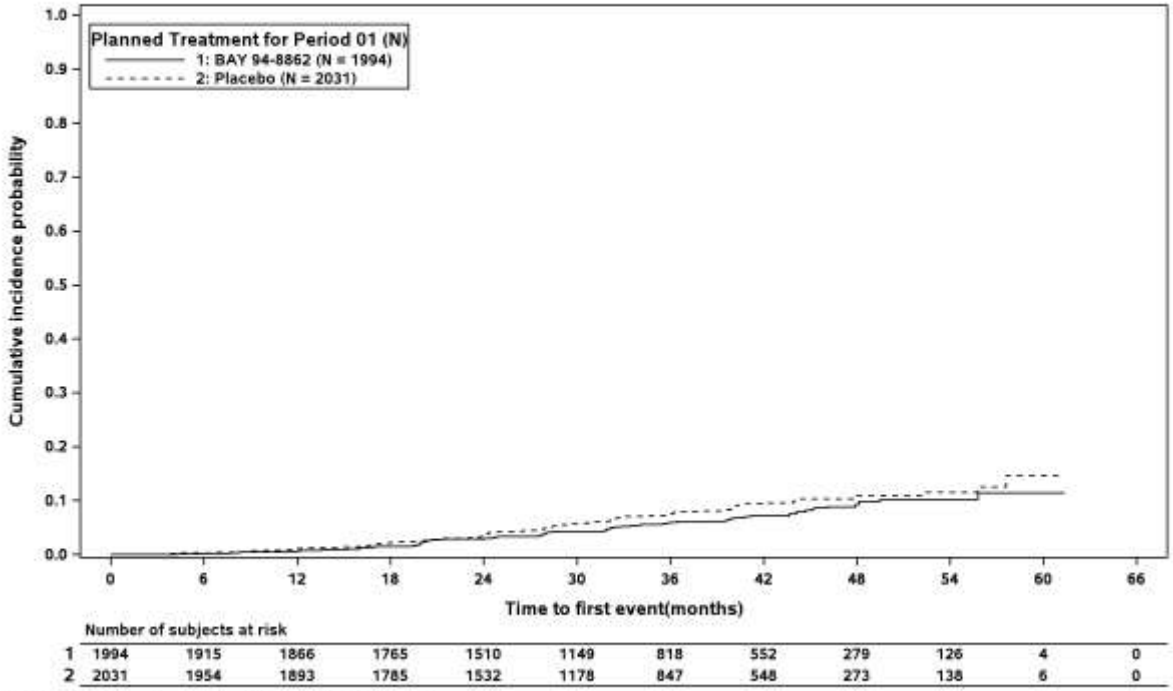


Figure 1.3.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1994	1915	1866	1765	1510	1149	818	552	279	126	4	0
2	2031	1954	1893	1785	1532	1178	847	548	273	138	6	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

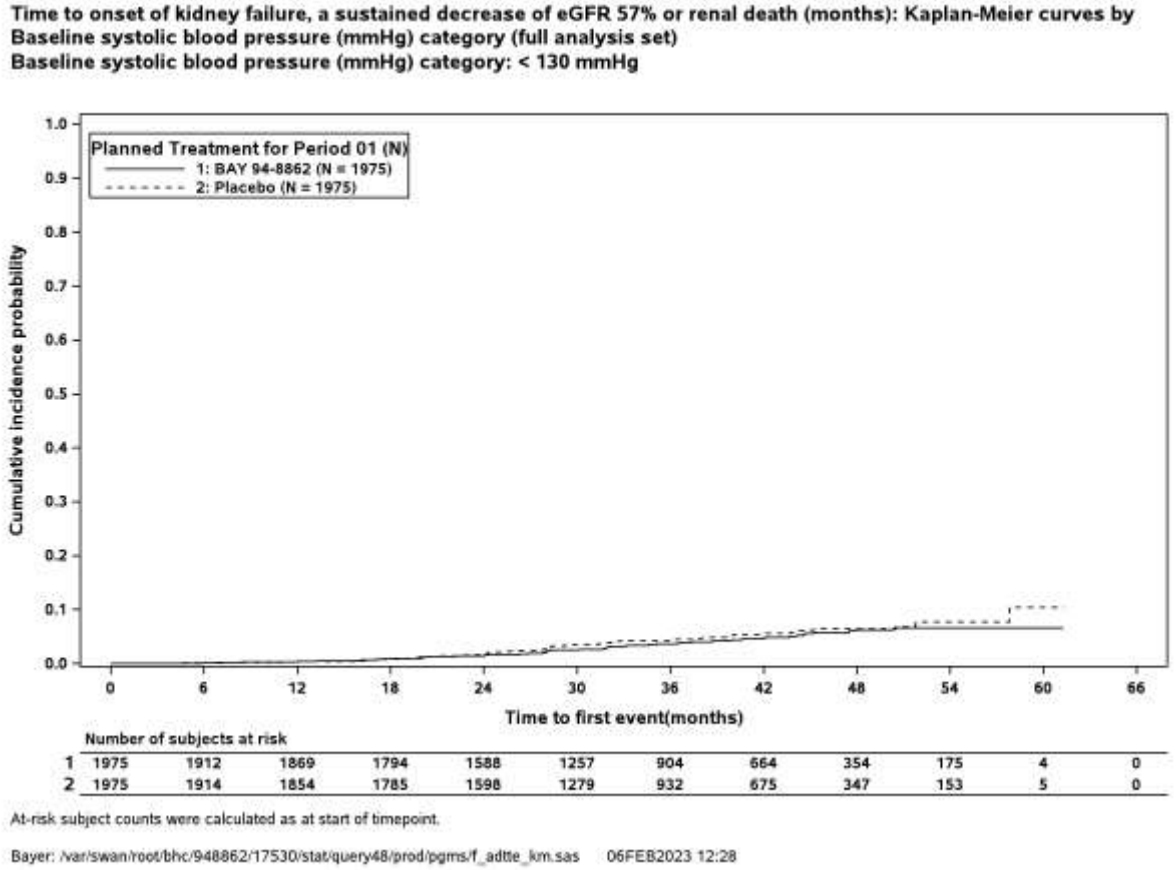
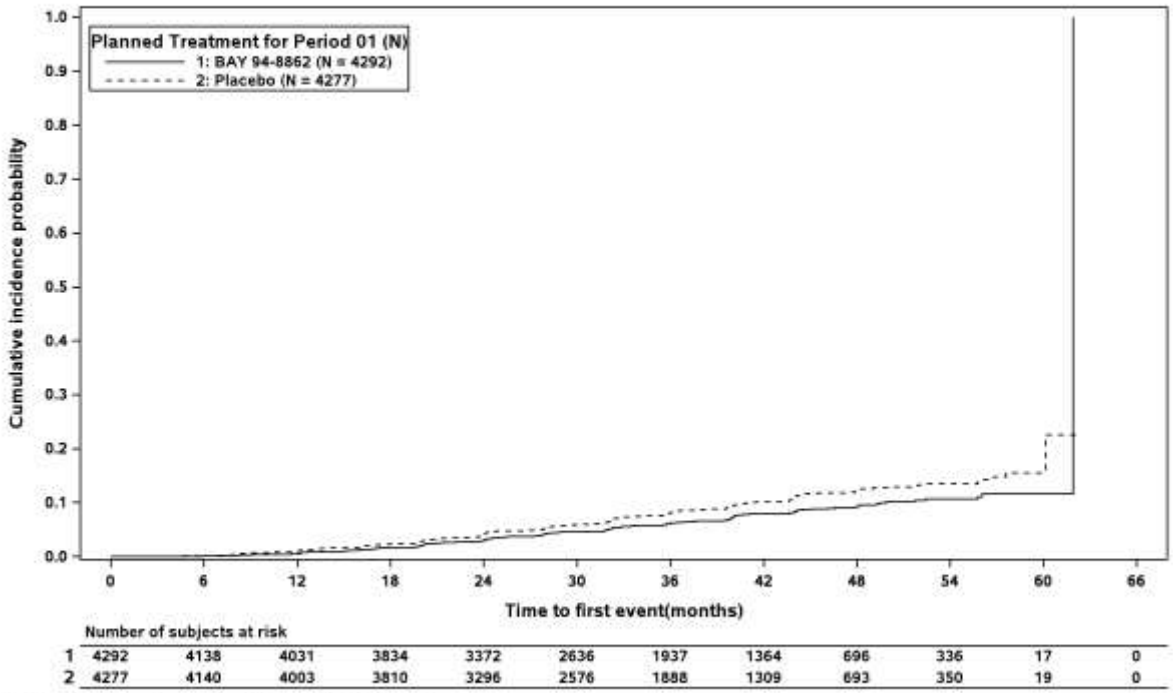


Figure 1.3.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)
Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg



Number of subjects at risk

1	4292	4138	4031	3834	3372	2636	1937	1364	696	336	17	0
2	4277	4140	4003	3810	3296	2576	1888	1309	693	350	19	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

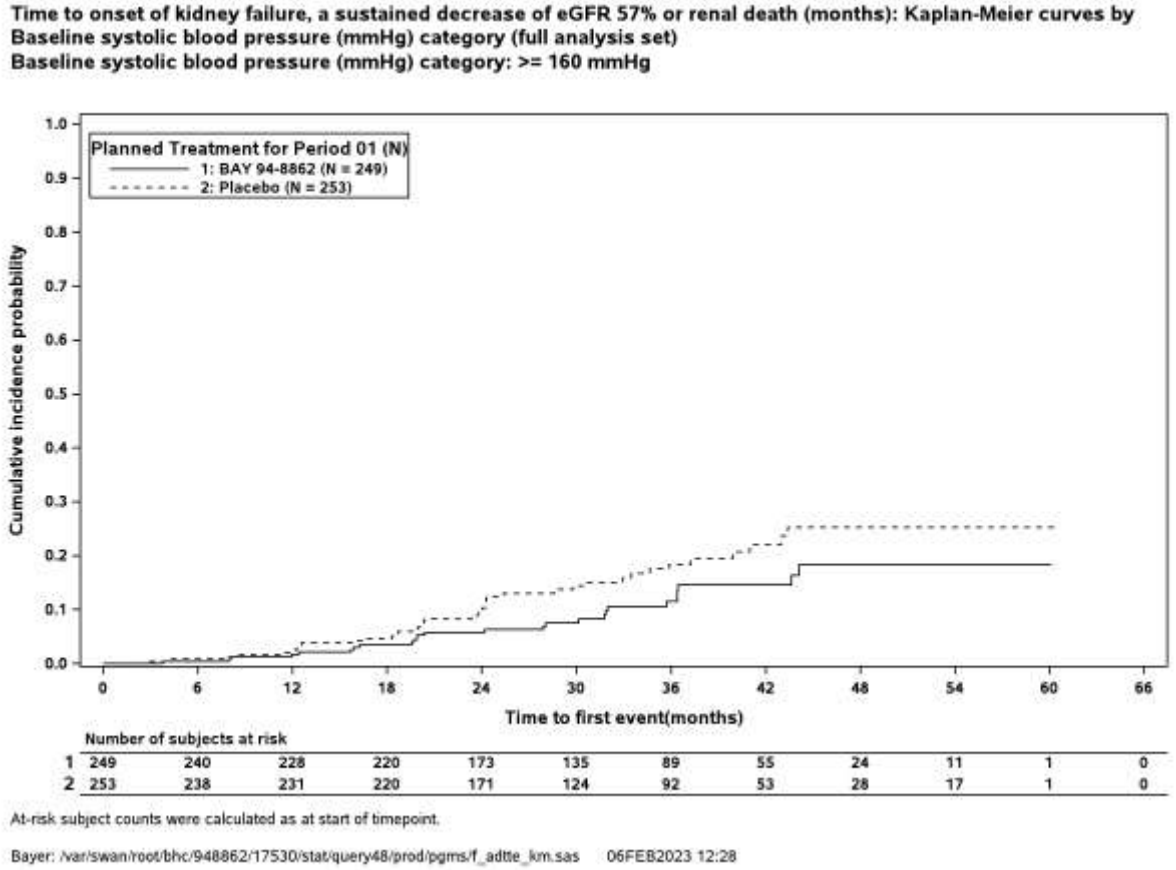


Figure 1.3.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

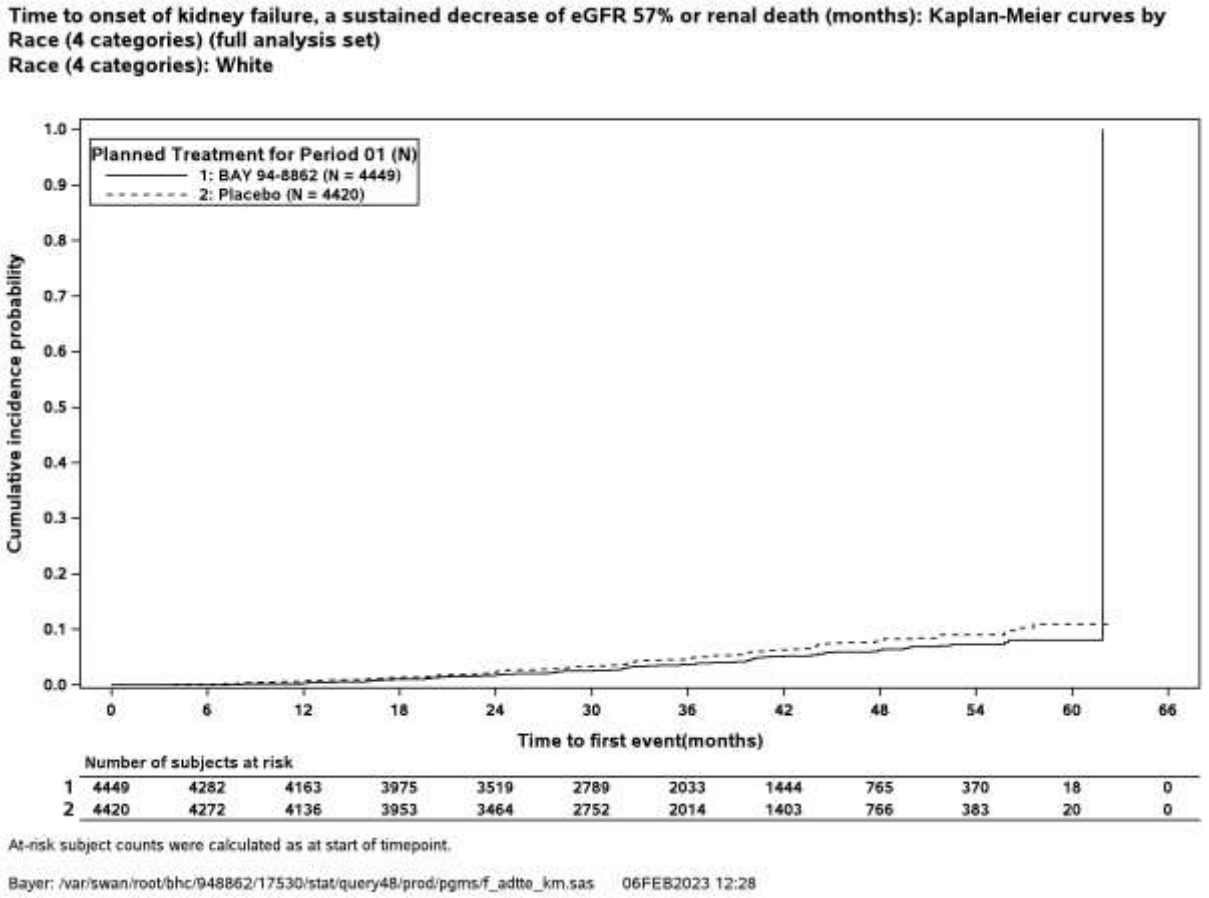
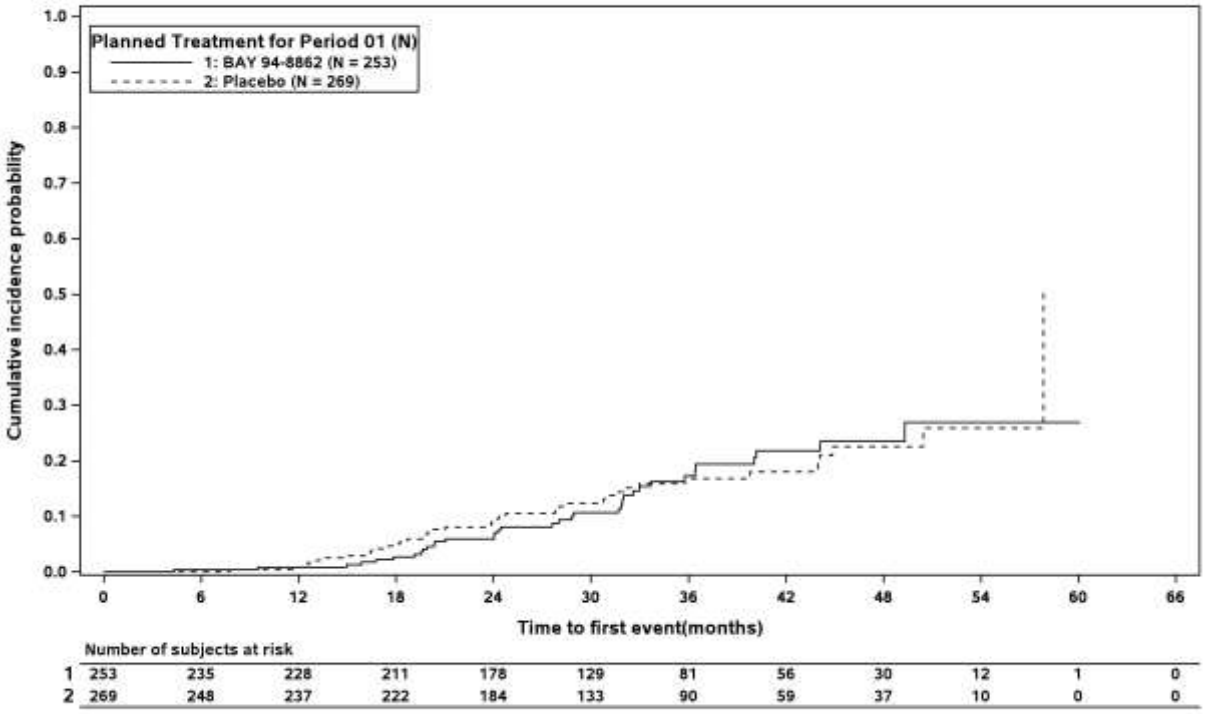


Figure 1.3.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)
Race (4 categories): Black



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

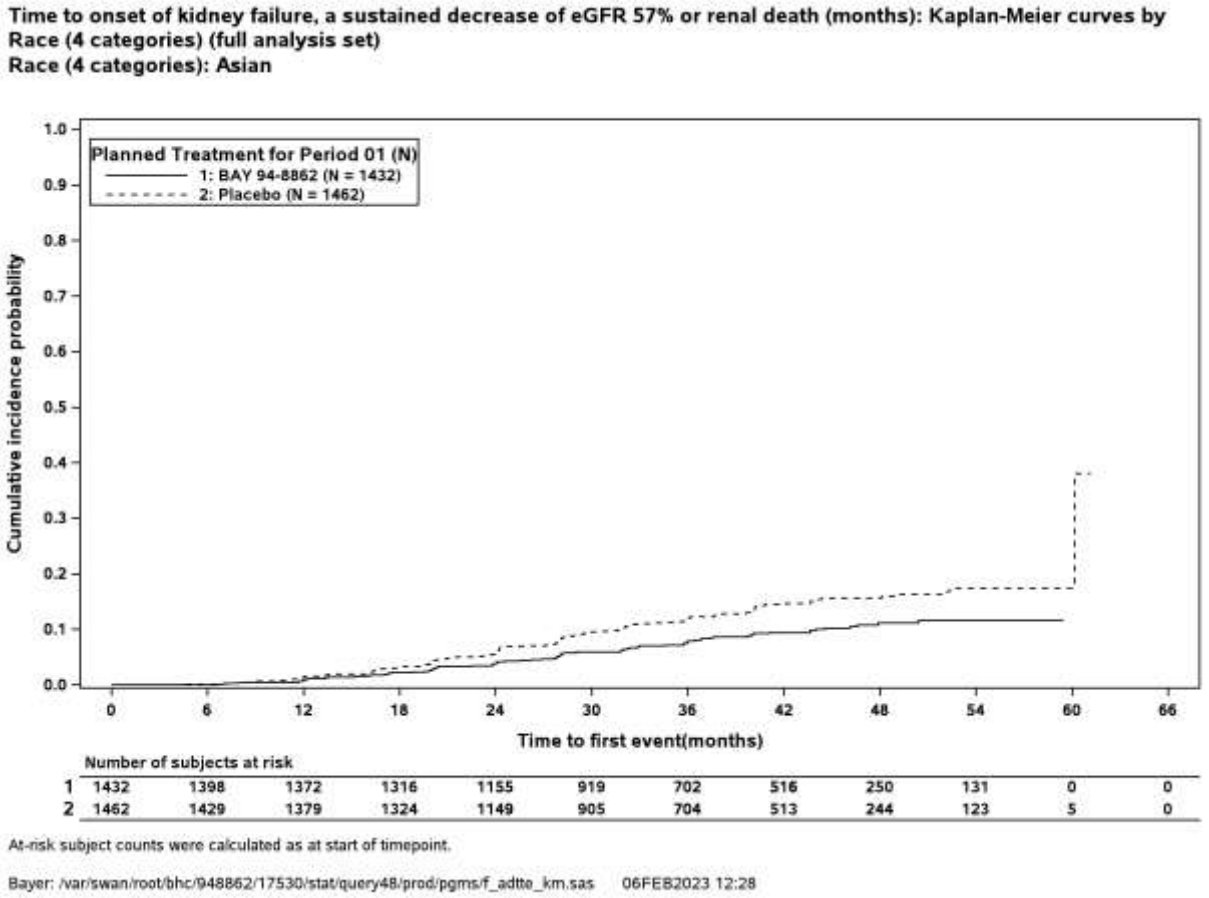
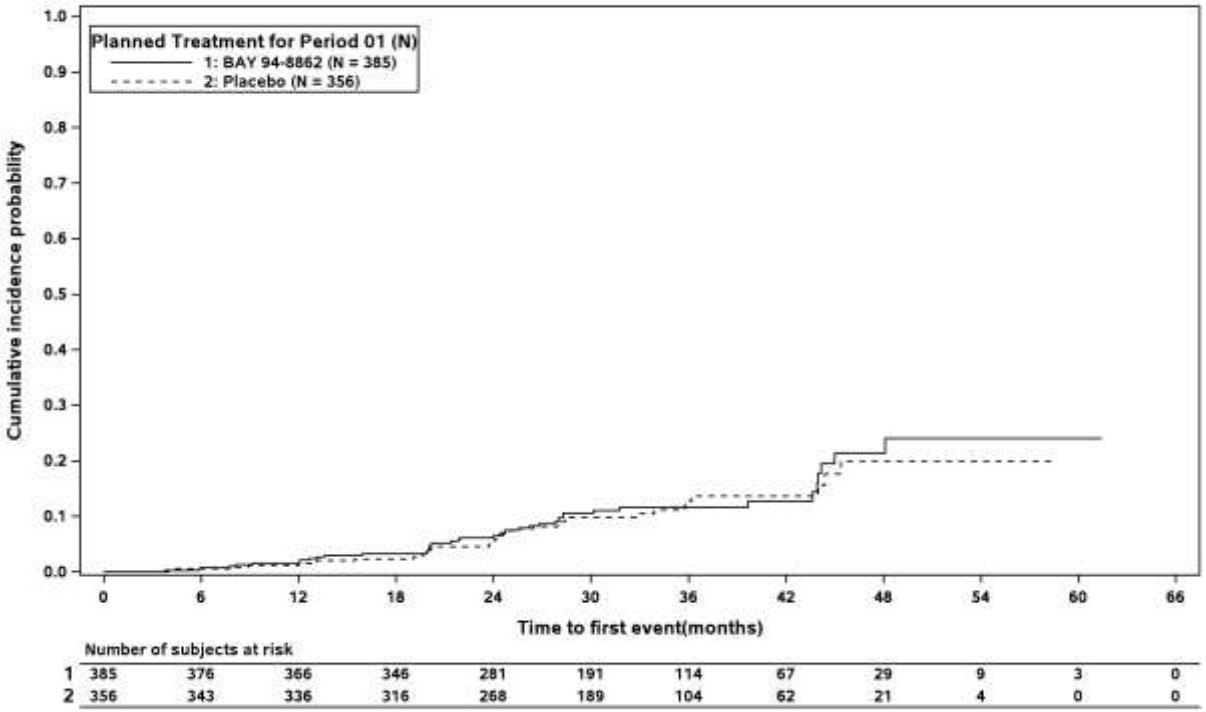


Figure 1.3.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)
Race (4 categories): Other



Number of subjects at risk

1	385	376	366	346	281	191	114	67	29	9	3	0
2	356	343	336	316	268	189	104	62	21	4	0	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 20: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

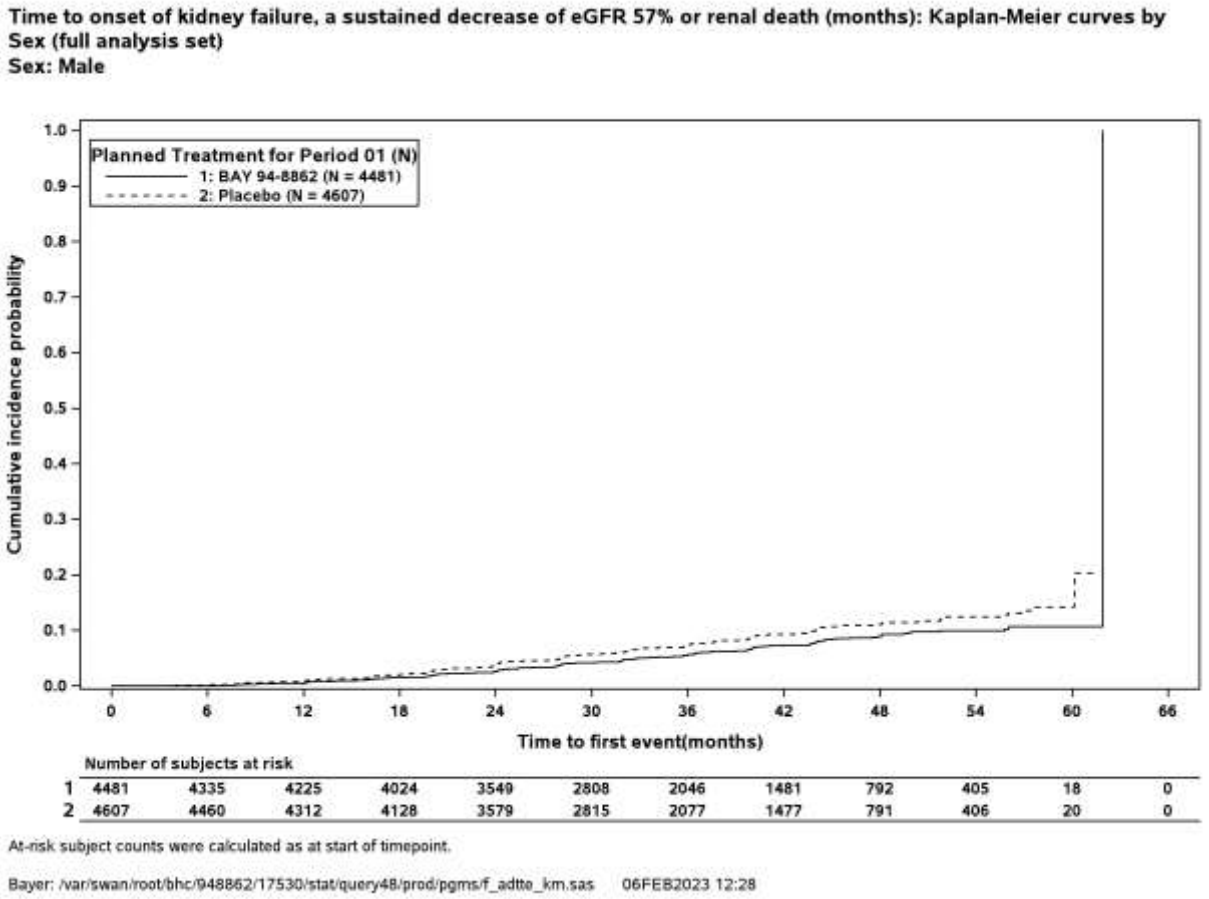


Figure 1.3.1 / 20: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

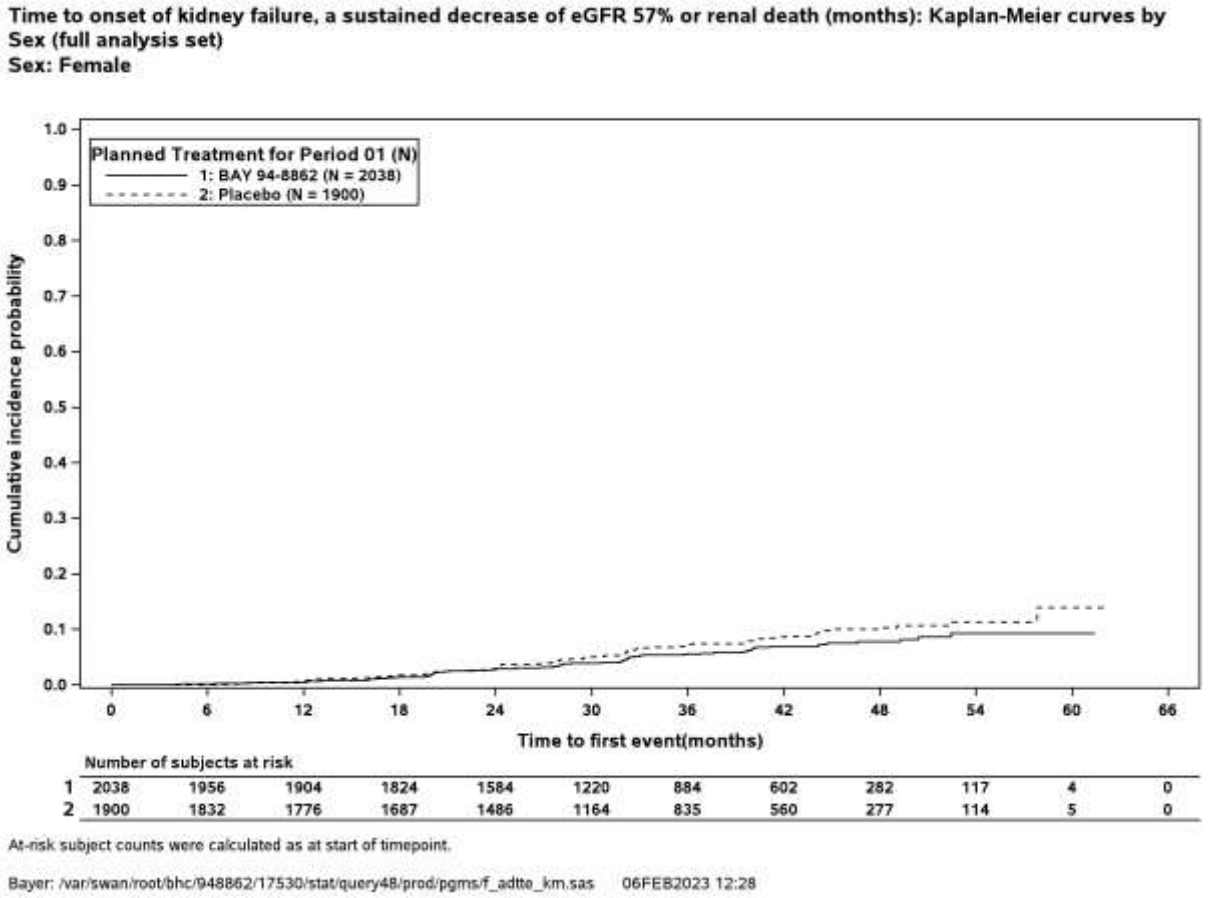


Figure 1.3.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

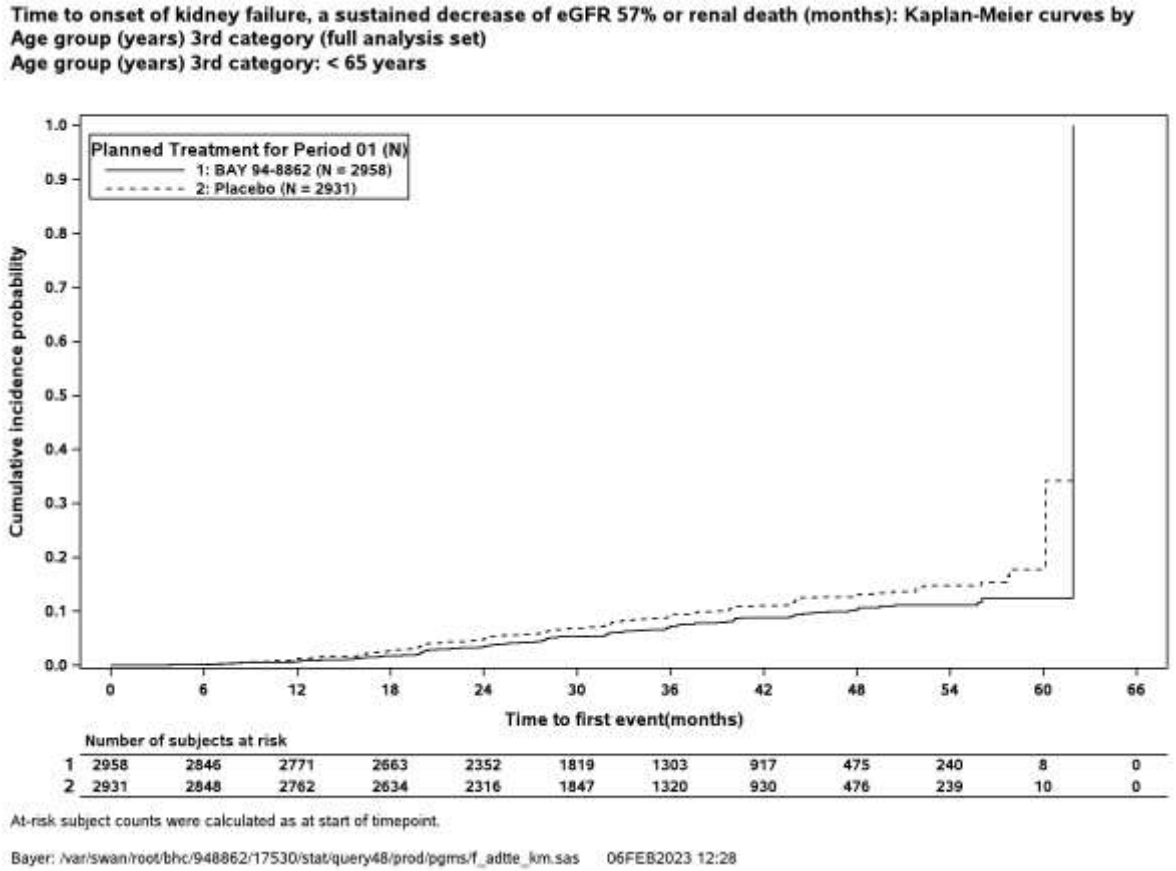


Figure 1.3.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

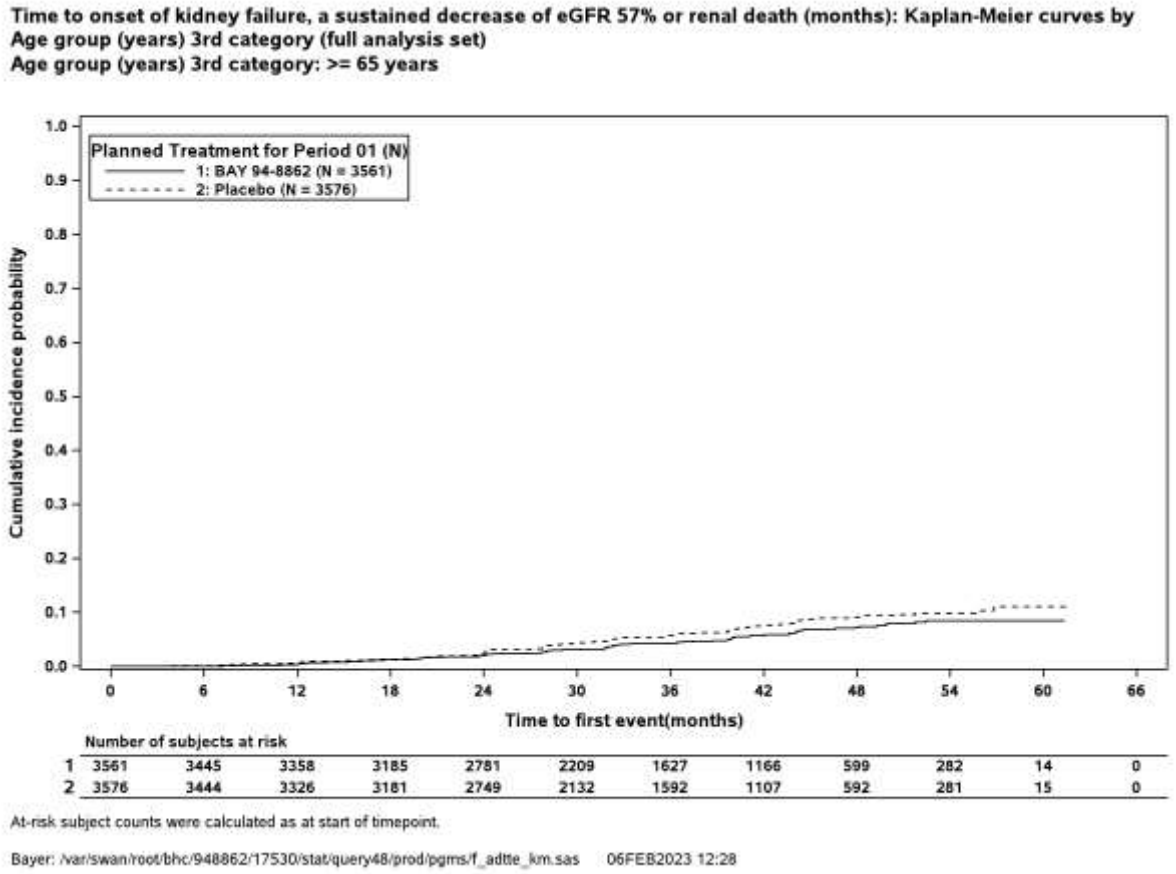


Figure 1.3.1 / 22: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set)

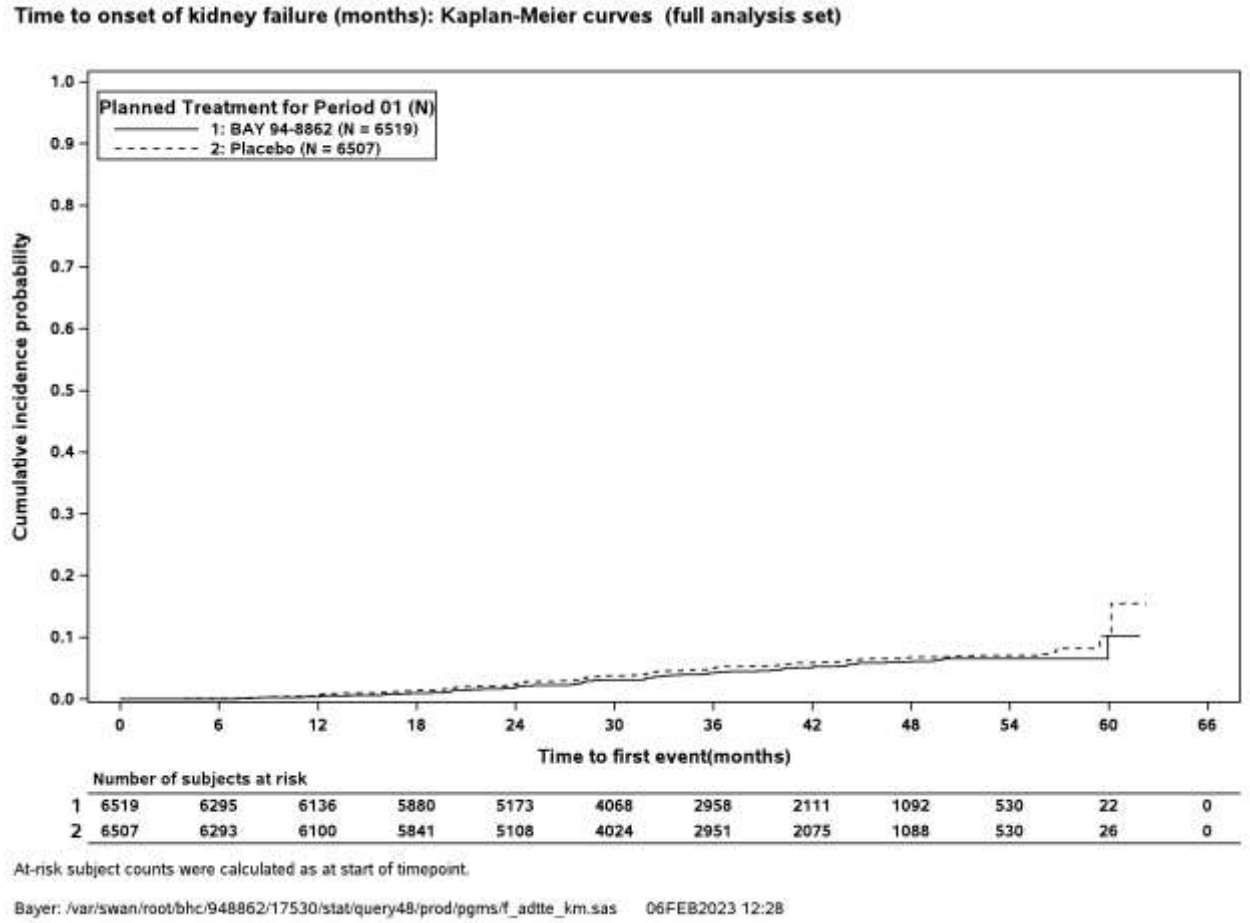


Figure 1.3.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

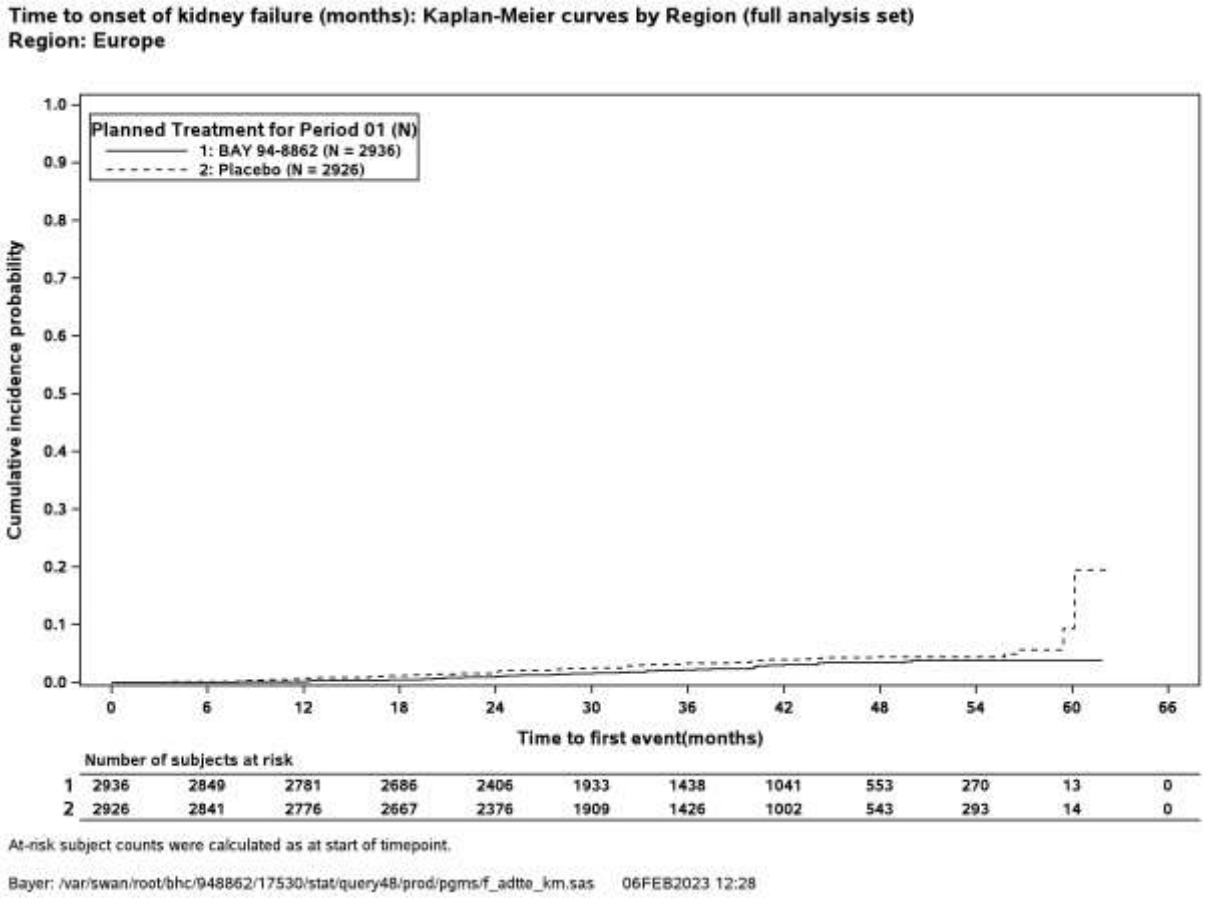


Figure 1.3.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

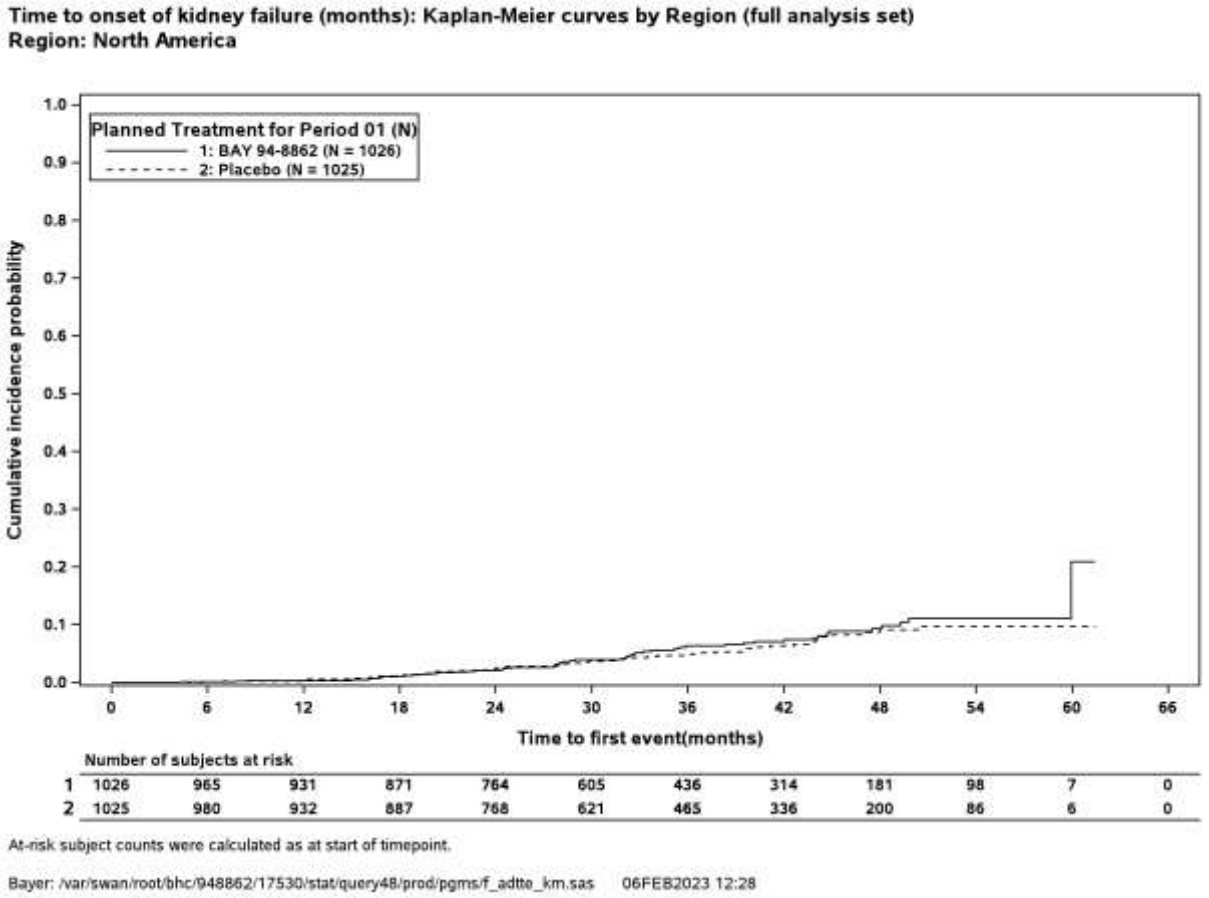


Figure 1.3.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

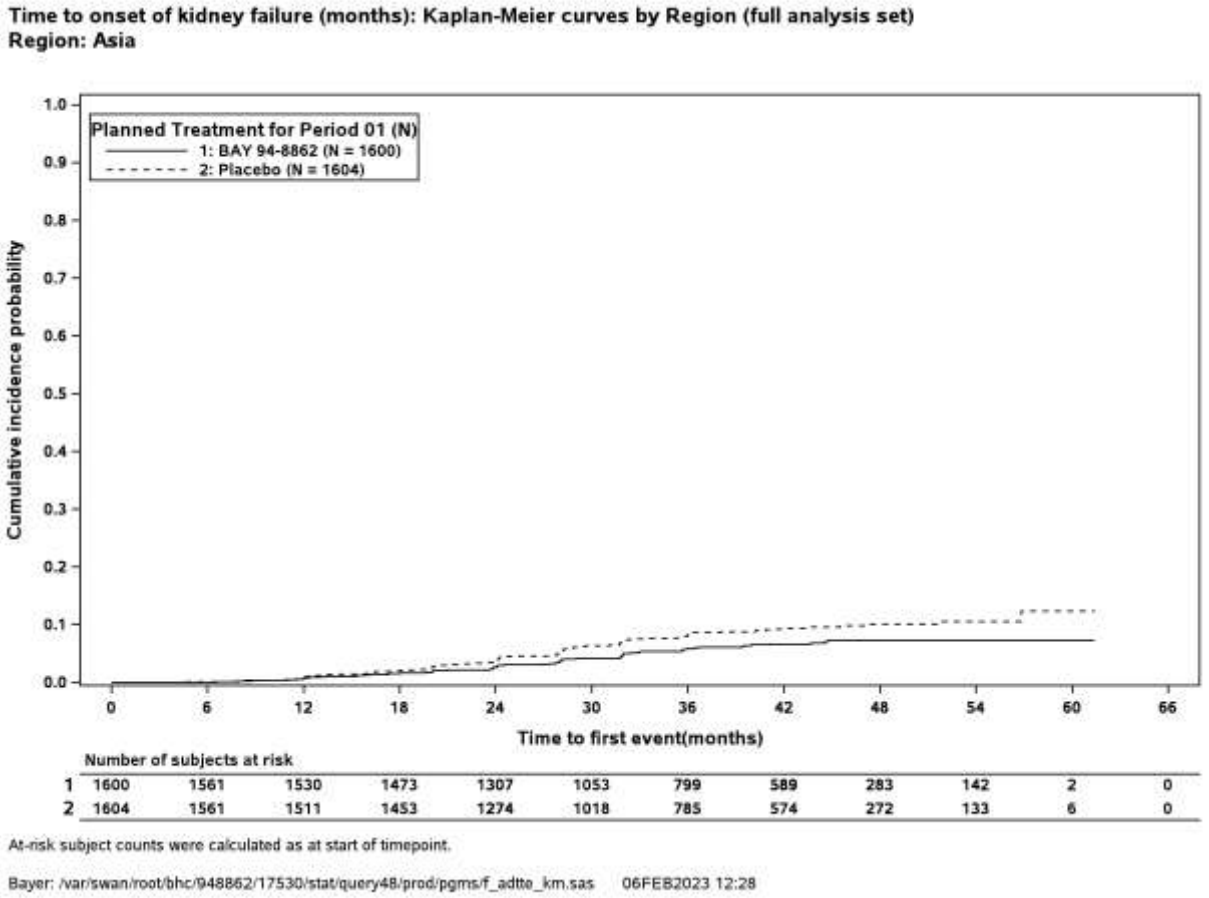


Figure 1.3.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

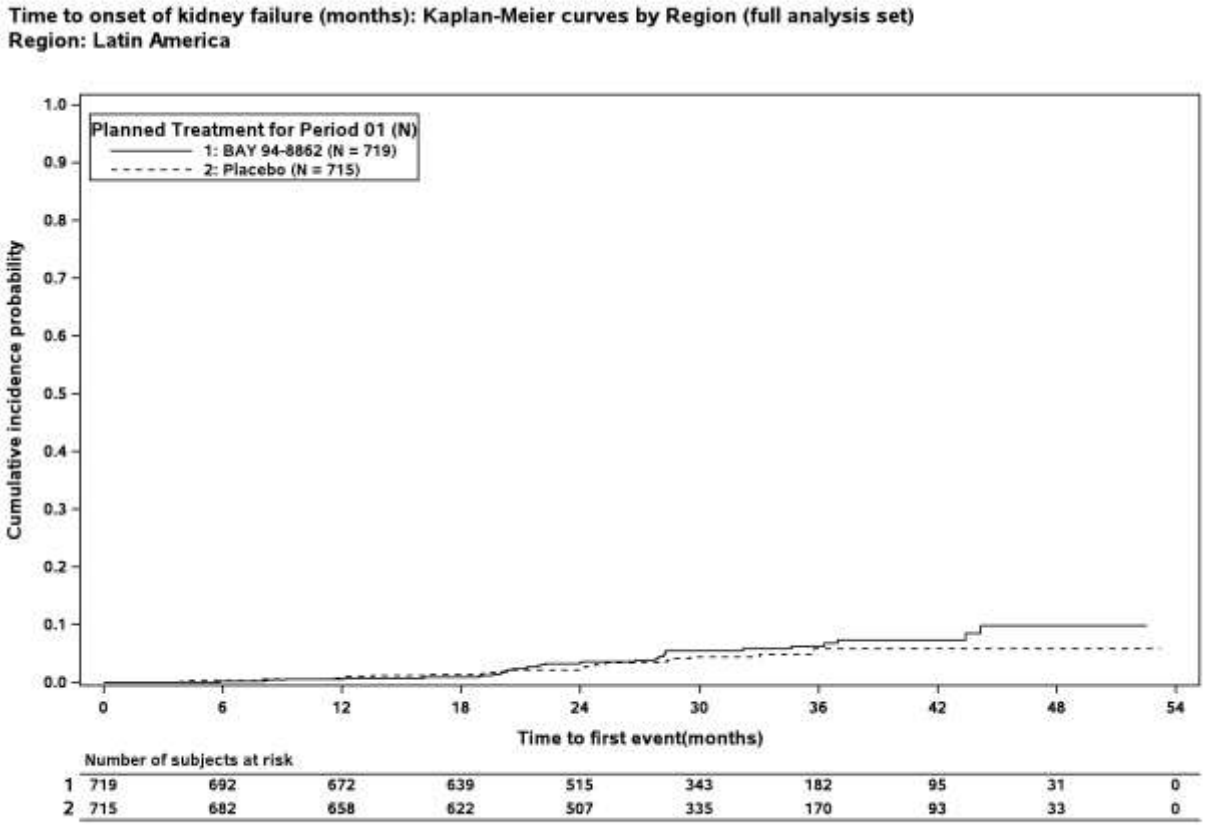


Figure 1.3.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

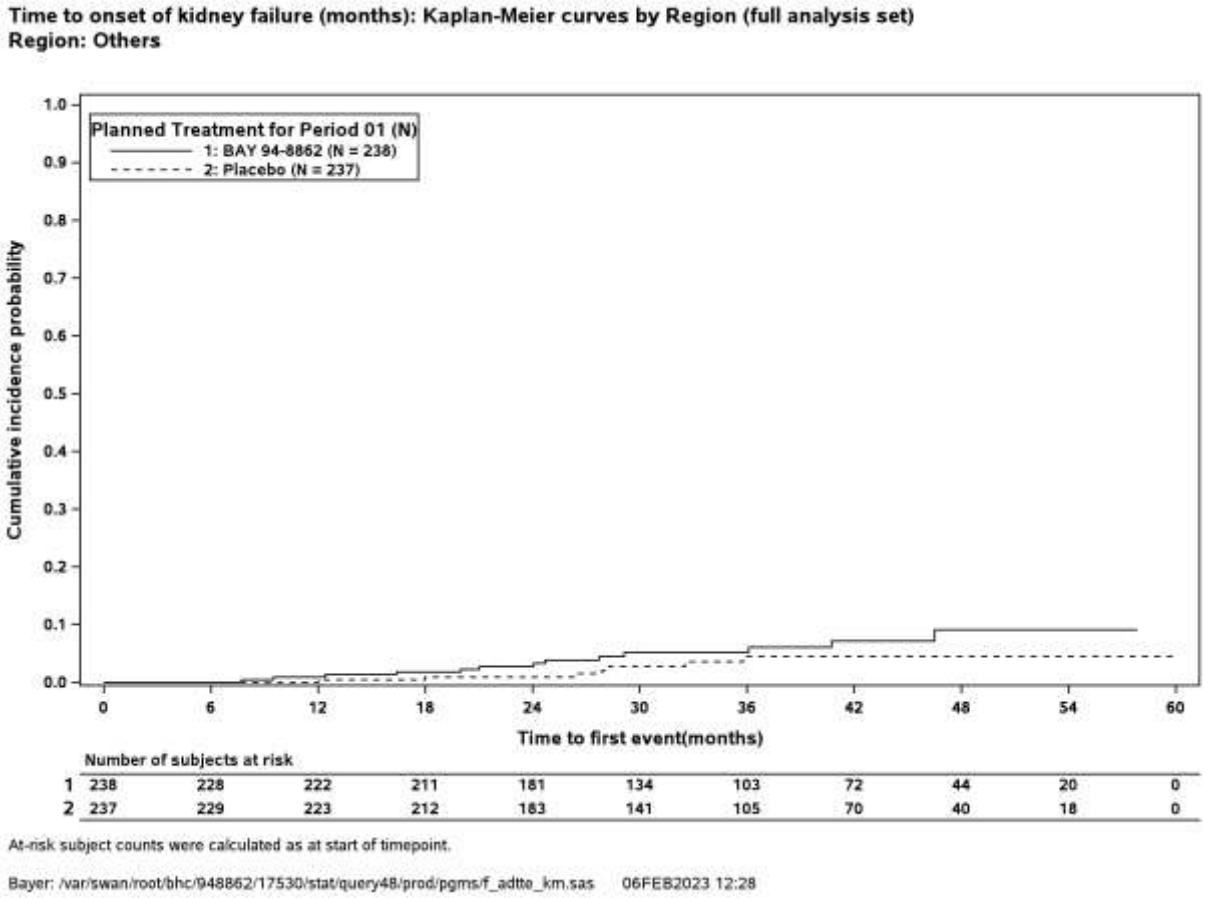


Figure 1.3.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

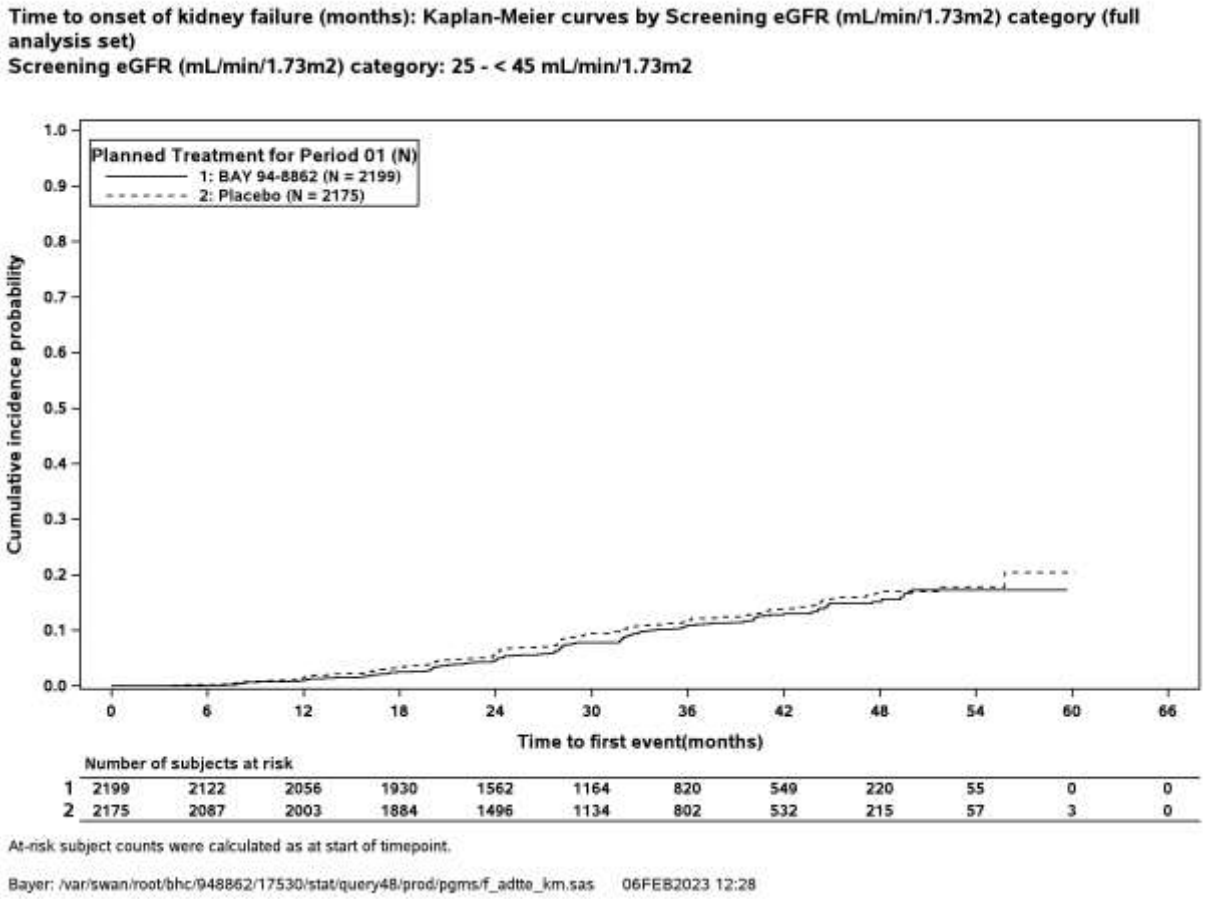


Figure 1.3.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

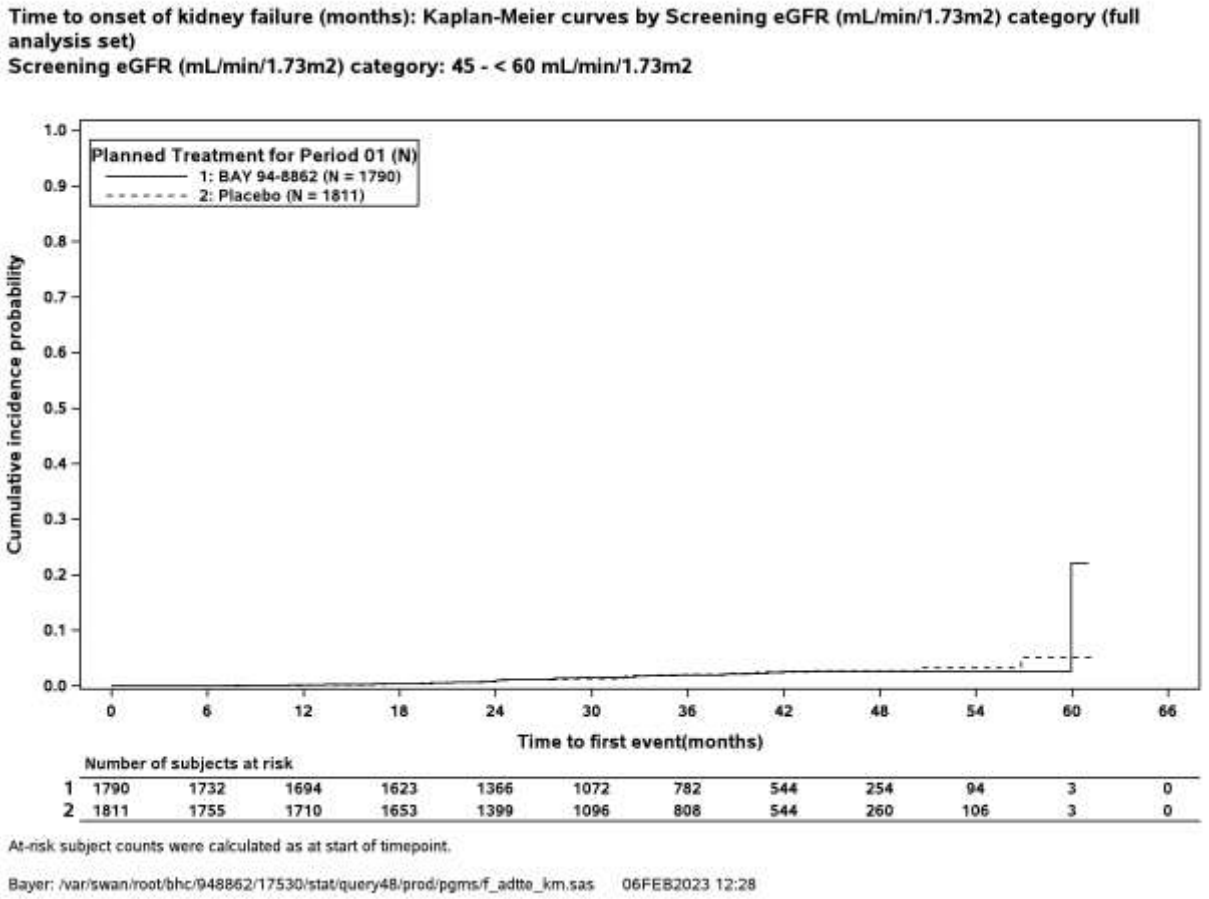


Figure 1.3.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

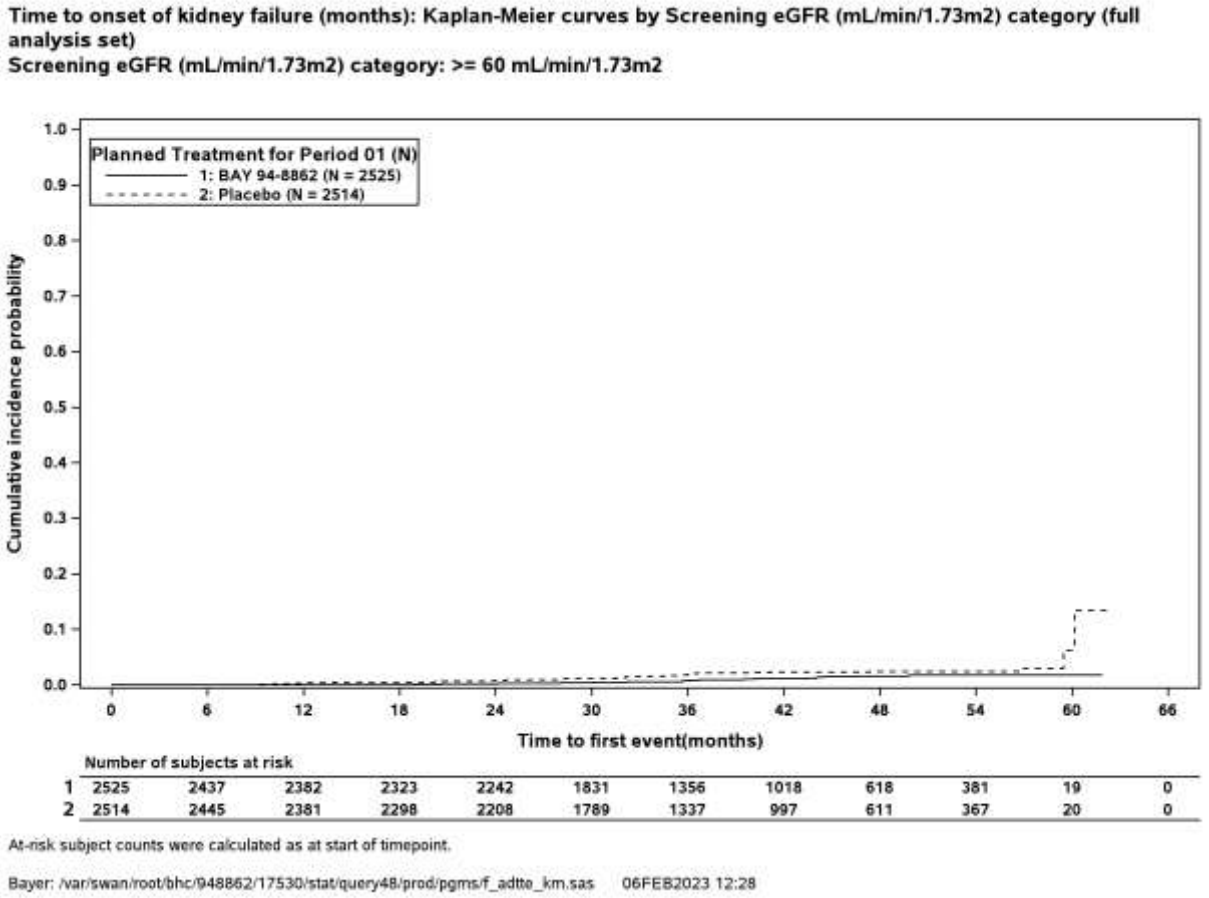


Figure 1.3.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

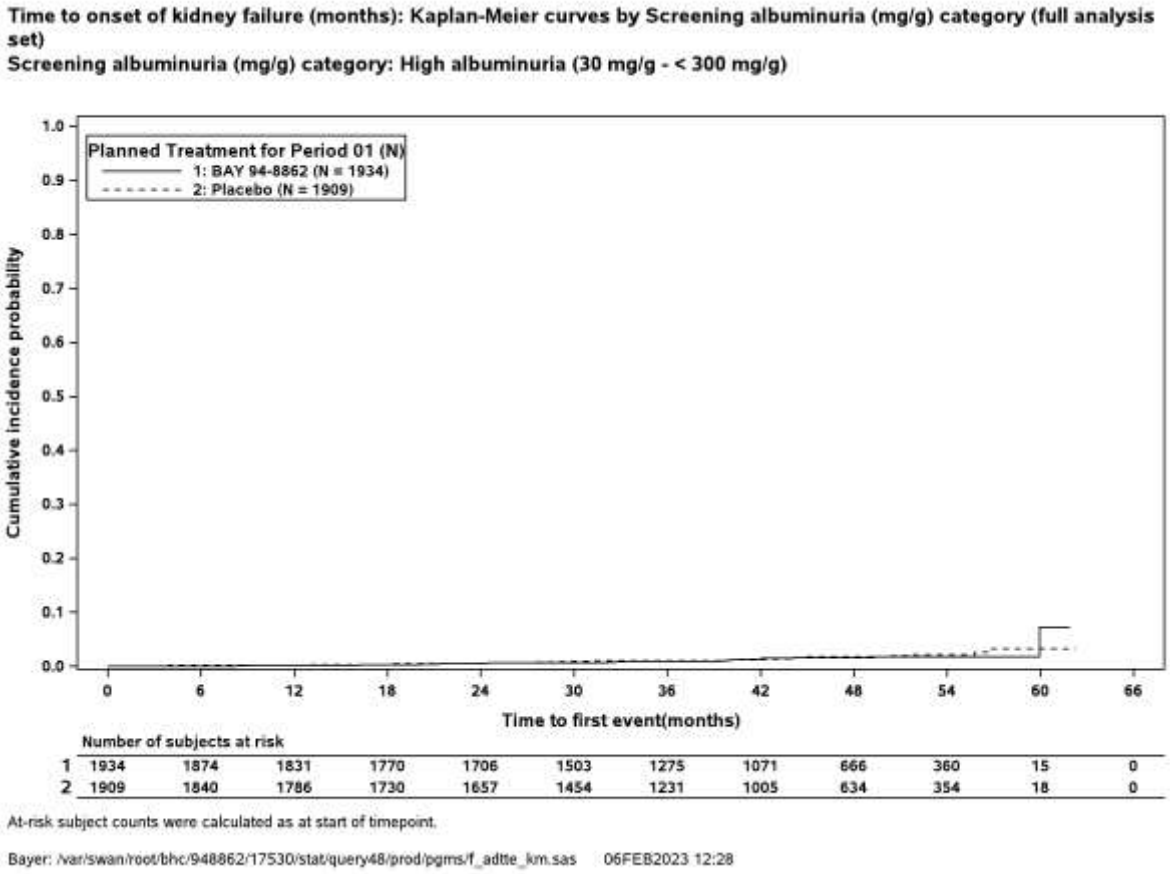


Figure 1.3.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

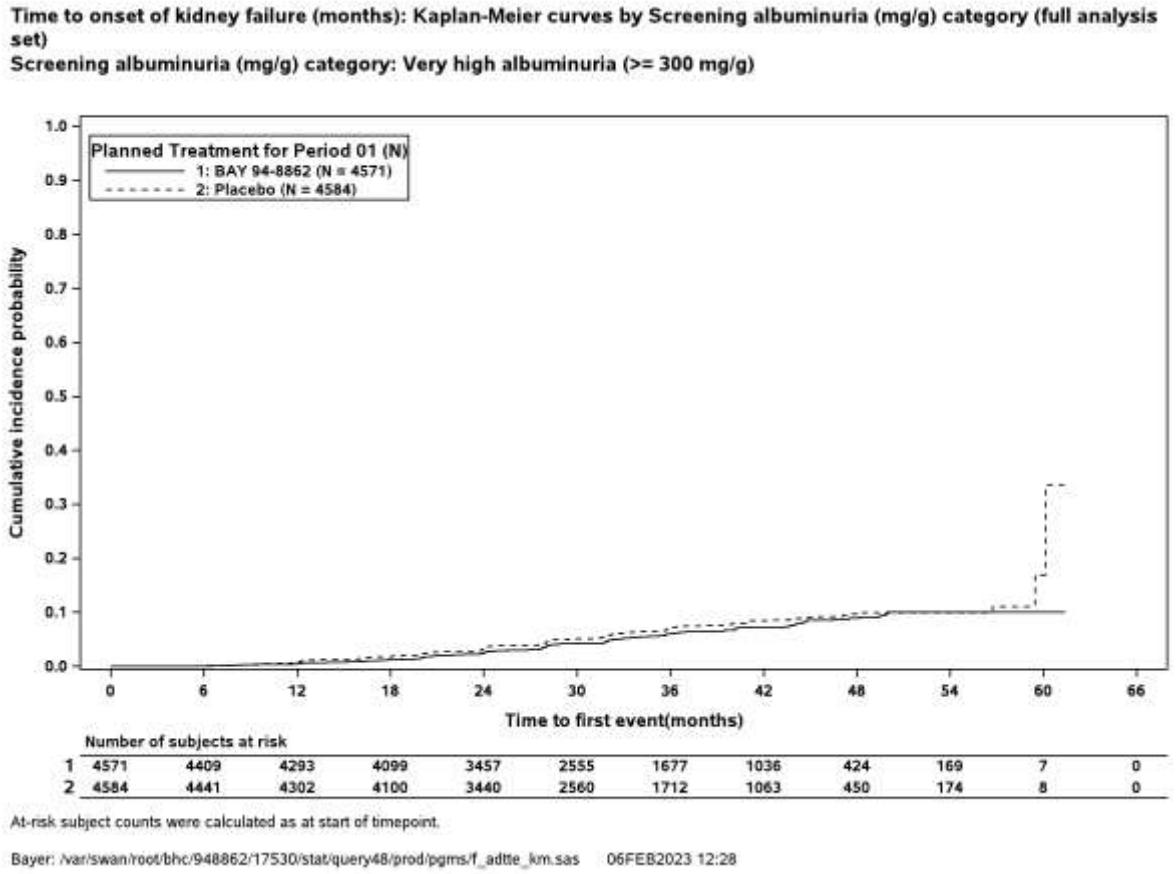


Figure 1.3.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

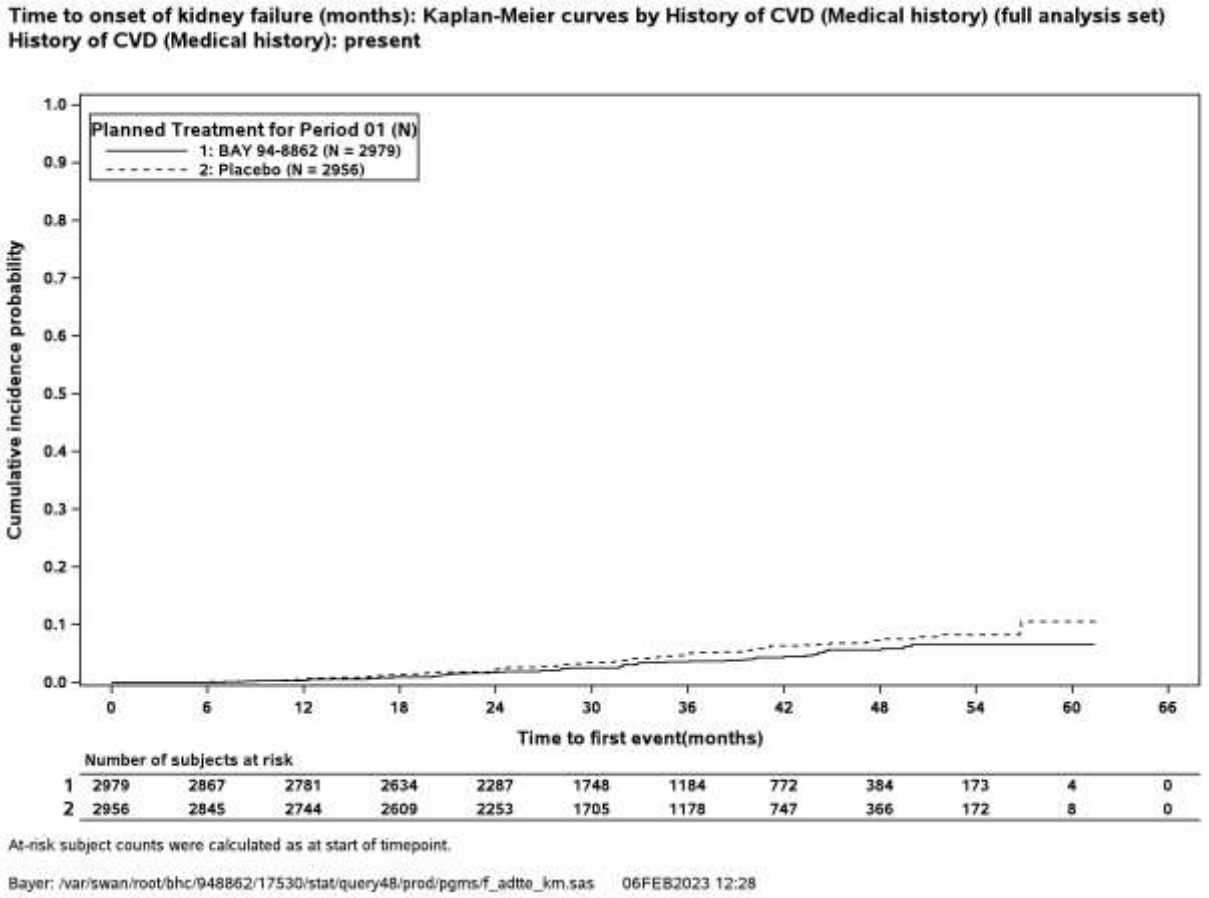


Figure 1.3.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

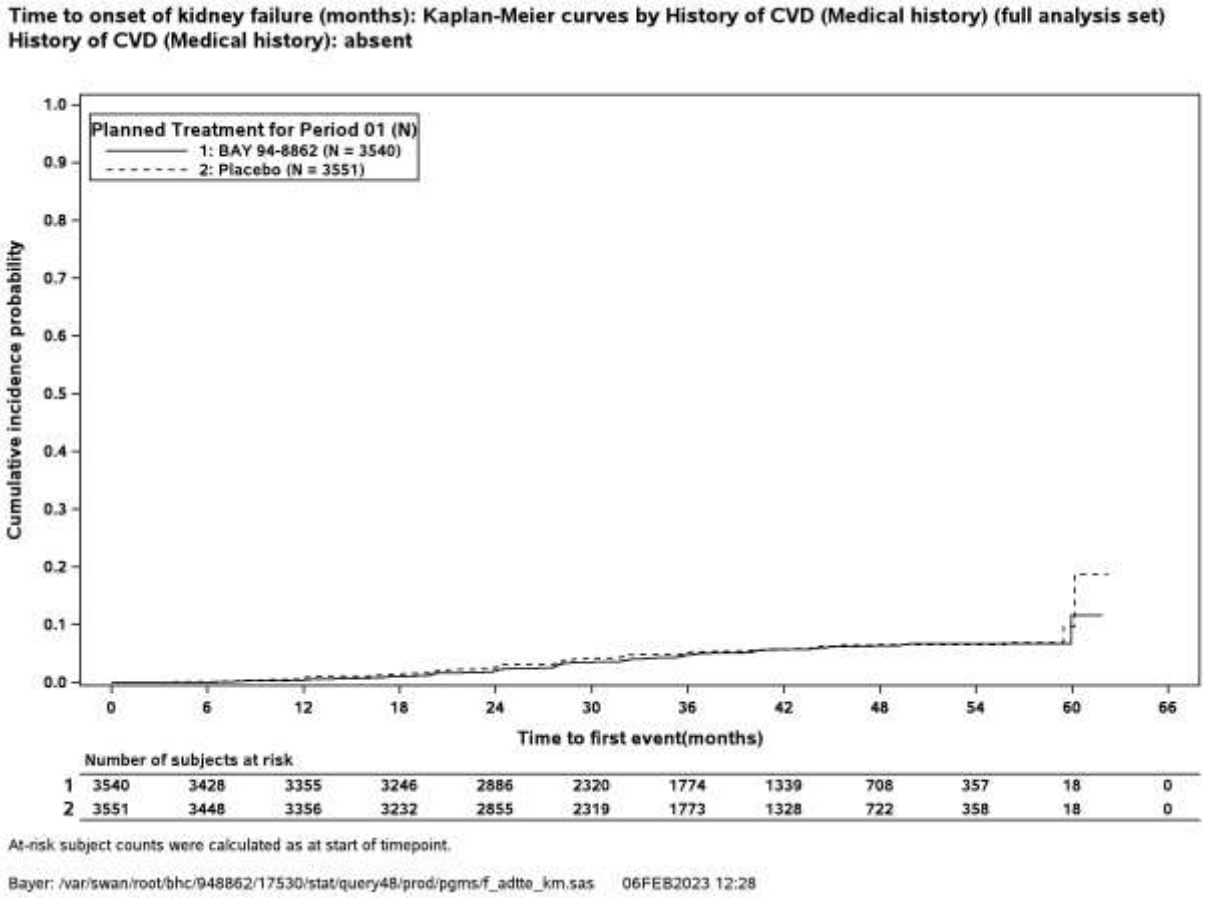


Figure 1.3.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

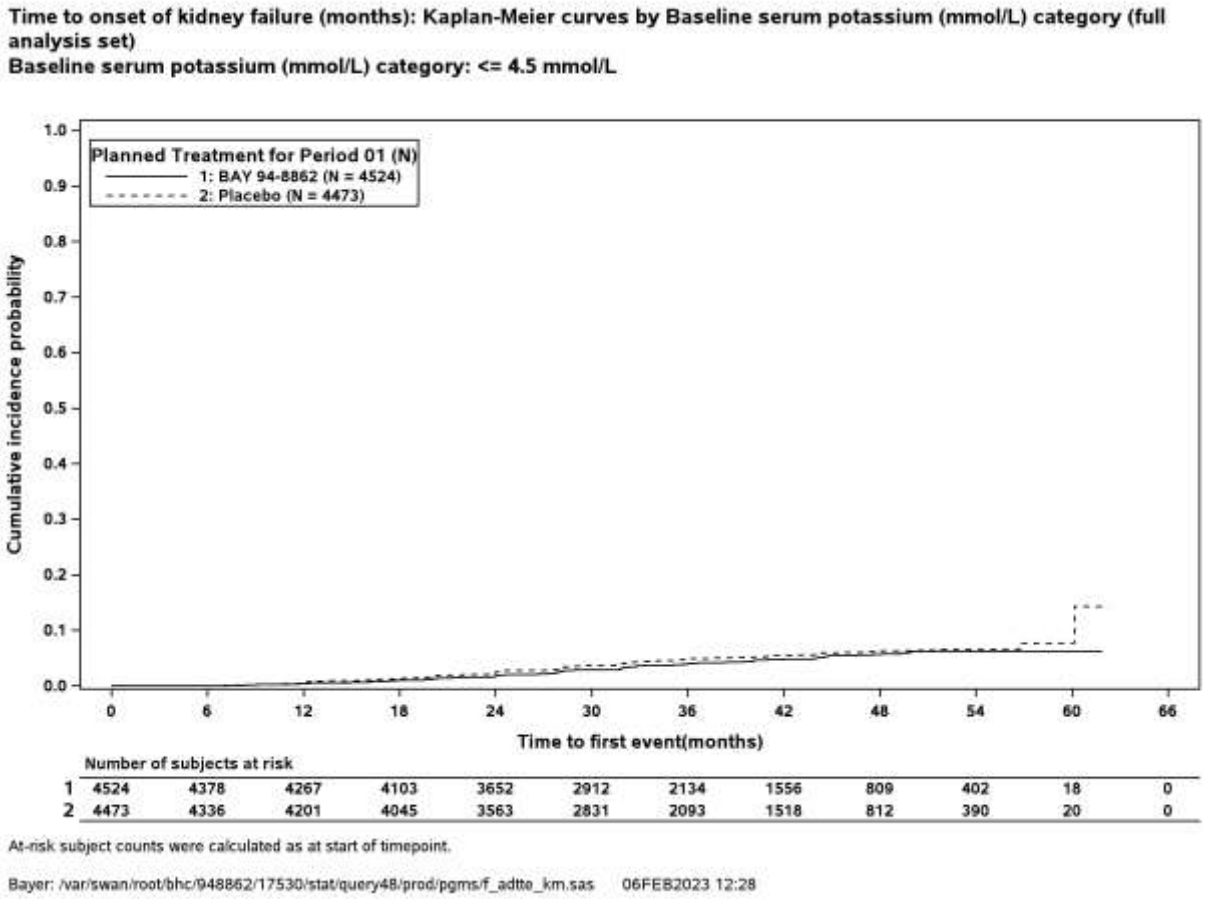
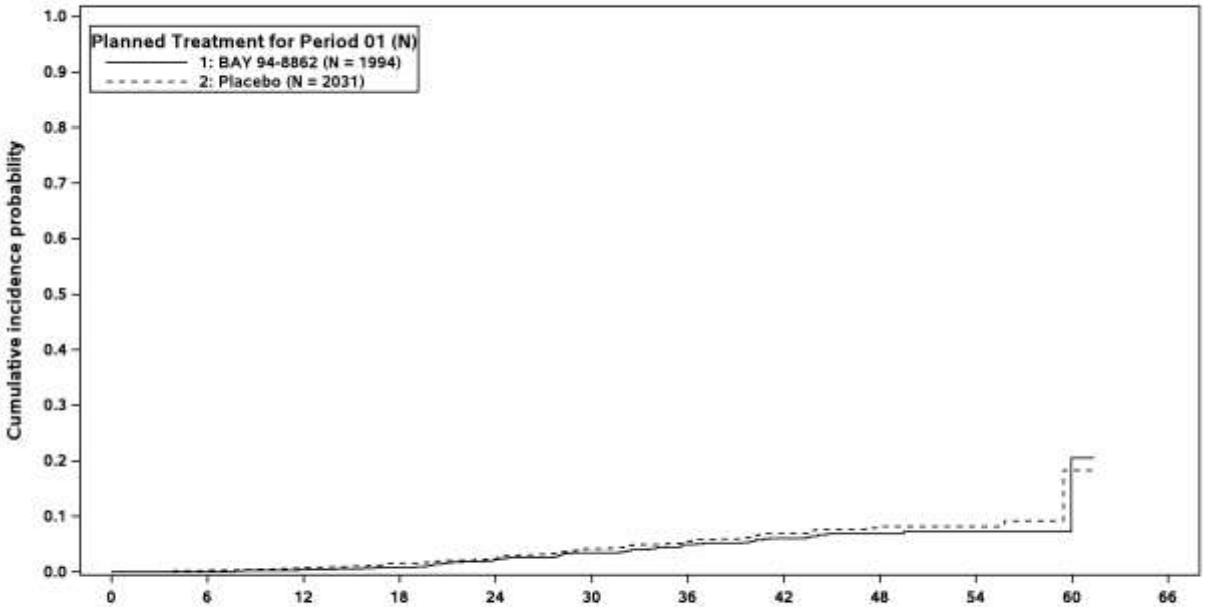


Figure 1.3.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1994	1917	1869	1777	1521	1156	824	555	283	128	4	0
2	2031	1955	1897	1794	1543	1191	857	556	275	139	6	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

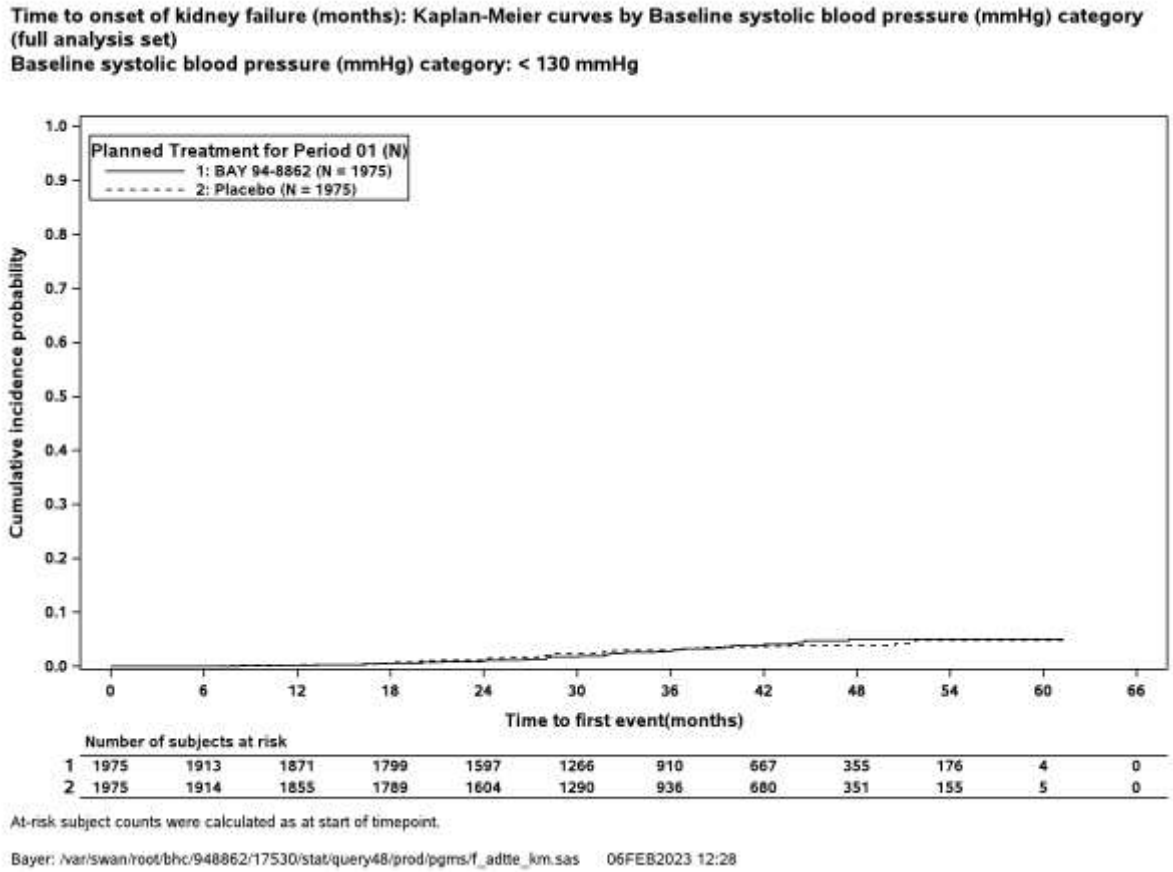


Figure 1.3.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

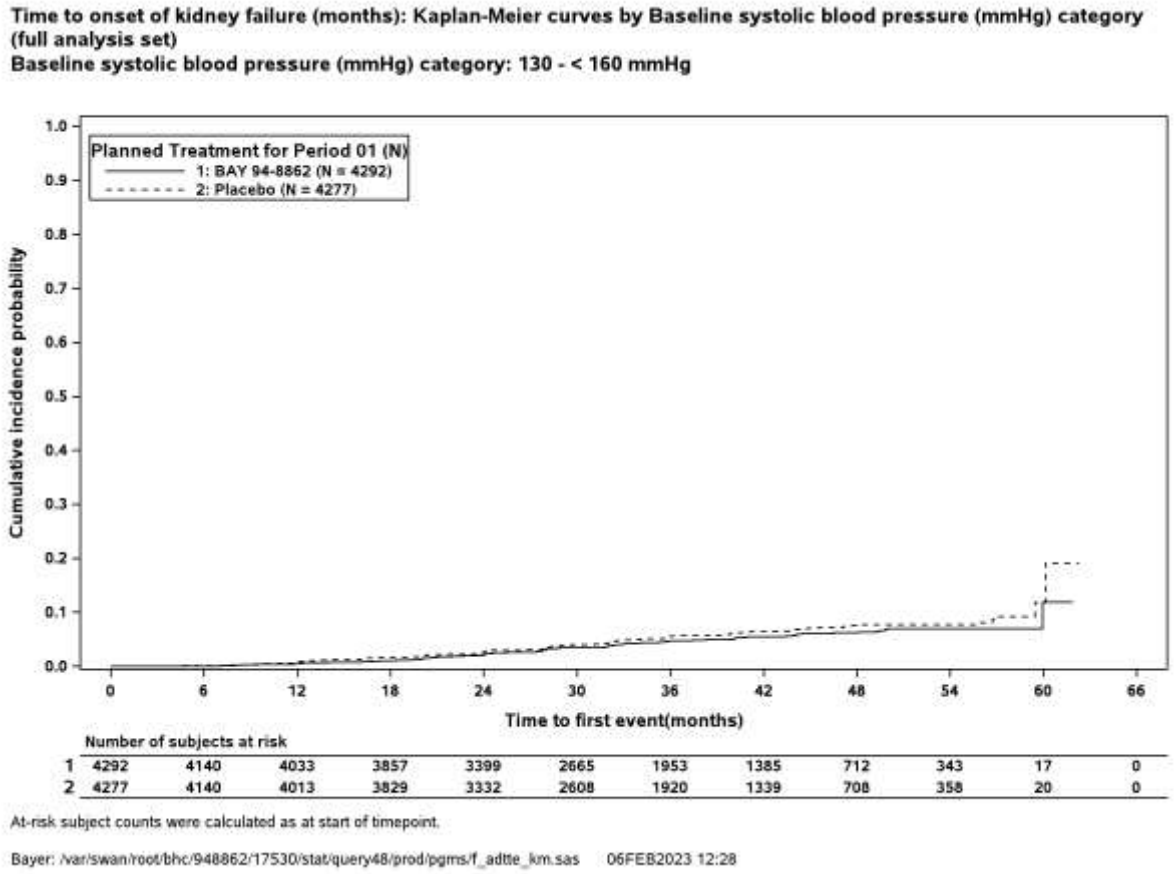


Figure 1.3.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

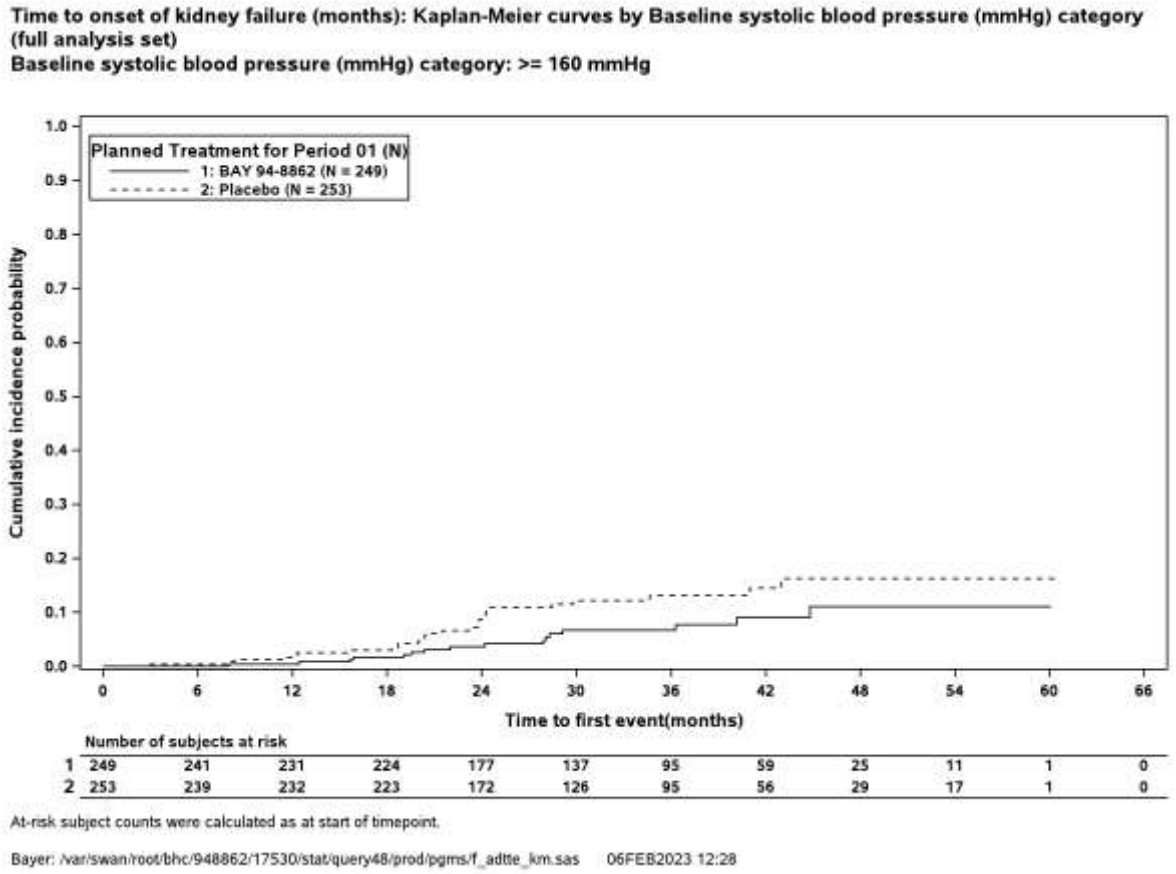


Figure 1.3.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

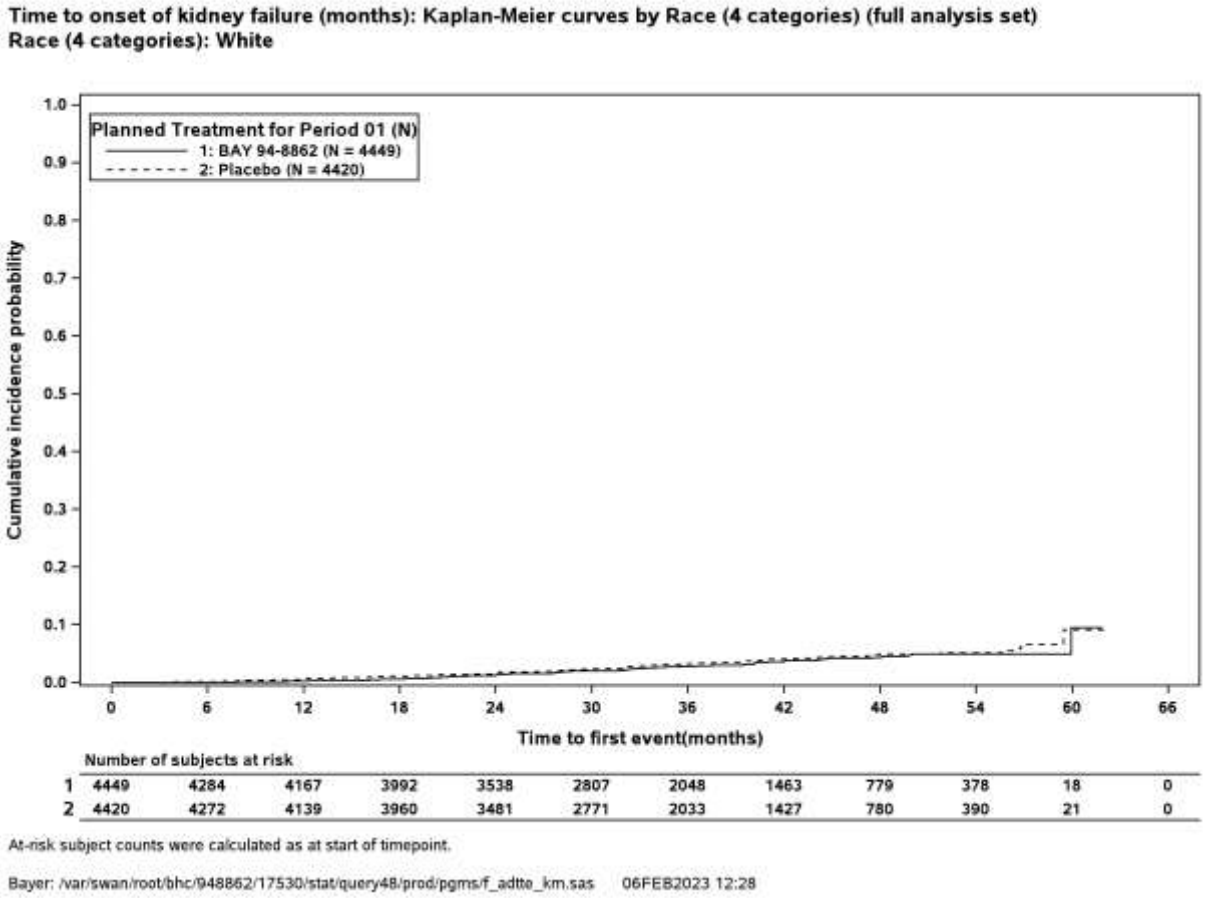


Figure 1.3.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

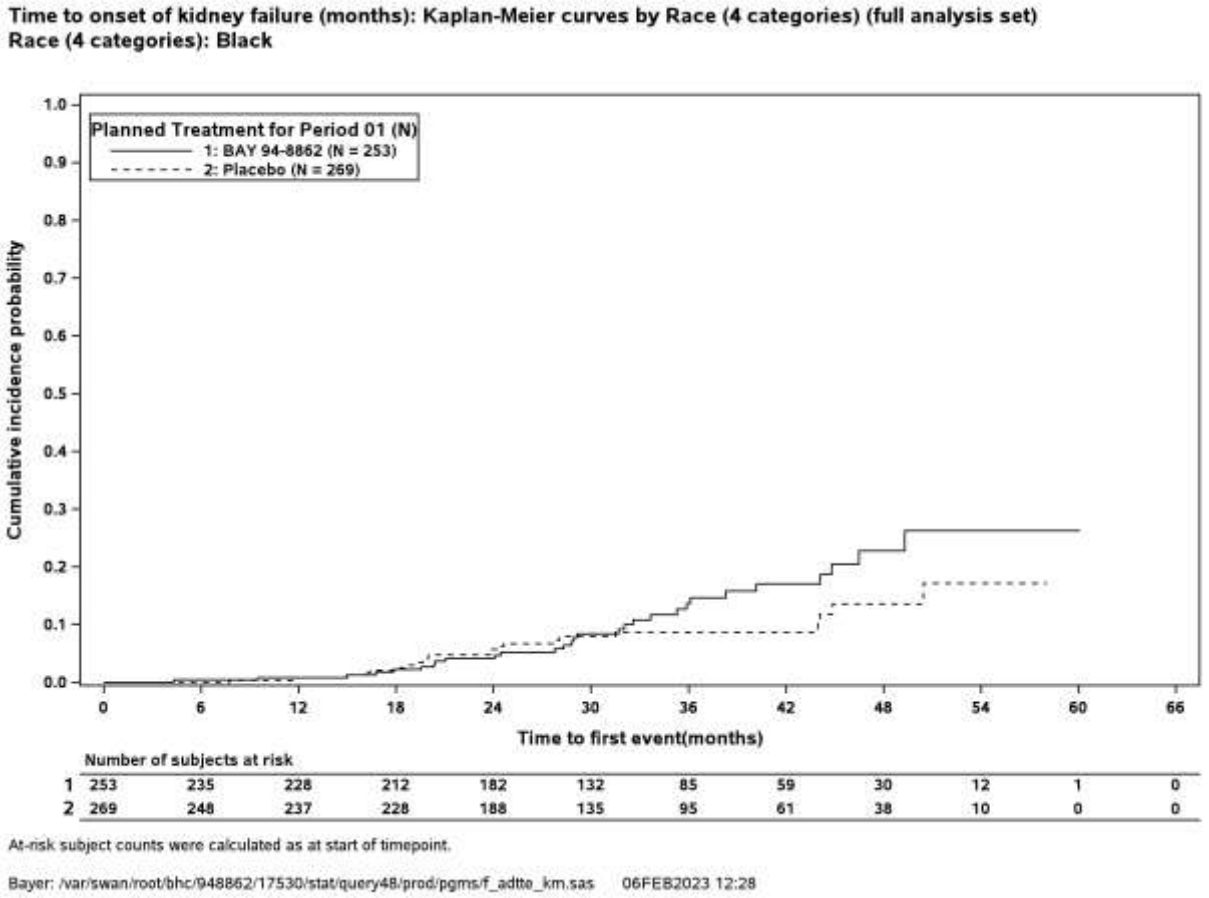


Figure 1.3.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

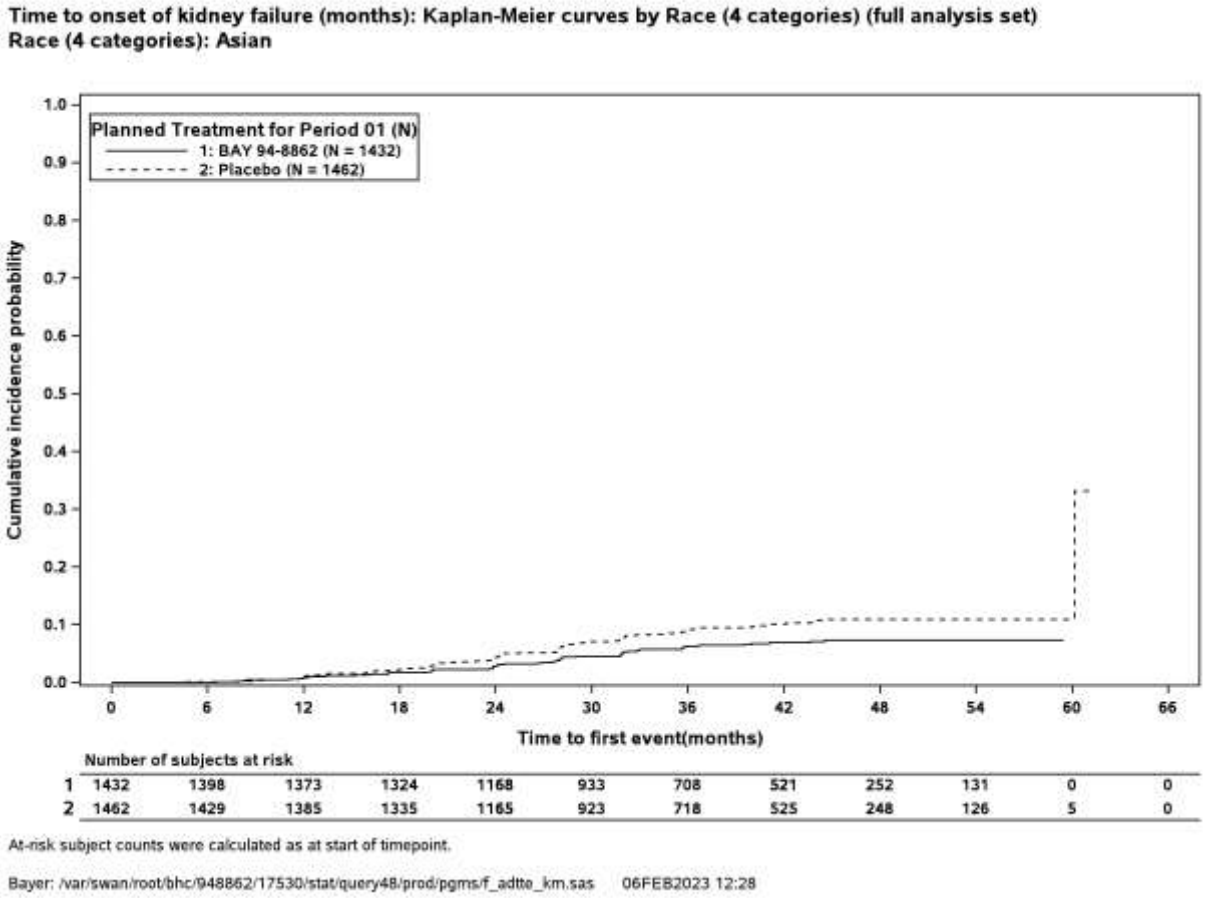


Figure 1.3.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

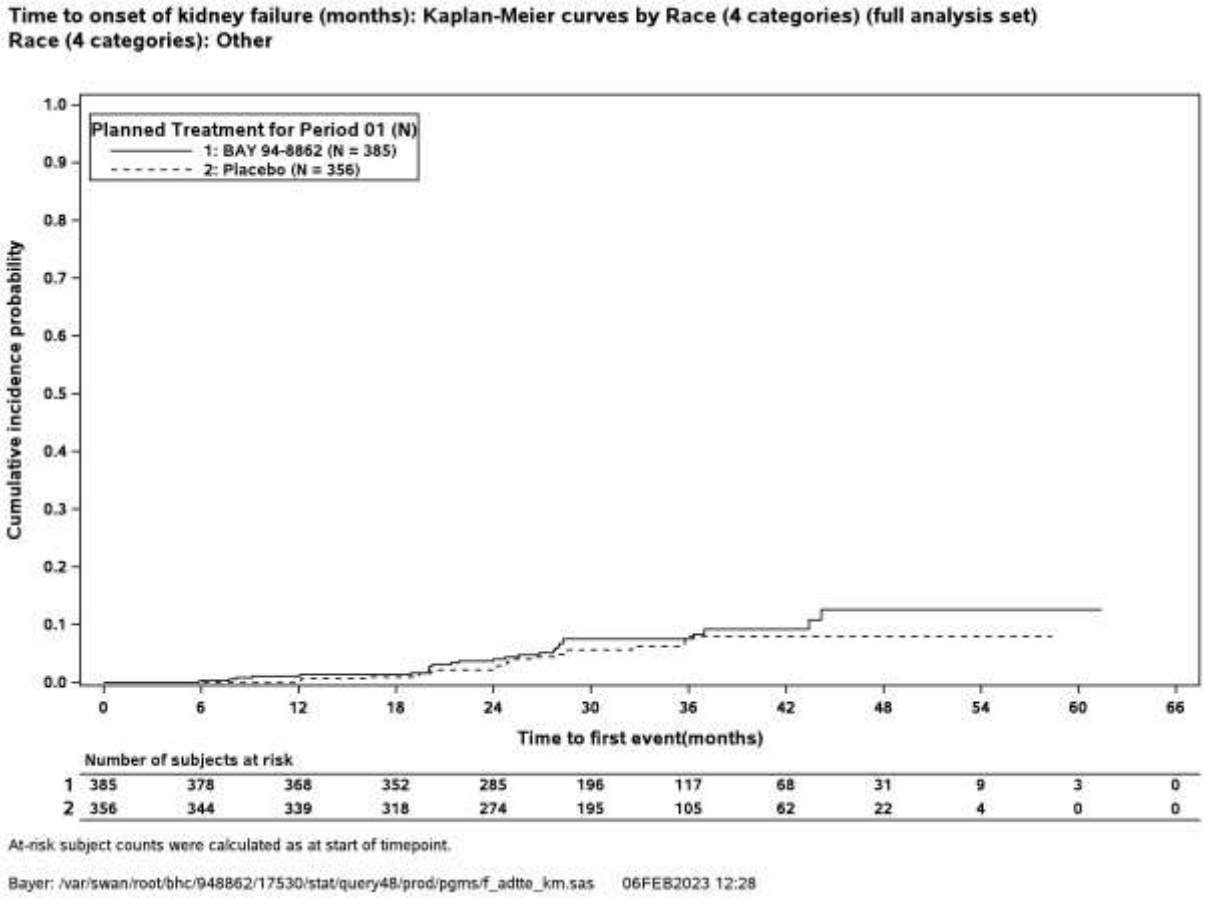


Figure 1.3.1 / 30: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

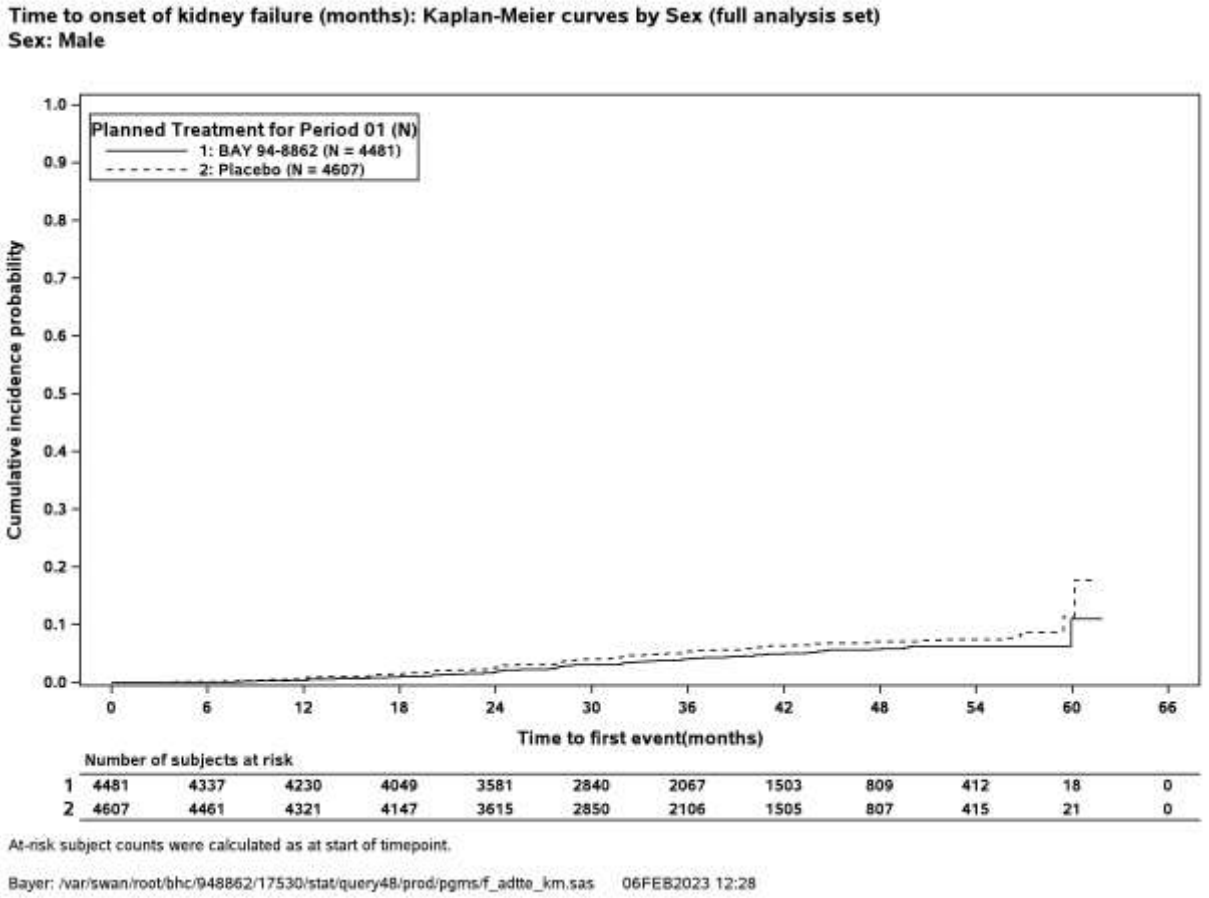


Figure 1.3.1 / 30: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

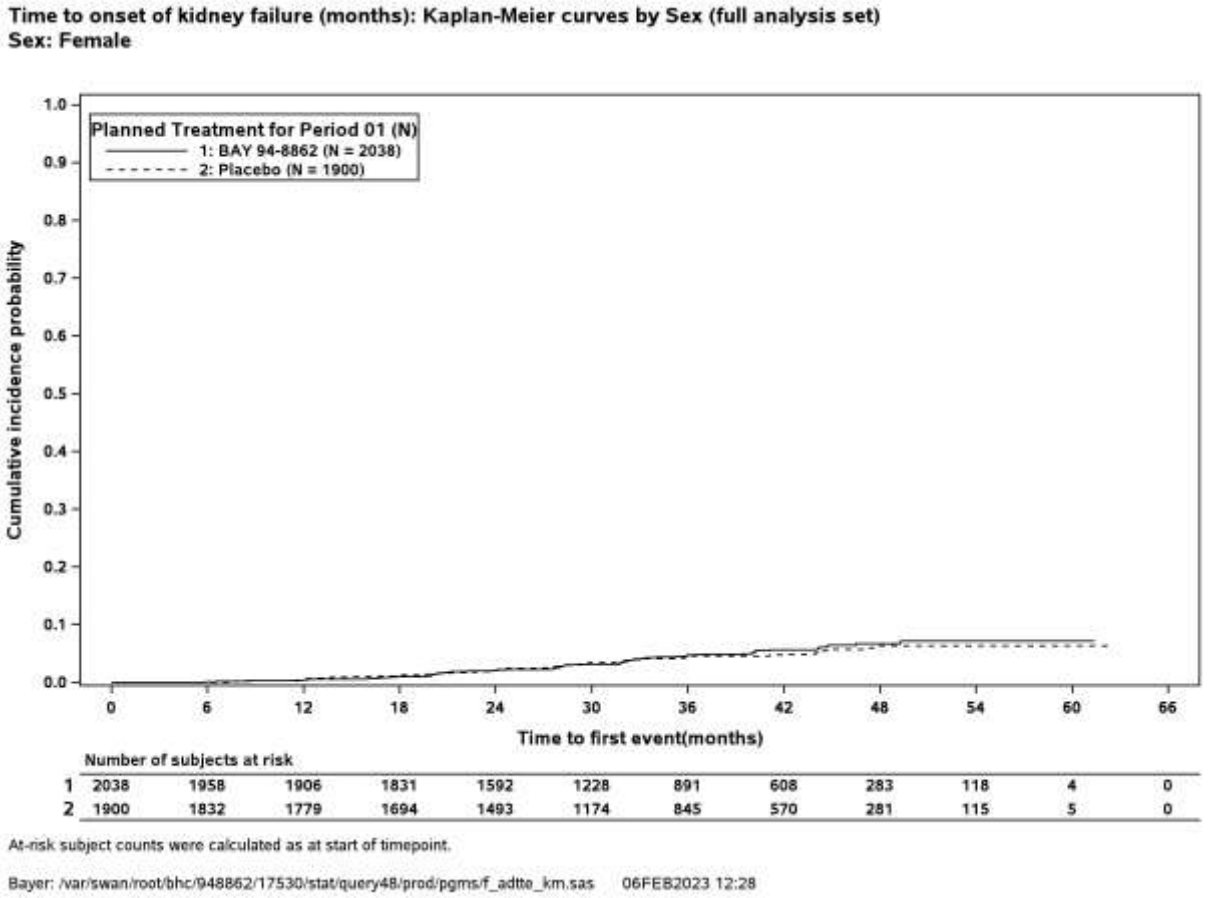


Figure 1.3.1 / 31: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

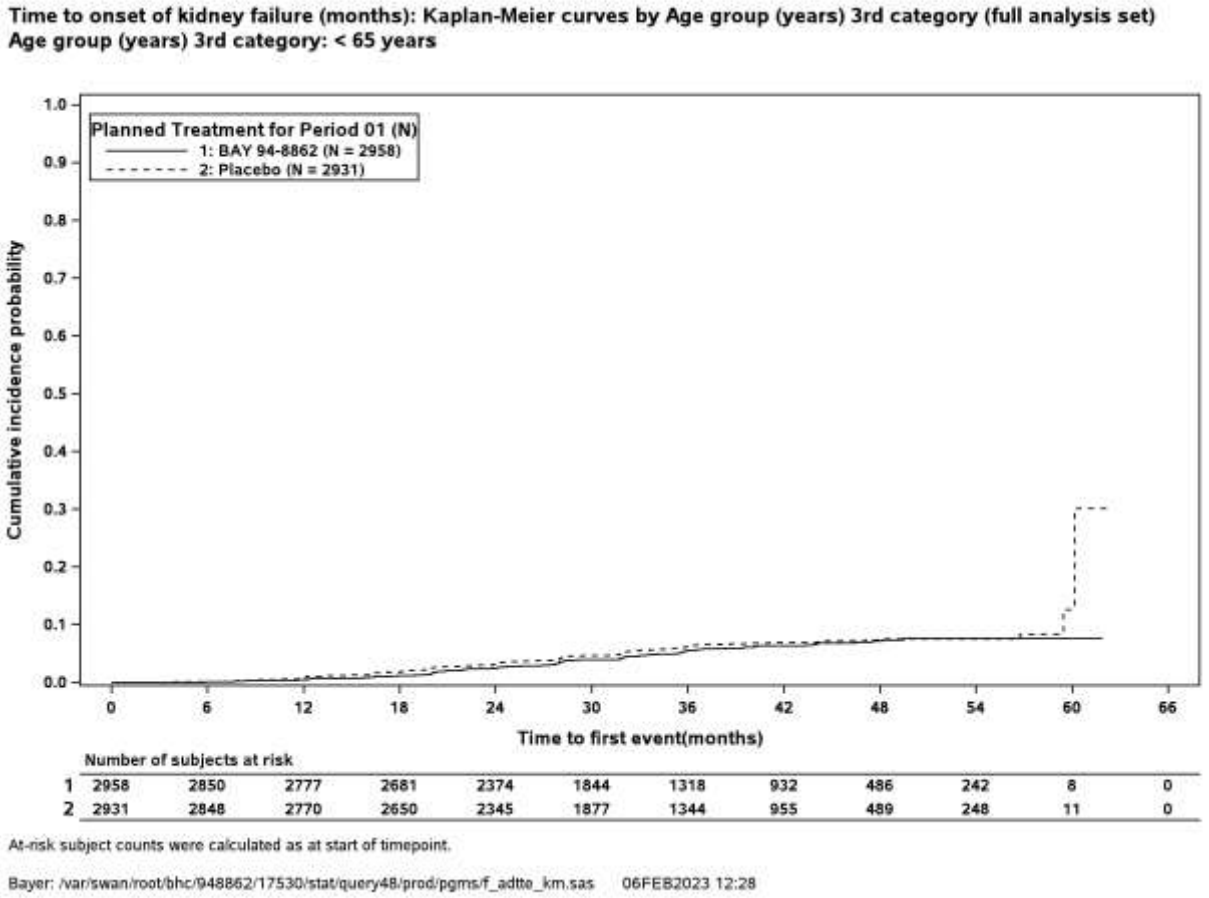


Figure 1.3.1 / 31: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

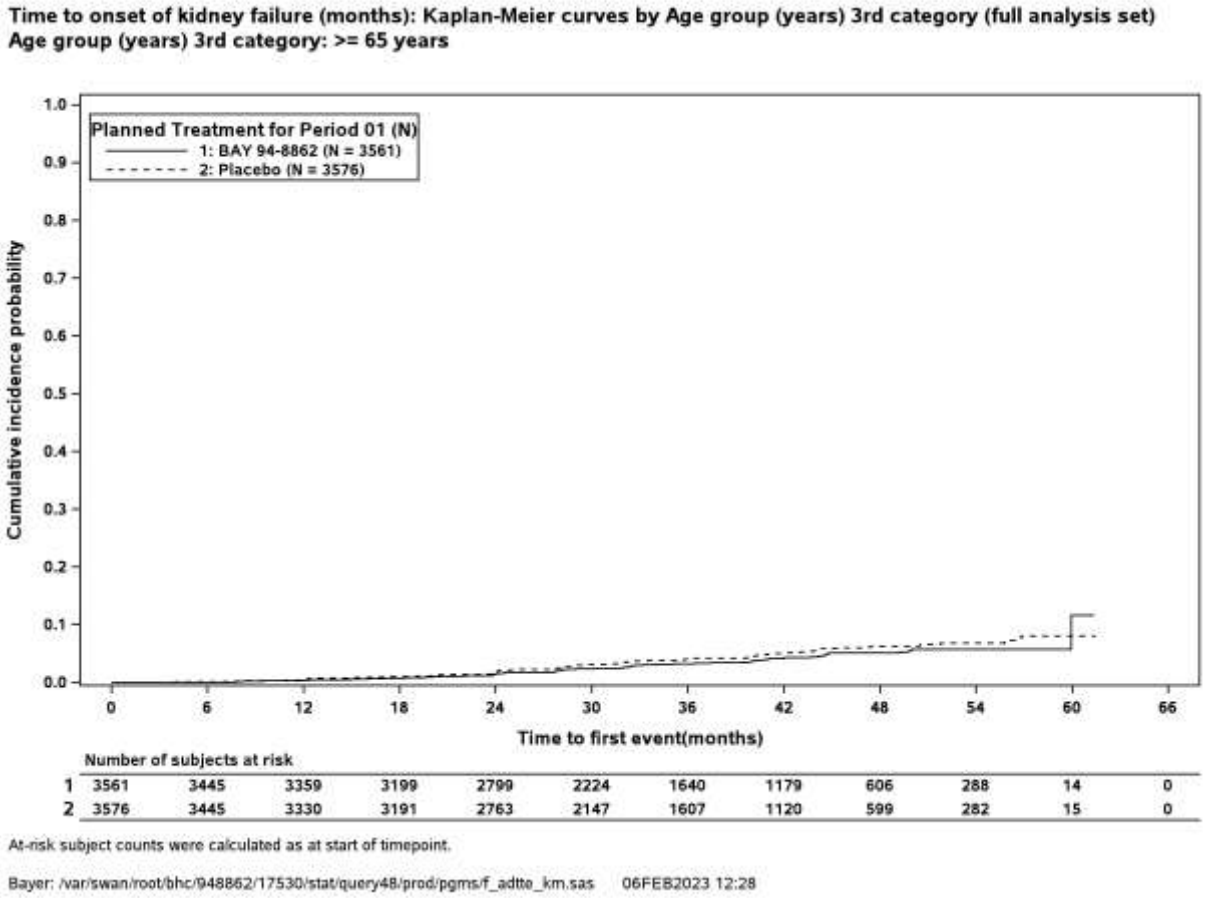


Figure 1.3.1 / 32: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set)

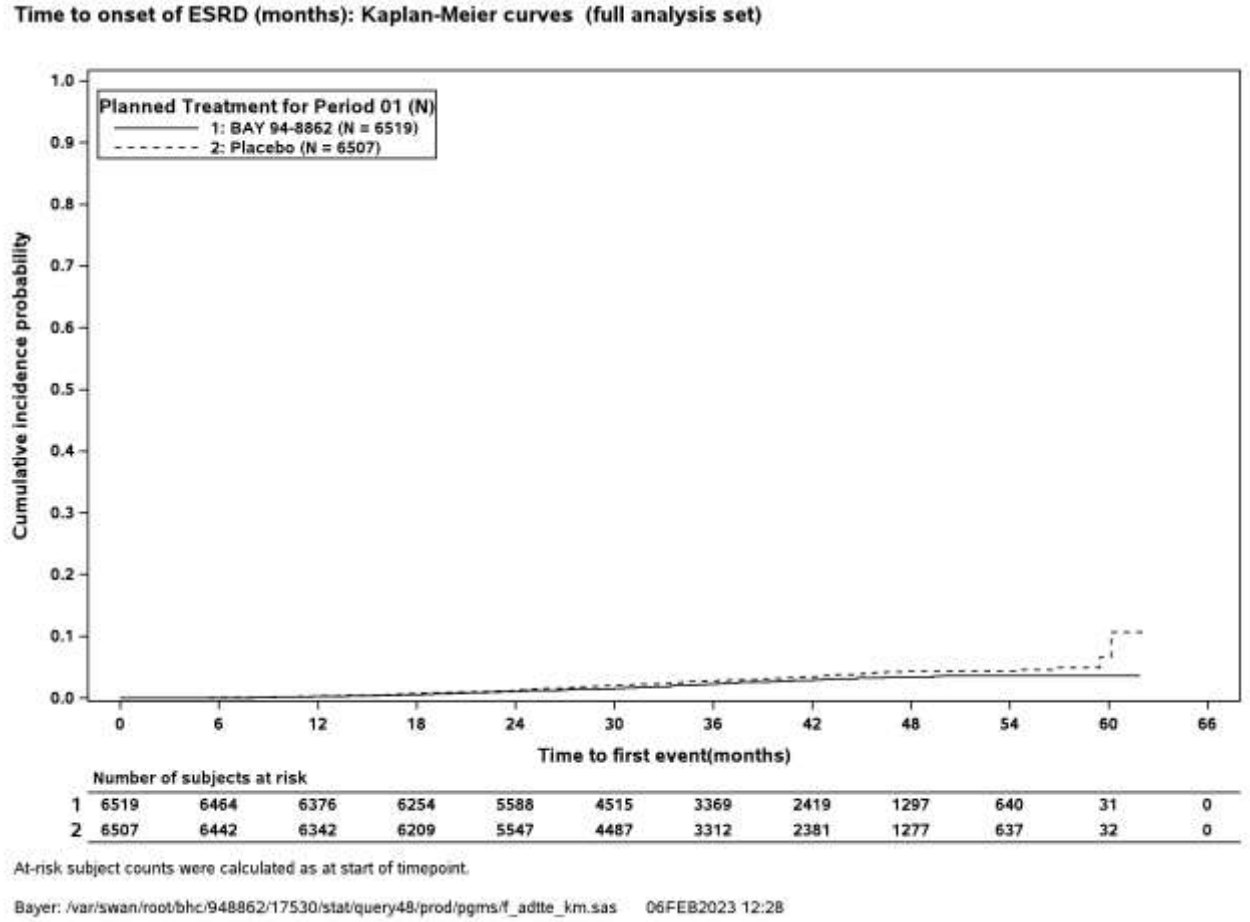


Figure 1.3.1 / 33: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set)

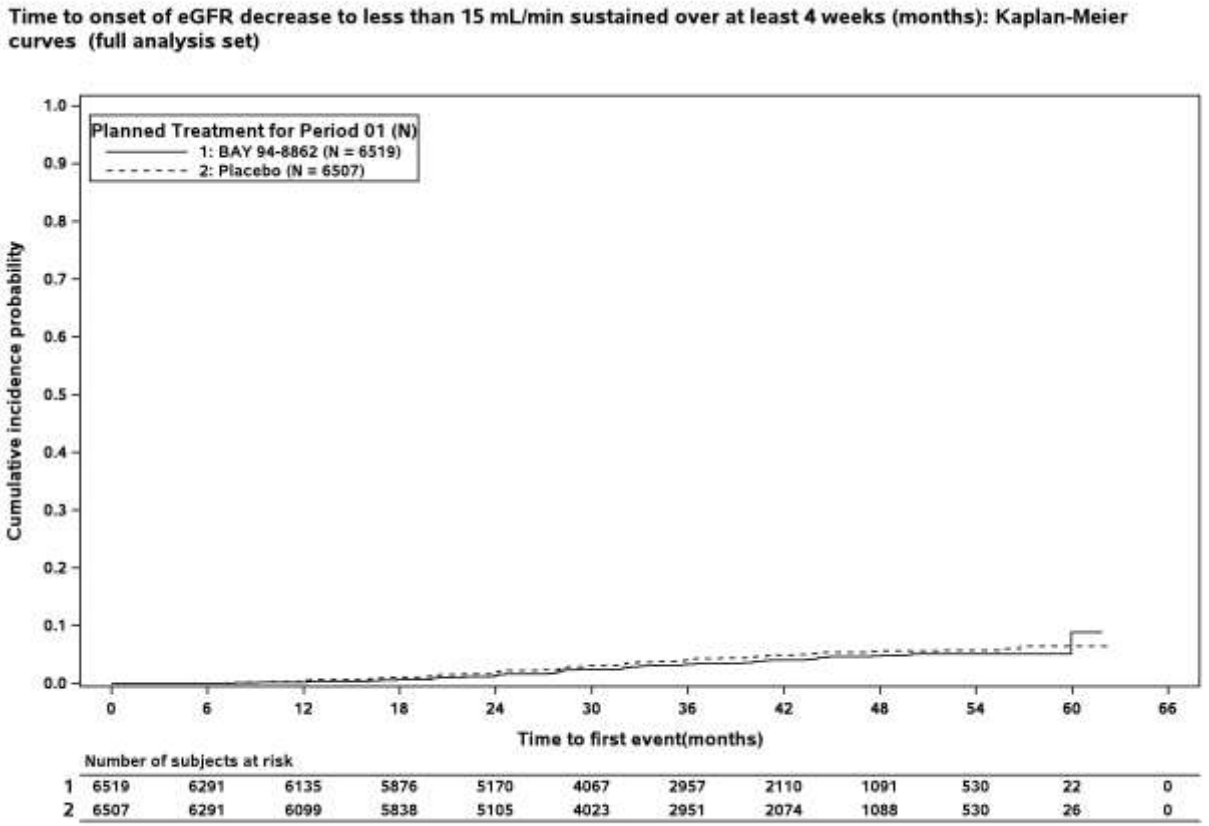


Figure 1.3.1 / 34: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set)

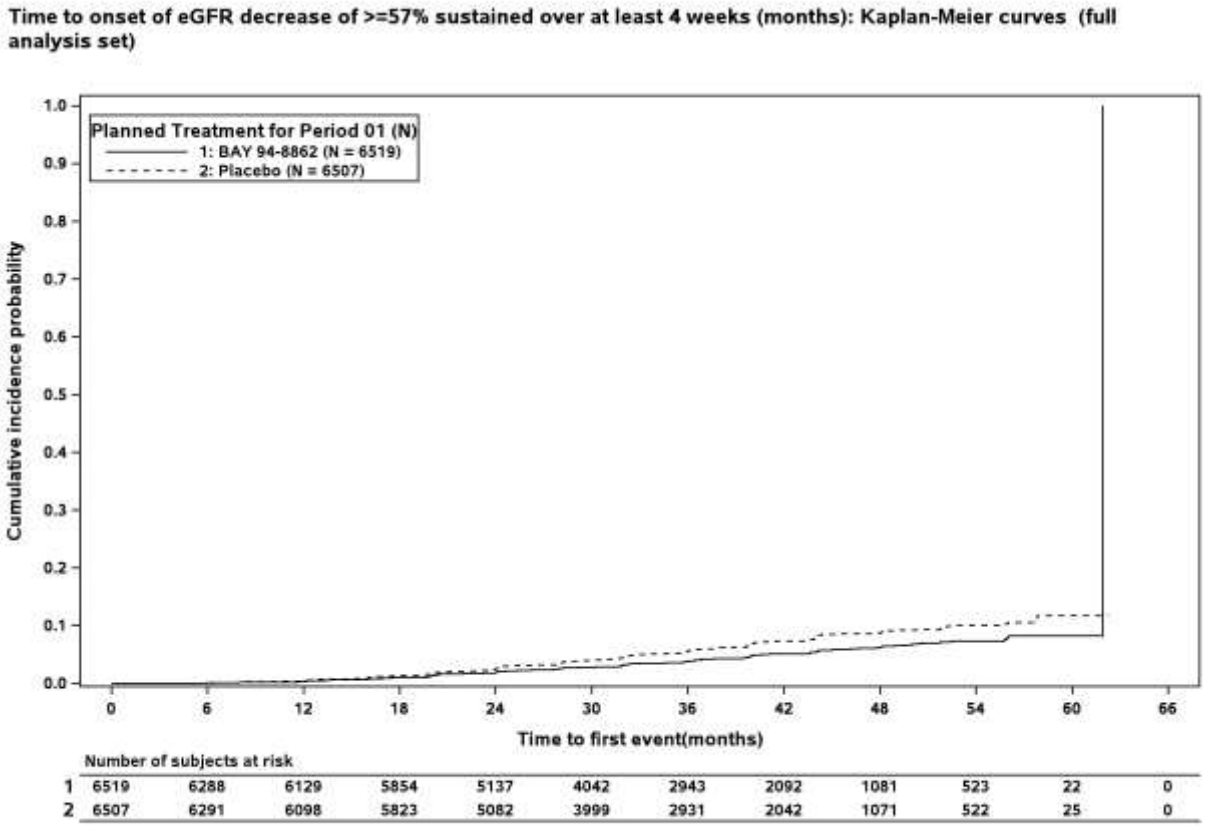


Figure 1.3.1 / 35: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set)

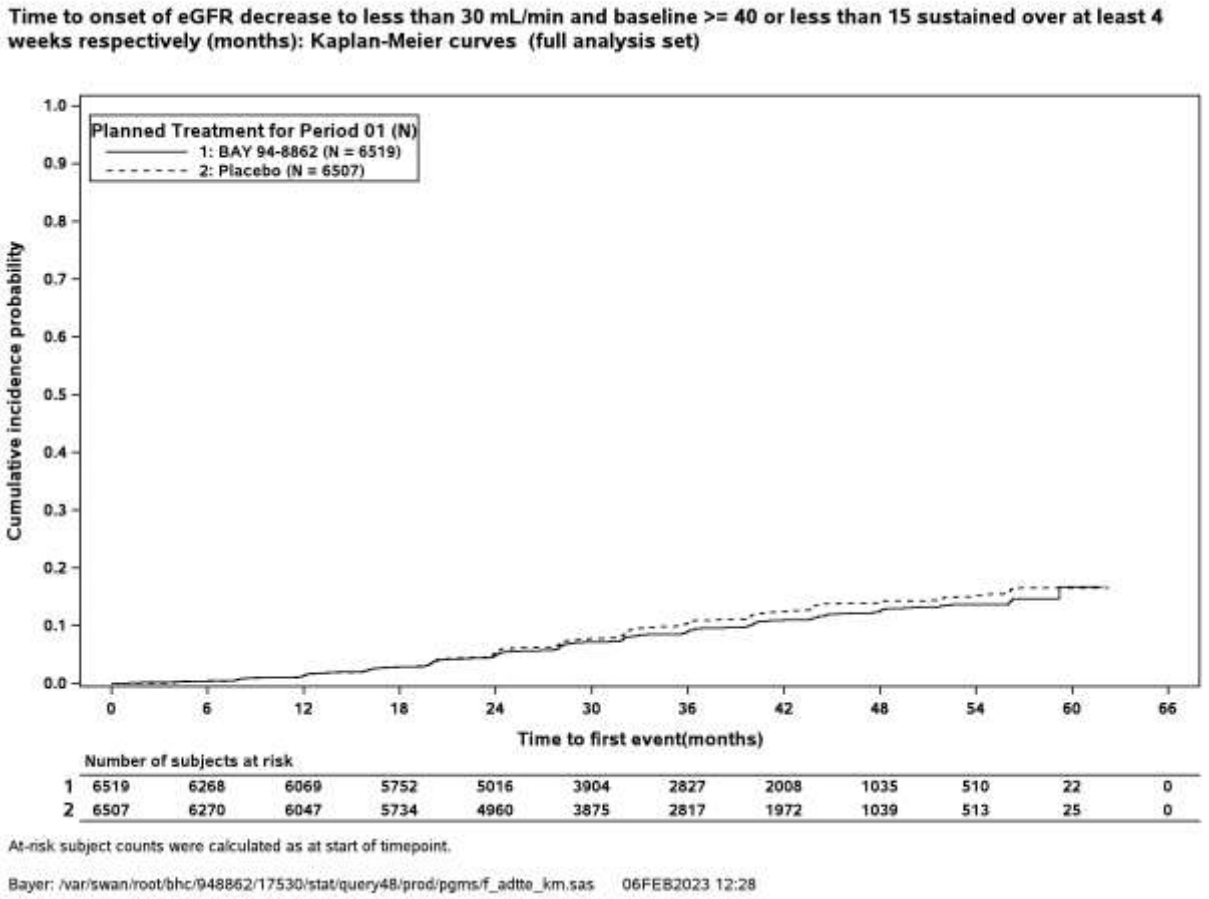


Figure 1.3.1 / 36: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set)

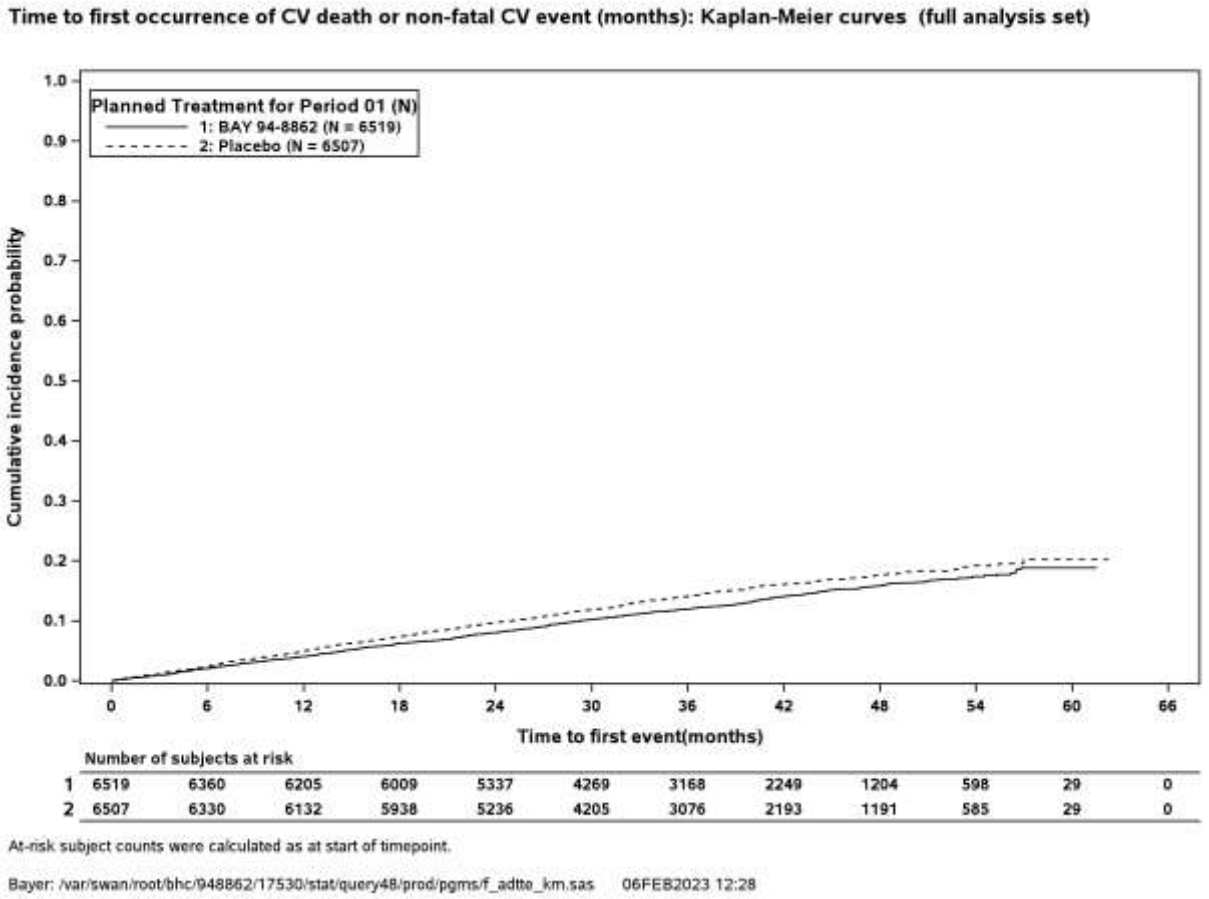


Figure 1.3.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

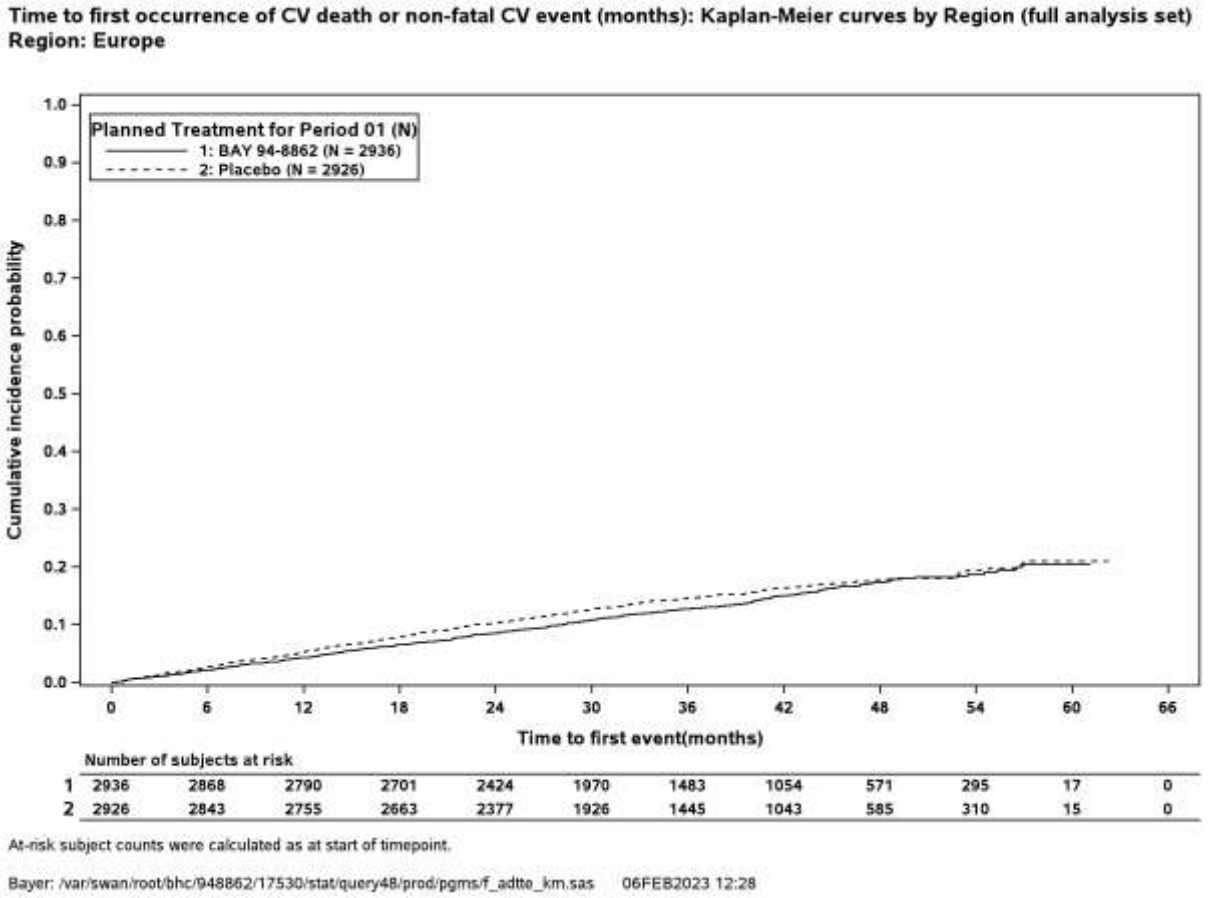


Figure 1.3.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

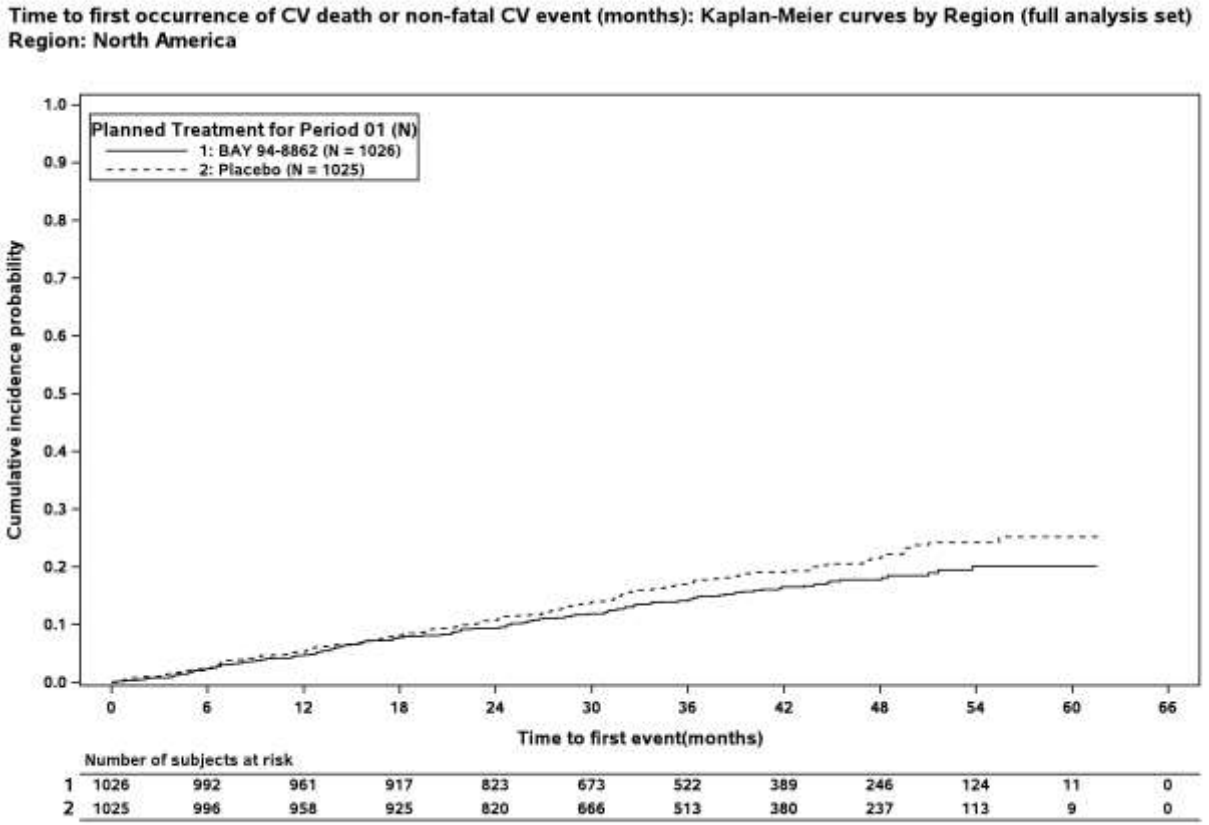


Figure 1.3.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

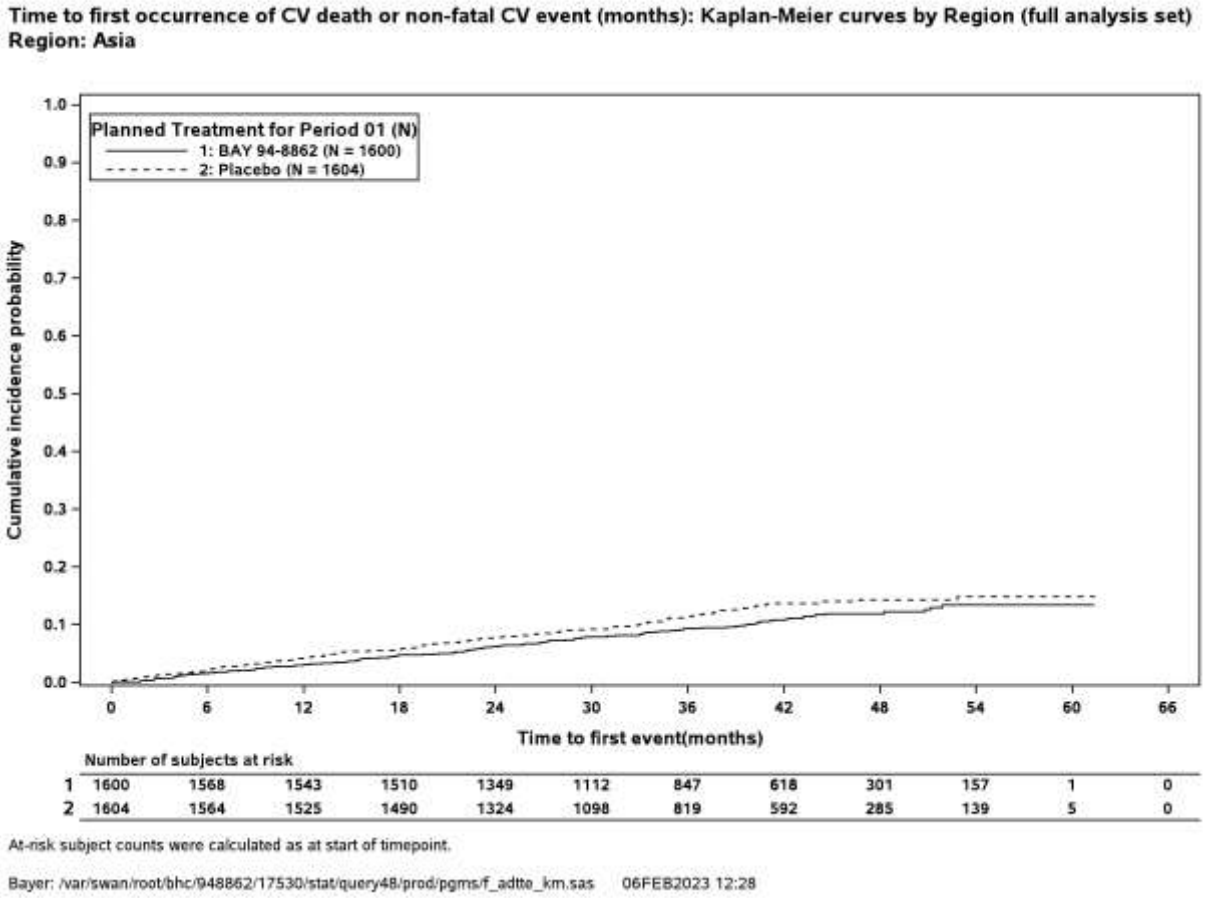


Figure 1.3.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

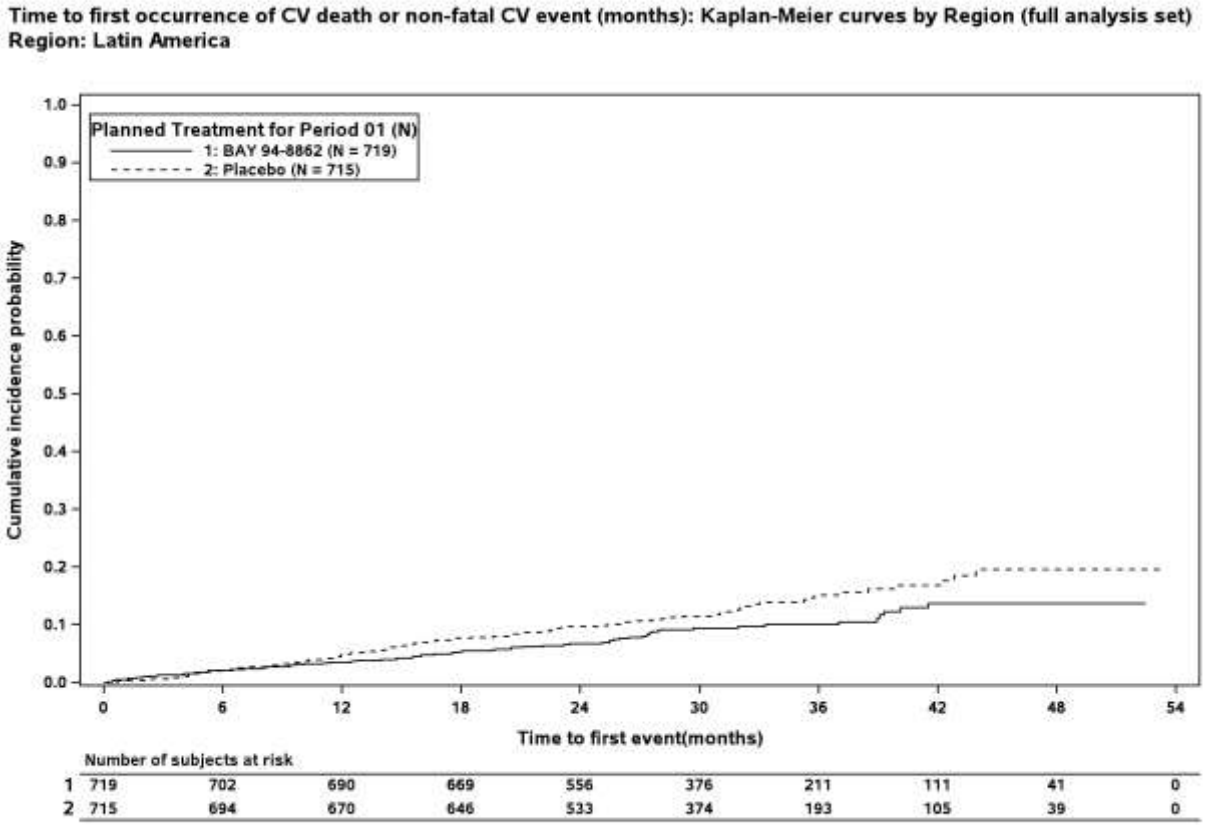


Figure 1.3.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

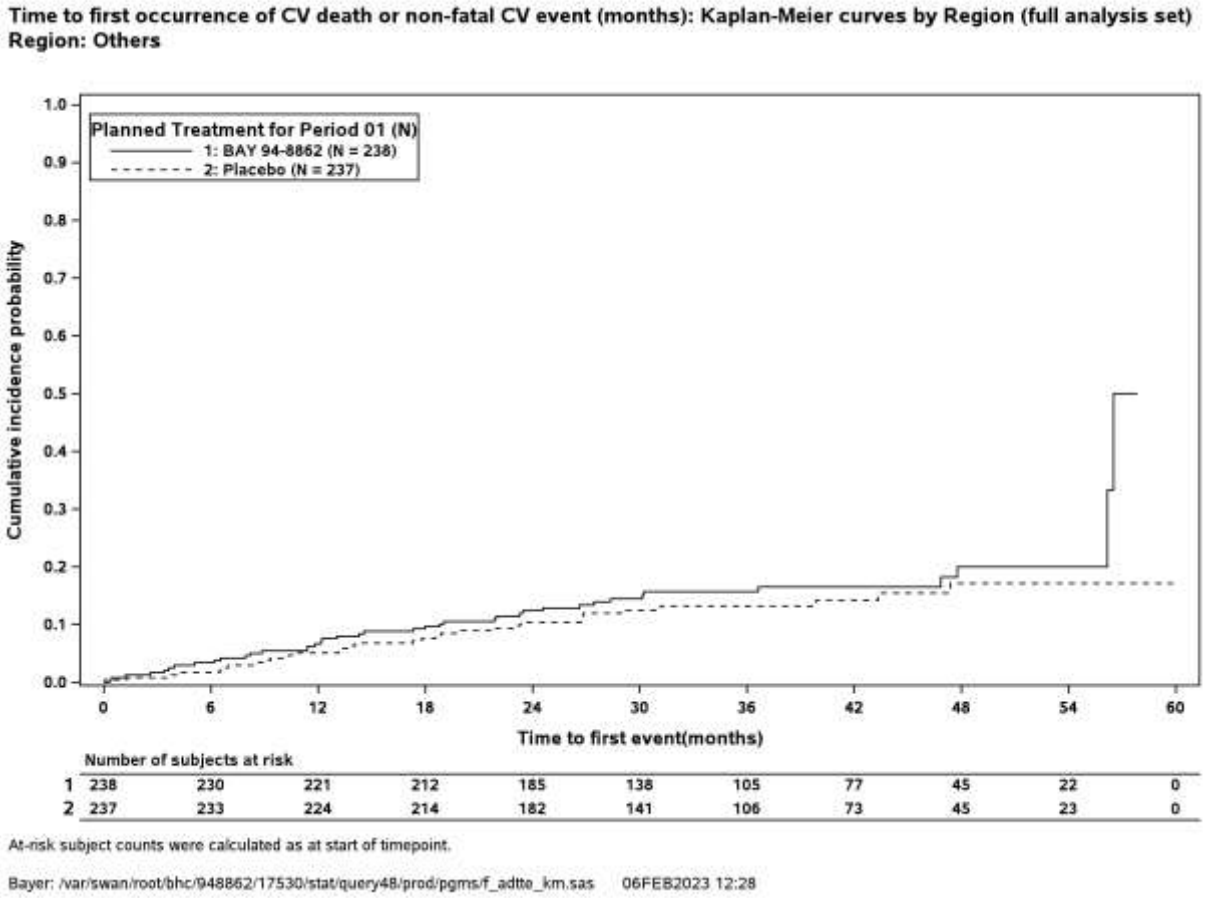


Figure 1.3.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

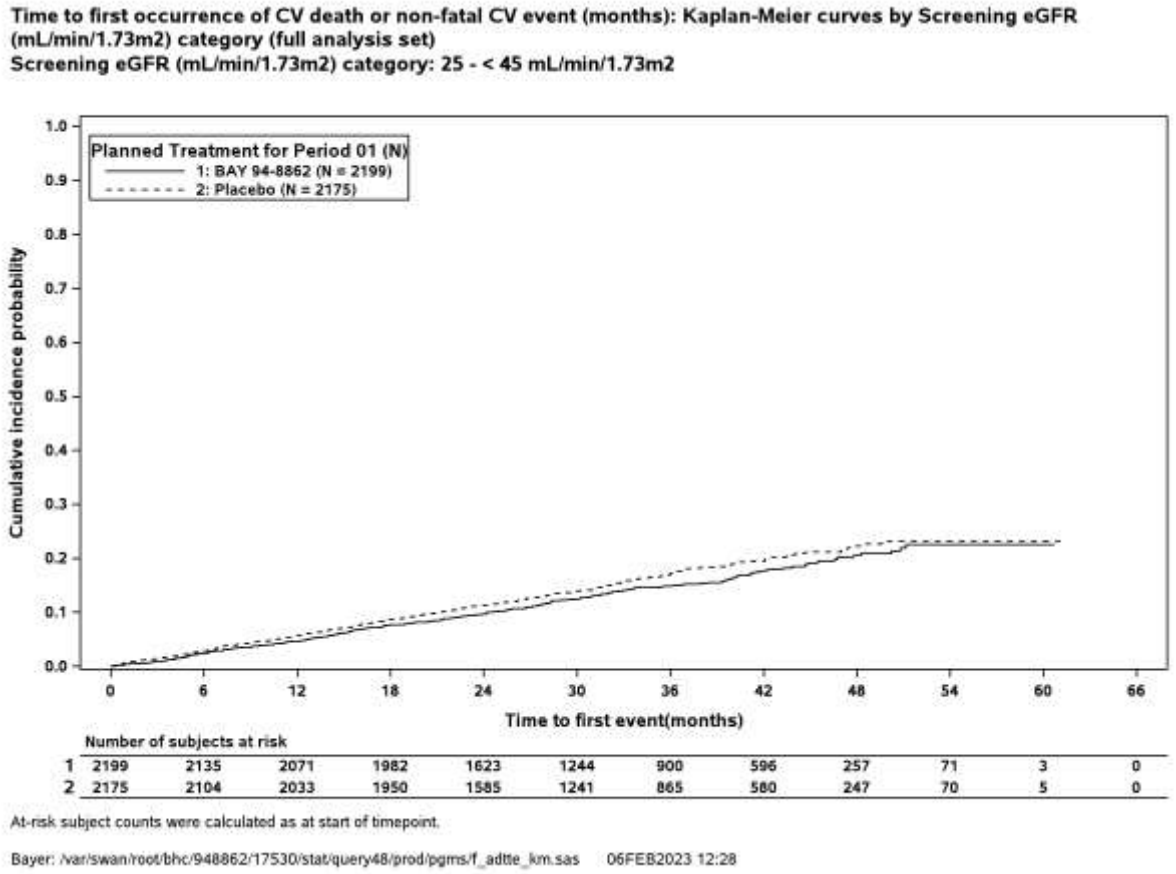


Figure 1.3.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

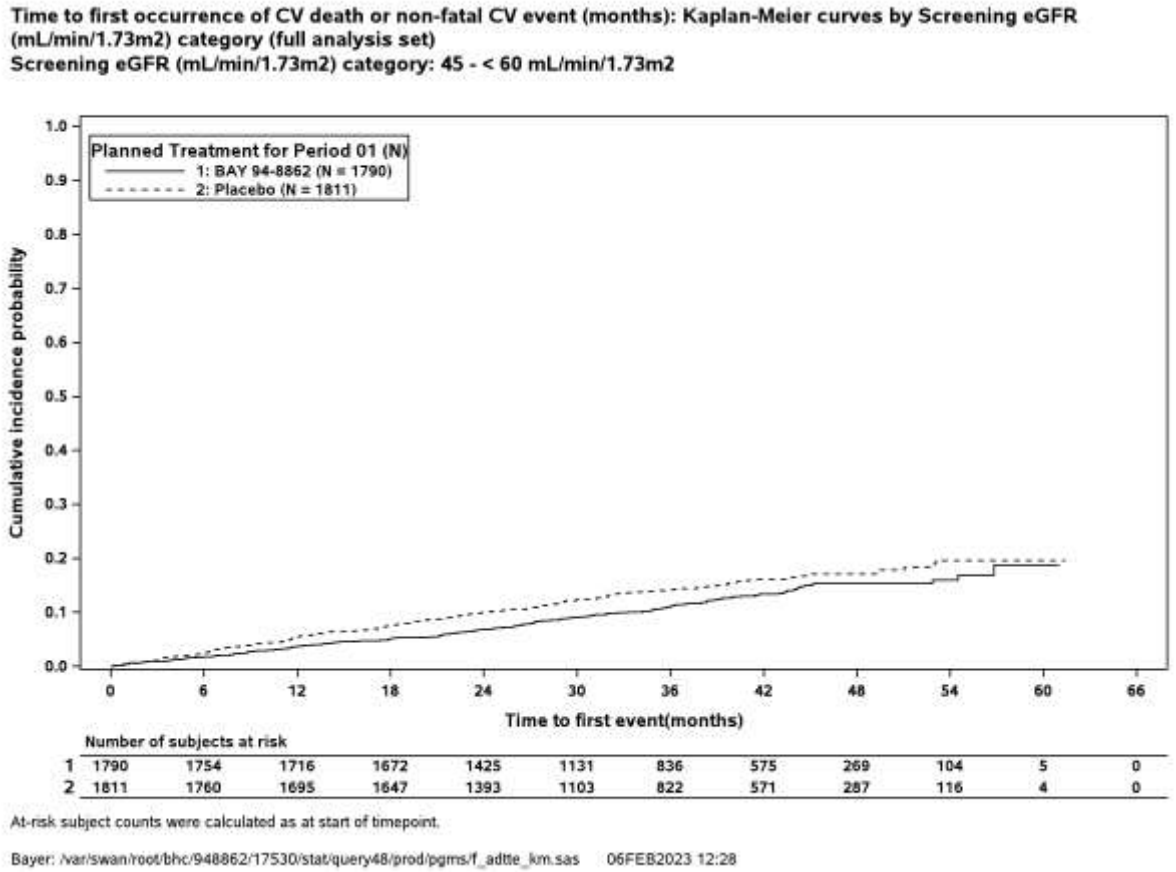


Figure 1.3.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

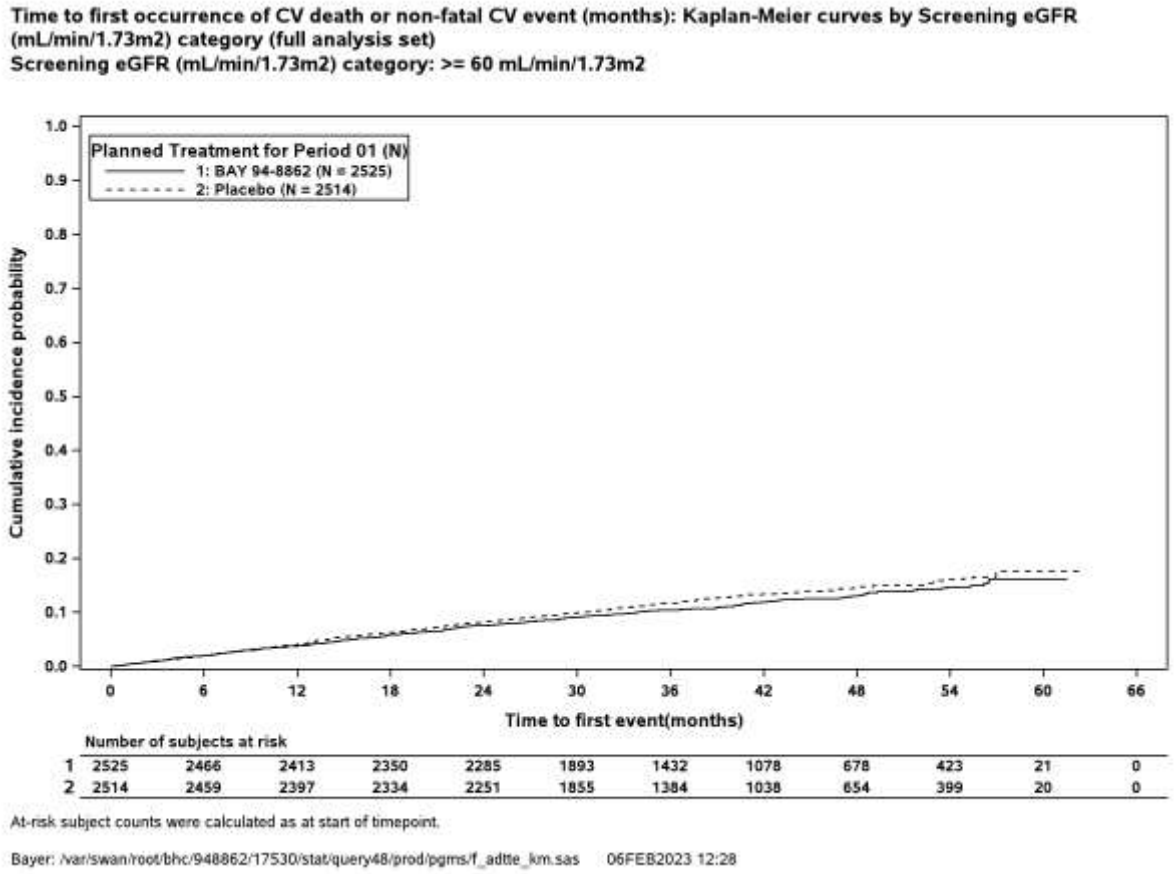


Figure 1.3.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

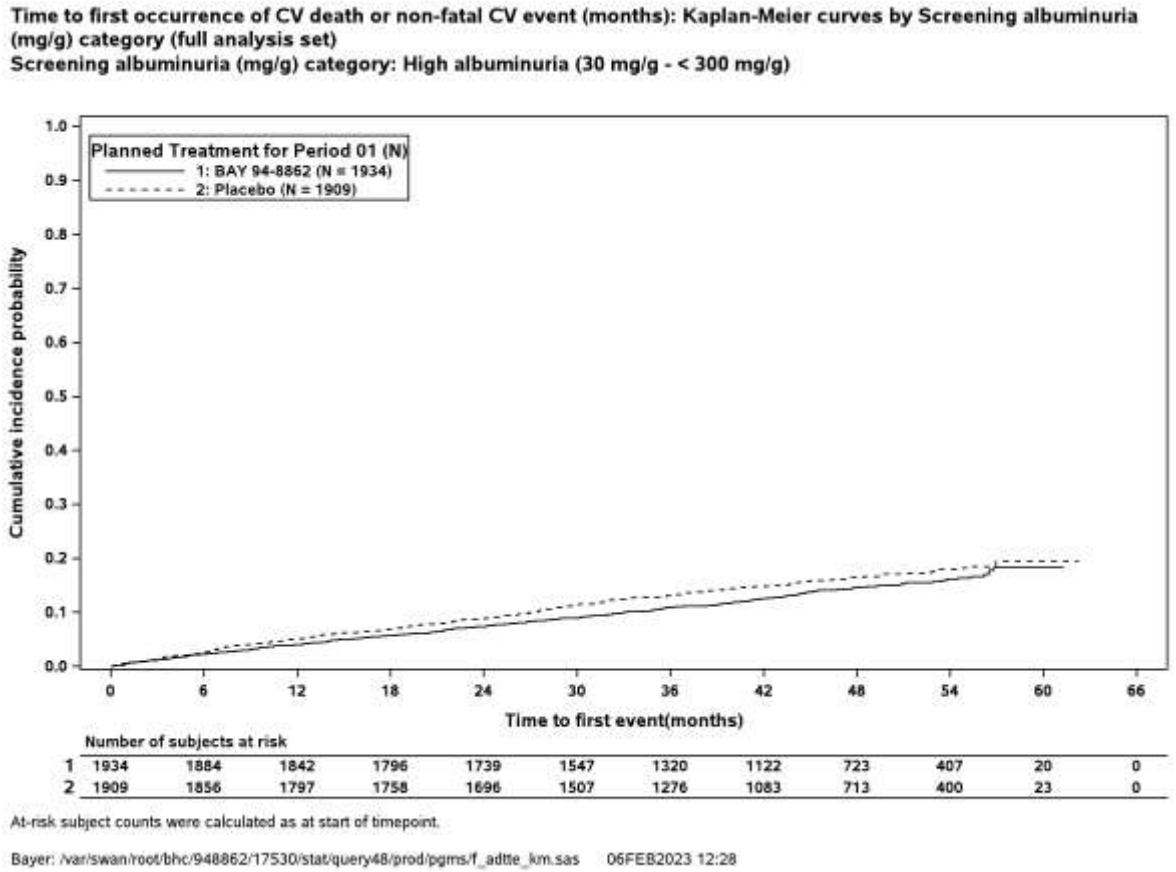
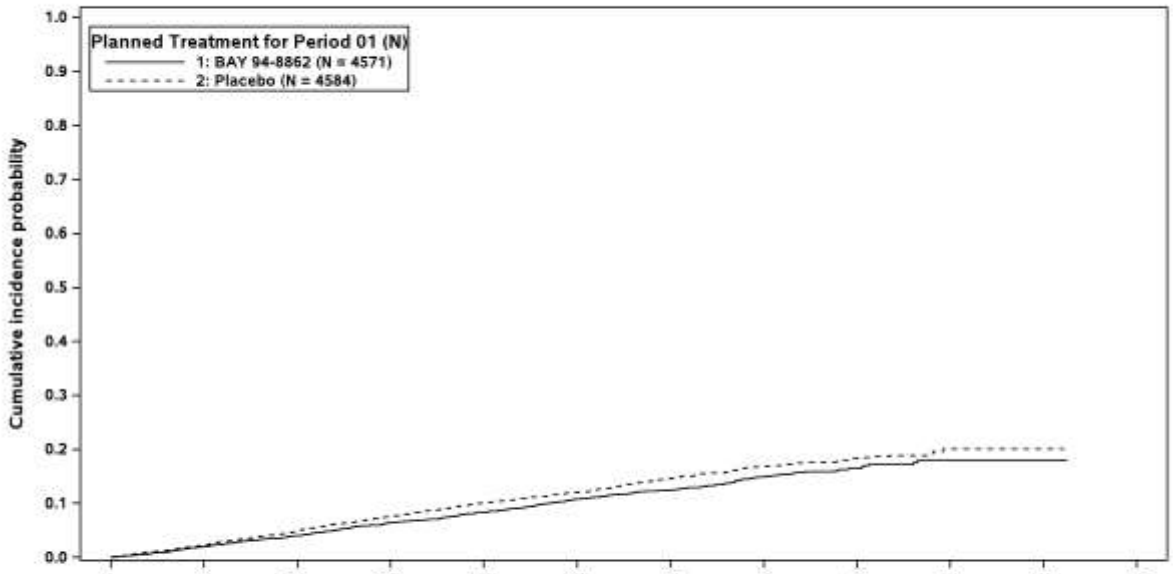


Figure 1.3.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4463	4350	4200	3585	2711	1842	1122	477	189	9	0
2	4584	4461	4322	4168	3528	2688	1792	1103	474	183	6	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

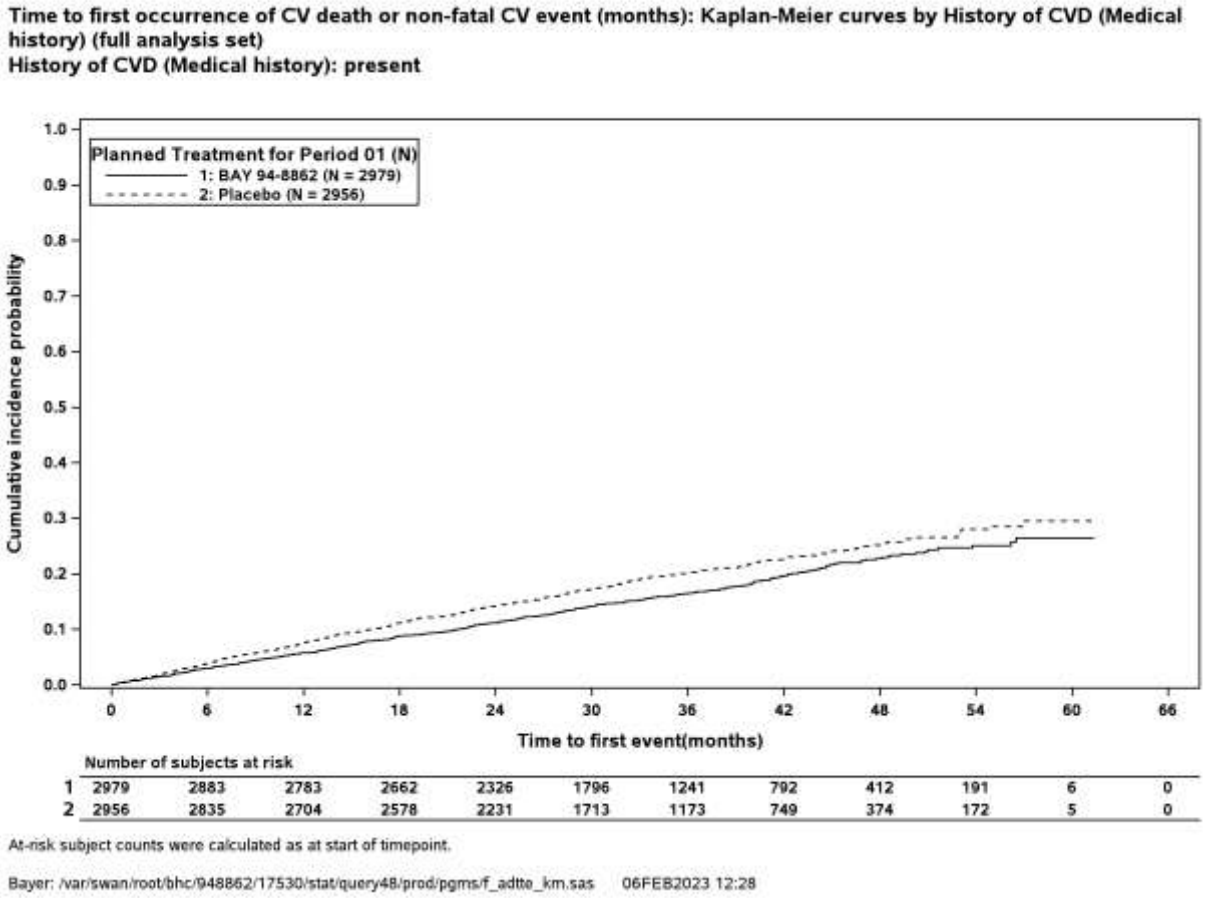


Figure 1.3.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

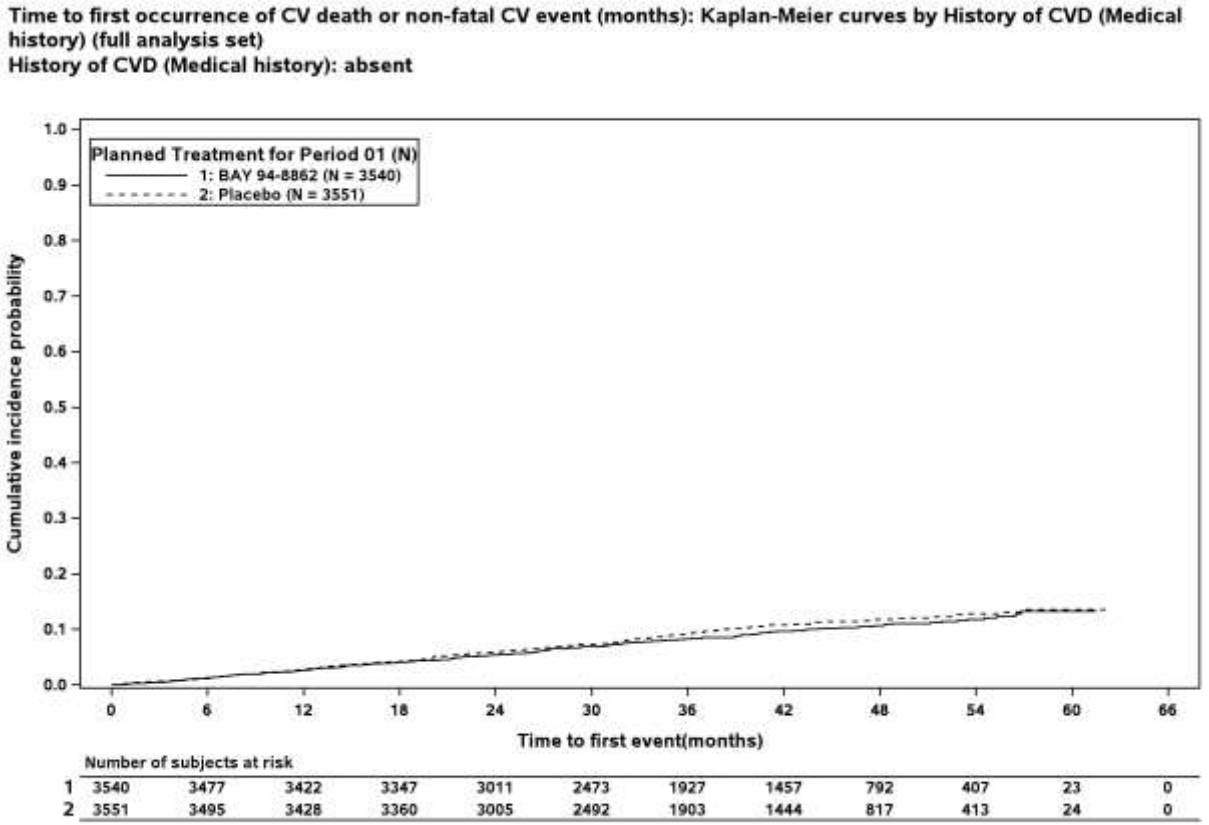


Figure 1.3.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

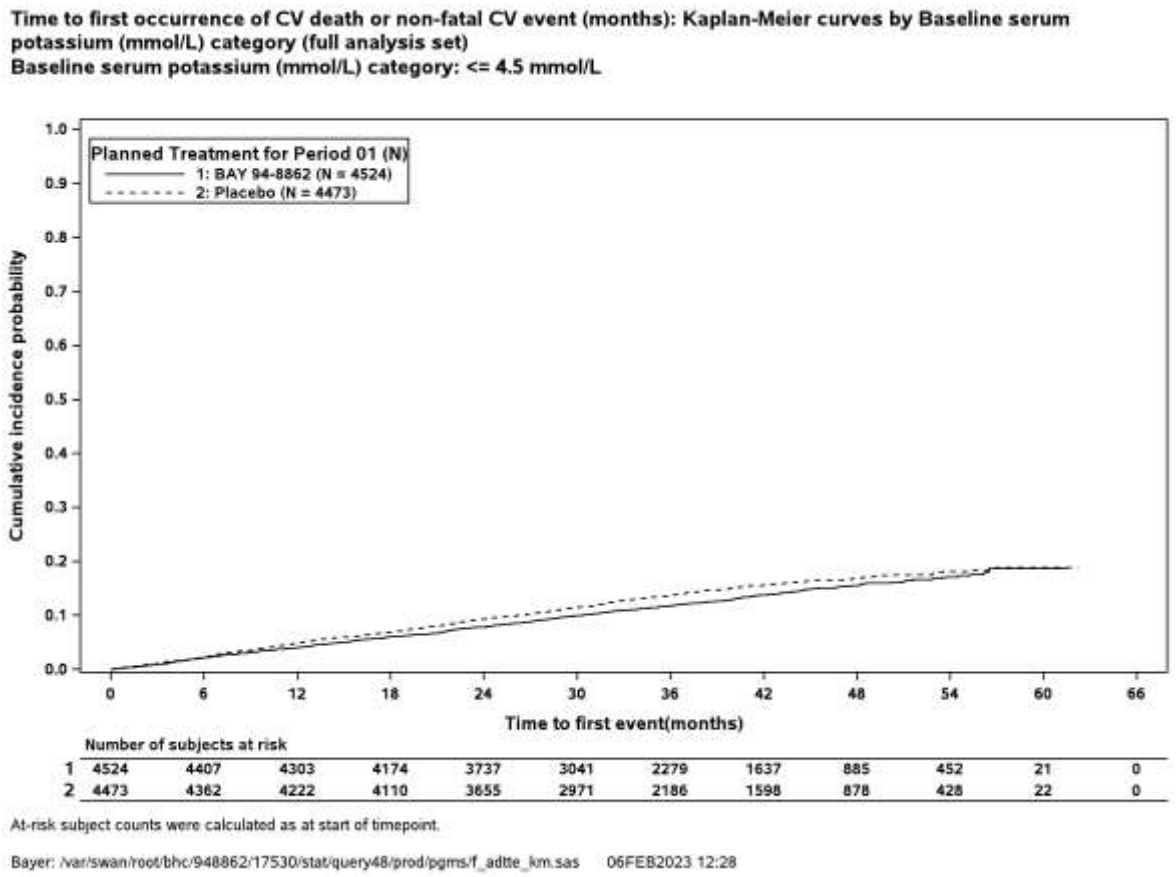
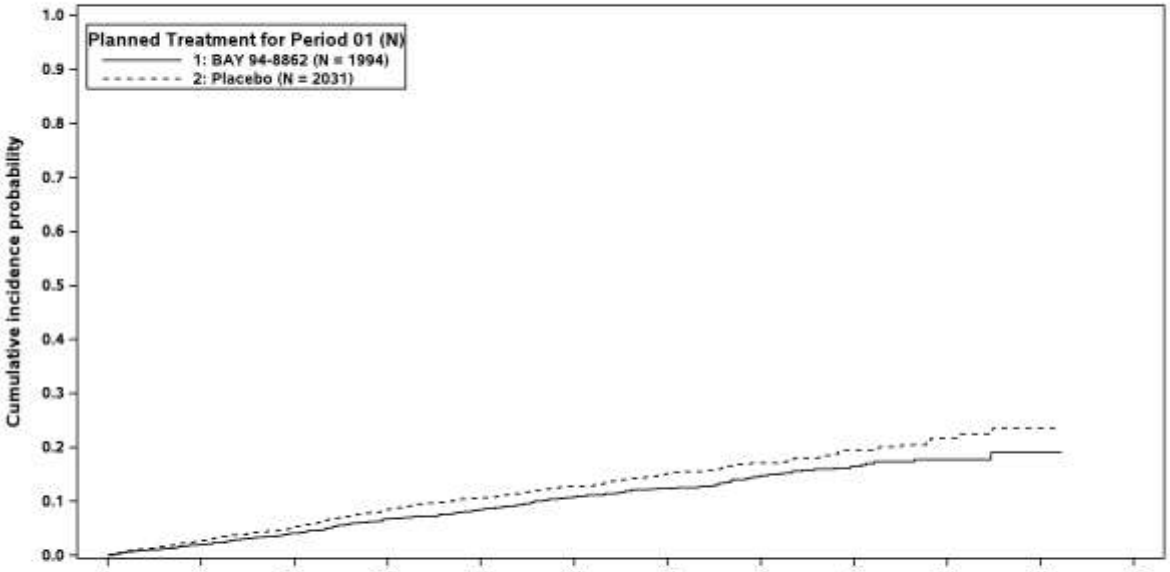


Figure 1.3.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

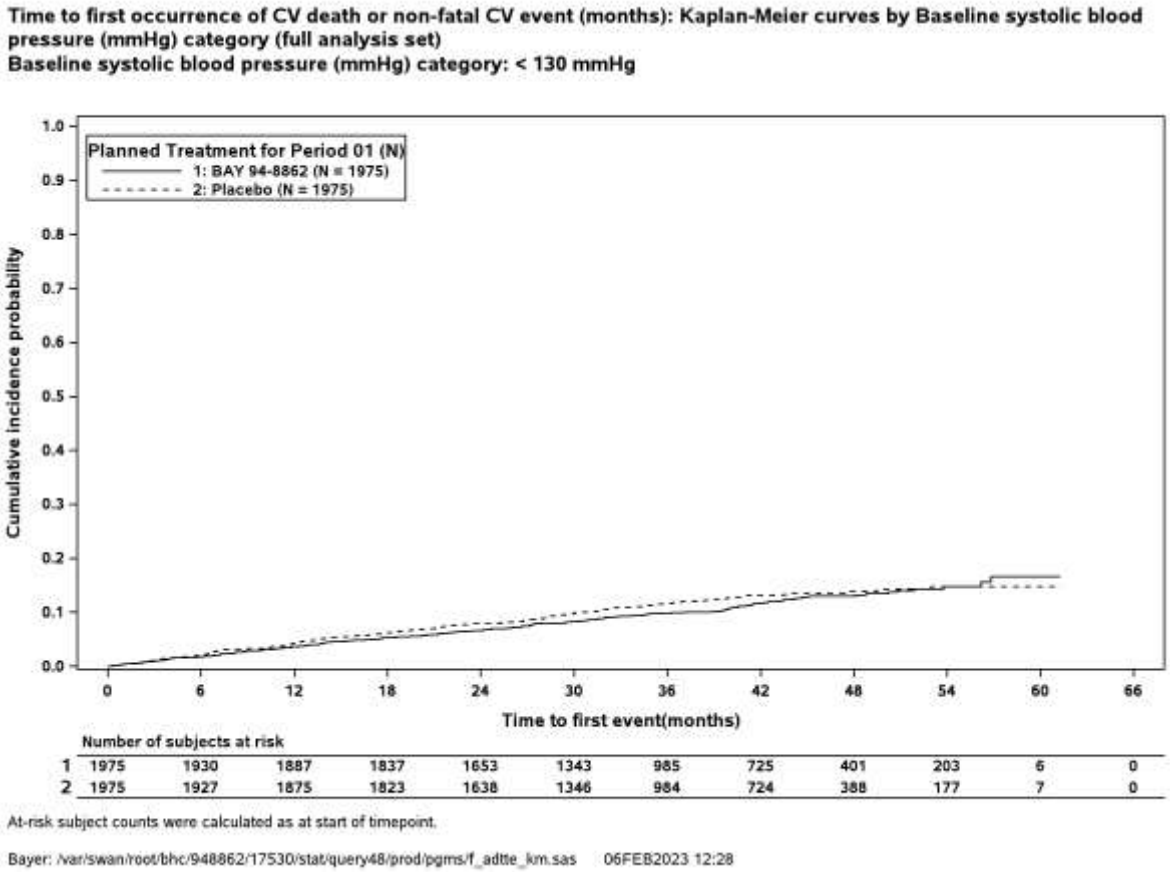


Figure 1.3.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

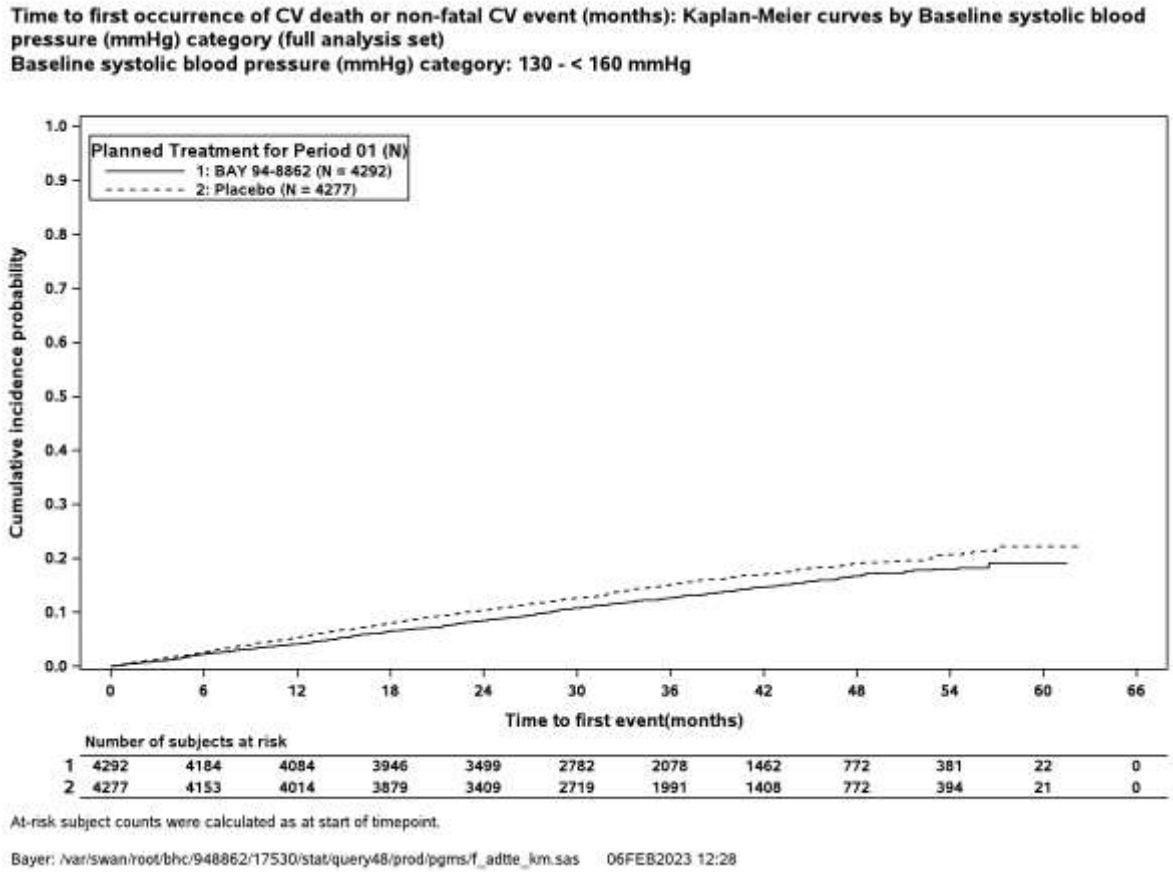


Figure 1.3.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

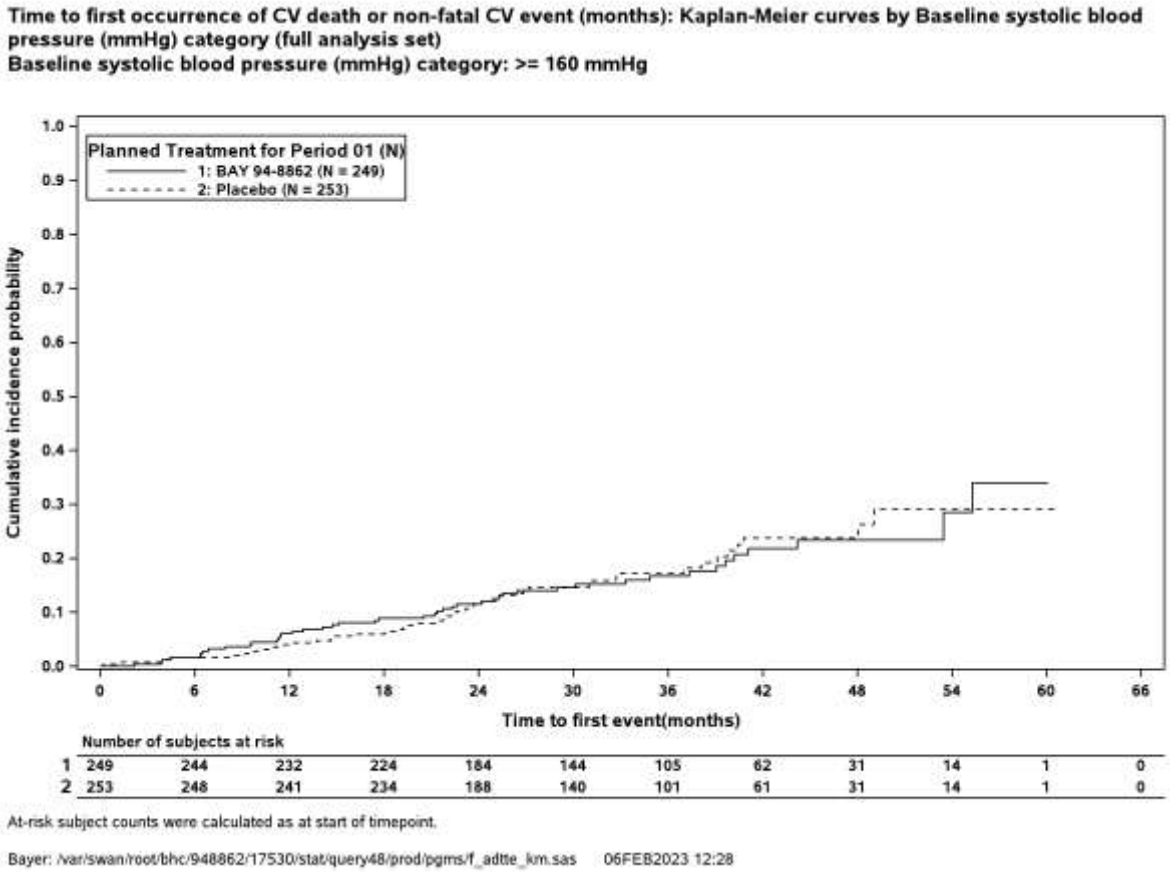


Figure 1.3.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

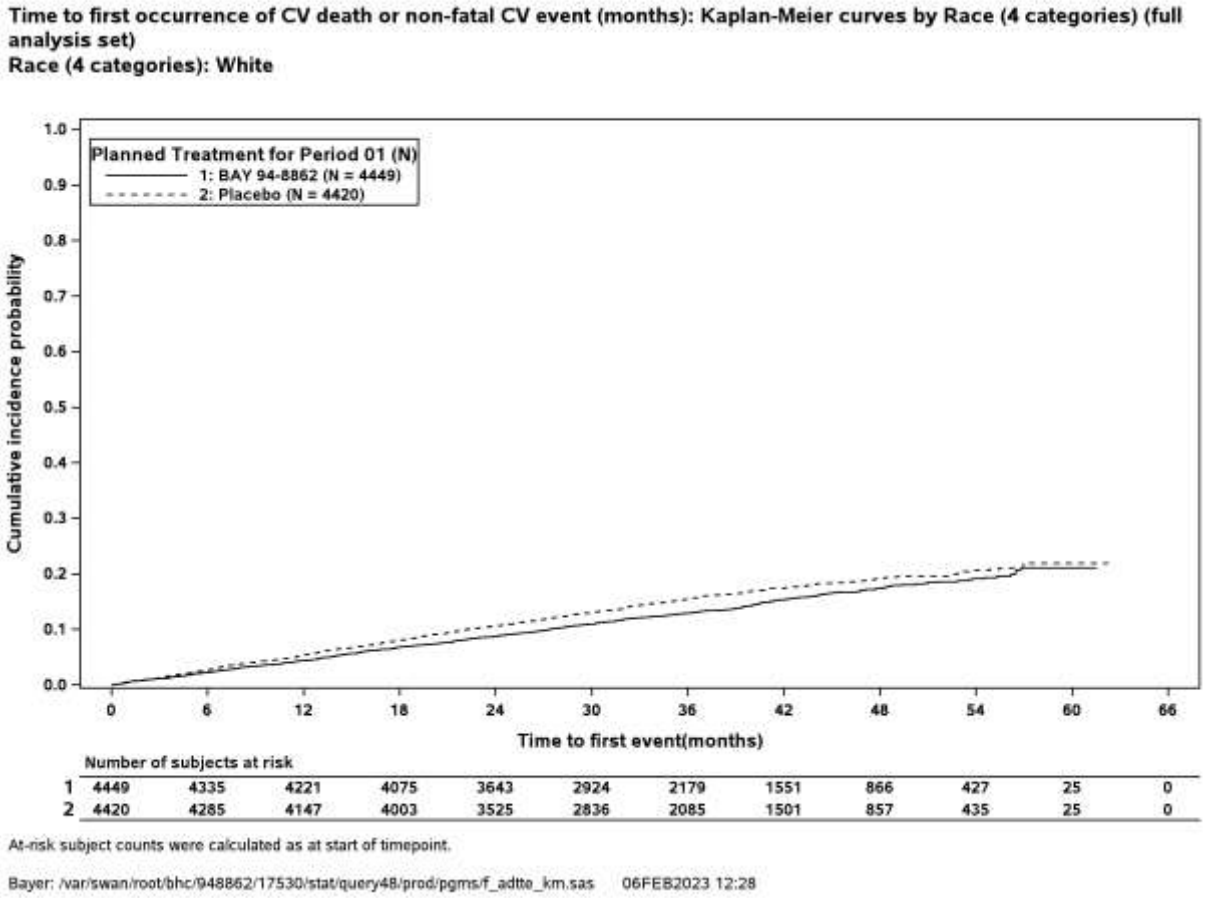


Figure 1.3.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

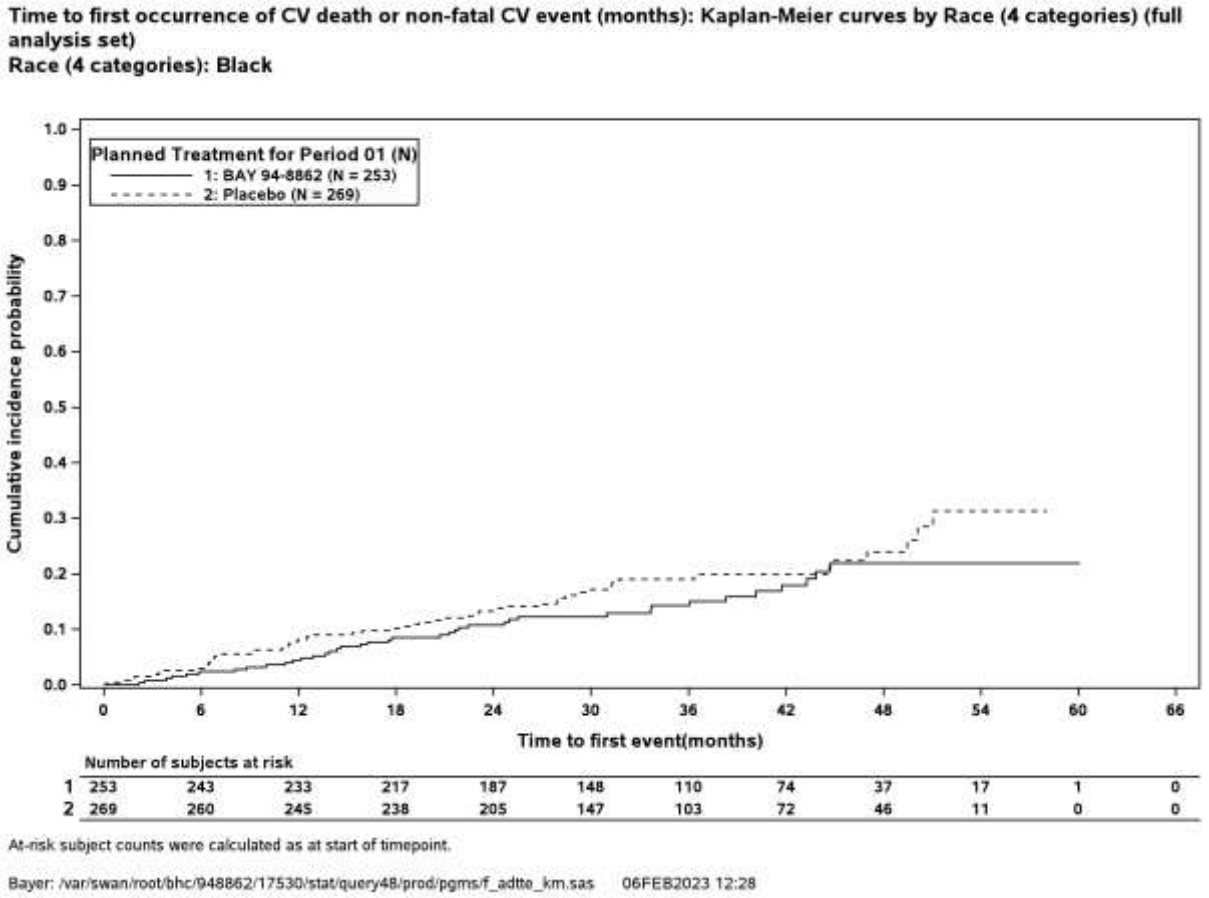


Figure 1.3.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

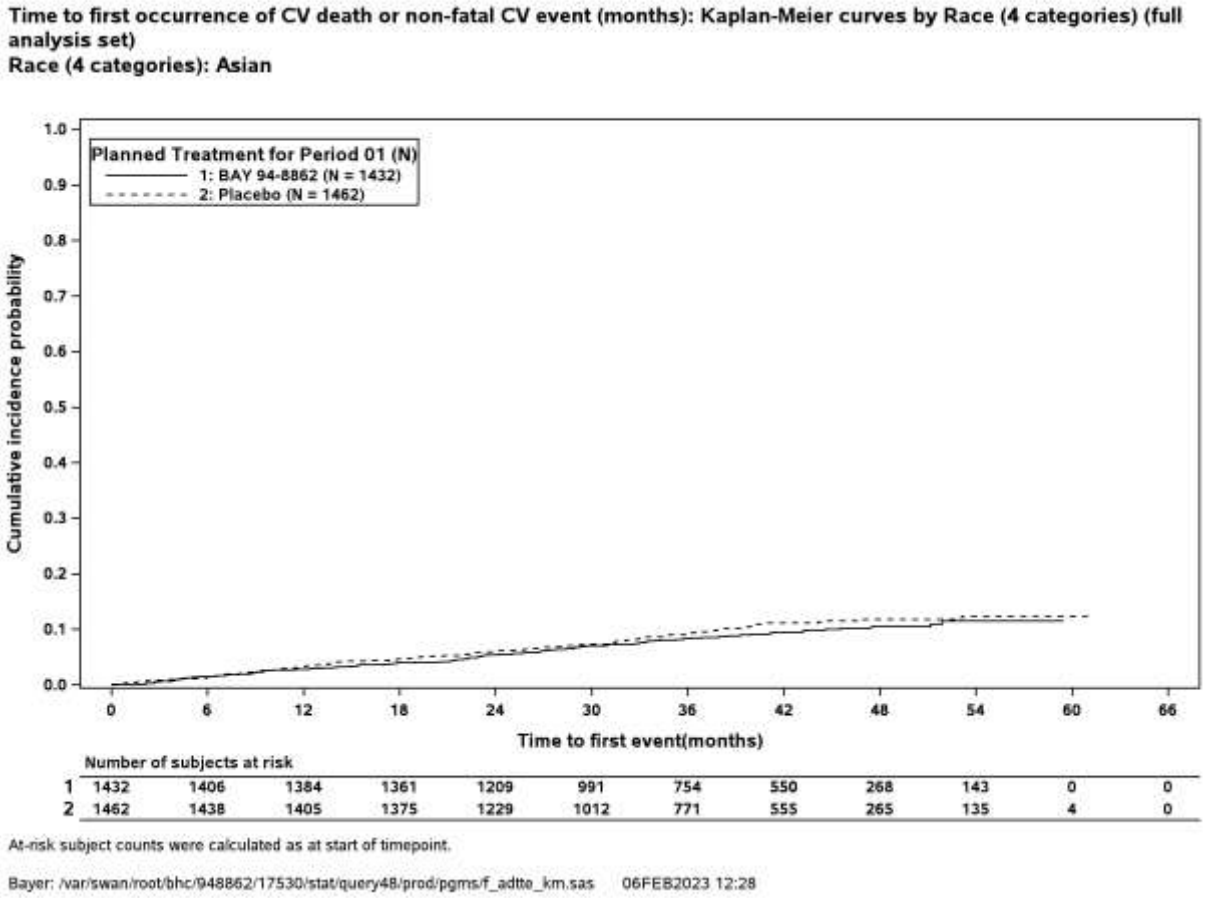


Figure 1.3.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

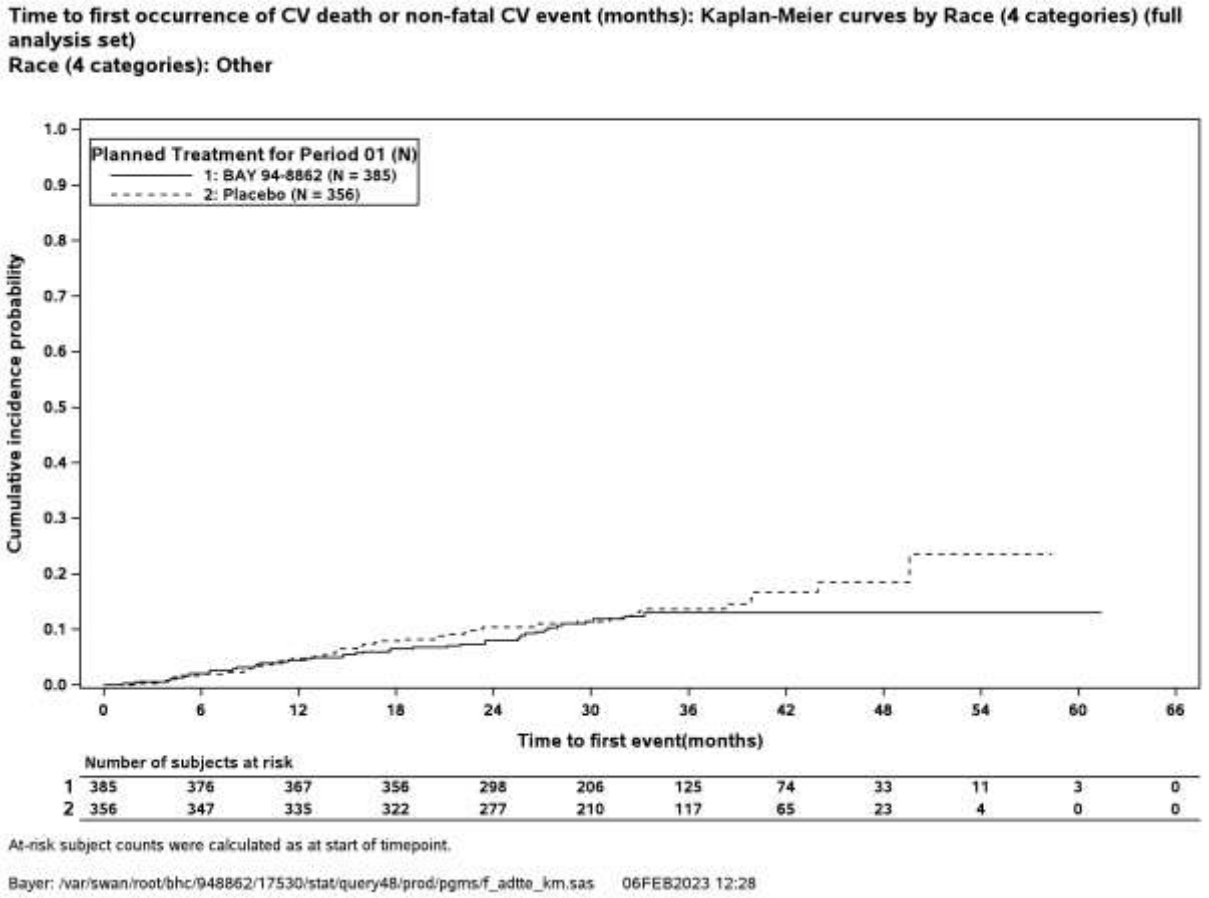


Figure 1.3.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

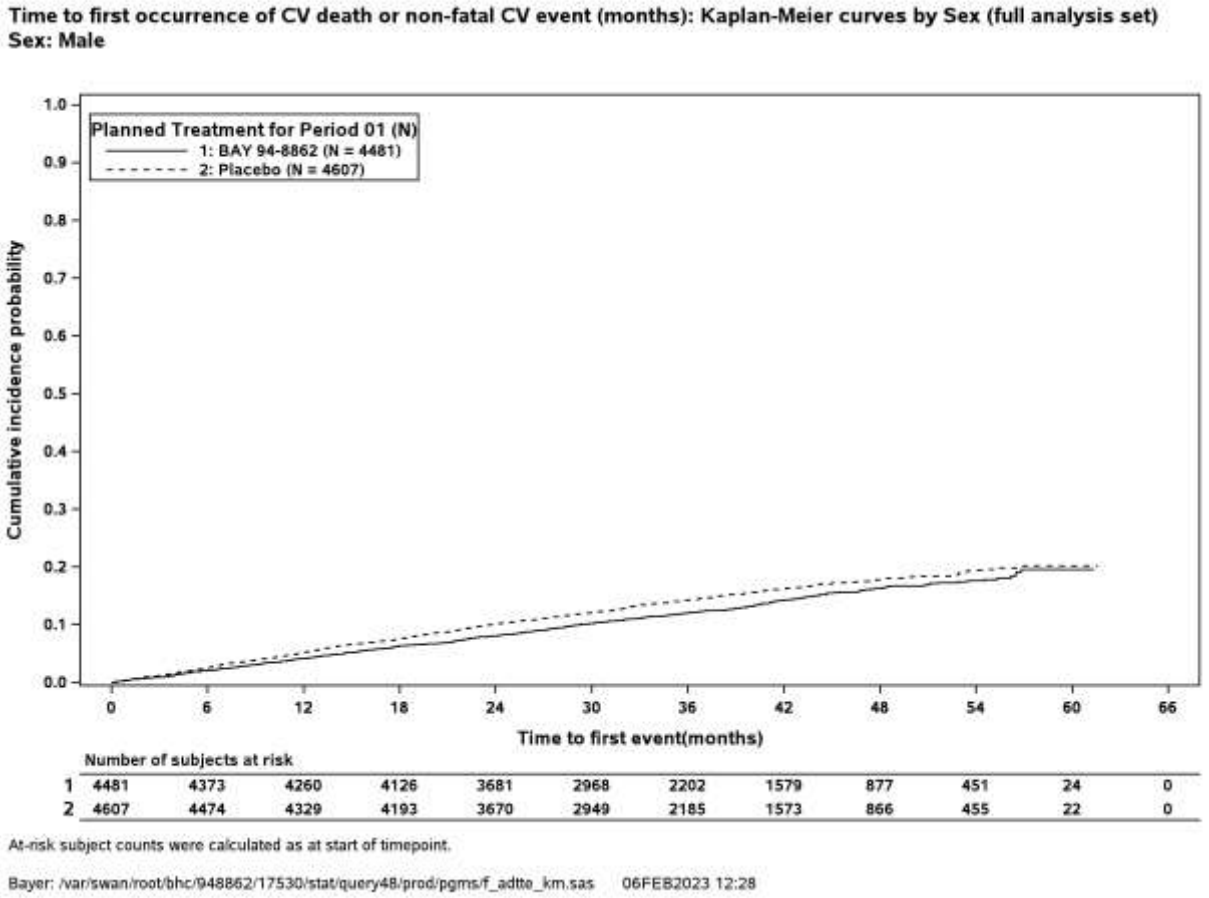


Figure 1.3.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

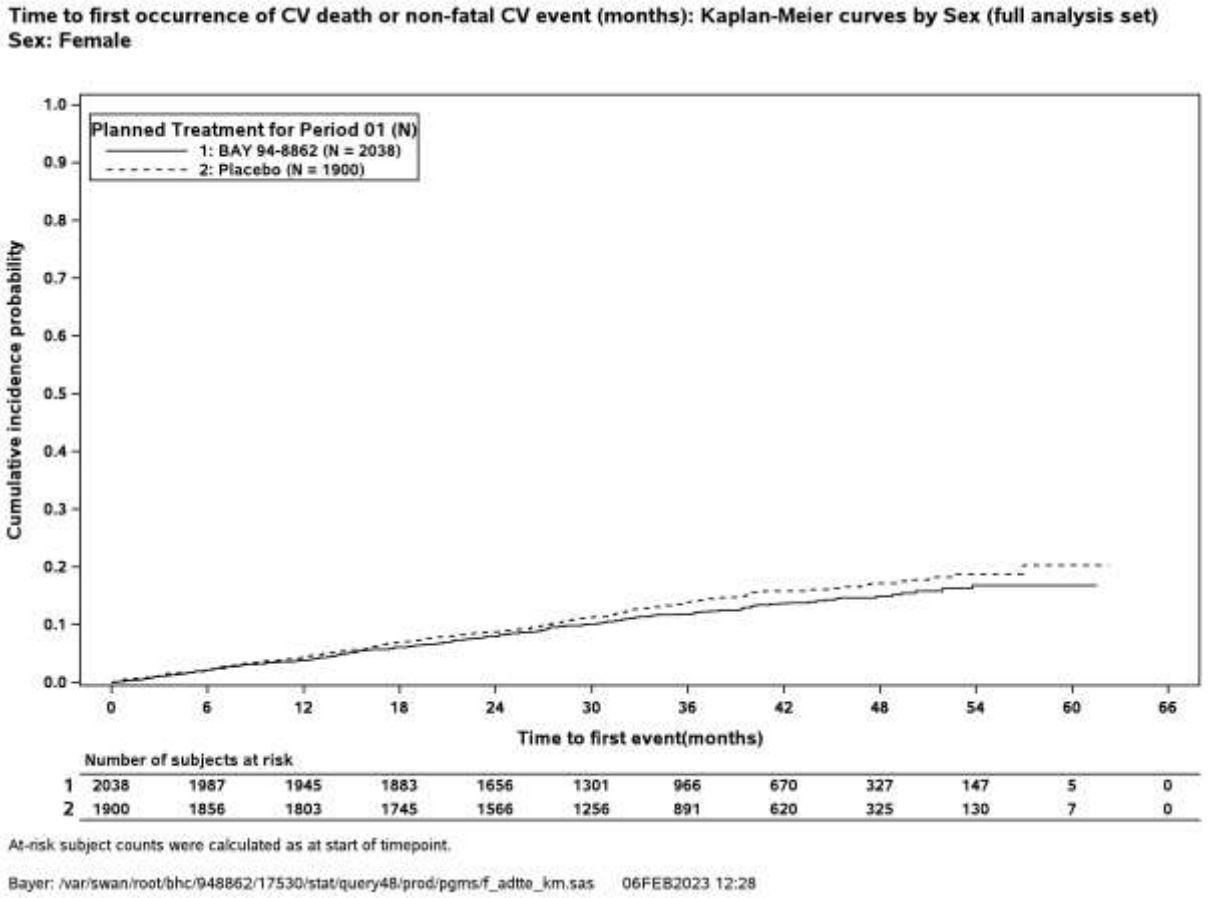


Figure 1.3.1 / 45: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

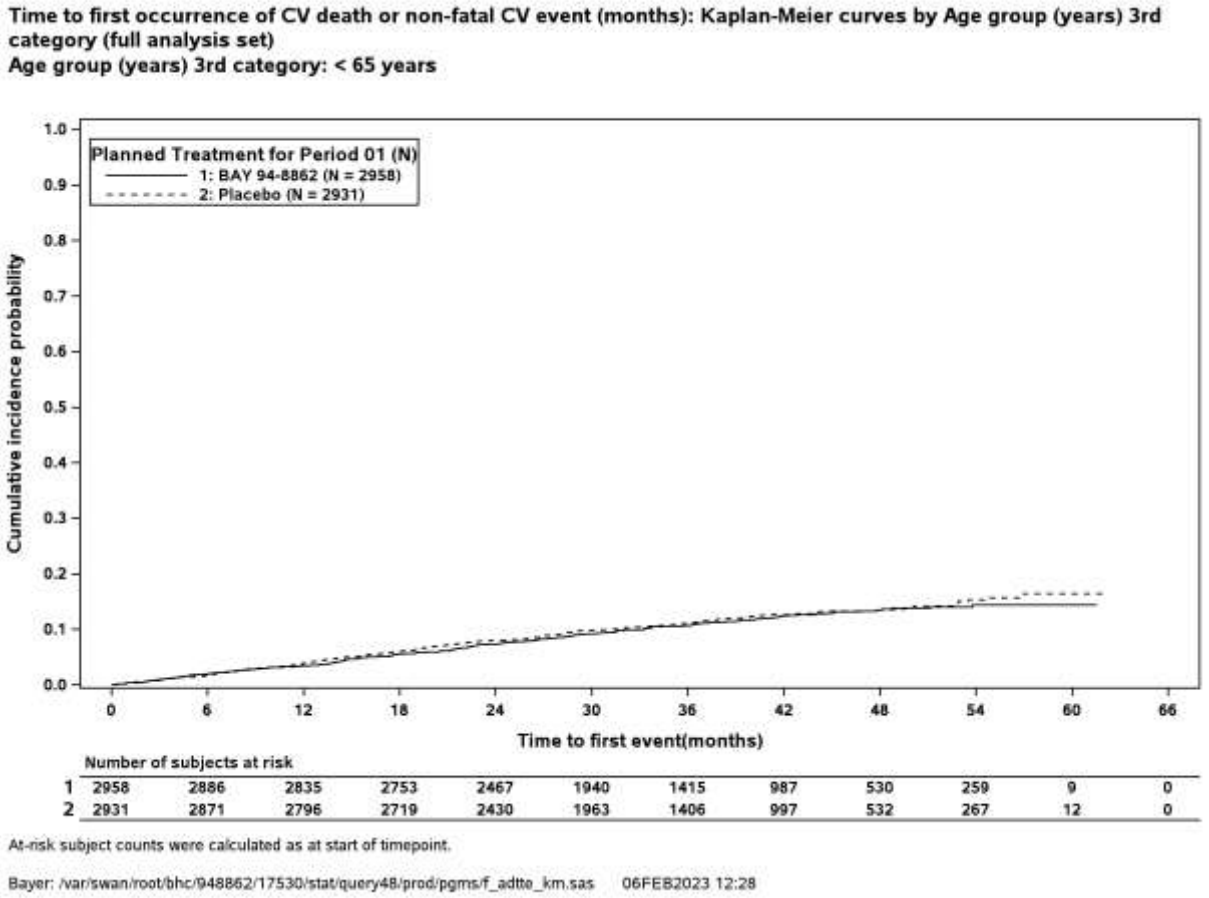


Figure 1.3.1 / 45: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

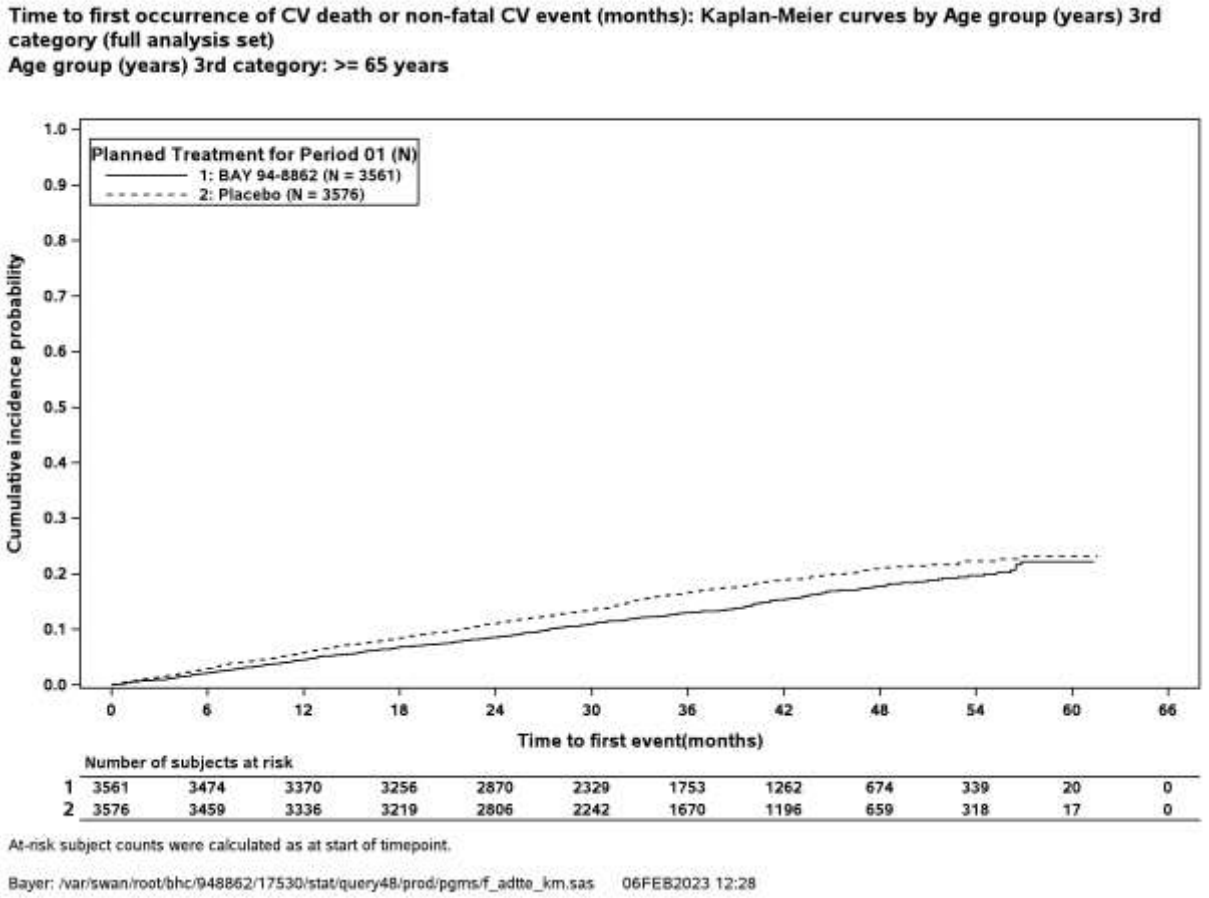


Figure 1.3.1 / 46: Time to CV death (months): Kaplan-Meier curves (full analysis set)

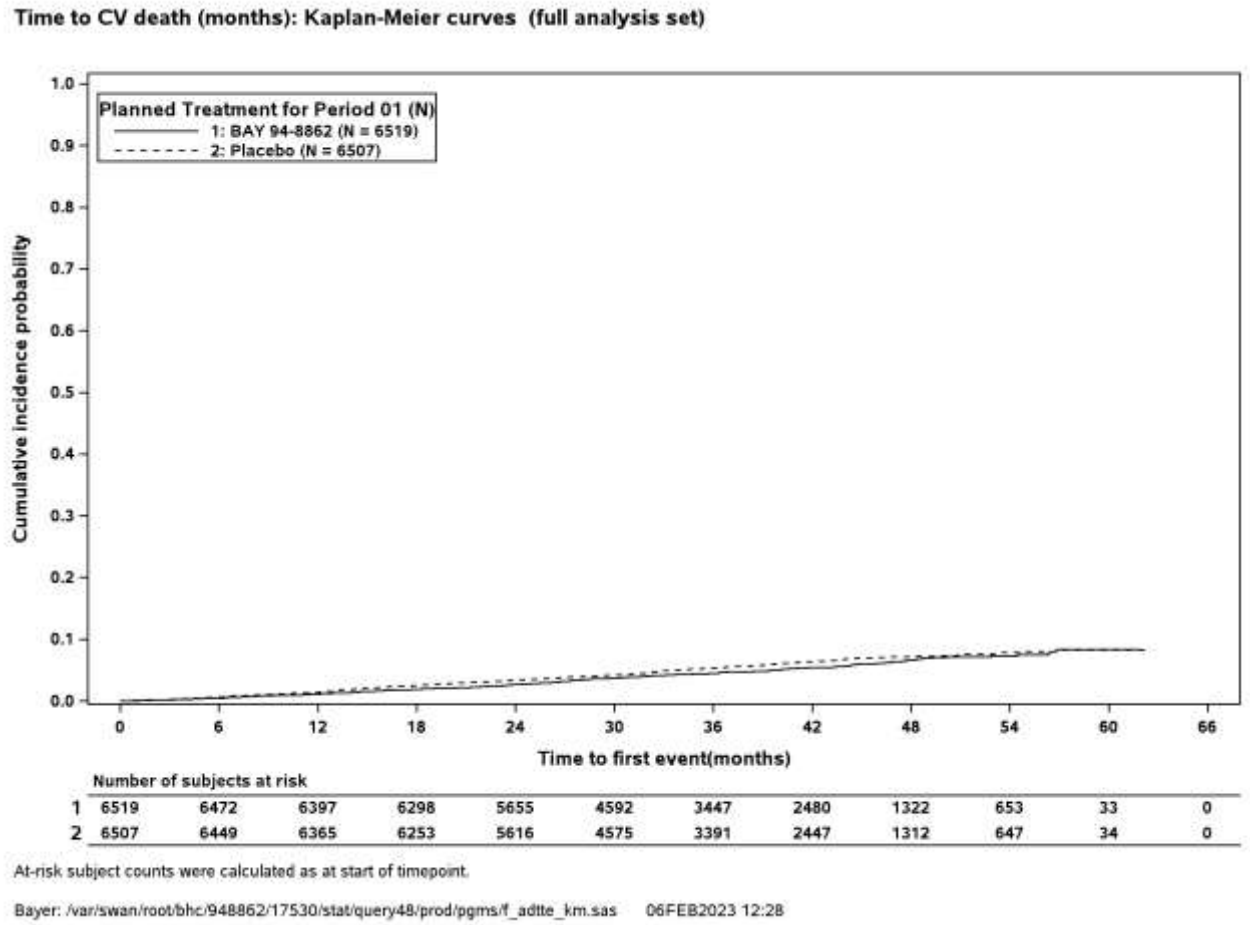


Figure 1.3.1 / 47: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set)

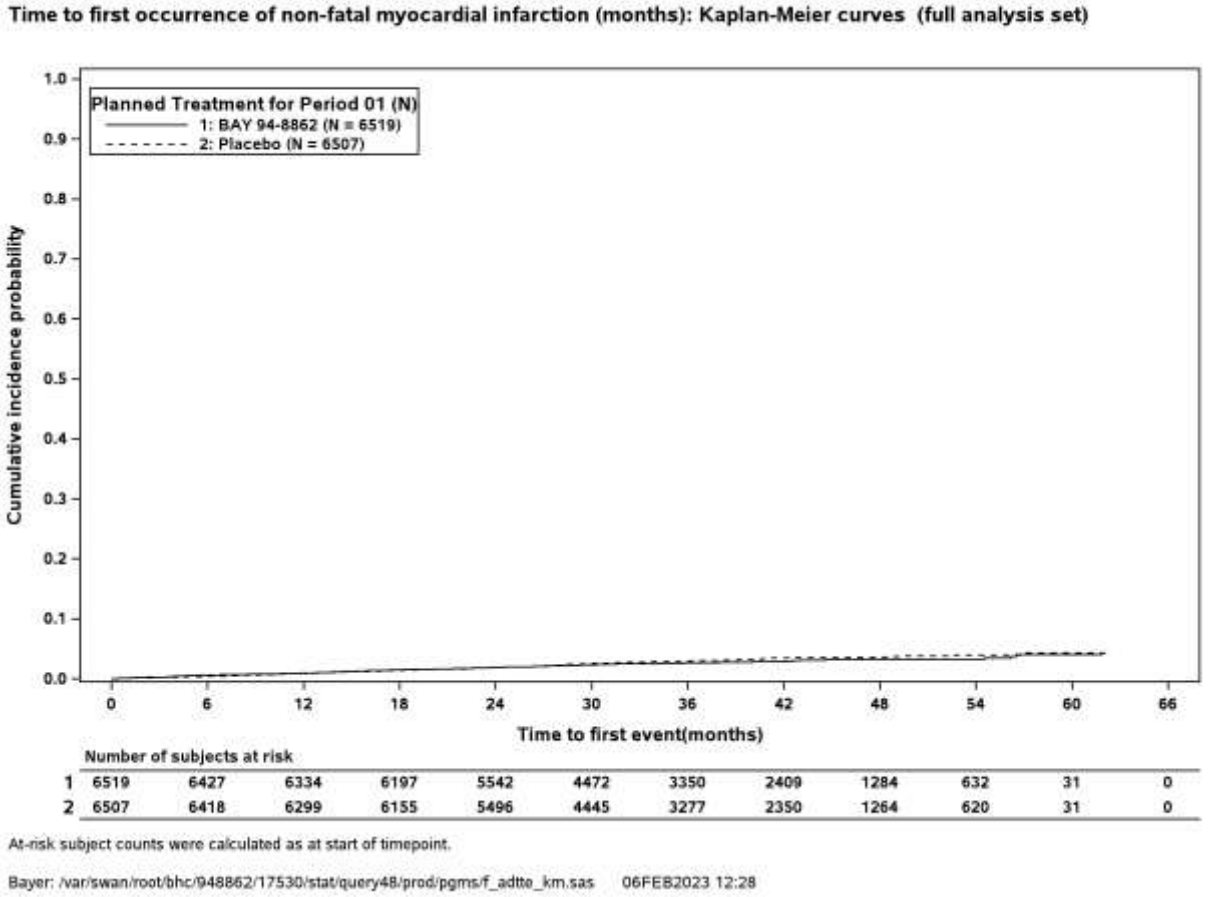


Figure 1.3.1 / 48: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set)

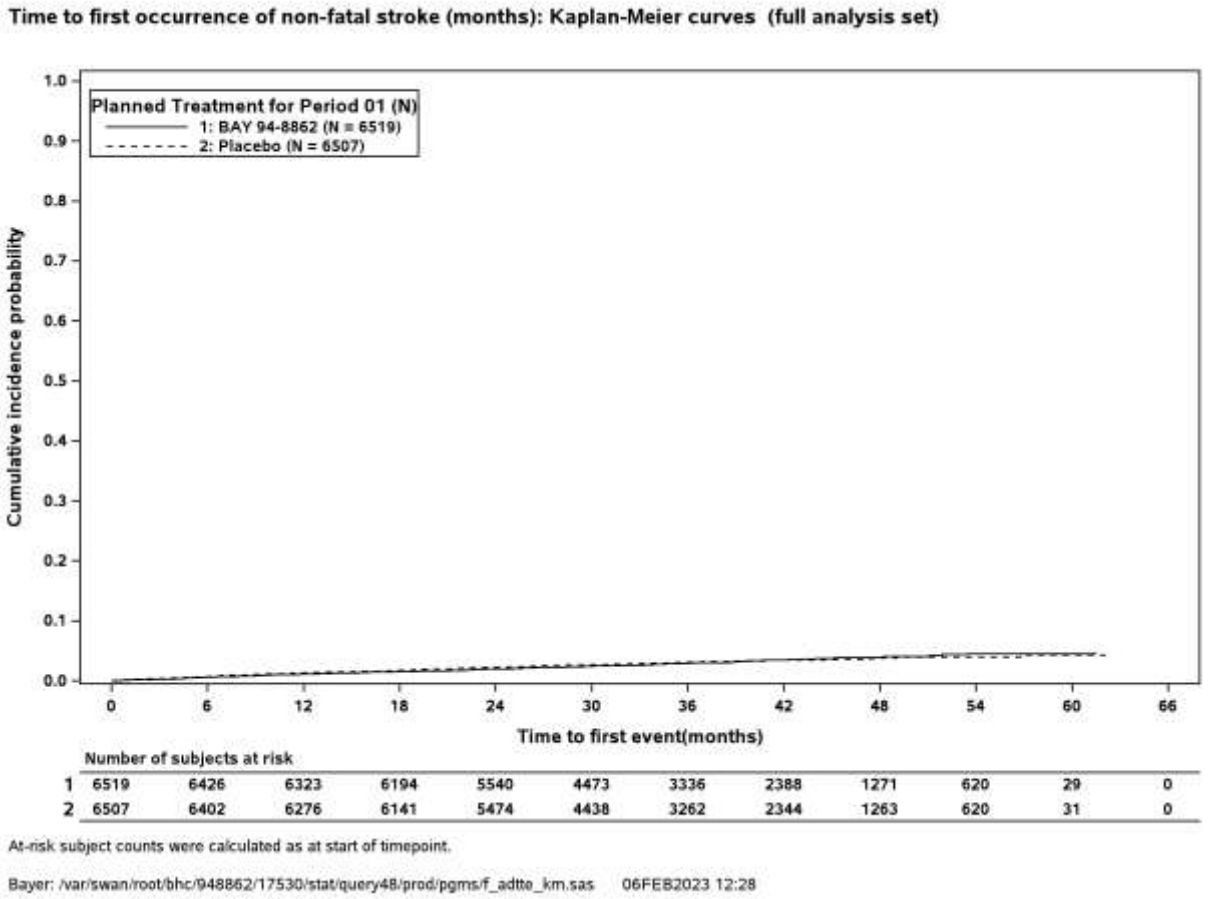


Figure 1.3.1 / 49: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set)

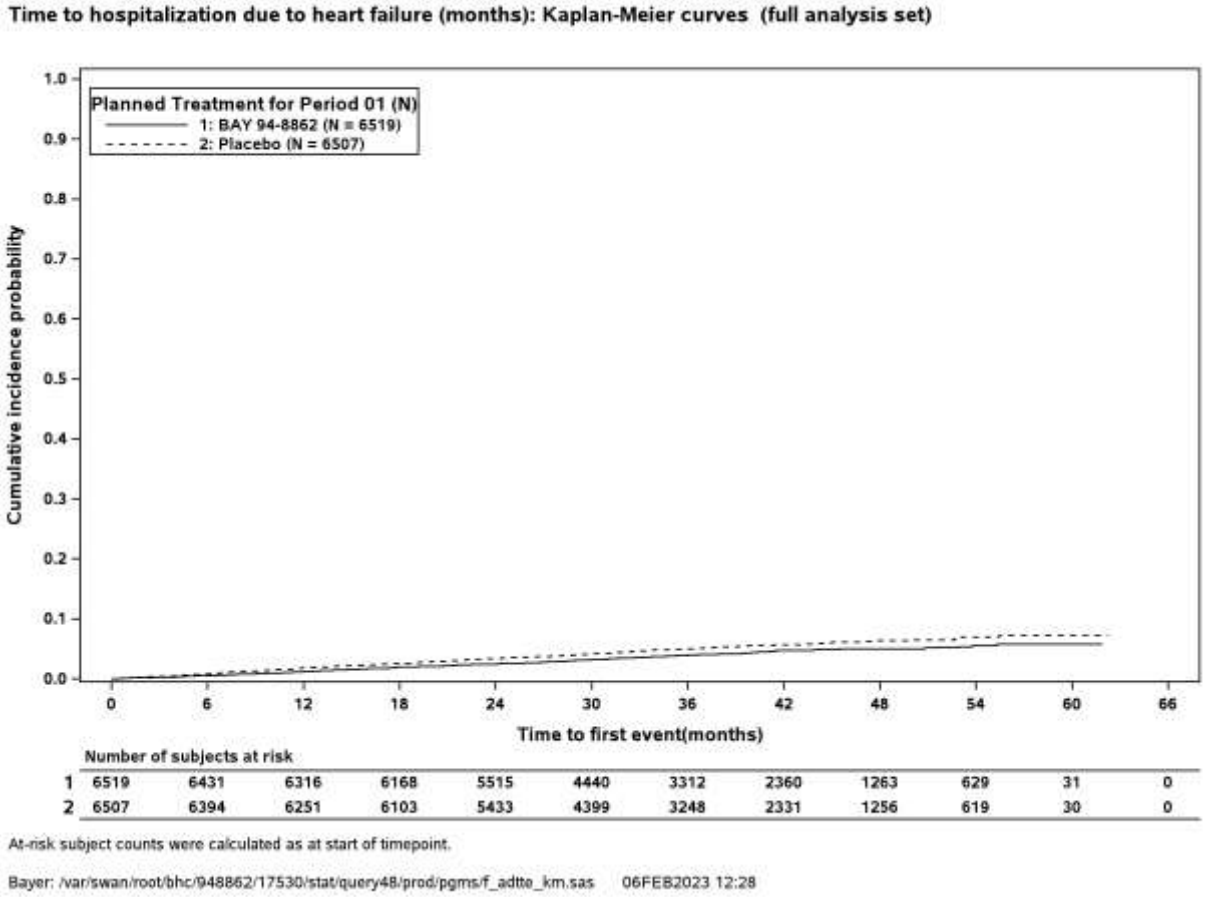


Figure 1.3.1 / 50: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set)

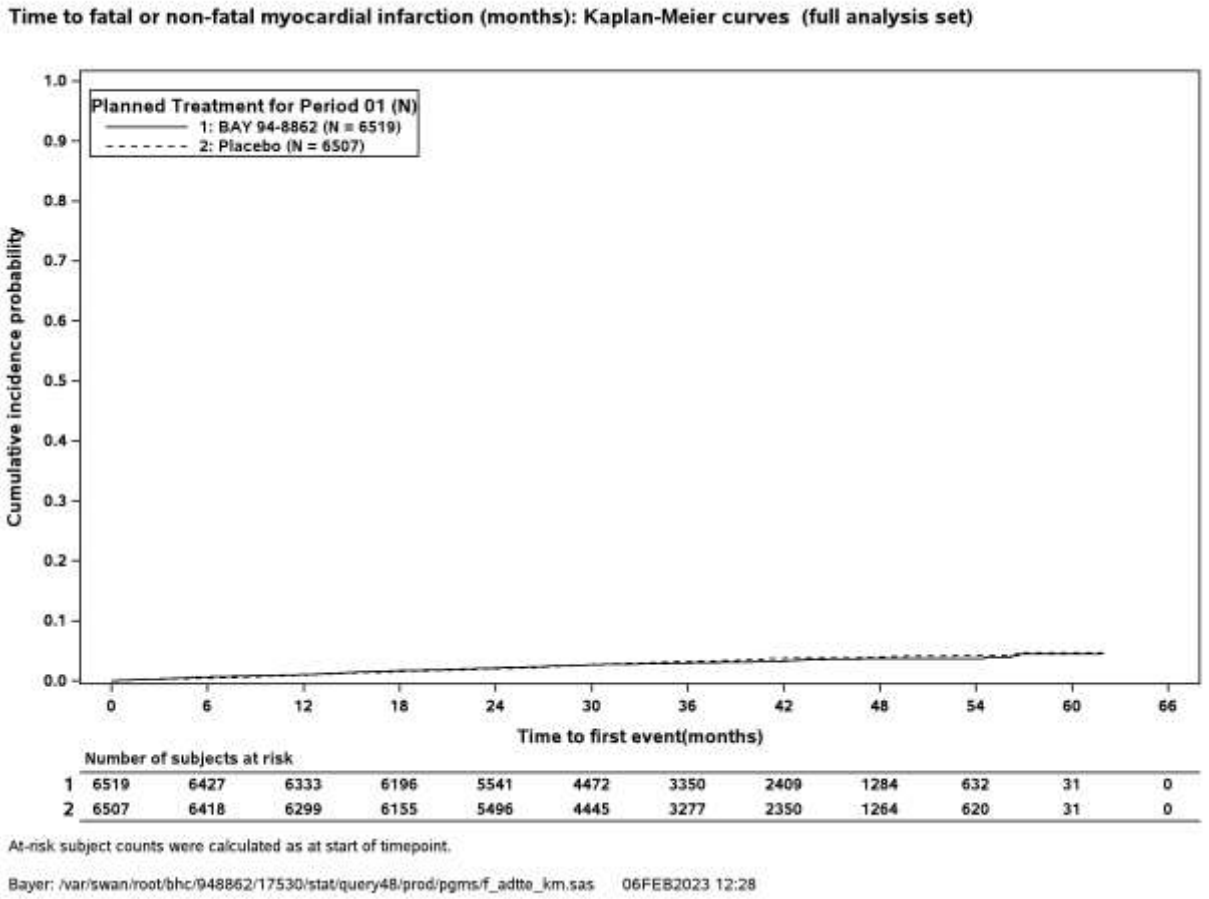


Figure 1.3.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

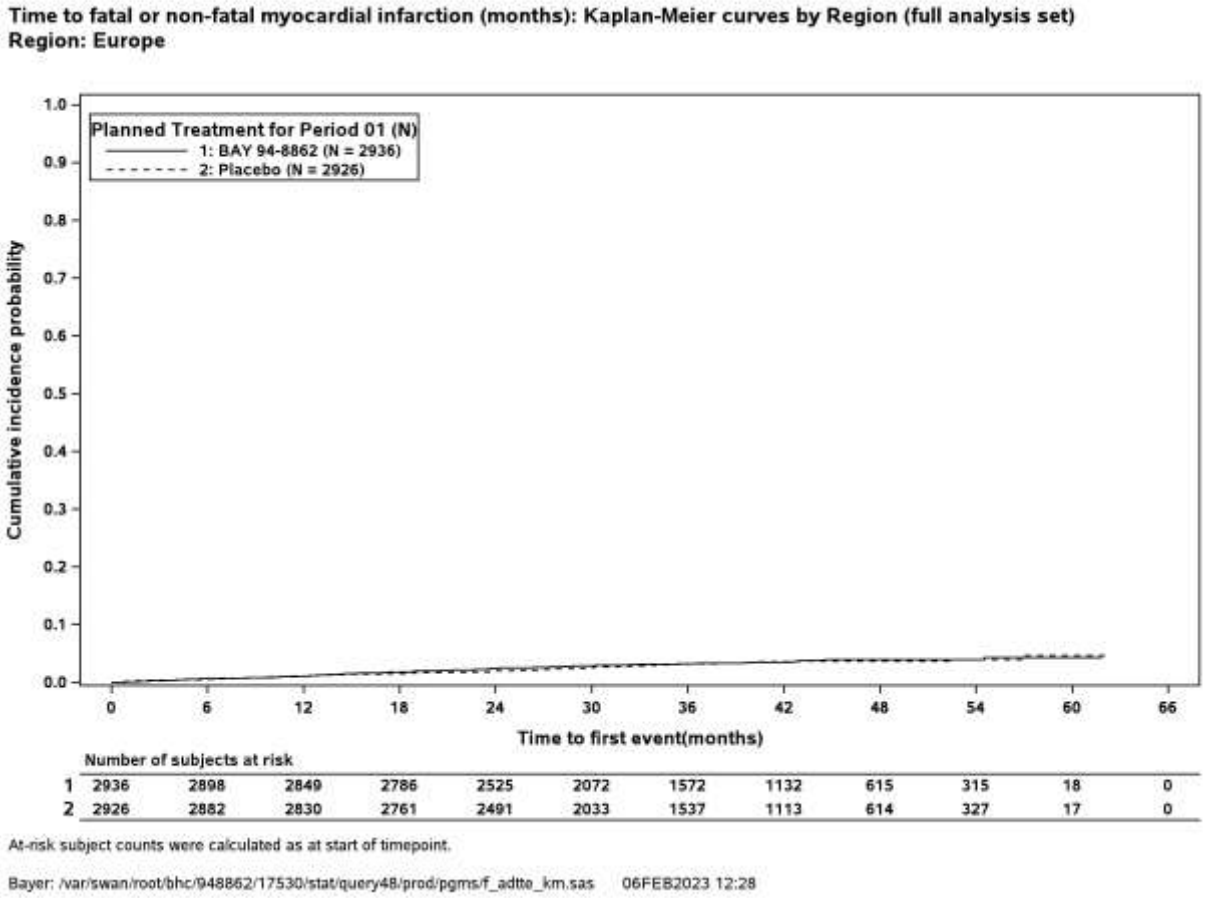


Figure 1.3.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

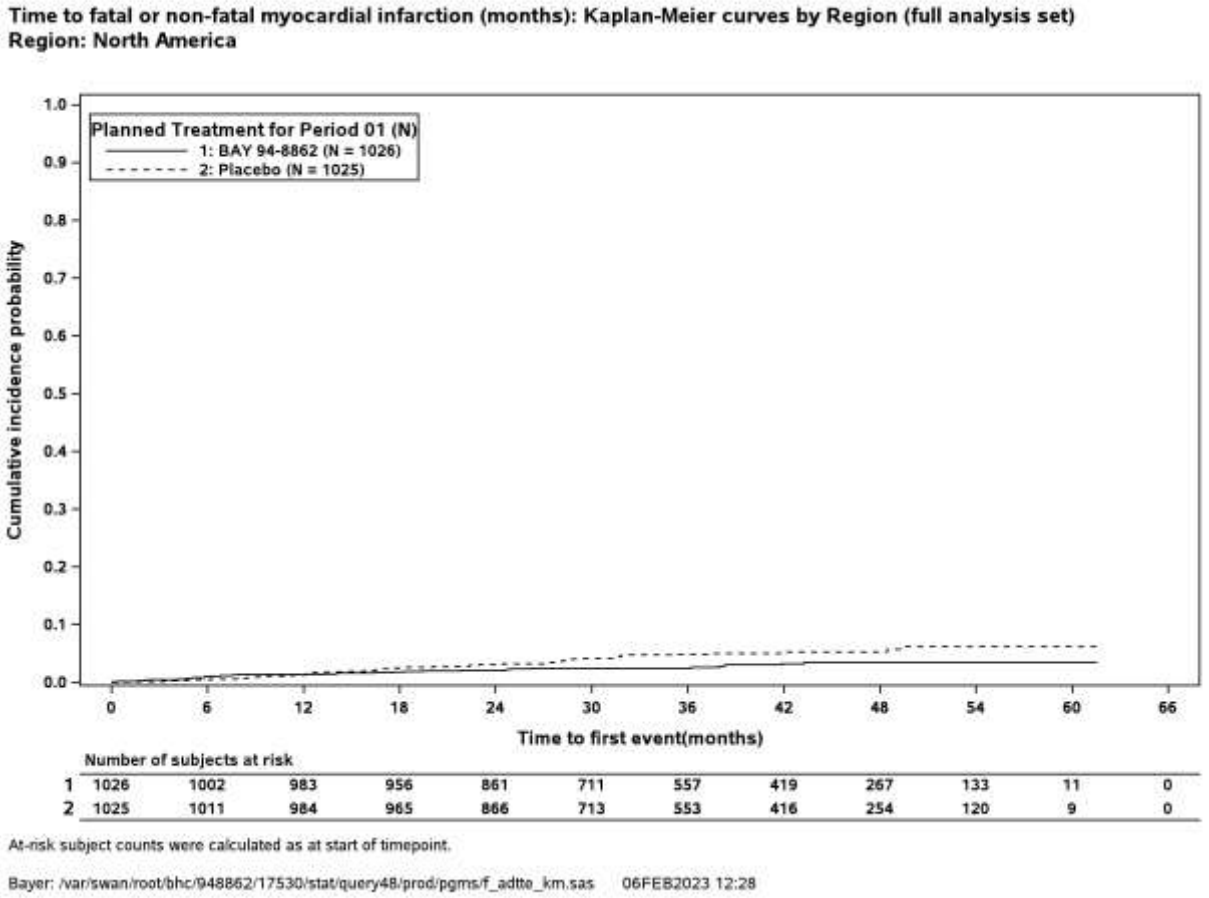


Figure 1.3.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

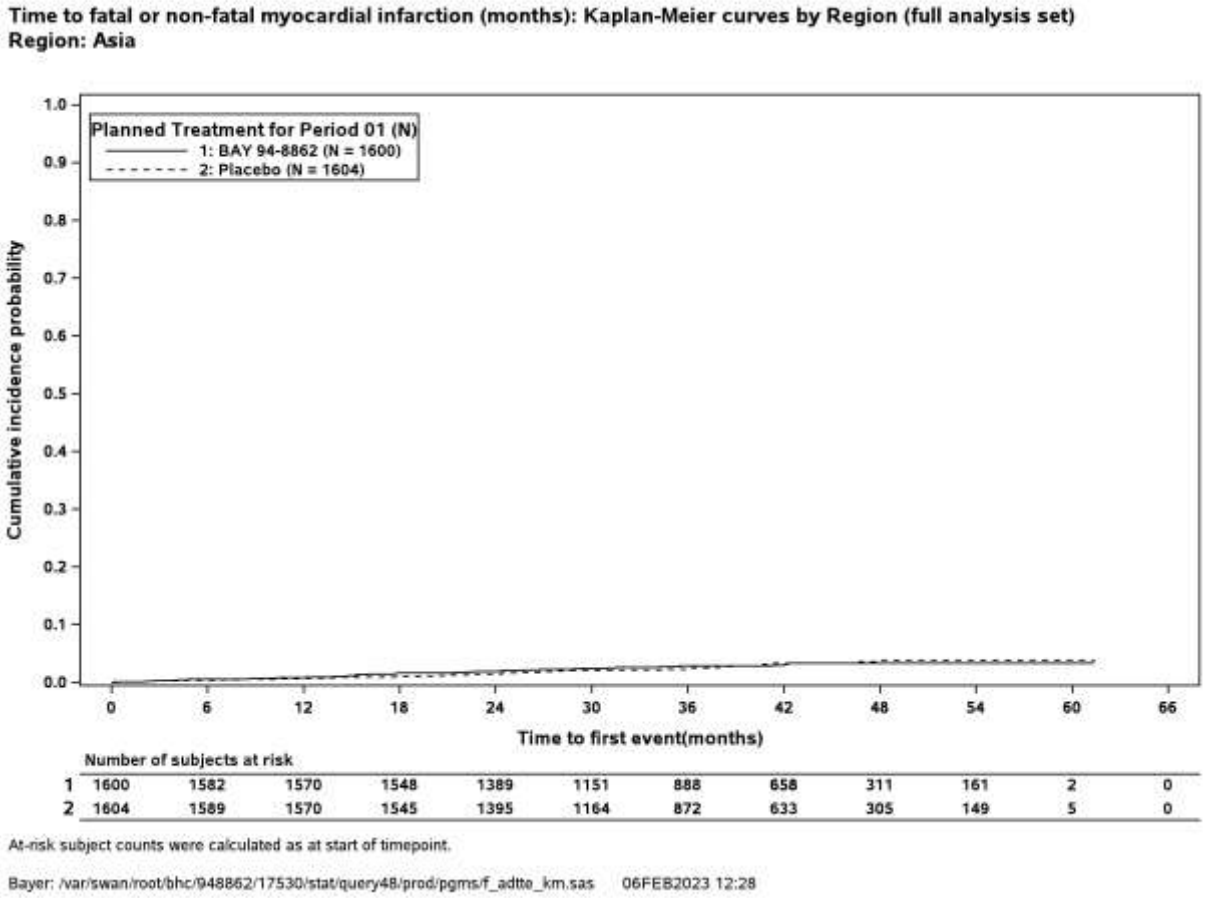


Figure 1.3.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

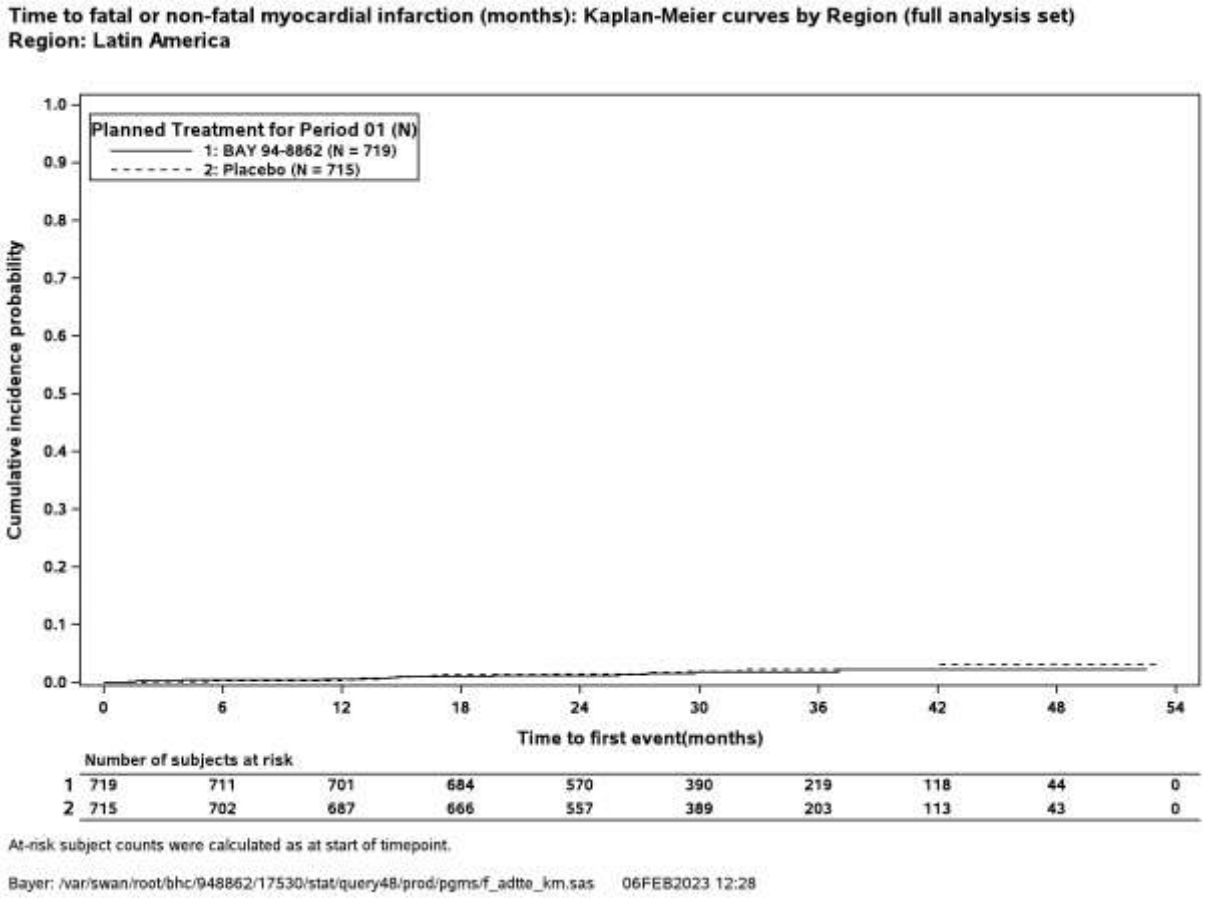


Figure 1.3.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

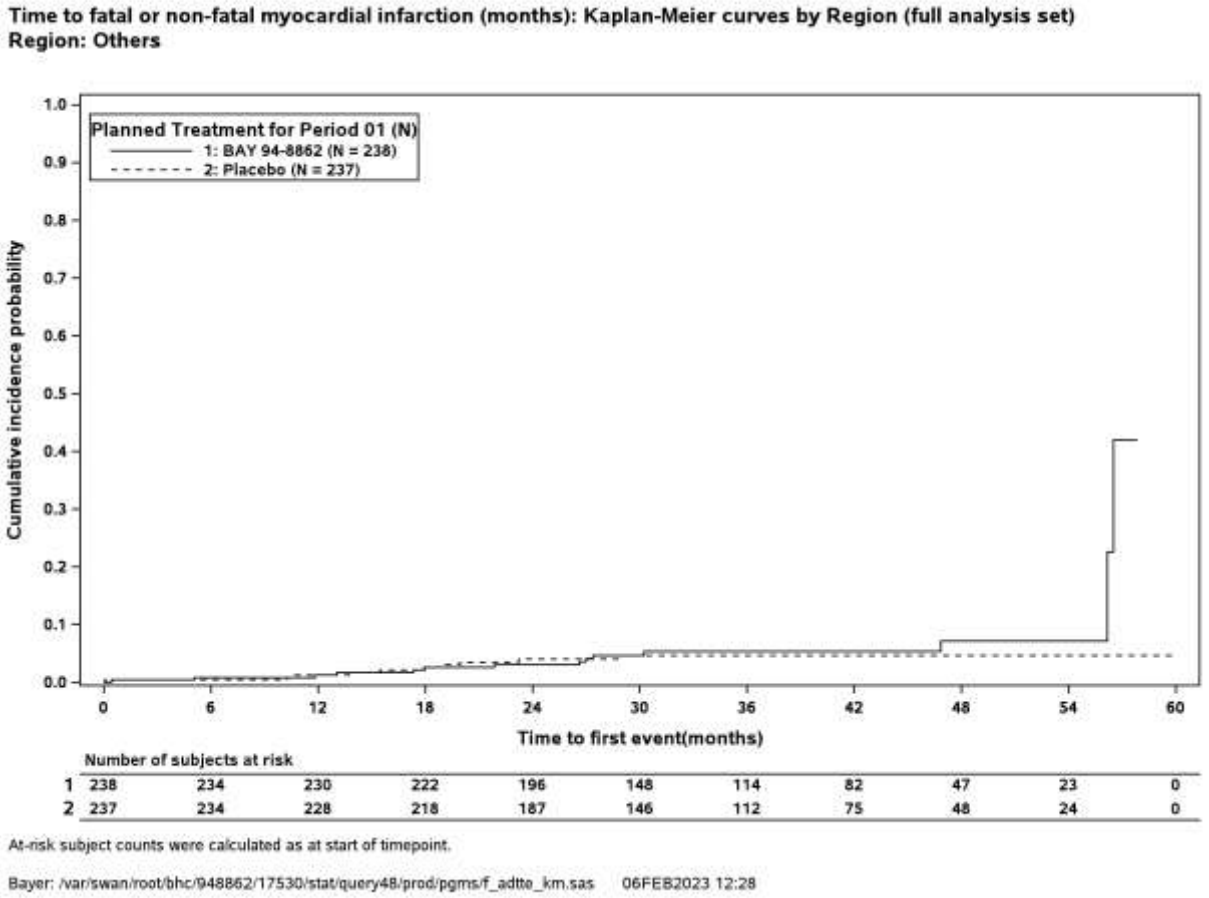


Figure 1.3.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

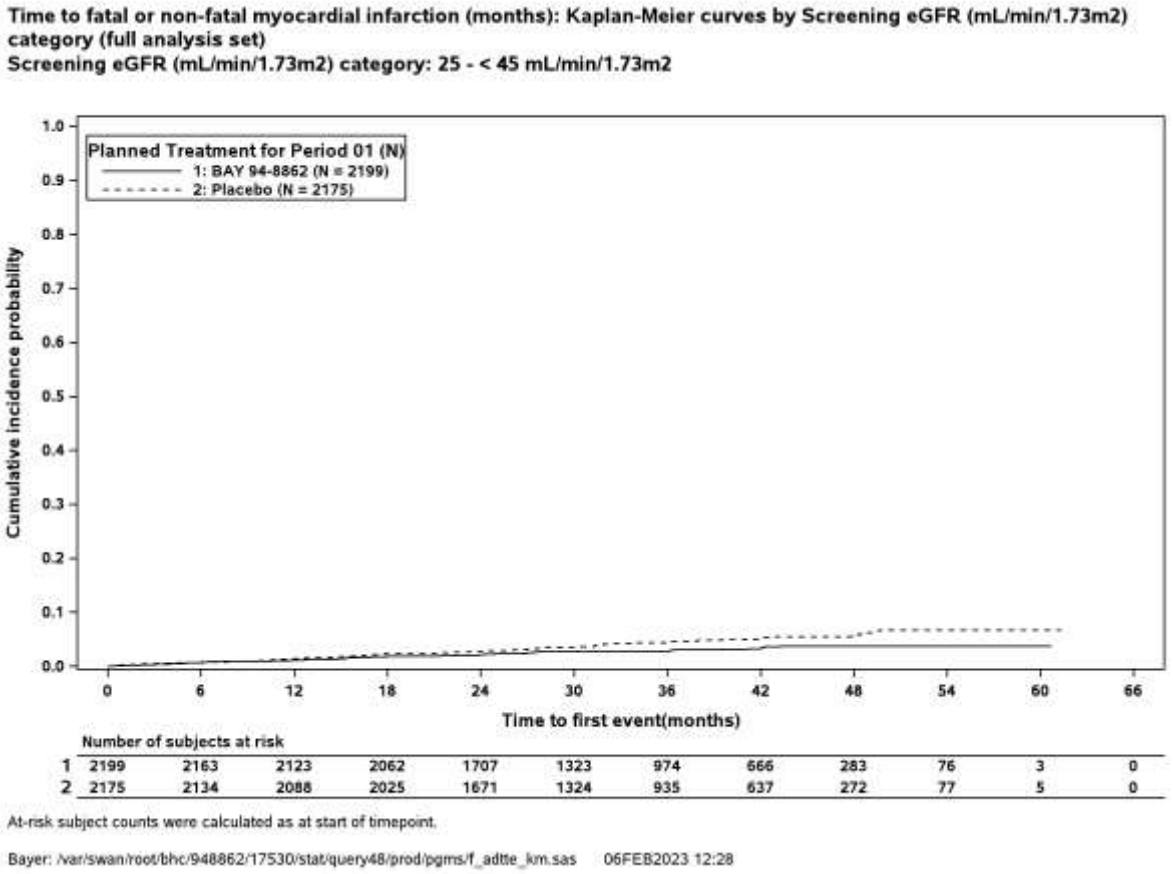


Figure 1.3.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

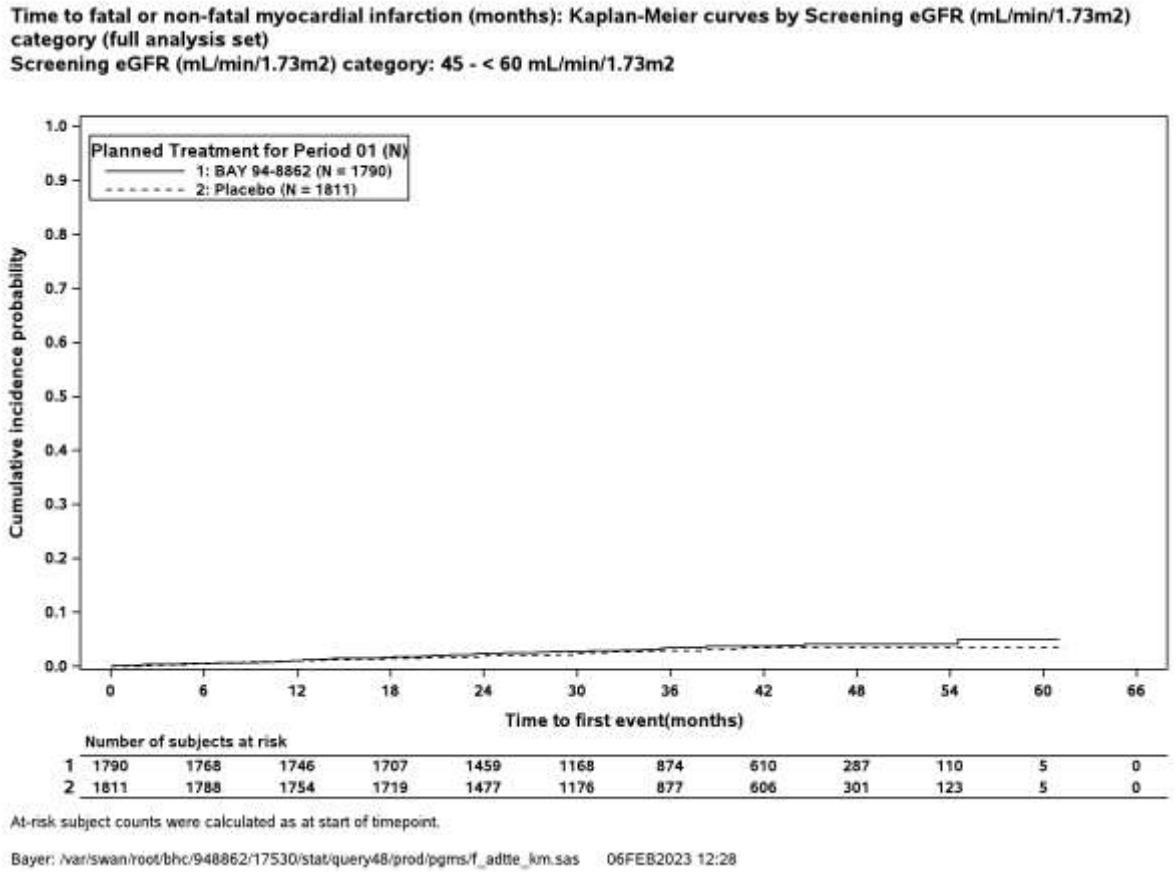


Figure 1.3.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

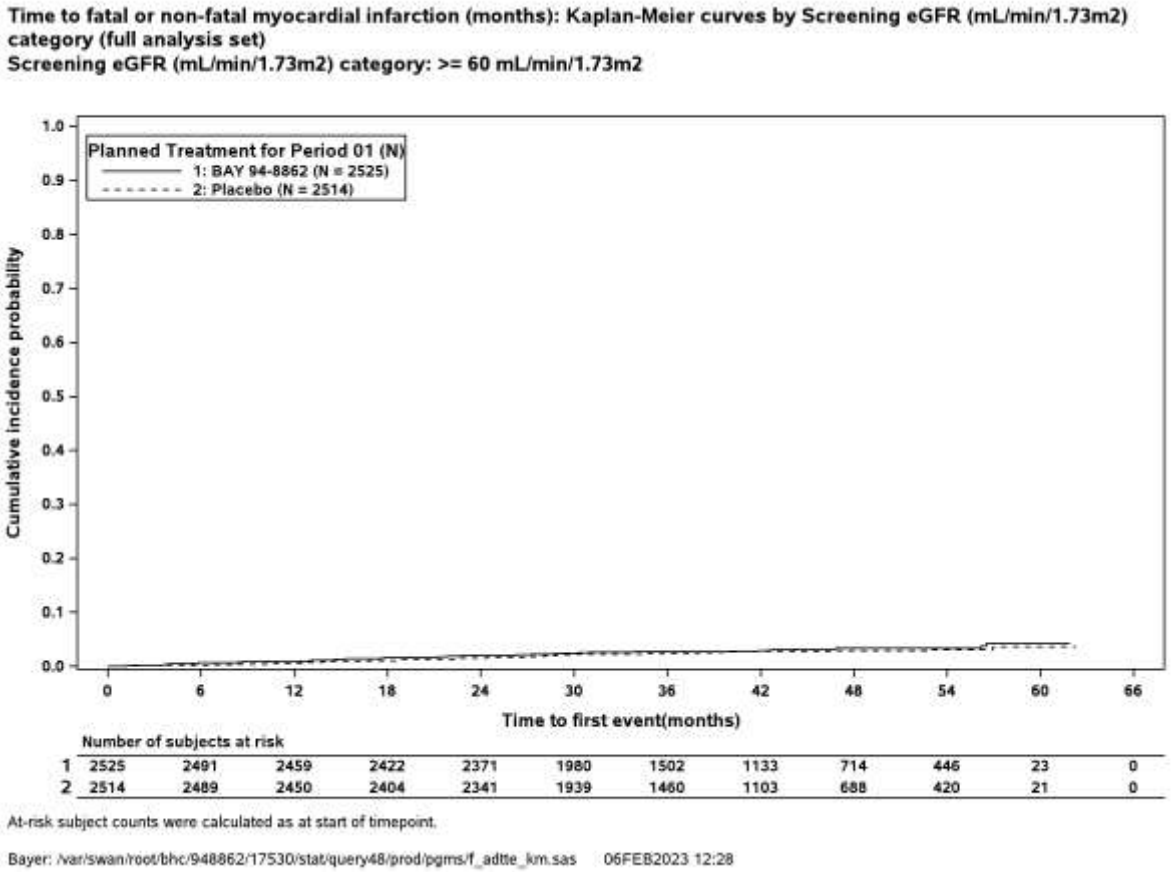


Figure 1.3.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

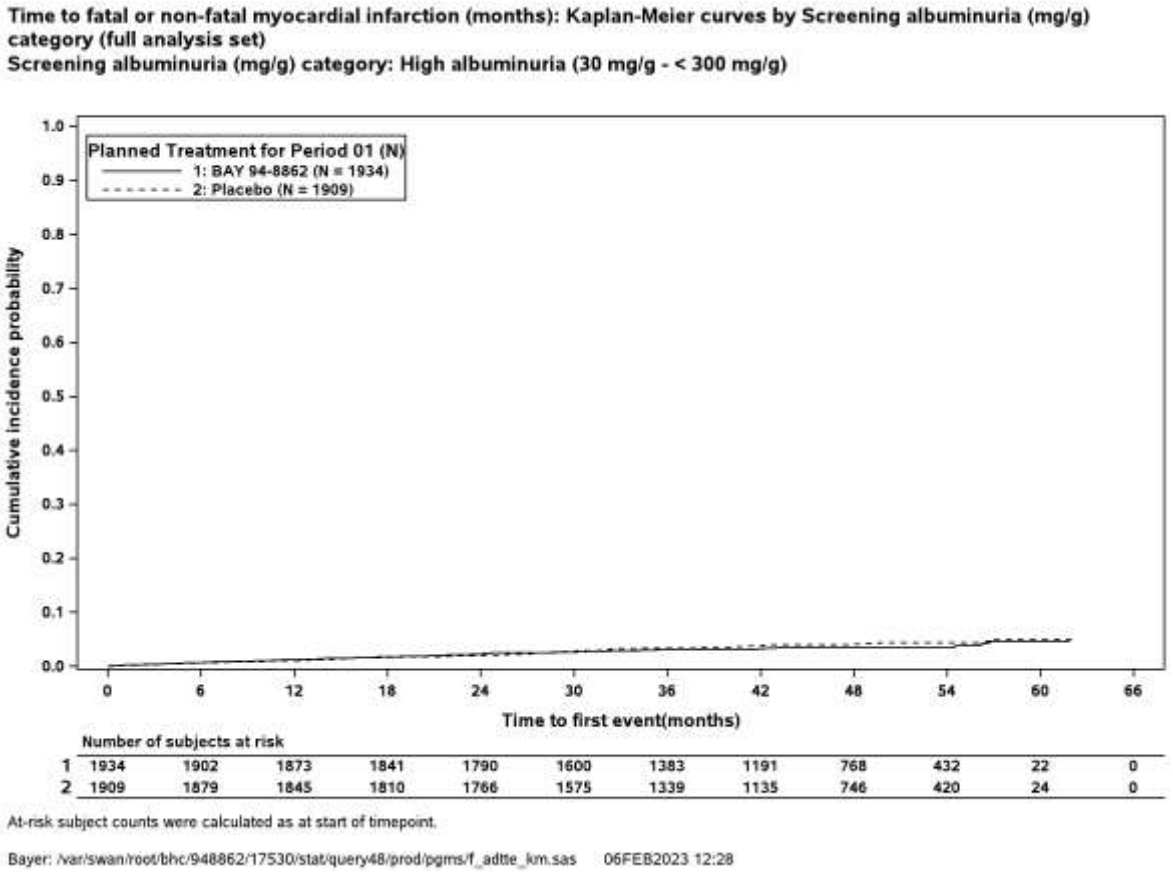
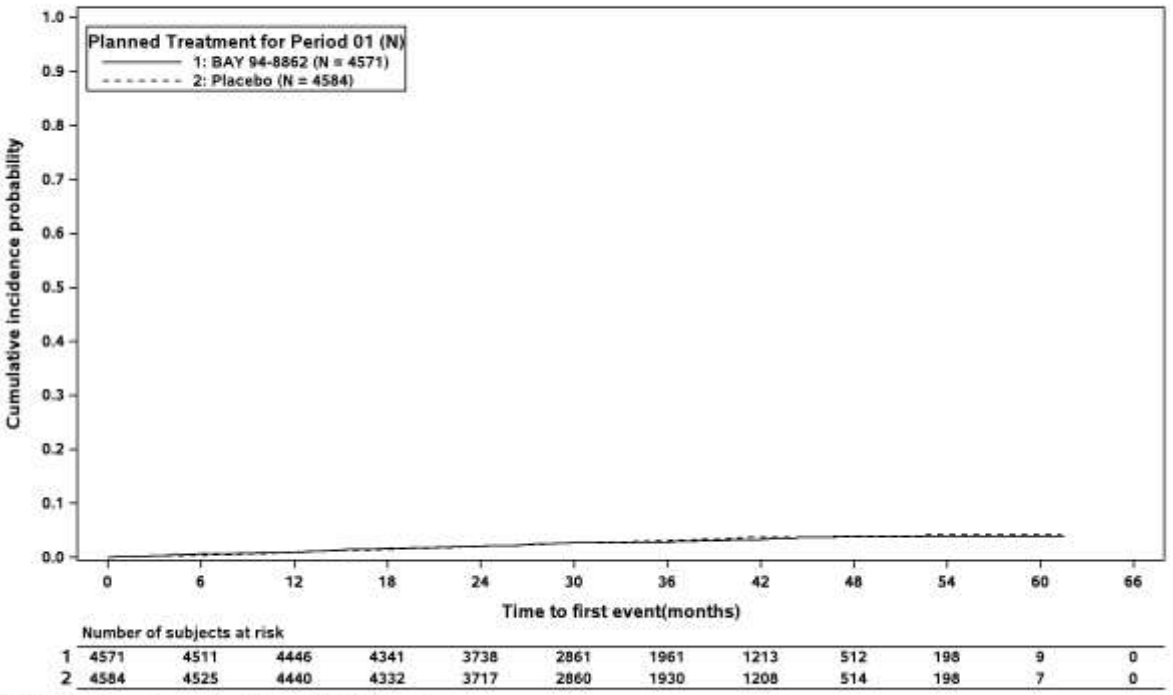


Figure 1.3.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4511	4446	4341	3738	2861	1961	1213	512	198	9	0
2	4584	4525	4440	4332	3717	2860	1930	1208	514	198	7	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

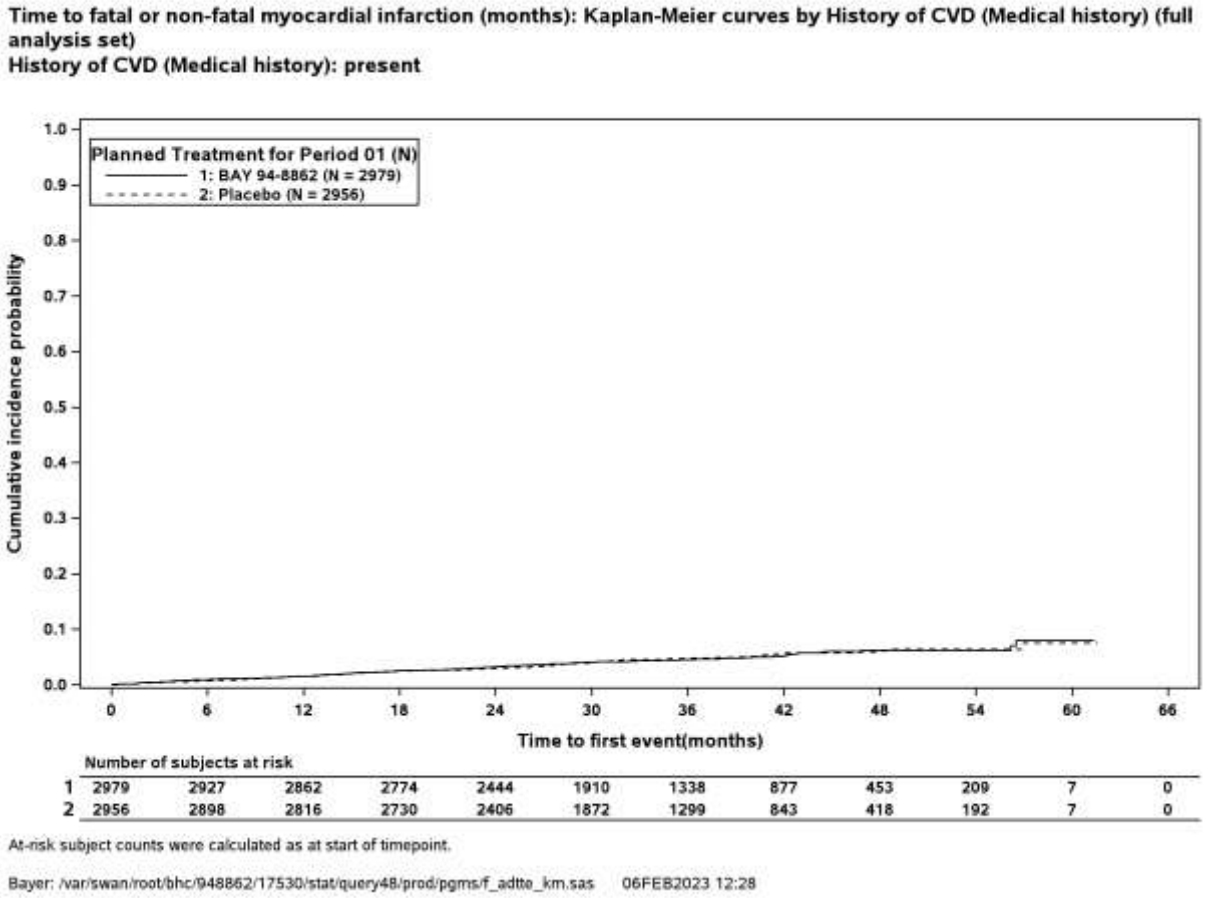


Figure 1.3.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

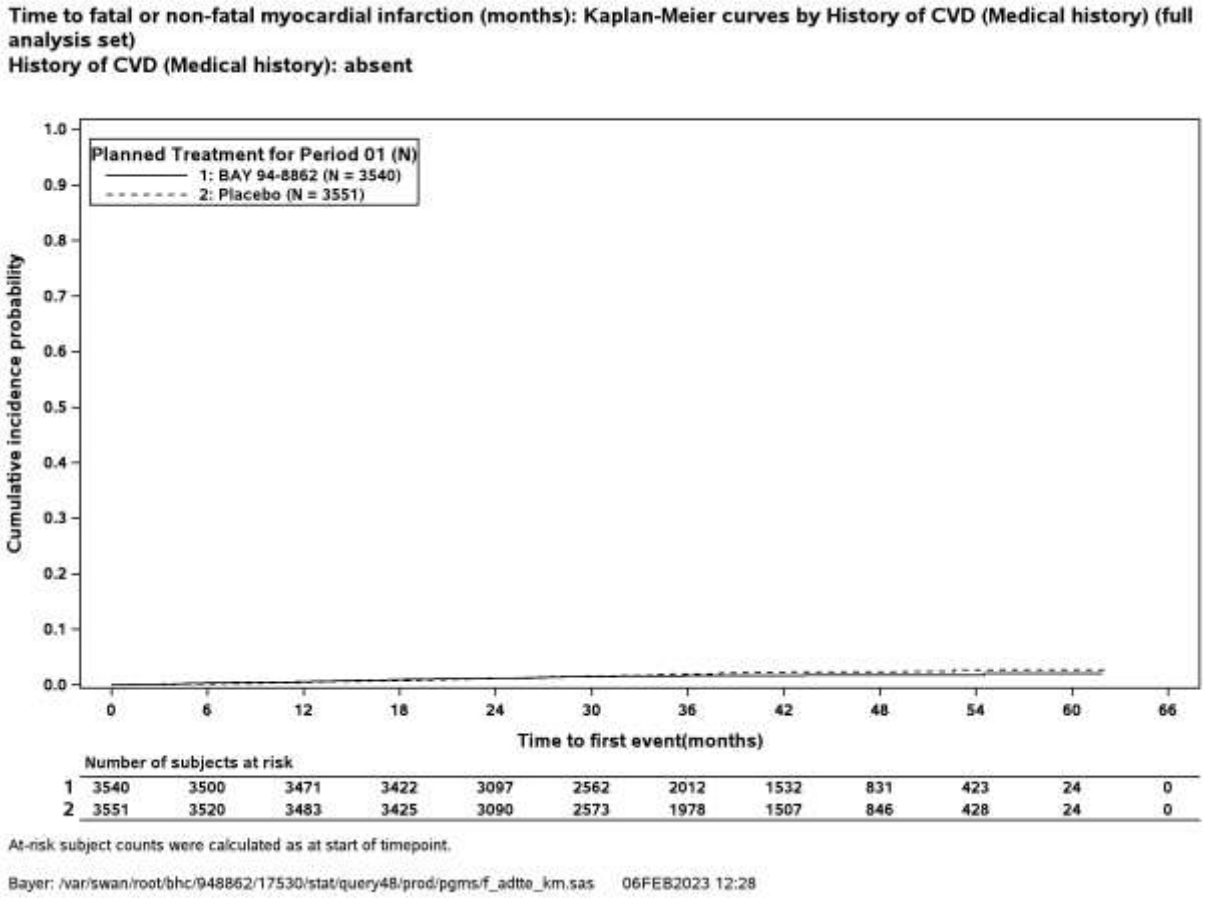


Figure 1.3.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

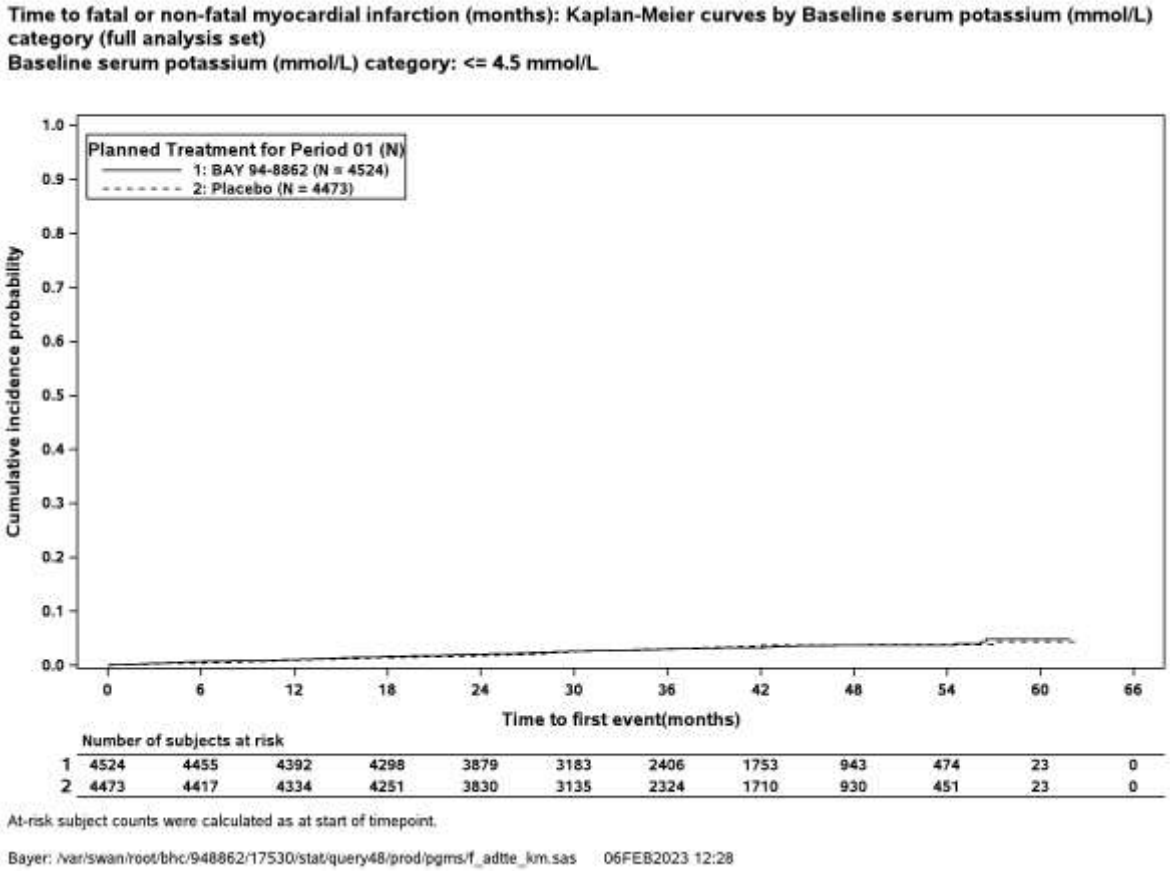


Figure 1.3.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

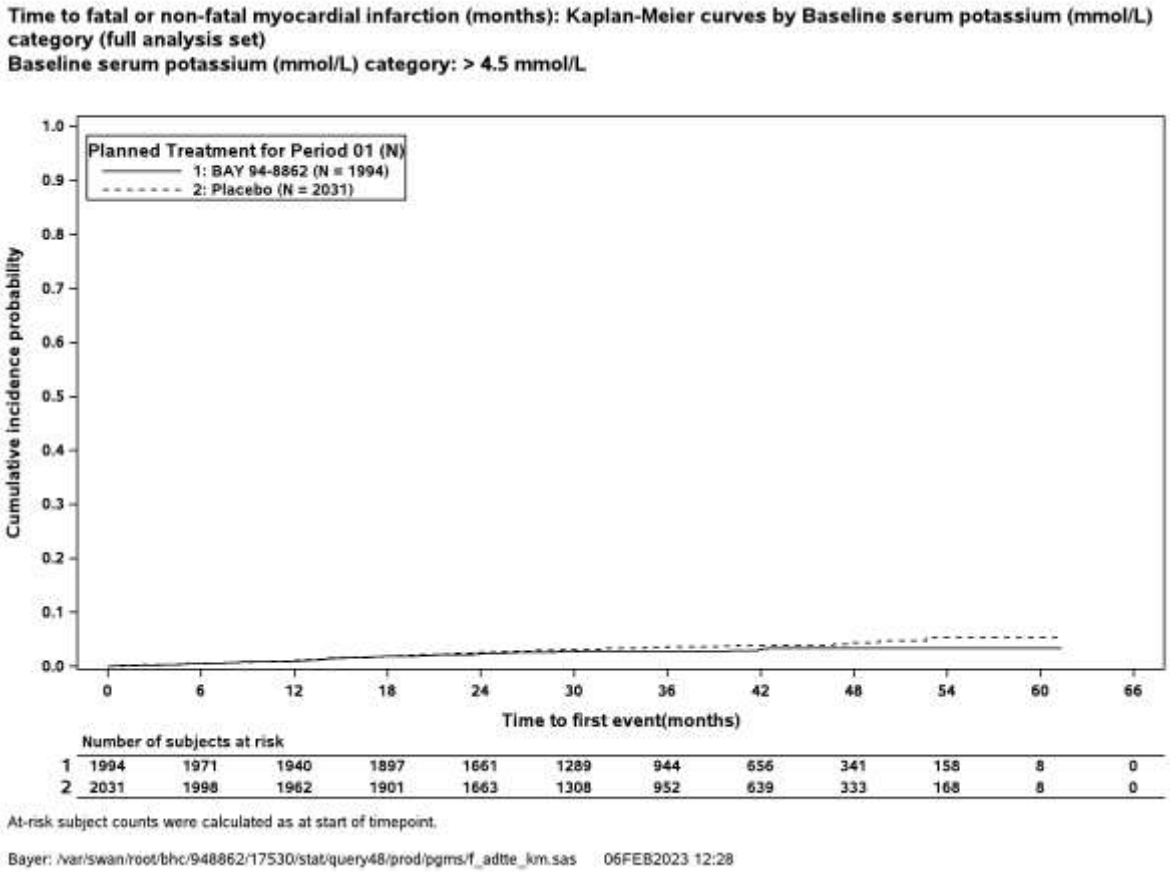


Figure 1.3.1 / 56: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

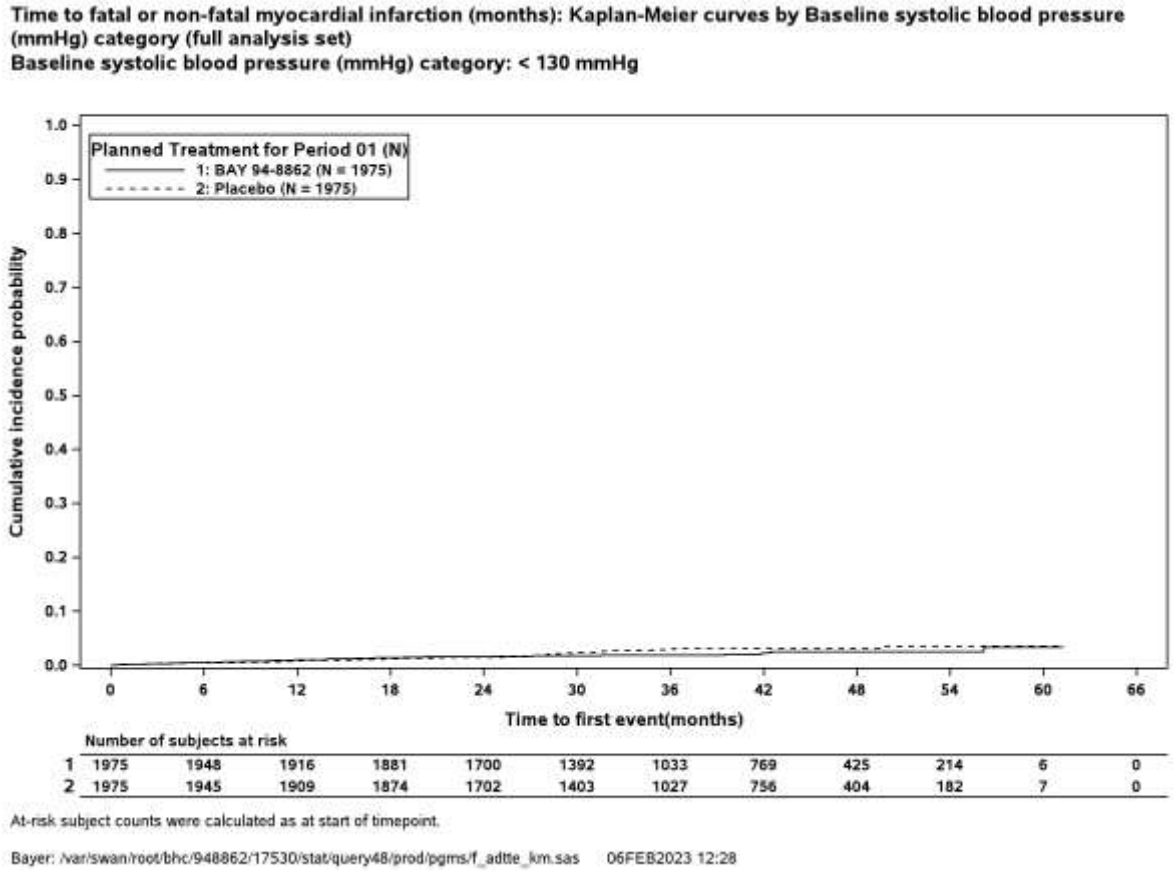
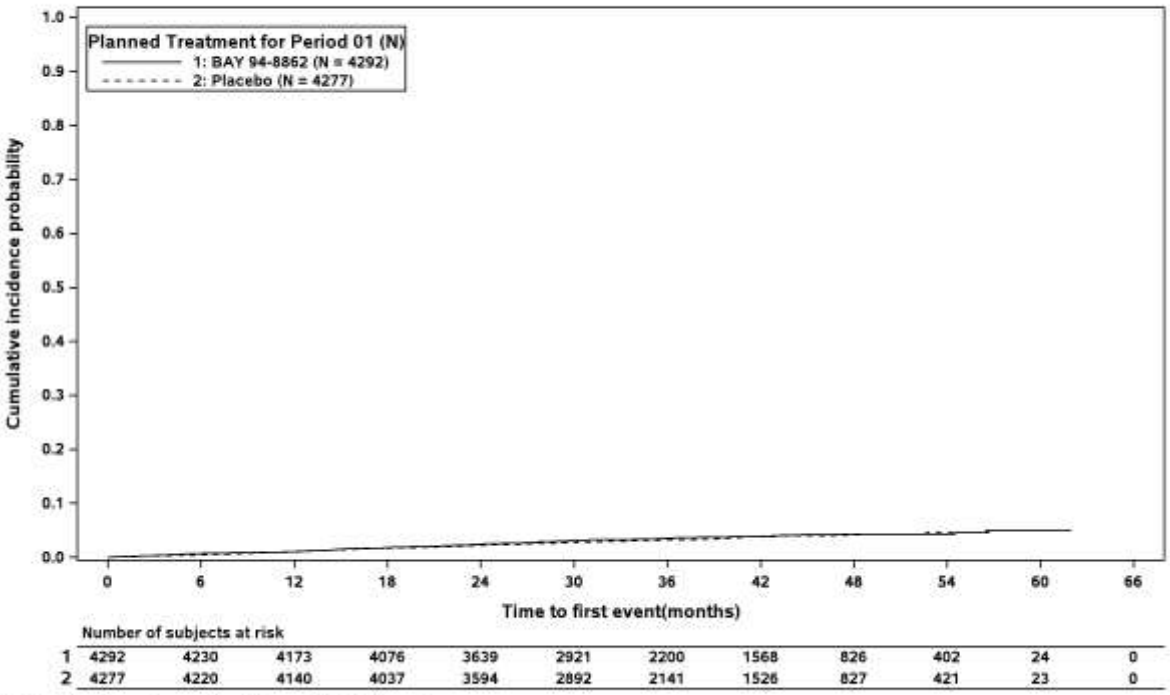


Figure 1.3.1 / 56: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)
Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg



Number of subjects at risk

1	4292	4230	4173	4076	3639	2921	2200	1568	826	402	24	0
2	4277	4220	4140	4037	3594	2892	2141	1526	827	421	23	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 56: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

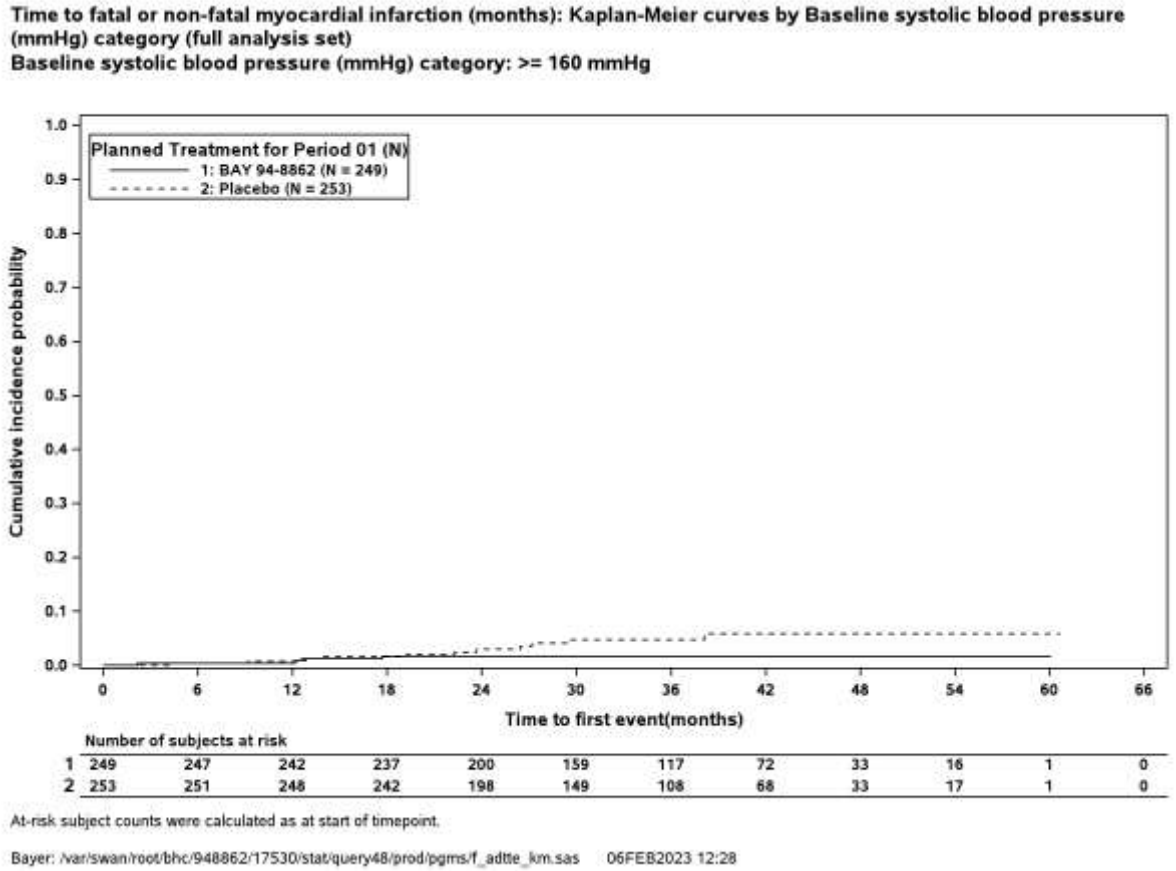


Figure 1.3.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

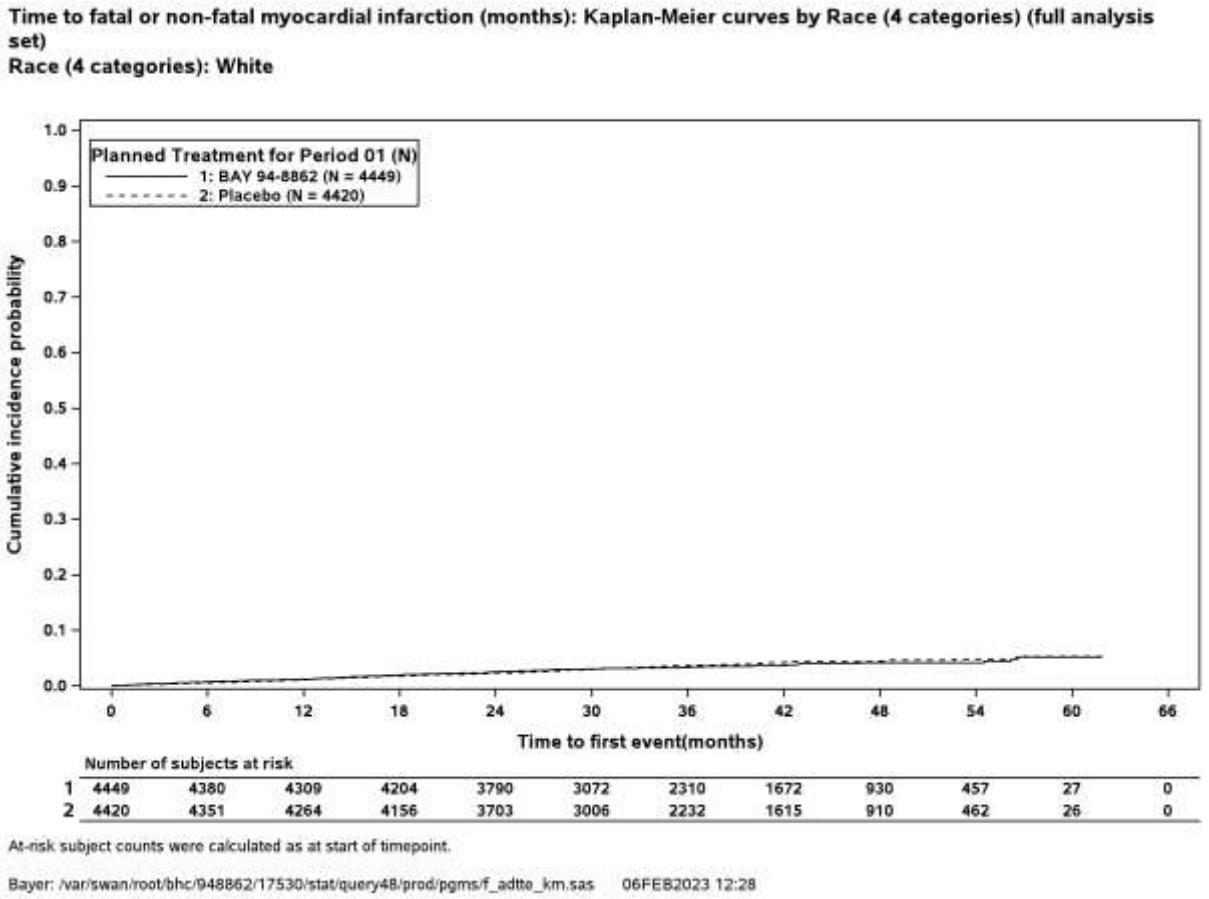


Figure 1.3.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

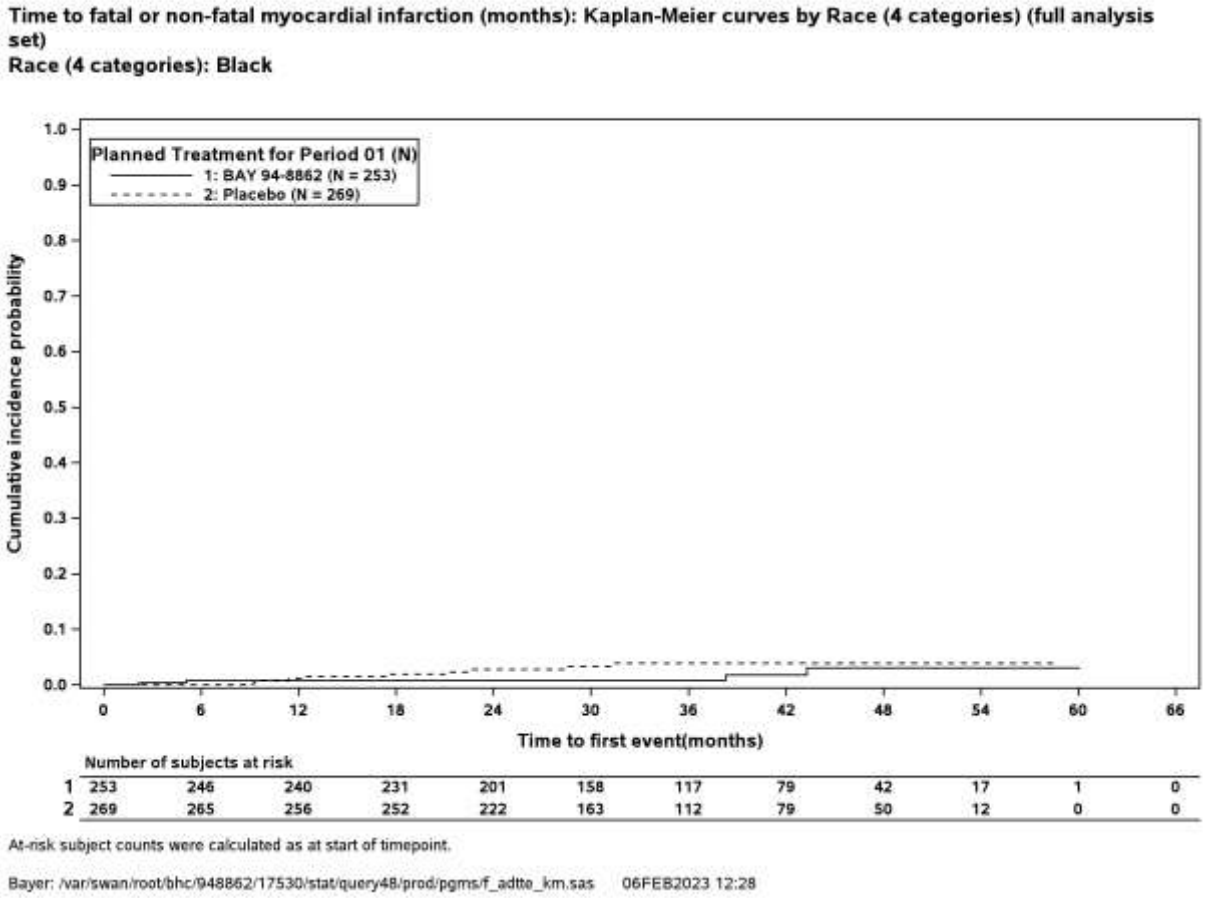


Figure 1.3.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

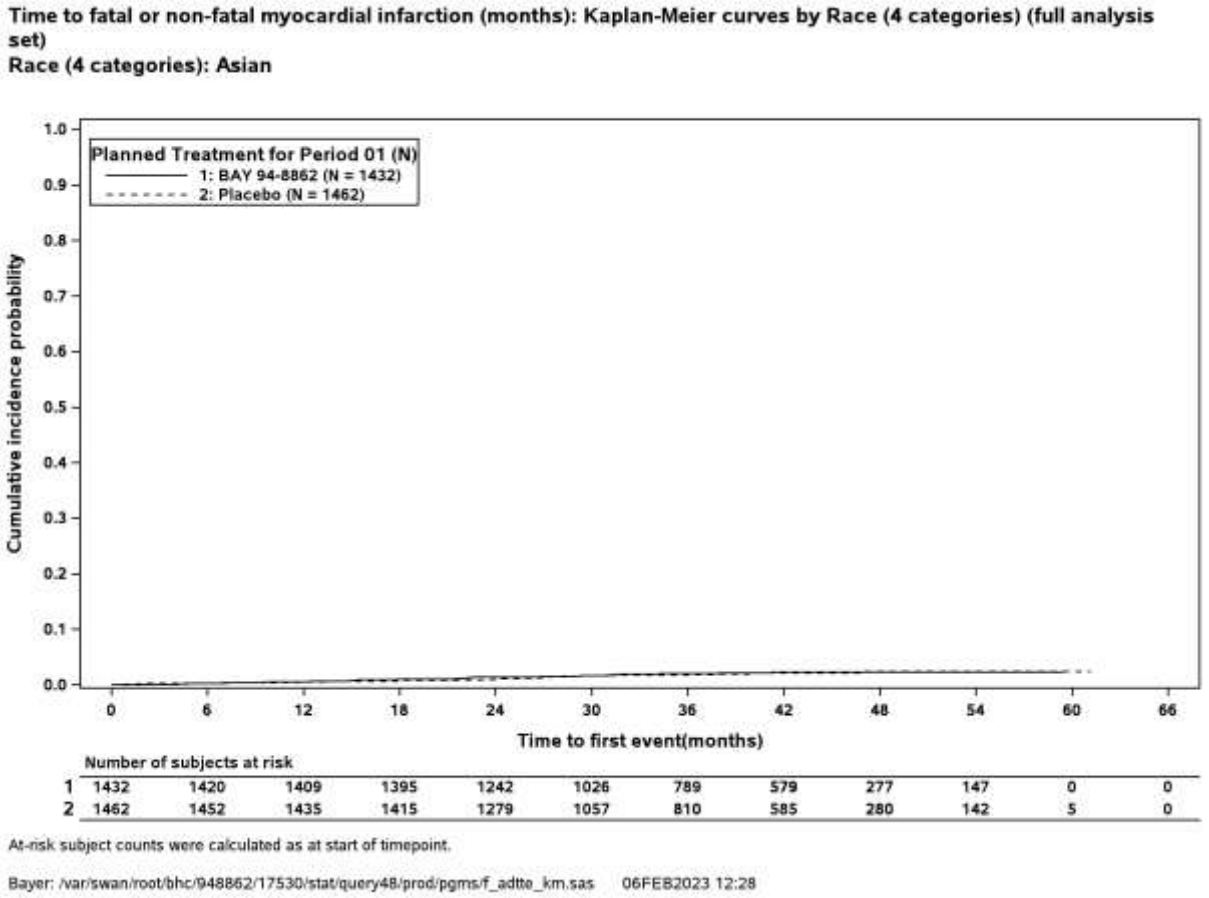
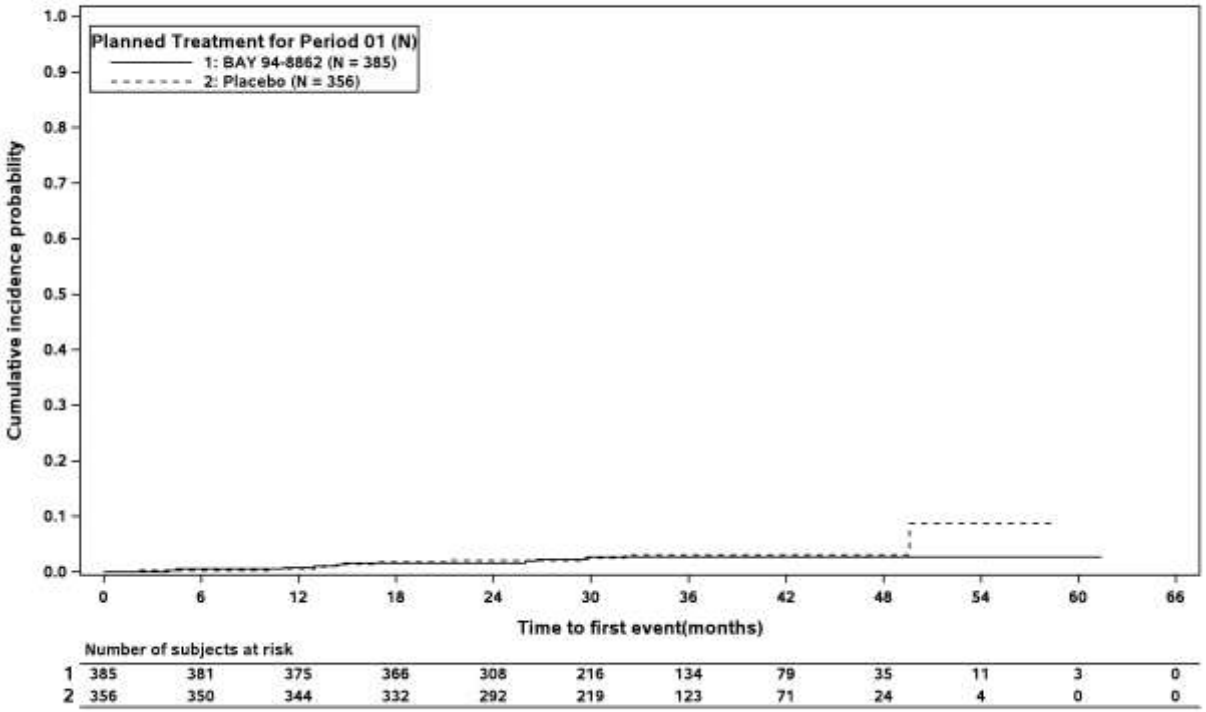


Figure 1.3.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)
Race (4 categories): Other



Number of subjects at risk

1	385	381	375	366	308	216	134	79	35	11	3	0
2	356	350	344	332	292	219	123	71	24	4	0	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

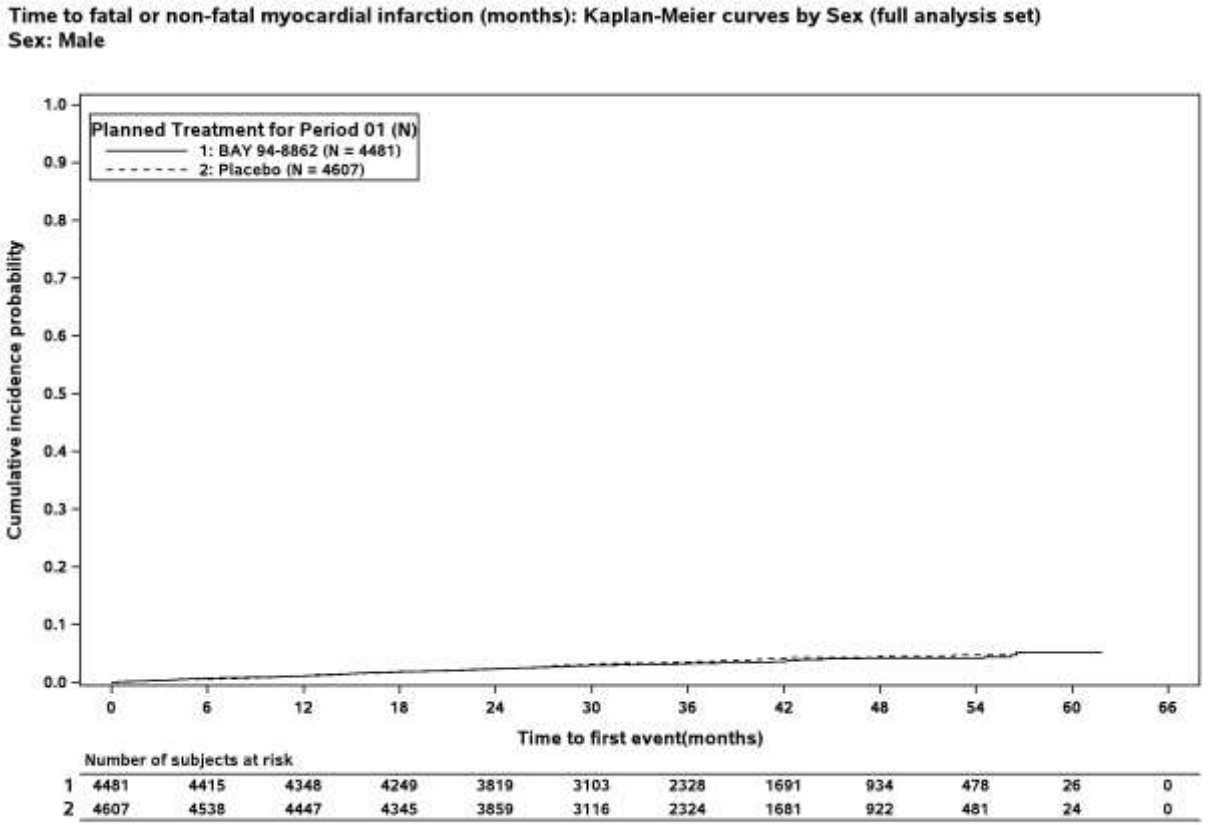


Figure 1.3.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

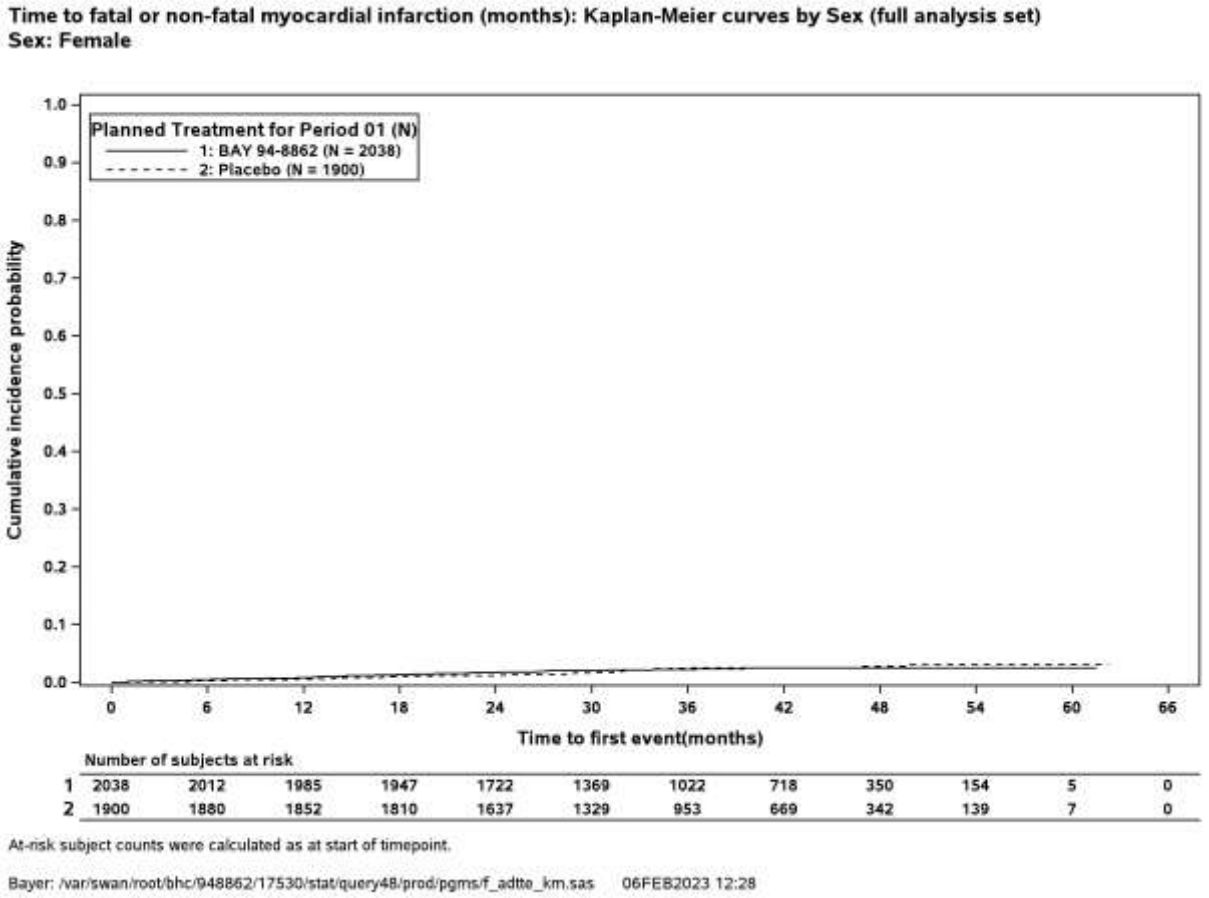


Figure 1.3.1 / 59: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

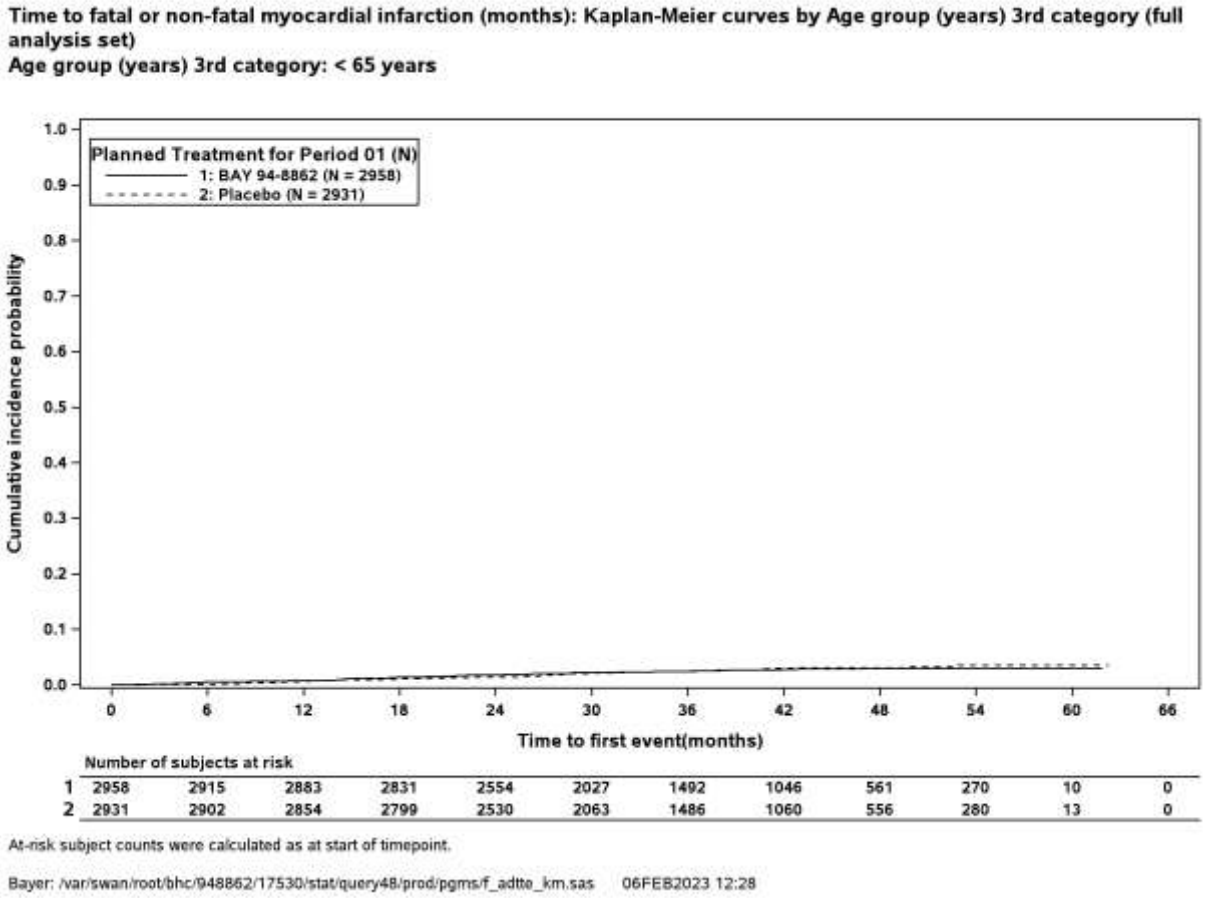


Figure 1.3.1 / 59: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

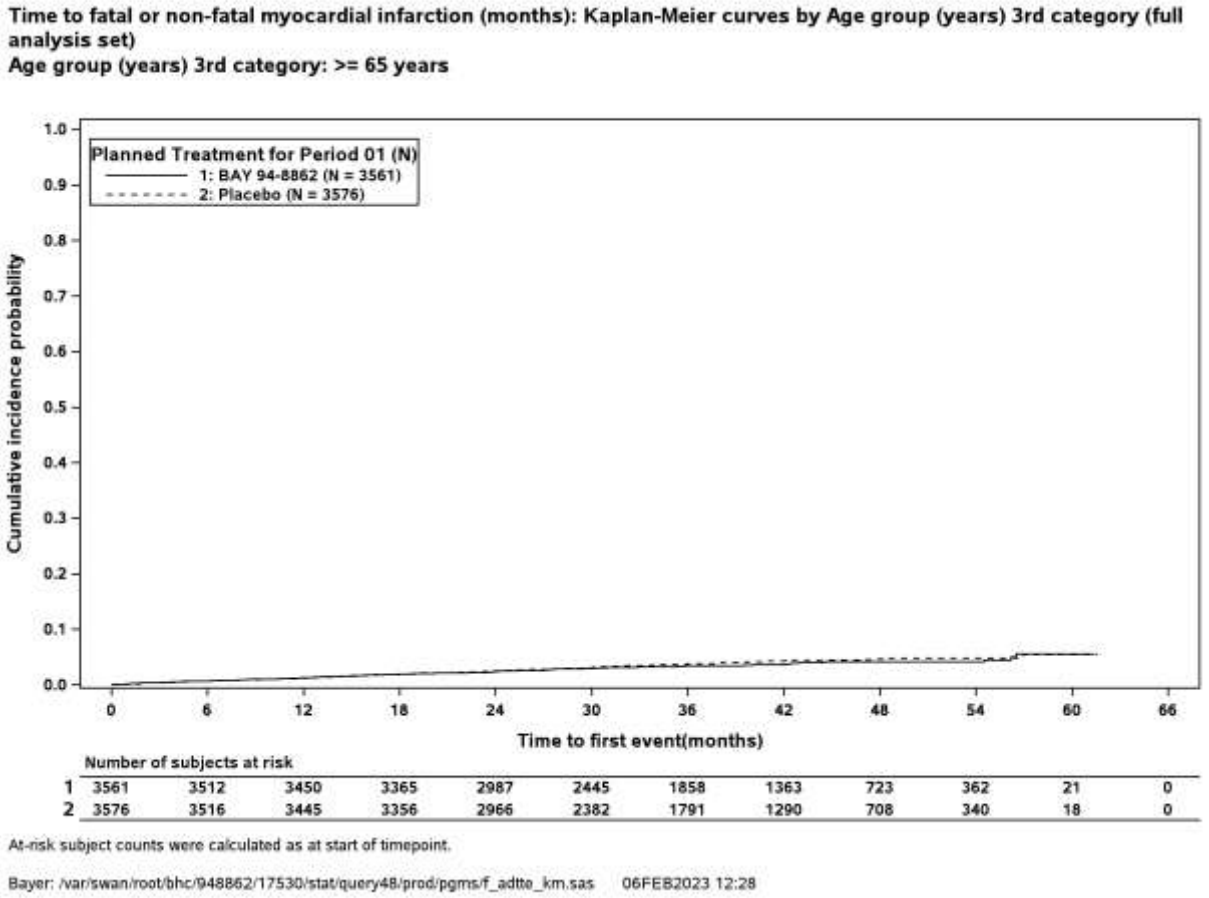


Figure 1.3.1 / 60: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set)

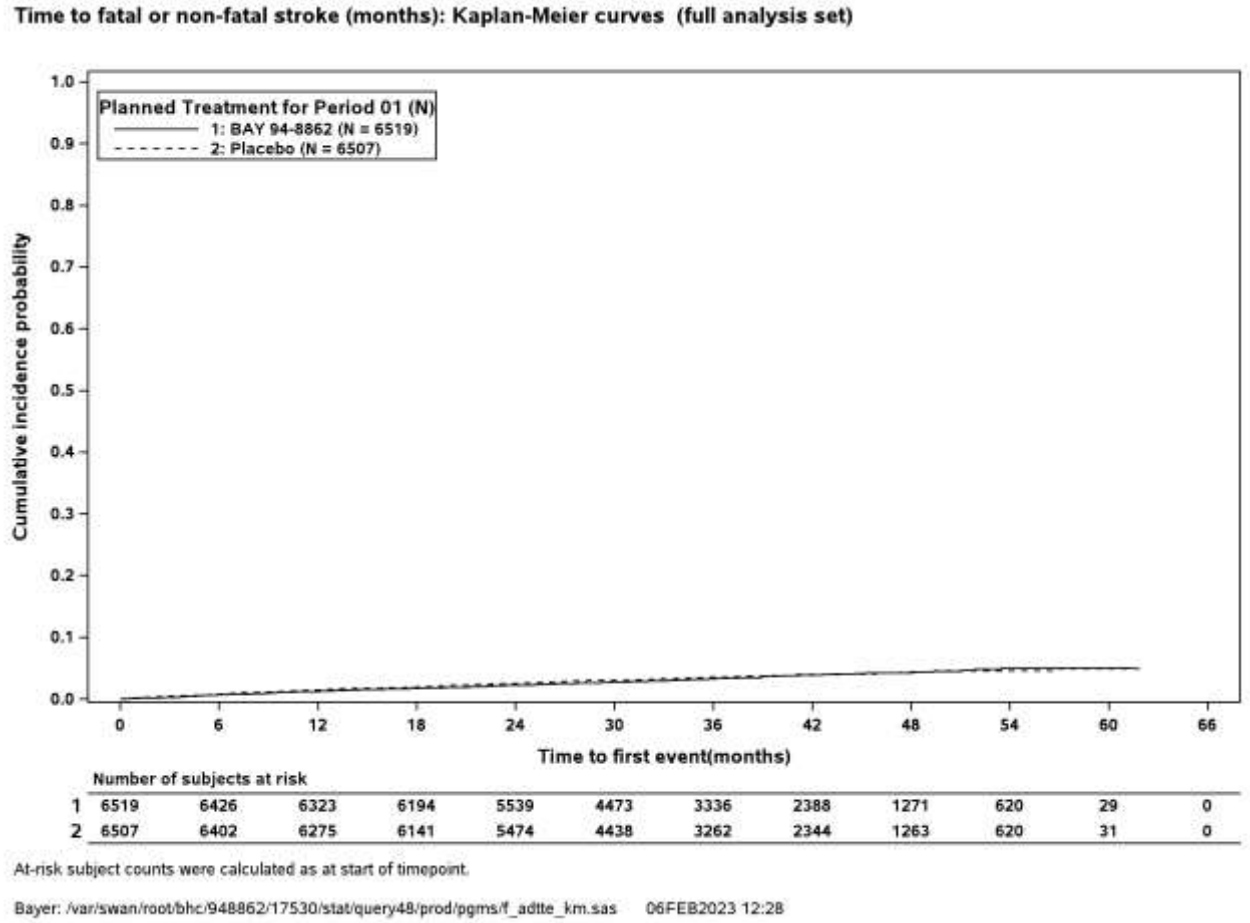


Figure 1.3.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

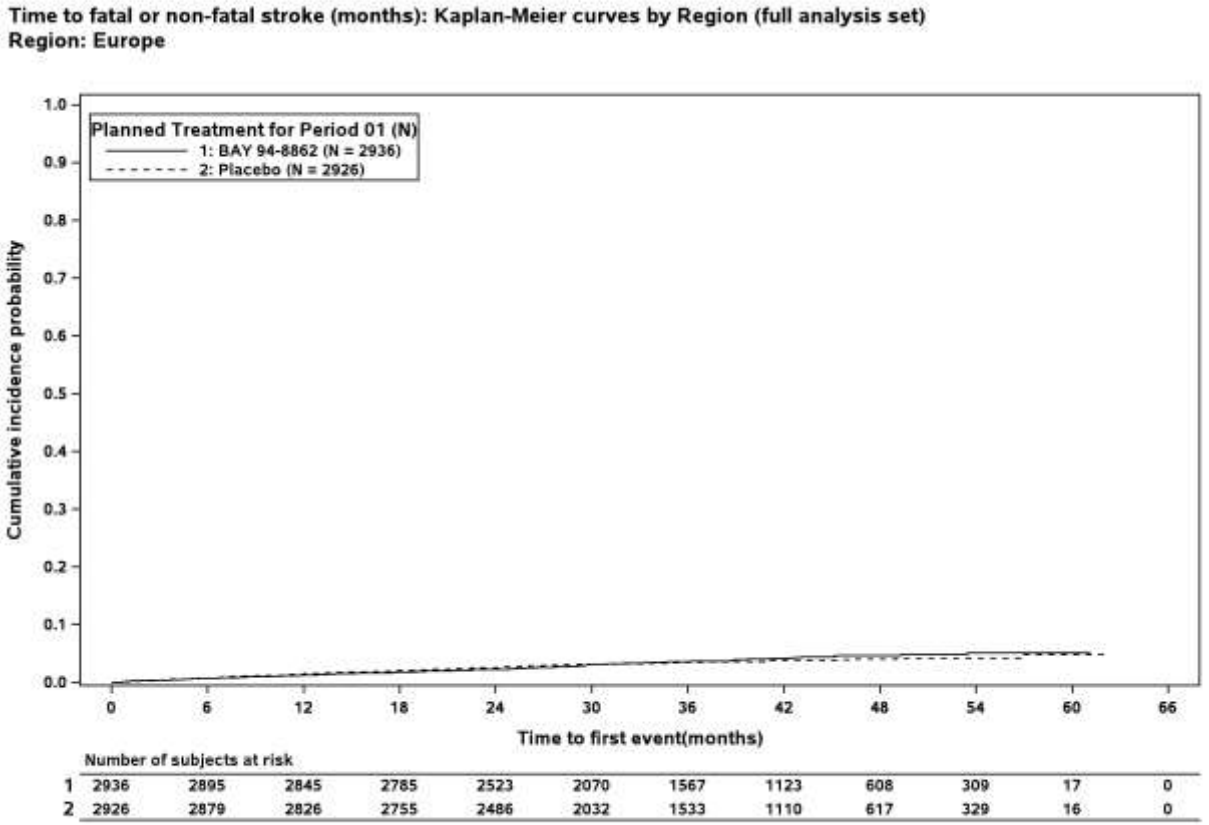


Figure 1.3.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

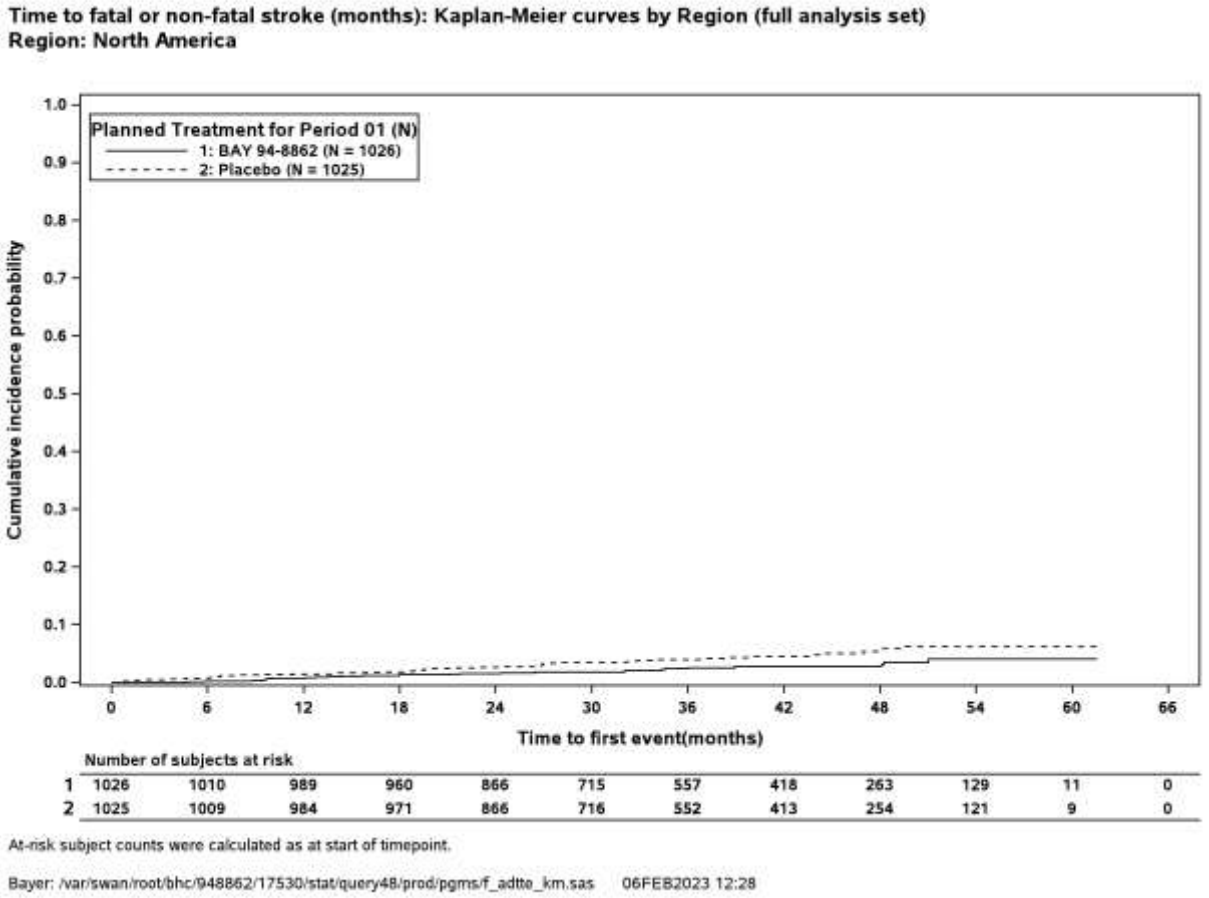


Figure 1.3.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

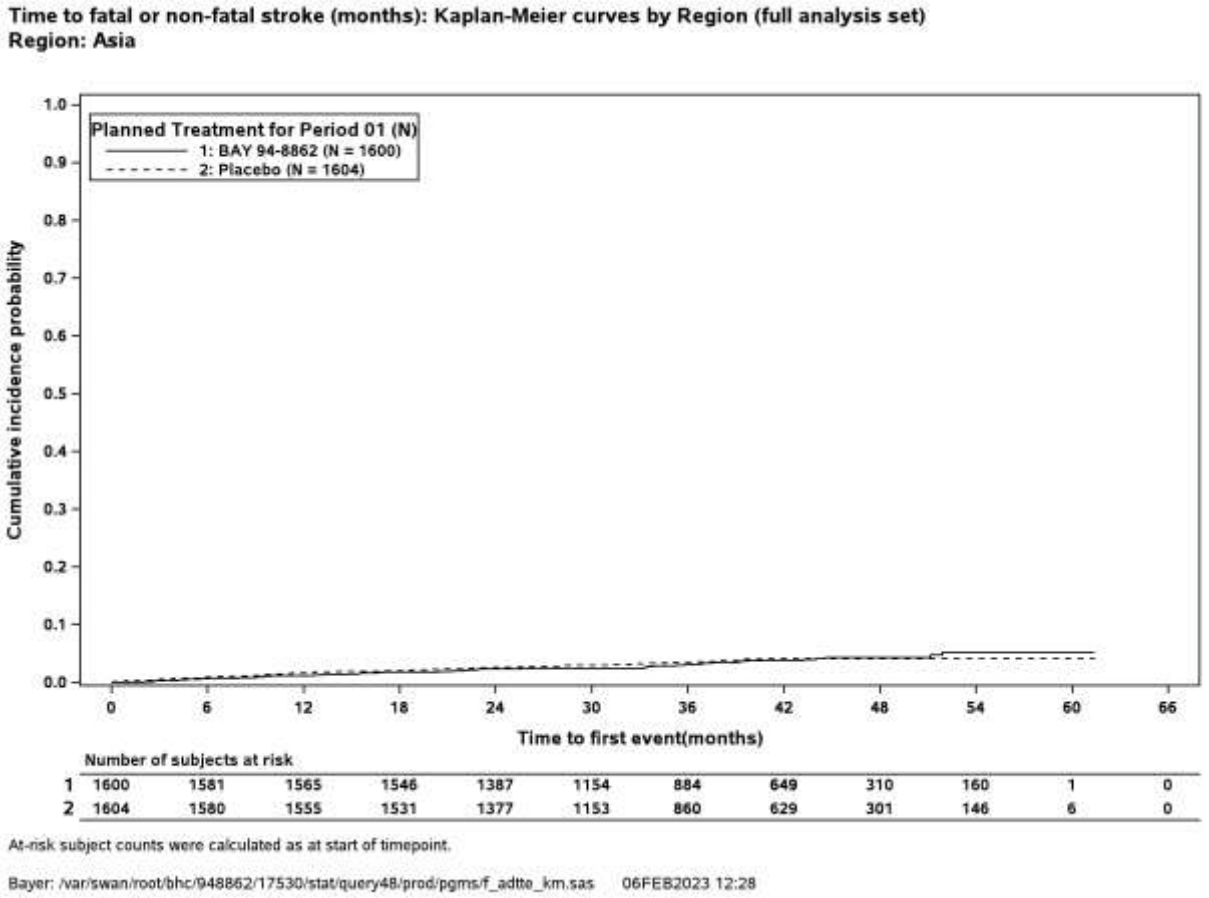


Figure 1.3.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

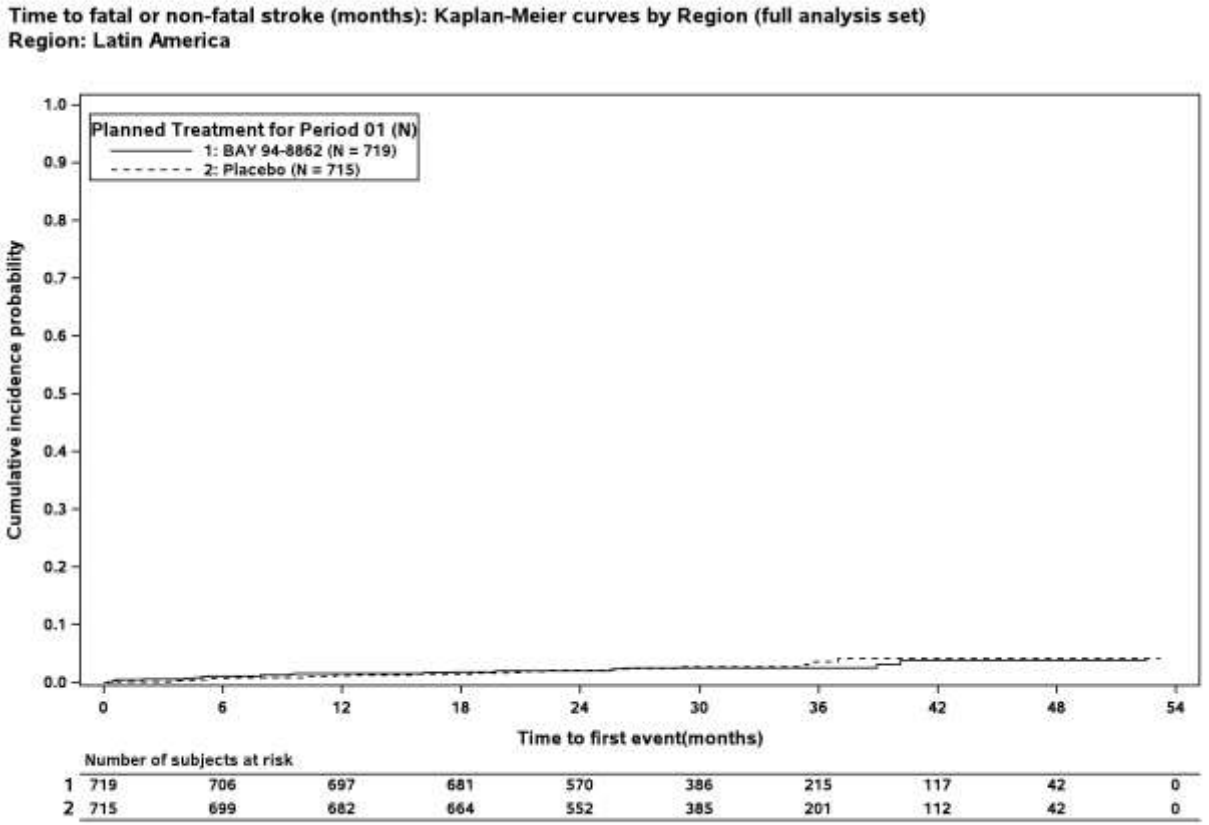


Figure 1.3.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

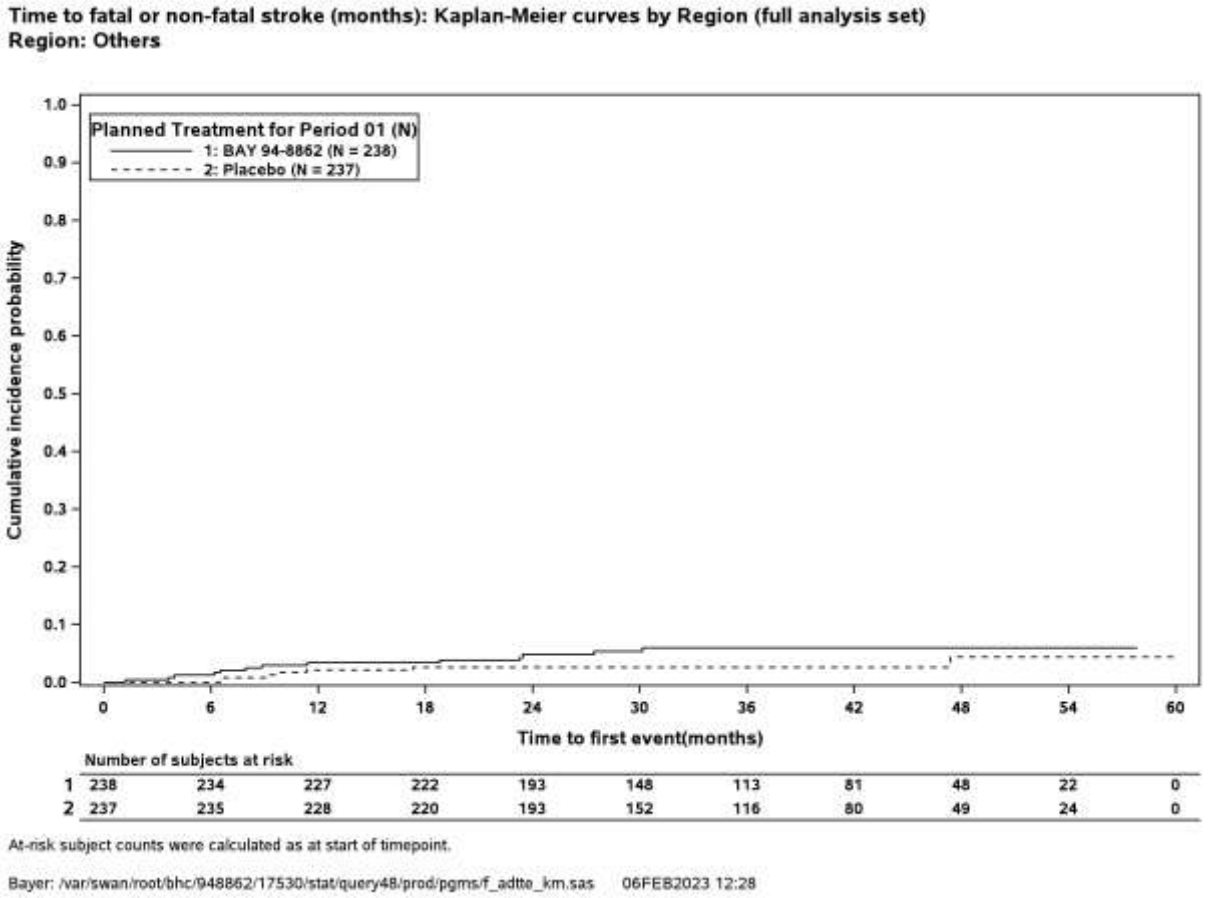


Figure 1.3.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

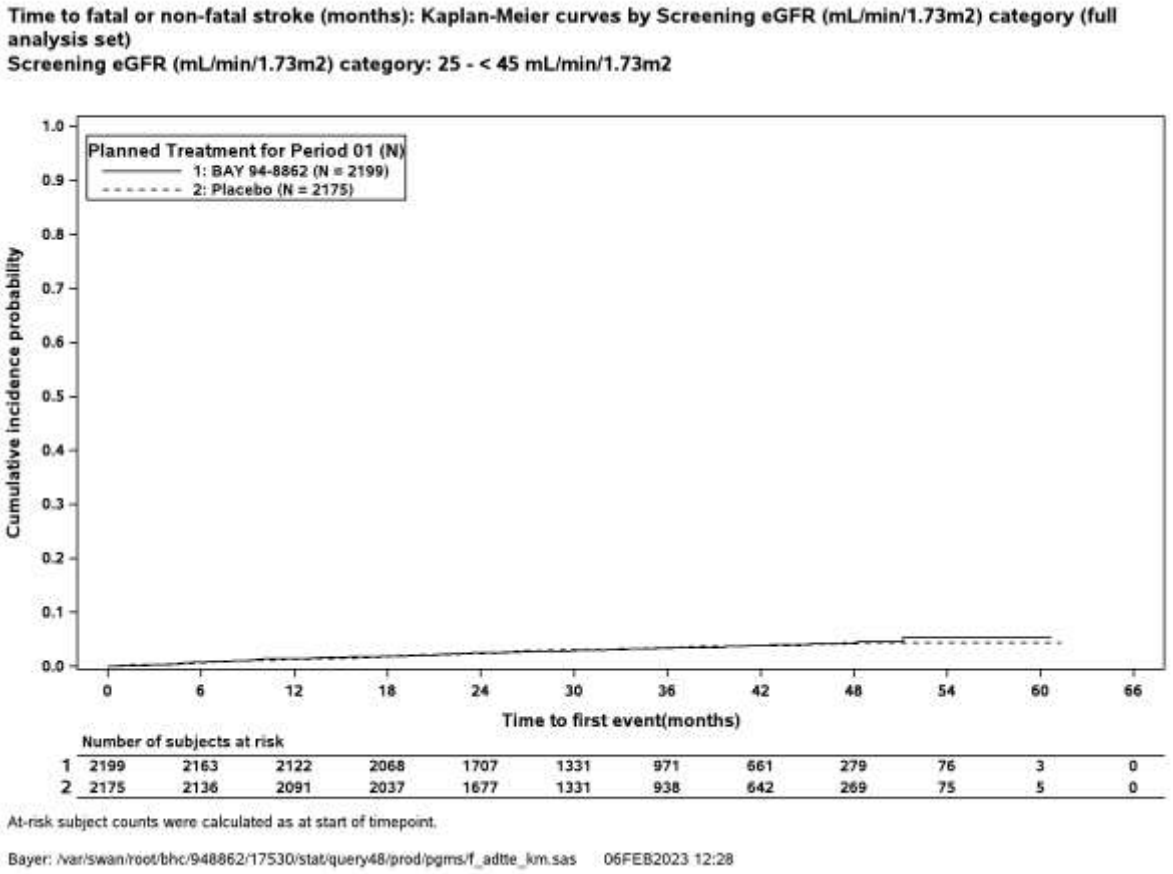


Figure 1.3.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

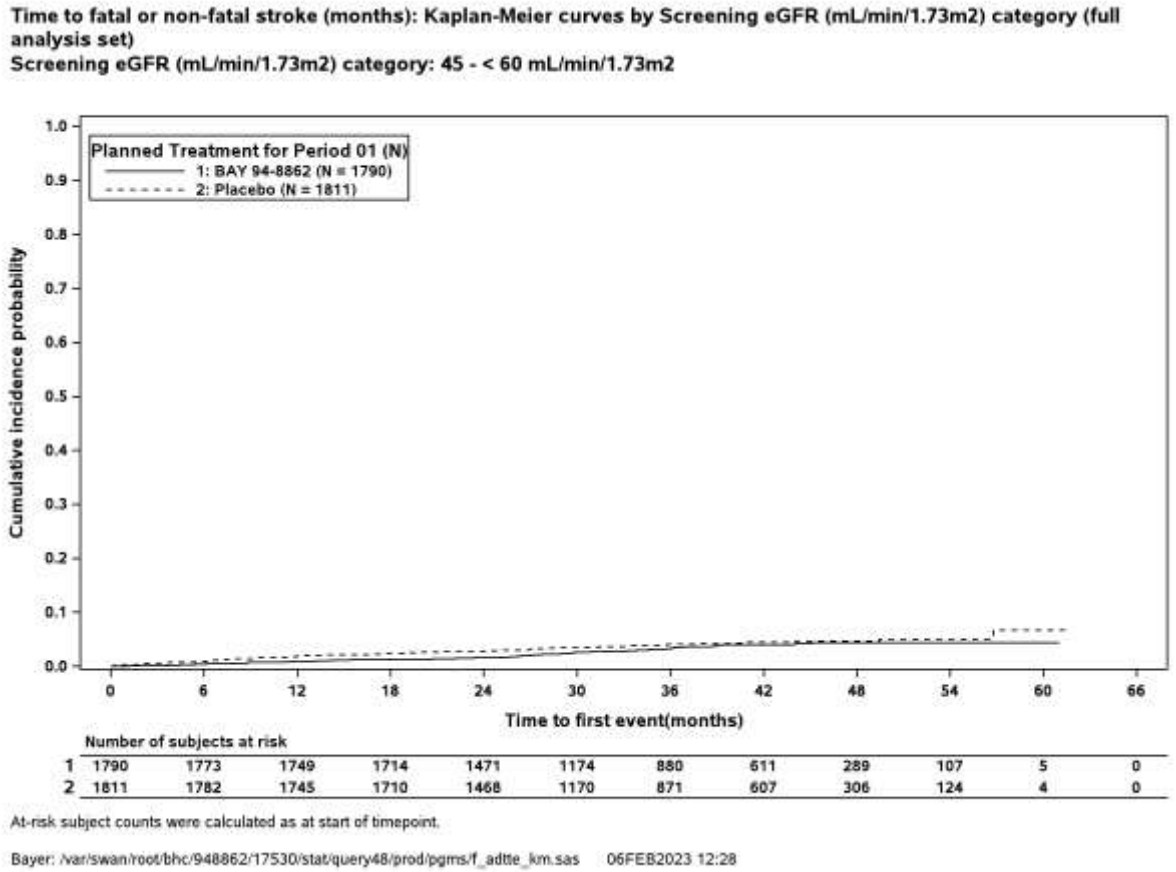
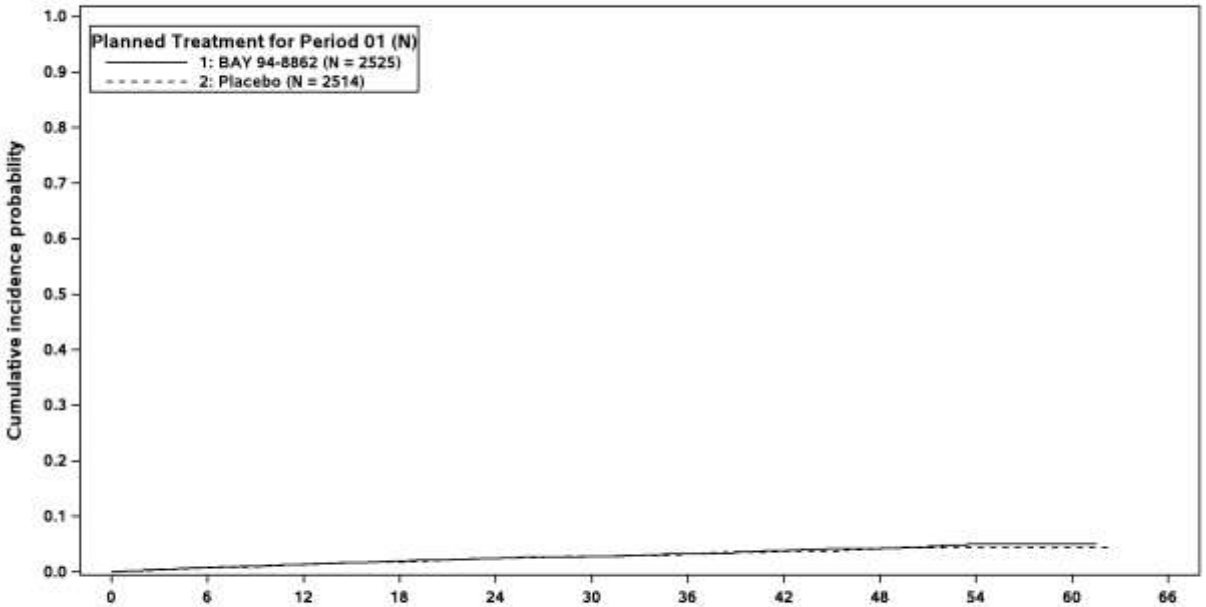


Figure 1.3.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)
Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2



Number of subjects at risk

1	2525	2485	2447	2407	2357	1967	1485	1116	703	437	21	0
2	2514	2477	2432	2387	2322	1931	1448	1091	685	421	22	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

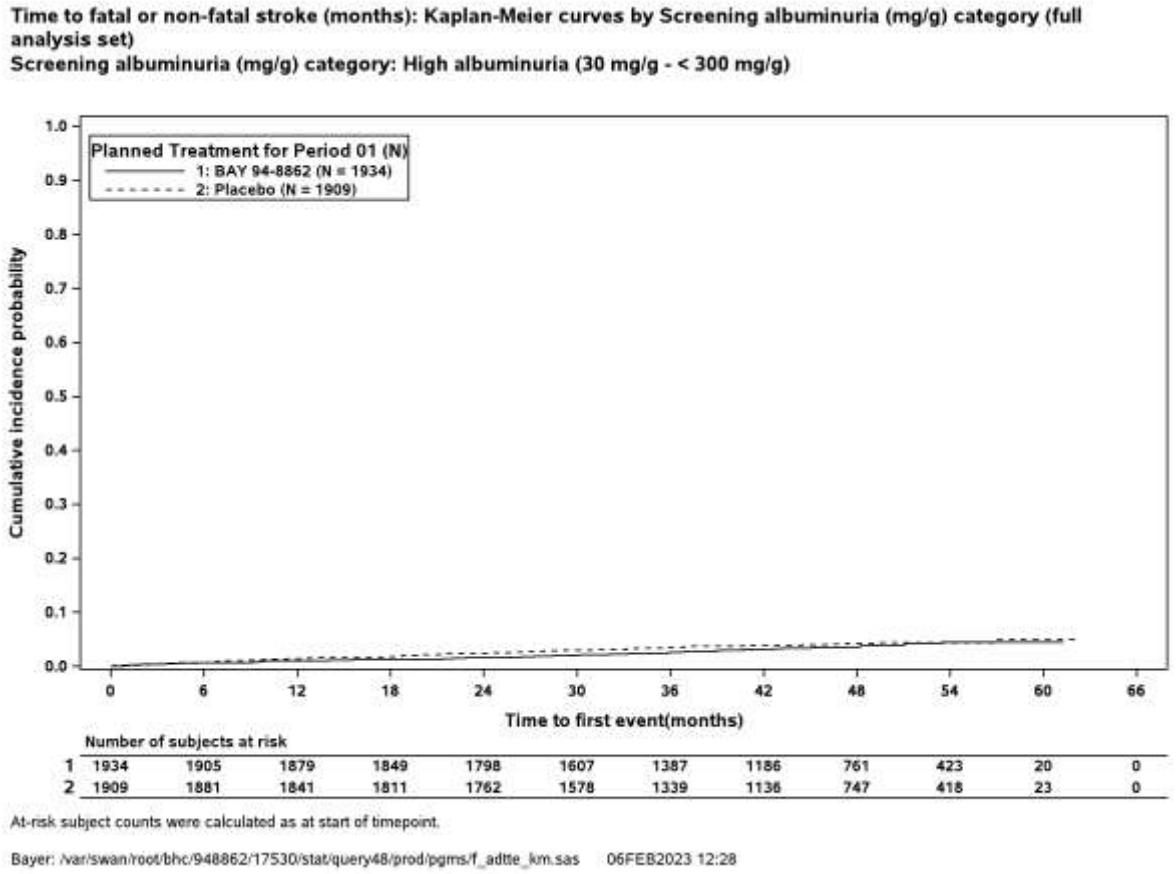
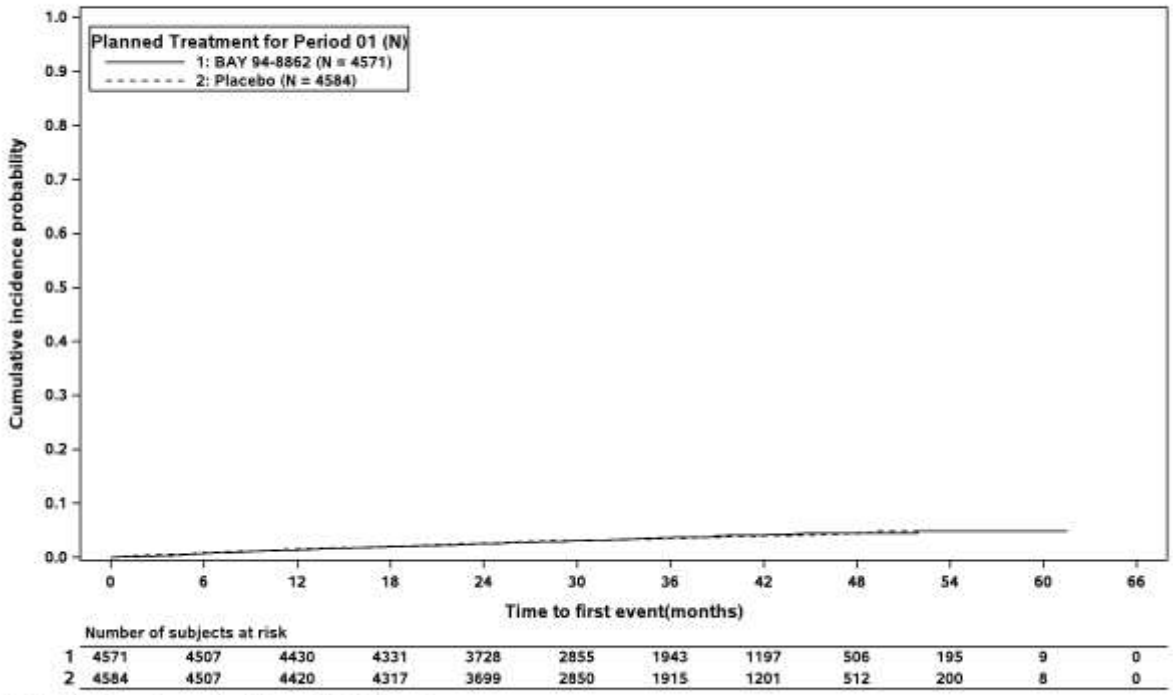


Figure 1.3.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4507	4430	4331	3728	2855	1943	1197	506	195	9	0
2	4584	4507	4420	4317	3699	2850	1915	1201	512	200	8	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

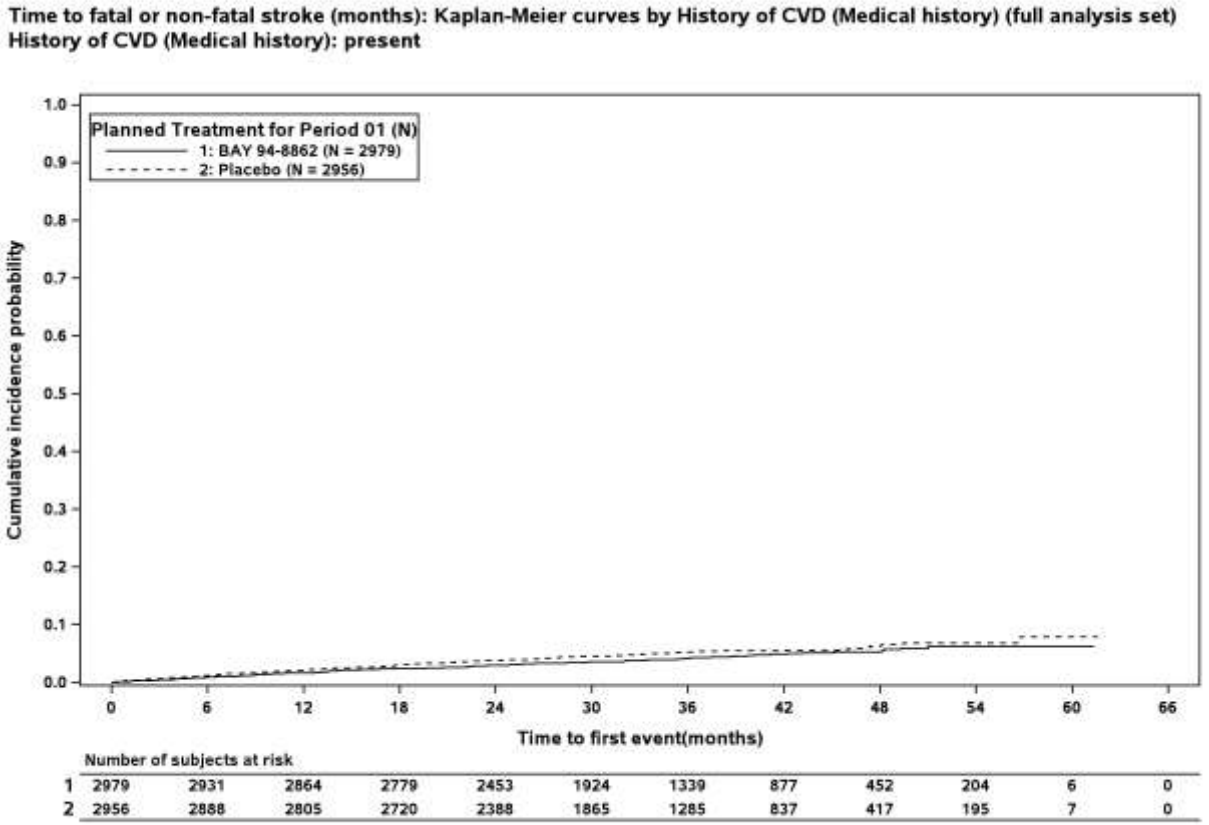


Figure 1.3.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

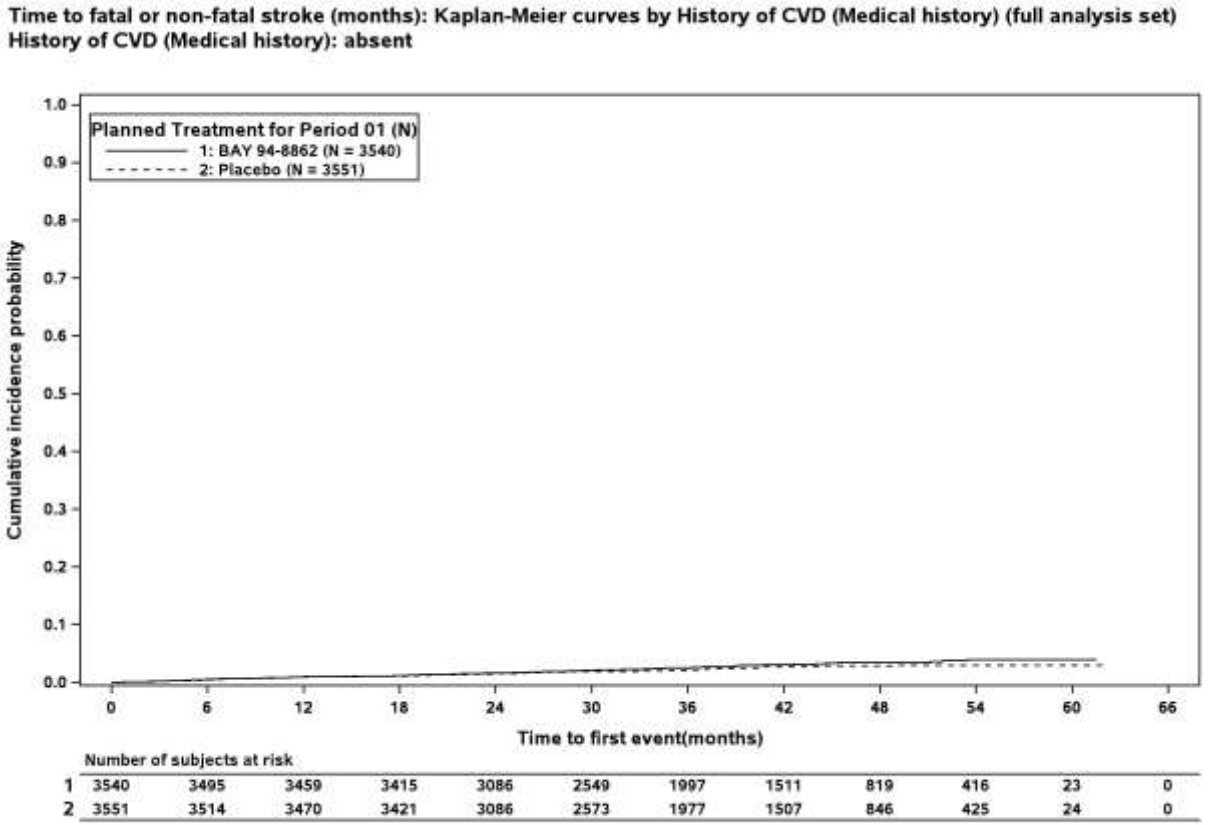


Figure 1.3.1 / 65: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

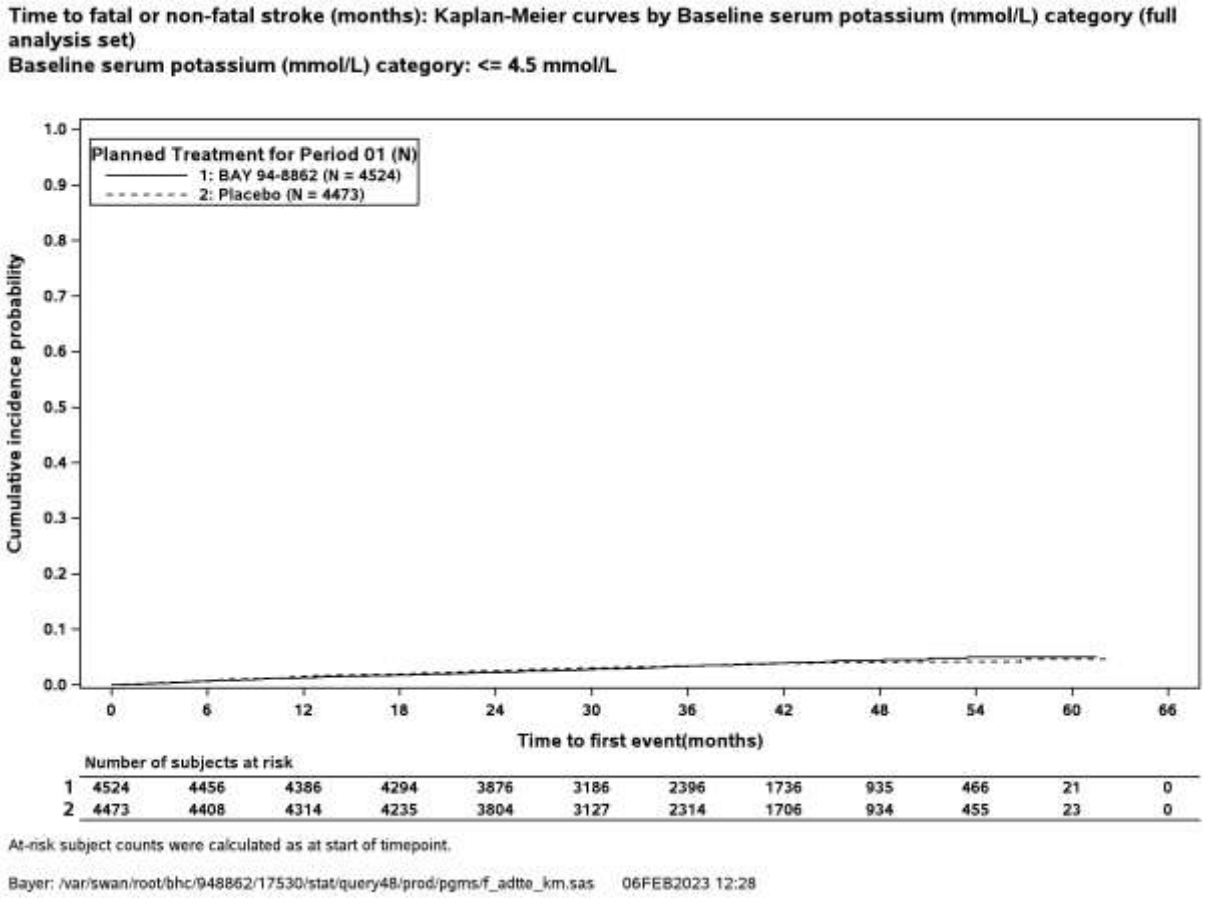
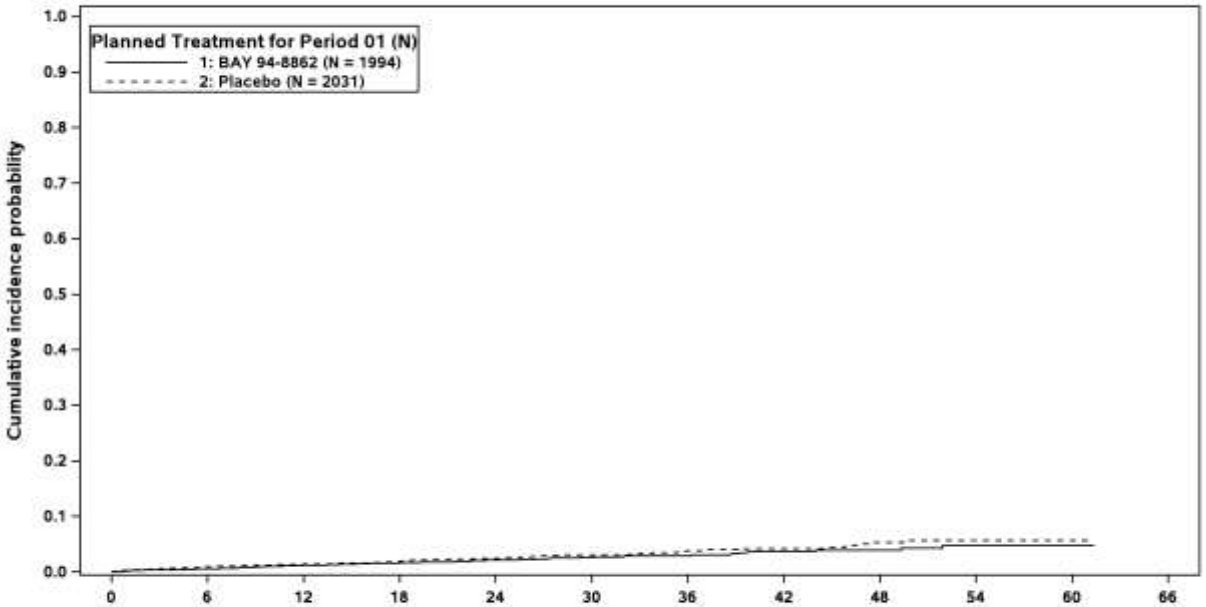


Figure 1.3.1 / 65: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1994	1969	1936	1899	1662	1287	940	652	336	154	8	0
2	2031	1991	1958	1903	1667	1309	947	637	328	164	8	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 66: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

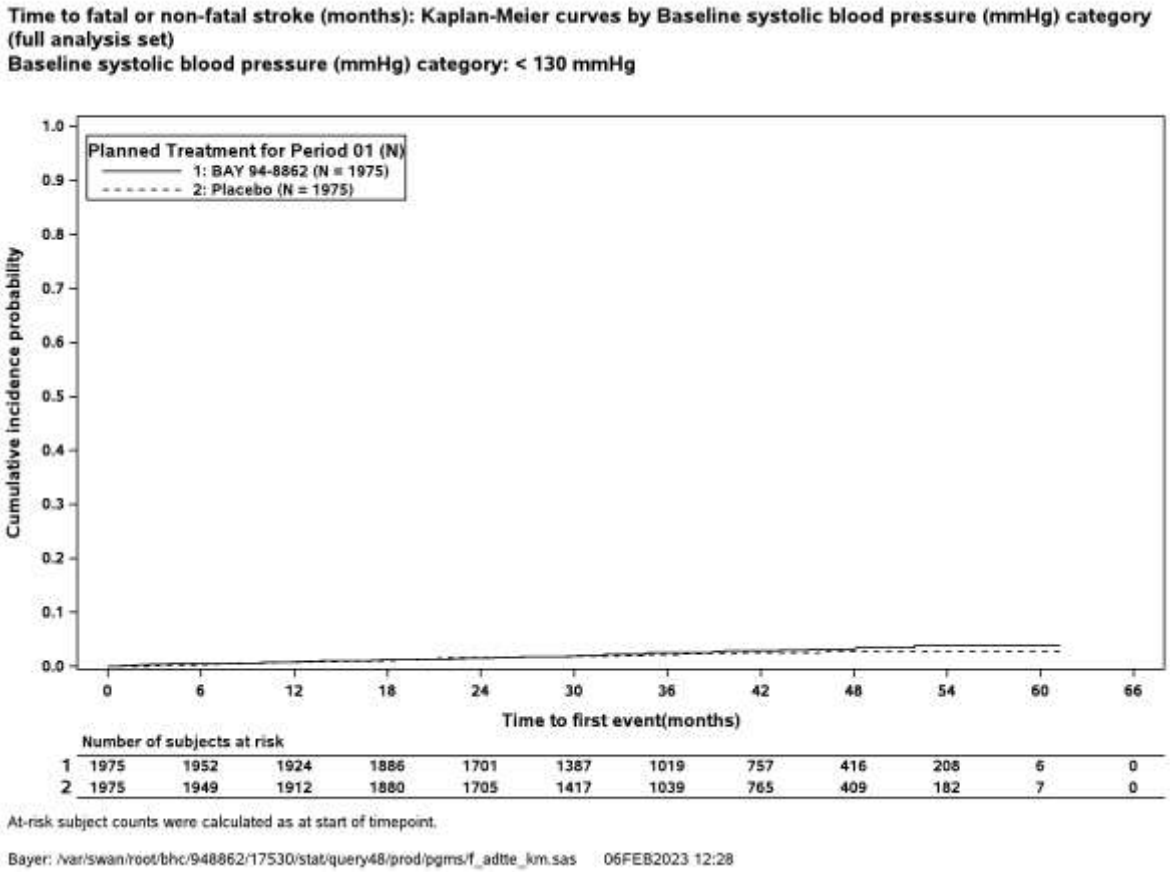


Figure 1.3.1 / 66: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

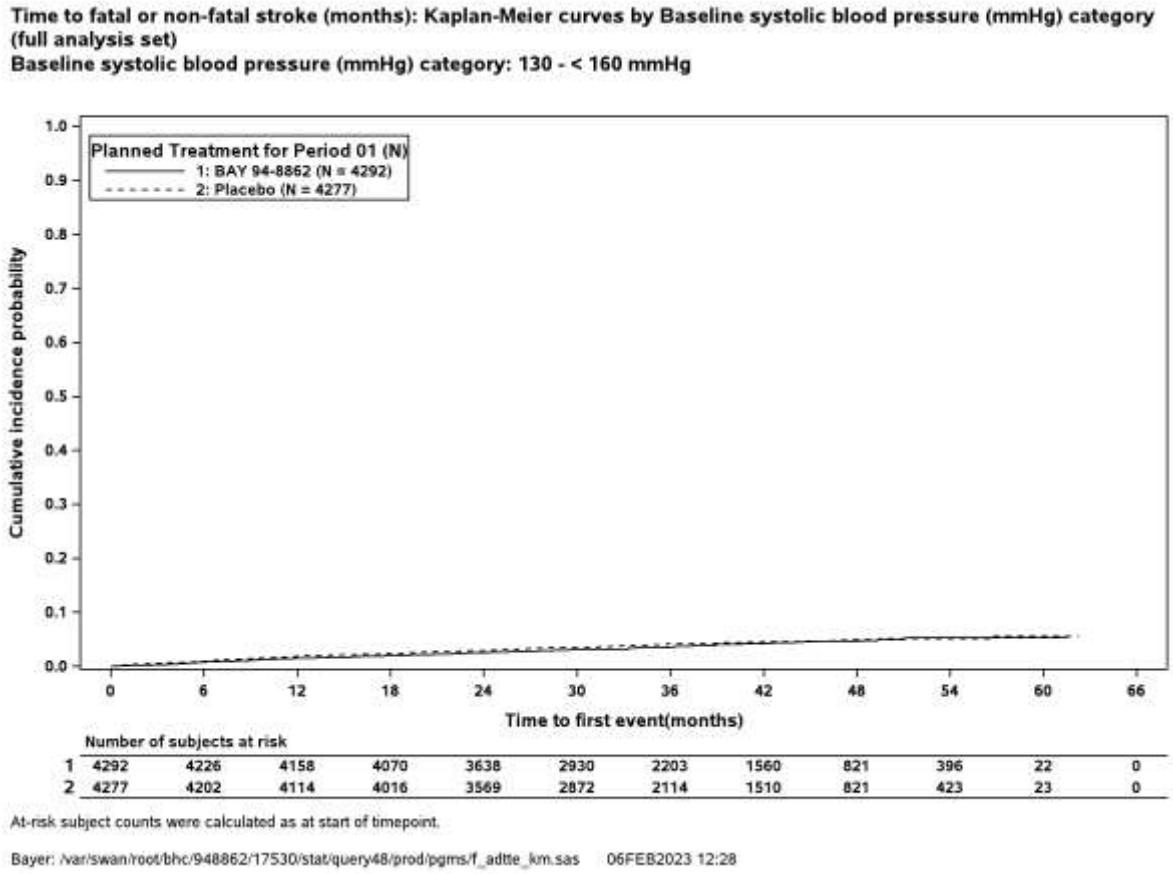


Figure 1.3.1 / 66: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

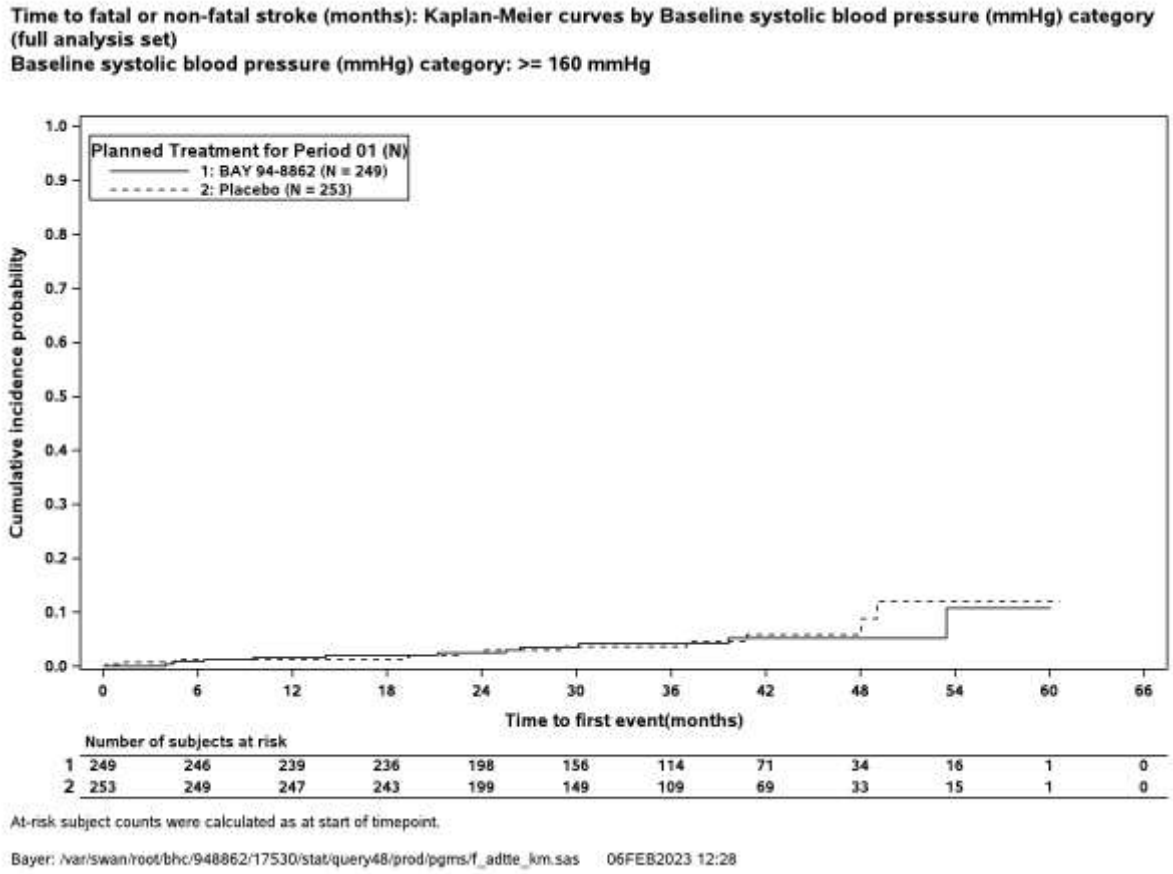


Figure 1.3.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

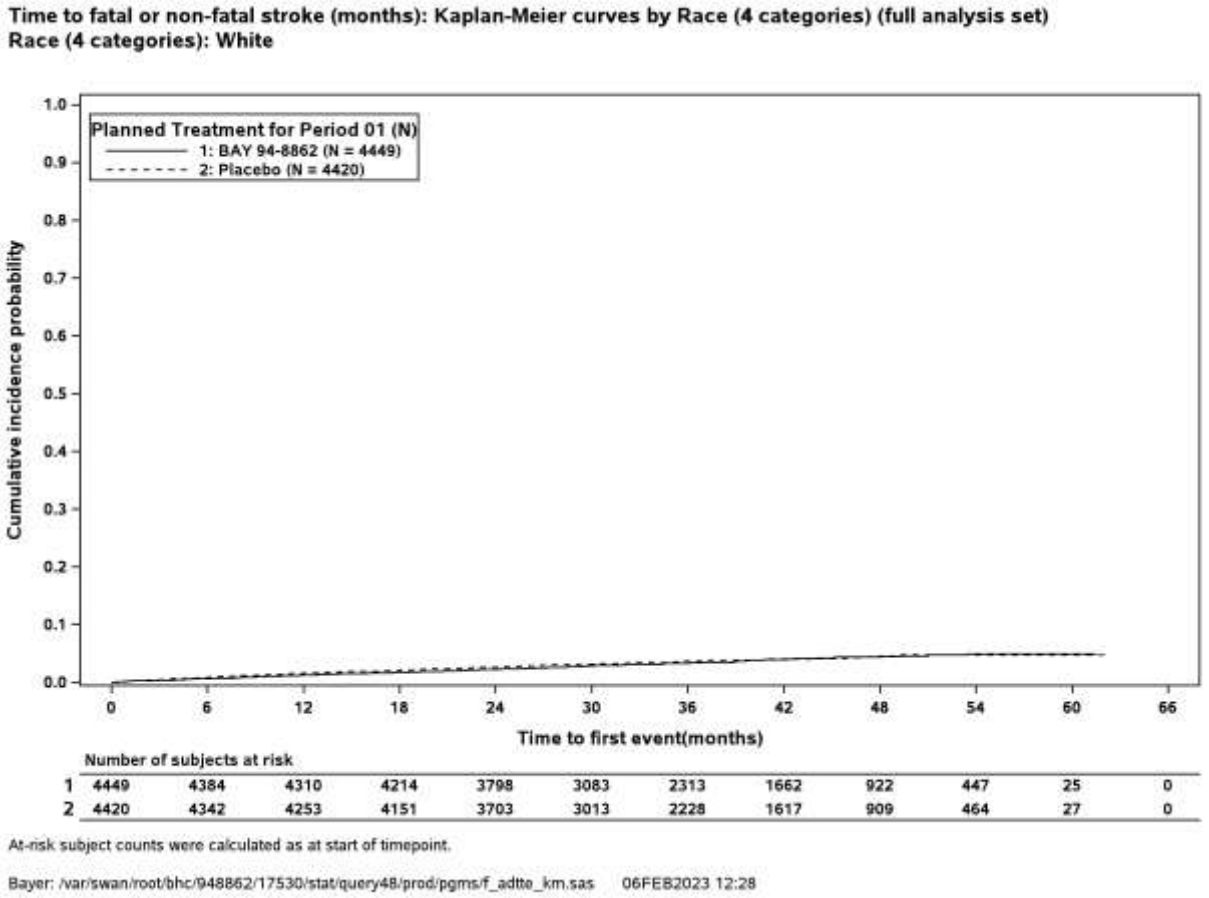


Figure 1.3.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

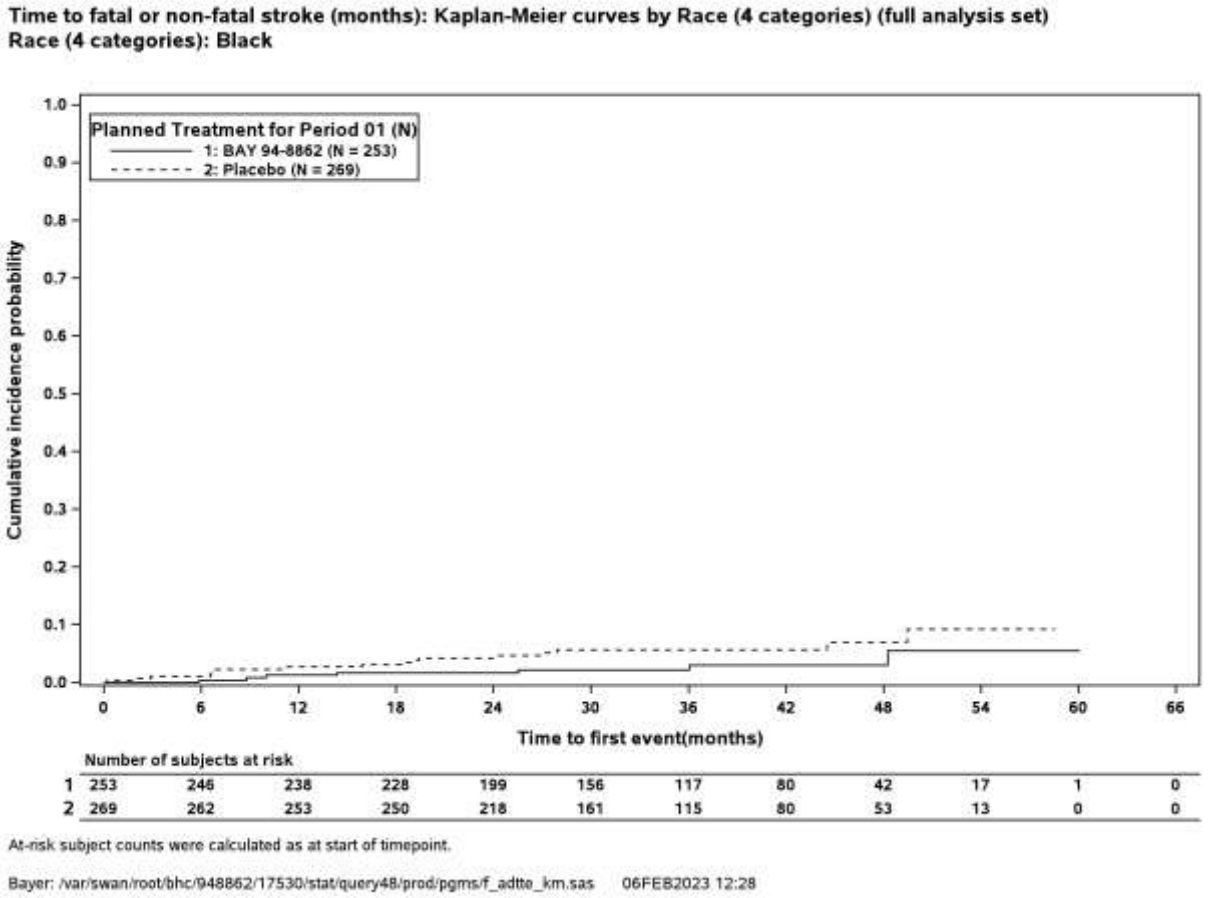


Figure 1.3.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

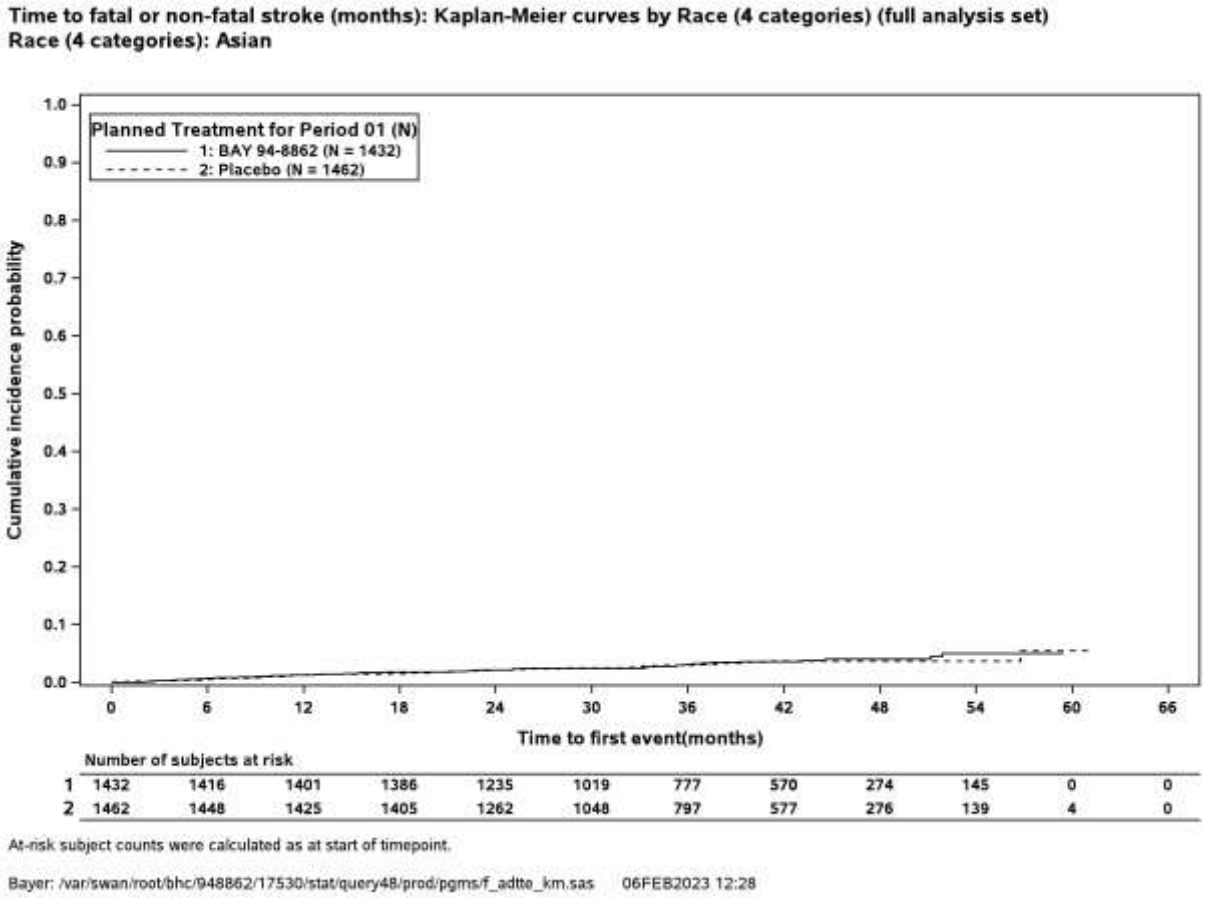


Figure 1.3.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

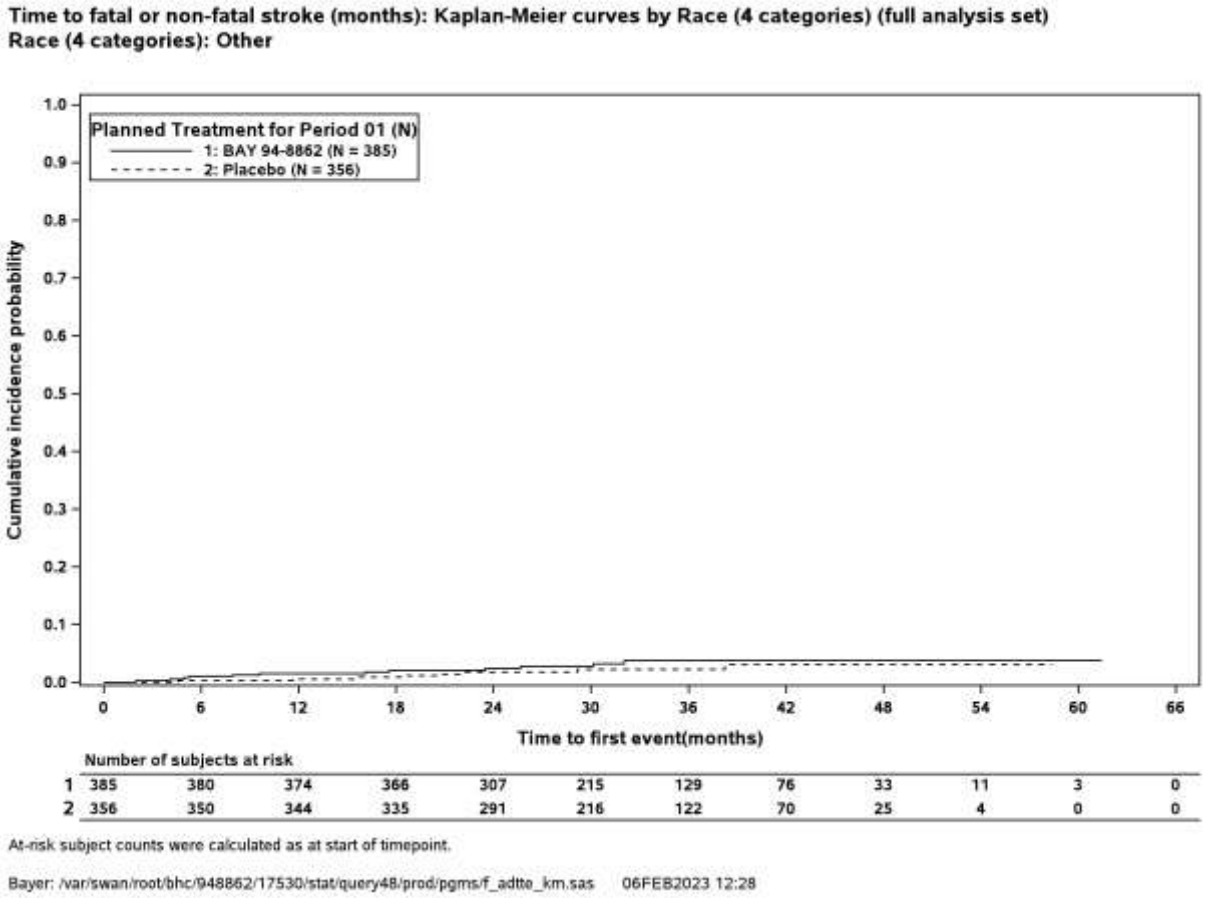


Figure 1.3.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

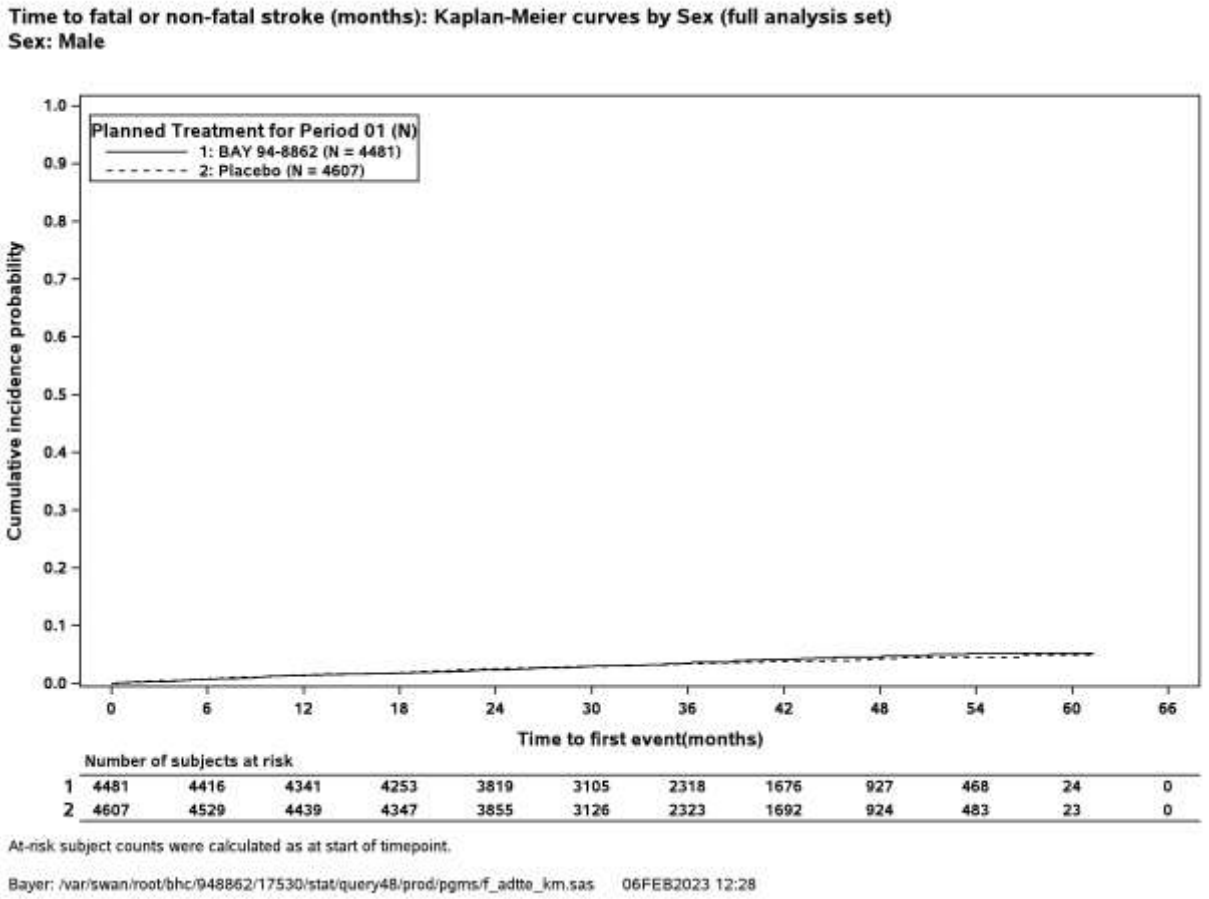


Figure 1.3.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

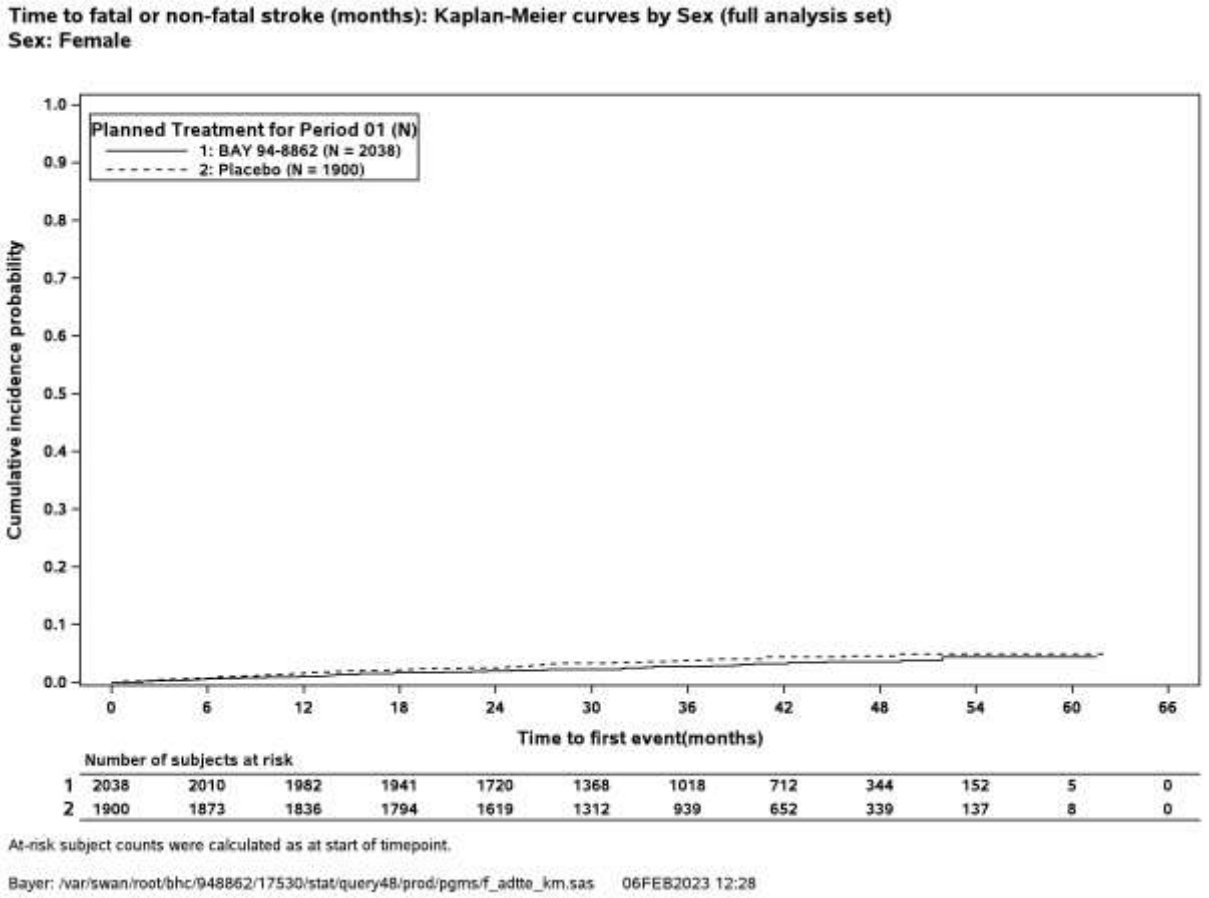


Figure 1.3.1 / 69: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

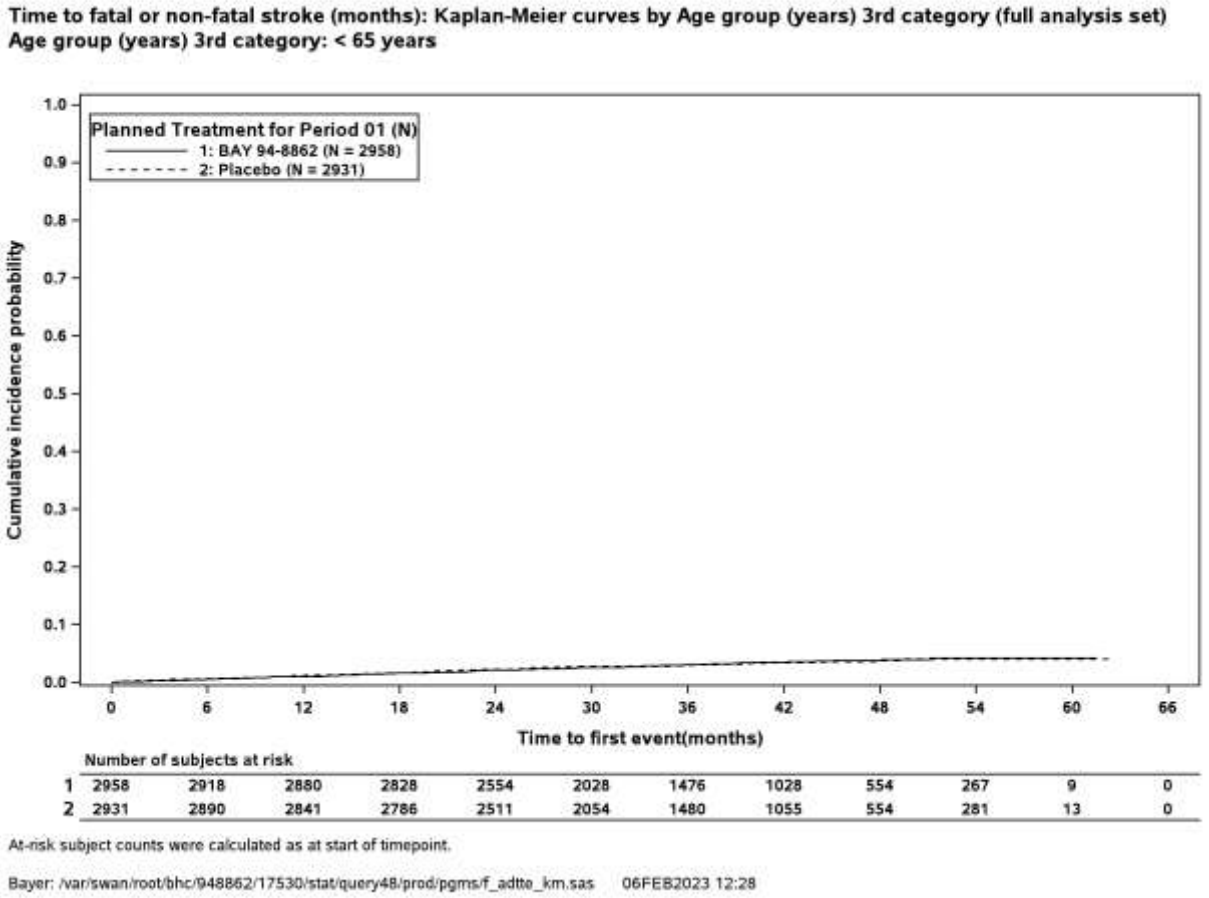


Figure 1.3.1 / 69: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

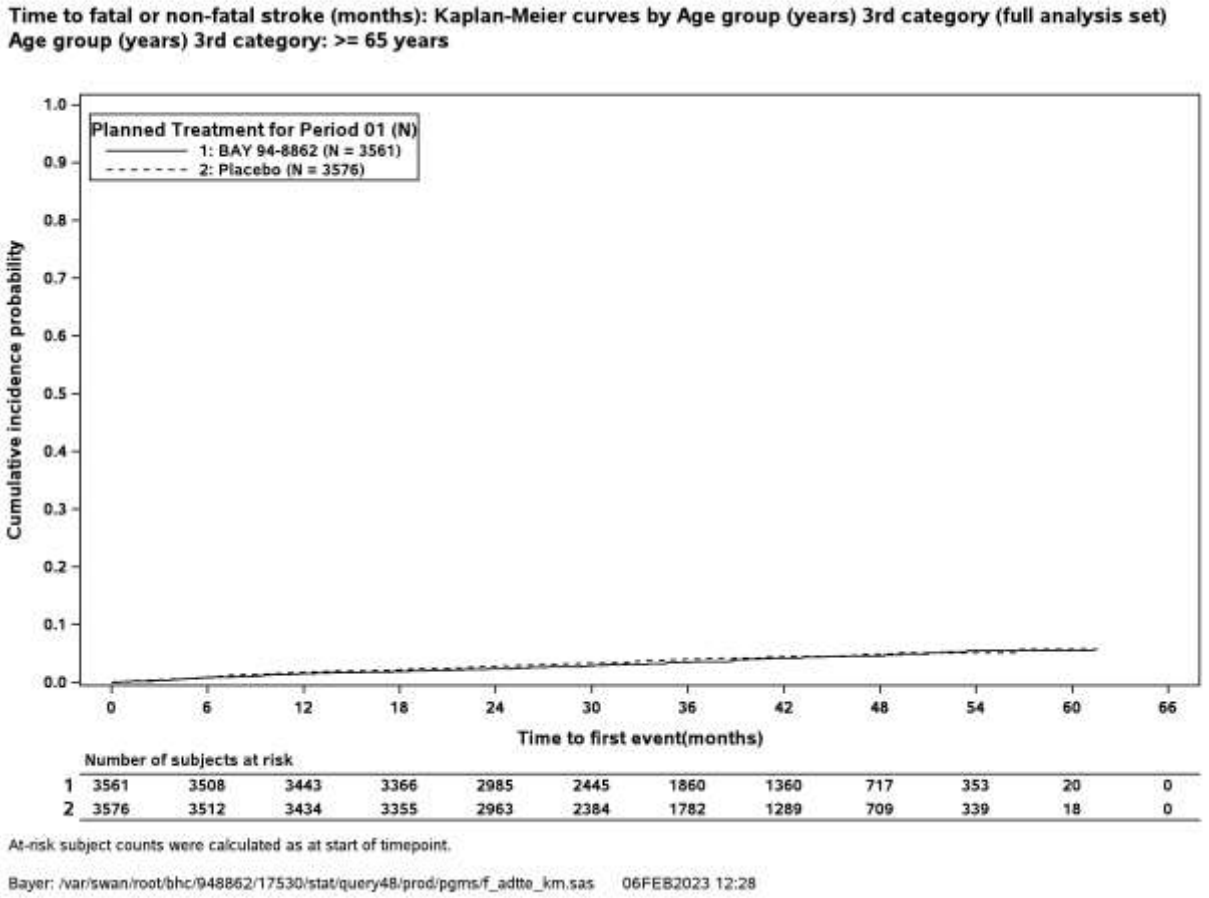
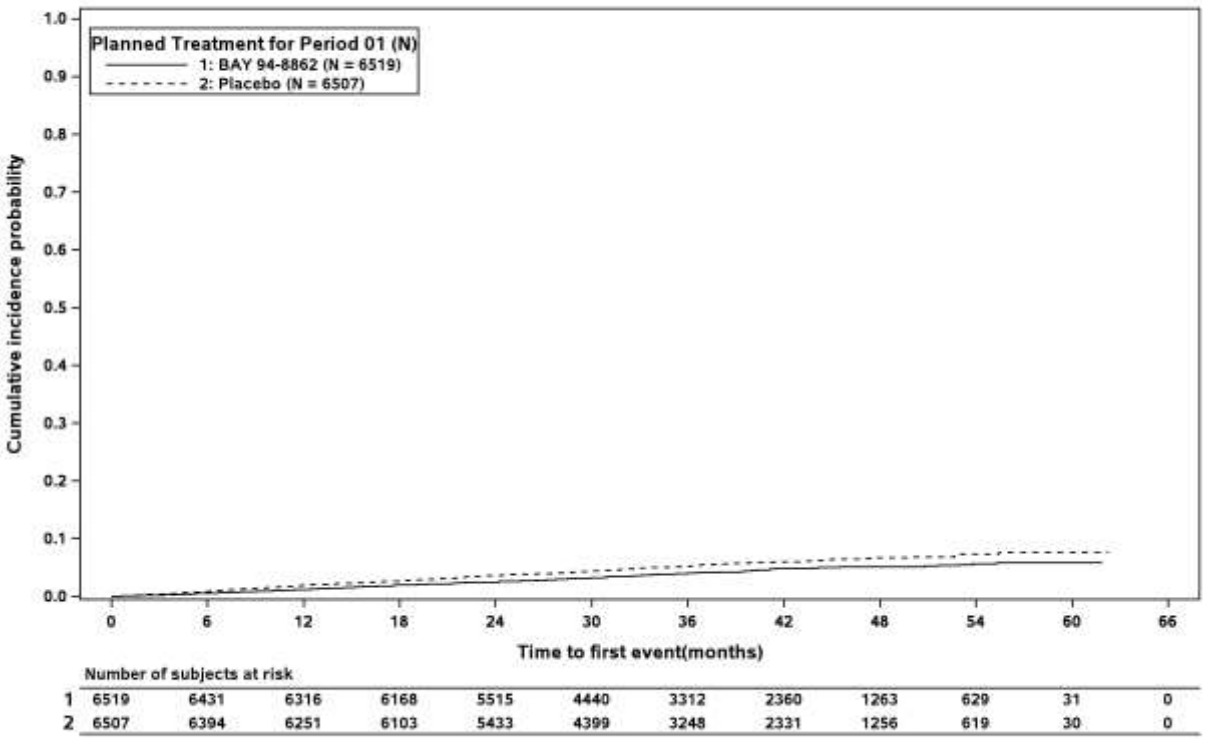


Figure 1.3.1 / 70: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set)

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set)



Number of subjects at risk

1	6519	6431	6316	6168	5515	4440	3312	2360	1263	629	31	0
2	6507	6394	6251	6103	5433	4399	3248	2331	1256	619	30	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

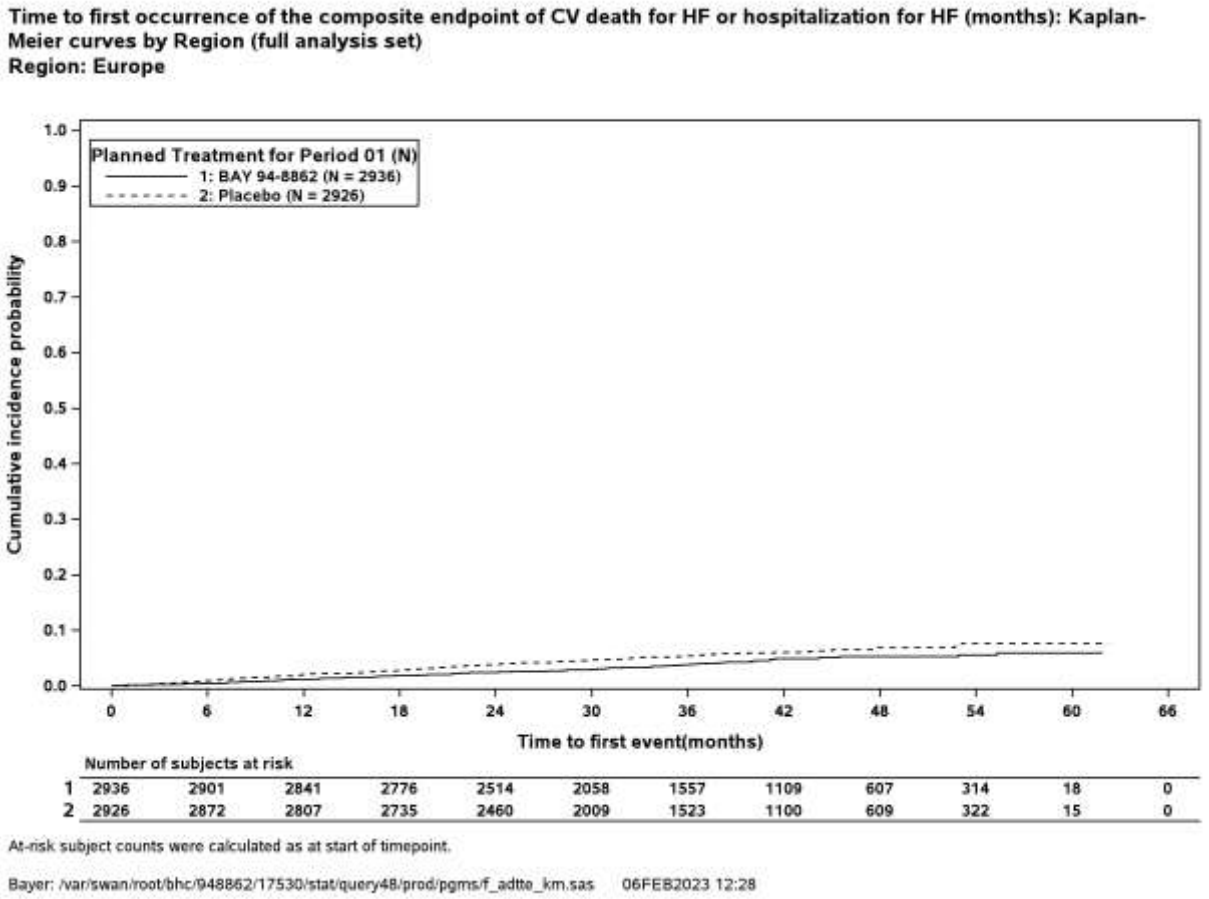


Figure 1.3.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

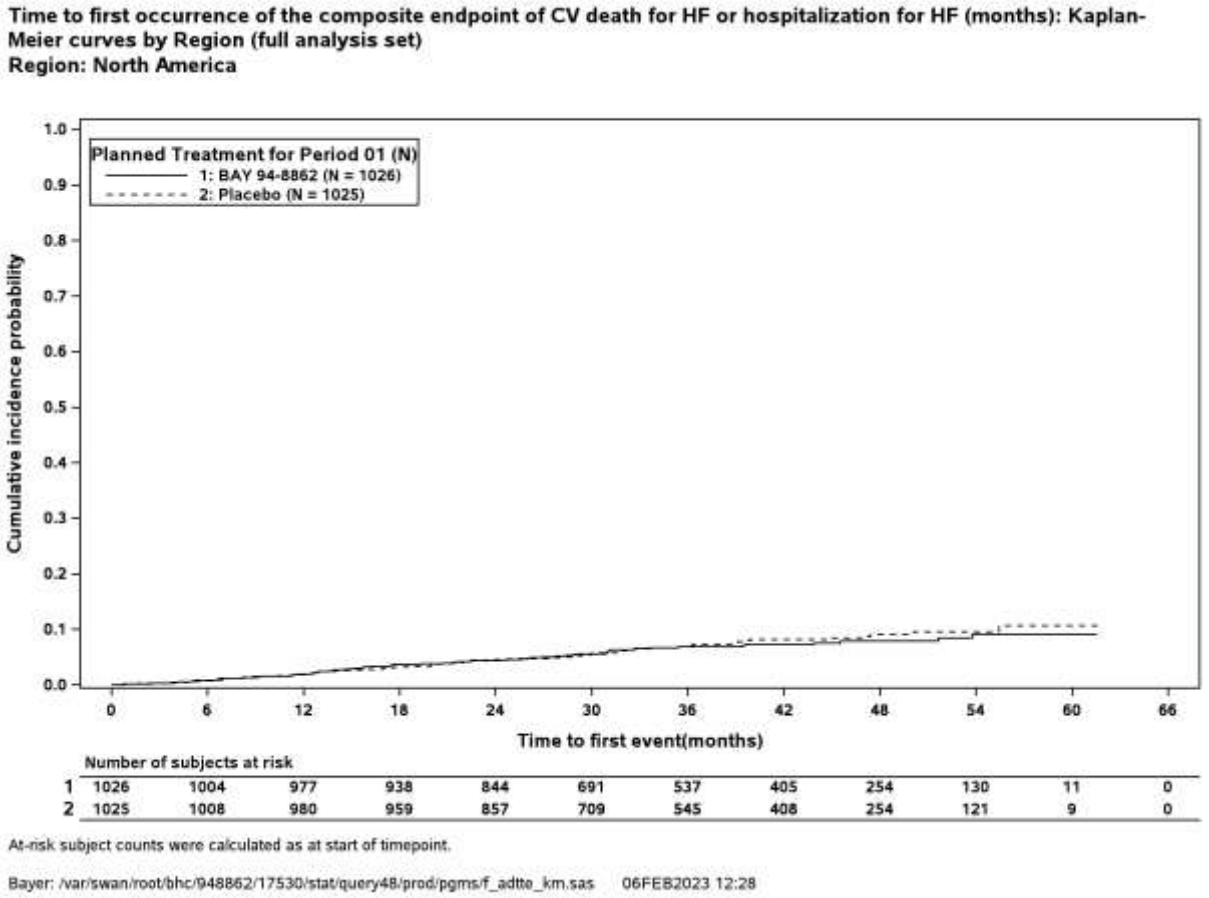


Figure 1.3.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

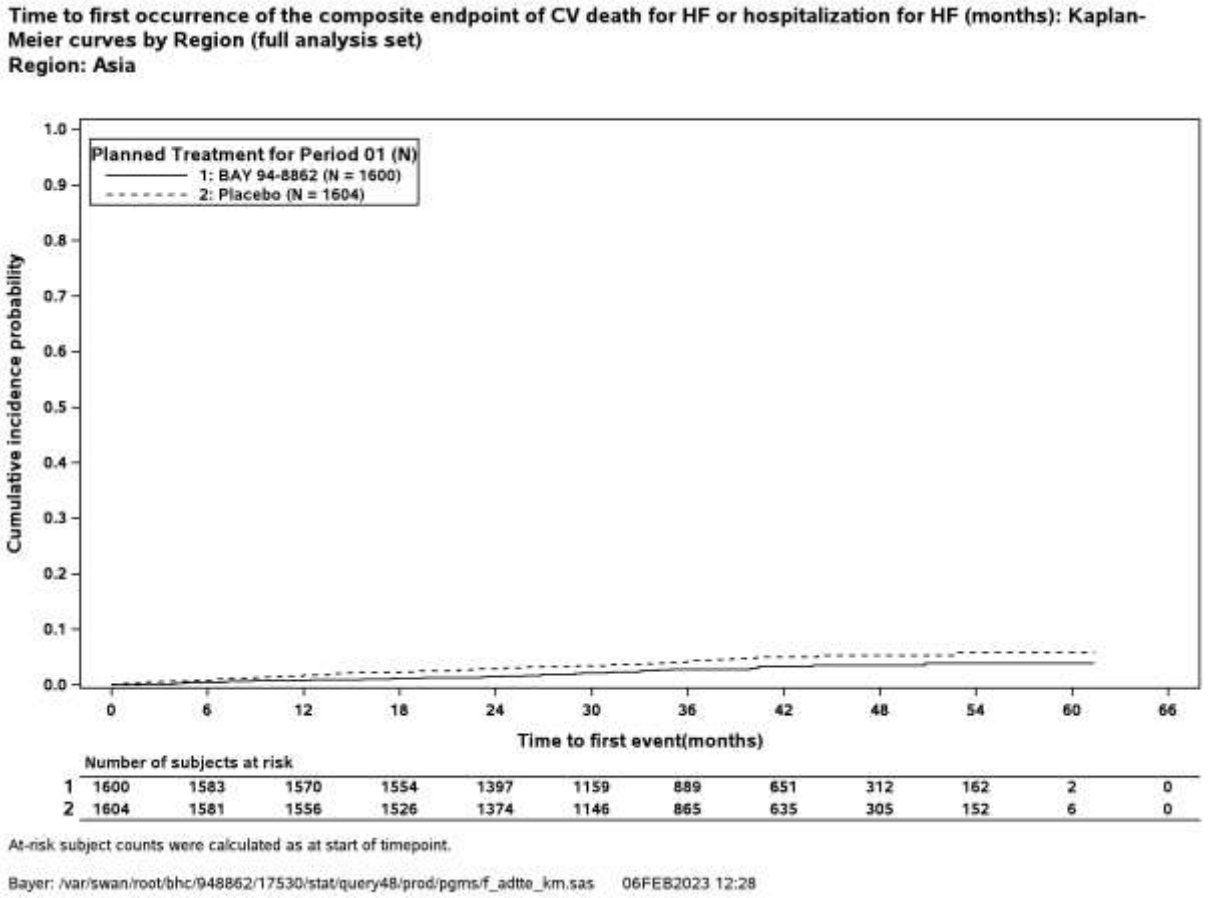


Figure 1.3.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

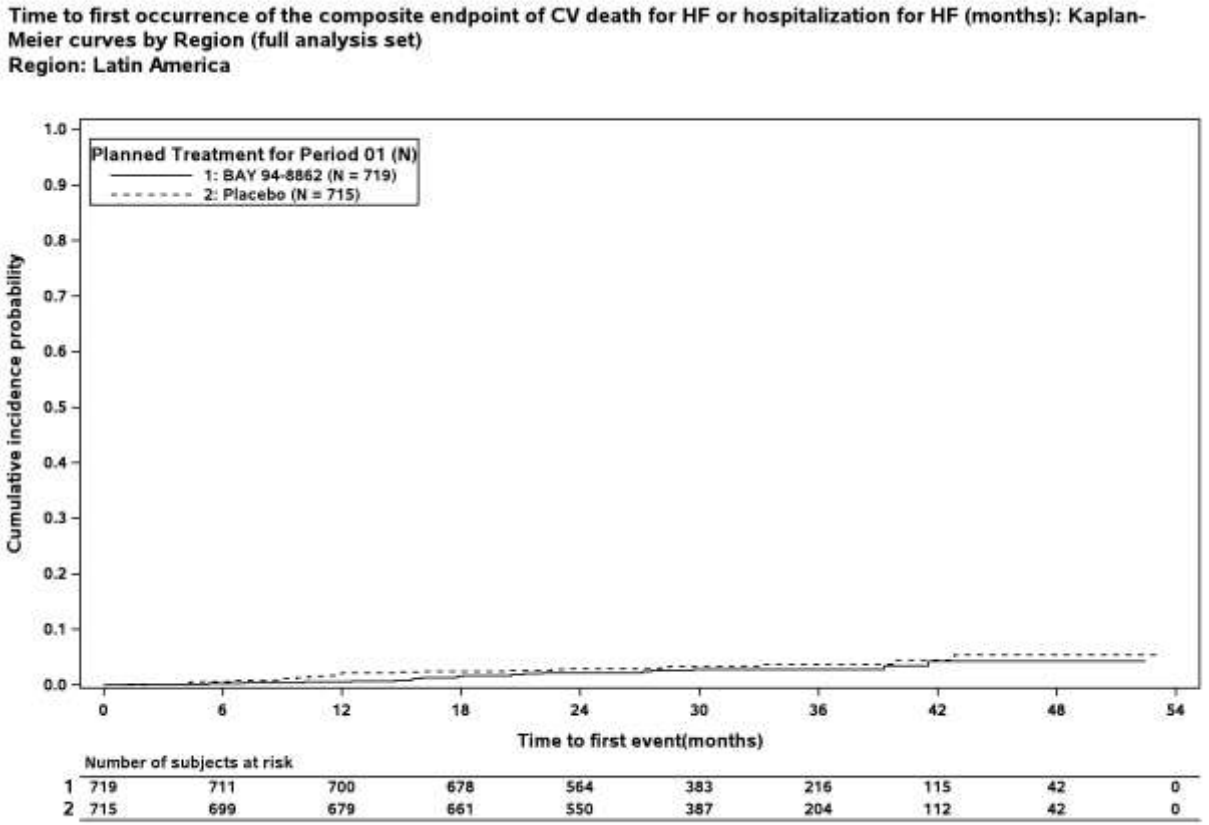


Figure 1.3.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

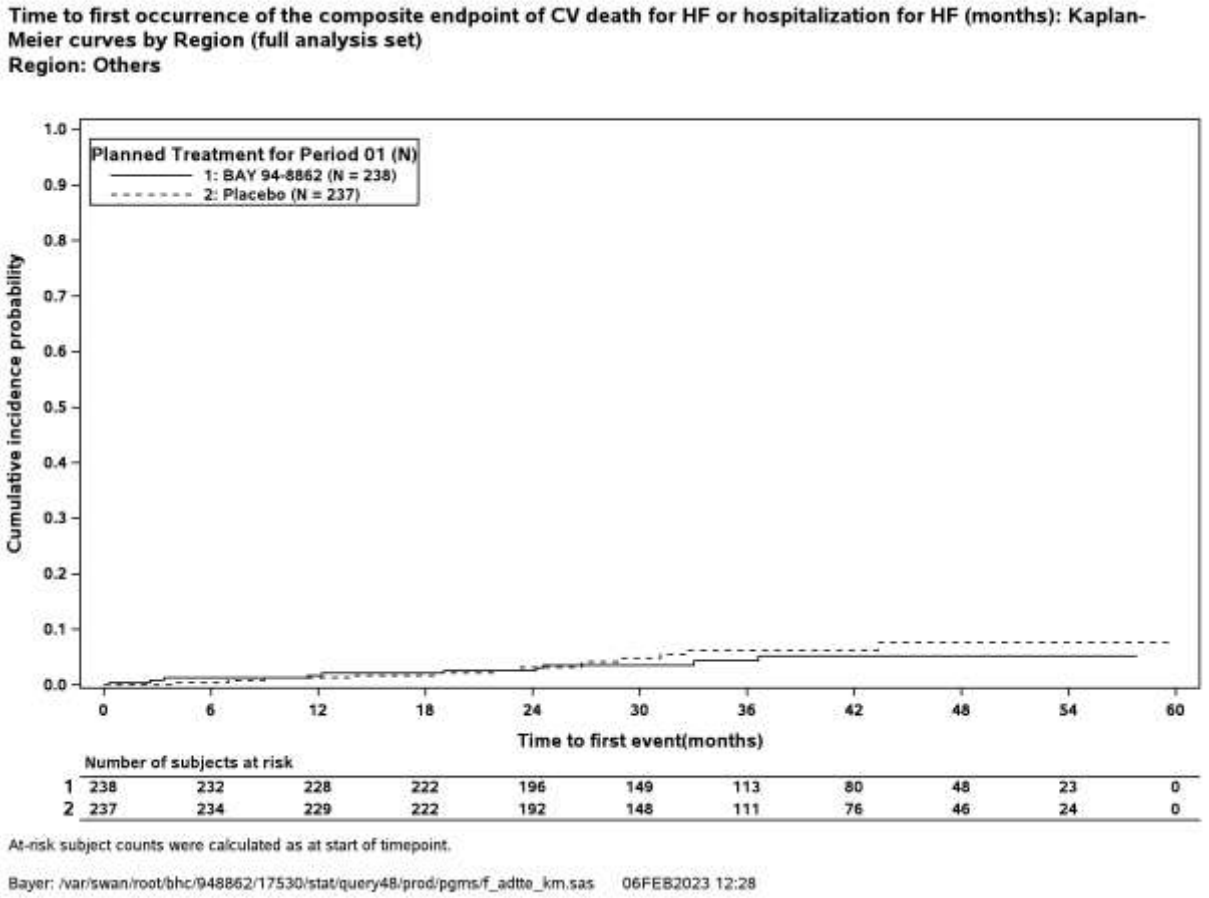


Figure 1.3.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

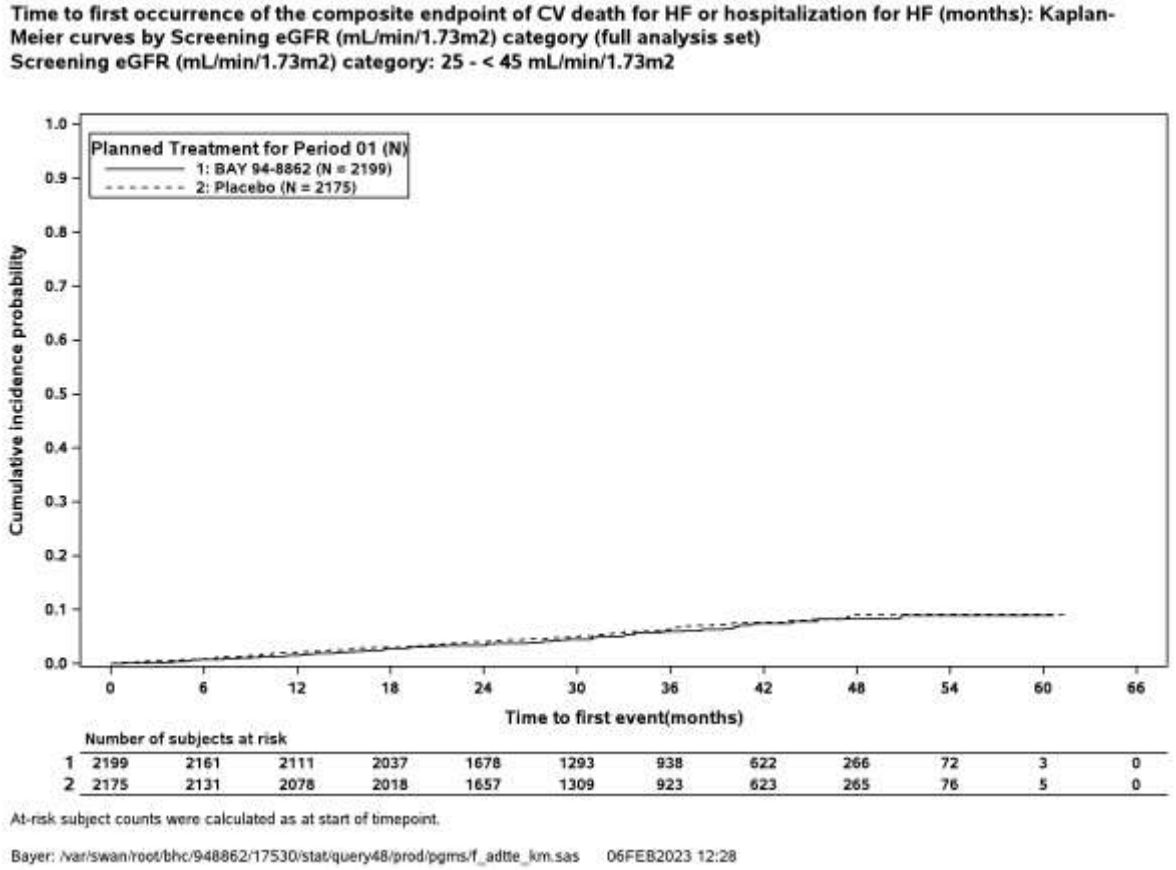


Figure 1.3.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

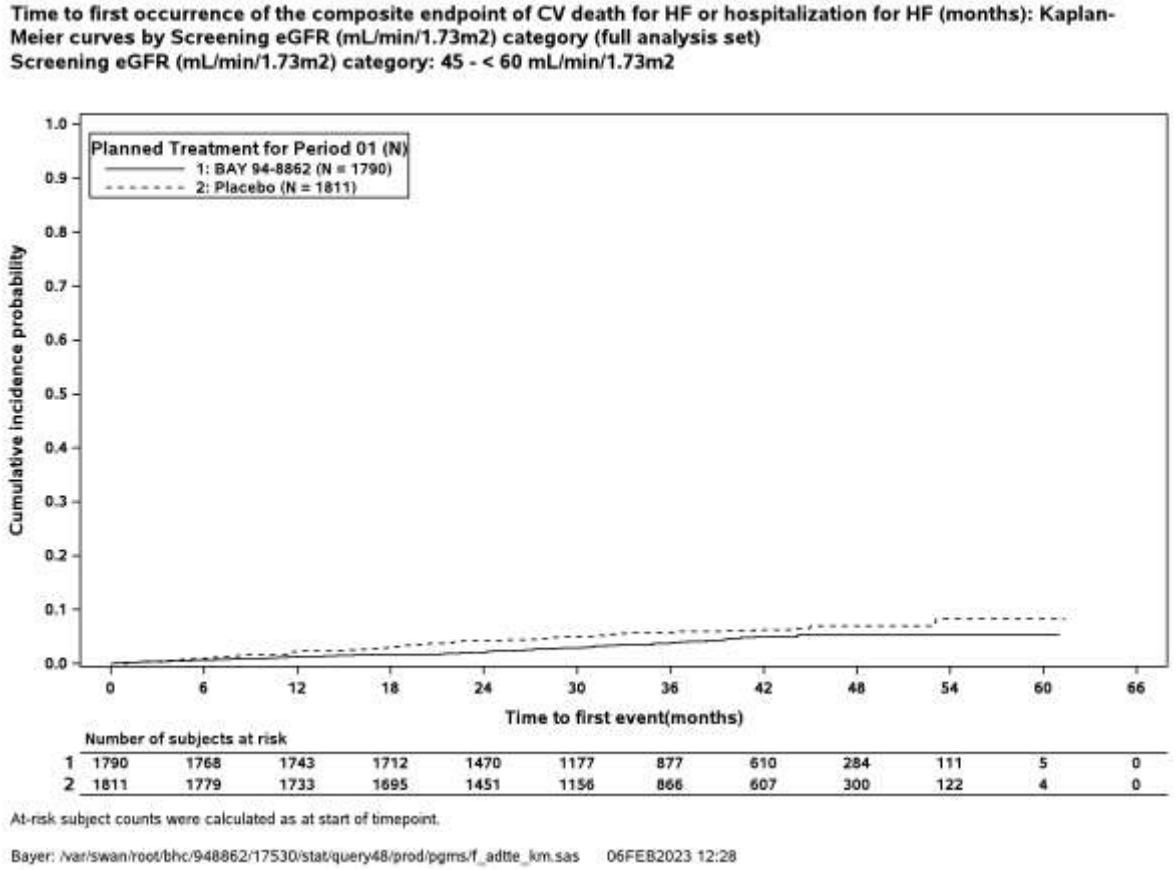


Figure 1.3.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

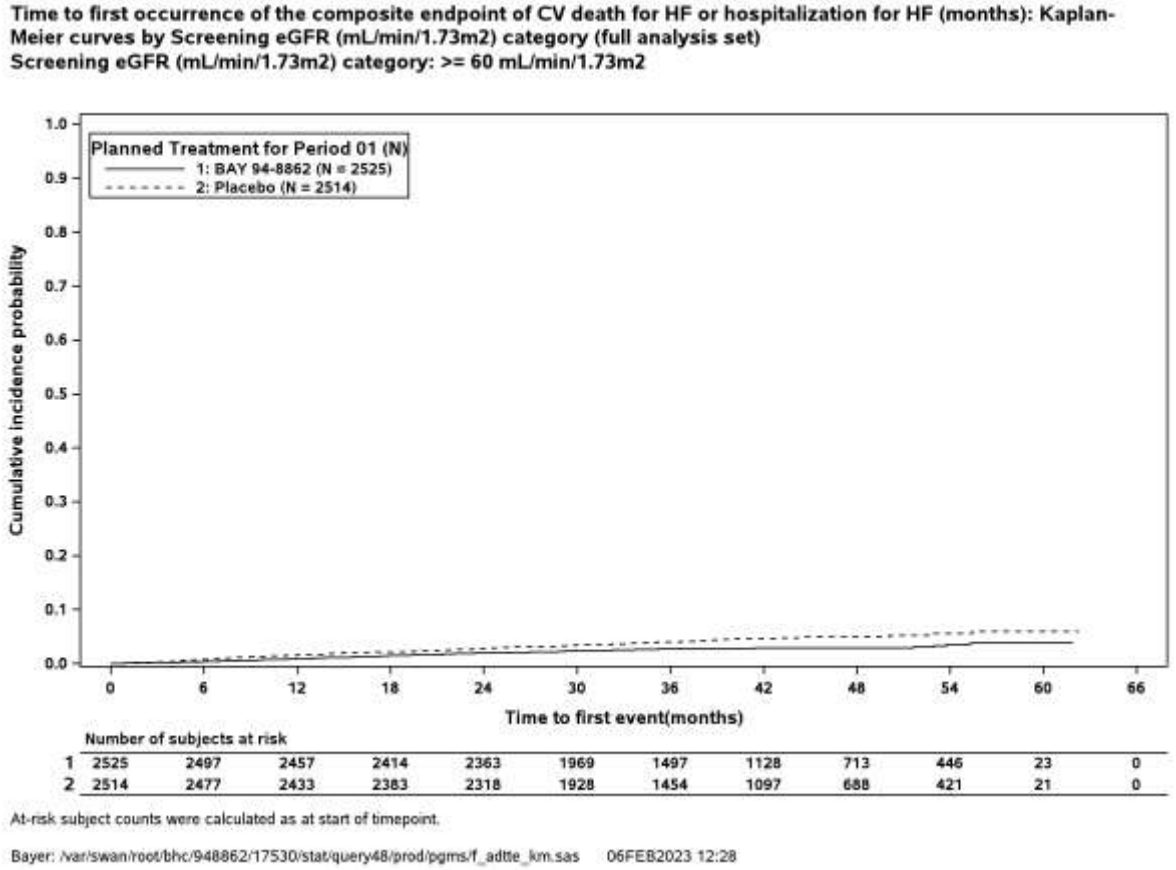


Figure 1.3.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

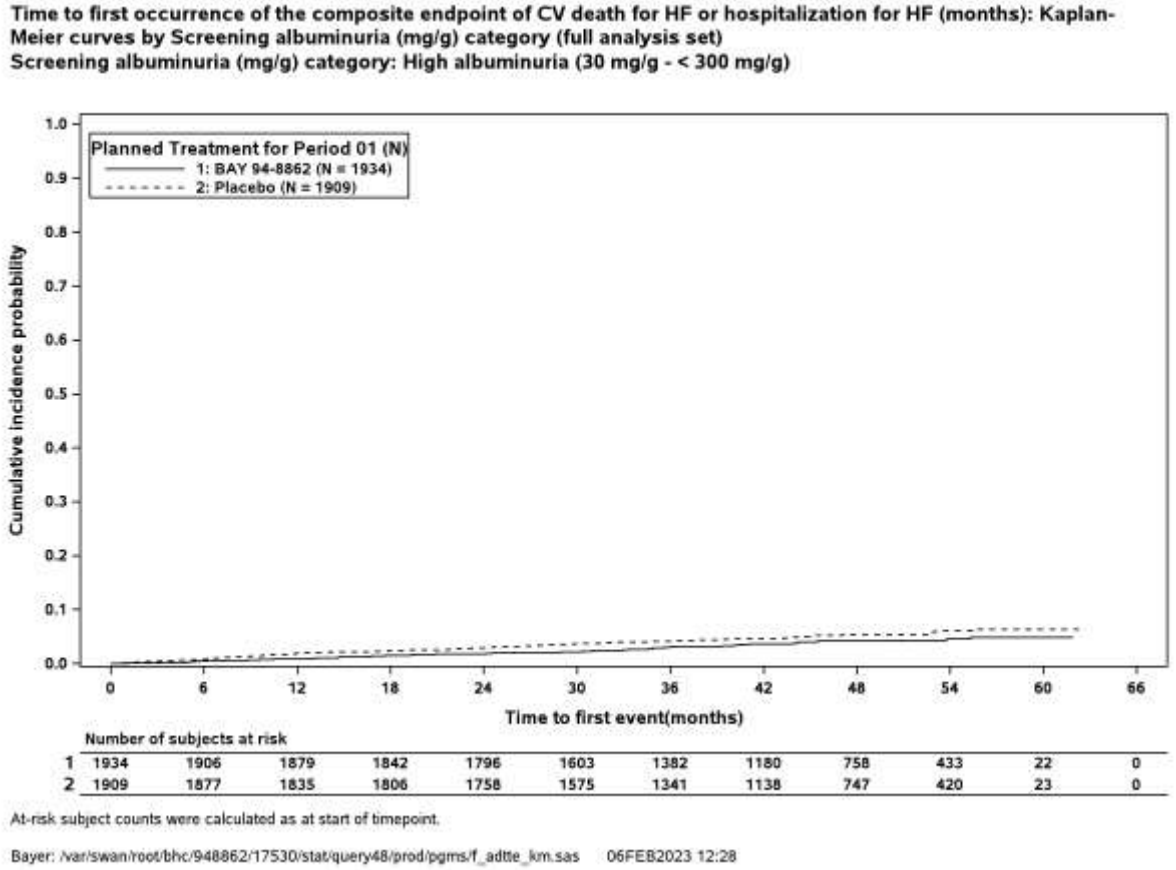
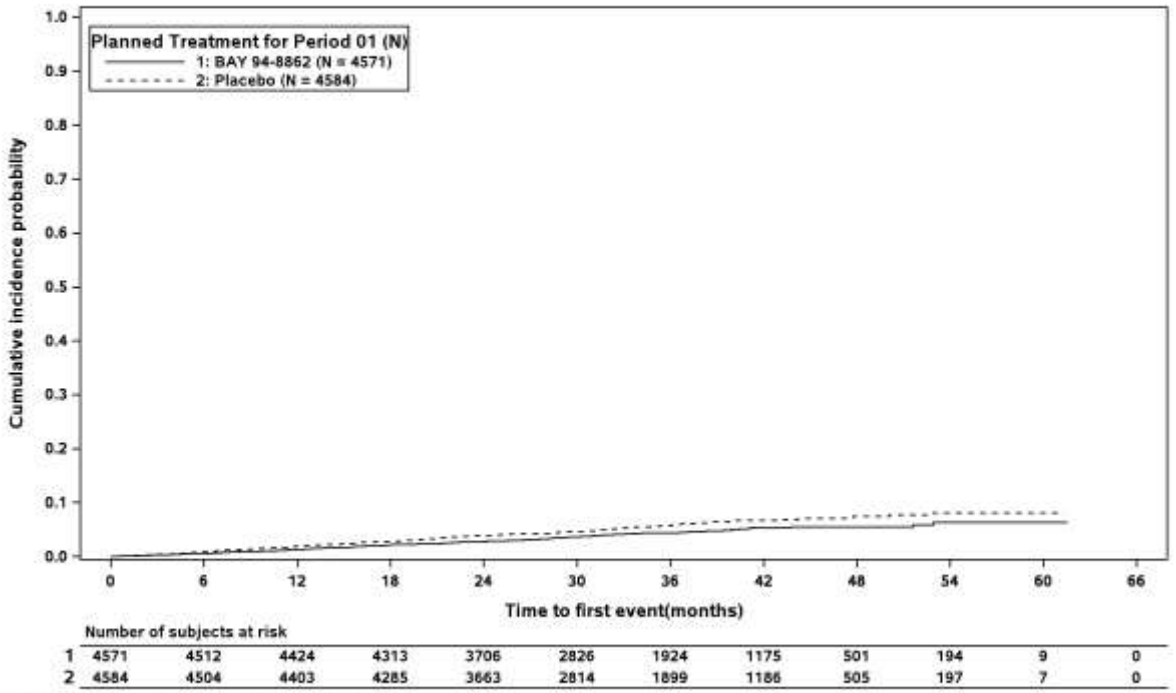


Figure 1.3.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4512	4424	4313	3706	2826	1924	1175	501	194	9	0
2	4584	4504	4403	4285	3663	2814	1899	1186	505	197	7	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 74: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

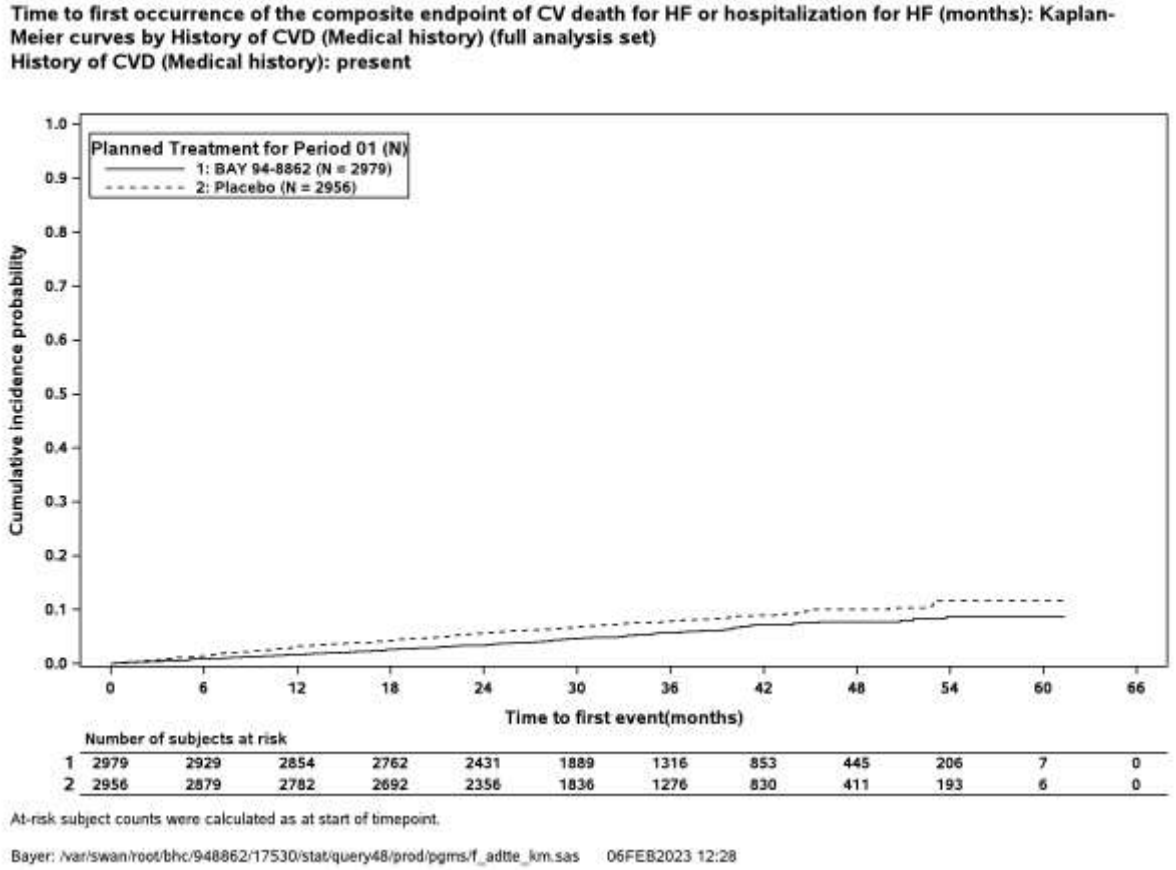


Figure 1.3.1 / 74: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

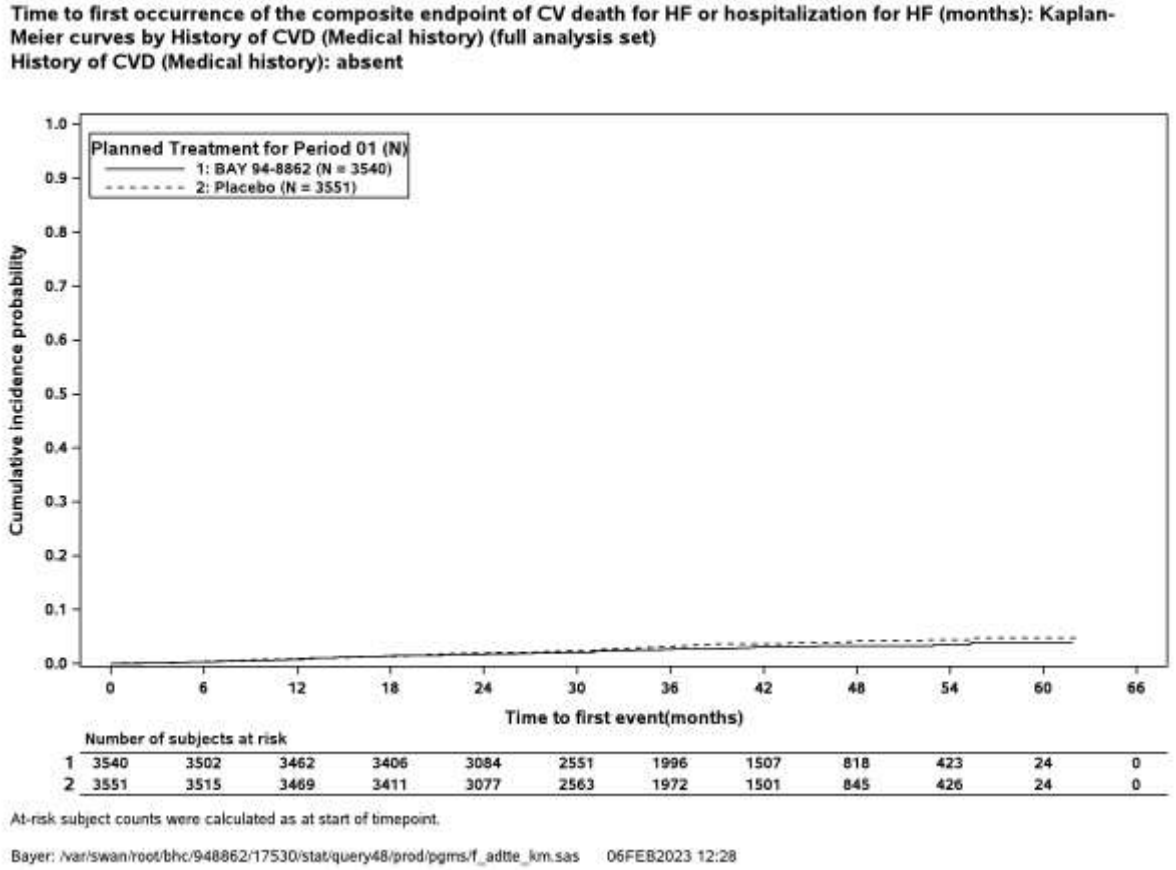


Figure 1.3.1 / 75: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

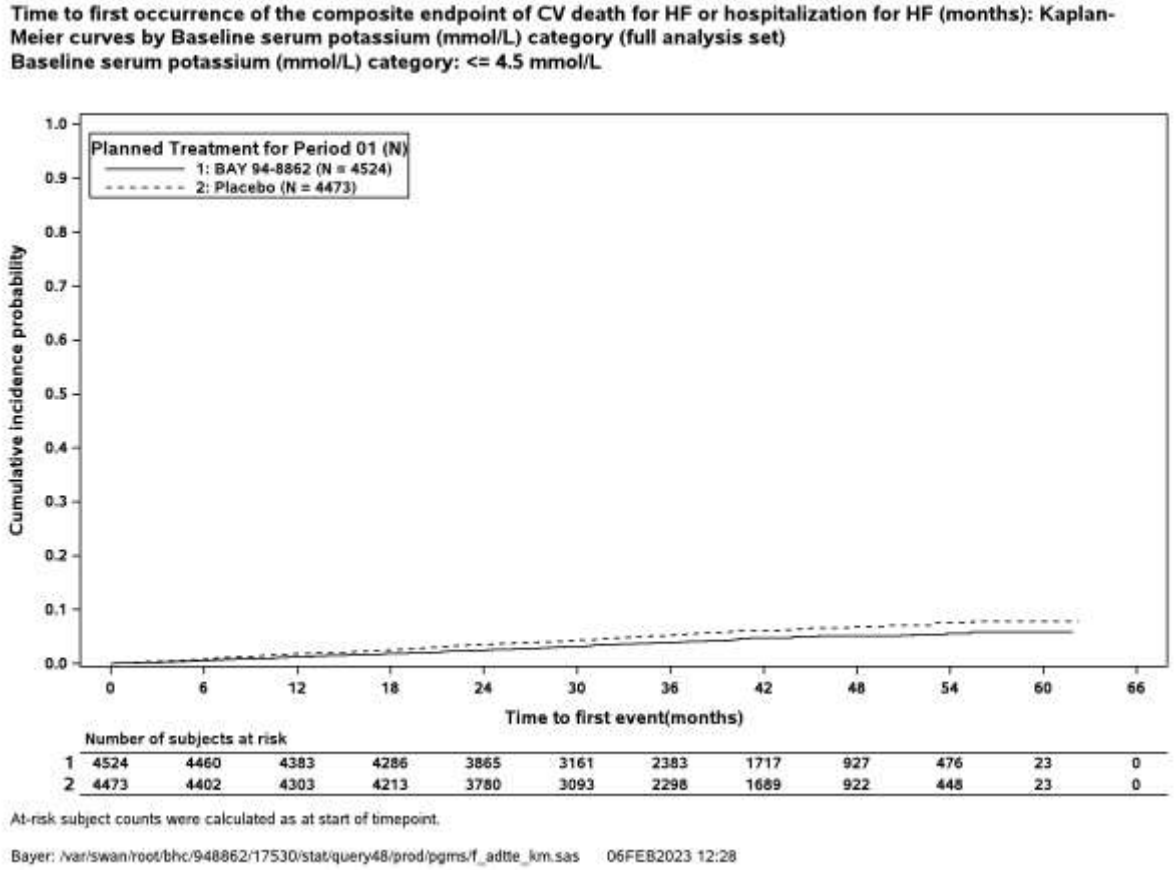
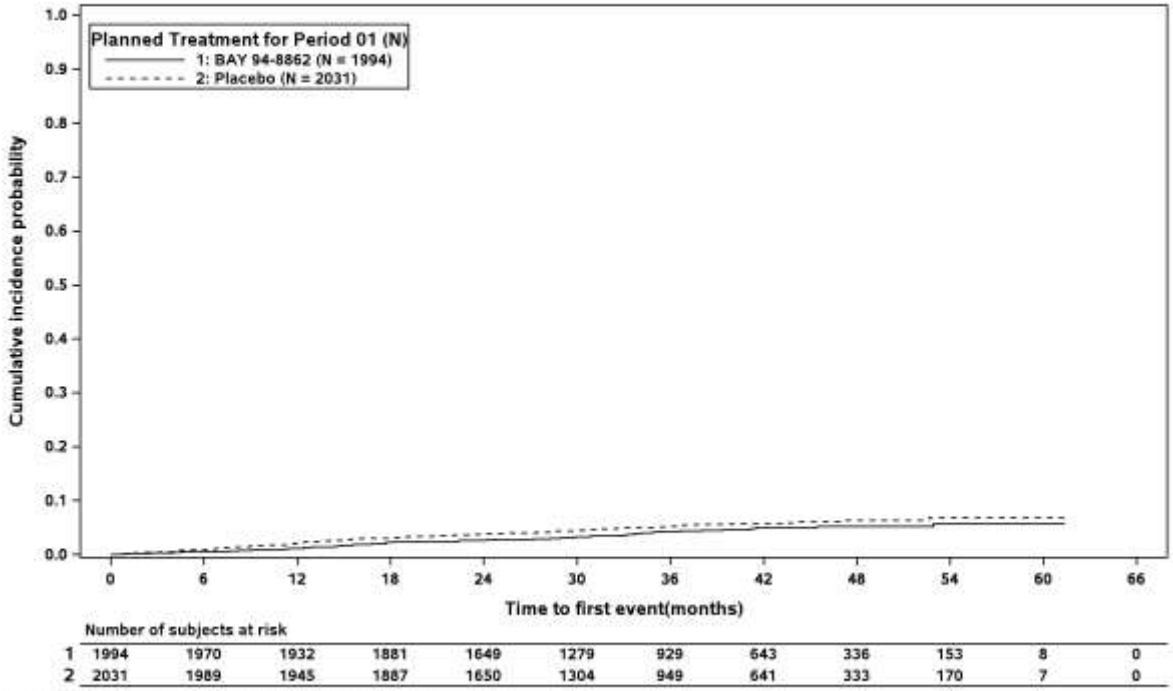


Figure 1.3.1 / 75: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1994	1970	1932	1881	1649	1279	929	643	336	153	8	0
2	2031	1989	1945	1887	1650	1304	949	641	333	170	7	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 76: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

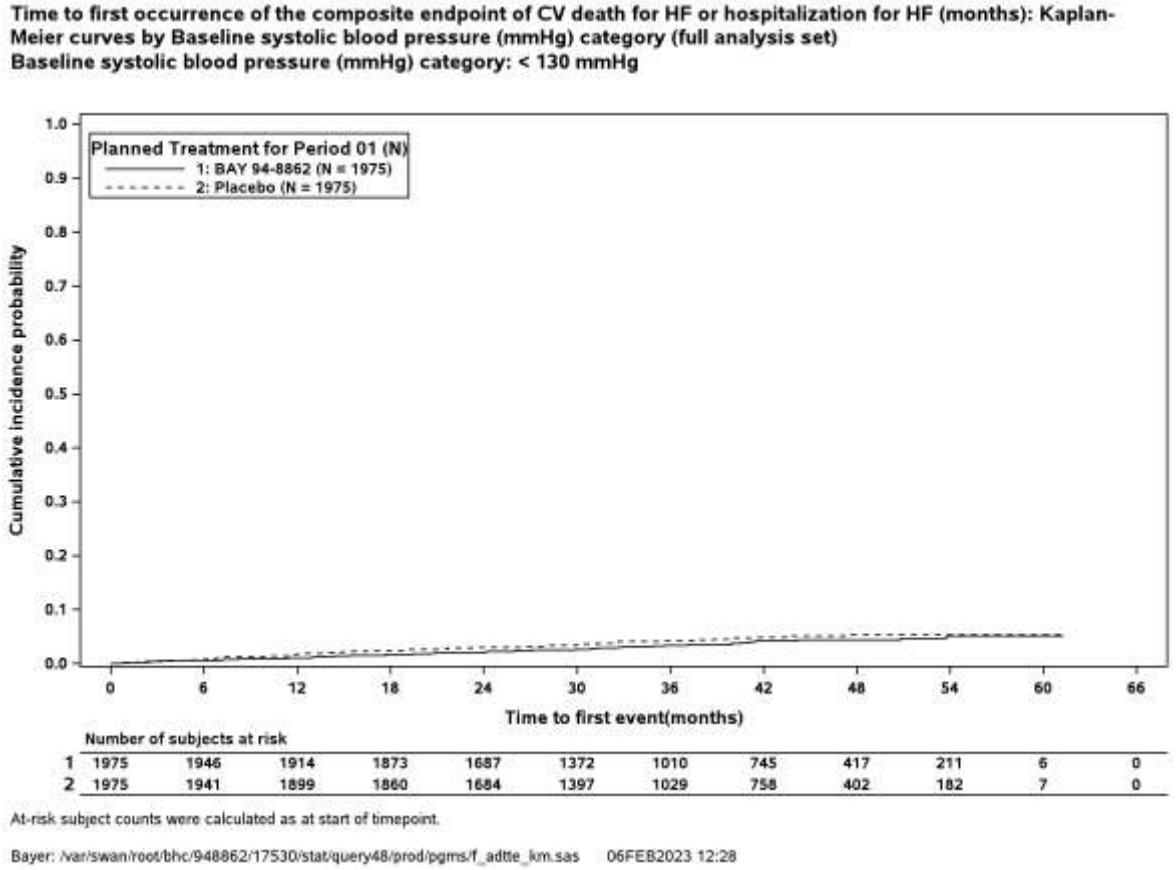


Figure 1.3.1 / 76: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

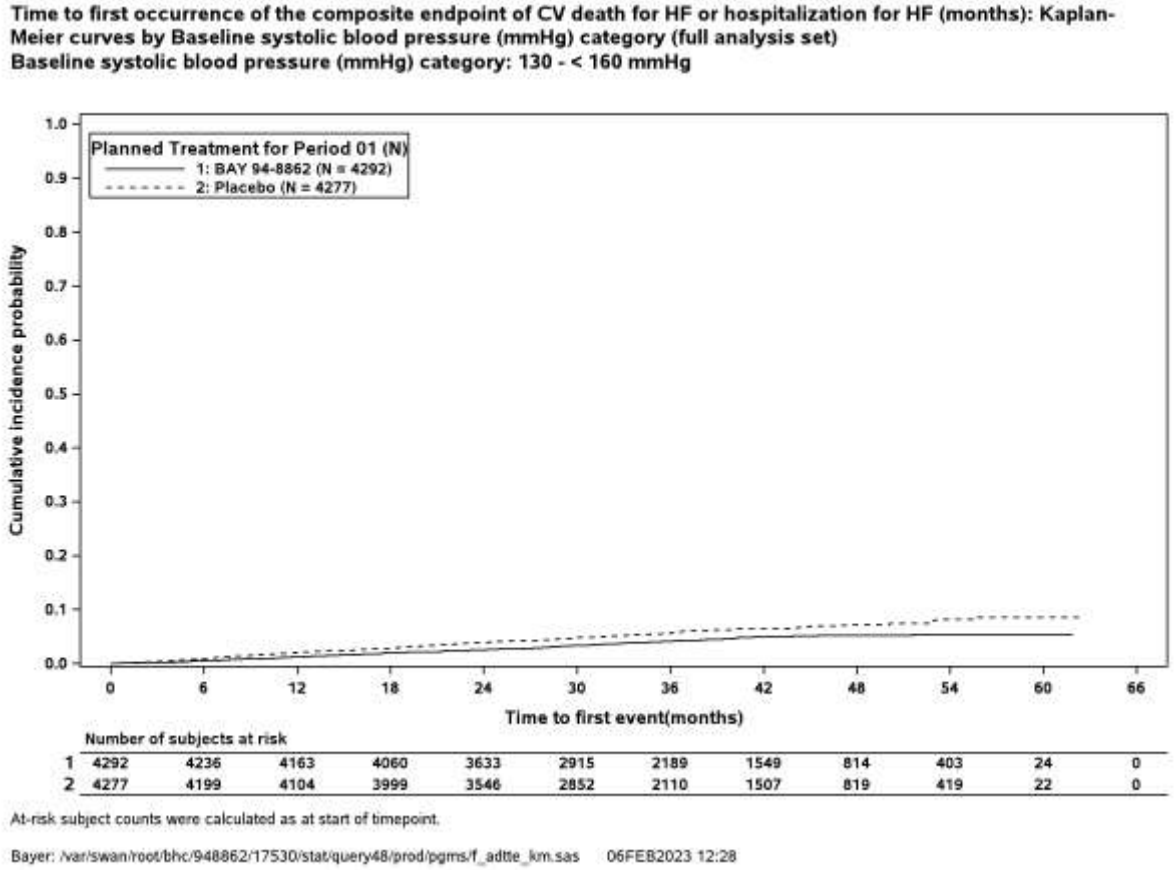
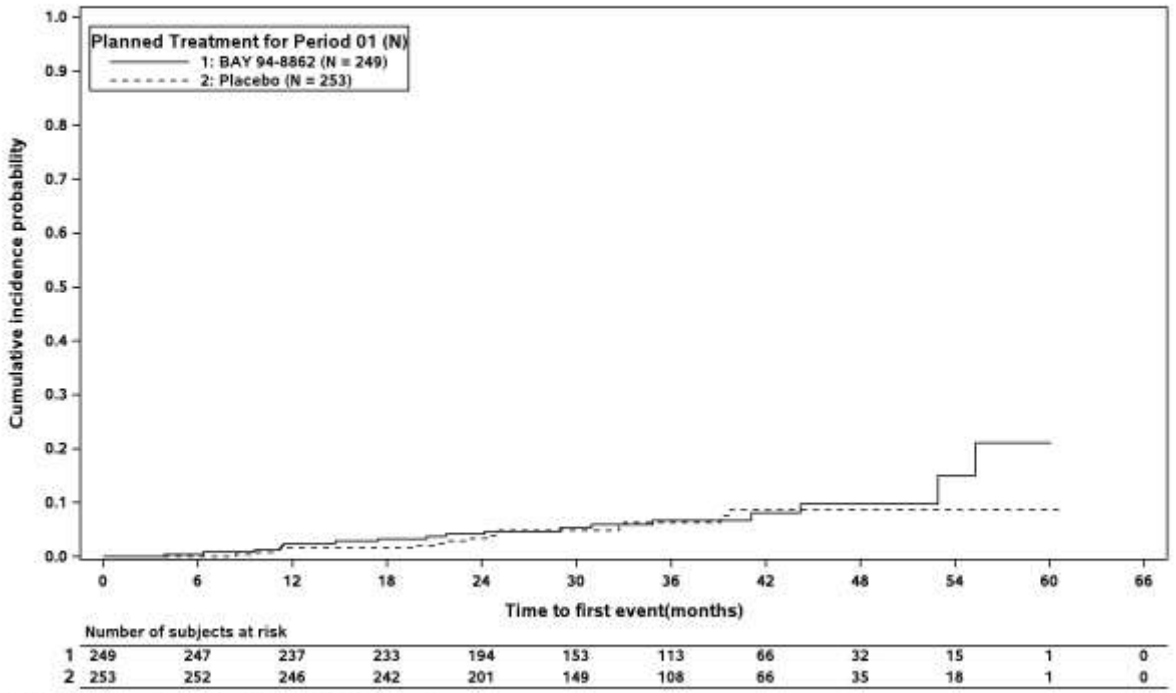


Figure 1.3.1 / 76: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)
Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

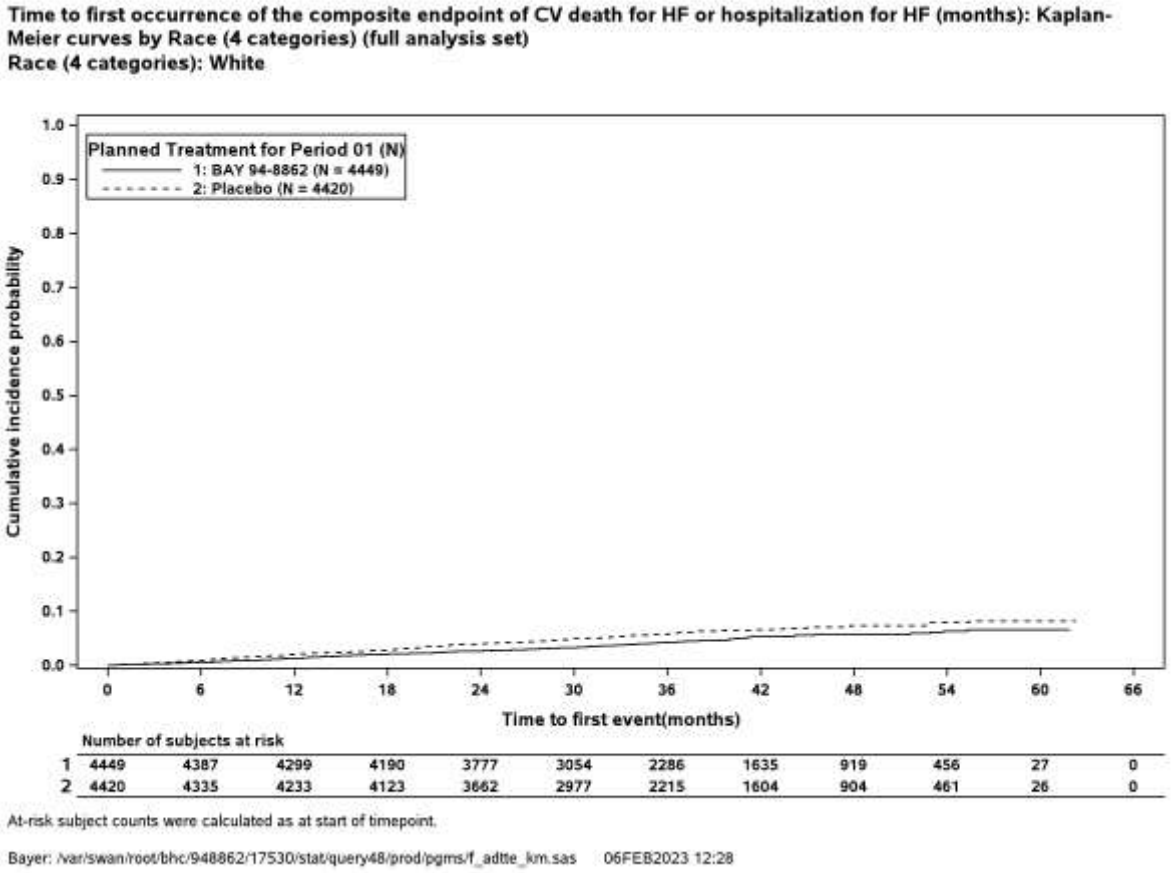


Figure 1.3.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

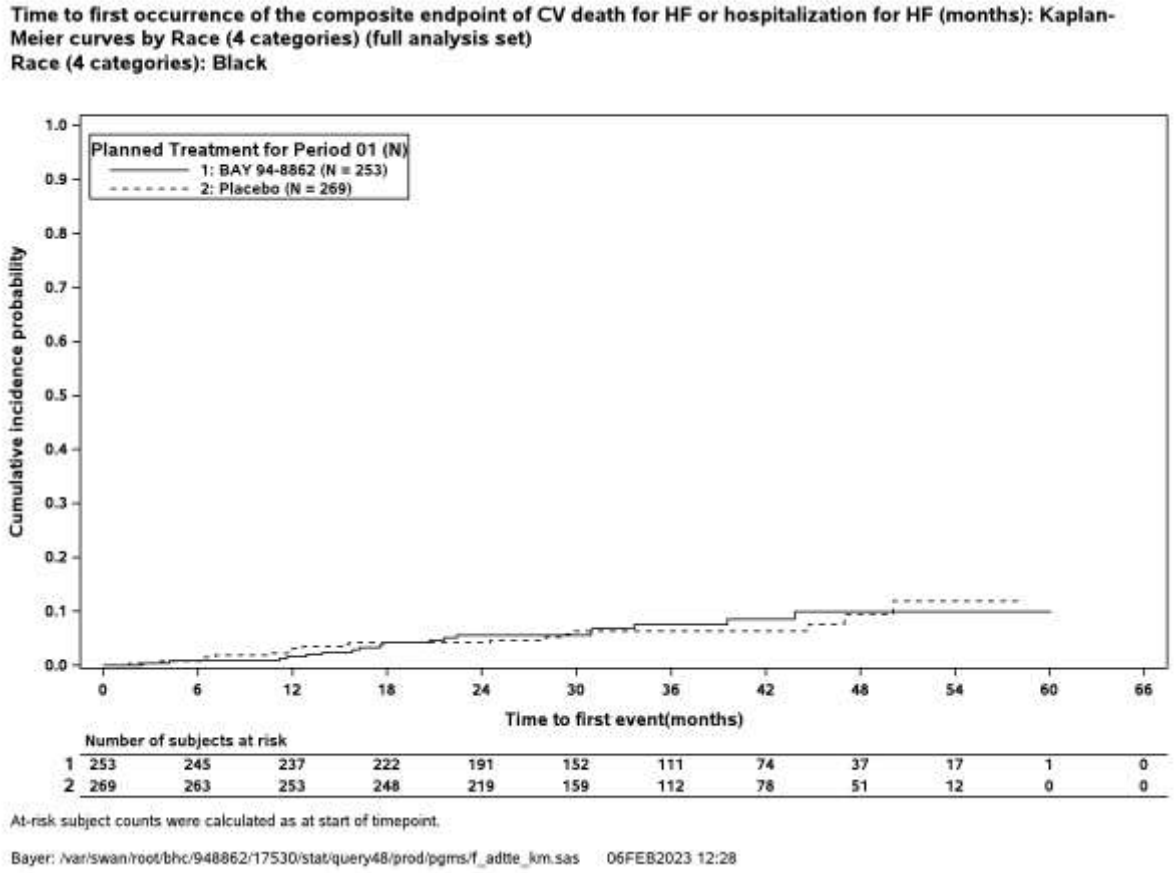
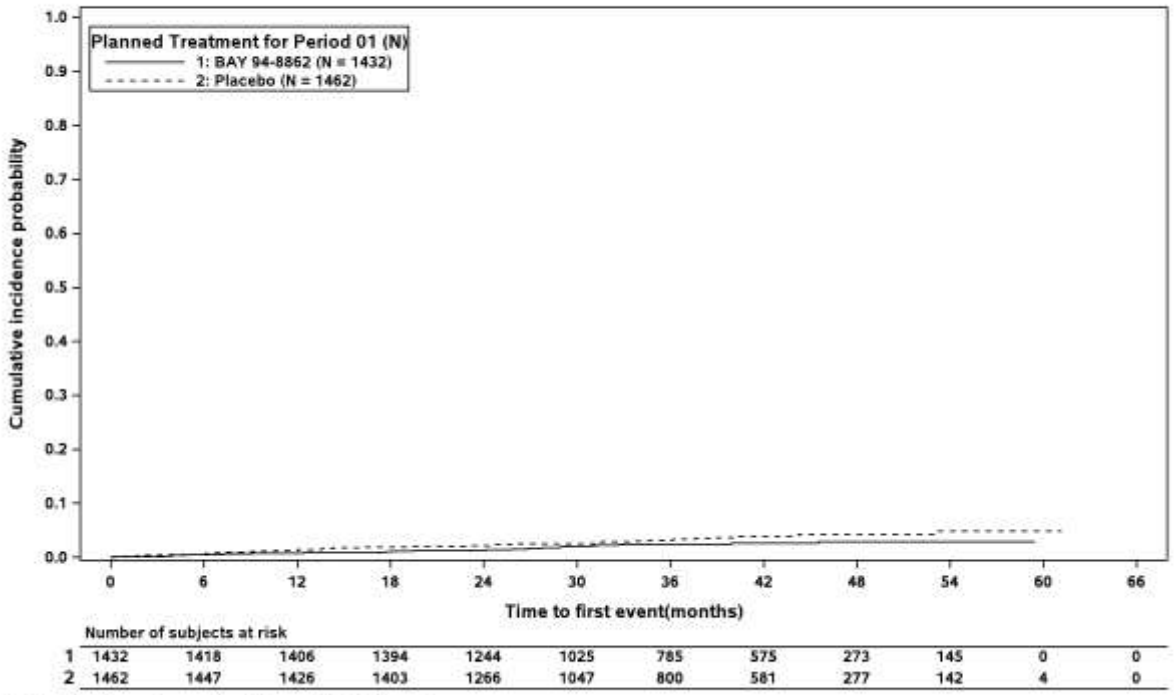


Figure 1.3.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)
Race (4 categories): Asian



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

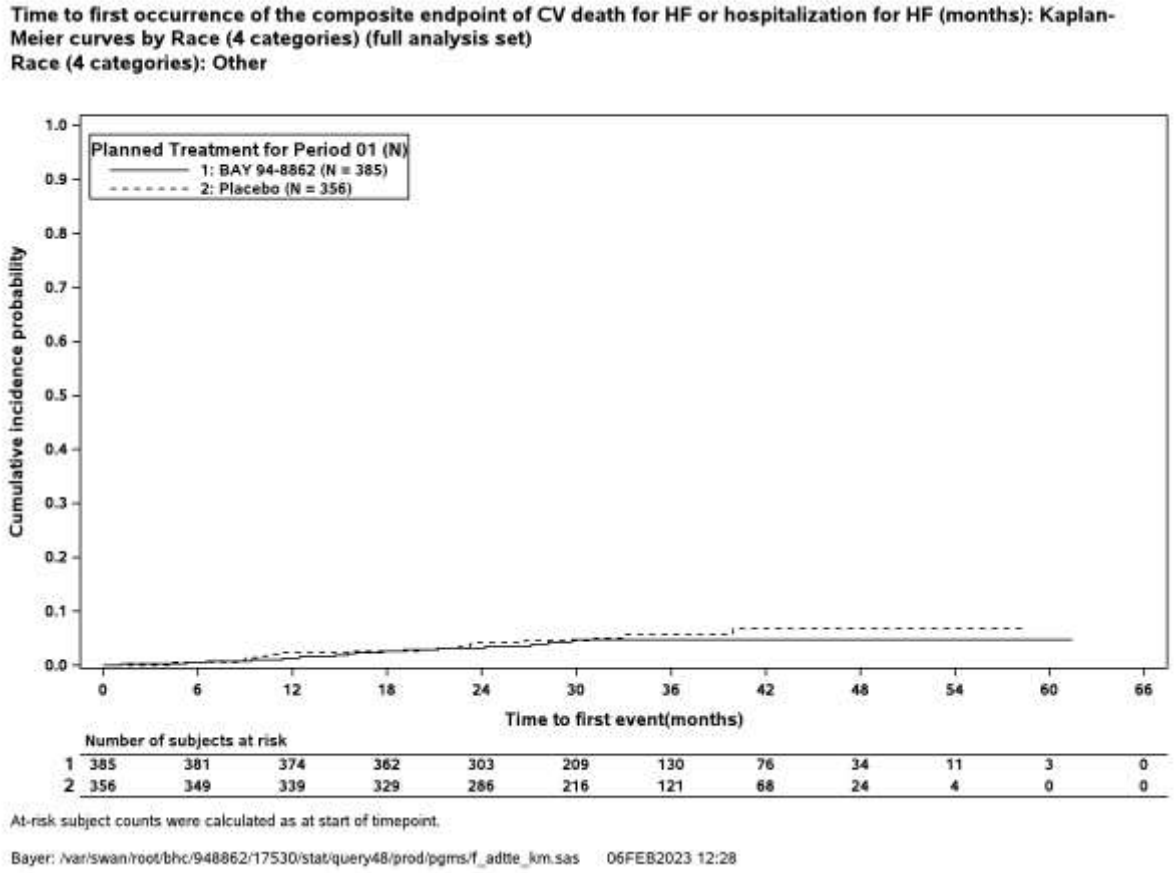


Figure 1.3.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

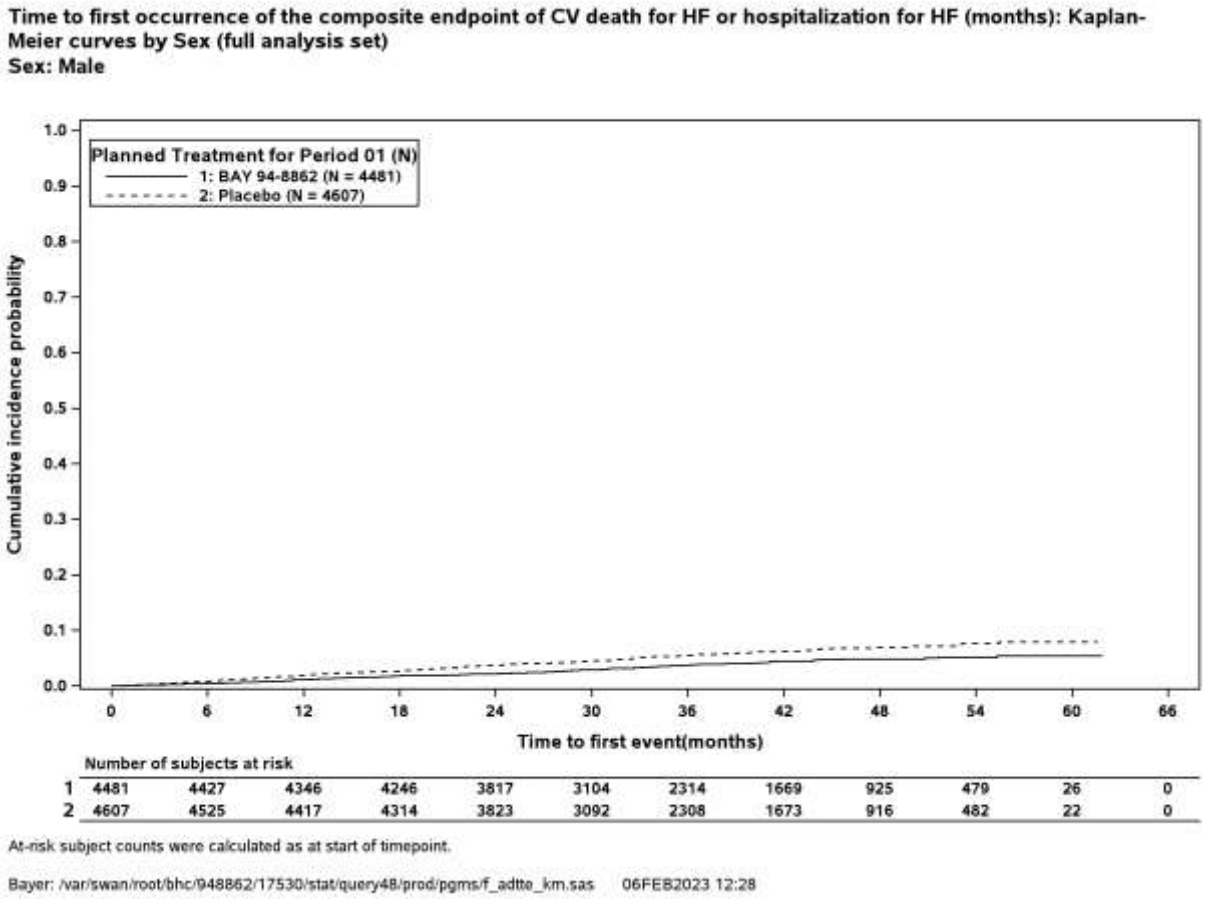


Figure 1.3.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

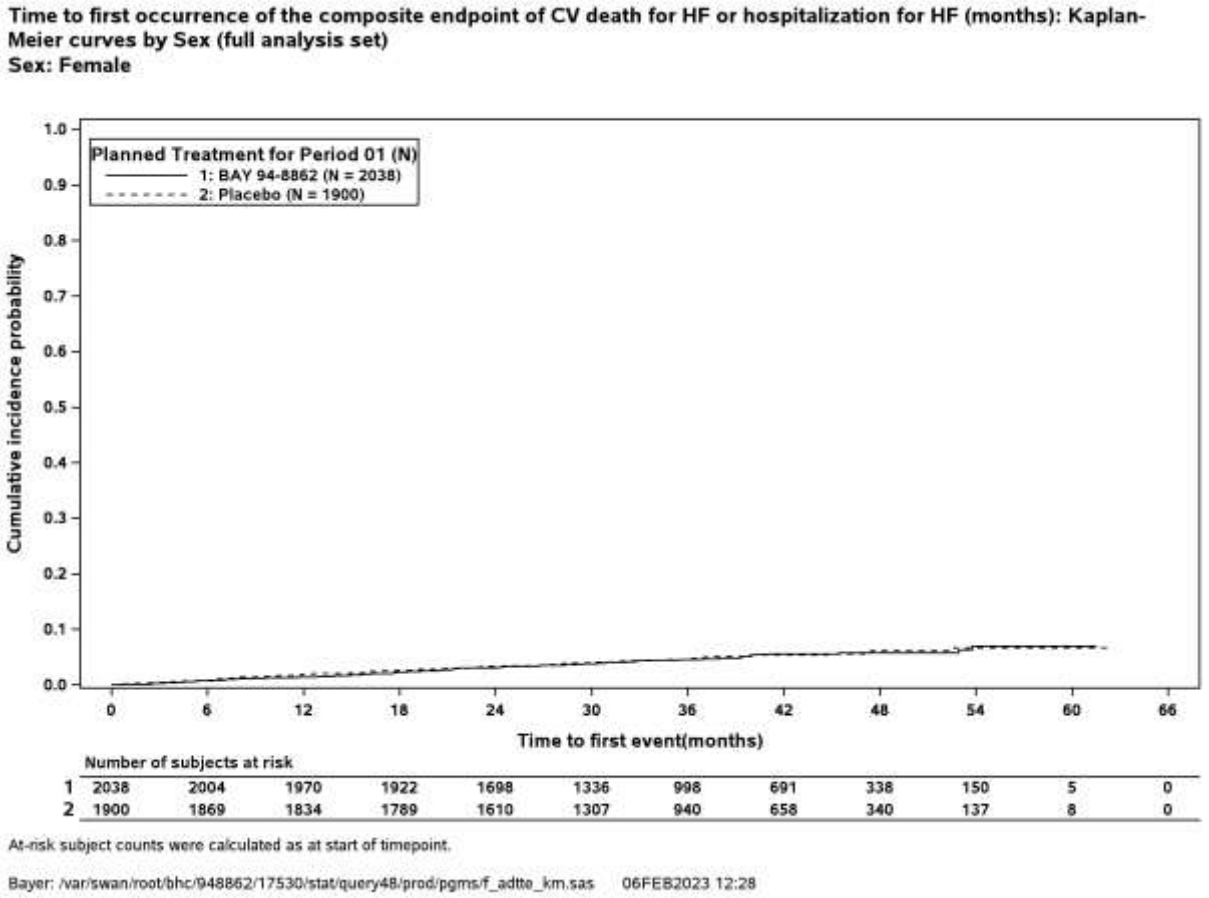


Figure 1.3.1 / 79: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

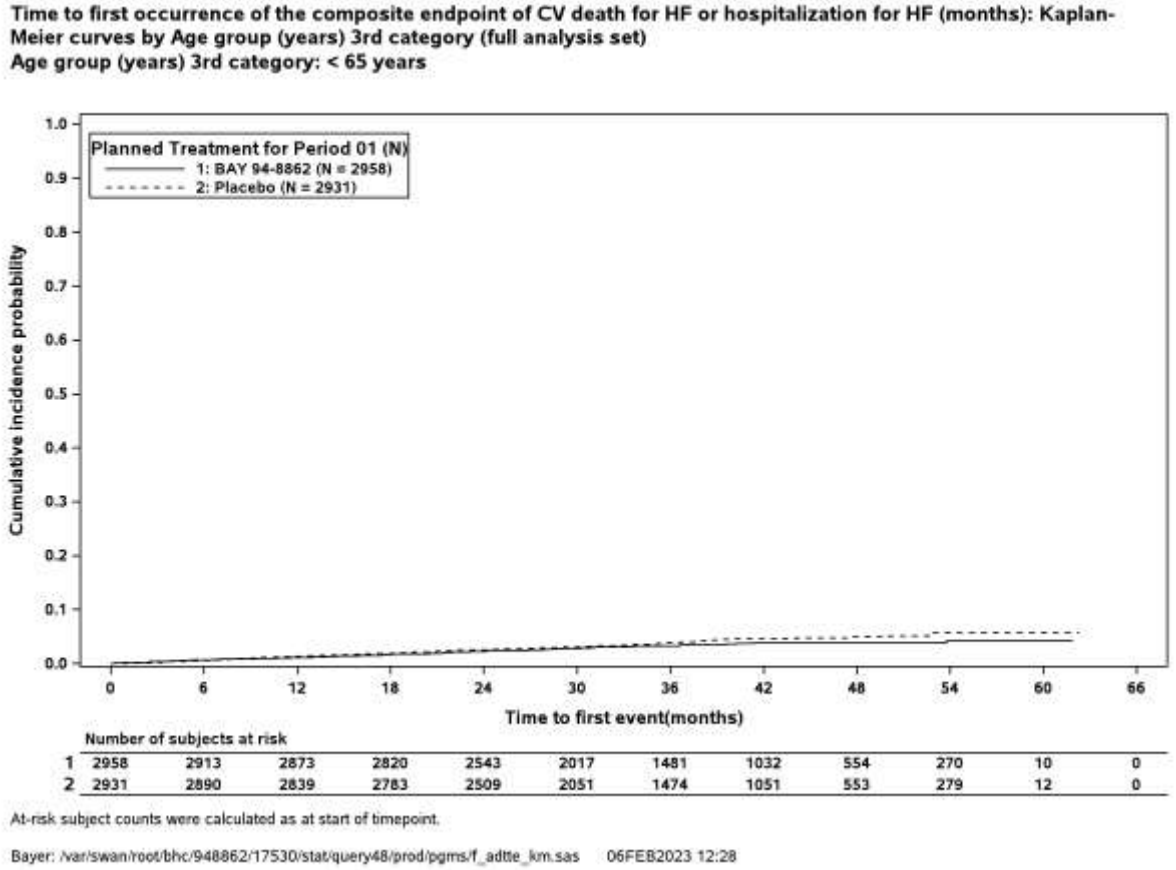


Figure 1.3.1 / 79: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years

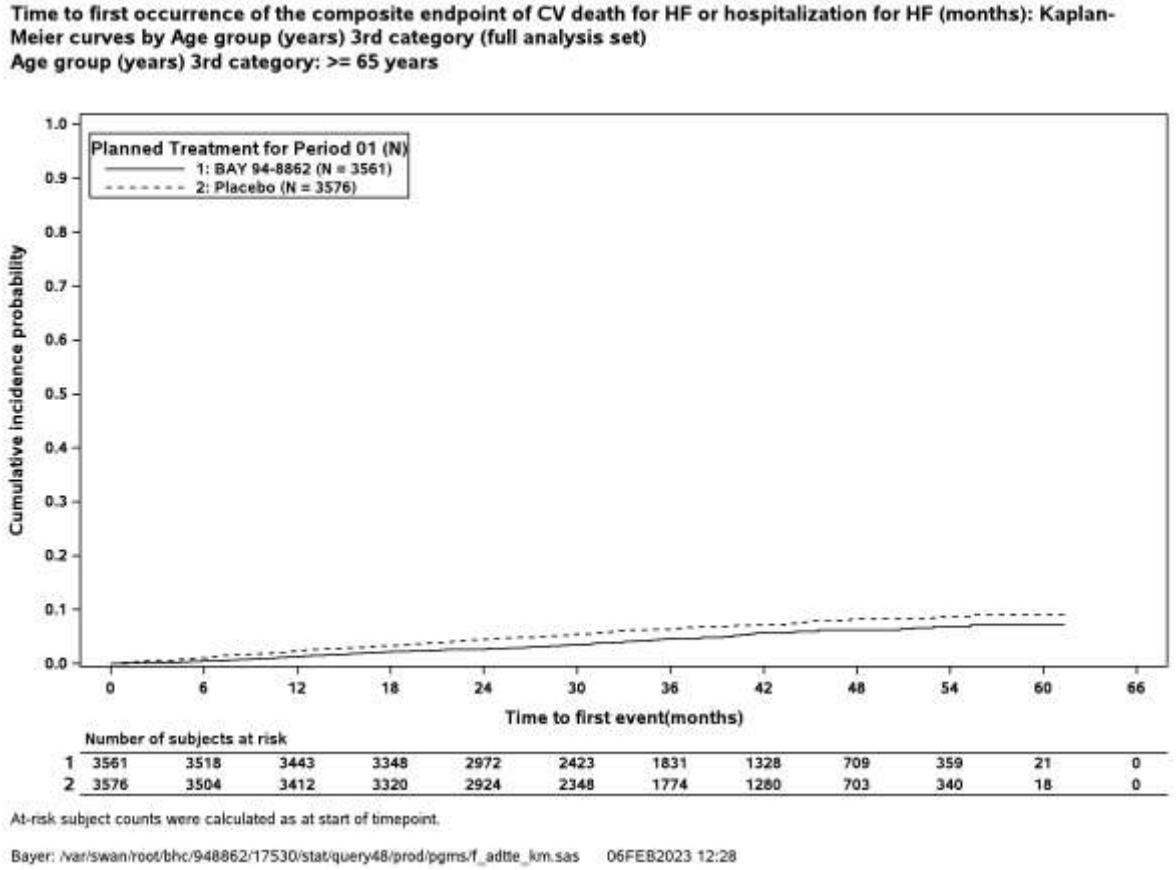


Figure 1.3.1 / 80: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set)

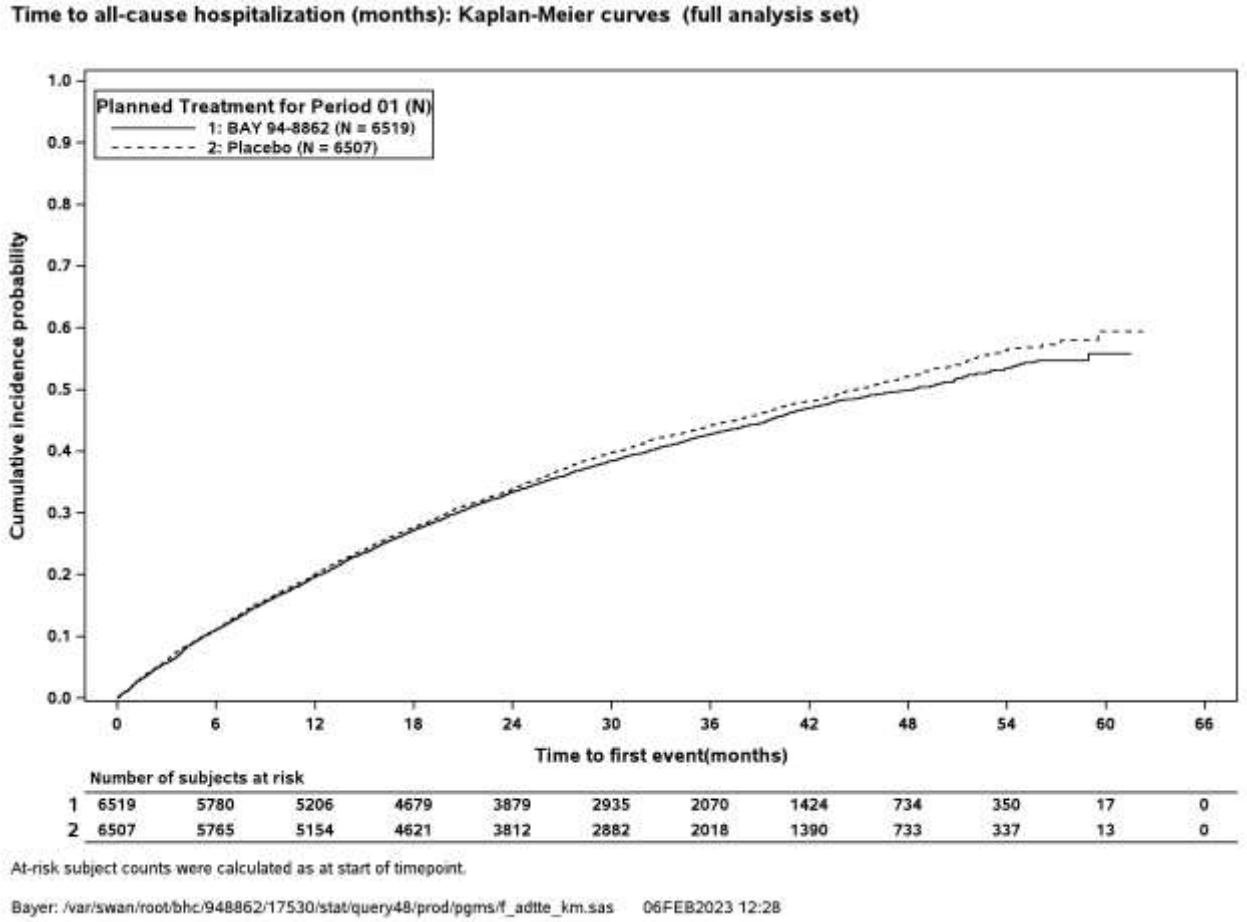


Figure 1.3.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set)

Region: Europe

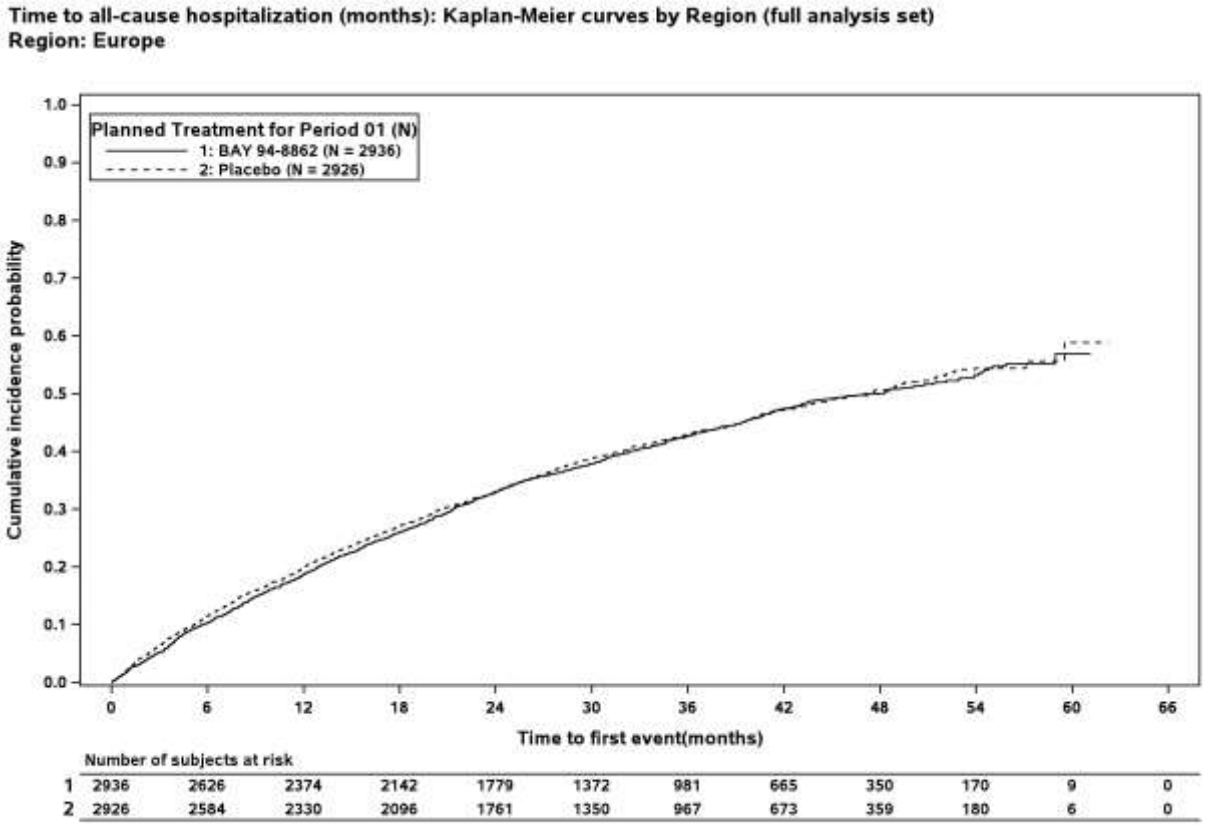


Figure 1.3.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: North America

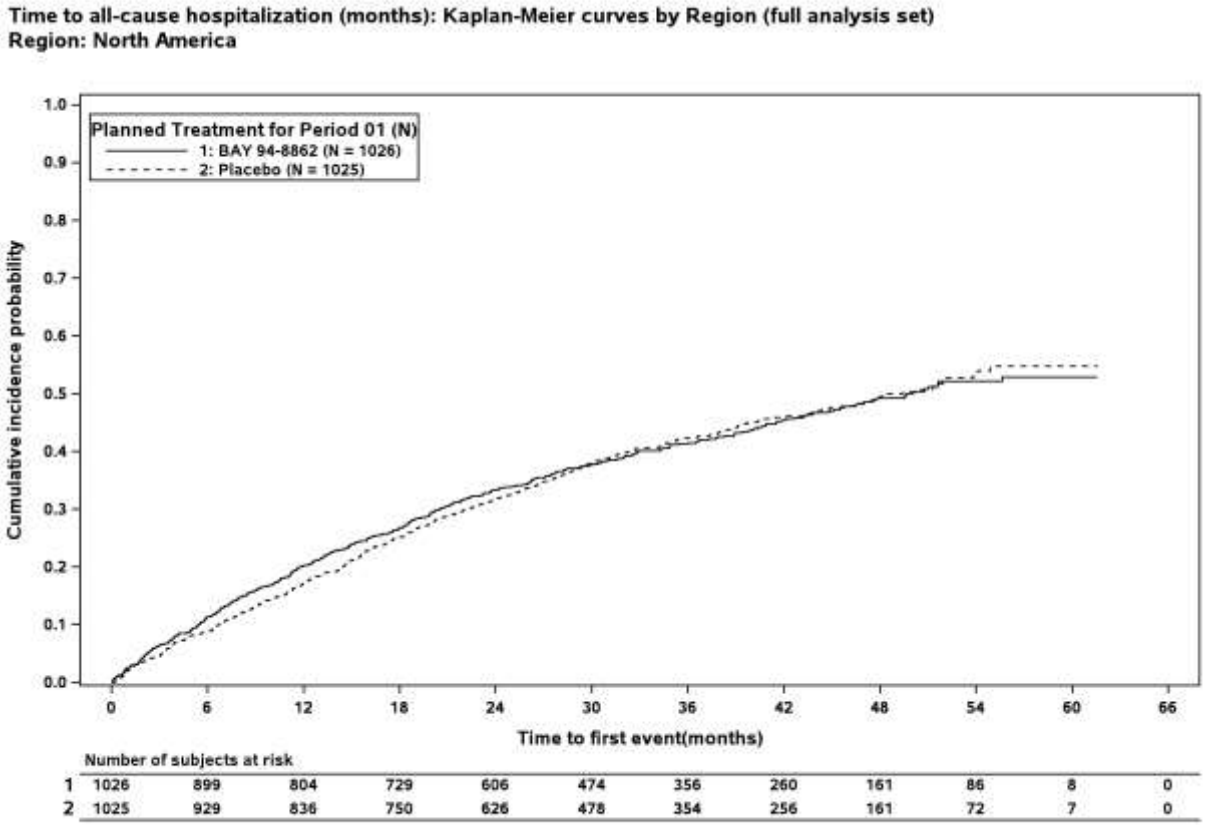


Figure 1.3.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Asia

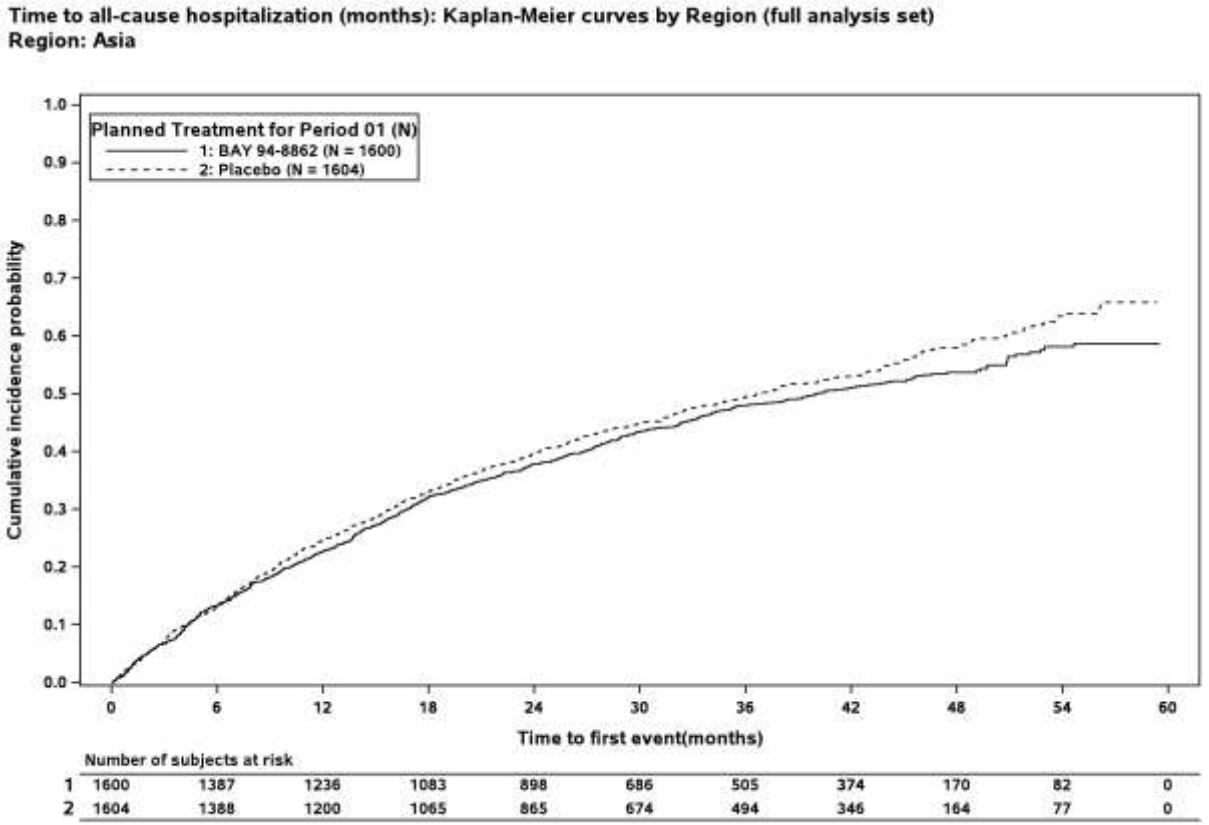


Figure 1.3.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Latin America

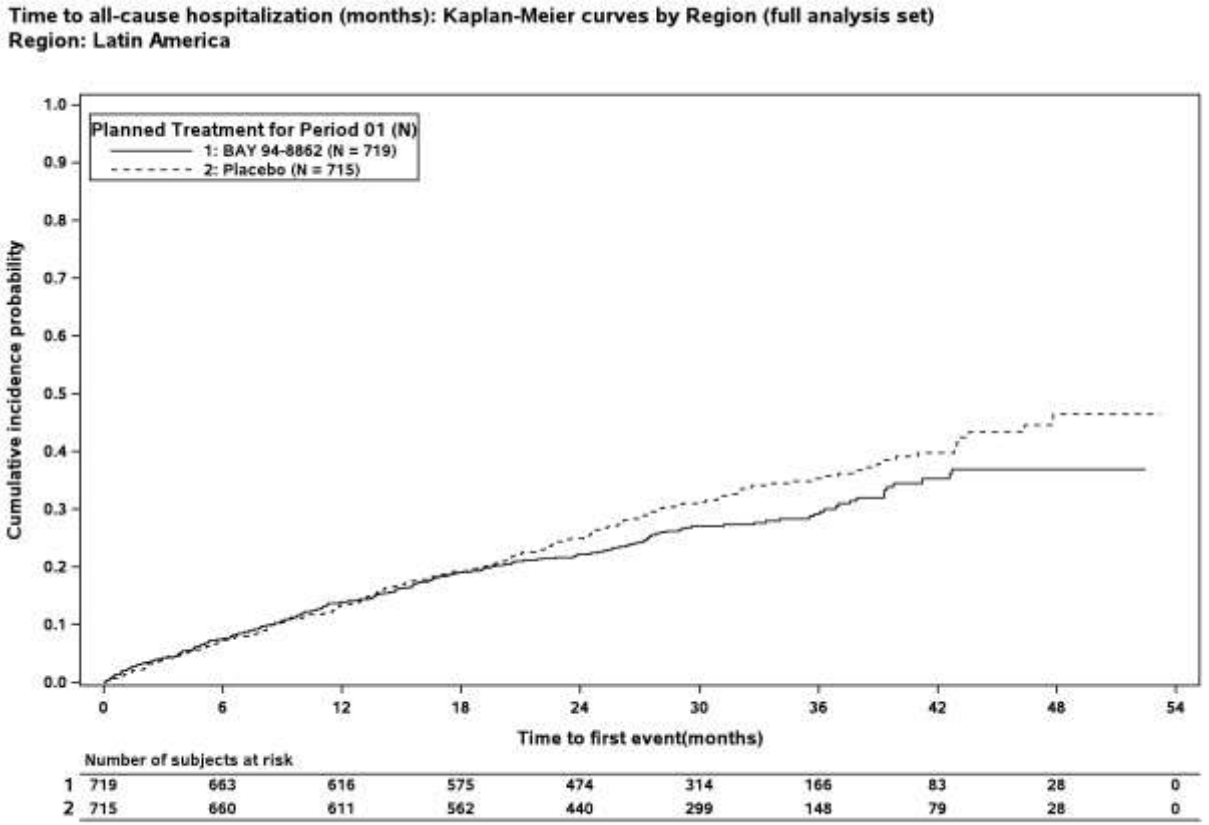


Figure 1.3.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set) (cont.)

Region: Others

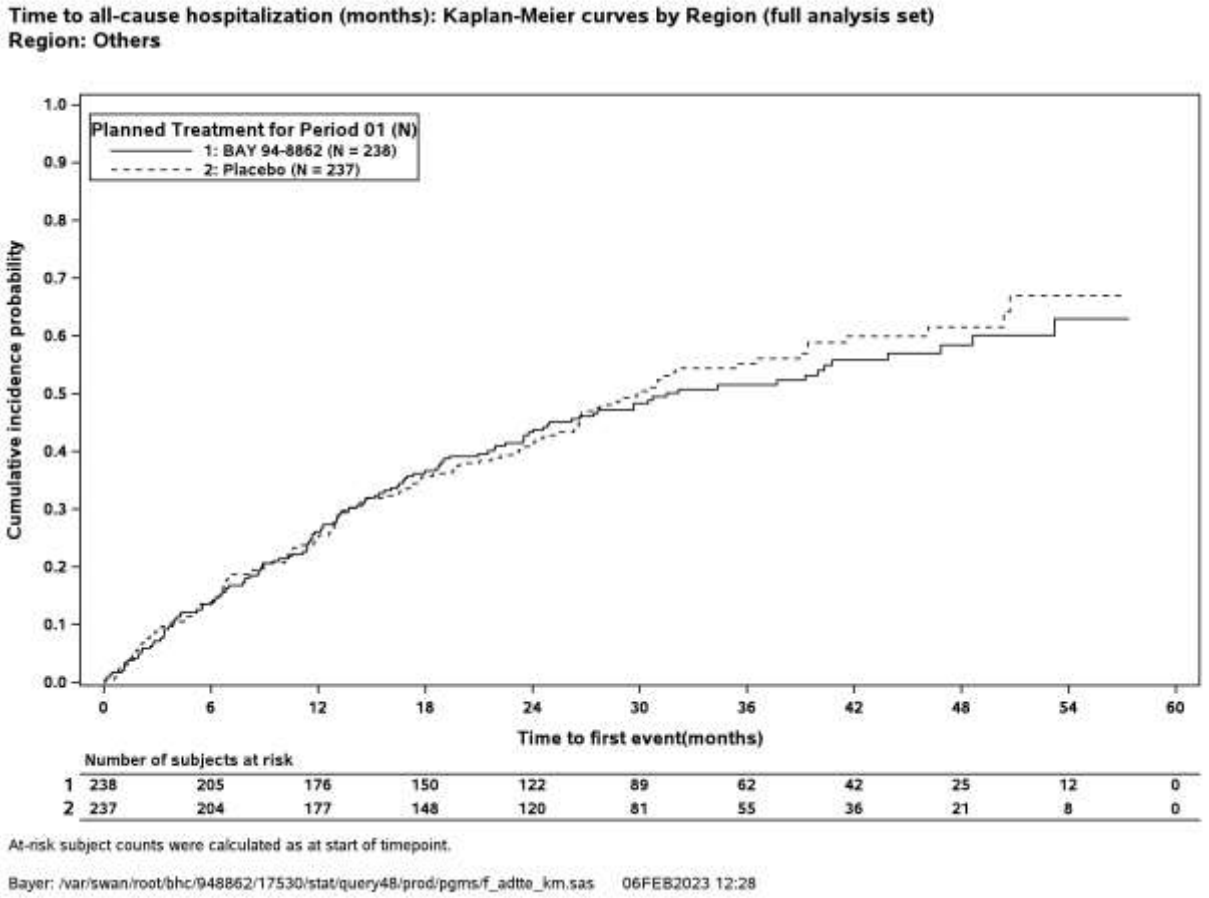


Figure 1.3.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

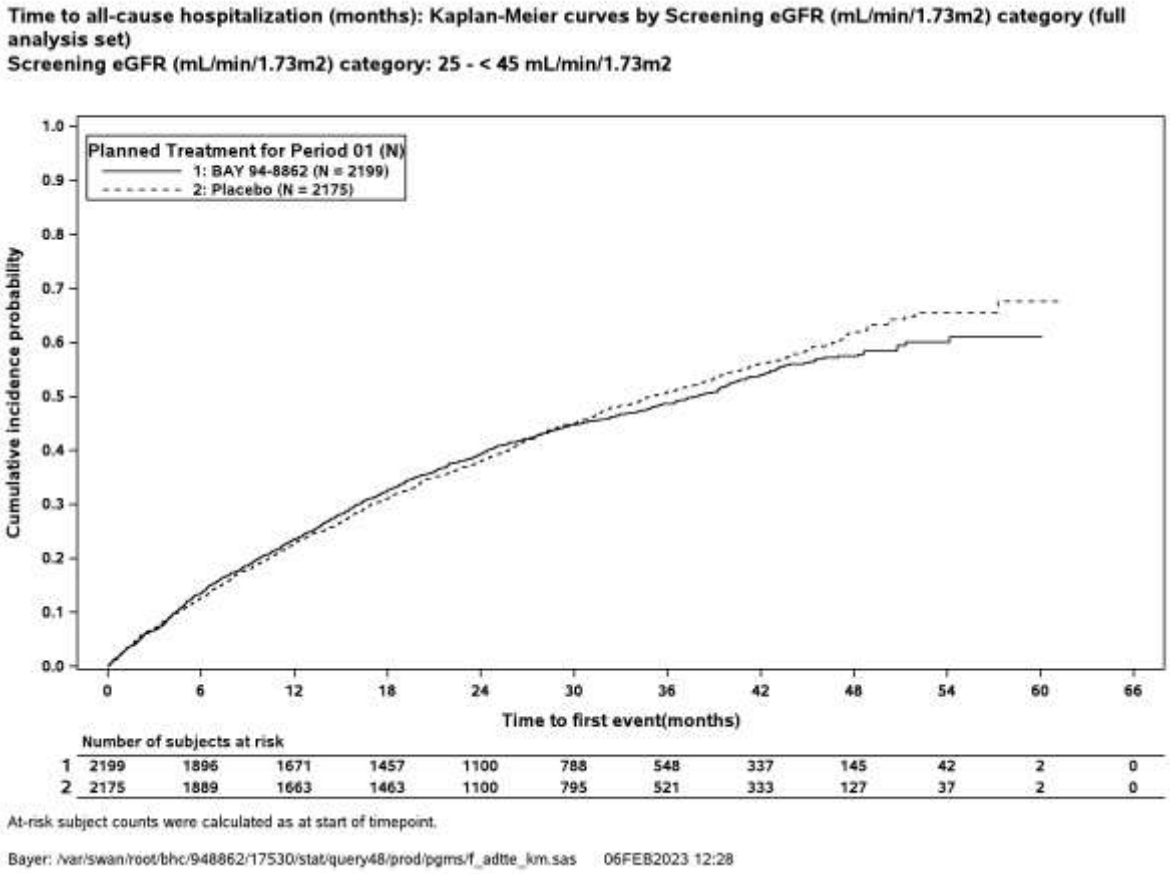


Figure 1.3.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

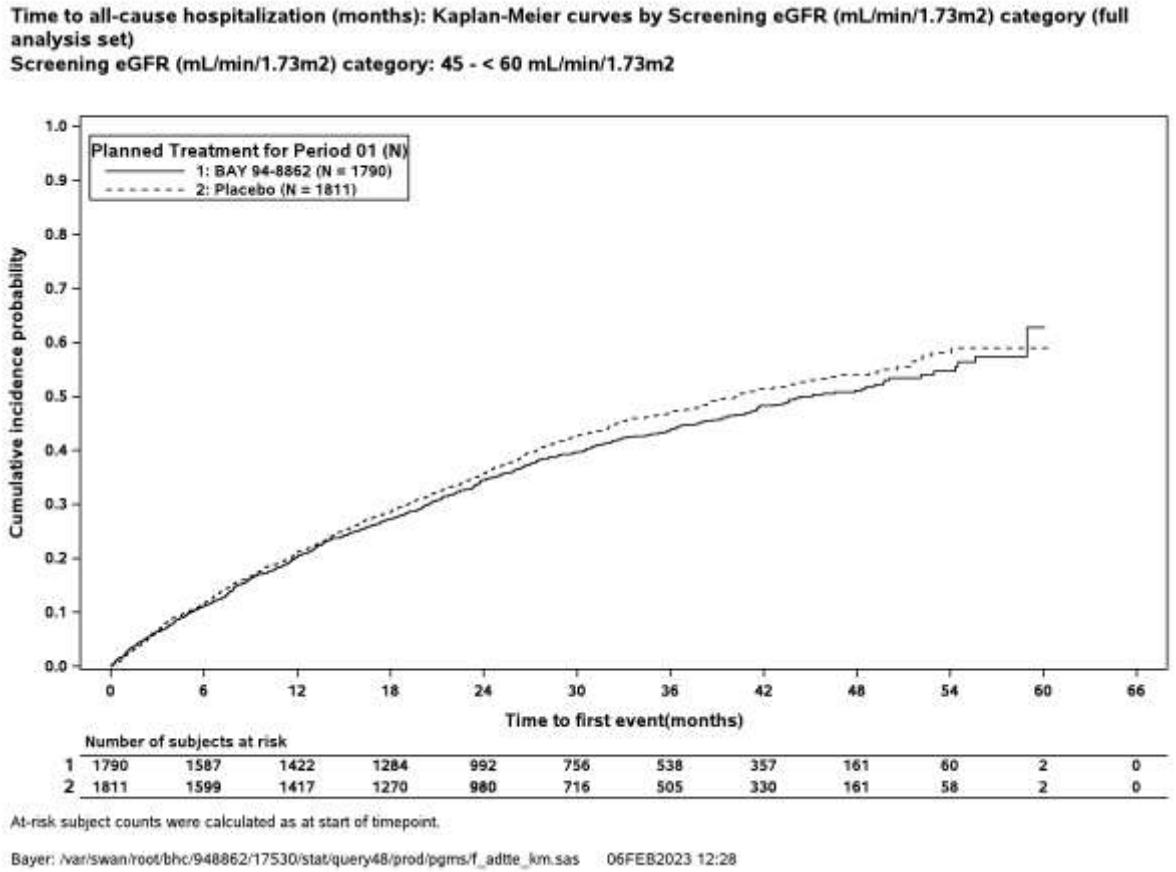


Figure 1.3.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set) (cont.)

Screening eGFR (mL/min/1.73m2) category: >= 60 mL/min/1.73m2

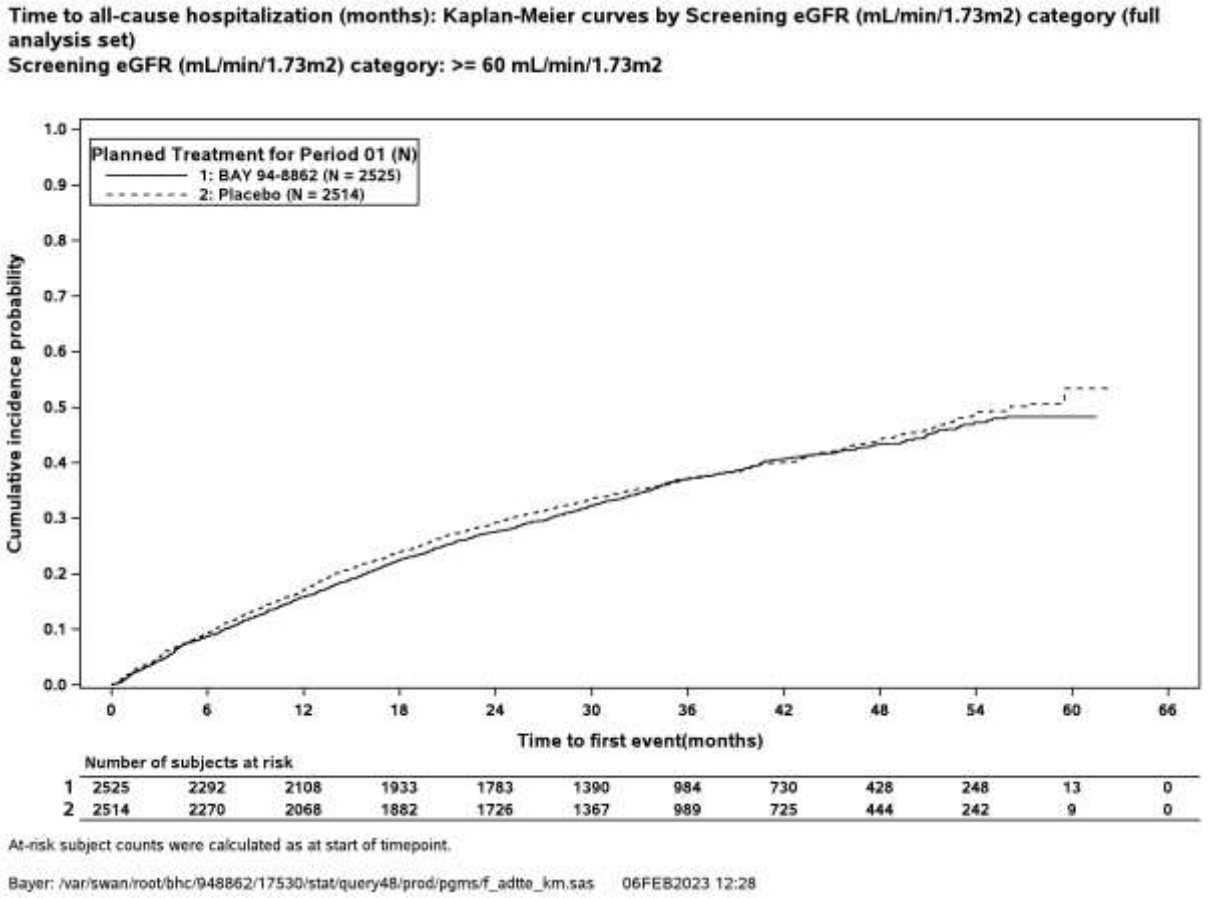


Figure 1.3.1 / 83: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

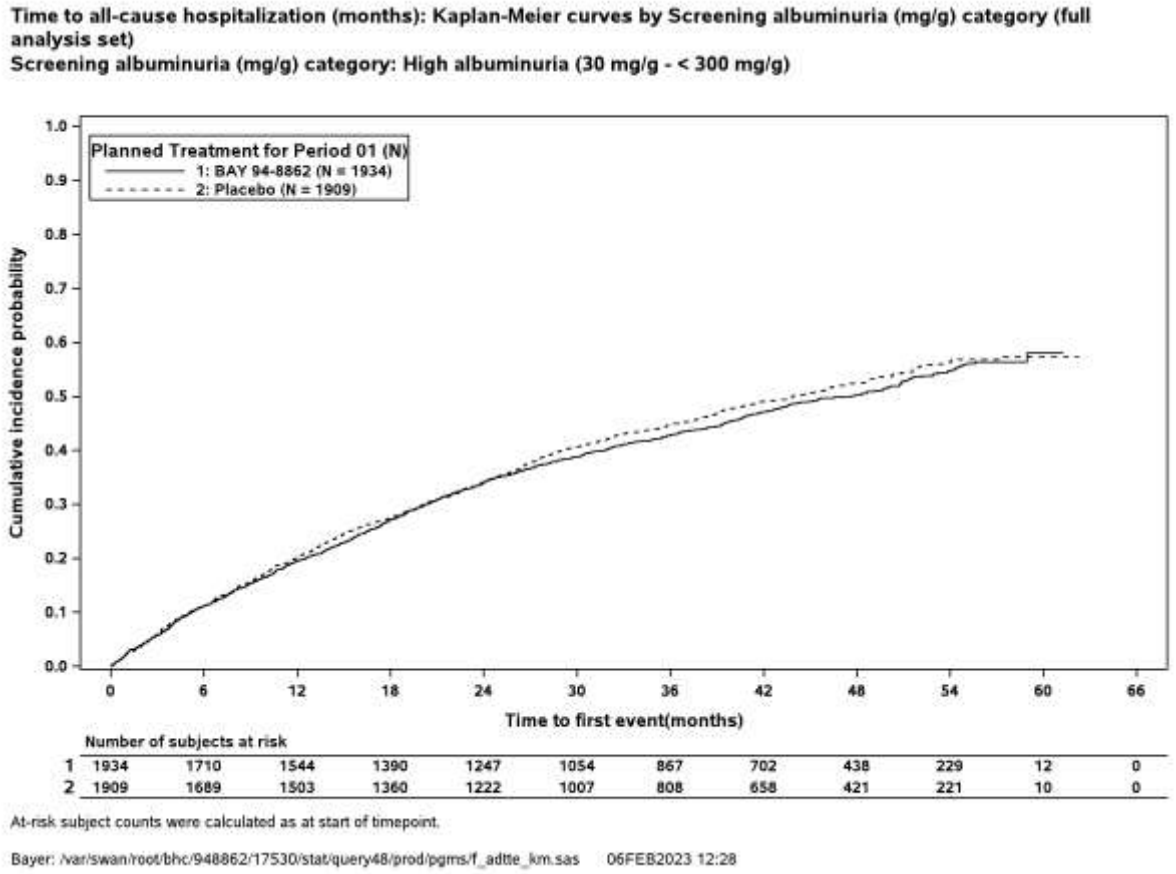
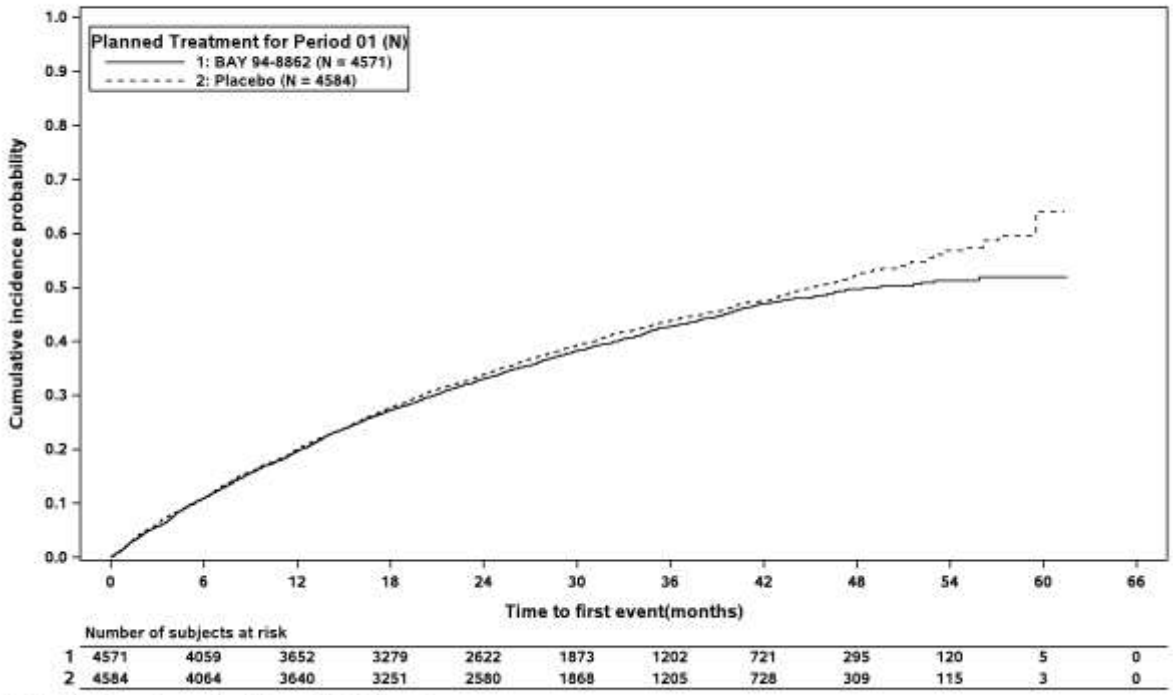


Figure 1.3.1 / 83: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	4571	4059	3652	3279	2622	1873	1202	721	295	120	5	0
2	4584	4064	3640	3251	2580	1868	1205	728	309	115	3	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km.sas 06FEB2023 12:28

Figure 1.3.1 / 84: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set)

History of CVD (Medical history): present

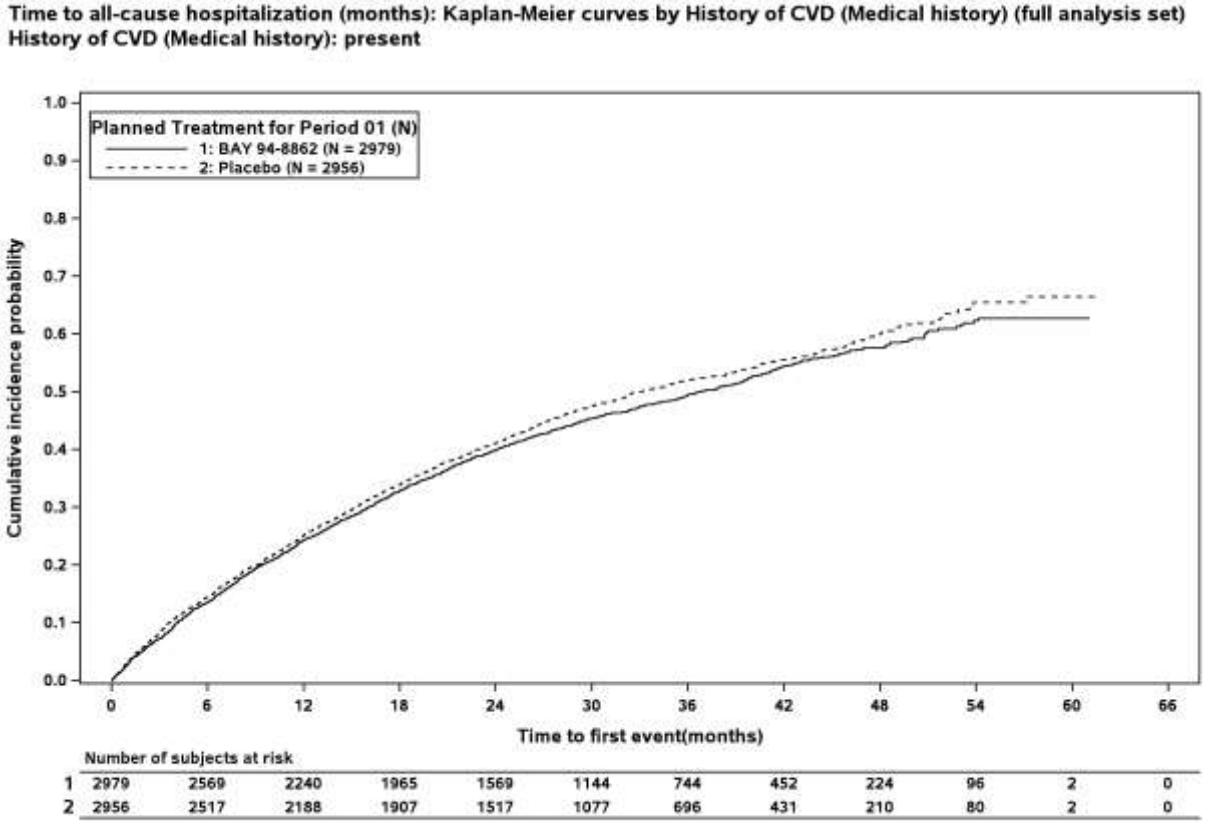


Figure 1.3.1 / 84: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set) (cont.)

History of CVD (Medical history): absent

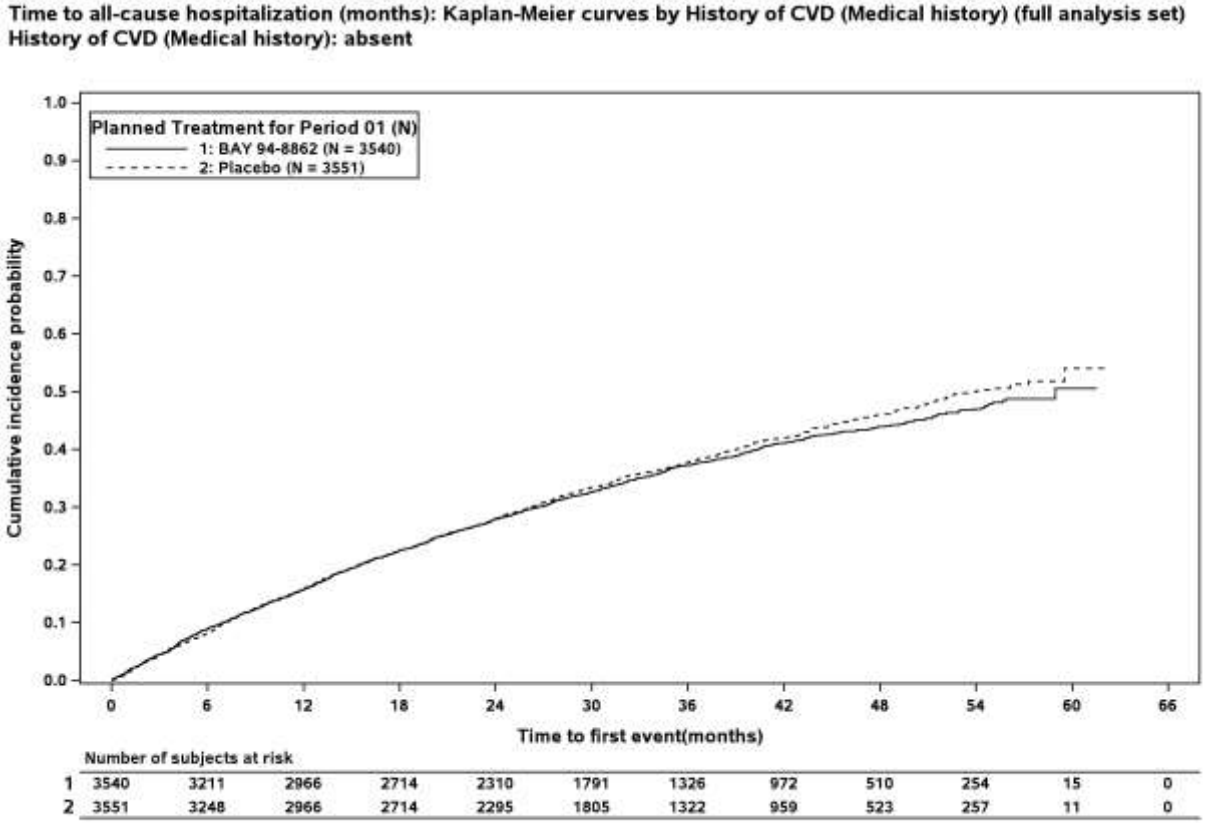


Figure 1.3.1 / 85: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

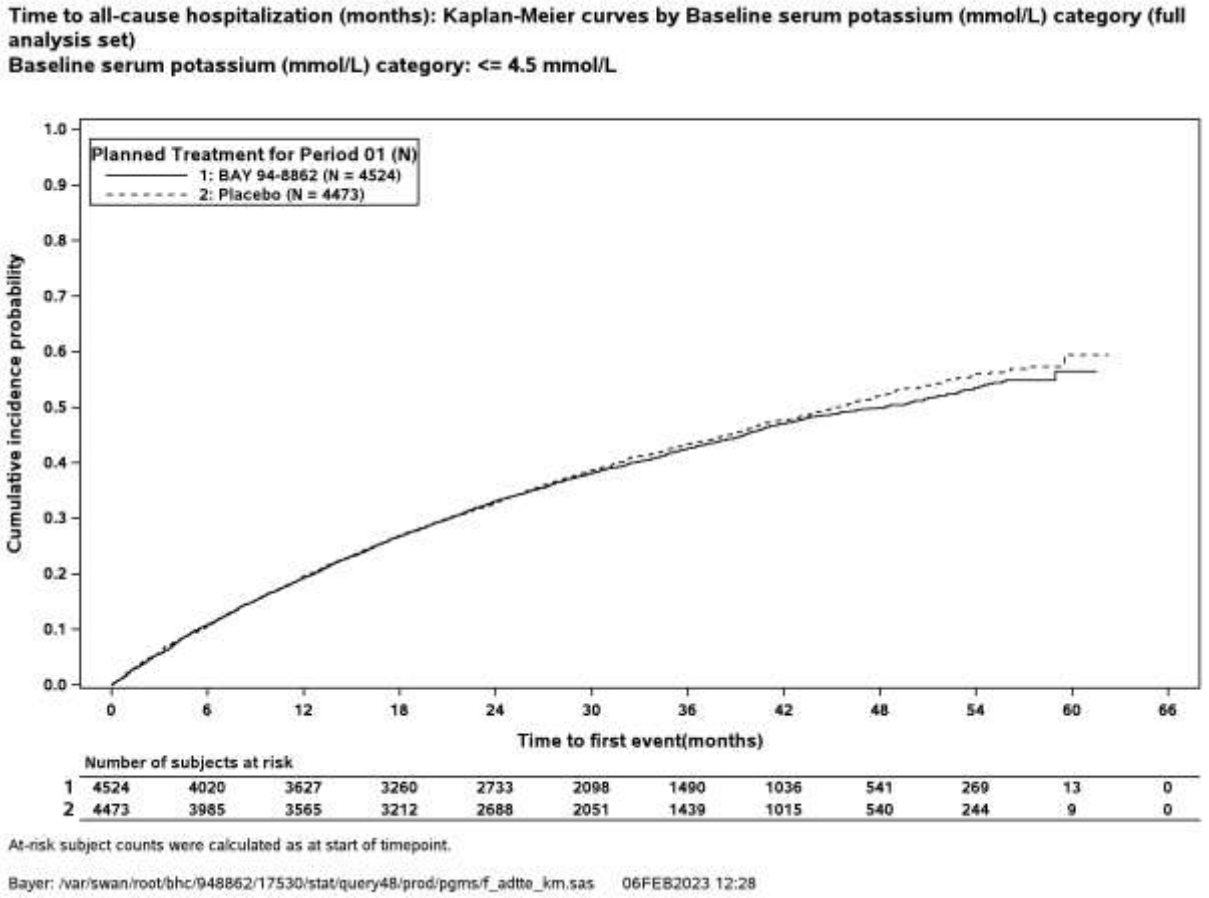


Figure 1.3.1 / 85: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

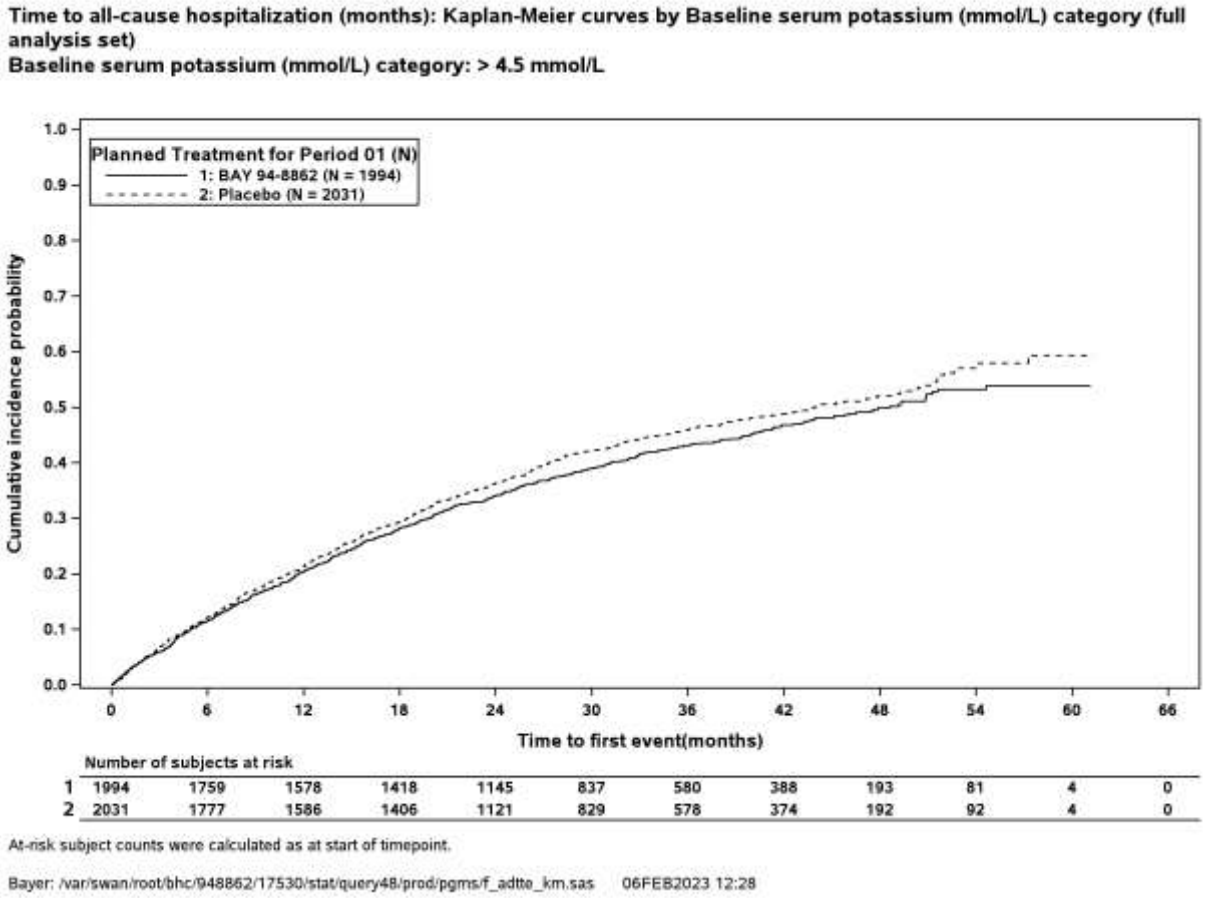


Figure 1.3.1 / 86: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

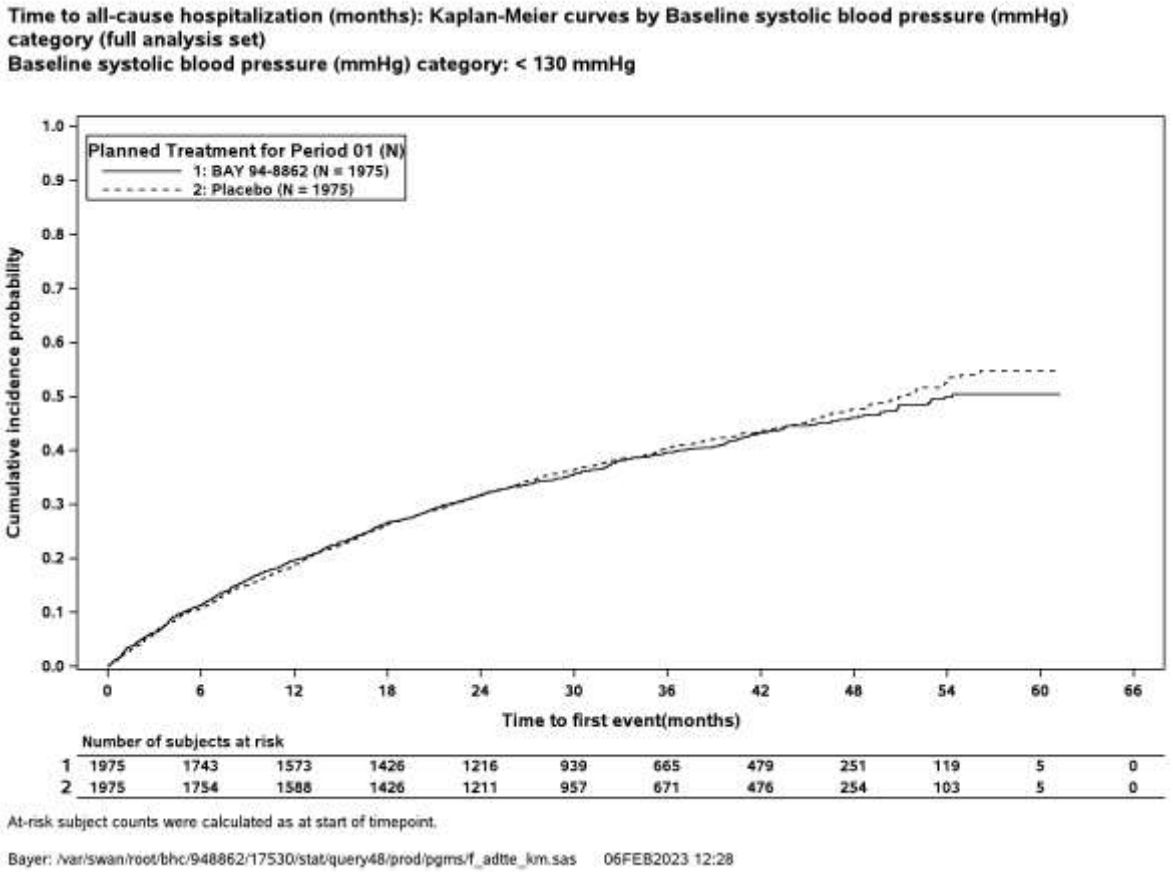
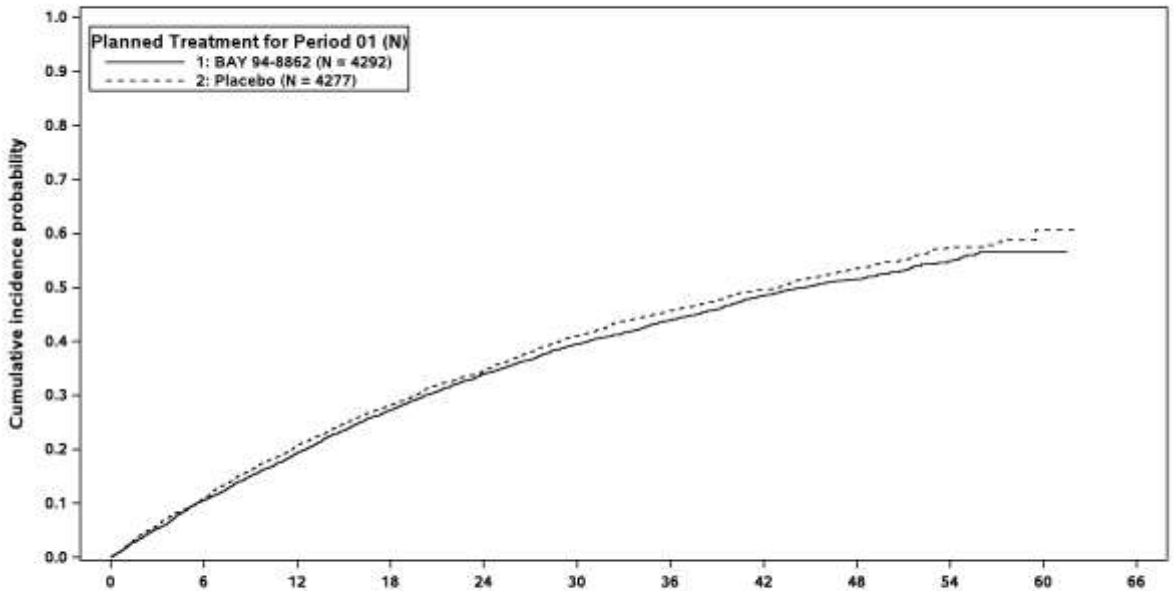


Figure 1.3.1 / 86: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set)
Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg



Number of subjects at risk

1	4292	3827	3445	3081	2535	1901	1337	908	465	223	11	0
2	4277	3795	3365	3019	2474	1838	1283	880	465	229	8	0

At-risk subject counts were calculated as at start of timepoint.

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Figure 1.3.1 / 86: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

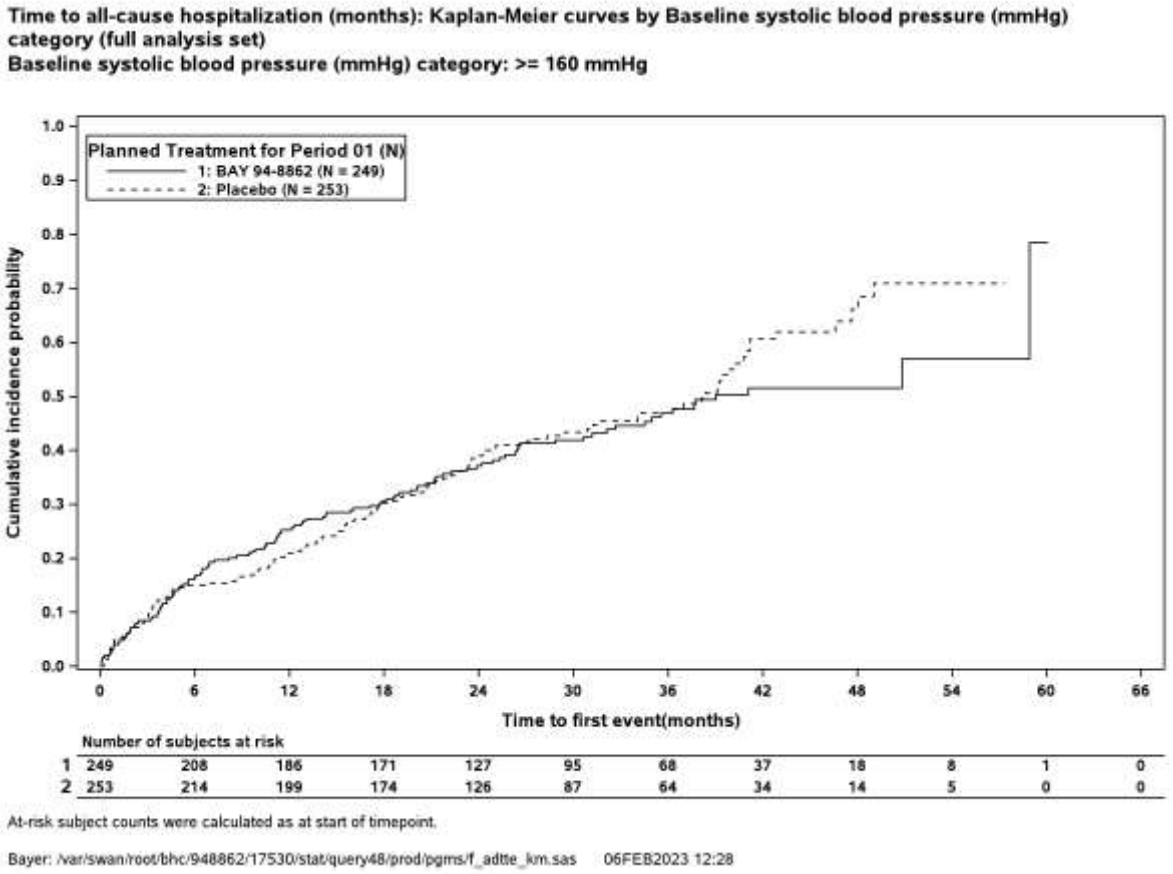


Figure 1.3.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set)

Race (4 categories): White

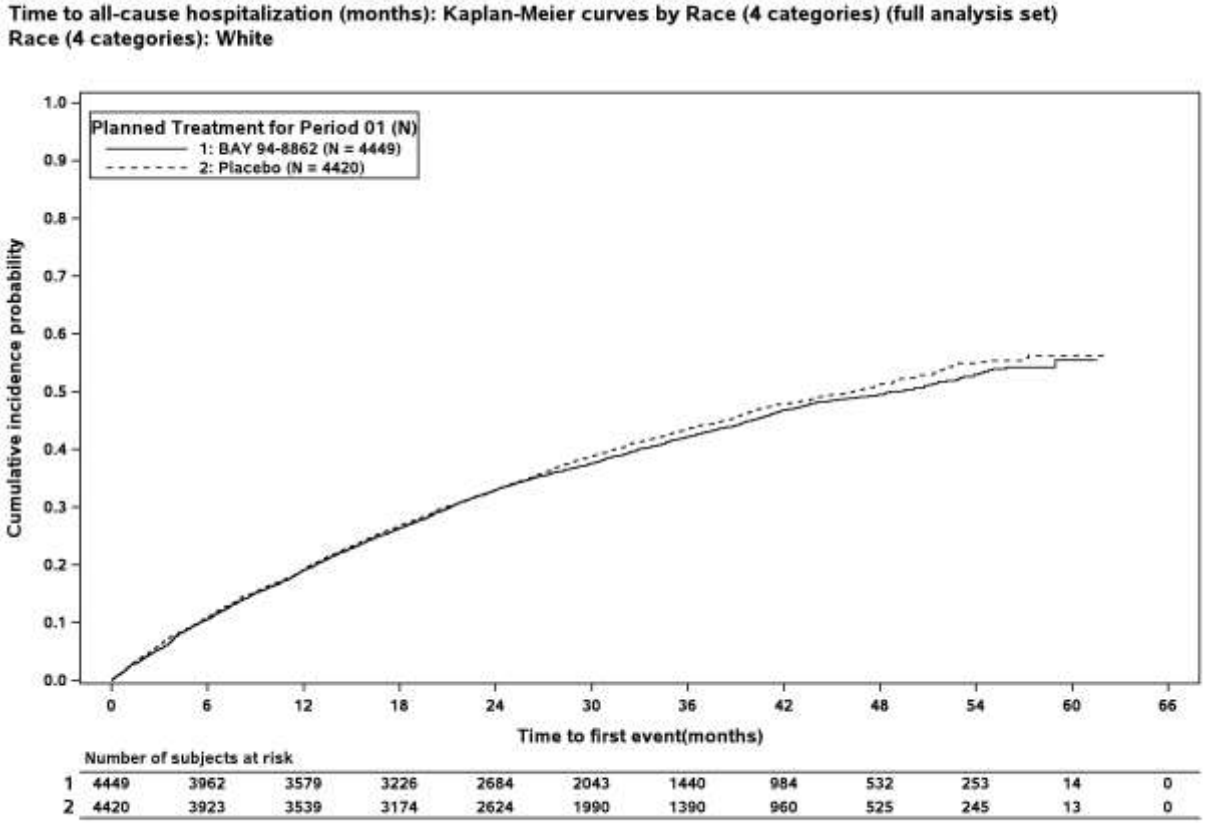


Figure 1.3.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Black

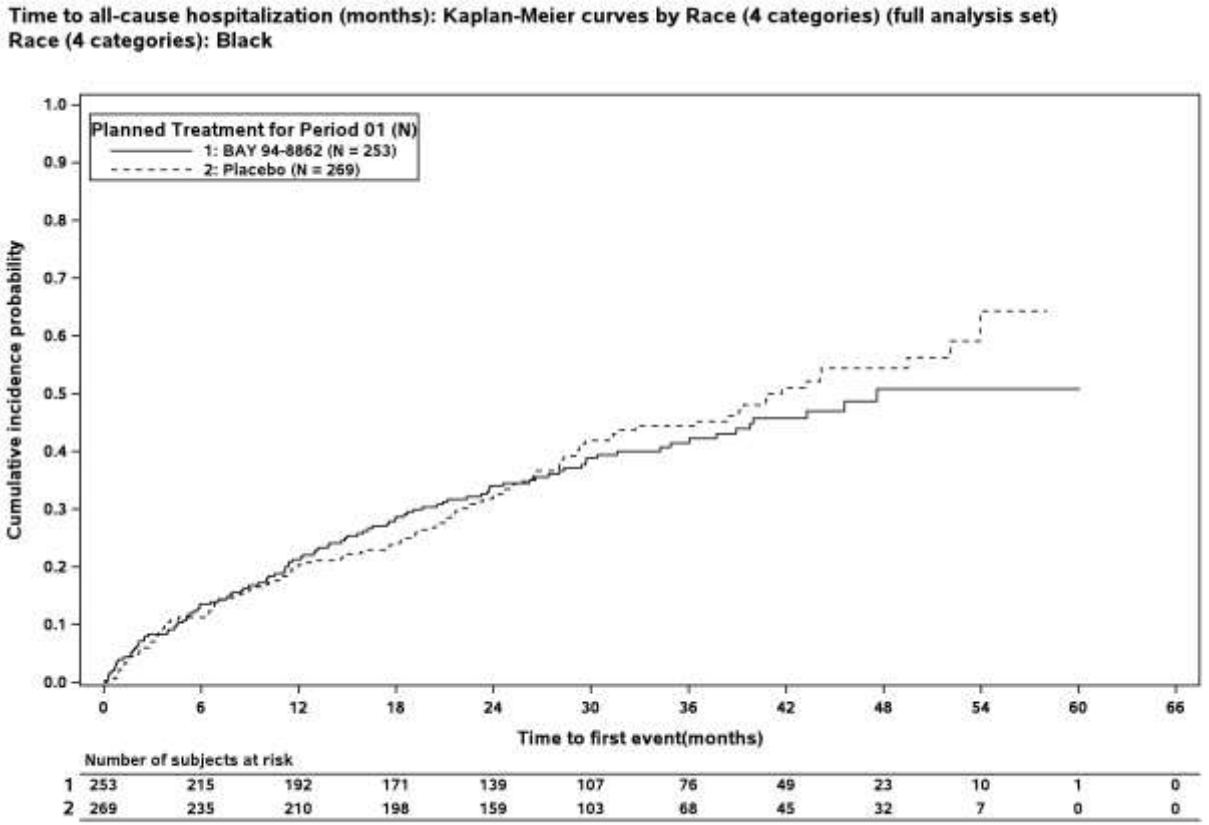


Figure 1.3.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Asian

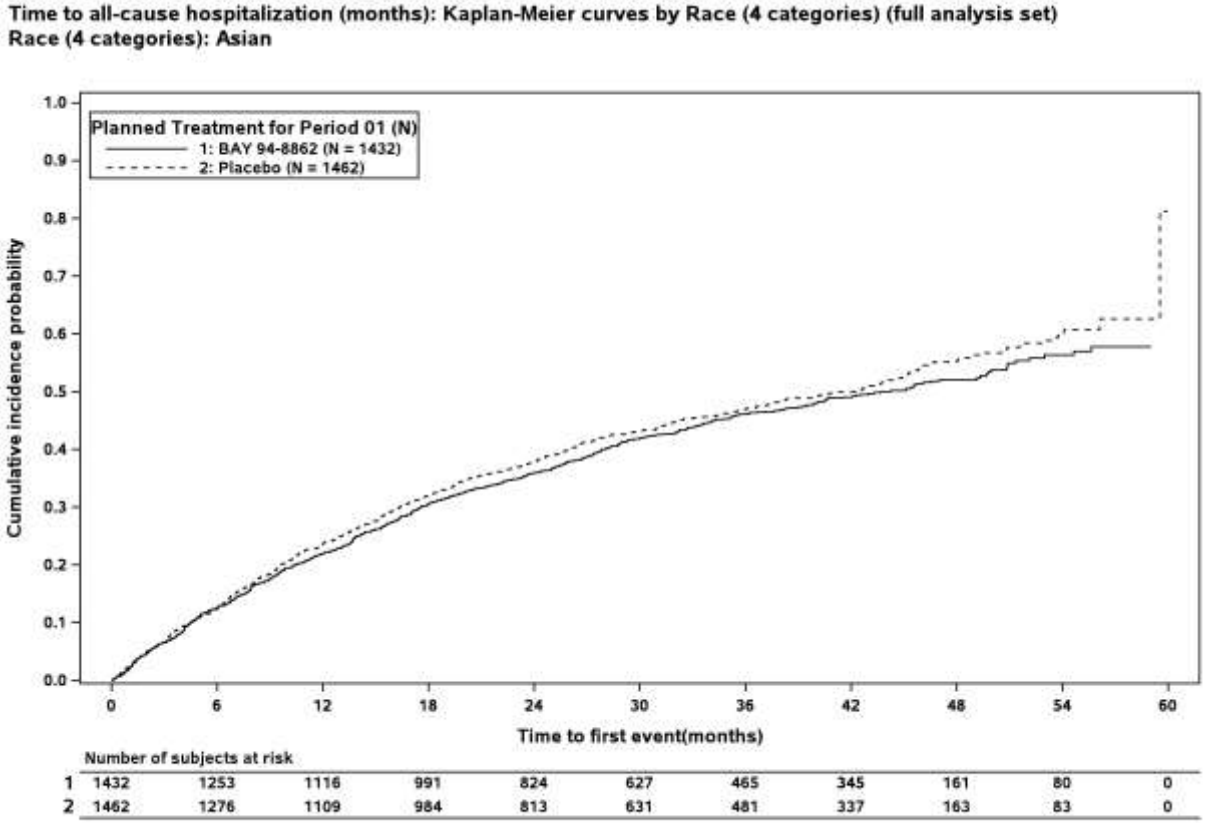


Figure 1.3.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set) (cont.)

Race (4 categories): Other

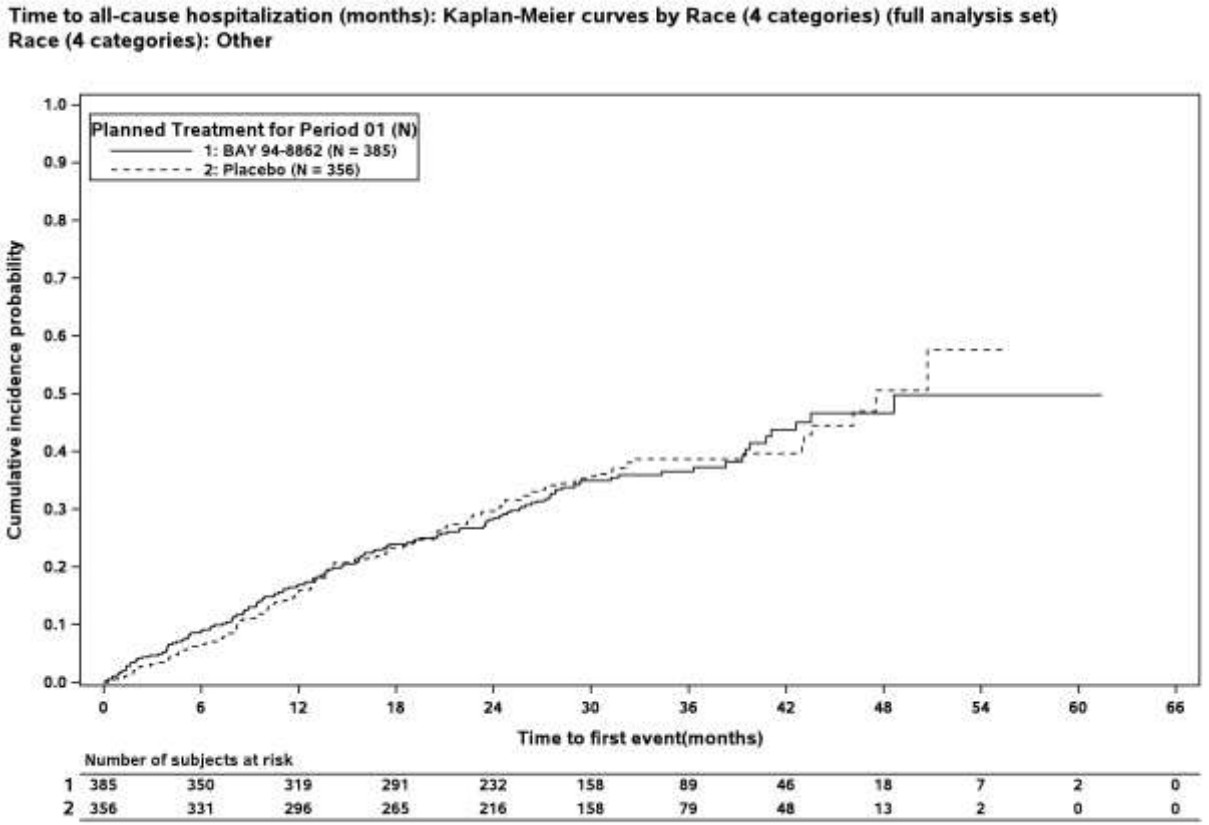


Figure 1.3.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set)

Sex: Male

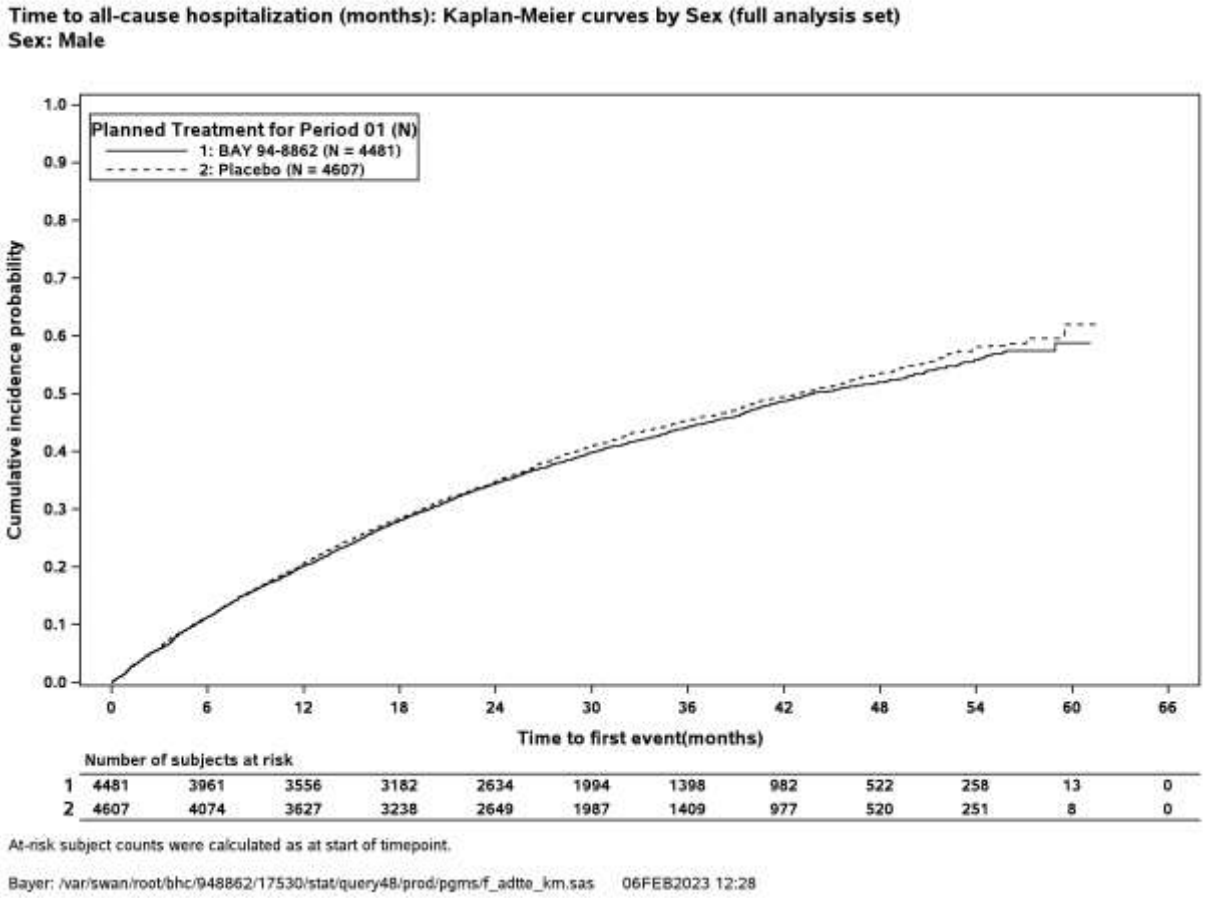


Figure 1.3.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set) (cont.)

Sex: Female

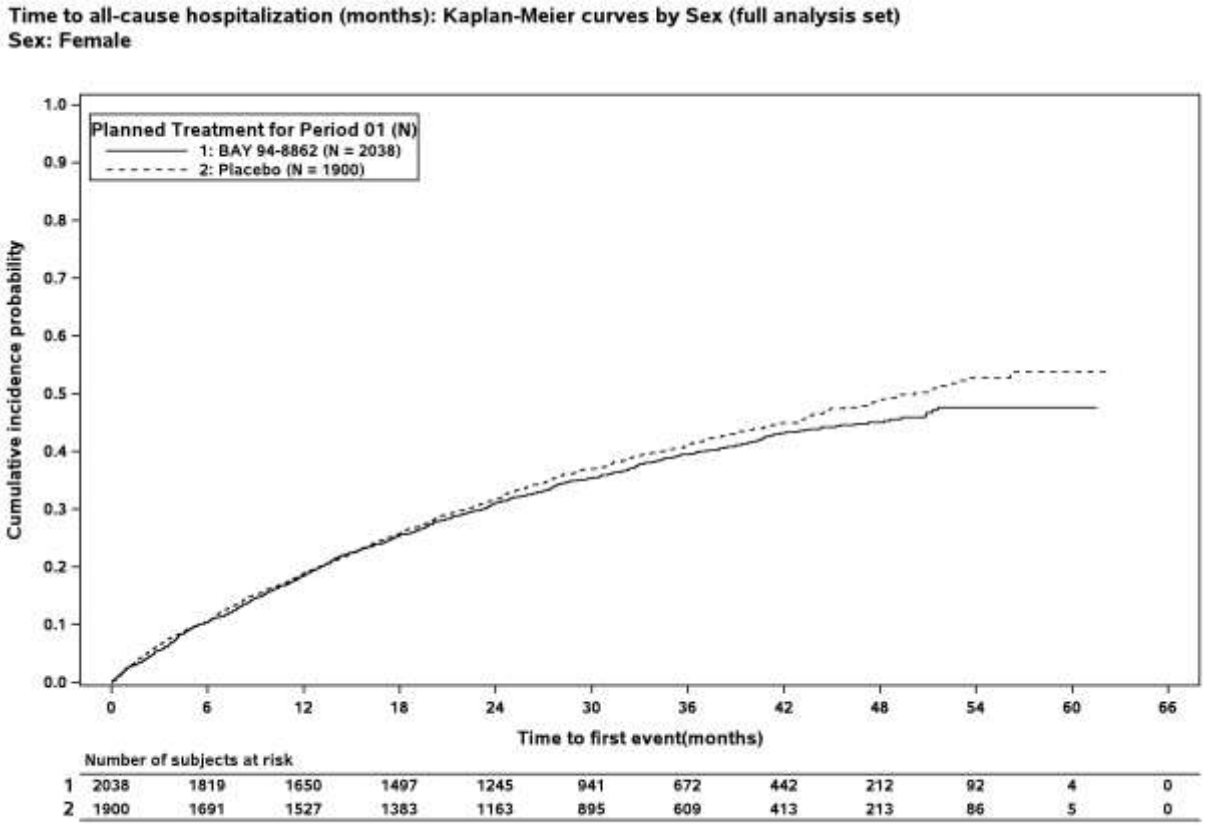


Figure 1.3.1 / 89: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set)

Age group (years) 3rd category: < 65 years

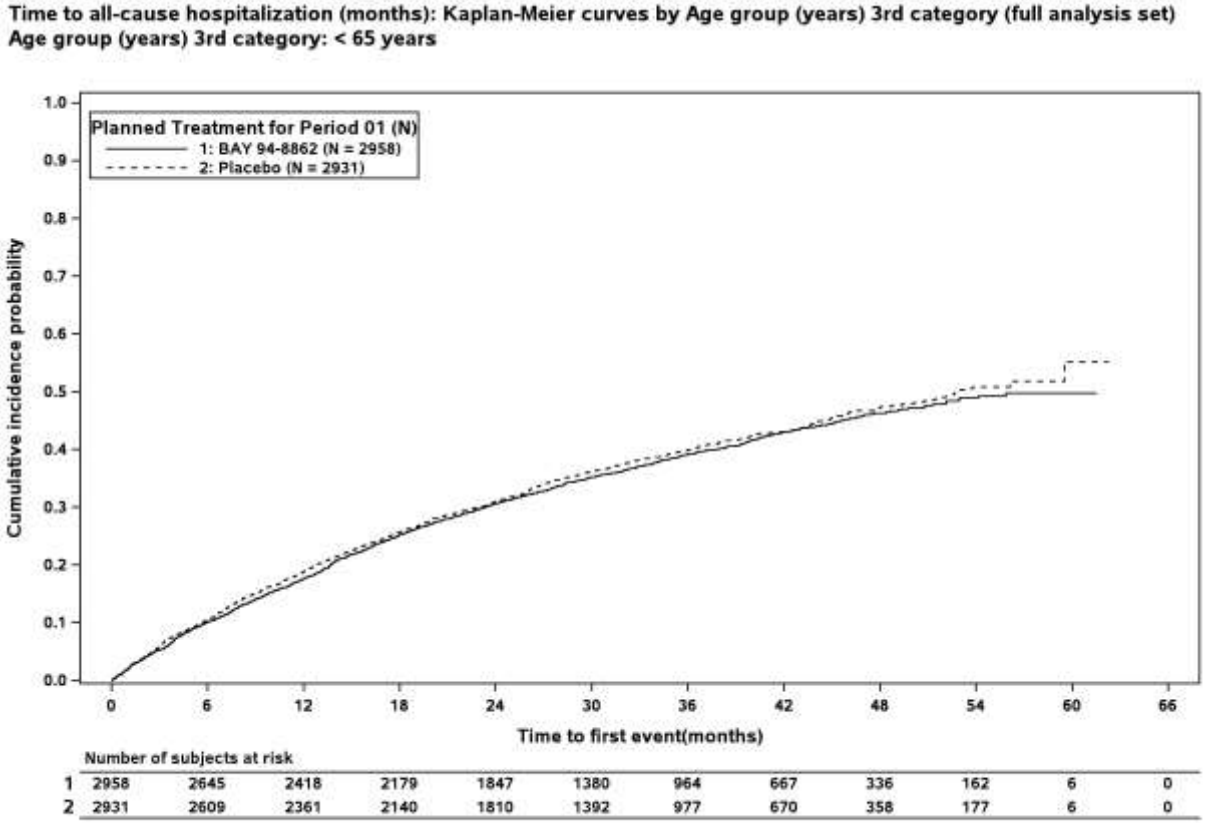
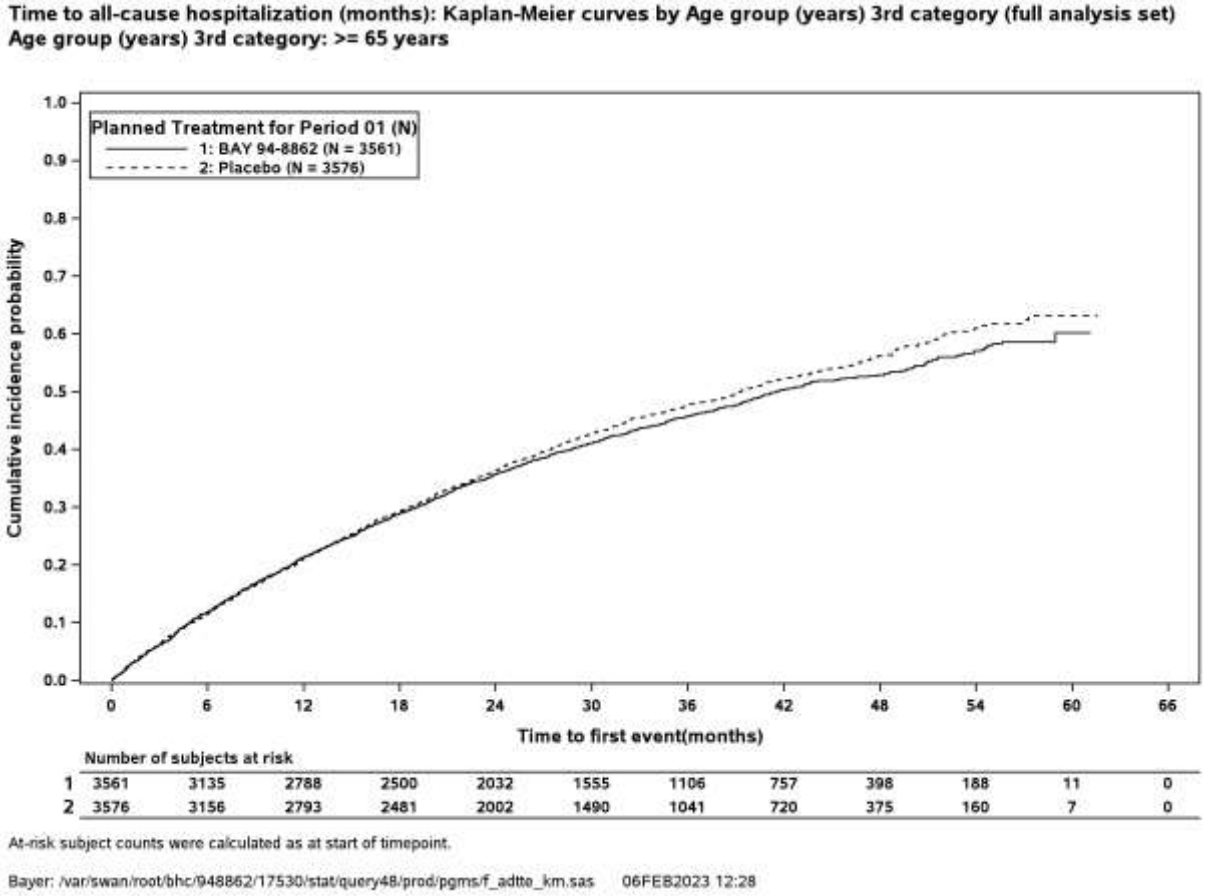


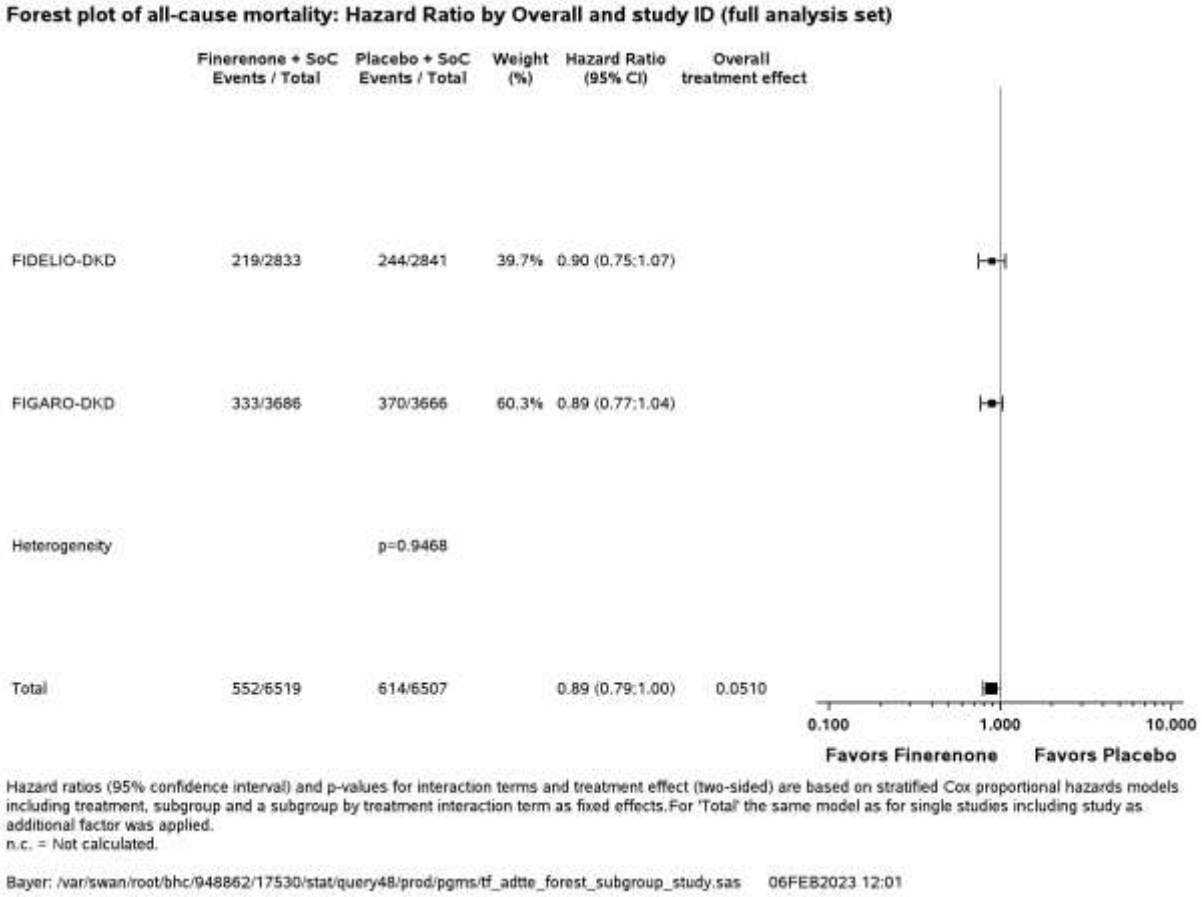
Figure 1.3.1 / 89: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set) (cont.)

Age group (years) 3rd category: >= 65 years



1.3.2 Forest plots for time-to-event Analyses

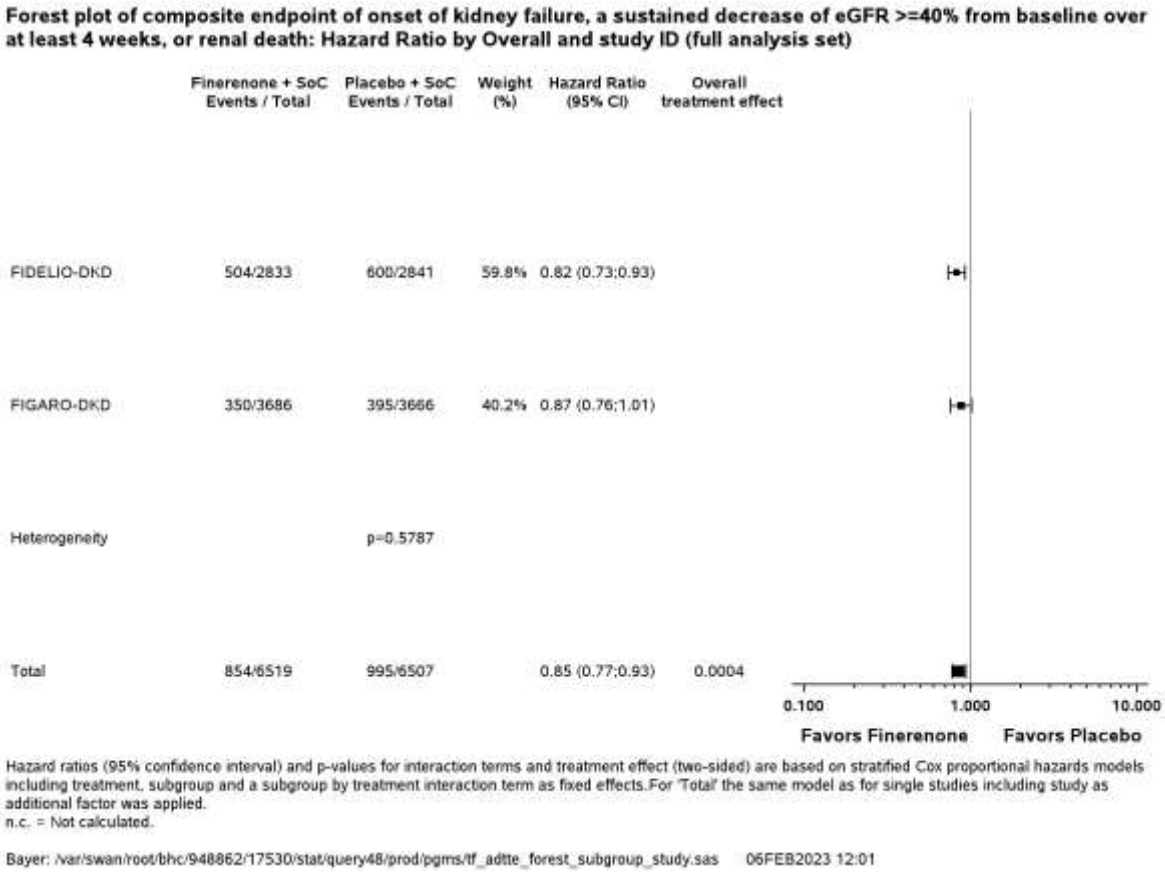
Figure 1.3.2 / 1: Forest plot of all-cause mortality: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

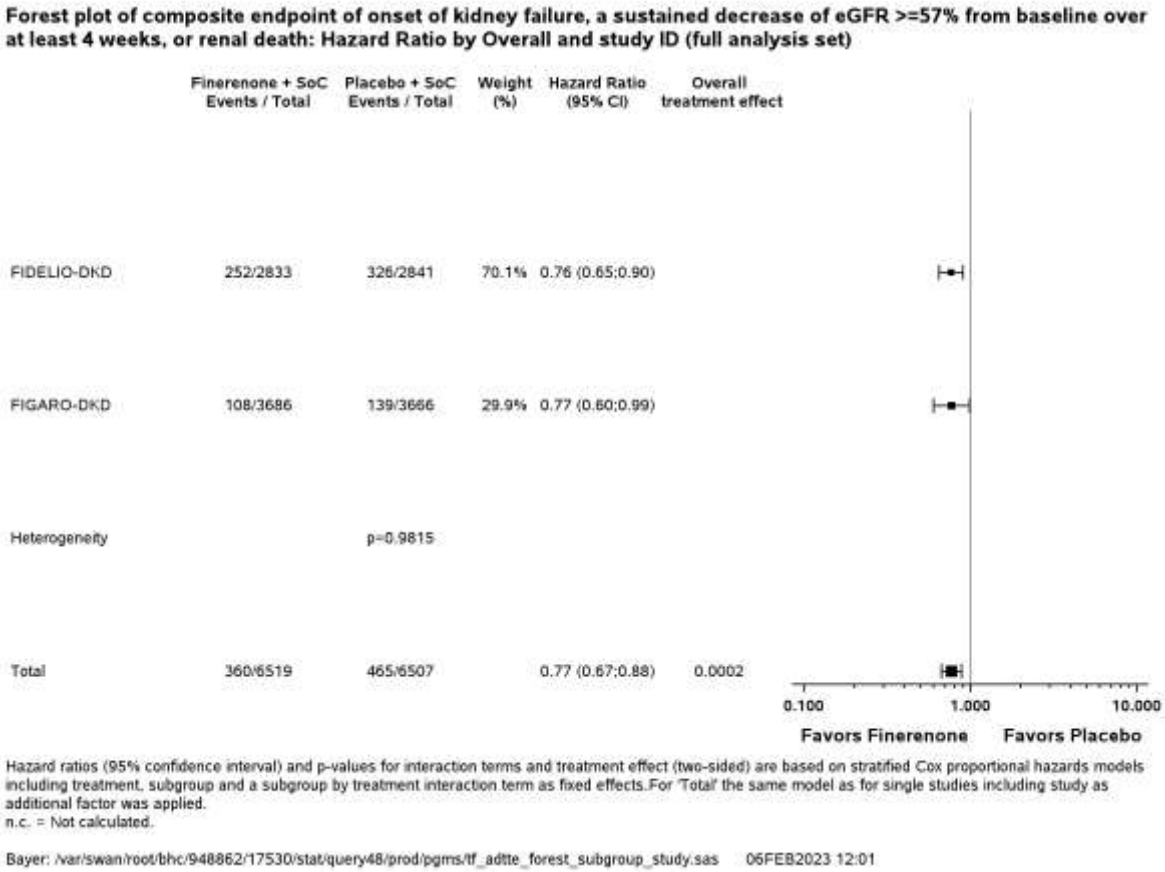
Figure 1.3.2 / 2: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=40% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

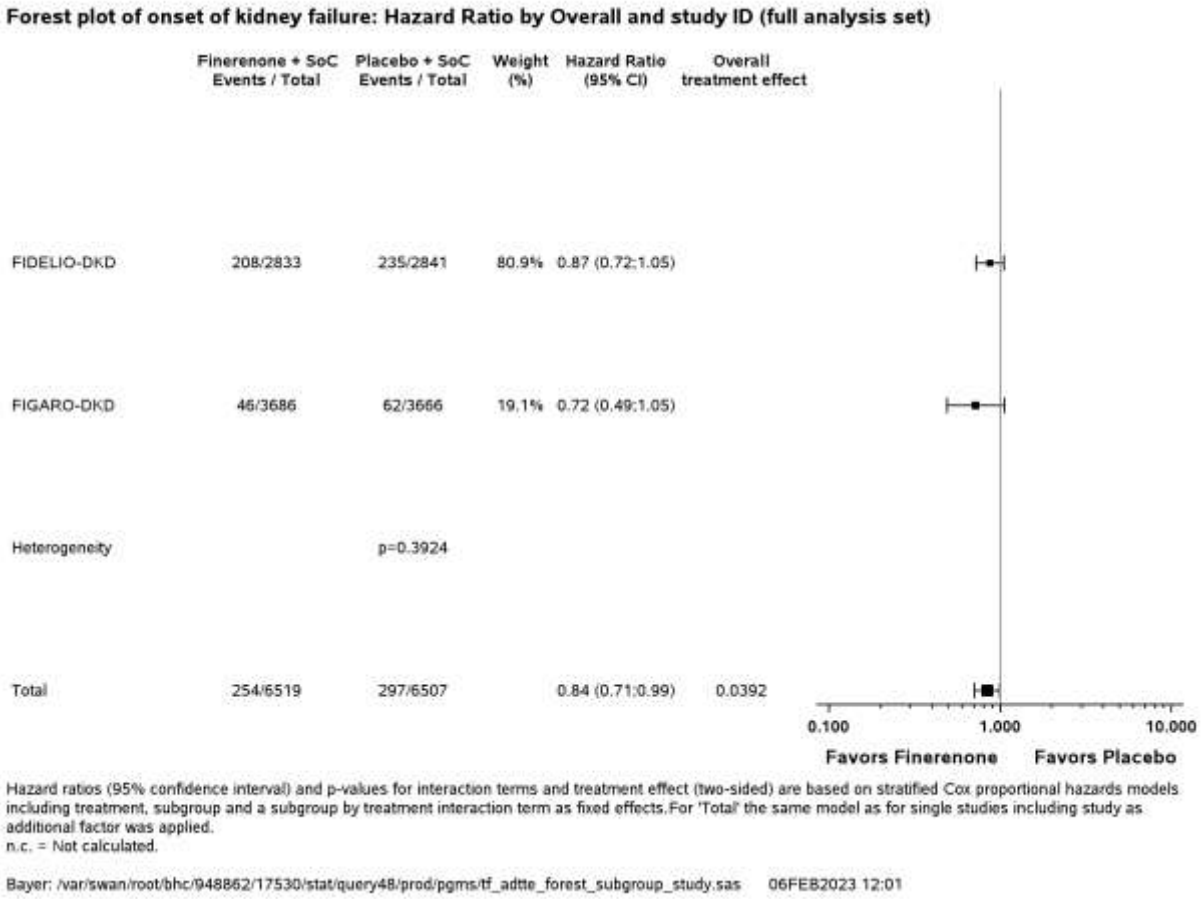
Figure 1.3.2 / 3: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

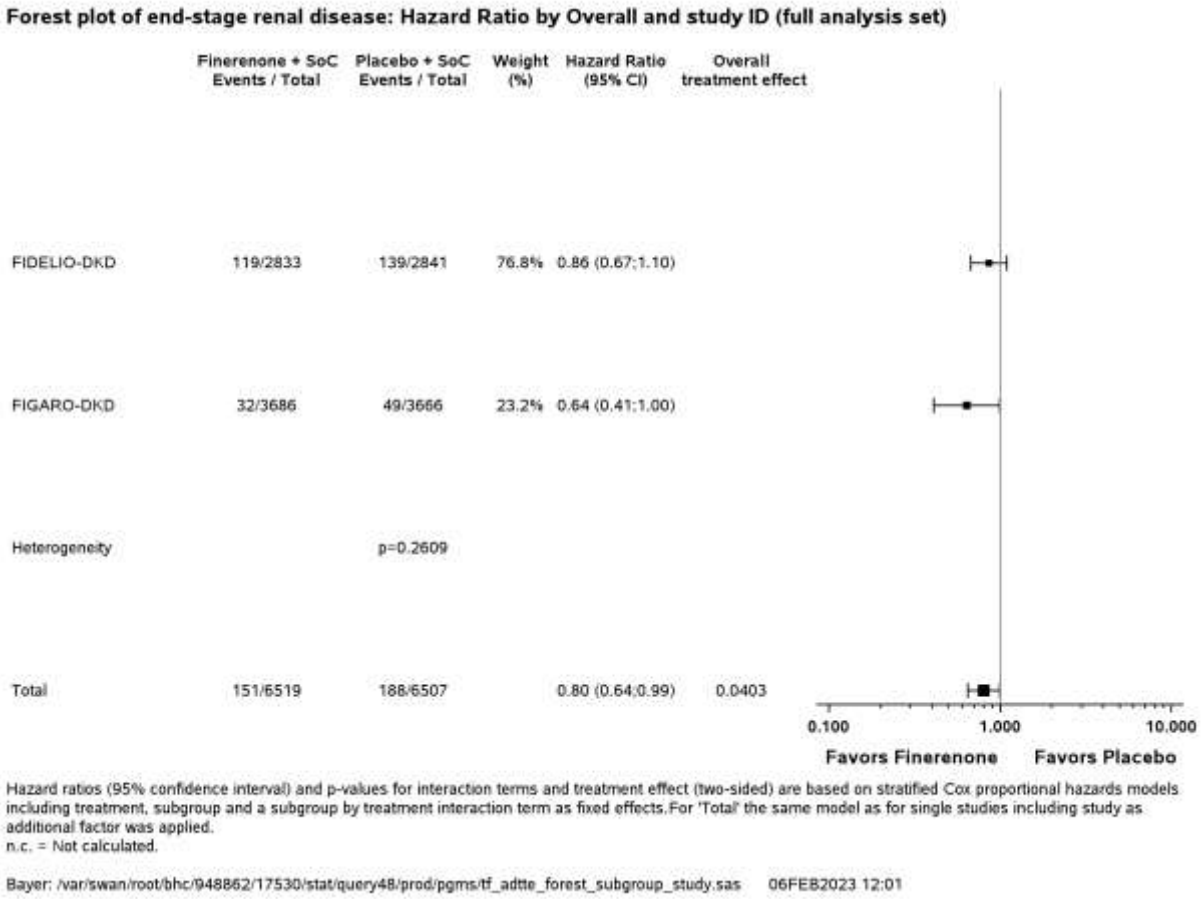
Figure 1.3.2 / 4: Forest plot of onset of kidney failure: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 5: Forest plot of end-stage renal disease: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 6: Forest plot of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set)

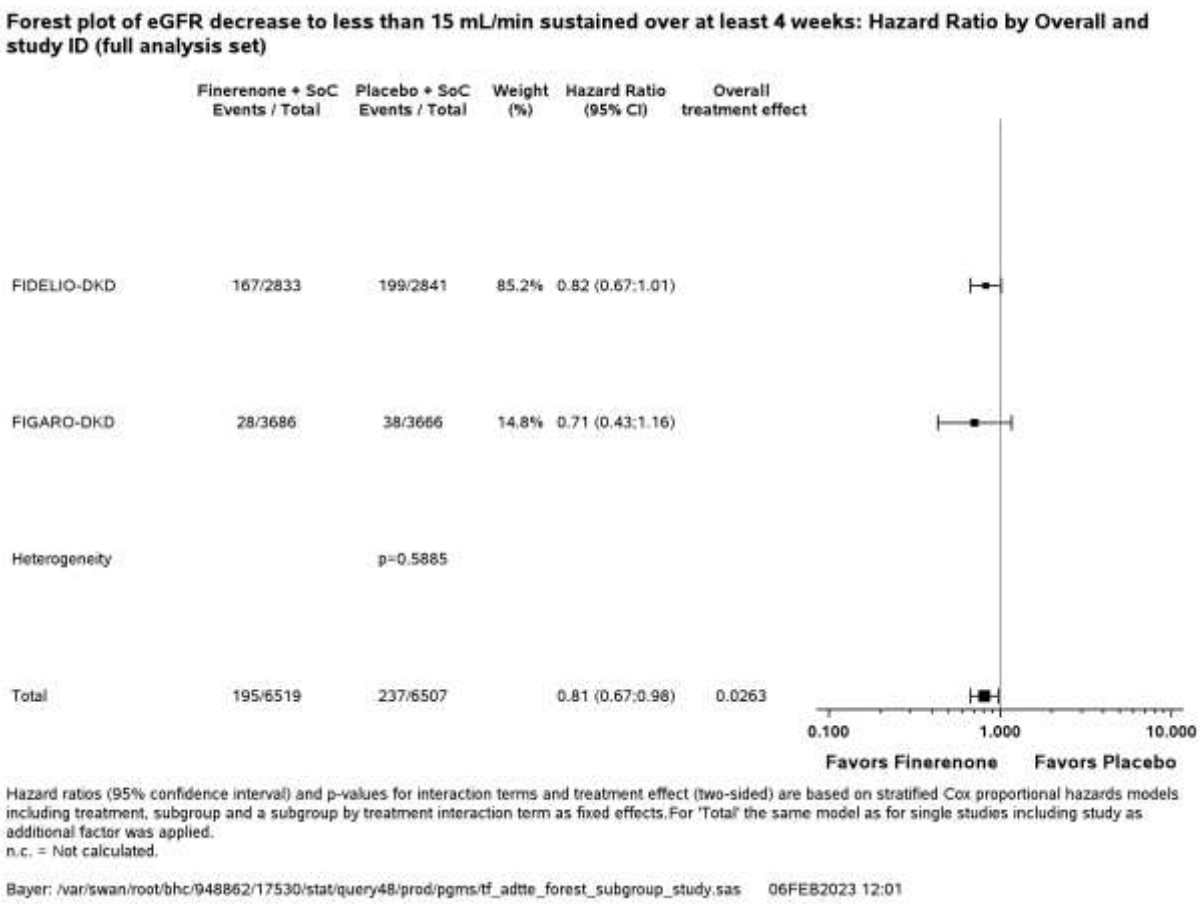


Figure 1.3.2 / 7: Forest plot of a sustained decrease of eGFR >=57% from baseline over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set)

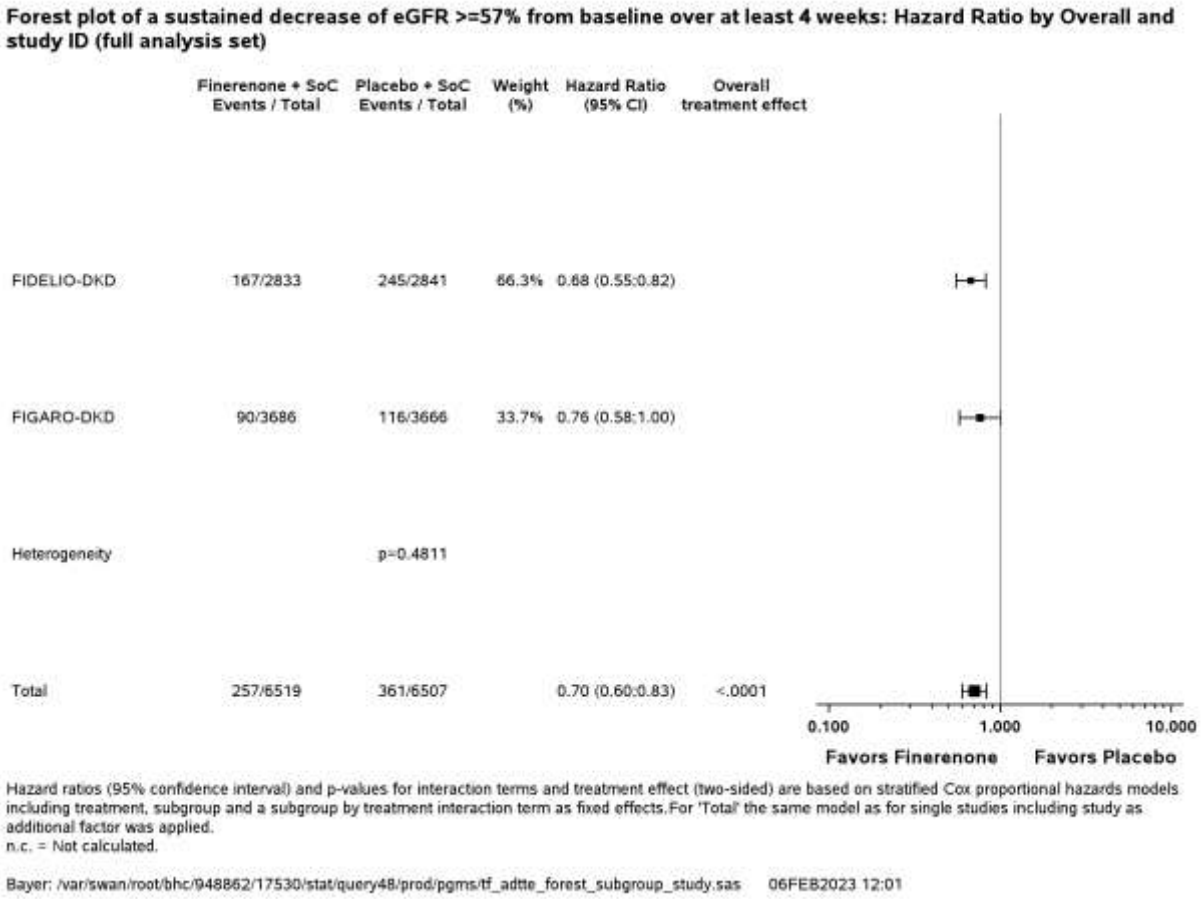
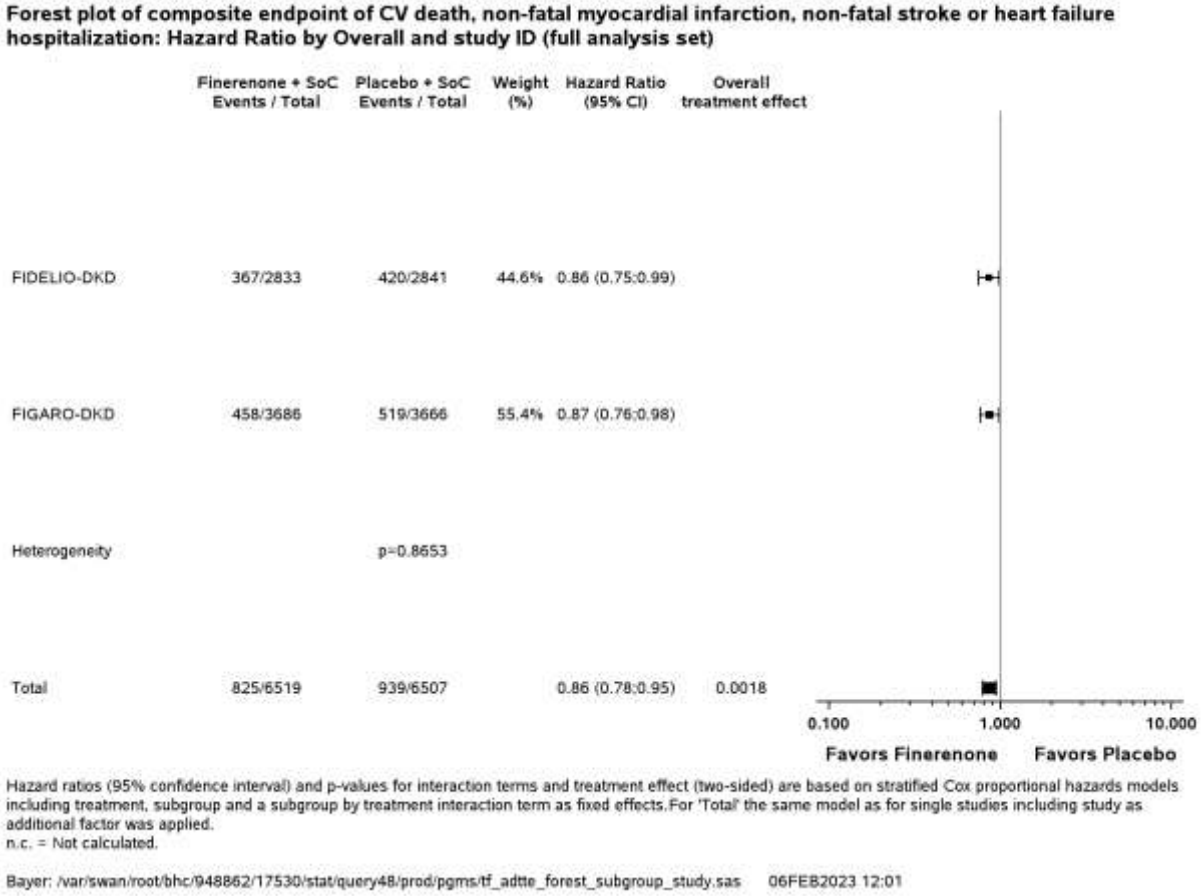


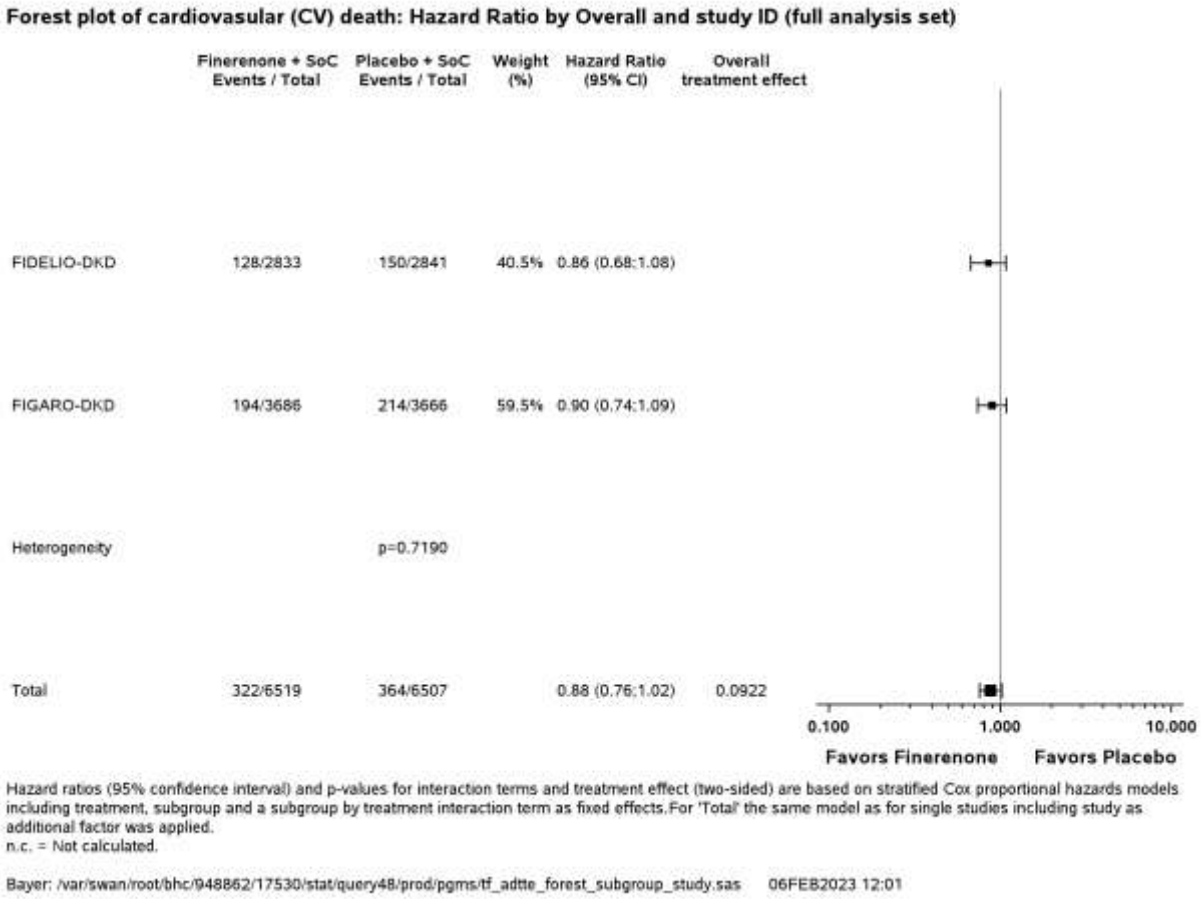
Figure 1.3.2 / 8: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 9: Forest plot of cardiovasular (CV) death: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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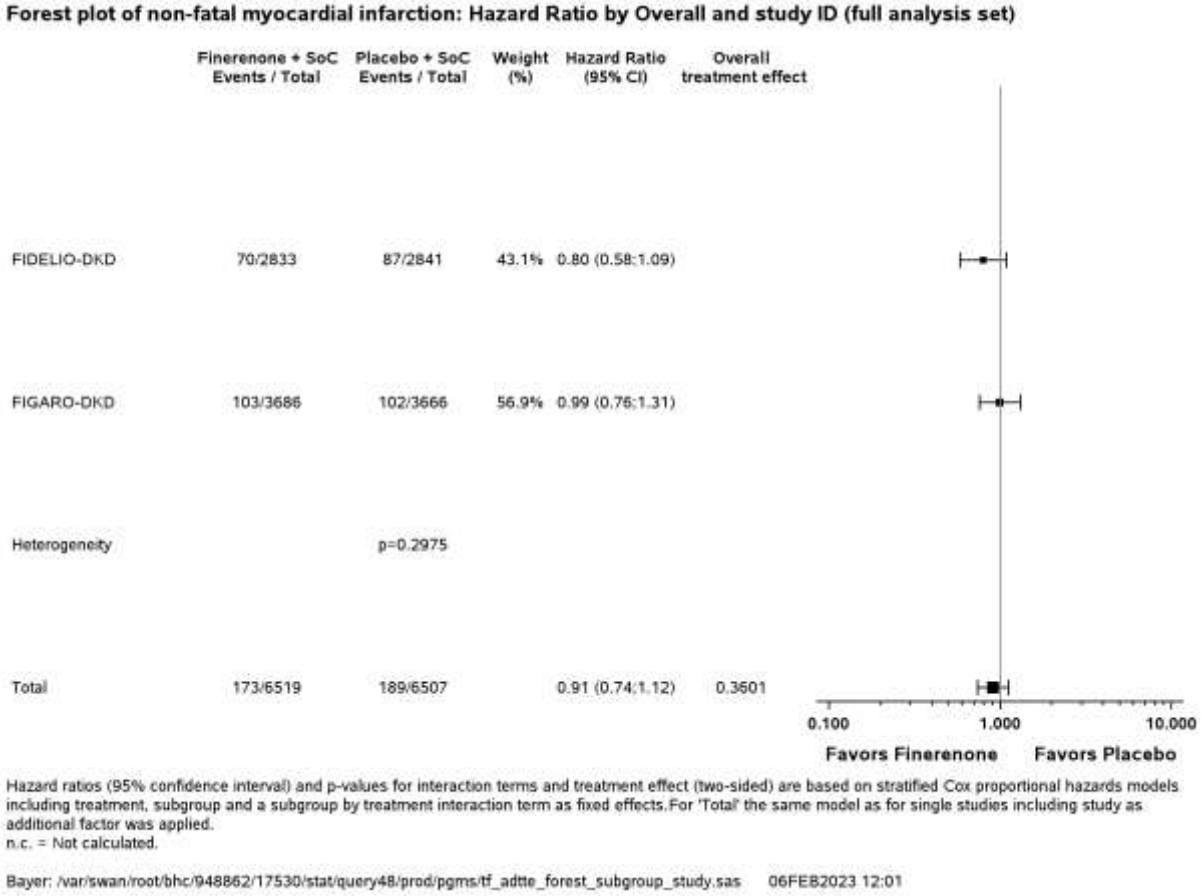
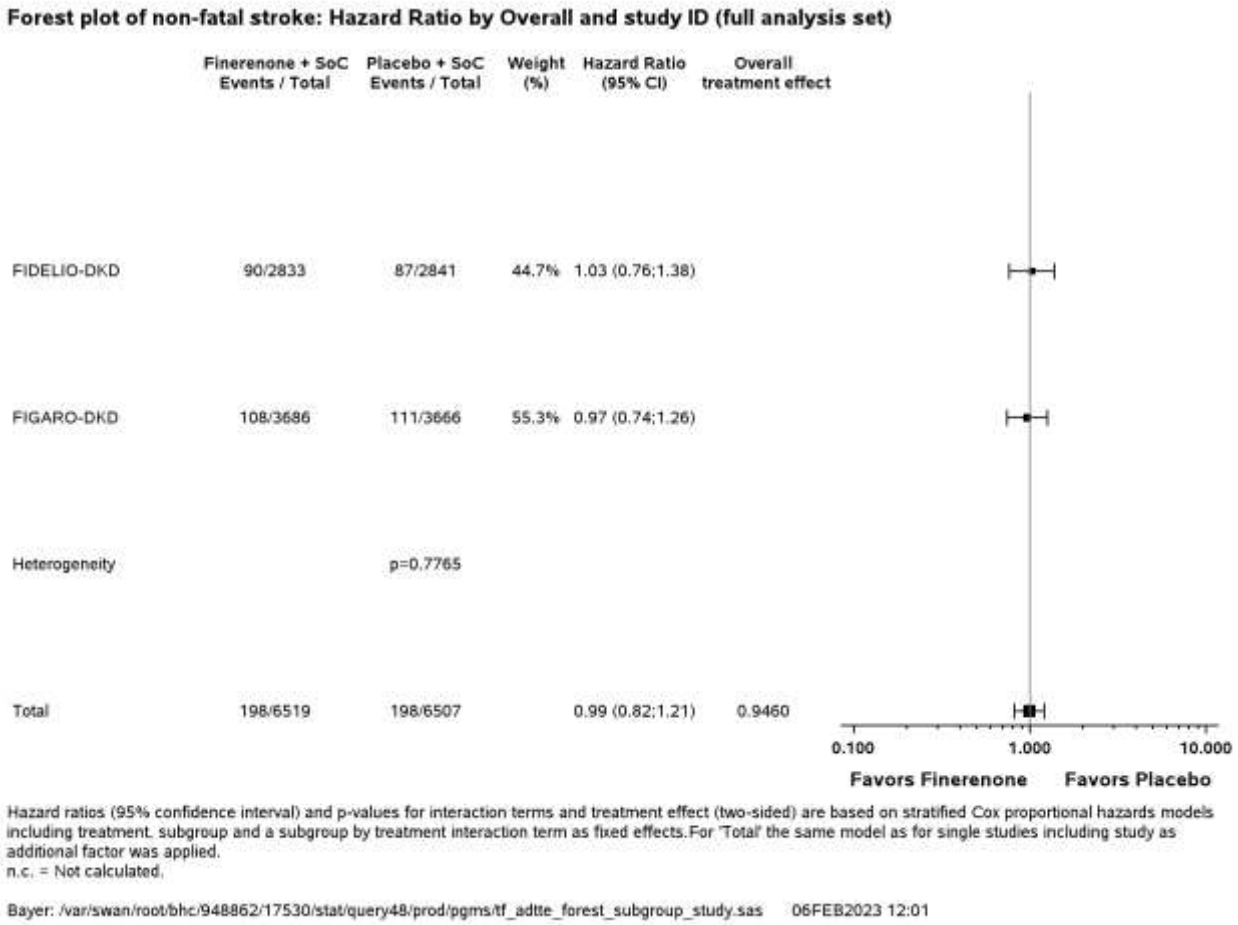
Figure 1.3.2 / 10: Forest plot of non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 11: Forest plot of non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 12: Forest plot of hospitalization due to heart failure: Hazard Ratio by Overall and study ID (full analysis set)

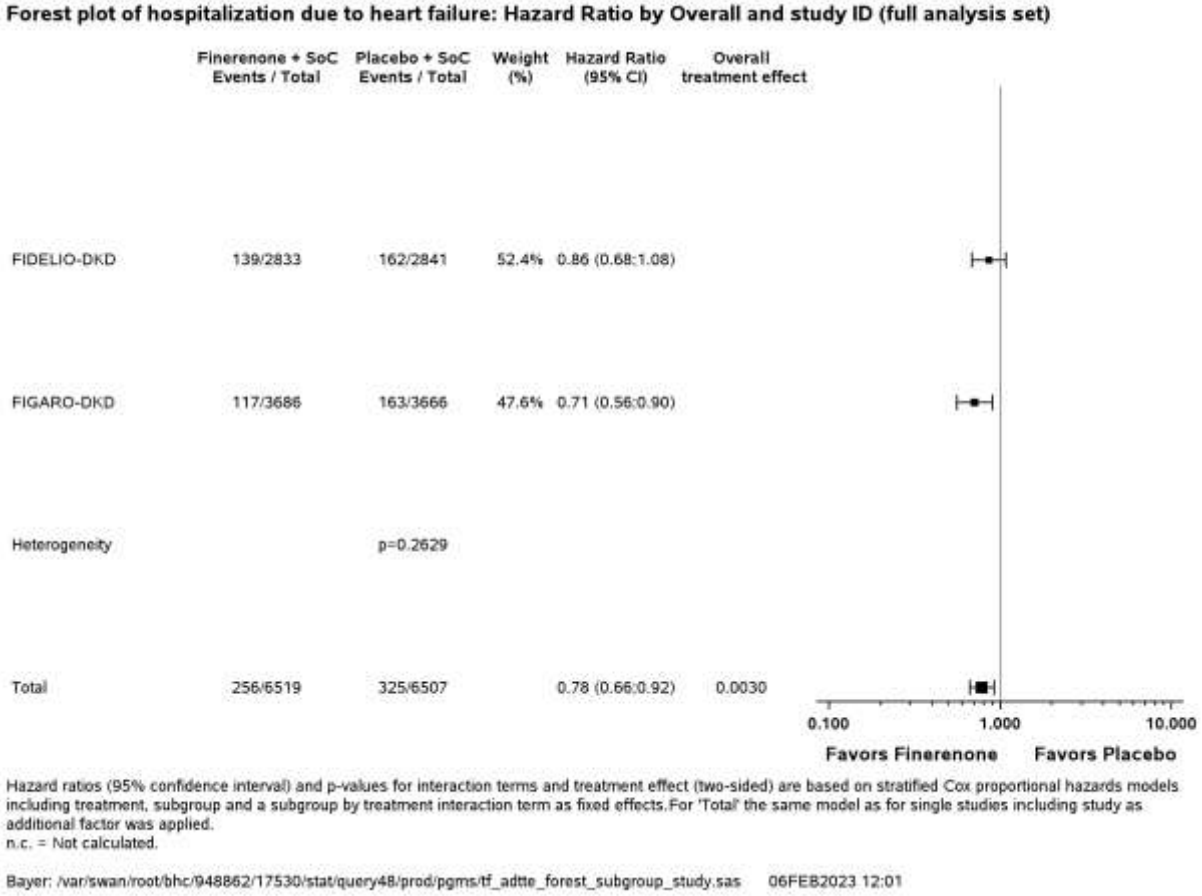


Figure 1.3.2 / 13: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set)

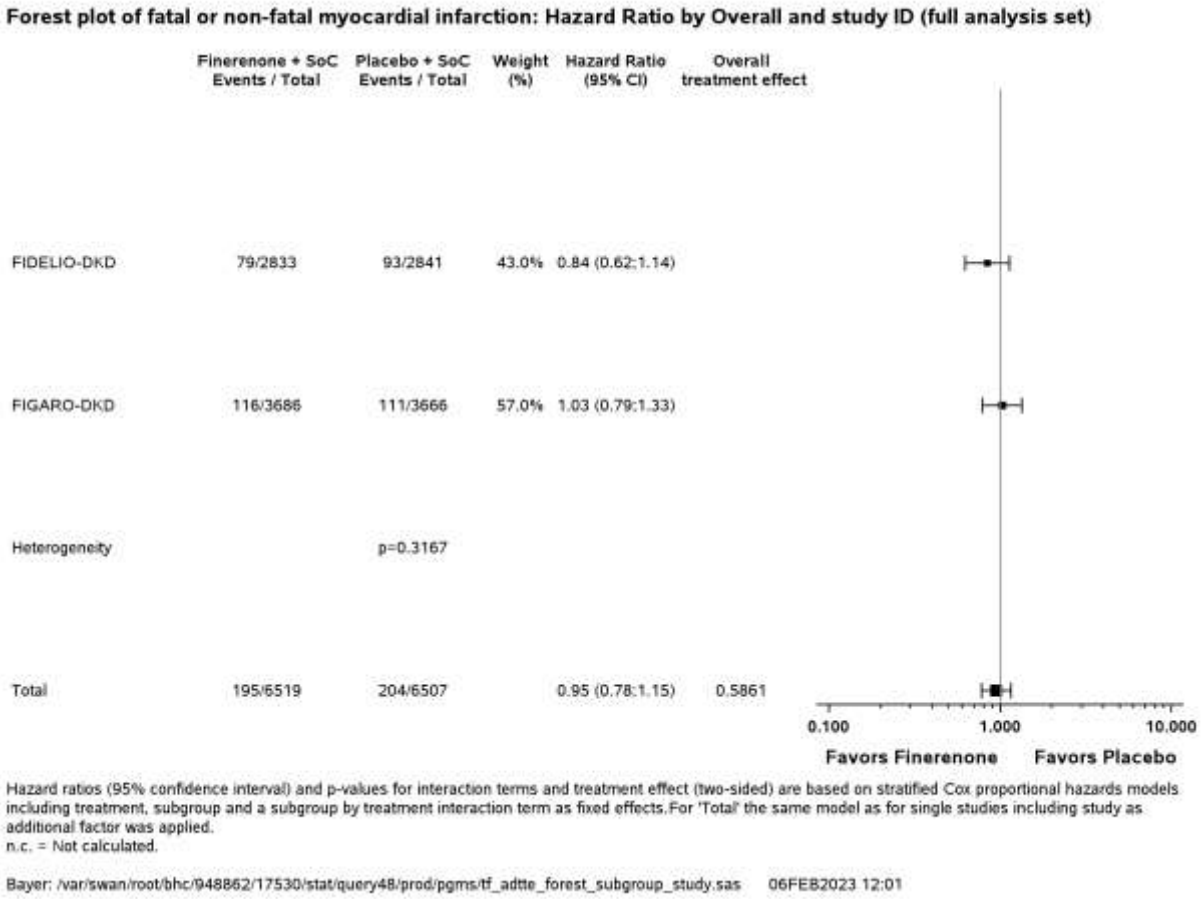
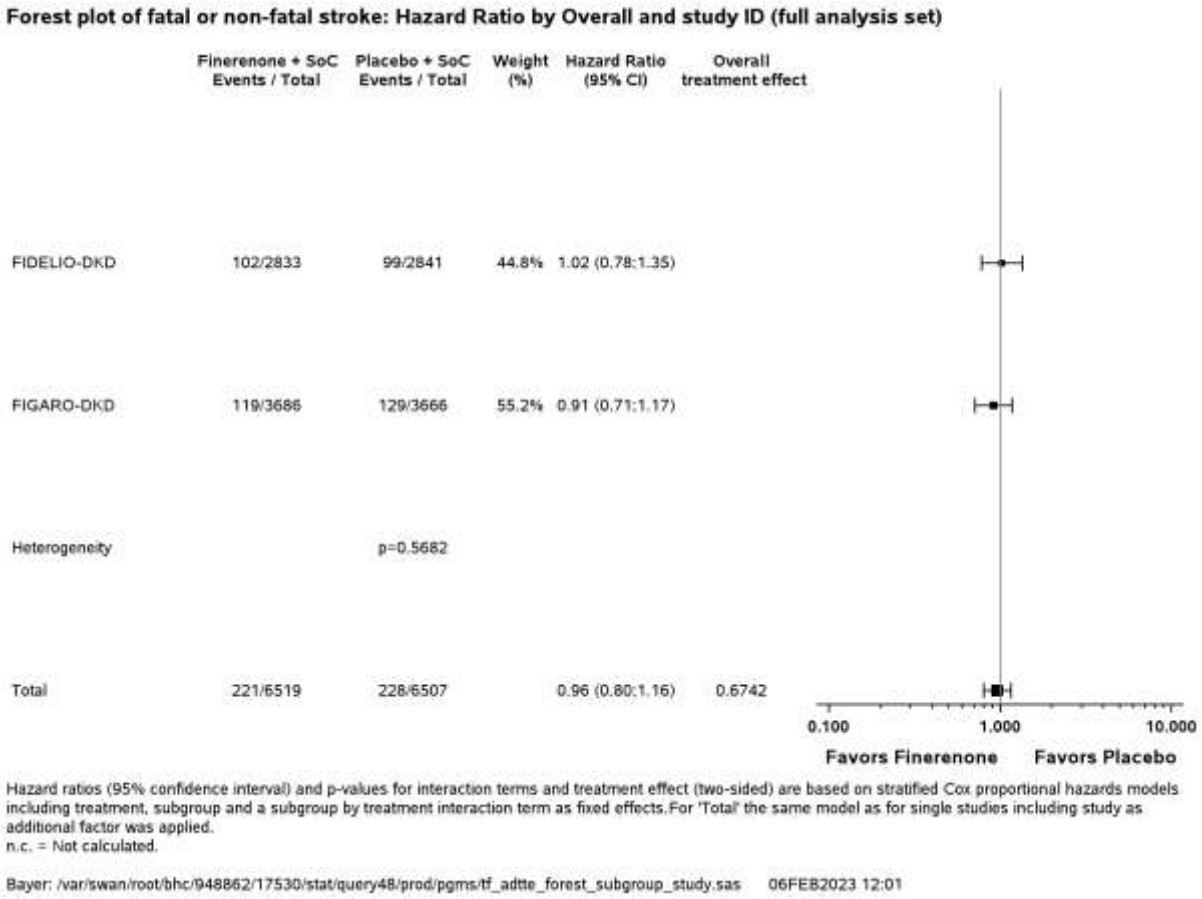


Figure 1.3.2 / 14: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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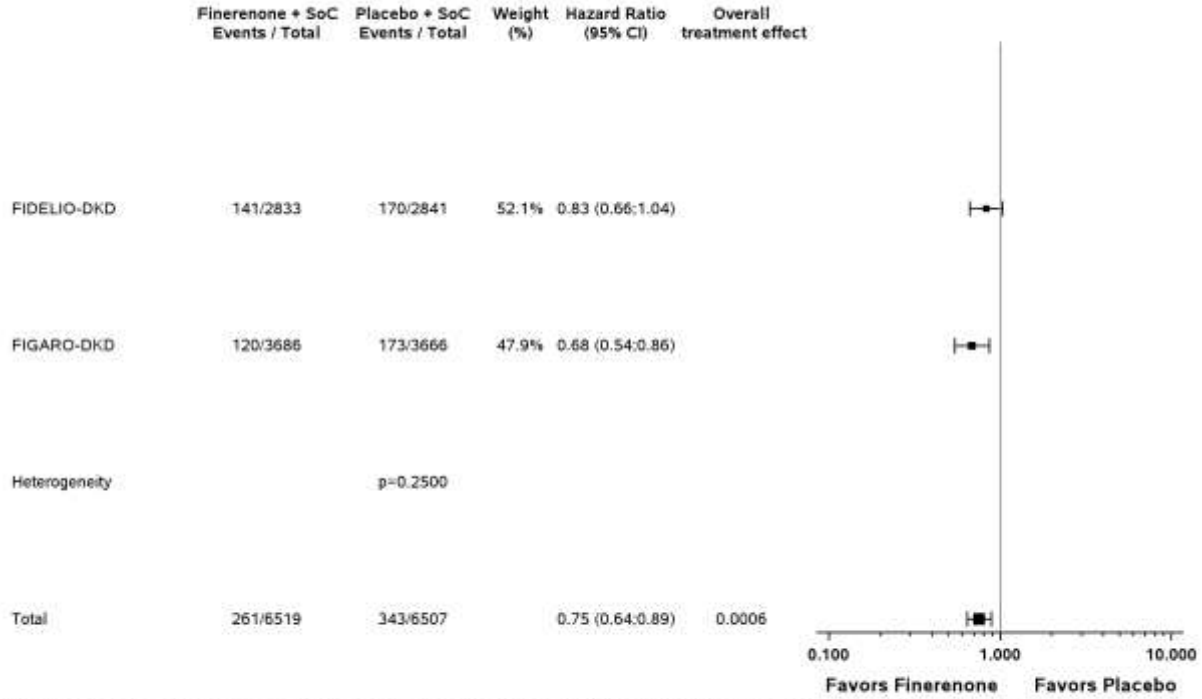
Figure 1.3.2 / 15: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Overall and study ID (full analysis set)

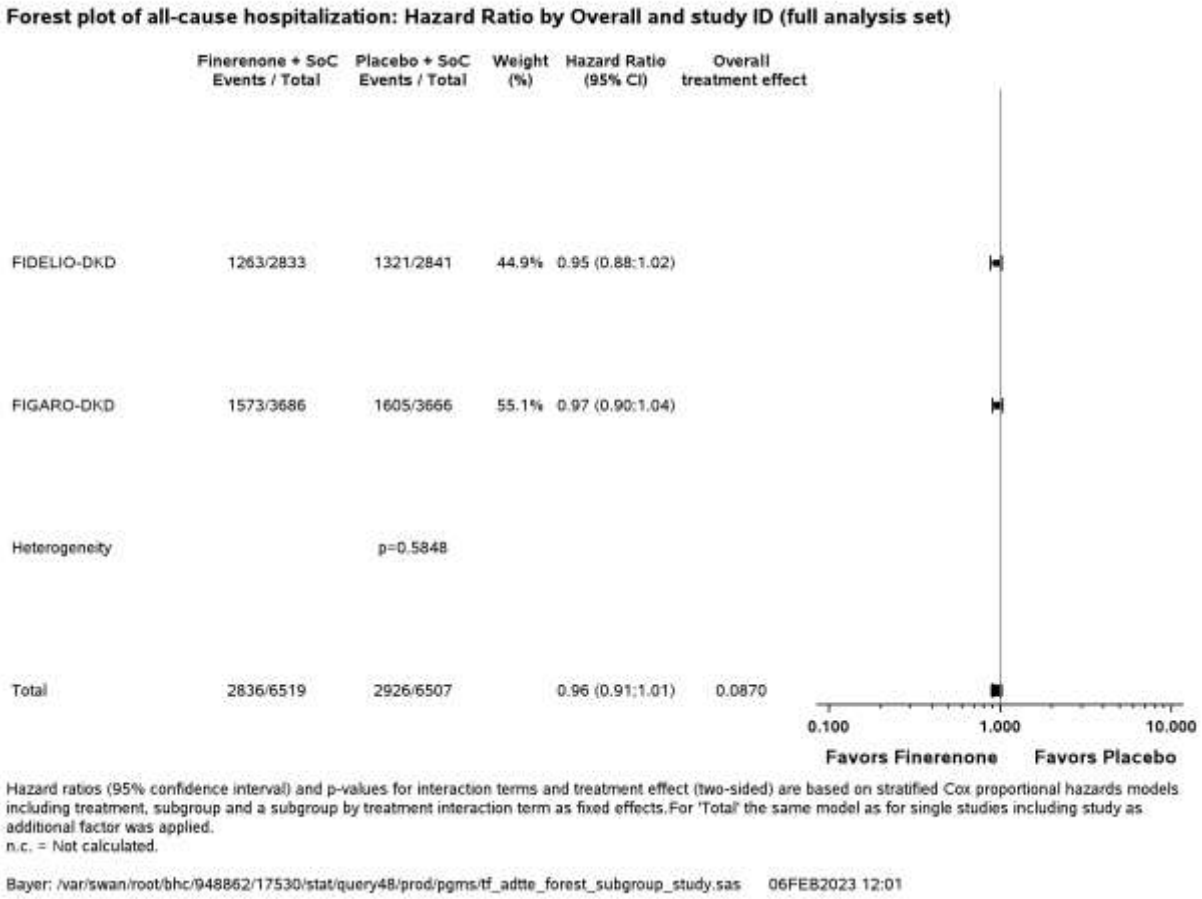
Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

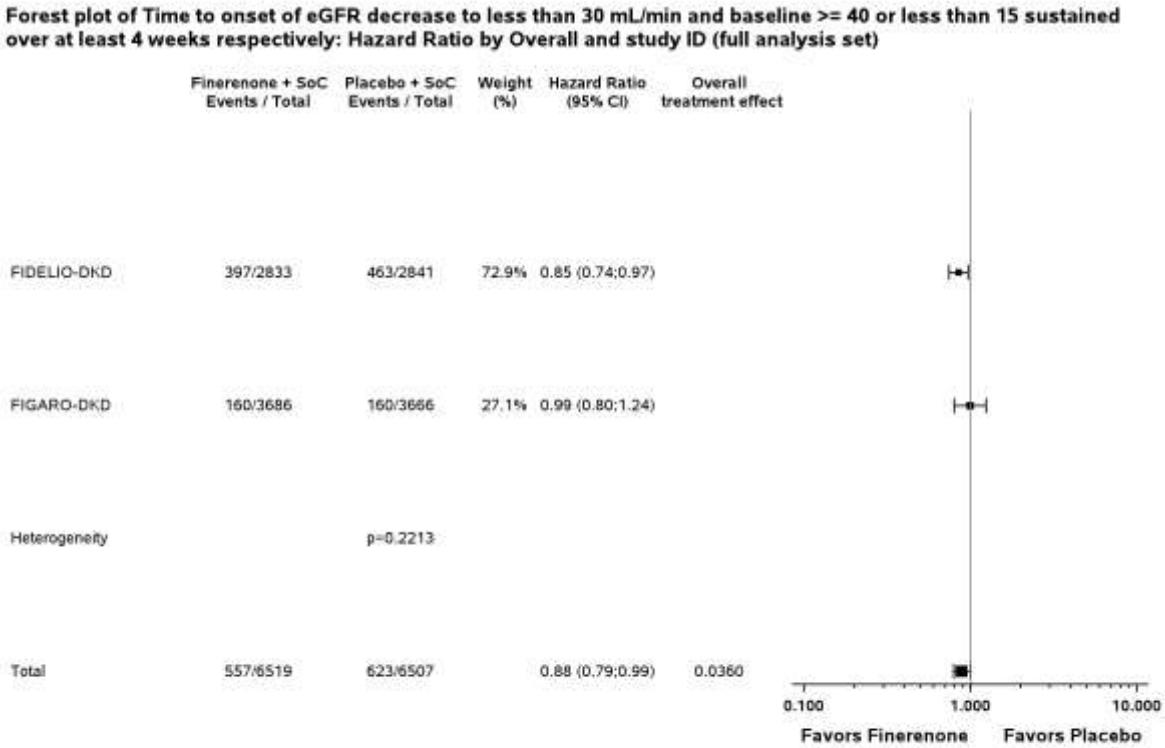
Figure 1.3.2 / 16: Forest plot of all-cause hospitalization: Hazard Ratio by Overall and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 17: Forest plot of Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively: Hazard Ratio by Overall and study ID (full analysis set)



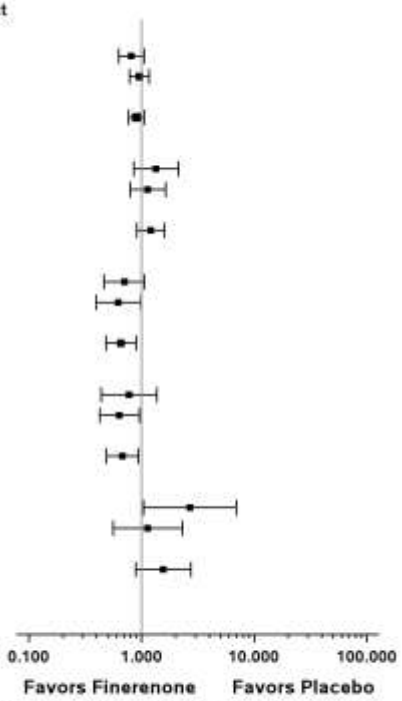
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study.sas 06FEB2023 12:01

Figure 1.3.2 / 18: Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	103/1182	126/1176	37.5%	0.81 (0.62;1.05)	
FIGARO-DKD	186/1754	193/1750	62.5%	0.95 (0.78;1.17)	
Heterogeneity		p=0.3244			
Total	289/2936	319/2926		0.90 (0.77;1.06)	0.1927
North America					
FIDELIO-DKD	42/467	32/477	38.6%	1.35 (0.85;2.13)	
FIGARO-DKD	61/559	55/548	61.4%	1.14 (0.79;1.64)	
Heterogeneity		p=0.5916			
Total	103/1026	87/1025		1.21 (0.91;1.61)	0.1935
Asia					
FIDELIO-DKD	38/790	53/789	54.6%	0.70 (0.46;1.06)	
FIGARO-DKD	30/810	48/815	45.4%	0.62 (0.39;0.98)	
Heterogeneity		p=0.7429			
Total	68/1600	101/1604		0.66 (0.48;0.89)	0.0069
Latin America					
FIDELIO-DKD	21/295	27/298	33.4%	0.77 (0.44;1.37)	
FIGARO-DKD	39/424	60/417	66.6%	0.64 (0.42;0.95)	
Heterogeneity		p=0.6357			
Total	60/719	87/715		0.68 (0.49;0.94)	0.0192
Others					
FIDELIO-DKD	15/99	6/101	35.9%	2.68 (1.04;6.92)	
FIGARO-DKD	17/139	14/136	64.1%	1.13 (0.56;2.31)	
Heterogeneity		p=0.1617			
Total	32/238	20/237		1.55 (0.89;2.73)	0.1217
Subgroup Heterogeneity		p=0.0055			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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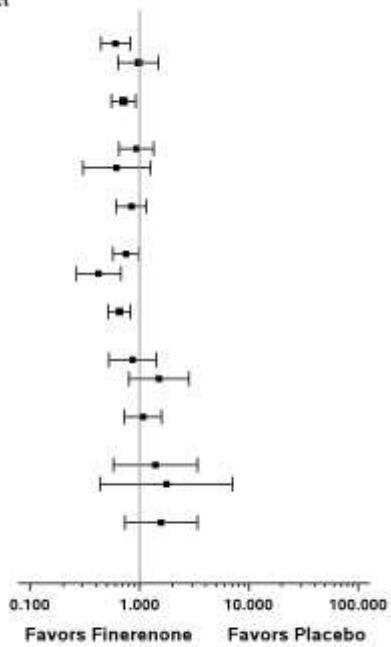
Figure 1.3.2 / 19: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	64/1182	105/1176	65.7%	0.60 (0.44;0.82)	
FIGARO-DKD	41/1754	42/1750	34.3%	0.97 (0.63;1.50)	
Heterogeneity		p=0.0827			
Total	105/2936	147/2926		0.71 (0.55;0.92)	0.0078
North America					
FIDELIO-DKD	57/467	61/477	79.6%	0.93 (0.65;1.34)	
FIGARO-DKD	12/559	21/548	20.4%	0.61 (0.30;1.25)	
Heterogeneity		p=0.3396			
Total	69/1026	82/1025		0.84 (0.61;1.16)	0.2913
Asia					
FIDELIO-DKD	91/790	118/789	74.7%	0.75 (0.57;0.98)	
FIGARO-DKD	25/810	57/815	25.3%	0.42 (0.26;0.67)	
Heterogeneity		p=0.0318			
Total	116/1600	175/1604		0.65 (0.51;0.82)	0.0003
Latin America					
FIDELIO-DKD	29/295	33/298	61.7%	0.86 (0.52;1.42)	
FIGARO-DKD	24/424	16/417	38.3%	1.51 (0.80;2.84)	
Heterogeneity		p=0.1682			
Total	53/719	49/715		1.07 (0.73;1.58)	0.7300
Others					
FIDELIO-DKD	11/99	9/101	71.5%	1.40 (0.58;3.39)	
FIGARO-DKD	6/139	3/136	28.5%	1.75 (0.43;7.10)	
Heterogeneity		p=0.7750			
Total	17/238	12/237		1.57 (0.73;3.39)	0.2428
Subgroup Heterogeneity		p=0.0692			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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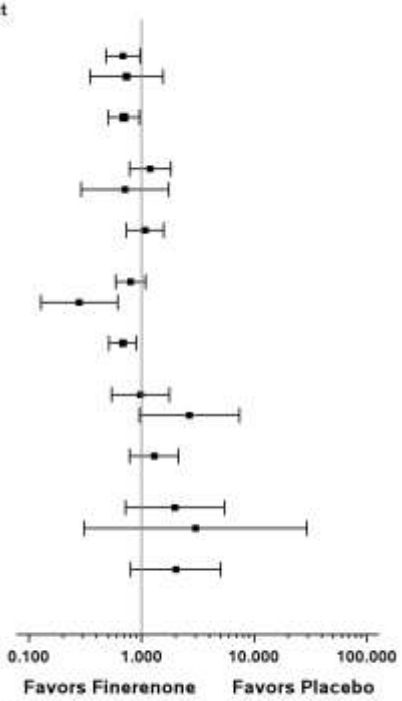
Figure 1.3.2 / 20: Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	53/1182	77/1176	82.1%	0.68 (0.48;0.97)	
FIGARO-DKD	12/1754	16/1750	17.9%	0.74 (0.35;1.56)	
Heterogeneity		p=0.8561			
Total	65/2936	93/2926		0.70 (0.51;0.96)	0.0244
North America					
FIDELIO-DKD	48/467	40/477	82.0%	1.19 (0.78;1.81)	
FIGARO-DKD	9/559	12/548	18.0%	0.71 (0.29;1.75)	
Heterogeneity		p=0.3425			
Total	57/1026	52/1025		1.07 (0.73;1.56)	0.7267
Asia					
FIDELIO-DKD	75/790	90/789	86.8%	0.80 (0.59;1.08)	
FIGARO-DKD	8/810	28/815	13.2%	0.28 (0.13;0.61)	
Heterogeneity		p=0.0138			
Total	83/1600	118/1604		0.68 (0.51;0.90)	0.0067
Latin America					
FIDELIO-DKD	22/295	22/298	74.9%	0.98 (0.54;1.77)	
FIGARO-DKD	14/424	5/417	25.1%	2.65 (0.95;7.36)	
Heterogeneity		p=0.0957			
Total	36/719	27/715		1.29 (0.79;2.13)	0.3095
Others					
FIDELIO-DKD	10/99	6/101	83.4%	1.97 (0.72;5.44)	
FIGARO-DKD	3/139	1/136	16.6%	3.01 (0.31;29.3)	
Heterogeneity		p=0.6978			
Total	13/238	7/237		2.01 (0.80;5.08)	0.1319
Subgroup Heterogeneity		p=0.0225			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.3.2 / 21: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	168/1182	194/1176	42.6%	0.84 (0.69;1.04)	
FIGARO-DKD	237/1754	248/1750	57.4%	0.95 (0.79;1.14)	
Heterogeneity		p=0.3742			
Total	405/2936	442/2926		0.90 (0.79;1.03)	0.1264
North America					
FIDELIO-DKD	73/467	93/477	48.7%	0.78 (0.58;1.07)	
FIGARO-DKD	81/559	92/548	51.3%	0.88 (0.65;1.19)	
Heterogeneity		p=0.6671			
Total	154/1026	185/1025		0.84 (0.68;1.04)	0.1044
Asia					
FIDELIO-DKD	81/790	94/789	51.0%	0.83 (0.62;1.12)	
FIGARO-DKD	76/810	93/815	49.0%	0.79 (0.58;1.06)	
Heterogeneity		p=0.9123			
Total	157/1600	187/1604		0.80 (0.65;0.99)	0.0419
Latin America					
FIDELIO-DKD	26/295	29/298	34.8%	0.90 (0.53;1.53)	
FIGARO-DKD	43/424	64/417	65.2%	0.65 (0.44;0.96)	
Heterogeneity		p=0.3638			
Total	69/719	93/715		0.72 (0.53;0.99)	0.0419
Others					
FIDELIO-DKD	19/99	10/101	37.9%	2.11 (0.98;4.54)	
FIGARO-DKD	21/139	22/136	62.1%	0.87 (0.48;1.58)	
Heterogeneity		p=0.0761			
Total	40/238	32/237		1.22 (0.76;1.94)	0.4113
Subgroup Heterogeneity		p=0.3822			

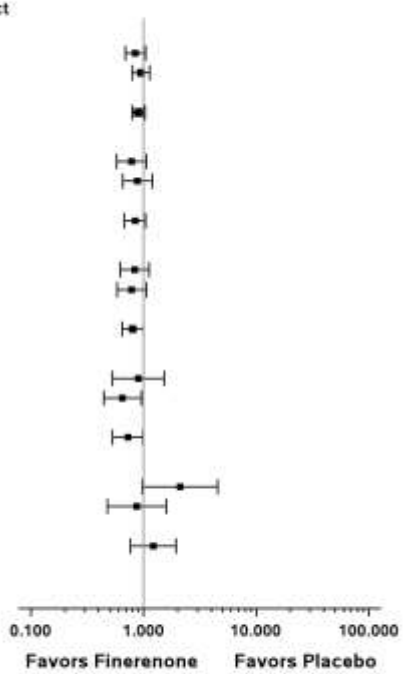

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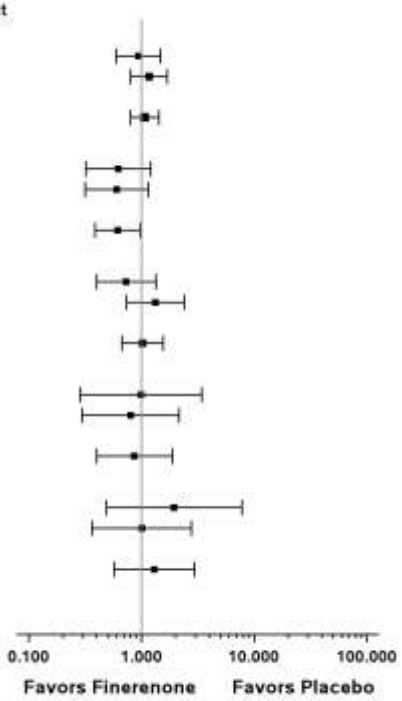
Figure 1.3.2 / 22: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	36/1182	38/1176	40.1%	0.94 (0.59;1.48)	
FIGARO-DKD	60/1754	51/1750	59.9%	1.17 (0.80;1.69)	
Heterogeneity		p=0.4563			
Total	96/2936	89/2926		1.06 (0.80;1.42)	0.6770
North America					
FIDELIO-DKD	14/467	23/477	48.1%	0.62 (0.32;1.21)	
FIGARO-DKD	15/559	25/548	51.9%	0.60 (0.32;1.14)	
Heterogeneity		p=0.9442			
Total	29/1026	48/1025		0.61 (0.39;0.97)	0.0353
Asia					
FIDELIO-DKD	18/790	24/789	48.4%	0.73 (0.40;1.35)	
FIGARO-DKD	26/810	19/815	51.6%	1.33 (0.73;2.40)	
Heterogeneity		p=0.1534			
Total	44/1600	43/1604		1.02 (0.67;1.56)	0.9316
Latin America					
FIDELIO-DKD	5/295	5/298	39.1%	0.99 (0.28;3.41)	
FIGARO-DKD	7/424	9/417	60.9%	0.80 (0.30;2.16)	
Heterogeneity		p=0.8122			
Total	12/719	14/715		0.86 (0.40;1.87)	0.7094
Others					
FIDELIO-DKD	6/99	3/101	34.9%	1.94 (0.48;7.77)	
FIGARO-DKD	8/139	7/136	65.1%	1.01 (0.36;2.78)	
Heterogeneity		p=0.3837			
Total	14/238	10/237		1.30 (0.57;2.94)	0.5314
Subgroup Heterogeneity		p=0.3099			



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n.c. = Not calculated.

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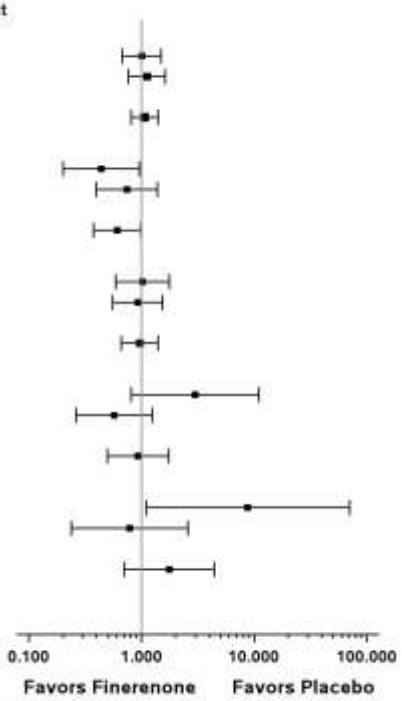
Figure 1.3.2 / 23: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	50/1182	49/1176	47.5%	1.00 (0.68;1.49)	
FIGARO-DKD	58/1754	52/1750	52.5%	1.11 (0.77;1.62)	
Heterogeneity		p=0.6979			
Total	108/2936	101/2926		1.06 (0.81;1.39)	0.6695
North America					
FIDELIO-DKD	9/467	21/477	39.2%	0.44 (0.20;0.96)	
FIGARO-DKD	17/559	23/548	60.8%	0.74 (0.39;1.38)	
Heterogeneity		p=0.3389			
Total	26/1026	44/1025		0.61 (0.37;0.99)	0.0433
Asia					
FIDELIO-DKD	26/790	25/789	46.0%	1.02 (0.59;1.77)	
FIGARO-DKD	29/810	31/815	54.0%	0.92 (0.55;1.53)	
Heterogeneity		p=0.8327			
Total	55/1600	56/1604		0.96 (0.66;1.40)	0.8346
Latin America					
FIDELIO-DKD	9/295	3/298	26.4%	2.98 (0.81;11.0)	
FIGARO-DKD	10/424	17/417	73.6%	0.57 (0.26;1.25)	
Heterogeneity		p=0.0321			
Total	19/719	20/715		0.93 (0.49;1.74)	0.8144
Others					
FIDELIO-DKD	8/99	1/101	24.6%	8.78 (1.10;70.3)	
FIGARO-DKD	5/139	6/136	75.4%	0.78 (0.24;2.57)	
Heterogeneity		p=0.0615			
Total	13/238	7/237		1.76 (0.70;4.43)	0.2206
Subgroup Heterogeneity		p=0.2328			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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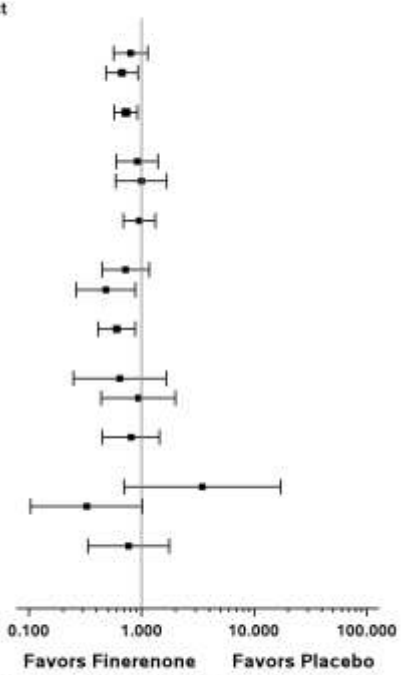
Figure 1.3.2 / 24: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	59/1182	73/1176	48.0%	0.80 (0.57;1.13)	
FIGARO-DKD	59/1754	88/1750	52.0%	0.67 (0.48;0.93)	
Heterogeneity		p=0.4543			
Total	118/2936	161/2926		0.73 (0.57;0.92)	0.0078
North America					
FIDELIO-DKD	40/467	45/477	59.8%	0.91 (0.60;1.40)	
FIGARO-DKD	28/559	29/548	40.2%	0.99 (0.59;1.67)	
Heterogeneity		p=0.8646			
Total	68/1026	74/1025		0.96 (0.69;1.33)	0.7904
Asia					
FIDELIO-DKD	29/790	39/789	61.2%	0.72 (0.45;1.16)	
FIGARO-DKD	16/810	31/815	38.8%	0.48 (0.26;0.88)	
Heterogeneity		p=0.3554			
Total	45/1600	70/1604		0.60 (0.41;0.87)	0.0071
Latin America					
FIDELIO-DKD	7/295	11/298	38.9%	0.64 (0.25;1.65)	
FIGARO-DKD	13/424	14/417	61.1%	0.93 (0.44;1.99)	
Heterogeneity		p=0.5174			
Total	20/719	25/715		0.80 (0.45;1.45)	0.4661
Others					
FIDELIO-DKD	6/99	2/101	33.8%	3.45 (0.69;17.1)	
FIGARO-DKD	4/139	11/136	66.2%	0.32 (0.10;1.02)	
Heterogeneity		p=0.0142			
Total	10/238	13/237		0.77 (0.33;1.76)	0.5286
Subgroup Heterogeneity		p=0.4693			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.3.2 / 25: Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	535/1182	539/1176	41.6%	0.97 (0.86;1.10)	
FIGARO-DKD	753/1754	754/1750	58.4%	0.98 (0.89;1.09)	
Heterogeneity		p=0.8808			
Total	1288/2936	1293/2926		0.98 (0.90;1.06)	0.5664
North America					
FIDELIO-DKD	214/467	240/477	51.2%	0.91 (0.76;1.09)	
FIGARO-DKD	227/559	205/548	48.8%	1.17 (0.97;1.42)	
Heterogeneity		p=0.0554			
Total	441/1026	445/1025		1.03 (0.90;1.17)	0.6964
Asia					
FIDELIO-DKD	376/790	406/789	48.8%	0.89 (0.78;1.03)	
FIGARO-DKD	403/810	421/815	51.2%	0.95 (0.83;1.09)	
Heterogeneity		p=0.4409			
Total	779/1600	827/1604		0.91 (0.83;1.01)	0.0764
Latin America					
FIDELIO-DKD	86/295	91/298	41.0%	0.96 (0.71;1.29)	
FIGARO-DKD	116/424	142/417	59.0%	0.78 (0.61;1.00)	
Heterogeneity		p=0.3232			
Total	202/719	233/715		0.85 (0.70;1.02)	0.0826
Others					
FIDELIO-DKD	52/99	45/101	38.4%	1.33 (0.89;1.99)	
FIGARO-DKD	74/139	83/136	61.6%	0.78 (0.57;1.07)	
Heterogeneity		p=0.0399			
Total	126/238	128/237		0.96 (0.75;1.23)	0.7470
Subgroup Heterogeneity		p=0.4332			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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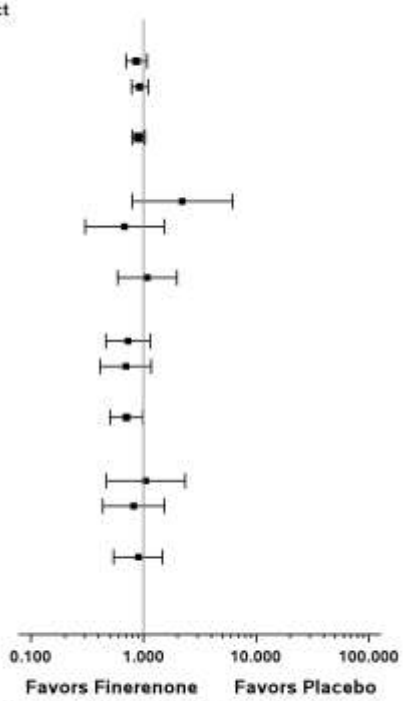
Figure 1.3.2 / 26: Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	156/1777	182/1815	37.2%	0.86 (0.70;1.07)	
FIGARO-DKD	277/2672	292/2605	62.8%	0.93 (0.79;1.09)	
Heterogeneity		p=0.5806			
Total	433/4449	474/4420		0.90 (0.79;1.03)	0.1303
Black					
FIDELIO-DKD	17/140	5/124	38.3%	2.21 (0.79;6.15)	
FIGARO-DKD	10/113	20/145	61.7%	0.68 (0.30;1.52)	
Heterogeneity		p=0.0494			
Total	27/253	25/269		1.07 (0.59;1.97)	0.8148
Asian					
FIDELIO-DKD	33/717	45/723	57.2%	0.73 (0.46;1.14)	
FIGARO-DKD	26/715	36/739	42.8%	0.69 (0.41;1.17)	
Heterogeneity		p=0.9863			
Total	59/1432	81/1462		0.70 (0.50;0.99)	0.0416
Other					
FIDELIO-DKD	13/199	12/179	38.3%	1.04 (0.46;2.33)	
FIGARO-DKD	20/186	22/177	61.7%	0.81 (0.43;1.54)	
Heterogeneity		p=0.6411			
Total	33/385	34/356		0.89 (0.54;1.47)	0.6574
Subgroup Heterogeneity		p=0.4893			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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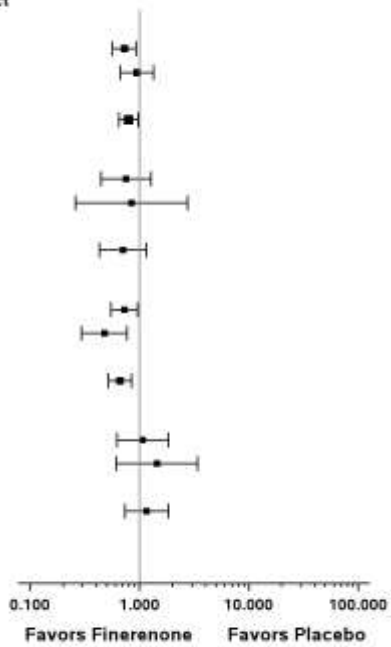
Figure 1.3.2 / 27: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	110/1777	154/1815	66.8%	0.72 (0.57;0.93)	
FIGARO-DKD	63/2672	65/2605	33.2%	0.95 (0.67;1.34)	
Heterogeneity		p=0.1987			
Total	173/4449	219/4420		0.79 (0.65;0.97)	0.0213
Black					
FIDELIO-DKD	30/140	29/124	83.3%	0.75 (0.44;1.27)	
FIGARO-DKD	5/113	10/145	16.7%	0.84 (0.26;2.74)	
Heterogeneity		p=0.8293			
Total	35/253	39/269		0.71 (0.43;1.16)	0.1652
Asian					
FIDELIO-DKD	84/717	116/723	73.9%	0.72 (0.55;0.96)	
FIGARO-DKD	25/715	54/739	26.1%	0.47 (0.29;0.76)	
Heterogeneity		p=0.1084			
Total	109/1432	170/1462		0.66 (0.52;0.84)	0.0007
Other					
FIDELIO-DKD	28/199	27/179	71.5%	1.07 (0.62;1.83)	
FIGARO-DKD	15/186	10/177	28.5%	1.44 (0.61;3.39)	
Heterogeneity		p=0.5577			
Total	43/385	37/356		1.16 (0.73;1.84)	0.5259
Subgroup Heterogeneity		p=0.1362			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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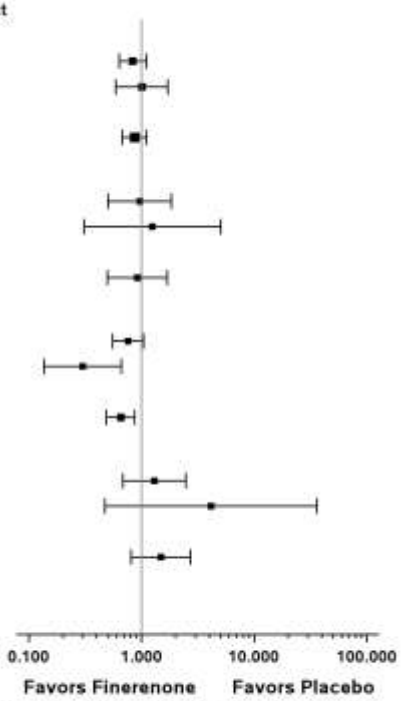
Figure 1.3.2 / 28: Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	92/1777	111/1815	78.8%	0.84 (0.63;1.10)	
FIGARO-DKD	29/2672	27/2605	21.2%	1.00 (0.59;1.71)	
Heterogeneity		p=0.5106			
Total	121/4449	138/4420		0.87 (0.68;1.11)	0.2514
Black					
FIDELIO-DKD	25/140	17/124	82.3%	0.96 (0.50;1.84)	
FIGARO-DKD	4/113	5/145	17.7%	1.25 (0.31;5.06)	
Heterogeneity		p=0.6209			
Total	29/253	22/269		0.92 (0.50;1.68)	0.7801
Asian					
FIDELIO-DKD	69/717	89/723	86.2%	0.75 (0.55;1.03)	
FIGARO-DKD	8/715	29/739	13.8%	0.30 (0.14;0.66)	
Heterogeneity		p=0.0285			
Total	77/1432	118/1462		0.65 (0.49;0.87)	0.0037
Other					
FIDELIO-DKD	22/199	18/179	91.9%	1.30 (0.68;2.46)	
FIGARO-DKD	5/186	1/177	8.1%	4.12 (0.47;35.8)	
Heterogeneity		p=0.3303			
Total	27/385	19/356		1.48 (0.81;2.72)	0.2027
Subgroup Heterogeneity		p=0.0699			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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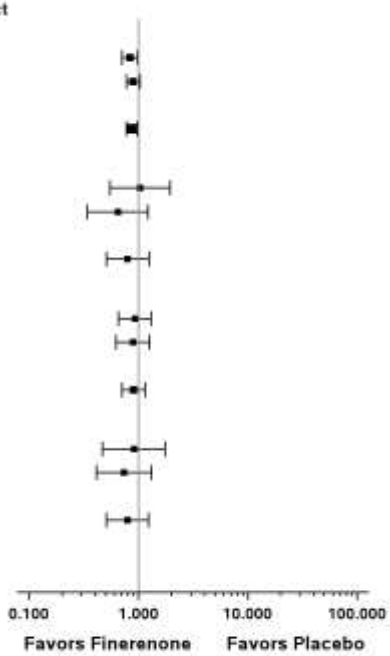
Figure 1.3.2 / 29: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	260/1777	309/1815	43.0%	0.83 (0.70;0.98)	
FIGARO-DKD	361/2672	390/2605	57.0%	0.89 (0.77;1.03)	
Heterogeneity		p=0.5331			
Total	621/4449	699/4420		0.86 (0.78;0.96)	0.0083
Black					
FIDELIO-DKD	24/140	20/124	50.4%	1.03 (0.55;1.94)	
FIGARO-DKD	15/113	33/145	49.6%	0.64 (0.34;1.22)	
Heterogeneity		p=0.3237			
Total	39/253	53/269		0.79 (0.51;1.24)	0.3106
Asian					
FIDELIO-DKD	64/717	72/723	52.0%	0.92 (0.66;1.30)	
FIGARO-DKD	58/715	67/739	48.0%	0.88 (0.62;1.26)	
Heterogeneity		p=0.9471			
Total	122/1432	139/1462		0.90 (0.70;1.15)	0.3878
Other					
FIDELIO-DKD	19/199	19/179	43.3%	0.90 (0.47;1.75)	
FIGARO-DKD	24/186	29/177	56.7%	0.73 (0.41;1.31)	
Heterogeneity		p=0.5981			
Total	43/385	48/356		0.79 (0.51;1.22)	0.2895
Subgroup Heterogeneity		p=0.9114			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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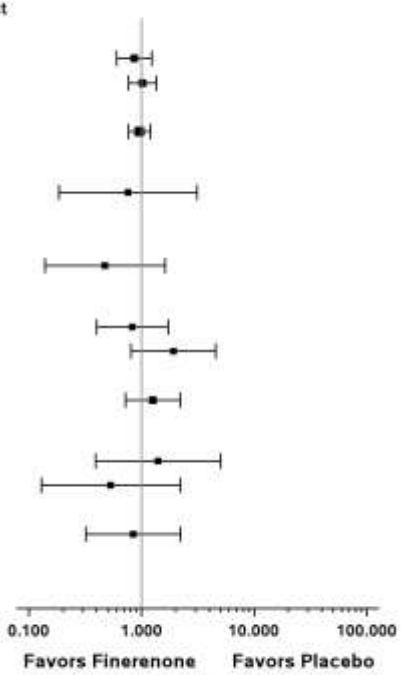
Figure 1.3.2 / 30: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	56/1777	65/1815	38.8%	0.86 (0.60;1.23)	
FIGARO-DKD	98/2672	93/2605	61.2%	1.02 (0.76;1.35)	
Heterogeneity		p=0.4924			
Total	154/4449	158/4420		0.96 (0.77;1.20)	0.7056
Black					
FIDELIO-DKD	4/140	5/124	100%	0.76 (0.18;3.13)	
FIGARO-DKD	0/113	4/145		N.C.	
Heterogeneity		p=0.9950			
Total	4/253	9/269		0.47 (0.14;1.61)	0.2226
Asian					
FIDELIO-DKD	13/717	19/723	58.3%	0.82 (0.40;1.72)	
FIGARO-DKD	15/715	8/739	41.7%	1.91 (0.80;4.54)	
Heterogeneity		p=0.1062			
Total	28/1432	27/1462		1.26 (0.72;2.21)	0.4205
Other					
FIDELIO-DKD	6/199	4/179	55.1%	1.40 (0.39;5.03)	
FIGARO-DKD	3/186	6/177	44.9%	0.53 (0.13;2.19)	
Heterogeneity		p=0.3171			
Total	9/385	10/356		0.84 (0.32;2.22)	0.7298
Subgroup Heterogeneity		p=0.5999			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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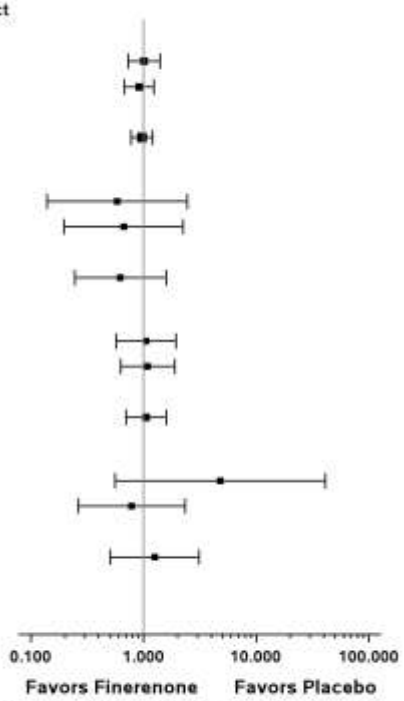
Figure 1.3.2 / 31: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	73/1777	72/1815	46.2%	1.01 (0.73;1.40)	
FIGARO-DKD	82/2672	87/2605	53.8%	0.91 (0.67;1.23)	
Heterogeneity		p=0.6201			
Total	155/4449	159/4420		0.96 (0.77;1.20)	0.7327
Black					
FIDELIO-DKD	3/140	6/124	42.1%	0.58 (0.14;2.44)	
FIGARO-DKD	4/113	10/145	57.9%	0.66 (0.20;2.25)	
Heterogeneity		p=0.6666			
Total	7/253	16/269		0.62 (0.24;1.58)	0.3140
Asian					
FIDELIO-DKD	21/717	20/723	45.0%	1.05 (0.57;1.94)	
FIGARO-DKD	26/715	25/739	55.0%	1.09 (0.62;1.90)	
Heterogeneity		p=0.8633			
Total	47/1432	45/1462		1.05 (0.70;1.59)	0.8067
Other					
FIDELIO-DKD	5/199	1/179	20.4%	4.78 (0.56;41.1)	
FIGARO-DKD	7/186	7/177	79.6%	0.79 (0.26;2.33)	
Heterogeneity		p=0.1572			
Total	12/385	8/356		1.25 (0.50;3.13)	0.6322
Subgroup Heterogeneity		p=0.3671			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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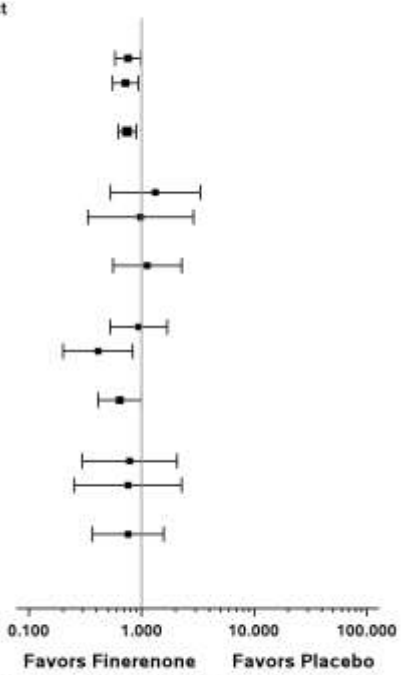
Figure 1.3.2 / 32: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	98/1777	129/1815	50.4%	0.76 (0.58;0.99)	
FIGARO-DKD	96/2672	128/2605	49.6%	0.72 (0.55;0.94)	
Heterogeneity		p=0.7367			
Total	194/4449	257/4420		0.75 (0.62;0.90)	0.0020
Black					
FIDELIO-DKD	12/140	8/124	58.2%	1.33 (0.53;3.32)	
FIGARO-DKD	6/113	10/145	41.8%	0.98 (0.33;2.89)	
Heterogeneity		p=0.6835			
Total	18/253	18/269		1.12 (0.56;2.26)	0.7457
Asian					
FIDELIO-DKD	22/717	24/723	59.8%	0.94 (0.53;1.69)	
FIGARO-DKD	11/715	26/739	40.2%	0.41 (0.20;0.84)	
Heterogeneity		p=0.0891			
Total	33/1432	50/1462		0.64 (0.41;1.00)	0.0487
Other					
FIDELIO-DKD	9/199	9/179	56.3%	0.78 (0.30;2.06)	
FIGARO-DKD	7/186	9/177	43.7%	0.76 (0.25;2.28)	
Heterogeneity		p=0.8785			
Total	16/385	18/356		0.76 (0.37;1.57)	0.4534
Subgroup Heterogeneity		p=0.7409			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 33: Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	796/1777	834/1815	42.2%	0.95 (0.87;1.05)	
FIGARO-DKD	1122/2672	1116/2605	57.8%	0.98 (0.91;1.07)	
Heterogeneity		p=0.7062			
Total	1918/4449	1950/4420		0.97 (0.91;1.04)	0.3722
Black					
FIDELIO-DKD	65/140	64/124	59.0%	0.92 (0.65;1.33)	
FIGARO-DKD	39/113	57/145	41.0%	0.95 (0.62;1.47)	
Heterogeneity		p=0.8521			
Total	104/253	121/269		0.89 (0.67;1.18)	0.4004
Asian					
FIDELIO-DKD	338/717	358/723	50.1%	0.93 (0.80;1.08)	
FIGARO-DKD	336/715	364/739	49.9%	0.95 (0.81;1.10)	
Heterogeneity		p=0.7385			
Total	674/1432	722/1462		0.93 (0.84;1.04)	0.1968
Other					
FIDELIO-DKD	64/199	65/179	49.9%	0.90 (0.62;1.28)	
FIGARO-DKD	76/186	68/177	50.1%	1.03 (0.72;1.48)	
Heterogeneity		p=0.4756			
Total	140/385	133/356		0.95 (0.73;1.23)	0.7010
Subgroup Heterogeneity		p=0.8190			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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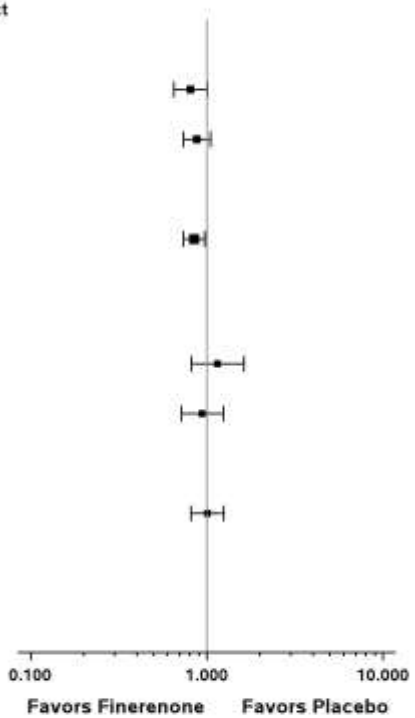
Figure 1.3.2 / 34: Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	146/1953	183/2030	39.9%	0.81 (0.65;1.01)	
FIGARO-DKD	228/2528	265/2577	60.1%	0.88 (0.73;1.05)	
Heterogeneity		p=0.5402			
Total	374/4481	448/4607		0.85 (0.74;0.97)	0.0181
Female					
FIDELIO-DKD	73/880	61/811	38.9%	1.15 (0.82;1.62)	
FIGARO-DKD	105/1158	105/1089	61.1%	0.94 (0.72;1.24)	
Heterogeneity		p=0.4293			
Total	178/2038	166/1900		1.01 (0.81;1.25)	0.9366
Subgroup Heterogeneity		p=0.1693			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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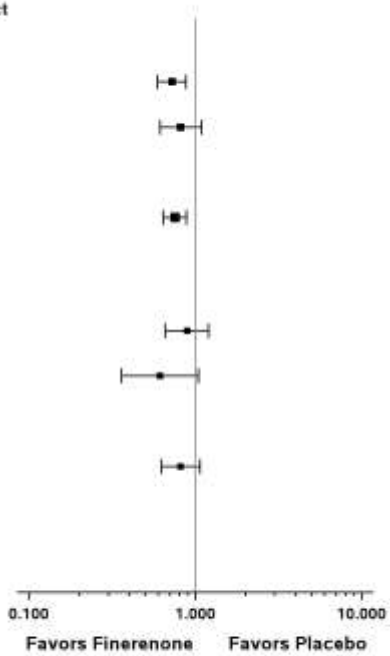
Figure 1.3.2 / 35: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	172/1953	236/2030	68.2%	0.72 (0.59;0.88)	
FIGARO-DKD	85/2528	105/2577	31.8%	0.81 (0.61;1.09)	
Heterogeneity		p=0.5223			
Total	257/4481	341/4607		0.75 (0.64;0.89)	0.0006
Female					
FIDELIO-DKD	80/880	90/811	75.5%	0.89 (0.65;1.20)	
FIGARO-DKD	23/1158	34/1089	24.5%	0.61 (0.36;1.04)	
Heterogeneity		p=0.3034			
Total	103/2038	124/1900		0.81 (0.62;1.06)	0.1266
Subgroup Heterogeneity		p=0.6256			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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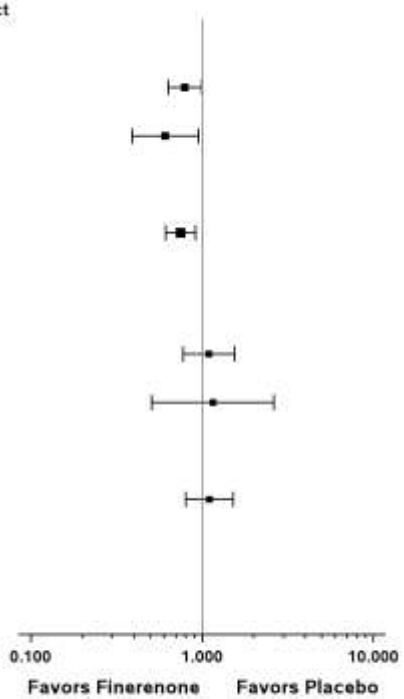
Figure 1.3.2 / 36: Forest plot of onset of kidney failure: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	139/1953	172/2030	79.9%	0.79 (0.63;0.99)	
FIGARO-DKD	32/2528	52/2577	20.1%	0.61 (0.39;0.95)	
Heterogeneity		p=0.3086			
Total	171/4481	224/4607		0.75 (0.61;0.91)	0.0043
Female					
FIDELIO-DKD	69/880	63/811	85.0%	1.09 (0.77;1.54)	
FIGARO-DKD	14/1158	10/1089	15.0%	1.15 (0.51;2.62)	
Heterogeneity		p=0.7874			
Total	83/2038	73/1900		1.10 (0.80;1.52)	0.5438
Subgroup Heterogeneity		p=0.0400			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 37: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Sex and study ID (full analysis set)

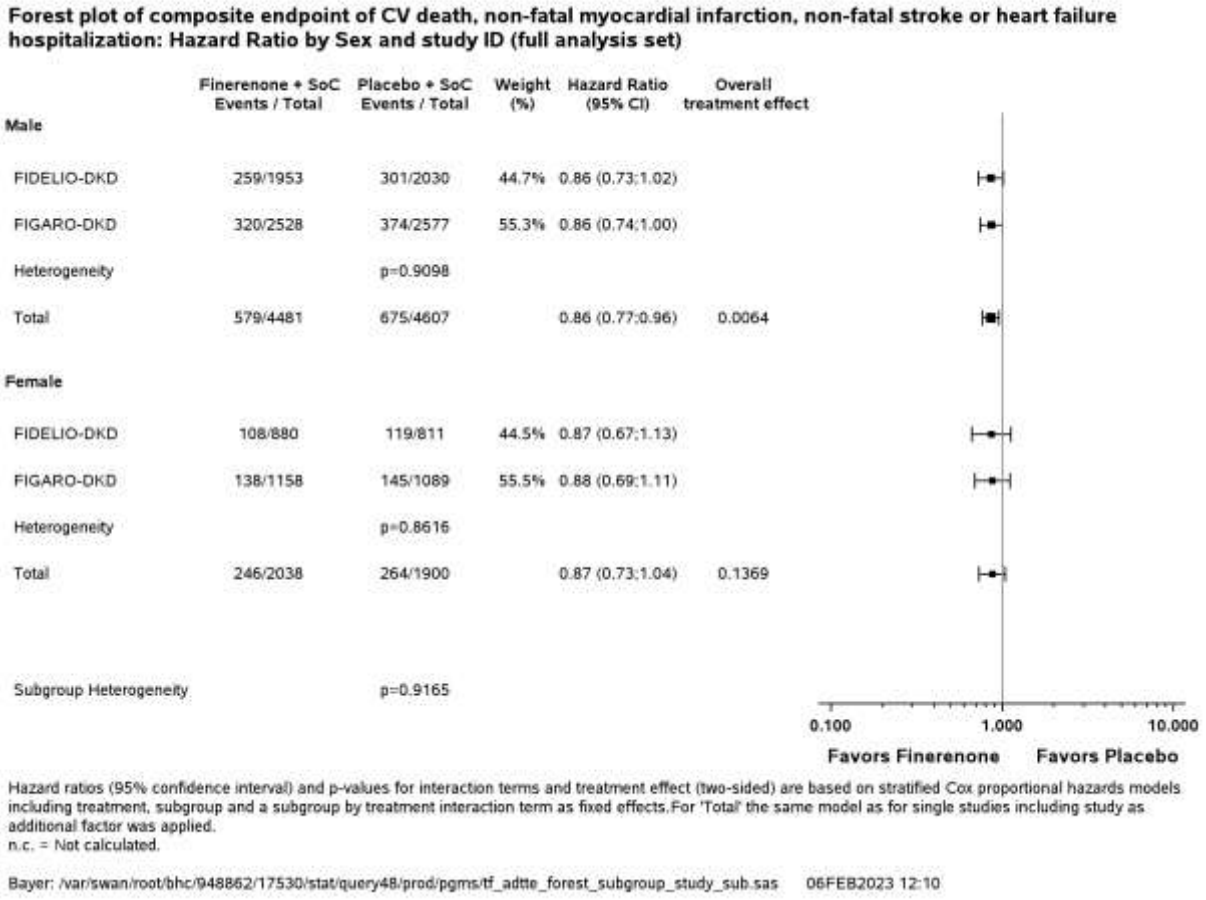
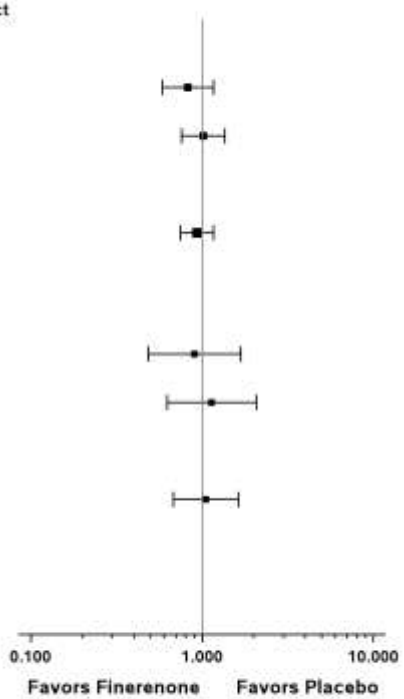


Figure 1.3.2 / 38: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	59/1953	72/2030	41.5%	0.83 (0.59;1.17)	
FIGARO-DKD	92/2528	91/2577	58.5%	1.02 (0.76;1.36)	
Heterogeneity		p=0.3561			
Total	151/4481	163/4607		0.93 (0.75;1.16)	0.5390
Female					
FIDELIO-DKD	20/880	21/811	47.8%	0.90 (0.48;1.68)	
FIGARO-DKD	24/1158	20/1089	52.2%	1.14 (0.63;2.06)	
Heterogeneity		p=0.5221			
Total	44/2038	41/1900		1.05 (0.68;1.63)	0.8188
Subgroup Heterogeneity		p=0.7748			



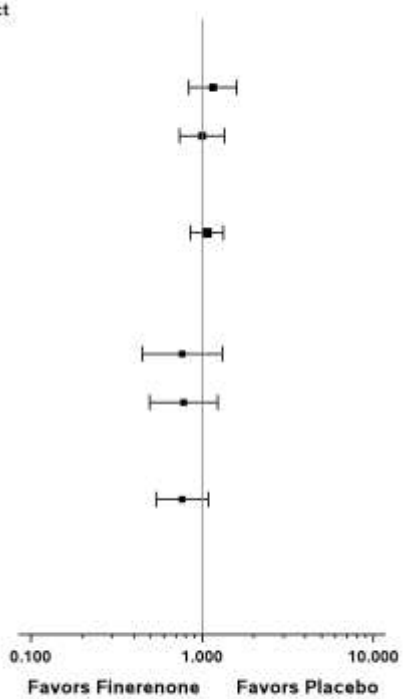
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 39: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	78/1953	69/2030	46.0%	1.15 (0.83;1.59)	
FIGARO-DKD	85/2528	88/2577	54.0%	1.00 (0.74;1.34)	
Heterogeneity		p=0.5378			
Total	163/4481	157/4607		1.06 (0.85;1.32)	0.5868
Female					
FIDELIO-DKD	24/880	30/811	42.3%	0.77 (0.45;1.31)	
FIGARO-DKD	34/1158	41/1089	57.7%	0.78 (0.49;1.24)	
Heterogeneity		p=0.8913			
Total	58/2038	71/1900		0.76 (0.54;1.09)	0.1334
Subgroup Heterogeneity		p=0.1069			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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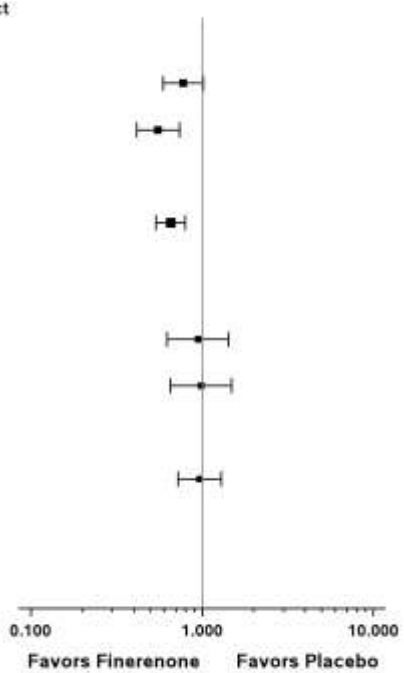
Figure 1.3.2 / 40: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	95/1953	124/2030	53.9%	0.77 (0.59;1.01)	
FIGARO-DKD	72/2528	129/2577	46.1%	0.55 (0.41;0.74)	
Heterogeneity		p=0.1151			
Total	167/4481	253/4607		0.65 (0.54;0.79)	<.0001
Female					
FIDELIO-DKD	46/880	46/811	50.3%	0.94 (0.63;1.42)	
FIGARO-DKD	48/1158	44/1089	49.7%	0.99 (0.65;1.49)	
Heterogeneity		p=0.8938			
Total	94/2038	90/1900		0.96 (0.72;1.29)	0.8101
Subgroup Heterogeneity		p=0.0197			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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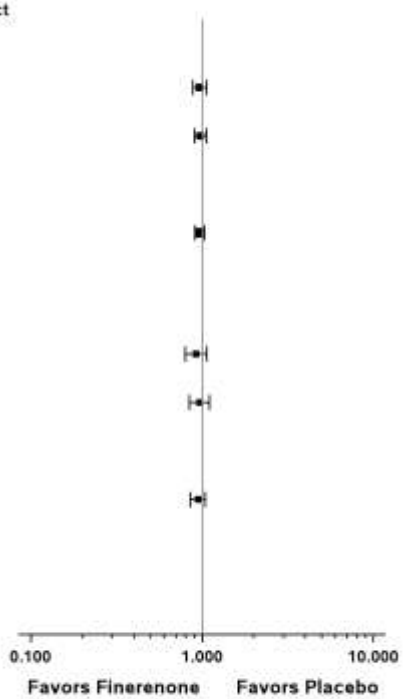
Figure 1.3.2 / 41: Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	901/1953	955/2030	44.6%	0.97 (0.88;1.06)	
FIGARO-DKD	1136/2528	1177/2577	55.4%	0.97 (0.90;1.06)	
Heterogeneity		p=0.7757			
Total	2037/4481	2132/4607		0.97 (0.91;1.03)	0.2927
Female					
FIDELIO-DKD	362/880	366/811	45.9%	0.92 (0.79;1.06)	
FIGARO-DKD	437/1158	428/1089	54.1%	0.96 (0.84;1.10)	
Heterogeneity		p=0.5884			
Total	799/2038	794/1900		0.94 (0.85;1.04)	0.2634
Subgroup Heterogeneity		p=0.5212			



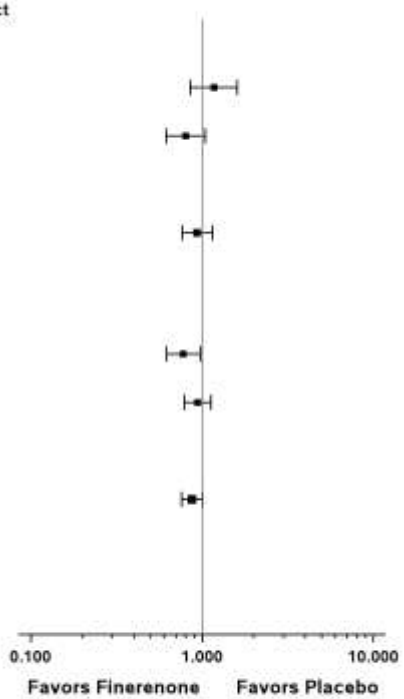
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 42: Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	85/1205	72/1174	41.0%	1.17 (0.85;1.61)	
FIGARO-DKD	102/1753	125/1757	59.0%	0.80 (0.62;1.05)	
Heterogeneity		p=0.0908			
Total	187/2958	197/2931		0.94 (0.76;1.15)	0.5218
>= 65 years					
FIDELIO-DKD	134/1628	172/1667	38.8%	0.78 (0.62;0.97)	
FIGARO-DKD	231/1933	245/1909	61.2%	0.94 (0.78;1.12)	
Heterogeneity		p=0.1785			
Total	365/3561	417/3576		0.87 (0.76;1.00)	0.0554
Subgroup Heterogeneity		p=0.5623			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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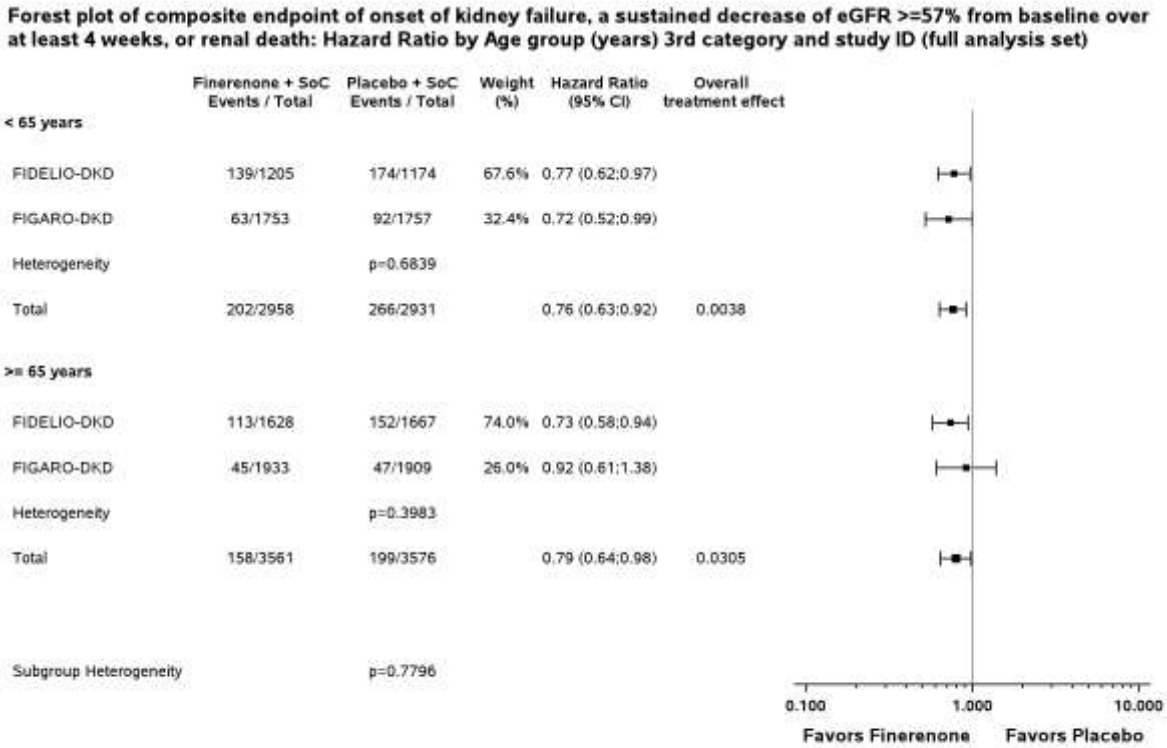
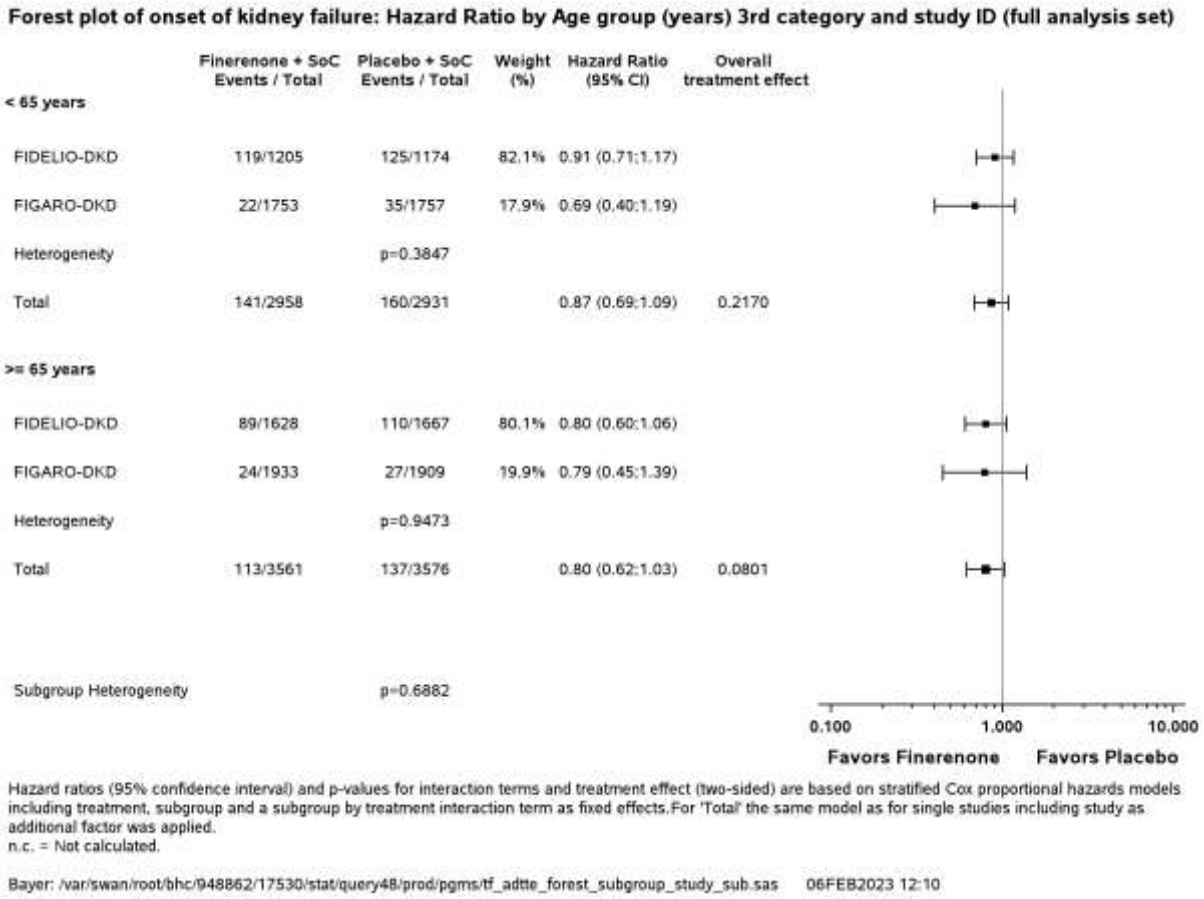
Figure 1.3.2 / 43: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 44: Forest plot of onset of kidney failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)



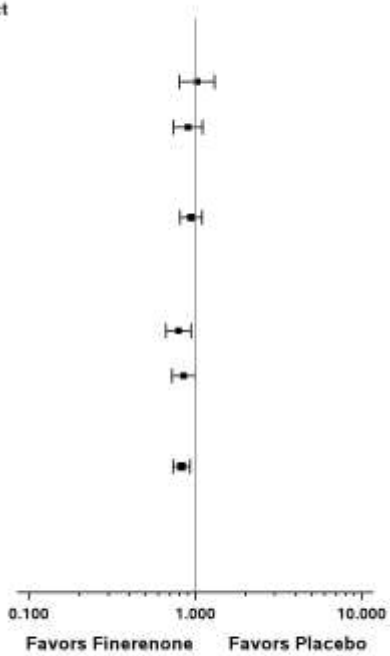
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 45: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	136/1205	131/1174	40.6%	1.02 (0.80;1.30)	
FIGARO-DKD	187/1753	206/1757	59.4%	0.90 (0.74;1.10)	
Heterogeneity		p=0.5650			
Total	323/2958	337/2931		0.94 (0.81;1.10)	0.4395
>= 65 years					
FIDELIO-DKD	231/1628	289/1667	47.0%	0.79 (0.66;0.94)	
FIGARO-DKD	271/1933	313/1909	53.0%	0.85 (0.72;1.00)	
Heterogeneity		p=0.6131			
Total	502/3561	602/3576		0.82 (0.73;0.93)	0.0014
Subgroup Heterogeneity		p=0.2018			



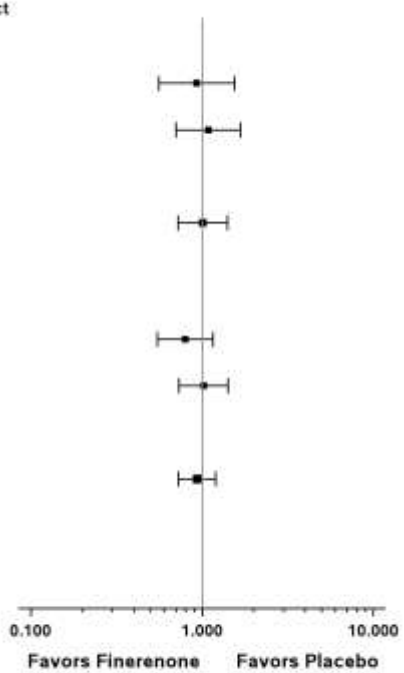
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 46: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	29/1205	31/1174	42.1%	0.93 (0.56;1.54)	
FIGARO-DKD	43/1753	41/1757	57.9%	1.09 (0.70;1.68)	
Heterogeneity		p=0.6810			
Total	72/2958	72/2931		1.01 (0.72;1.40)	0.9596
>= 65 years					
FIDELIO-DKD	50/1628	62/1667	43.6%	0.79 (0.55;1.15)	
FIGARO-DKD	73/1933	70/1909	56.4%	1.02 (0.73;1.42)	
Heterogeneity		p=0.4028			
Total	123/3561	132/3576		0.93 (0.73;1.20)	0.5863
Subgroup Heterogeneity		p=0.8208			



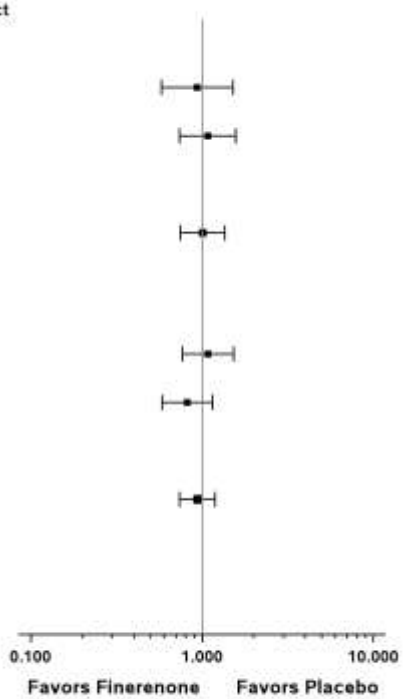
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 47: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	33/1205	35/1174	37.7%	0.94 (0.58;1.52)	
FIGARO-DKD	57/1753	54/1757	62.3%	1.08 (0.74;1.57)	
Heterogeneity		p=0.5431			
Total	90/2958	89/2931		1.01 (0.75;1.35)	0.9714
>= 65 years					
FIDELIO-DKD	69/1628	64/1667	49.6%	1.08 (0.77;1.52)	
FIGARO-DKD	62/1933	75/1909	50.4%	0.82 (0.58;1.15)	
Heterogeneity		p=0.2591			
Total	131/3561	139/3576		0.94 (0.74;1.19)	0.6027
Subgroup Heterogeneity		p=0.8170			



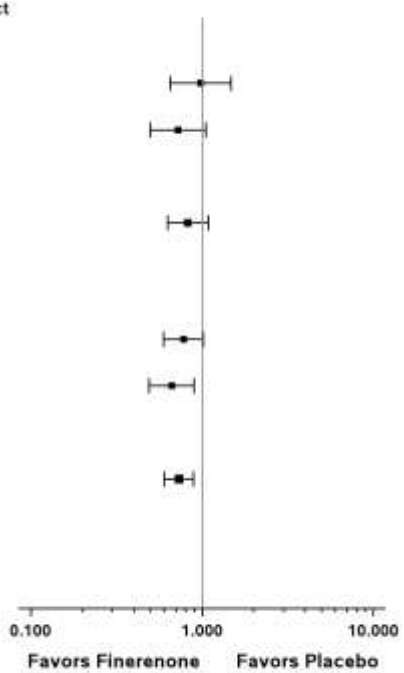
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 48: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	46/1205	47/1174	45.5%	0.98 (0.65;1.47)	
FIGARO-DKD	49/1753	67/1757	54.5%	0.72 (0.50;1.05)	
Heterogeneity		p=0.3282			
Total	95/2958	114/2931		0.83 (0.63;1.09)	0.1720
>= 65 years					
FIDELIO-DKD	95/1628	123/1667	55.8%	0.78 (0.59;1.02)	
FIGARO-DKD	71/1933	106/1909	44.2%	0.66 (0.49;0.90)	
Heterogeneity		p=0.4277			
Total	166/3561	229/3576		0.73 (0.60;0.89)	0.0020
Subgroup Heterogeneity		p=0.4885			



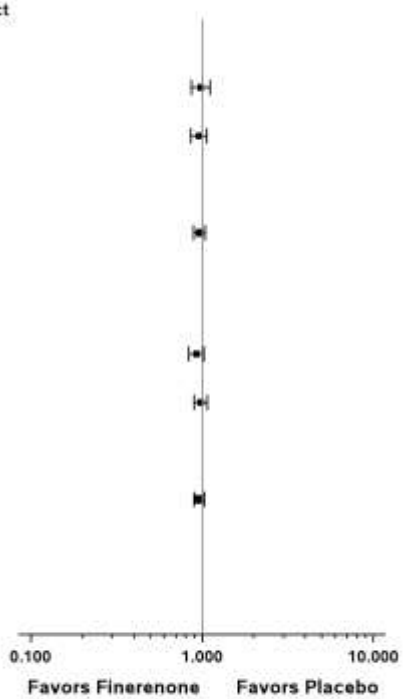
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 49: Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	512/1205	511/1174	43.3%	0.98 (0.87;1.11)	
FIGARO-DKD	658/1753	683/1757	56.7%	0.96 (0.86;1.07)	
Heterogeneity		p=0.9400			
Total	1170/2958	1194/2931		0.96 (0.89;1.05)	0.3678
>= 65 years					
FIDELIO-DKD	751/1628	810/1667	45.9%	0.93 (0.84;1.02)	
FIGARO-DKD	915/1933	922/1909	54.1%	0.98 (0.89;1.07)	
Heterogeneity		p=0.4252			
Total	1666/3561	1732/3576		0.96 (0.90;1.02)	0.2125
Subgroup Heterogeneity		p=0.9866			



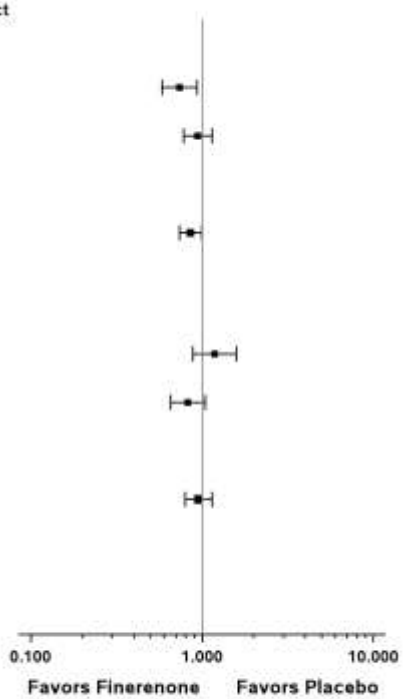
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 50: Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

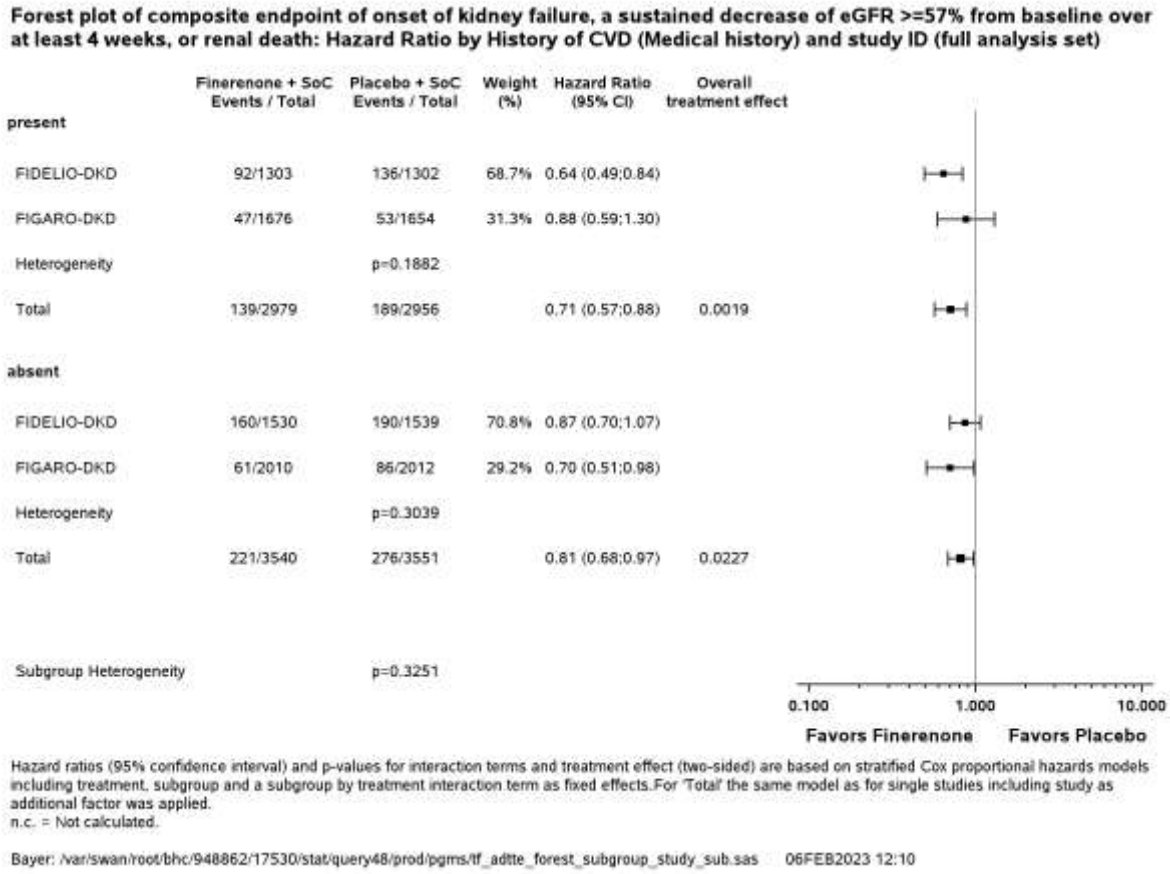
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	120/1303	160/1302	39.7%	0.74 (0.58;0.93)	
FIGARO-DKD	203/1676	212/1654	60.3%	0.94 (0.78;1.14)	
Heterogeneity		p=0.1074			
Total	323/2979	372/2956		0.85 (0.74;0.99)	0.0384
absent					
FIDELIO-DKD	99/1530	84/1539	38.9%	1.18 (0.89;1.59)	
FIGARO-DKD	130/2010	158/2012	61.1%	0.83 (0.65;1.04)	
Heterogeneity		p=0.0608			
Total	229/3540	242/3551		0.95 (0.79;1.14)	0.5791
Subgroup Heterogeneity		p=0.3752			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

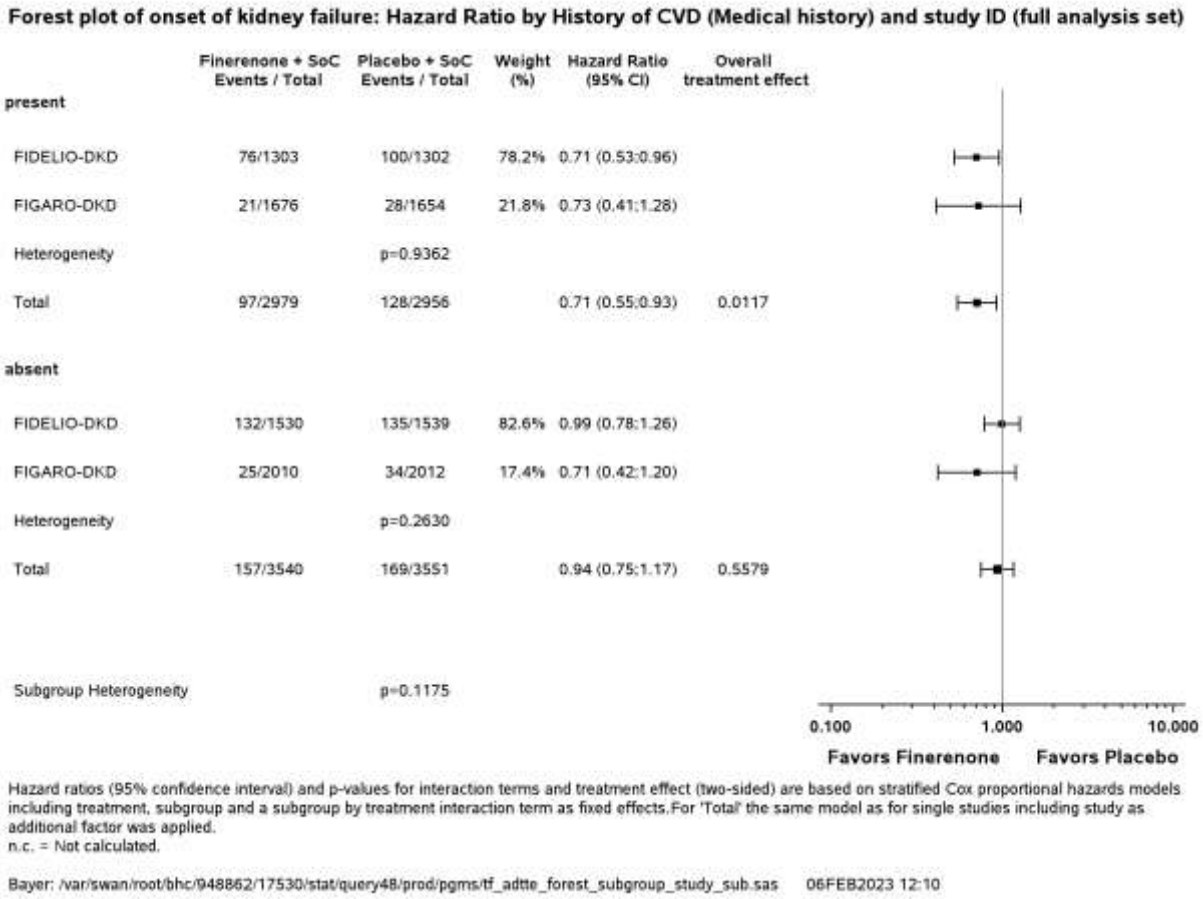
Figure 1.3.2 / 51: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 52: Forest plot of onset of kidney failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)



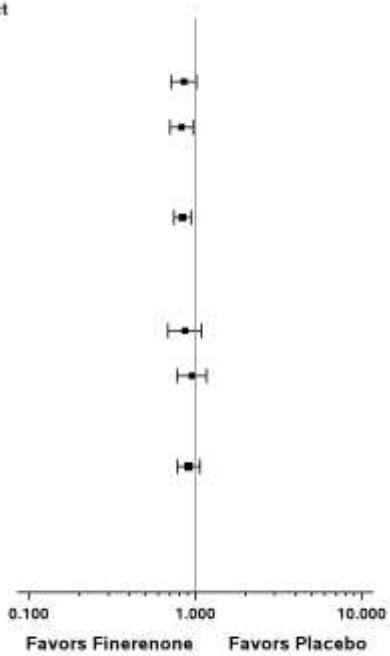
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 53: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	231/1303	263/1302	44.6%	0.85 (0.71;1.02)	
FIGARO-DKD	280/1676	332/1654	55.4%	0.82 (0.70;0.96)	
Heterogeneity		p=0.8069			
Total	511/2979	595/2956		0.83 (0.74;0.94)	0.0026
absent					
FIDELIO-DKD	136/1530	157/1539	44.3%	0.86 (0.68;1.08)	
FIGARO-DKD	178/2010	187/2012	55.7%	0.95 (0.77;1.17)	
Heterogeneity		p=0.5560			
Total	314/3540	344/3551		0.91 (0.78;1.06)	0.2288
Subgroup Heterogeneity		p=0.3750			



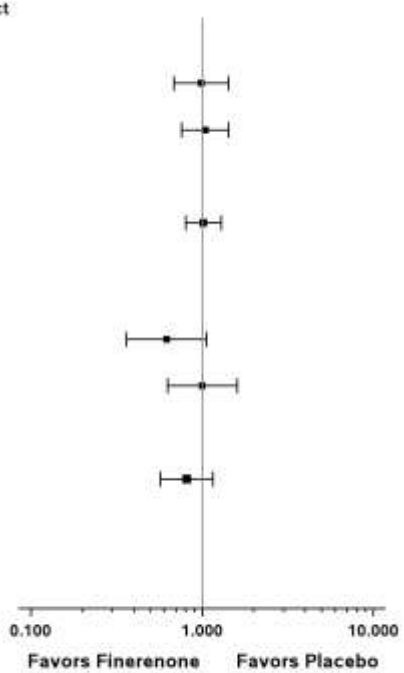
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 54: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	57/1303	59/1302	42.1%	0.99 (0.68;1.42)	
FIGARO-DKD	81/1676	76/1654	57.9%	1.04 (0.76;1.42)	
Heterogeneity		p=0.7502			
Total	138/2979	135/2956		1.02 (0.80;1.29)	0.8919
absent					
FIDELIO-DKD	22/1530	34/1539	43.2%	0.62 (0.36;1.06)	
FIGARO-DKD	35/2010	35/2012	56.8%	1.00 (0.63;1.60)	
Heterogeneity		p=0.2037			
Total	57/3540	69/3551		0.81 (0.57;1.15)	0.2435
Subgroup Heterogeneity		p=0.2997			



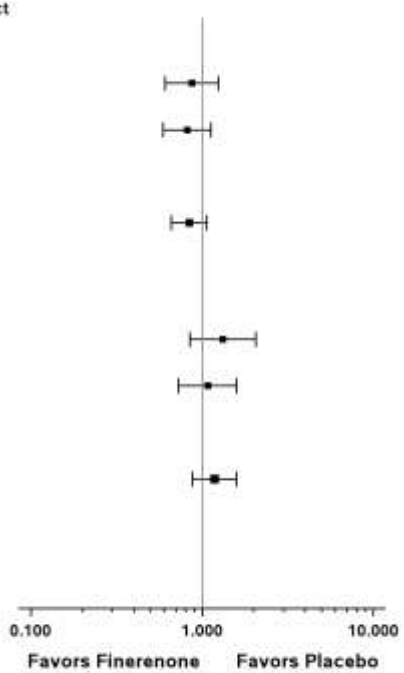
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 55: Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	57/1303	65/1302	45.2%	0.87 (0.61;1.24)	
FIGARO-DKD	67/1676	81/1654	54.8%	0.82 (0.59;1.13)	
Heterogeneity		p=0.8542			
Total	124/2979	146/2956		0.84 (0.66;1.07)	0.1520
absent					
FIDELIO-DKD	45/1530	34/1539	43.7%	1.32 (0.85;2.06)	
FIGARO-DKD	52/2010	48/2012	56.3%	1.08 (0.73;1.60)	
Heterogeneity		p=0.4773			
Total	97/3540	82/3551		1.18 (0.88;1.58)	0.2751
Subgroup Heterogeneity		p=0.0810			



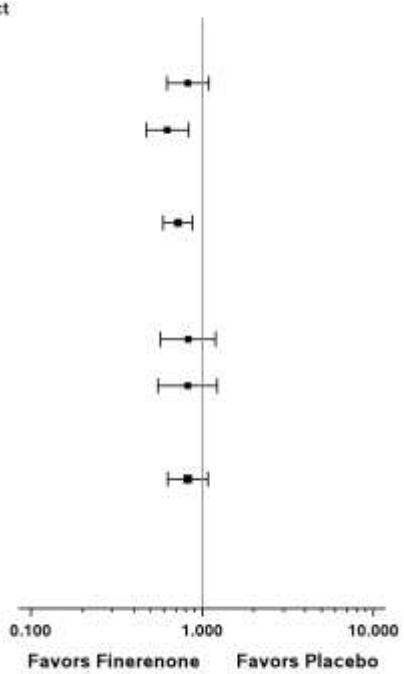
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 56: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	90/1303	108/1302	51.2%	0.83 (0.62;1.09)	
FIGARO-DKD	76/1676	120/1654	48.8%	0.62 (0.47;0.83)	
Heterogeneity		p=0.1736			
Total	166/2979	228/2956		0.72 (0.59;0.88)	0.0012
absent					
FIDELIO-DKD	51/1530	62/1539	53.7%	0.83 (0.57;1.20)	
FIGARO-DKD	44/2010	53/2012	46.3%	0.82 (0.55;1.22)	
Heterogeneity		p=0.9626			
Total	95/3540	115/3551		0.82 (0.63;1.08)	0.1632
Subgroup Heterogeneity		p=0.4303			



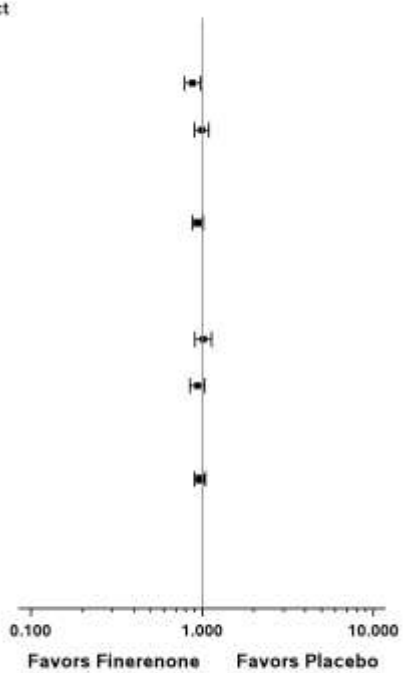
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 57: Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	646/1303	695/1302	44.7%	0.88 (0.79;0.98)	
FIGARO-DKD	829/1676	818/1654	55.3%	1.00 (0.90;1.10)	
Heterogeneity		p=0.0925			
Total	1475/2979	1513/2956		0.94 (0.88;1.01)	0.1044
absent					
FIDELIO-DKD	617/1530	626/1539	44.7%	1.01 (0.91;1.13)	
FIGARO-DKD	744/2010	787/2012	55.3%	0.94 (0.85;1.04)	
Heterogeneity		p=0.3394			
Total	1361/3540	1413/3551		0.97 (0.90;1.05)	0.4340
Subgroup Heterogeneity		p=0.5713			



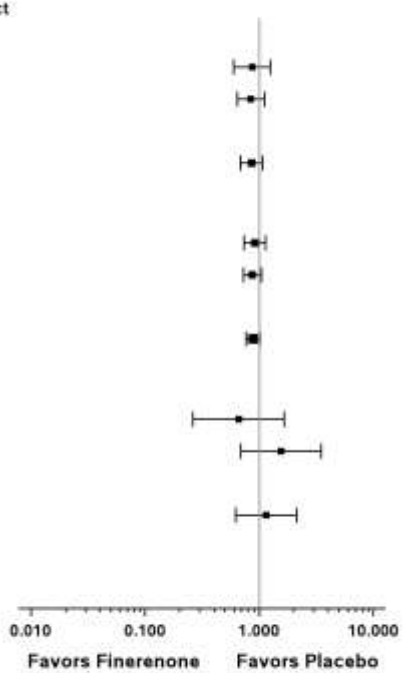
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 58: Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	54/788	61/778	35.8%	0.87 (0.60;1.25)	
FIGARO-DKD	96/1187	112/1197	64.2%	0.84 (0.64;1.11)	
Heterogeneity		p=0.9856			
Total	150/1975	173/1975		0.86 (0.69;1.07)	0.1678
130 - < 160 mmHg					
FIDELIO-DKD	155/1900	171/1922	41.3%	0.92 (0.74;1.14)	
FIGARO-DKD	218/2392	247/2355	58.7%	0.87 (0.73;1.05)	
Heterogeneity		p=0.8259			
Total	373/4292	418/4277		0.88 (0.77;1.02)	0.0862
>= 160 mmHg					
FIDELIO-DKD	8/142	12/139	44.0%	0.66 (0.26;1.65)	
FIGARO-DKD	19/107	11/114	56.0%	1.55 (0.69;3.49)	
Heterogeneity		p=0.2067			
Total	27/249	23/253		1.15 (0.62;2.13)	0.6512
Subgroup Heterogeneity		p=0.5567			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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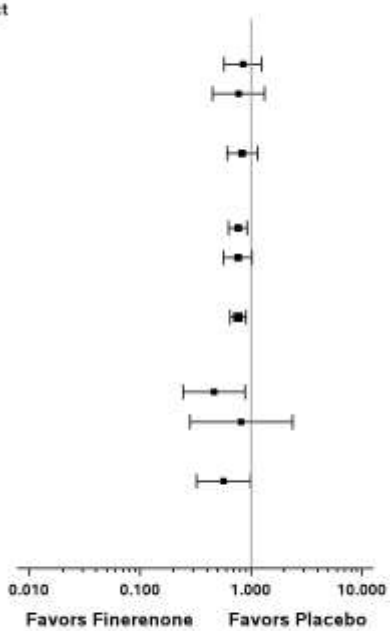
Figure 1.3.2 / 59: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	48/788	55/778	66.0%	0.85 (0.57;1.25)	
FIGARO-DKD	24/1187	31/1197	34.0%	0.78 (0.45;1.33)	
Heterogeneity		p=0.7661			
Total	72/1975	86/1975		0.83 (0.61;1.15)	0.2597
130 - < 160 mmHg					
FIDELIO-DKD	184/1900	241/1922	70.8%	0.77 (0.63;0.93)	
FIGARO-DKD	77/2392	98/2355	29.2%	0.76 (0.56;1.03)	
Heterogeneity		p=0.9823			
Total	261/4292	339/4277		0.77 (0.65;0.90)	0.0012
>= 160 mmHg					
FIDELIO-DKD	19/142	30/139	73.5%	0.46 (0.24;0.88)	
FIGARO-DKD	7/107	10/114	26.5%	0.82 (0.28;2.38)	
Heterogeneity		p=0.3243			
Total	26/249	40/253		0.57 (0.32;1.00)	0.0465
Subgroup Heterogeneity		p=0.3301			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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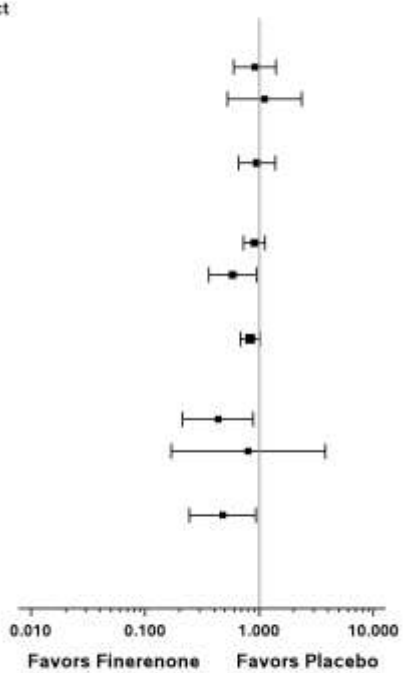
Figure 1.3.2 / 60: Forest plot of onset of kidney failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	41/788	43/778	75.2%	0.91 (0.59;1.40)	
FIGARO-DKD	15/1187	13/1197	24.8%	1.12 (0.53;2.36)	
Heterogeneity		p=0.6363			
Total	56/1975	56/1975		0.96 (0.66;1.39)	0.8173
130 - < 160 mmHg					
FIDELIO-DKD	153/1900	168/1922	82.7%	0.91 (0.73;1.13)	
FIGARO-DKD	28/2392	45/2355	17.3%	0.58 (0.36;0.95)	
Heterogeneity		p=0.1157			
Total	181/4292	213/4277		0.83 (0.68;1.02)	0.0724
>= 160 mmHg					
FIDELIO-DKD	13/142	24/139	82.6%	0.44 (0.21;0.89)	
FIGARO-DKD	3/107	4/114	17.4%	0.80 (0.17;3.78)	
Heterogeneity		p=0.4605			
Total	16/249	28/253		0.48 (0.24;0.93)	0.0276
Subgroup Heterogeneity		p=0.0777			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.3.2 / 61: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	84/788	89/778	39.6%	0.93 (0.69;1.25)	
FIGARO-DKD	126/1187	141/1197	60.4%	0.88 (0.69;1.12)	
Heterogeneity		p=0.8817			
Total	210/1975	230/1975		0.89 (0.74;1.08)	0.2421
130 - < 160 mmHg					
FIDELIO-DKD	259/1900	310/1922	46.3%	0.82 (0.70;0.97)	
FIGARO-DKD	309/2392	352/2355	53.7%	0.85 (0.73;0.99)	
Heterogeneity		p=0.6886			
Total	568/4292	662/4277		0.83 (0.75;0.93)	0.0016
>= 160 mmHg					
FIDELIO-DKD	22/142	20/139	51.9%	1.12 (0.60;2.07)	
FIGARO-DKD	23/107	26/114	48.1%	0.70 (0.37;1.33)	
Heterogeneity		p=0.1802			
Total	45/249	46/253		0.94 (0.60;1.48)	0.8013
Subgroup Heterogeneity		p=0.5596			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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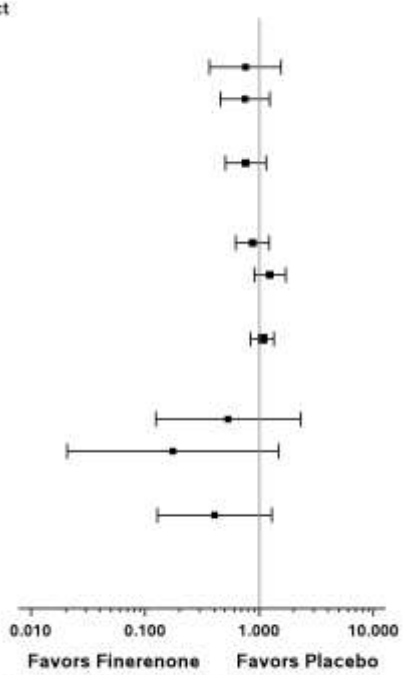
Figure 1.3.2 / 62: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	13/788	17/778	31.9%	0.75 (0.36;1.56)	
FIGARO-DKD	28/1187	36/1197	68.1%	0.75 (0.46;1.23)	
Heterogeneity		p=0.8704			
Total	41/1975	53/1975		0.76 (0.50;1.15)	0.1882
130 - < 160 mmHg					
FIDELIO-DKD	62/1900	71/1922	46.3%	0.87 (0.62;1.23)	
FIGARO-DKD	87/2392	69/2355	53.7%	1.24 (0.90;1.70)	
Heterogeneity		p=0.1359			
Total	149/4292	140/4277		1.06 (0.84;1.34)	0.6022
>= 160 mmHg					
FIDELIO-DKD	3/142	5/139	68.0%	0.53 (0.12;2.30)	
FIGARO-DKD	1/107	6/114	32.0%	0.17 (0.02;1.47)	
Heterogeneity		p=0.2866			
Total	4/249	11/253		0.41 (0.13;1.29)	0.1157
Subgroup Heterogeneity		p=0.1010			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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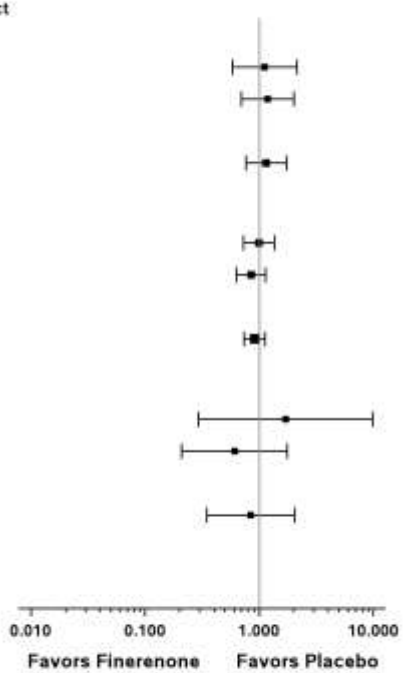
Figure 1.3.2 / 63: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	20/788	17/778	39.9%	1.12 (0.58;2.14)	
FIGARO-DKD	30/1187	26/1197	60.1%	1.18 (0.70;2.01)	
Heterogeneity		p=0.8452			
Total	50/1975	43/1975		1.15 (0.76;1.74)	0.4996
130 - < 160 mmHg					
FIDELIO-DKD	78/1900	79/1922	47.5%	1.00 (0.73;1.36)	
FIGARO-DKD	82/2392	93/2355	52.5%	0.85 (0.63;1.14)	
Heterogeneity		p=0.5165			
Total	160/4292	172/4277		0.91 (0.73;1.13)	0.3938
>= 160 mmHg					
FIDELIO-DKD	4/142	2/139	26.8%	1.70 (0.29;9.84)	
FIGARO-DKD	7/107	10/114	73.2%	0.61 (0.21;1.75)	
Heterogeneity		p=0.2594			
Total	11/249	12/253		0.84 (0.35;2.03)	0.6985
Subgroup Heterogeneity		p=0.5681			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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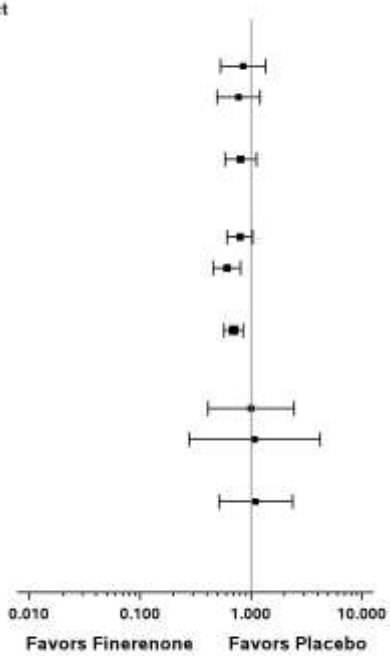
Figure 1.3.2 / 64: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	33/788	38/778	47.6%	0.85 (0.53;1.36)	
FIGARO-DKD	35/1187	45/1197	52.4%	0.77 (0.49;1.21)	
Heterogeneity		p=0.7255			
Total	68/1975	83/1975		0.81 (0.58;1.12)	0.2001
130 - < 160 mmHg					
FIDELIO-DKD	97/1900	122/1922	53.5%	0.79 (0.61;1.04)	
FIGARO-DKD	77/2392	123/2355	46.5%	0.61 (0.46;0.81)	
Heterogeneity		p=0.1923			
Total	174/4292	245/4277		0.70 (0.57;0.85)	0.0003
>= 160 mmHg					
FIDELIO-DKD	10/142	10/139	70.0%	1.00 (0.41;2.45)	
FIGARO-DKD	8/107	5/114	30.0%	1.08 (0.28;4.23)	
Heterogeneity		p=0.8427			
Total	18/249	15/253		1.11 (0.51;2.38)	0.7954
Subgroup Heterogeneity		p=0.2081			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.3.2 / 65: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	330/788	343/778	41.5%	0.95 (0.81;1.10)	
FIGARO-DKD	469/1187	480/1197	58.5%	1.00 (0.88;1.14)	
Heterogeneity		p=0.4543			
Total	799/1975	823/1975		0.98 (0.89;1.08)	0.6870
130 - < 160 mmHg					
FIDELIO-DKD	873/1900	913/1922	46.0%	0.95 (0.87;1.05)	
FIGARO-DKD	1048/2392	1061/2355	54.0%	0.95 (0.87;1.04)	
Heterogeneity		p=0.9246			
Total	1921/4292	1974/4277		0.95 (0.89;1.01)	0.0997
>= 160 mmHg					
FIDELIO-DKD	58/142	63/139	55.2%	0.94 (0.65;1.36)	
FIGARO-DKD	56/107	64/114	44.8%	1.28 (0.85;1.93)	
Heterogeneity		p=0.2633			
Total	114/249	127/253		1.08 (0.82;1.44)	0.5717
Subgroup Heterogeneity		p=0.7680			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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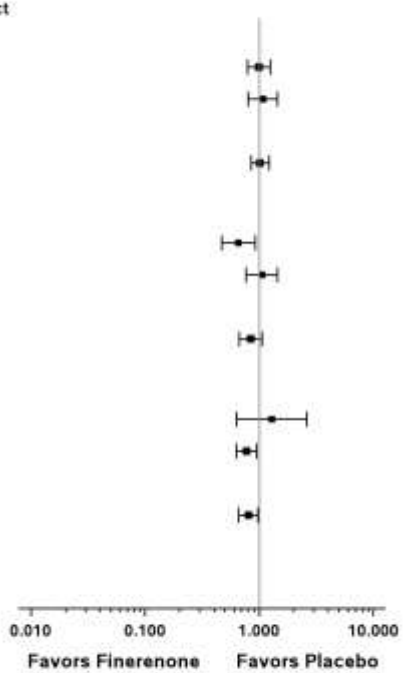
Figure 1.3.2 / 66: Forest plot of all-cause mortality: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	145/1558	145/1546	62.9%	0.99 (0.79;1.25)	
FIGARO-DKD	90/641	82/629	37.1%	1.07 (0.80;1.45)	
Heterogeneity		p=0.6171			
Total	235/2199	227/2175		1.02 (0.85;1.22)	0.8661
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	56/1062	85/1071	46.7%	0.66 (0.47;0.92)	
FIGARO-DKD	78/728	77/740	53.3%	1.05 (0.77;1.44)	
Heterogeneity		p=0.0481			
Total	134/1790	162/1811		0.84 (0.67;1.06)	0.1478
>= 60 mL/min/1.73m2					
FIDELIO-DKD	17/210	14/222	7.7%	1.29 (0.64;2.62)	
FIGARO-DKD	165/2315	210/2292	92.3%	0.77 (0.63;0.95)	
Heterogeneity		p=0.1939			
Total	182/2525	224/2514		0.80 (0.66;0.98)	0.0278
Subgroup Heterogeneity		p=0.1938			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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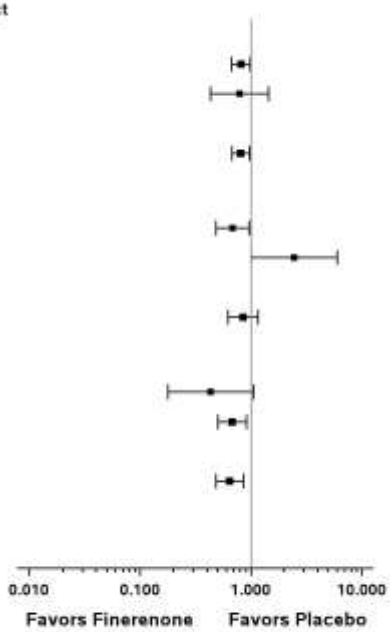
Figure 1.3.2 / 67: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	190/1558	228/1546	90.7%	0.81 (0.67;0.99)	
FIGARO-DKD	19/641	24/629	9.3%	0.79 (0.43;1.44)	
Heterogeneity		p=0.9506			
Total	209/2199	252/2175		0.81 (0.67;0.97)	0.0237
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	55/1062	82/1071	87.3%	0.68 (0.48;0.96)	
FIGARO-DKD	16/728	8/740	12.7%	2.45 (1.00;6.01)	
Heterogeneity		p=0.0112			
Total	71/1790	90/1811		0.85 (0.62;1.17)	0.3146
>= 60 mL/min/1.73m2					
FIDELIO-DKD	7/210	16/222	10.1%	0.43 (0.18;1.05)	
FIGARO-DKD	73/2315	106/2292	89.9%	0.68 (0.50;0.91)	
Heterogeneity		p=0.3780			
Total	80/2525	122/2514		0.64 (0.49;0.86)	0.0022
Subgroup Heterogeneity		p=0.3458			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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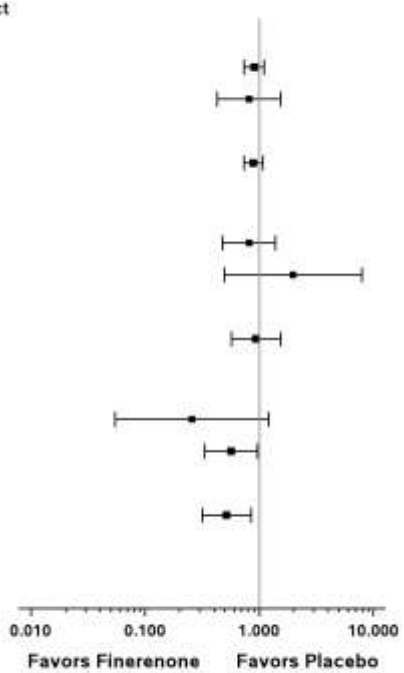
Figure 1.3.2 / 68: Forest plot of onset of kidney failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	182/1558	197/1546	91.0%	0.90 (0.74;1.10)	
FIGARO-DKD	17/641	21/629	9.0%	0.81 (0.43;1.54)	
Heterogeneity		p=0.7999			
Total	199/2199	218/2175		0.89 (0.73;1.08)	0.2319
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	24/1062	30/1071	87.0%	0.81 (0.48;1.39)	
FIGARO-DKD	7/728	3/740	13.0%	1.98 (0.49;7.94)	
Heterogeneity		p=0.2519			
Total	31/1790	33/1811		0.94 (0.57;1.54)	0.7964
>= 60 mL/min/1.73m2					
FIDELIO-DKD	2/210	8/222	10.3%	0.26 (0.05;1.20)	
FIGARO-DKD	22/2315	38/2292	89.7%	0.57 (0.33;0.96)	
Heterogeneity		p=0.3609			
Total	24/2525	46/2514		0.52 (0.32;0.85)	0.0079
Subgroup Heterogeneity		p=0.1222			



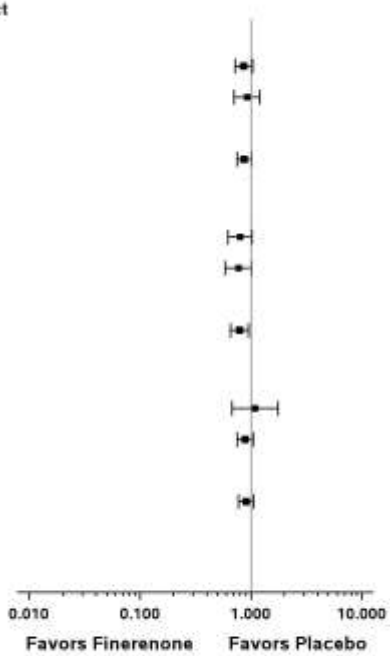
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 69: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	220/1558	248/1546	68.4%	0.86 (0.72;1.03)	
FIGARO-DKD	105/641	111/629	31.6%	0.92 (0.70;1.20)	
Heterogeneity		p=0.6160			
Total	325/2199	359/2175		0.87 (0.75;1.01)	0.0686
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	112/1062	139/1071	54.9%	0.80 (0.62;1.02)	
FIGARO-DKD	92/728	117/740	45.1%	0.77 (0.59;1.02)	
Heterogeneity		p=0.8366			
Total	204/1790	256/1811		0.79 (0.66;0.95)	0.0122
>= 60 mL/min/1.73m2					
FIDELIO-DKD	34/210	33/222	10.9%	1.09 (0.68;1.76)	
FIGARO-DKD	261/2315	290/2292	89.1%	0.89 (0.75;1.05)	
Heterogeneity		p=0.4724			
Total	295/2525	323/2514		0.91 (0.77;1.06)	0.2231
Subgroup Heterogeneity		p=0.5506			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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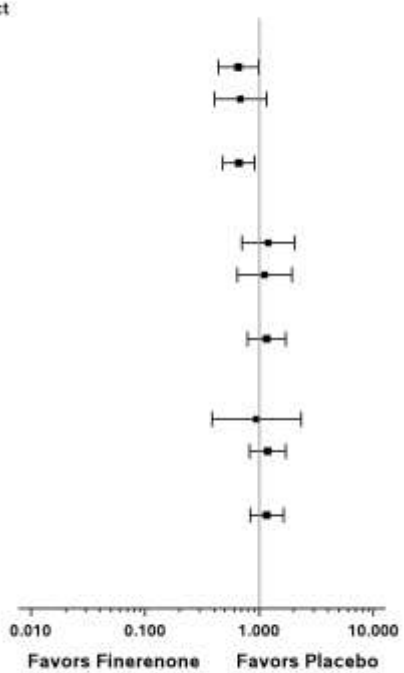
Figure 1.3.2 / 70: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	39/1558	58/1546	62.5%	0.66 (0.44;0.99)	
FIGARO-DKD	24/641	34/629	37.5%	0.69 (0.41;1.16)	
Heterogeneity		p=0.8852			
Total	63/2199	92/2175		0.66 (0.48;0.91)	0.0118
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	30/1062	25/1071	51.8%	1.19 (0.70;2.03)	
FIGARO-DKD	28/728	24/740	48.2%	1.11 (0.64;1.93)	
Heterogeneity		p=0.8254			
Total	58/1790	49/1811		1.16 (0.79;1.71)	0.4366
>= 60 mL/min/1.73m2					
FIDELIO-DKD	9/210	10/222	14.0%	0.95 (0.38;2.33)	
FIGARO-DKD	64/2315	53/2292	86.0%	1.19 (0.83;1.71)	
Heterogeneity		p=0.6092			
Total	73/2525	63/2514		1.17 (0.83;1.64)	0.3745
Subgroup Heterogeneity		p=0.0226			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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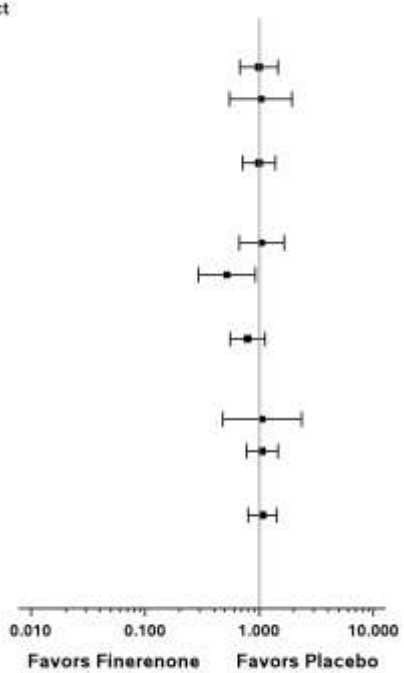
Figure 1.3.2 / 71: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	52/1558	51/1546	72.6%	1.00 (0.68;1.47)	
FIGARO-DKD	20/641	19/629	27.4%	1.03 (0.55;1.93)	
Heterogeneity		p=0.9066			
Total	72/2199	70/2175		0.99 (0.71;1.38)	0.9705
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	38/1062	36/1071	60.9%	1.05 (0.67;1.66)	
FIGARO-DKD	18/728	35/740	39.1%	0.52 (0.30;0.92)	
Heterogeneity		p=0.0591			
Total	56/1790	71/1811		0.79 (0.56;1.12)	0.1893
>= 60 mL/min/1.73m2					
FIDELIO-DKD	12/210	12/222	13.4%	1.06 (0.48;2.36)	
FIGARO-DKD	81/2315	75/2292	86.6%	1.06 (0.78;1.45)	
Heterogeneity		p=0.9823			
Total	93/2525	87/2514		1.07 (0.80;1.44)	0.6441
Subgroup Heterogeneity		p=0.4150			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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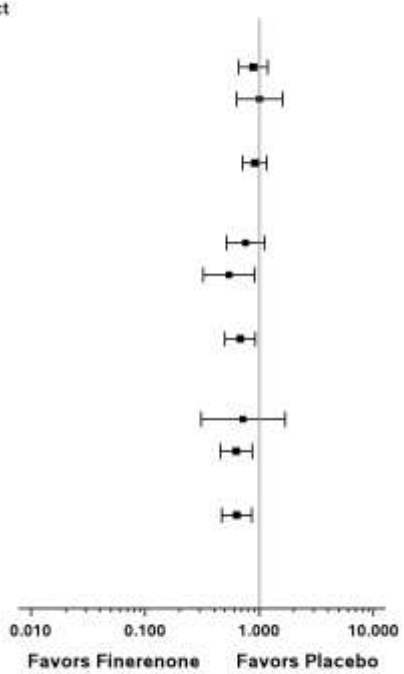
Figure 1.3.2 / 72: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	86/1558	96/1546	71.4%	0.88 (0.66;1.18)	
FIGARO-DKD	37/641	36/629	28.6%	1.01 (0.64;1.60)	
Heterogeneity		p=0.6154			
Total	123/2199	132/2175		0.91 (0.71;1.17)	0.4585
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	46/1062	61/1071	64.9%	0.76 (0.52;1.11)	
FIGARO-DKD	22/728	41/740	35.1%	0.54 (0.32;0.91)	
Heterogeneity		p=0.2870			
Total	68/1790	102/1811		0.68 (0.50;0.93)	0.0136
>= 60 mL/min/1.73m2					
FIDELIO-DKD	9/210	13/222	12.5%	0.72 (0.31;1.69)	
FIGARO-DKD	61/2315	96/2292	87.5%	0.63 (0.46;0.87)	
Heterogeneity		p=0.8086			
Total	70/2525	109/2514		0.64 (0.47;0.86)	0.0030
Subgroup Heterogeneity		p=0.1416			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 73: Forest plot of all-cause hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	730/1558	751/1546	69.4%	0.96 (0.87;1.06)	
FIGARO-DKD	331/641	328/629	30.6%	0.99 (0.85;1.16)	
Heterogeneity		p=0.6671			
Total	1061/2199	1079/2175		0.96 (0.88;1.05)	0.3816
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	445/1062	473/1071	56.7%	0.93 (0.82;1.06)	
FIGARO-DKD	343/728	365/740	43.3%	0.94 (0.81;1.09)	
Heterogeneity		p=0.8694			
Total	788/1790	838/1811		0.94 (0.85;1.03)	0.1798
>= 60 mL/min/1.73m2					
FIDELIO-DKD	87/210	95/222	9.1%	0.94 (0.70;1.26)	
FIGARO-DKD	899/2315	911/2292	90.9%	0.97 (0.89;1.07)	
Heterogeneity		p=0.8108			
Total	986/2525	1006/2514		0.97 (0.89;1.06)	0.5039
Subgroup Heterogeneity		p=0.8008			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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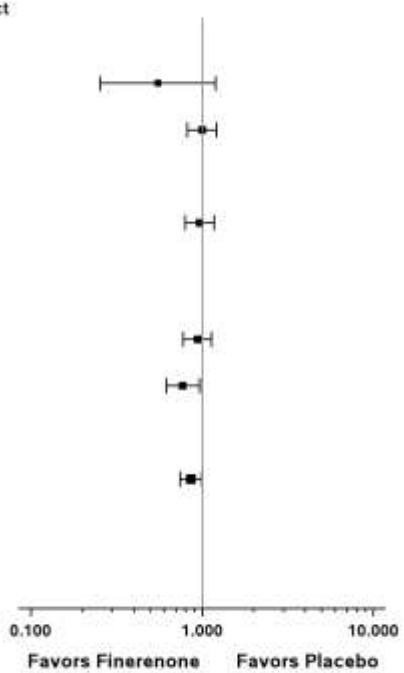
Figure 1.3.2 / 74: Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	10/215	22/228	6.2%	0.55 (0.25;1.20)	
FIGARO-DKD	197/1719	193/1681	93.8%	1.00 (0.82;1.22)	
Heterogeneity		p=0.1446			
Total	207/1934	215/1909		0.97 (0.80;1.17)	0.7351
Very high albuminuria					
FIDELIO-DKD	208/2610	222/2611	58.5%	0.94 (0.78;1.13)	
FIGARO-DKD	136/1961	175/1973	41.5%	0.77 (0.62;0.97)	
Heterogeneity		p=0.2198			
Total	344/4571	397/4584		0.86 (0.74;0.99)	0.0376
Subgroup Heterogeneity		p=0.4074			



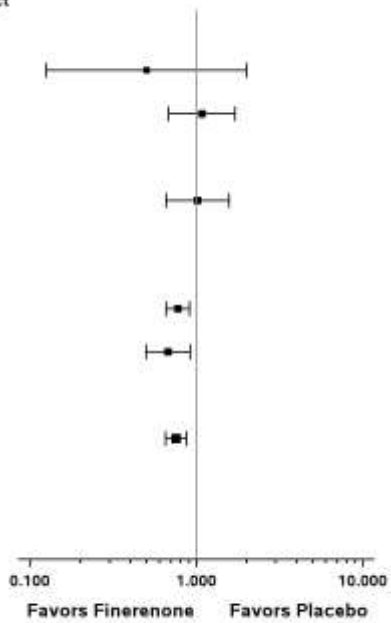
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 75: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	3/215	6/228	9.9%	0.50 (0.12;2.00)	
FIGARO-DKD	38/1719	35/1681	90.1%	1.08 (0.68;1.71)	
Heterogeneity		p=0.2771			
Total	41/1934	41/1909		1.01 (0.65;1.56)	0.9616
Very high albuminuria					
FIDELIO-DKD	249/2610	320/2611	77.4%	0.77 (0.65;0.91)	
FIGARO-DKD	70/1961	104/1973	22.6%	0.67 (0.50;0.91)	
Heterogeneity		p=0.4291			
Total	319/4571	424/4584		0.75 (0.65;0.87)	0.0001
Subgroup Heterogeneity		p=0.2074			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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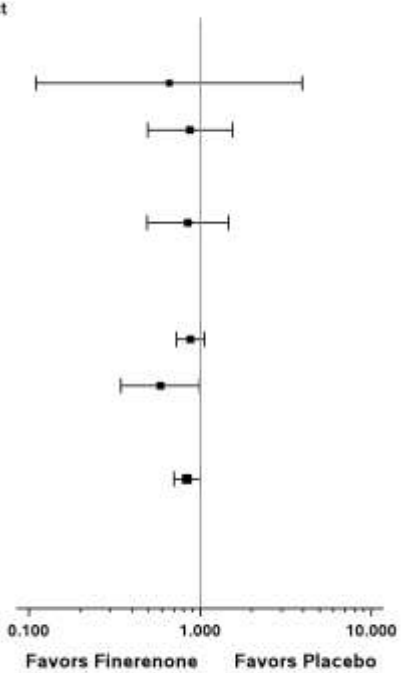
Figure 1.3.2 / 76: Forest plot of onset of kidney failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	2/215	3/228	9.3%	0.66 (0.11;3.95)	
FIGARO-DKD	23/1719	25/1681	90.7%	0.87 (0.49;1.55)	
Heterogeneity		p=0.7387			
Total	25/1934	28/1909		0.85 (0.49;1.46)	0.5472
Very high albuminuria					
FIDELIO-DKD	206/2610	232/2611	88.8%	0.88 (0.73;1.06)	
FIGARO-DKD	23/1961	37/1973	11.2%	0.58 (0.34;0.99)	
Heterogeneity		p=0.1602			
Total	229/4571	269/4584		0.84 (0.70;1.00)	0.0473
Subgroup Heterogeneity		p=0.9783			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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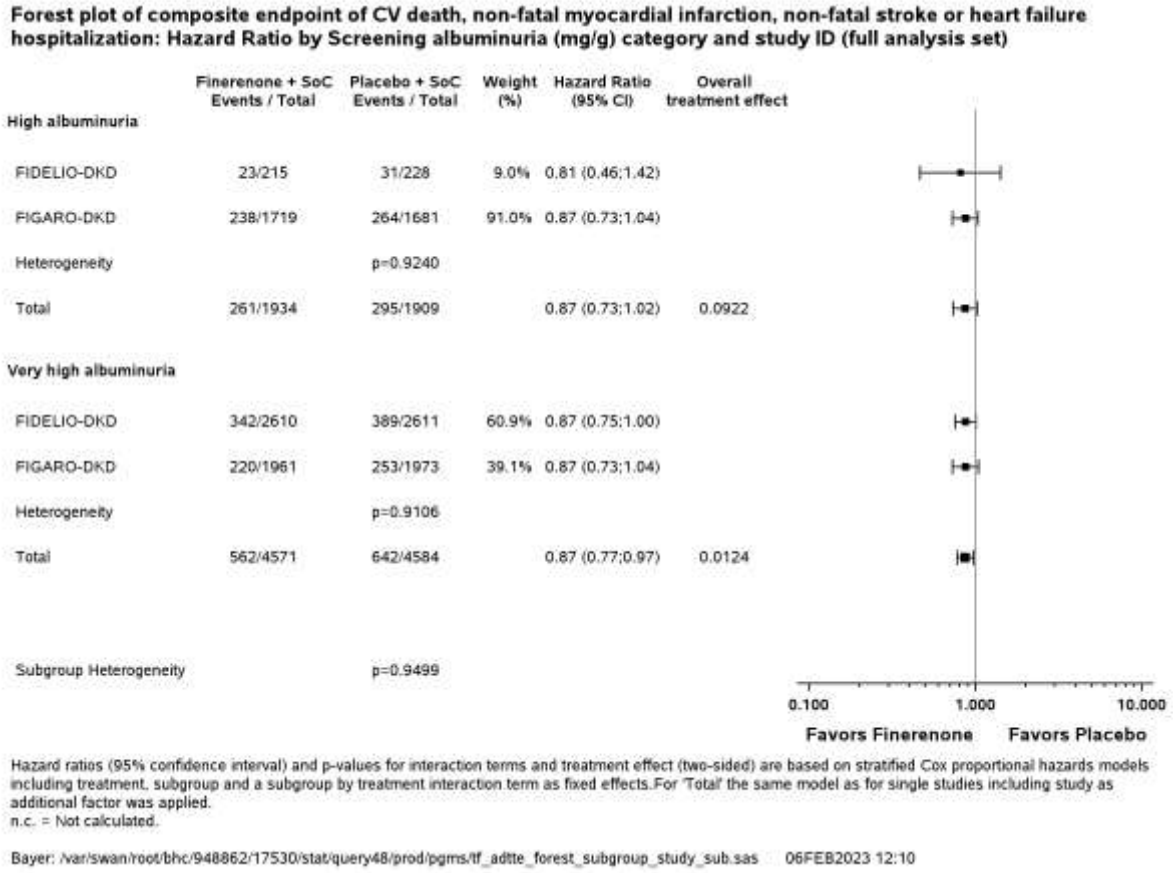
Figure 1.3.2 / 77: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)



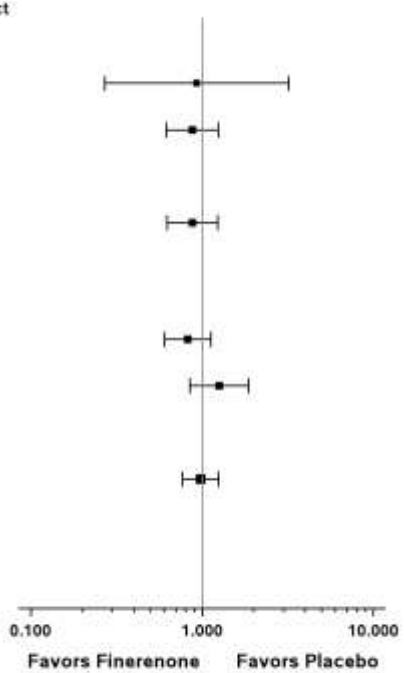
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 78: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	5/215	5/228	7.4%	0.93 (0.27;3.21)	
FIGARO-DKD	60/1719	66/1681	92.6%	0.87 (0.62;1.24)	
Heterogeneity		p=0.8257			
Total	65/1934	71/1909		0.88 (0.63;1.23)	0.4468
Very high albuminuria					
FIDELIO-DKD	73/2610	88/2611	61.5%	0.82 (0.60;1.13)	
FIGARO-DKD	56/1961	45/1973	38.5%	1.26 (0.85;1.86)	
Heterogeneity		p=0.0956			
Total	129/4571	133/4584		0.98 (0.77;1.25)	0.8569
Subgroup Heterogeneity		p=0.6494			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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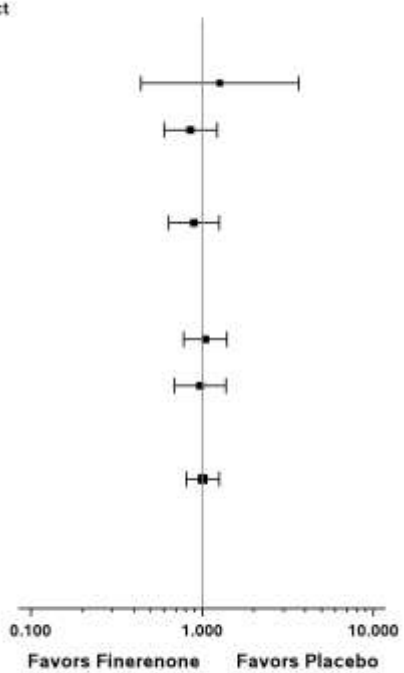
Figure 1.3.2 / 79: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	8/215	9/228	10.3%	1.27 (0.44;3.66)	
FIGARO-DKD	56/1719	64/1681	89.7%	0.85 (0.60;1.22)	
Heterogeneity		p=0.5352			
Total	64/1934	73/1909		0.89 (0.64;1.25)	0.5132
Very high albuminuria					
FIDELIO-DKD	94/2610	90/2611	59.0%	1.04 (0.78;1.39)	
FIGARO-DKD	63/1961	65/1973	41.0%	0.97 (0.69;1.37)	
Heterogeneity		p=0.8046			
Total	157/4571	155/4584		1.01 (0.81;1.26)	0.9391
Subgroup Heterogeneity		p=0.4389			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.3.2 / 80: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

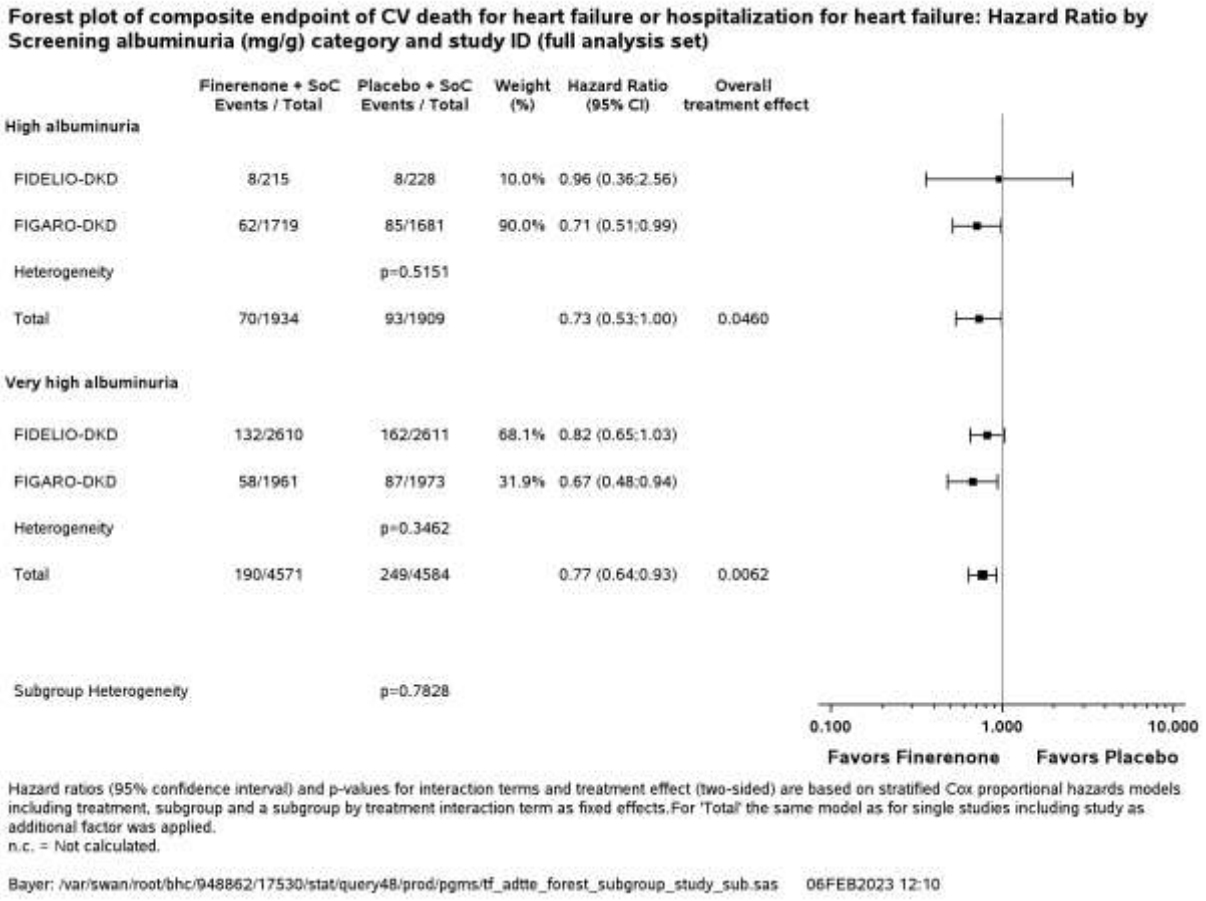

Figure 1.3.2 / 81: Forest plot of all-cause hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	102/215	117/228	10.9%	0.92 (0.70;1.21)	
FIGARO-DKD	839/1719	835/1681	89.1%	0.97 (0.88;1.07)	
Heterogeneity		p=0.7638			
Total	941/1934	952/1909		0.96 (0.88;1.05)	0.3971
Very high albuminuria					
FIDELIO-DKD	1156/2610	1203/2611	61.3%	0.95 (0.87;1.03)	
FIGARO-DKD	732/1961	764/1973	38.7%	0.97 (0.88;1.08)	
Heterogeneity		p=0.6032			
Total	1888/4571	1967/4584		0.95 (0.90;1.02)	0.1457
Subgroup Heterogeneity		p=0.8881			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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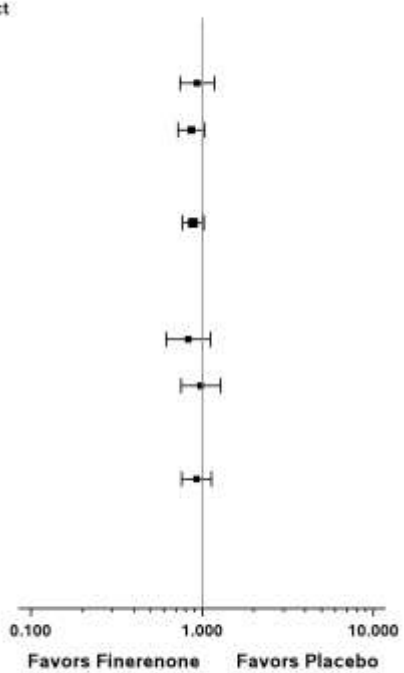
Figure 1.3.2 / 82: Forest plot of all-cause mortality: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of all-cause mortality: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	140/1881	147/1861	37.6%	0.93 (0.74;1.18)	
FIGARO-DKD	224/2643	256/2612	62.4%	0.86 (0.72;1.03)	
Heterogeneity		p=0.6664			
Total	364/4524	403/4473		0.88 (0.77;1.02)	0.0914
> 4.5 mmol/L					
FIDELIO-DKD	78/951	97/979	44.4%	0.83 (0.61;1.12)	
FIGARO-DKD	109/1043	113/1052	55.6%	0.98 (0.75;1.28)	
Heterogeneity		p=0.4815			
Total	187/1994	210/2031		0.93 (0.76;1.13)	0.4644
Subgroup Heterogeneity		p=0.7395			



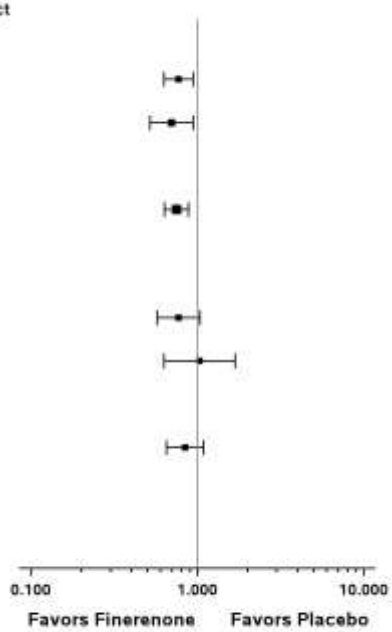
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 83: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	176/1881	220/1861	69.1%	0.77 (0.63;0.94)	
FIGARO-DKD	75/2643	106/2612	30.9%	0.70 (0.52;0.94)	
Heterogeneity		p=0.6002			
Total	251/4524	326/4473		0.75 (0.63;0.88)	0.0006
> 4.5 mmol/L					
FIDELIO-DKD	76/951	106/979	73.3%	0.77 (0.57;1.03)	
FIGARO-DKD	33/1043	33/1052	26.7%	1.03 (0.63;1.68)	
Heterogeneity		p=0.3133			
Total	109/1994	139/2031		0.84 (0.65;1.08)	0.1793
Subgroup Heterogeneity		p=0.5811			



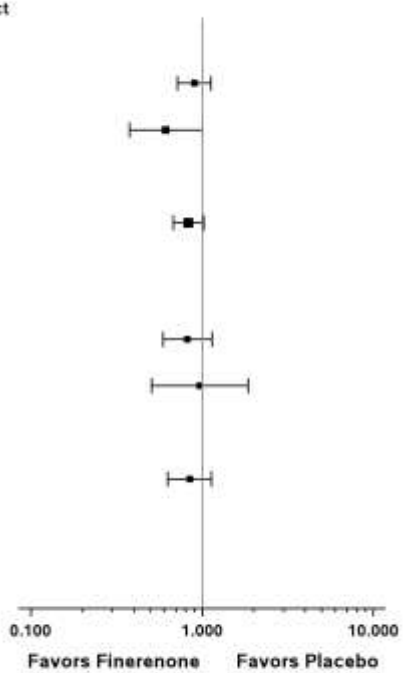
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 84: Forest plot of onset of kidney failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of onset of kidney failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	144/1881	153/1861	82.1%	0.90 (0.72;1.13)	
FIGARO-DKD	26/2643	43/2612	17.9%	0.61 (0.38;1.00)	
Heterogeneity		p=0.1858			
Total	170/4524	196/4473		0.83 (0.68;1.02)	0.0796
> 4.5 mmol/L					
FIDELIO-DKD	64/951	82/979	79.6%	0.82 (0.59;1.14)	
FIGARO-DKD	20/1043	19/1052	20.4%	0.97 (0.51;1.85)	
Heterogeneity		p=0.6175			
Total	84/1994	101/2031		0.85 (0.63;1.14)	0.2659
Subgroup Heterogeneity		p=0.9894			



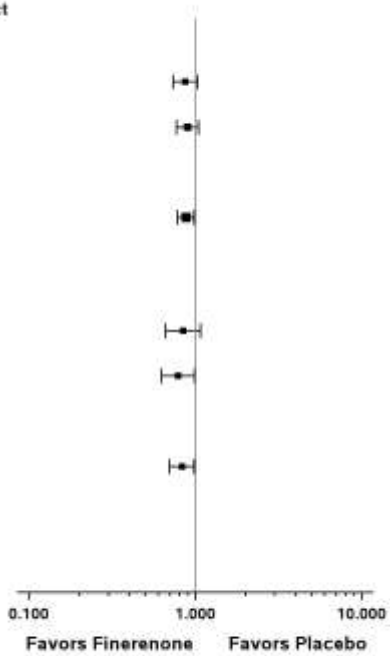
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub.sas 06FEB2023 12:10

Figure 1.3.2 / 85: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	246/1881	275/1861	43.7%	0.87 (0.73;1.03)	
FIGARO-DKD	323/2643	352/2612	56.3%	0.89 (0.77;1.04)	
Heterogeneity		p=0.6800			
Total	569/4524	627/4473		0.87 (0.78;0.98)	0.0203
> 4.5 mmol/L					
FIDELIO-DKD	120/951	145/979	47.3%	0.84 (0.66;1.08)	
FIGARO-DKD	135/1043	166/1052	52.7%	0.78 (0.62;0.99)	
Heterogeneity		p=0.5947			
Total	255/1994	311/2031		0.83 (0.70;0.98)	0.0262
Subgroup Heterogeneity		p=0.5782			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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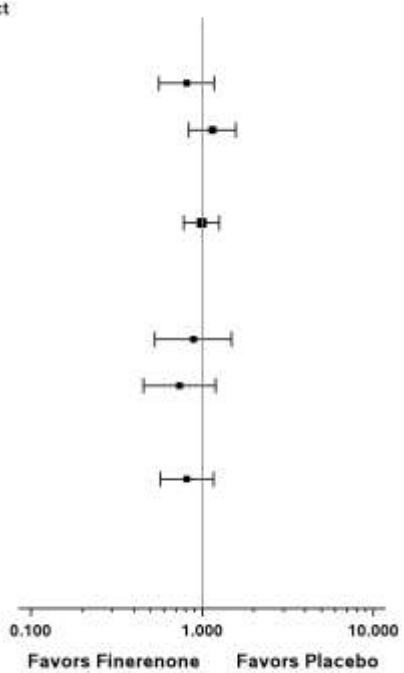
Figure 1.3.2 / 86: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	51/1881	62/1861	41.9%	0.81 (0.56;1.17)	
FIGARO-DKD	87/2643	72/2612	58.1%	1.15 (0.84;1.57)	
Heterogeneity		p=0.1425			
Total	138/4524	134/4473		0.99 (0.78;1.26)	0.9322
> 4.5 mmol/L					
FIDELIO-DKD	27/951	31/979	46.6%	0.89 (0.53;1.49)	
FIGARO-DKD	29/1043	39/1052	53.4%	0.74 (0.45;1.20)	
Heterogeneity		p=0.5444			
Total	56/1994	70/2031		0.81 (0.57;1.16)	0.2558
Subgroup Heterogeneity		p=0.3410			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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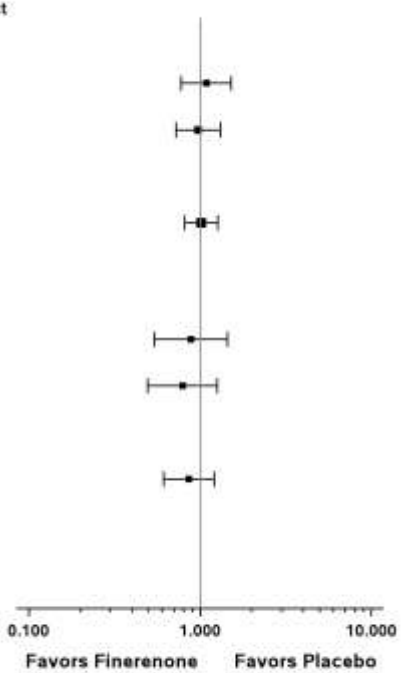
Figure 1.3.2 / 87: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	72/1881	65/1861	43.9%	1.09 (0.78;1.52)	
FIGARO-DKD	87/2643	88/2612	56.1%	0.97 (0.72;1.31)	
Heterogeneity		p=0.6768			
Total	159/4524	153/4473		1.01 (0.81;1.27)	0.9057
> 4.5 mmol/L					
FIDELIO-DKD	30/951	34/979	47.4%	0.88 (0.54;1.44)	
FIGARO-DKD	32/1043	41/1052	52.6%	0.79 (0.49;1.26)	
Heterogeneity		p=0.6766			
Total	62/1994	75/2031		0.86 (0.61;1.21)	0.3818
Subgroup Heterogeneity		p=0.3819			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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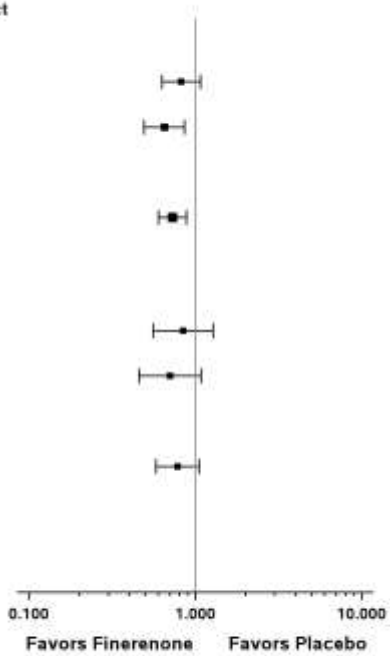
Figure 1.3.2 / 88: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	100/1881	119/1861	52.7%	0.82 (0.63;1.07)	
FIGARO-DKD	82/2643	122/2612	47.3%	0.65 (0.49;0.86)	
Heterogeneity		p=0.2598			
Total	182/4524	241/4473		0.73 (0.60;0.88)	0.0011
> 4.5 mmol/L					
FIDELIO-DKD	41/951	51/979	51.8%	0.84 (0.56;1.27)	
FIGARO-DKD	38/1043	51/1052	48.2%	0.70 (0.46;1.08)	
Heterogeneity		p=0.5542			
Total	79/1994	102/2031		0.78 (0.58;1.05)	0.1003
Subgroup Heterogeneity		p=0.5844			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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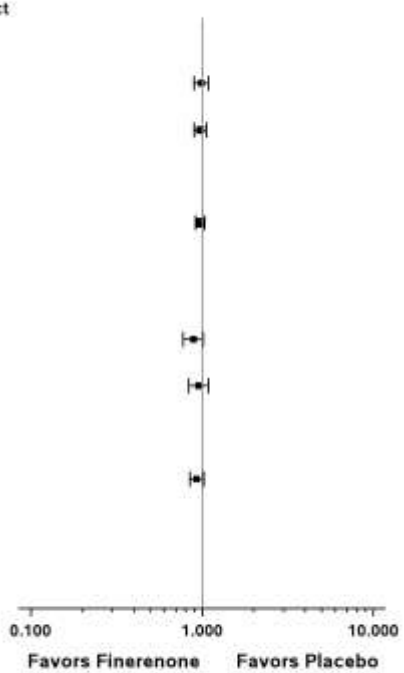
Figure 1.3.2 / 89: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	853/1881	857/1861	43.1%	0.98 (0.90;1.08)	
FIGARO-DKD	1128/2643	1142/2612	56.9%	0.97 (0.89;1.05)	
Heterogeneity		p=0.9783			
Total	1981/4524	1999/4473		0.97 (0.91;1.03)	0.3632
> 4.5 mmol/L					
FIDELIO-DKD	409/951	463/979	49.3%	0.89 (0.78;1.01)	
FIGARO-DKD	445/1043	463/1052	50.7%	0.95 (0.83;1.09)	
Heterogeneity		p=0.5656			
Total	854/1994	926/2031		0.93 (0.84;1.02)	0.1219
Subgroup Heterogeneity		p=0.3614			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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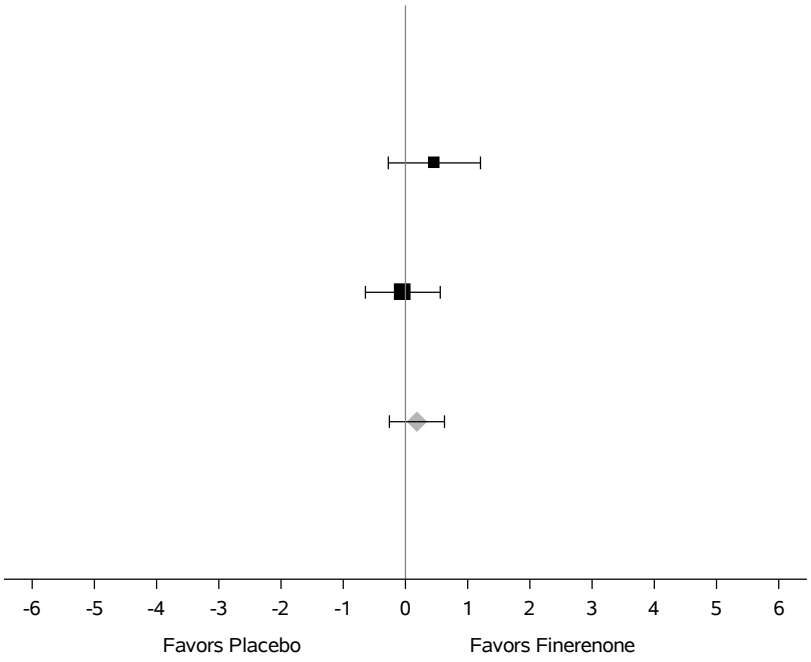
Figure 3.0.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set

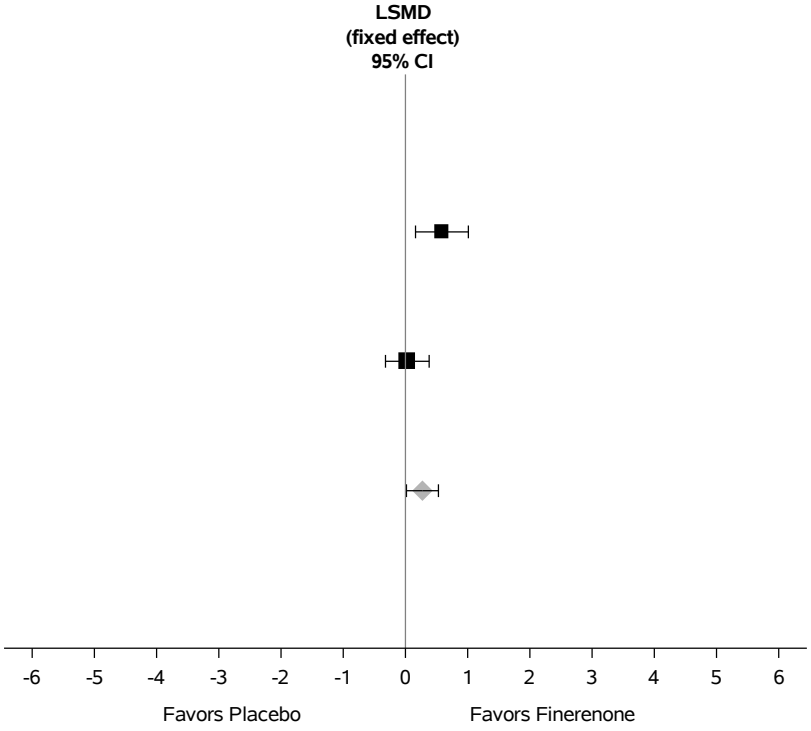
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2580	2571	39.7	0.46 [-0.28,1.21]	
FIGARO-DKD	3396	3367	60.3	-0.04 [-0.64,0.56]	
Total	5976	5938		0.18 [-0.26,0.63]	Z=0.82, p=0.4138
Heterogeneity:	Q=1.10 (df=1)	p=0.2952	I^2=8.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, KDIGO=Kidney Disease: Improving Global Outcomes, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care, VAS=Visual Analogue Scale.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.0.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set

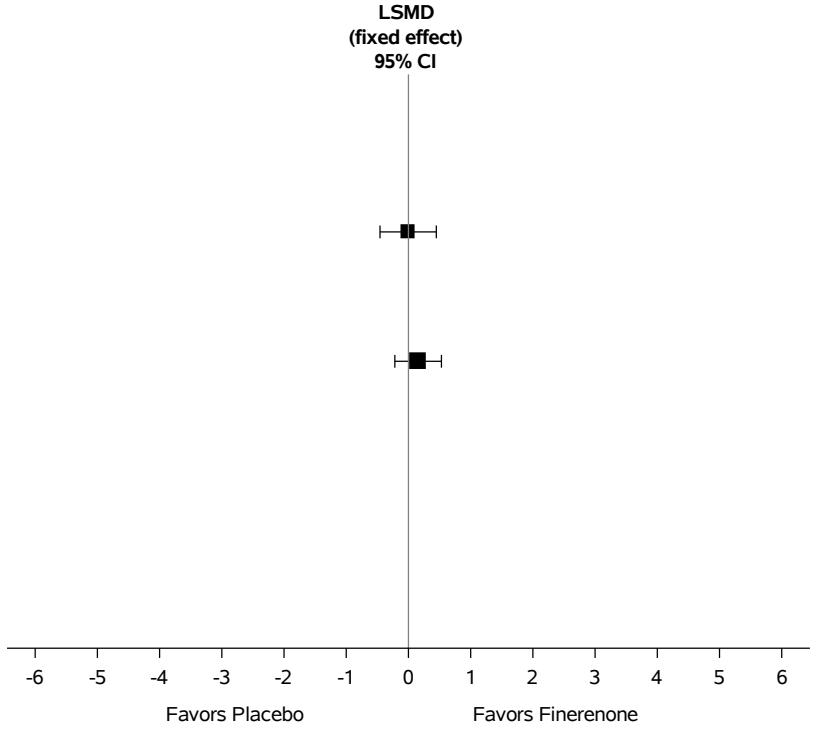
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2553	2535	40.6	0.59 [0.16,1.01]	
FIGARO-DKD	3374	3345	59.4	0.03 [-0.32,0.38]	
Total	5927	5880		0.27 [0.02,0.53]	Z=2.08, p=0.0372
Heterogeneity:	Q=3.94 (df=1)	p=0.0472	I^2=74.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.0.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set

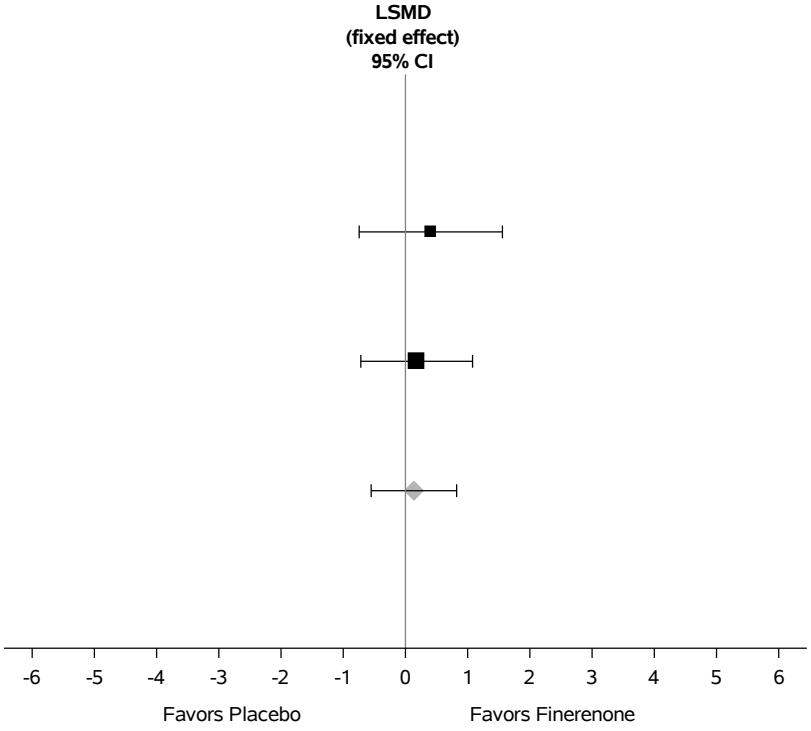
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2553	2535	40.7	0.00 [-0.46,0.45]	
FIGARO-DKD	3374	3345	59.3	0.16 [-0.22,0.53]	
Total	5927	5880		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.0.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set

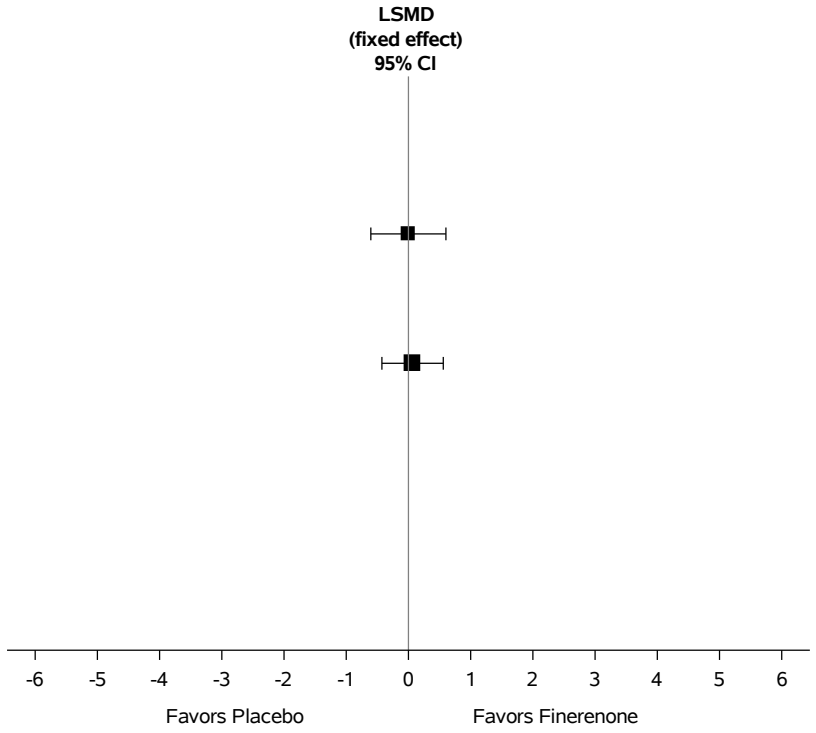
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2575	2566	37.8	0.41 [-0.74,1.56]	
FIGARO-DKD	3395	3364	62.2	0.18 [-0.72,1.08]	
Total	5970	5930		0.14 [-0.55,0.82]	Z=0.39, p=0.6981
Heterogeneity:	Q=0.22 (df=1)	p=0.6364	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.0.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set

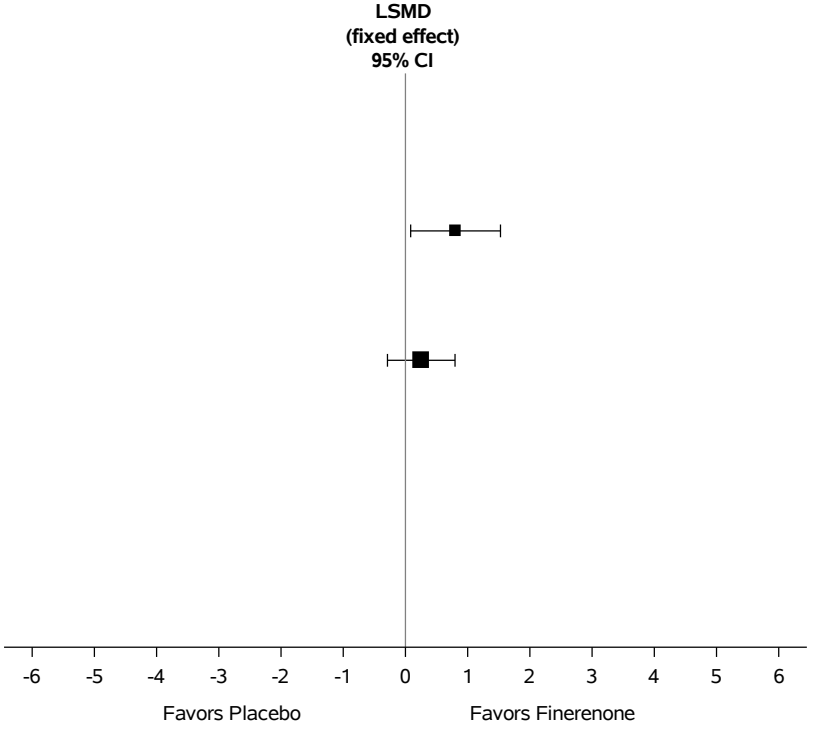
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2577	2571	40.1	0.00 [-0.60,0.60]	
FIGARO-DKD	3399	3371	59.9	0.07 [-0.43,0.56]	
Total	5976	5942		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.0.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set

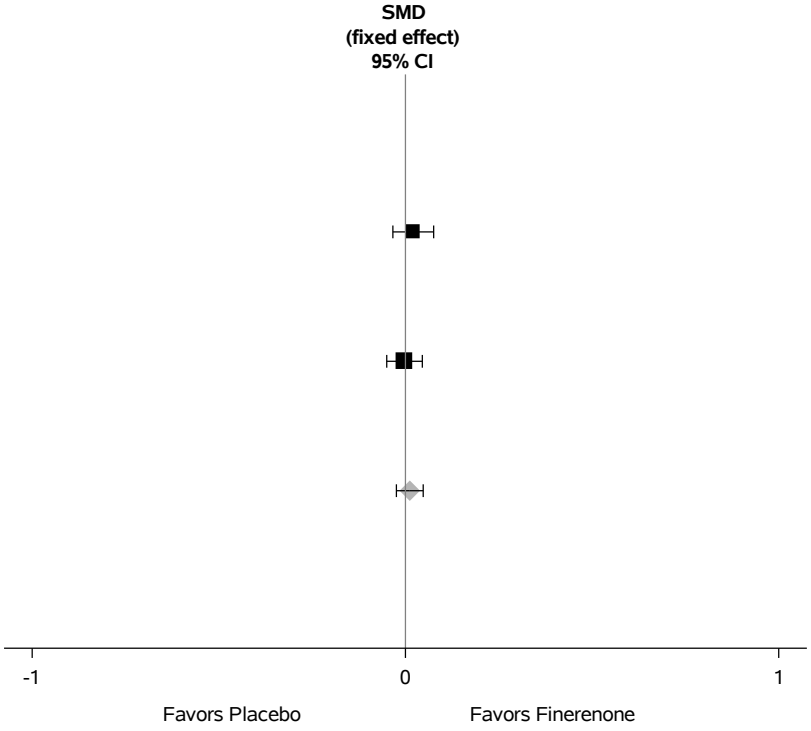
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2569	2563	36.2	0.81 [0.08,1.53]	
FIGARO-DKD	3389	3364	63.8	0.25 [-0.29,0.80]	
Total	5958	5927		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: LSMD is derived on study level by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set

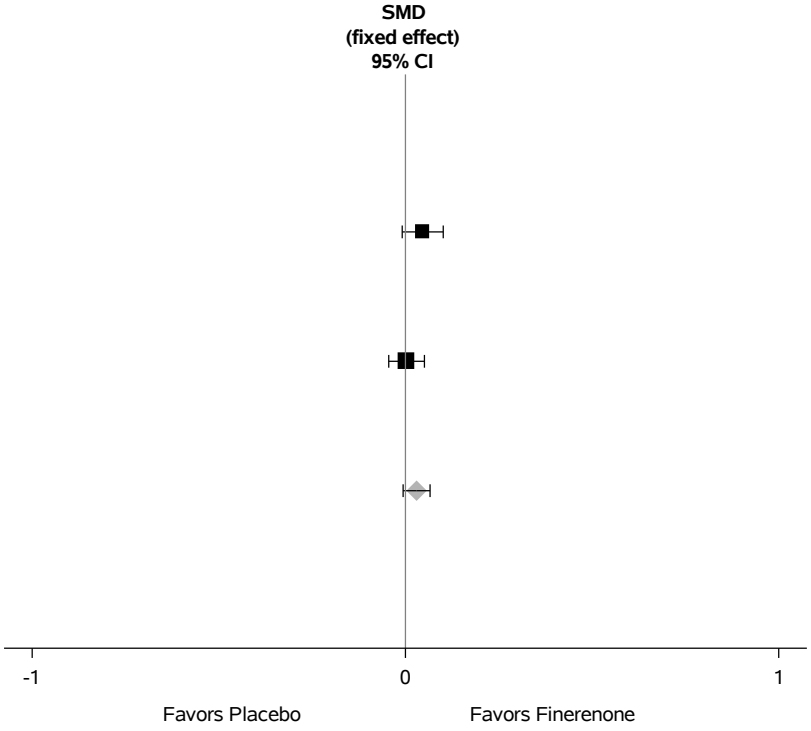
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2580	2571	43.2	0.02 [-0.03,0.08]	
FIGARO-DKD	3396	3367	56.8	0.00 [-0.05,0.05]	
Total	5976	5938		0.01 [-0.02,0.05]	Z=0.63, p=0.5255
Heterogeneity:	Q=0.45 (df=1)	p=0.5037	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, KDIGO=Kidney Disease: Improving Global Outcomes, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care, VAS=Visual Analogue Scale.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set

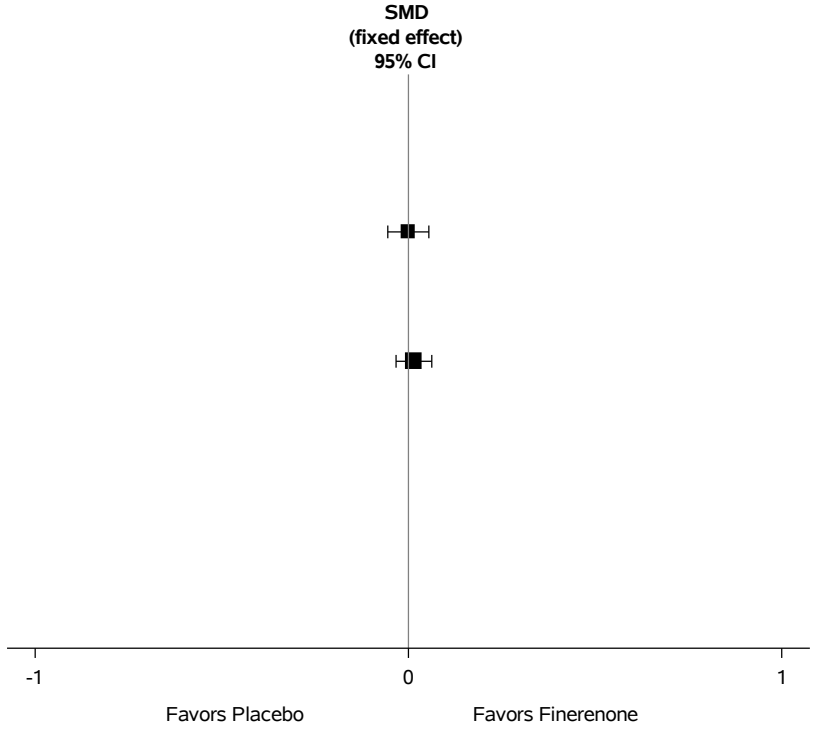
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2553	2535	43.1	0.05 [-0.01,0.10]	
FIGARO-DKD	3374	3345	56.9	0.00 [-0.04,0.05]	
Total	5927	5880		0.03 [-0.01,0.07]	Z=1.62, p=0.1050
Heterogeneity:	Q=1.55 (df=1)	p=0.2132	I^2=35.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set

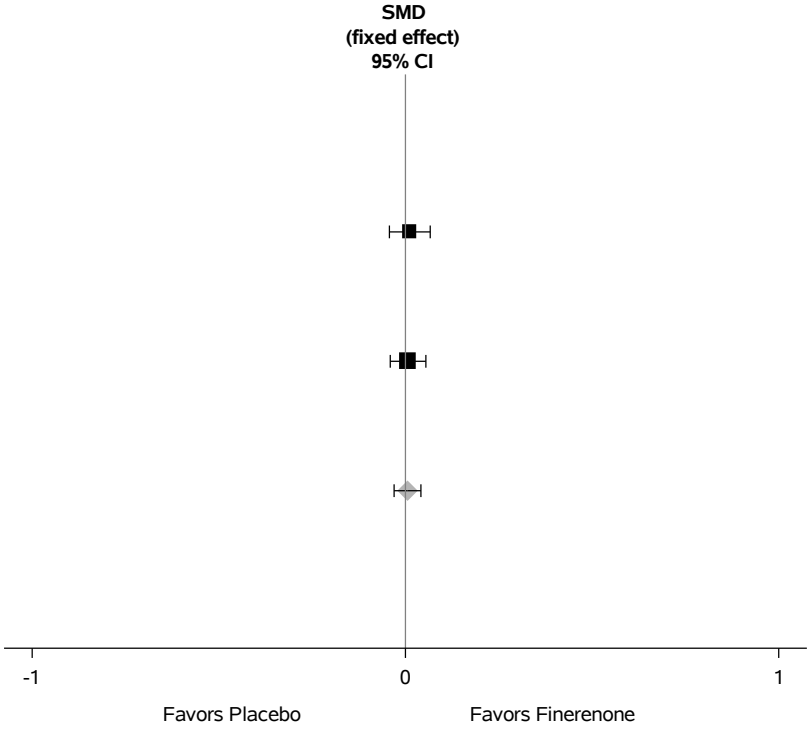
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2553	2535	43.1	0.00 [-0.06,0.05]	
FIGARO-DKD	3374	3345	56.9	0.01 [-0.03,0.06]	
Total	5927	5880		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set

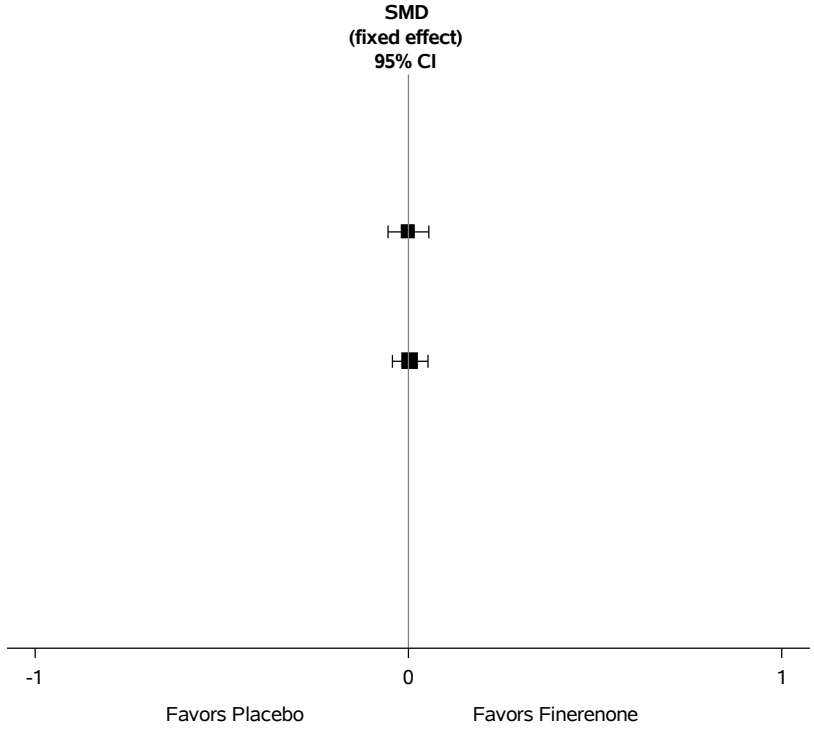
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2575	2566	43.2	0.01 [-0.04,0.07]	
FIGARO-DKD	3395	3364	56.8	0.01 [-0.04,0.05]	
Total	5970	5930		0.01 [-0.03,0.04]	Z=0.30, p=0.7639
Heterogeneity:	Q=0.05 (df=1)	p=0.8186	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set

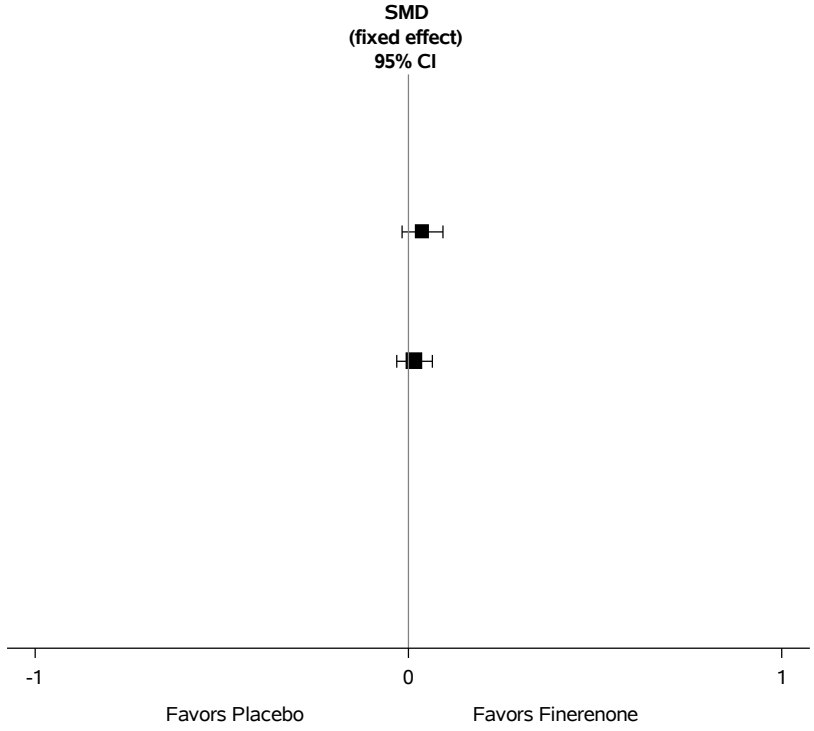
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2577	2571	43.2	0.00 [-0.05,0.05]	
FIGARO-DKD	3399	3371	56.8	0.00 [-0.04,0.05]	
Total	5976	5942		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.1.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set

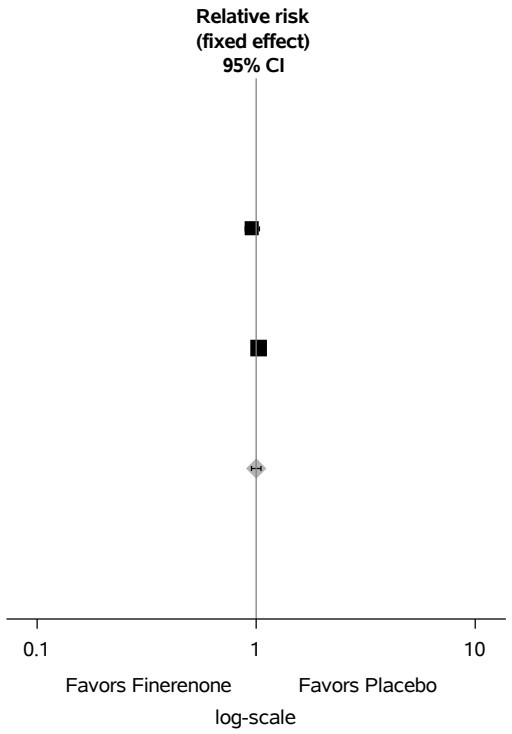
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2569	2563	43.2	0.04 [-0.02,0.09]	
FIGARO-DKD	3389	3364	56.8	0.02 [-0.03,0.06]	
Total	5958	5927		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. On study level this was derived by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, time, treatment*time, baseline value and baseline value*time as covariate.
For 'Total' the same model as for single studies including study as additional factor was applied using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set

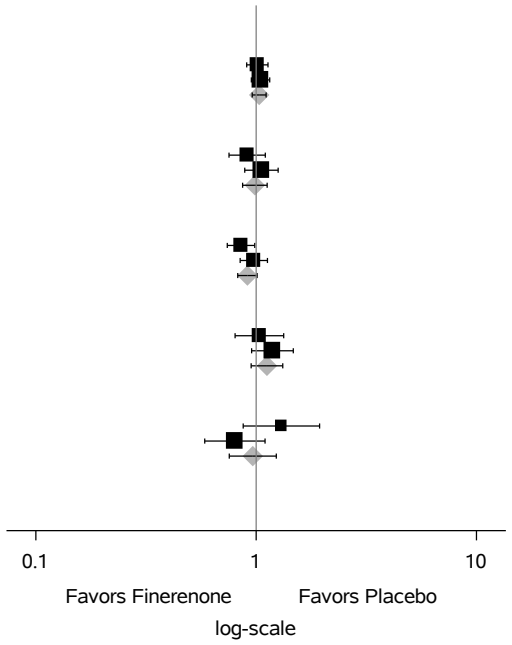
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	907 / 2833	947 / 2841	44.7	0.96 [0.89,1.03]	
FIGARO-DKD	1187 / 3686	1143 / 3666	55.3	1.03 [0.97,1.10]	
Total	2094 / 6519	2090 / 6507		1.00 [0.95,1.05]	Z=0.02, p=0.9873
Heterogeneity:	Q=2.04 (df=1)	p=0.1536	I^2=50.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.1.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set

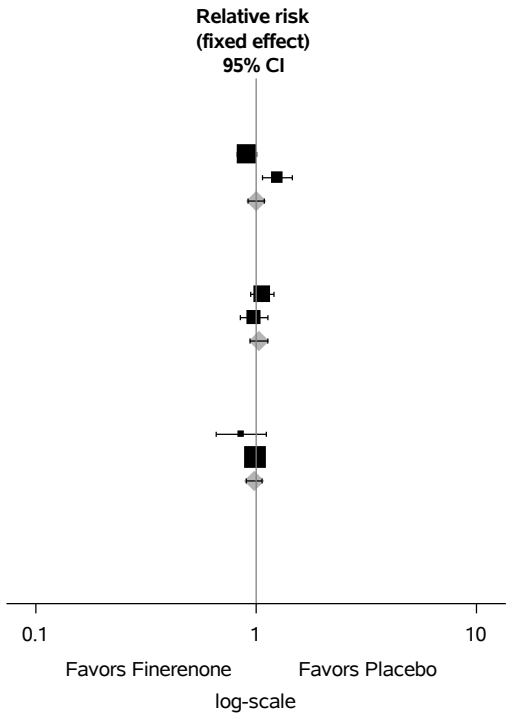
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	410 / 1182	403 / 1176	42.6	1.01 [0.91,1.13]	
FIGARO-DKD	579 / 1754	552 / 1750	57.4	1.05 [0.95,1.15]	
Total	989 / 2936	955 / 2926		1.03 [0.96,1.11]	Z=0.84, p=0.3992
Heterogeneity:	Q=0.20 (df=1)	p=0.6566	I^2=0.0%		
North America					
FIDELIO-DKD	139 / 467	156 / 477	45.8	0.91 [0.75,1.10]	
FIGARO-DKD	180 / 559	167 / 548	54.2	1.06 [0.89,1.26]	
Total	319 / 1026	323 / 1025		0.99 [0.87,1.12]	Z=-0.21, p=0.8375
Heterogeneity:	Q=1.29 (df=1)	p=0.2563	I^2=22.4%		
Asia					
FIDELIO-DKD	235 / 790	275 / 789	49.7	0.85 [0.74,0.99]	
FIGARO-DKD	254 / 810	262 / 815	50.3	0.98 [0.85,1.12]	
Total	489 / 1600	537 / 1604		0.91 [0.82,1.01]	Z=-1.77, p=0.0761
Heterogeneity:	Q=1.68 (df=1)	p=0.1955	I^2=40.3%		
Latin America					
FIDELIO-DKD	86 / 295	84 / 298	42.4	1.03 [0.80,1.33]	
FIGARO-DKD	129 / 424	107 / 417	57.6	1.19 [0.95,1.47]	
Total	215 / 719	191 / 715		1.12 [0.95,1.32]	Z=1.34, p=0.1812
Heterogeneity:	Q=0.64 (df=1)	p=0.4232	I^2=0.0%		
Others					
FIDELIO-DKD	37 / 99	29 / 101	38.4	1.30 [0.87,1.94]	
FIGARO-DKD	45 / 139	55 / 136	61.6	0.80 [0.58,1.10]	
Total	82 / 238	84 / 237		0.97 [0.75,1.23]	Z=-0.28, p=0.7777
Heterogeneity:	Q=3.51 (df=1)	p=0.0611	I^2=71.5%		
Subgroup Heterogeneity:	Q=5.77 (df=4)	p=0.2174	I^2=30.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.1.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

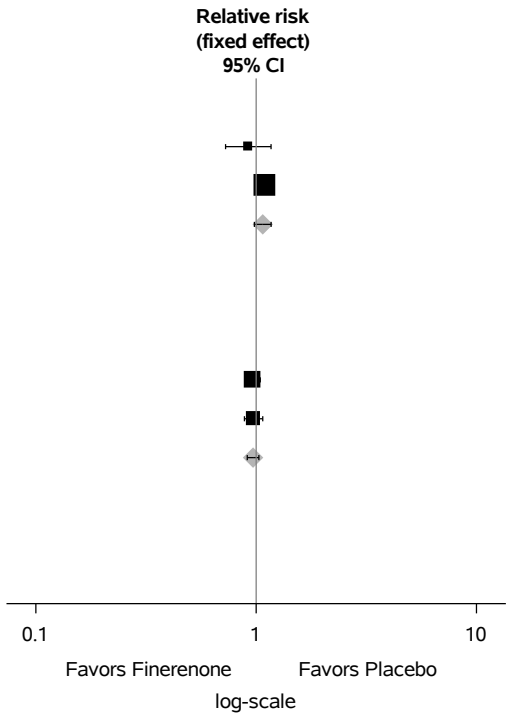
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	480 / 1559	525 / 1549	70.1	0.91 [0.82,1.01]	
FIGARO-DKD	239 / 639	189 / 631	29.9	1.25 [1.07,1.46]	
Total	719 / 2198	714 / 2180		1.00 [0.92,1.09]	Z=0.00, p=0.9989
Heterogeneity:	Q=11.22 (df=1)	p=0.0008	I^2=91.1%		
45 - < 60					
FIDELIO-DKD	360 / 1063	340 / 1071	58.4	1.07 [0.94,1.20]	
FIGARO-DKD	241 / 720	250 / 731	41.6	0.98 [0.85,1.13]	
Total	601 / 1783	590 / 1802		1.03 [0.94,1.13]	Z=0.61, p=0.5430
Heterogeneity:	Q=0.80 (df=1)	p=0.3700	I^2=0.0%		
>= 60					
FIDELIO-DKD	67 / 211	82 / 221	9.9	0.86 [0.66,1.11]	
FIGARO-DKD	707 / 2327	704 / 2304	90.1	0.99 [0.91,1.08]	
Total	774 / 2538	786 / 2525		0.98 [0.90,1.06]	Z=-0.49, p=0.6224
Heterogeneity:	Q=1.14 (df=1)	p=0.2866	I^2=11.9%		
Subgroup Heterogeneity:	Q=0.61 (df=2)	p=0.7365	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.1.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

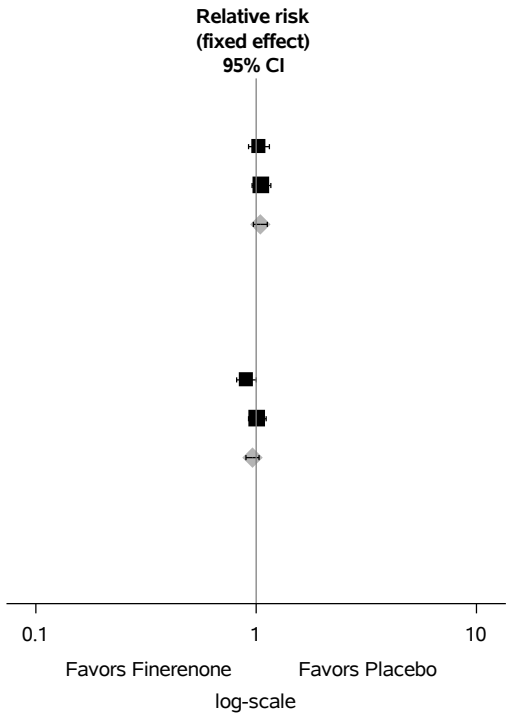
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	79 / 210	87 / 213	13.6	0.92 [0.73,1.17]	
FIGARO-DKD	607 / 1722	548 / 1705	86.4	1.10 [1.00,1.20]	
Total	686 / 1932	635 / 1918		1.07 [0.98,1.17]	Z=1.54, p=0.1238
Heterogeneity:	Q=1.79 (df=1)	p=0.1805	I^2=44.2%		
Very High					
FIDELIO-DKD	828 / 2623	860 / 2628	59.7	0.96 [0.89,1.04]	
FIGARO-DKD	580 / 1964	595 / 1961	40.3	0.97 [0.88,1.07]	
Total	1408 / 4587	1455 / 4589		0.97 [0.91,1.03]	Z=-1.05, p=0.2958
Heterogeneity:	Q=0.02 (df=1)	p=0.8874	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.46 (df=1)	p=0.0628	I^2=71.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.1.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set

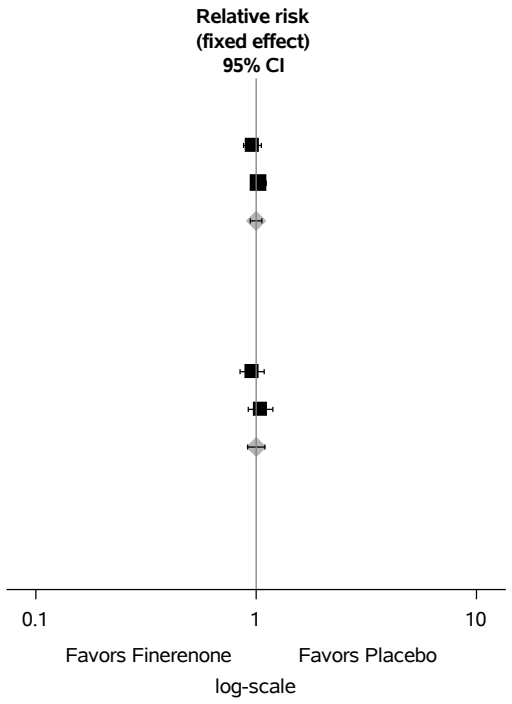
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	439 / 1303	426 / 1302	44.8	1.03 [0.92,1.15]	
FIGARO-DKD	559 / 1676	522 / 1654	55.2	1.06 [0.96,1.17]	
Total	998 / 2979	948 / 2956		1.04 [0.97,1.12]	Z=1.17, p=0.2405
Heterogeneity:	Q=0.12 (df=1)	p=0.7283	I^2=0.0%		
Absent					
FIDELIO-DKD	468 / 1530	521 / 1539	44.5	0.90 [0.82,1.00]	
FIGARO-DKD	628 / 2010	621 / 2012	55.5	1.01 [0.92,1.11]	
Total	1096 / 3540	1142 / 3551		0.96 [0.90,1.03]	Z=-1.10, p=0.2717
Heterogeneity:	Q=2.60 (df=1)	p=0.1067	I^2=61.6%		
Subgroup Heterogeneity:	Q=2.59 (df=1)	p=0.1078	I^2=61.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.1.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

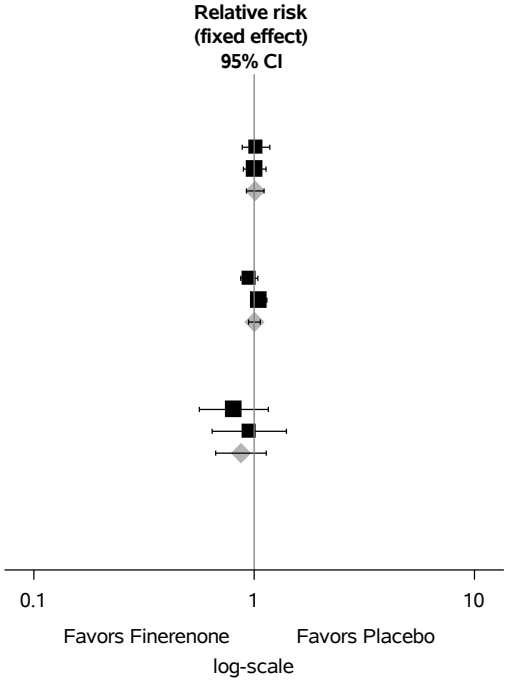
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	596 / 1881	613 / 1861	41.8	0.96 [0.88,1.06]	
FIGARO-DKD	859 / 2643	827 / 2612	58.2	1.03 [0.95,1.11]	
Total	1455 / 4524	1440 / 4473		1.00 [0.94,1.06]	Z=-0.03, p=0.9733
Heterogeneity:	Q=1.10 (df=1)	p=0.2951	I^2=8.8%		
> 4.5					
FIDELIO-DKD	311 / 951	334 / 979	51.0	0.96 [0.85,1.09]	
FIGARO-DKD	328 / 1043	316 / 1052	49.0	1.05 [0.92,1.19]	
Total	639 / 1994	650 / 2031		1.00 [0.91,1.10]	Z=0.02, p=0.9848
Heterogeneity:	Q=0.92 (df=1)	p=0.3371	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9725	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.1.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

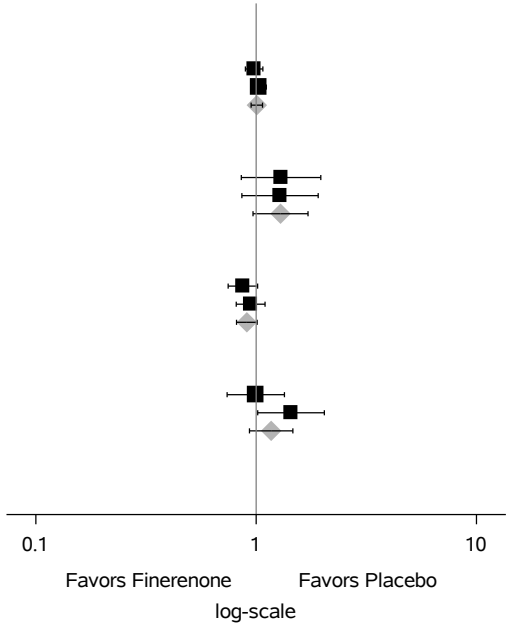
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	255 / 788	247 / 778	40.3	1.02 [0.88,1.18]	
FIGARO-DKD	375 / 1187	376 / 1197	59.7	1.01 [0.89,1.13]	
Total	630 / 1975	623 / 1975		1.01 [0.92,1.11]	Z=0.24, p=0.8119
Heterogeneity:	Q=0.02 (df=1)	p=0.8883	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	614 / 1900	654 / 1922	46.2	0.95 [0.87,1.04]	
FIGARO-DKD	779 / 2392	730 / 2355	53.8	1.05 [0.97,1.14]	
Total	1393 / 4292	1384 / 4277		1.00 [0.94,1.07]	Z=0.09, p=0.9297
Heterogeneity:	Q=2.60 (df=1)	p=0.1069	I^2=61.5%		
>= 160					
FIDELIO-DKD	38 / 142	46 / 139	53.7	0.81 [0.56,1.16]	
FIGARO-DKD	33 / 107	37 / 114	46.3	0.95 [0.64,1.40]	
Total	71 / 249	83 / 253		0.87 [0.67,1.13]	Z=-1.02, p=0.3054
Heterogeneity:	Q=0.36 (df=1)	p=0.5504	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.11 (df=2)	p=0.5727	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.1.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set

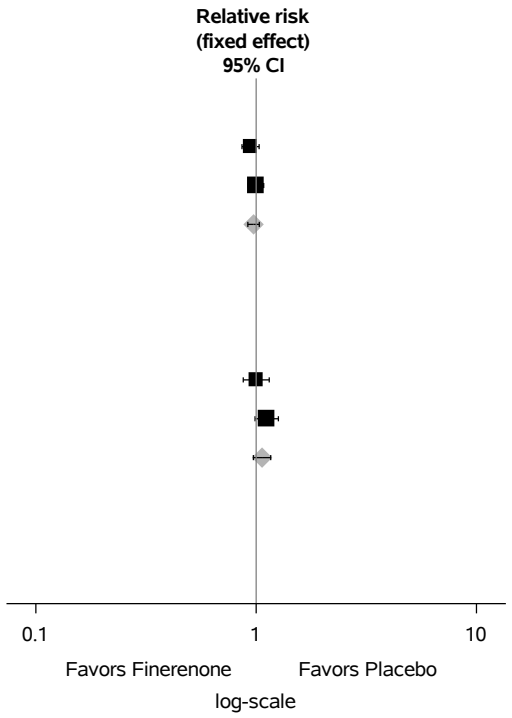
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	596 / 1777	622 / 1815	42.4	0.98 [0.89,1.07]	
FIGARO-DKD	872 / 2672	827 / 2605	57.6	1.03 [0.95,1.11]	
Total	1468 / 4449	1449 / 4420		1.01 [0.95,1.07]	Z=0.22, p=0.8235
Heterogeneity:	Q=0.64 (df=1)	p=0.4236	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 140	28 / 124	48.0	1.30 [0.86,1.96]	
FIGARO-DKD	35 / 113	35 / 145	52.0	1.28 [0.86,1.91]	
Total	76 / 253	63 / 269		1.29 [0.97,1.72]	Z=1.73, p=0.0828
Heterogeneity:	Q=0.00 (df=1)	p=0.9711	I^2=0.0%		
Asian					
FIDELIO-DKD	208 / 717	241 / 723	48.9	0.87 [0.75,1.02]	
FIGARO-DKD	221 / 715	242 / 739	51.1	0.94 [0.81,1.10]	
Total	429 / 1432	483 / 1462		0.91 [0.81,1.01]	Z=-1.77, p=0.0759
Heterogeneity:	Q=0.55 (df=1)	p=0.4603	I^2=0.0%		
Others					
FIDELIO-DKD	62 / 199	56 / 179	57.5	1.00 [0.74,1.34]	
FIGARO-DKD	59 / 186	39 / 177	42.5	1.44 [1.02,2.04]	
Total	121 / 385	95 / 356		1.17 [0.93,1.47]	Z=1.35, p=0.1758
Heterogeneity:	Q=2.47 (df=1)	p=0.1158	I^2=59.6%		
Subgroup Heterogeneity:	Q=8.04 (df=3)	p=0.0452	I^2=62.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.1.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set

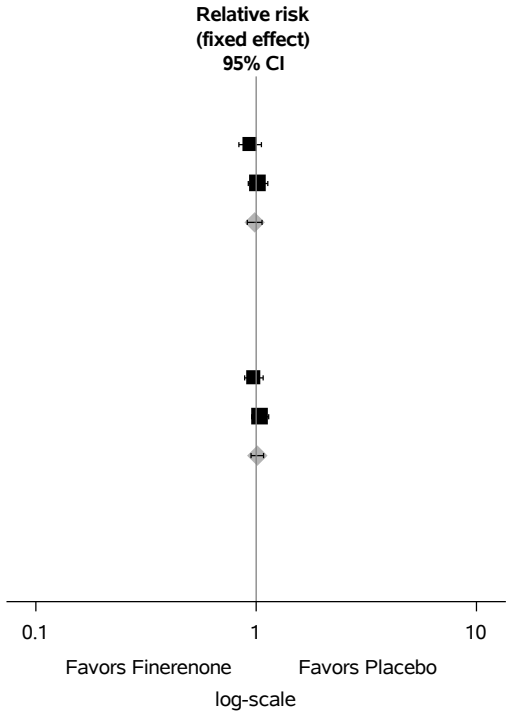
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	616 / 1953	679 / 2030	44.7	0.94 [0.86,1.03]	
FIGARO-DKD	800 / 2528	817 / 2577	55.3	1.00 [0.92,1.08]	
Total	1416 / 4481	1496 / 4607		0.97 [0.92,1.03]	Z=-0.89, p=0.3722
Heterogeneity:	Q=0.86 (df=1)	p=0.3550	I^2=0.0%		
Female					
FIDELIO-DKD	291 / 880	268 / 811	44.6	1.00 [0.87,1.15]	
FIGARO-DKD	387 / 1158	326 / 1089	55.4	1.12 [0.99,1.26]	
Total	678 / 2038	594 / 1900		1.06 [0.97,1.16]	Z=1.33, p=0.1843
Heterogeneity:	Q=1.38 (df=1)	p=0.2399	I^2=27.6%		
Subgroup Heterogeneity:	Q=2.56 (df=1)	p=0.1097	I^2=60.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.1.9: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set

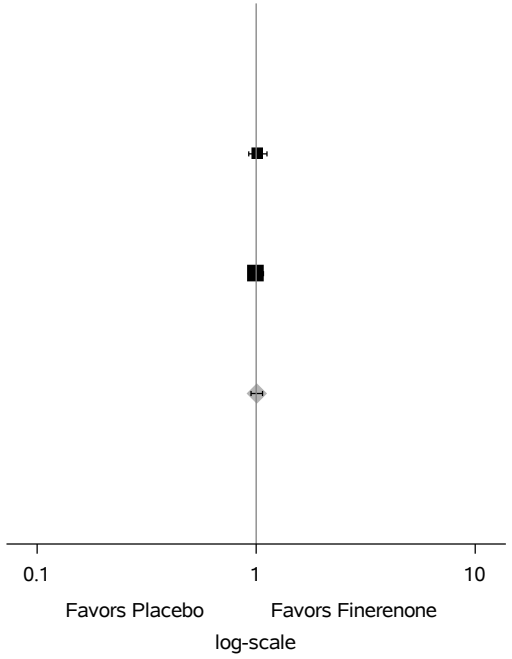
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	371 / 1205	385 / 1174	42.8	0.94 [0.83,1.06]	
FIGARO-DKD	525 / 1753	516 / 1757	57.2	1.02 [0.92,1.13]	
Total	896 / 2958	901 / 2931		0.98 [0.91,1.06]	Z=-0.40, p=0.6872
Heterogeneity:	Q=1.08 (df=1)	p=0.2981	I^2=7.6%		
>= 65					
FIDELIO-DKD	536 / 1628	562 / 1667	45.9	0.98 [0.89,1.08]	
FIGARO-DKD	662 / 1933	627 / 1909	54.1	1.04 [0.95,1.14]	
Total	1198 / 3561	1189 / 3576		1.01 [0.95,1.08]	Z=0.35, p=0.7252
Heterogeneity:	Q=0.95 (df=1)	p=0.3285	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set

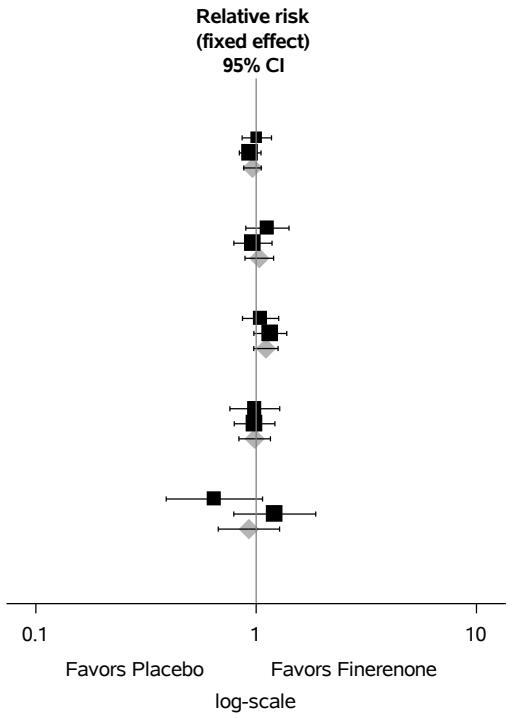
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	650 / 2833	641 / 2841	39.8	1.02 [0.93,1.12]	
FIGARO-DKD	944 / 3686	938 / 3666	60.2	1.00 [0.92,1.08]	
Total	1594 / 6519	1579 / 6507		1.01 [0.95,1.07]	Z=0.21, p=0.8311
Heterogeneity:	Q=0.09 (df=1)	p=0.7643	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set

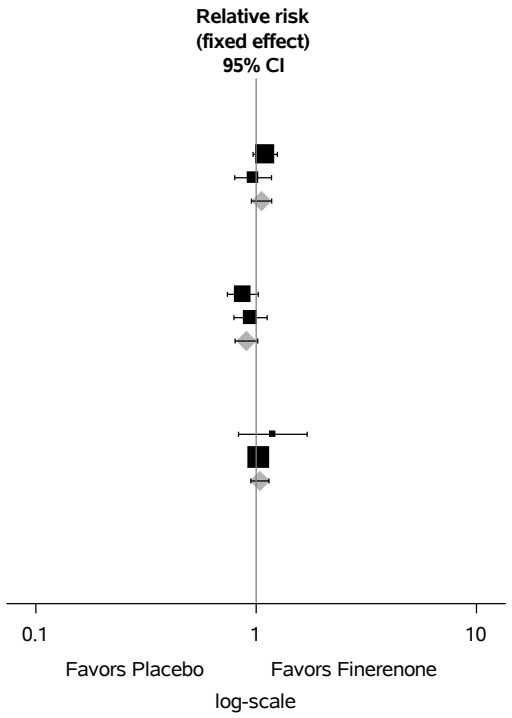
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	257 / 1182	254 / 1176	35.3	1.01 [0.86,1.17]	
FIGARO-DKD	433 / 1754	460 / 1750	64.7	0.94 [0.84,1.05]	
Total	690 / 2936	714 / 2926		0.96 [0.88,1.05]	Z=-0.82, p=0.4102
Heterogeneity:	Q=0.51 (df=1)	p=0.4757	I^2=0.0%		
North America					
FIDELIO-DKD	120 / 467	109 / 477	43.9	1.12 [0.90,1.41]	
FIGARO-DKD	142 / 559	144 / 548	56.1	0.97 [0.79,1.18]	
Total	262 / 1026	253 / 1025		1.03 [0.89,1.20]	Z=0.43, p=0.6694
Heterogeneity:	Q=0.97 (df=1)	p=0.3255	I^2=0.0%		
Asia					
FIDELIO-DKD	173 / 790	165 / 789	45.2	1.05 [0.87,1.27]	
FIGARO-DKD	212 / 810	184 / 815	54.8	1.16 [0.98,1.38]	
Total	385 / 1600	349 / 1604		1.11 [0.98,1.26]	Z=1.57, p=0.1163
Heterogeneity:	Q=0.61 (df=1)	p=0.4352	I^2=0.0%		
Latin America					
FIDELIO-DKD	81 / 295	83 / 298	40.0	0.99 [0.76,1.28]	
FIGARO-DKD	121 / 424	121 / 417	60.0	0.98 [0.80,1.22]	
Total	202 / 719	204 / 715		0.98 [0.83,1.16]	Z=-0.19, p=0.8518
Heterogeneity:	Q=0.00 (df=1)	p=0.9890	I^2=0.0%		
Others					
FIDELIO-DKD	19 / 99	30 / 101	42.0	0.65 [0.39,1.07]	
FIGARO-DKD	36 / 139	29 / 136	58.0	1.21 [0.79,1.86]	
Total	55 / 238	59 / 237		0.93 [0.67,1.28]	Z=-0.46, p=0.6426
Heterogeneity:	Q=3.51 (df=1)	p=0.0612	I^2=71.5%		
Subgroup Heterogeneity:	Q=3.53 (df=4)	p=0.4732	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

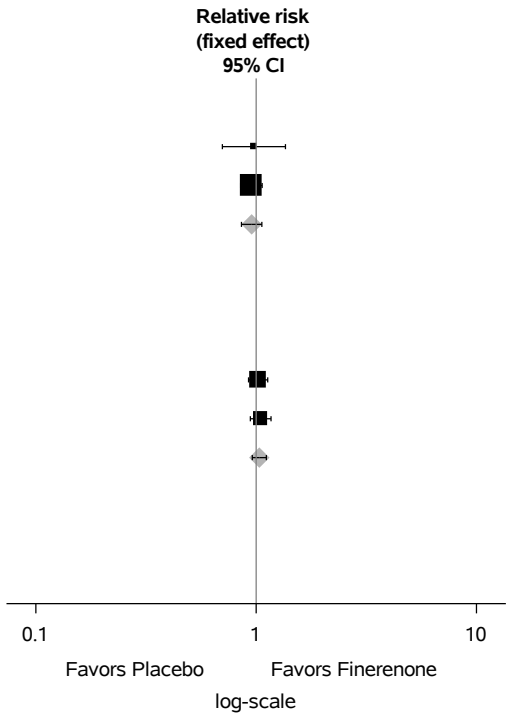
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	385 / 1559	348 / 1549	69.7	1.10 [0.97,1.25]	
FIGARO-DKD	155 / 639	158 / 631	30.3	0.97 [0.80,1.17]	
Total	540 / 2198	506 / 2180		1.06 [0.95,1.18]	Z=1.04, p=0.2962
Heterogeneity:	Q=1.16 (df=1)	p=0.2823	I^2=13.5%		
45 - < 60					
FIDELIO-DKD	215 / 1063	249 / 1071	53.6	0.87 [0.74,1.02]	
FIGARO-DKD	182 / 720	196 / 731	46.4	0.94 [0.79,1.12]	
Total	397 / 1783	445 / 1802		0.90 [0.80,1.02]	Z=-1.69, p=0.0906
Heterogeneity:	Q=0.44 (df=1)	p=0.5064	I^2=0.0%		
>= 60					
FIDELIO-DKD	50 / 211	44 / 221	6.9	1.19 [0.83,1.70]	
FIGARO-DKD	607 / 2327	584 / 2304	93.1	1.03 [0.93,1.13]	
Total	657 / 2538	628 / 2525		1.04 [0.95,1.14]	Z=0.81, p=0.4204
Heterogeneity:	Q=0.59 (df=1)	p=0.4431	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.54 (df=2)	p=0.1032	I^2=56.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

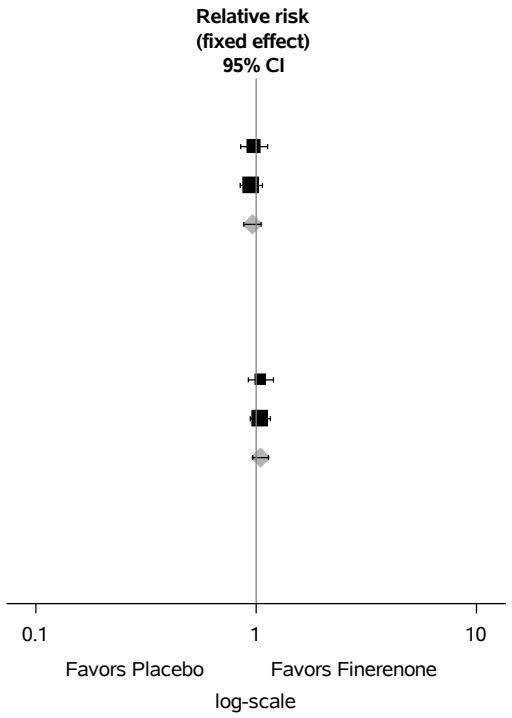
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	52 / 210	54 / 213	10.4	0.98 [0.70,1.36]	
FIGARO-DKD	439 / 1722	457 / 1705	89.6	0.95 [0.85,1.06]	
Total	491 / 1932	511 / 1918		0.95 [0.86,1.06]	Z=-0.87, p=0.3838
Heterogeneity:	Q=0.02 (df=1)	p=0.8813	I^2=0.0%		
Very High					
FIDELIO-DKD	598 / 2623	587 / 2628	53.8	1.02 [0.92,1.13]	
FIGARO-DKD	505 / 1964	481 / 1961	46.2	1.05 [0.94,1.17]	
Total	1103 / 4587	1068 / 4589		1.03 [0.96,1.11]	Z=0.88, p=0.3814
Heterogeneity:	Q=0.13 (df=1)	p=0.7226	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.47 (df=1)	p=0.2248	I^2=32.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set

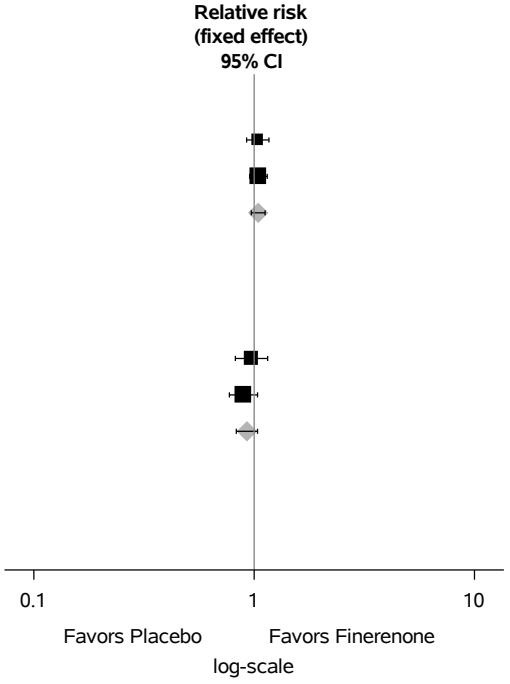
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	296 / 1303	302 / 1302	40.6	0.98 [0.85,1.13]	
FIGARO-DKD	416 / 1676	432 / 1654	59.4	0.95 [0.85,1.07]	
Total	712 / 2979	734 / 2956		0.96 [0.88,1.05]	Z=-0.85, p=0.3968
Heterogeneity:	Q=0.10 (df=1)	p=0.7464	I^2=0.0%		
Absent					
FIDELIO-DKD	354 / 1530	339 / 1539	39.1	1.05 [0.92,1.20]	
FIGARO-DKD	528 / 2010	506 / 2012	60.9	1.04 [0.94,1.16]	
Total	882 / 3540	845 / 3551		1.05 [0.96,1.14]	Z=1.09, p=0.2741
Heterogeneity:	Q=0.00 (df=1)	p=0.9478	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.86 (df=1)	p=0.1728	I^2=46.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

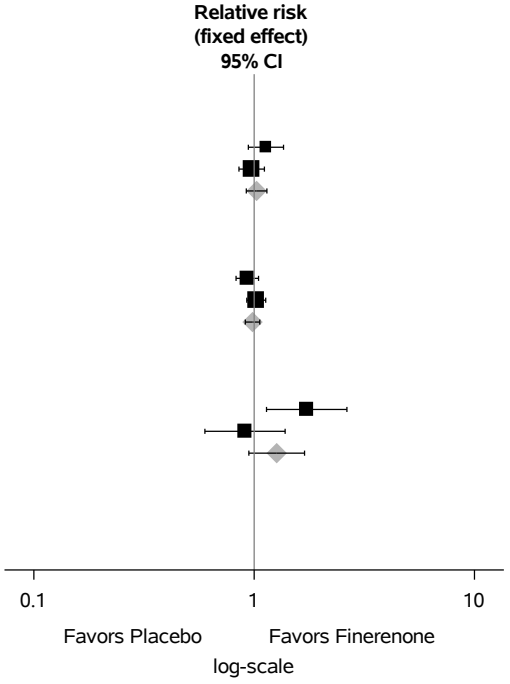
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	445 / 1881	424 / 1861	38.4	1.04 [0.92,1.17]	
FIGARO-DKD	694 / 2643	656 / 2612	61.6	1.05 [0.95,1.15]	
Total	1139 / 4524	1080 / 4473		1.04 [0.97,1.12]	Z=1.14, p=0.2558
Heterogeneity:	Q=0.01 (df=1)	p=0.9278	I^2=0.0%		
> 4.5					
FIDELIO-DKD	205 / 951	217 / 979	43.2	0.97 [0.82,1.15]	
FIGARO-DKD	250 / 1043	282 / 1052	56.8	0.89 [0.77,1.04]	
Total	455 / 1994	499 / 2031		0.93 [0.83,1.04]	Z=-1.34, p=0.1812
Heterogeneity:	Q=0.54 (df=1)	p=0.4622	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.03 (df=1)	p=0.0818	I^2=67.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.2.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

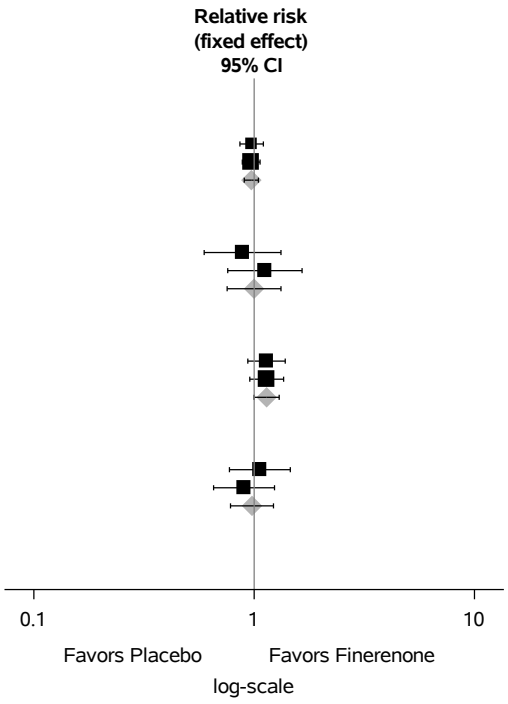
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	189 / 788	165 / 778	34.4	1.13 [0.94,1.36]	
FIGARO-DKD	313 / 1187	324 / 1197	65.6	0.97 [0.85,1.11]	
Total	502 / 1975	489 / 1975		1.03 [0.92,1.14]	Z=0.46, p=0.6461
Heterogeneity:	Q=1.66 (df=1)	p=0.1975	I^2=39.8%		
130 - < 160					
FIDELIO-DKD	414 / 1900	450 / 1922	41.5	0.93 [0.83,1.05]	
FIGARO-DKD	602 / 2392	580 / 2355	58.5	1.02 [0.93,1.13]	
Total	1016 / 4292	1030 / 4277		0.98 [0.91,1.06]	Z=-0.44, p=0.6566
Heterogeneity:	Q=1.43 (df=1)	p=0.2325	I^2=29.9%		
>= 160					
FIDELIO-DKD	46 / 142	26 / 139	49.9	1.73 [1.14,2.64]	
FIGARO-DKD	29 / 107	34 / 114	50.1	0.91 [0.60,1.38]	
Total	75 / 249	60 / 253		1.27 [0.95,1.69]	Z=1.59, p=0.1127
Heterogeneity:	Q=4.54 (df=1)	p=0.0332	I^2=78.0%		
Subgroup Heterogeneity:	Q=2.87 (df=2)	p=0.2381	I^2=30.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.2.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set

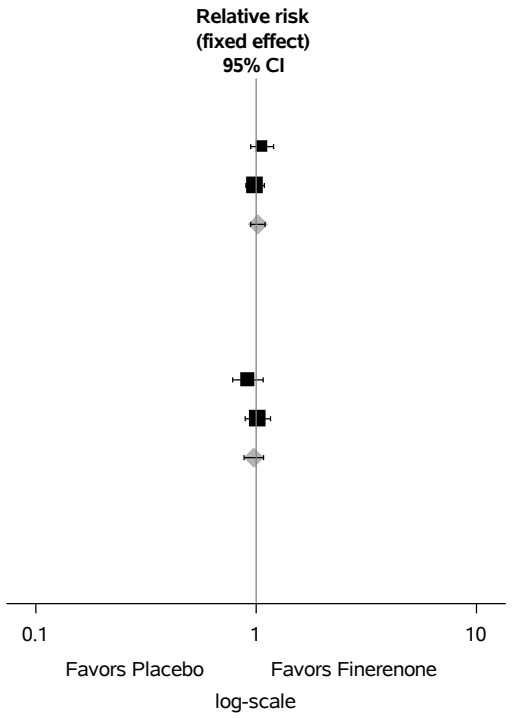
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	389 / 1777	408 / 1815	36.4	0.97 [0.86,1.10]	
FIGARO-DKD	665 / 2672	669 / 2605	63.6	0.97 [0.88,1.06]	
Total	1054 / 4449	1077 / 4420		0.97 [0.90,1.05]	Z=-0.78, p=0.4325
Heterogeneity:	Q=0.00 (df=1)	p=0.9506	I^2=0.0%		
Black					
FIDELIO-DKD	35 / 140	35 / 124	48.4	0.89 [0.59,1.32]	
FIGARO-DKD	34 / 113	39 / 145	51.6	1.12 [0.76,1.65]	
Total	69 / 253	74 / 269		1.00 [0.75,1.32]	Z=-0.01, p=0.9932
Heterogeneity:	Q=0.67 (df=1)	p=0.4127	I^2=0.0%		
Asian					
FIDELIO-DKD	167 / 717	148 / 723	45.0	1.14 [0.94,1.38]	
FIGARO-DKD	193 / 715	175 / 739	55.0	1.14 [0.96,1.36]	
Total	360 / 1432	323 / 1462		1.14 [1.00,1.30]	Z=1.94, p=0.0520
Heterogeneity:	Q=0.00 (df=1)	p=0.9893	I^2=0.0%		
Others					
FIDELIO-DKD	59 / 199	50 / 179	50.0	1.06 [0.77,1.46]	
FIGARO-DKD	52 / 186	55 / 177	50.0	0.90 [0.65,1.24]	
Total	111 / 385	105 / 356		0.98 [0.78,1.22]	Z=-0.20, p=0.8422
Heterogeneity:	Q=0.52 (df=1)	p=0.4716	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.39 (df=3)	p=0.2220	I^2=31.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.2.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set

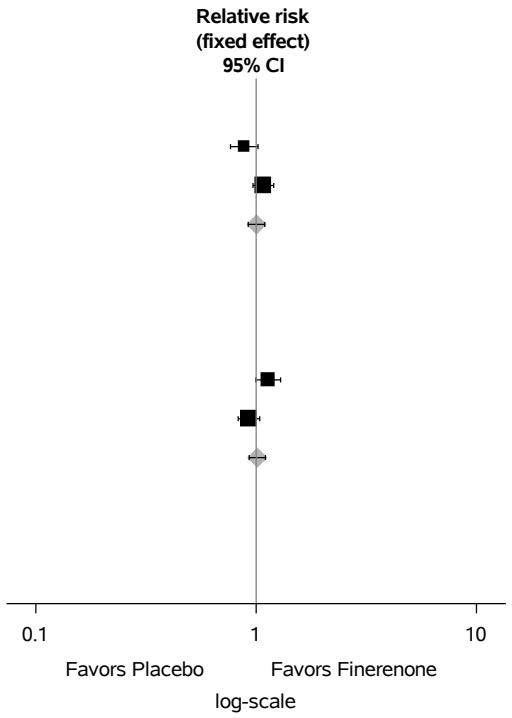
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	428 / 1953	418 / 2030	39.4	1.06 [0.94,1.20]	
FIGARO-DKD	615 / 2528	634 / 2577	60.6	0.99 [0.90,1.09]	
Total	1043 / 4481	1052 / 4607		1.02 [0.94,1.10]	Z=0.46, p=0.6433
Heterogeneity:	Q=0.88 (df=1)	p=0.3481	I^2=0.0%		
Female					
FIDELIO-DKD	222 / 880	223 / 811	40.7	0.92 [0.78,1.08]	
FIGARO-DKD	329 / 1158	304 / 1089	59.3	1.02 [0.89,1.16]	
Total	551 / 2038	527 / 1900		0.98 [0.88,1.08]	Z=-0.47, p=0.6354
Heterogeneity:	Q=0.96 (df=1)	p=0.3262	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5116	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.2.9: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set

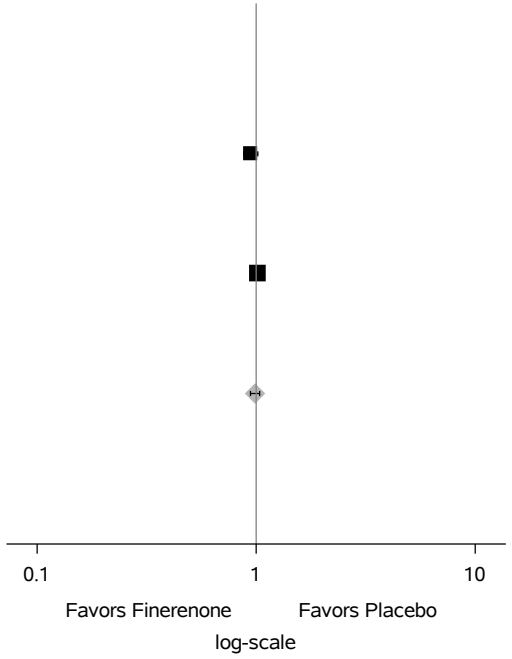
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	270 / 1205	298 / 1174	36.1	0.88 [0.76,1.02]	
FIGARO-DKD	497 / 1753	462 / 1757	63.9	1.08 [0.97,1.20]	
Total	767 / 2958	760 / 2931		1.00 [0.92,1.09]	Z=0.07, p=0.9446
Heterogeneity:	Q=4.76 (df=1)	p=0.0292	I^2=79.0%		
>= 65					
FIDELIO-DKD	380 / 1628	343 / 1667	43.2	1.13 [1.00,1.29]	
FIGARO-DKD	447 / 1933	476 / 1909	56.8	0.93 [0.83,1.04]	
Total	827 / 3561	819 / 3576		1.01 [0.93,1.10]	Z=0.27, p=0.7852
Heterogeneity:	Q=5.32 (df=1)	p=0.0211	I^2=81.2%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8876	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set

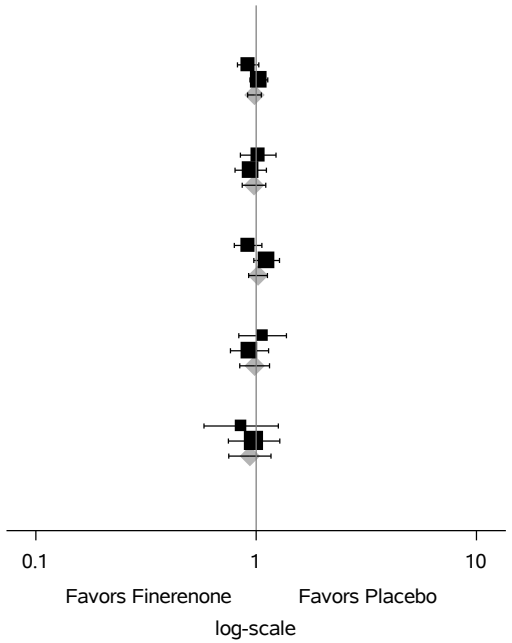
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	904 / 2833	958 / 2841	42.1	0.94 [0.88,1.02]	
FIGARO-DKD	1268 / 3686	1235 / 3666	57.9	1.02 [0.96,1.09]	
Total	2172 / 6519	2193 / 6507		0.99 [0.94,1.04]	Z=-0.49, p=0.6276
Heterogeneity:	Q=2.35 (df=1)	p=0.1254	I^2=57.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.3.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set

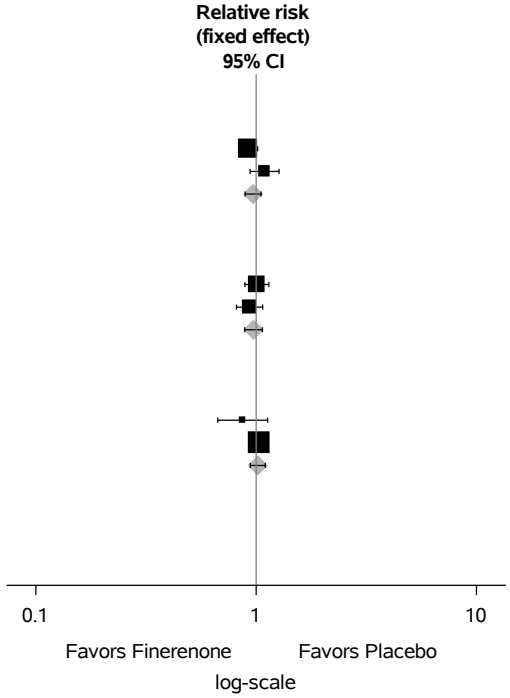
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	390 / 1182	422 / 1176	41.0	0.92 [0.82,1.03]	
FIGARO-DKD	599 / 1754	581 / 1750	59.0	1.03 [0.94,1.13]	
Total	989 / 2936	1003 / 2926		0.98 [0.91,1.06]	Z=-0.49, p=0.6250
Heterogeneity:	Q=2.29 (df=1)	p=0.1299	I^2=56.4%		
North America					
FIDELIO-DKD	151 / 467	151 / 477	43.7	1.02 [0.85,1.23]	
FIGARO-DKD	185 / 559	192 / 548	56.3	0.94 [0.80,1.11]	
Total	336 / 1026	343 / 1025		0.98 [0.86,1.11]	Z=-0.36, p=0.7160
Heterogeneity:	Q=0.38 (df=1)	p=0.5365	I^2=0.0%		
Asia					
FIDELIO-DKD	242 / 790	263 / 789	46.5	0.92 [0.80,1.06]	
FIGARO-DKD	295 / 810	266 / 815	53.5	1.12 [0.98,1.28]	
Total	537 / 1600	529 / 1604		1.02 [0.92,1.12]	Z=0.39, p=0.6967
Heterogeneity:	Q=3.73 (df=1)	p=0.0533	I^2=73.2%		
Latin America					
FIDELIO-DKD	90 / 295	85 / 298	39.1	1.07 [0.83,1.37]	
FIGARO-DKD	129 / 424	136 / 417	60.9	0.93 [0.76,1.14]	
Total	219 / 719	221 / 715		0.98 [0.84,1.15]	Z=-0.20, p=0.8399
Heterogeneity:	Q=0.71 (df=1)	p=0.4006	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	37 / 101	32.4	0.85 [0.58,1.26]	
FIGARO-DKD	60 / 139	60 / 136	67.6	0.98 [0.75,1.28]	
Total	91 / 238	97 / 237		0.94 [0.75,1.17]	Z=-0.58, p=0.5593
Heterogeneity:	Q=0.31 (df=1)	p=0.5750	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.68 (df=4)	p=0.9536	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

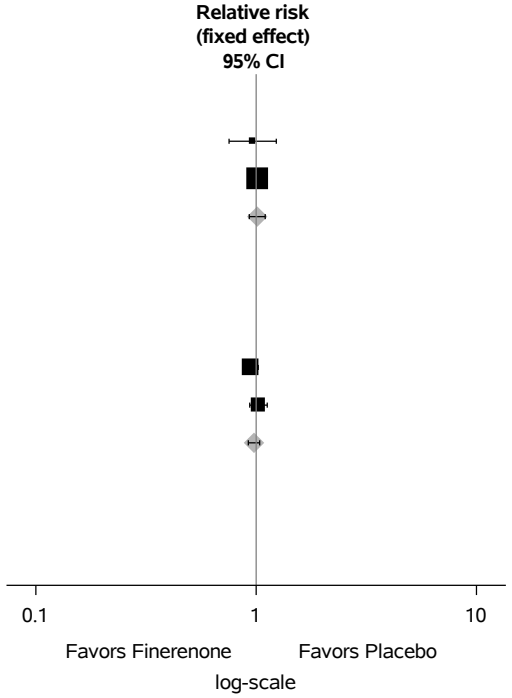
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	500 / 1559	540 / 1549	69.9	0.92 [0.83,1.02]	
FIGARO-DKD	231 / 639	209 / 631	30.1	1.09 [0.94,1.27]	
Total	731 / 2198	749 / 2180		0.97 [0.89,1.05]	Z=-0.76, p=0.4499
Heterogeneity:	Q=3.42 (df=1)	p=0.0643	I^2=70.8%		
45 - < 60					
FIDELIO-DKD	336 / 1063	336 / 1071	54.5	1.01 [0.89,1.14]	
FIGARO-DKD	251 / 720	273 / 731	45.5	0.93 [0.81,1.07]	
Total	587 / 1783	609 / 1802		0.97 [0.89,1.07]	Z=-0.58, p=0.5631
Heterogeneity:	Q=0.65 (df=1)	p=0.4201	I^2=0.0%		
>= 60					
FIDELIO-DKD	68 / 211	82 / 221	9.0	0.87 [0.67,1.13]	
FIGARO-DKD	786 / 2327	753 / 2304	91.0	1.03 [0.95,1.12]	
Total	854 / 2538	835 / 2525		1.02 [0.94,1.10]	Z=0.43, p=0.6643
Heterogeneity:	Q=1.56 (df=1)	p=0.2116	I^2=35.9%		
Subgroup Heterogeneity:	Q=0.87 (df=2)	p=0.6476	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set

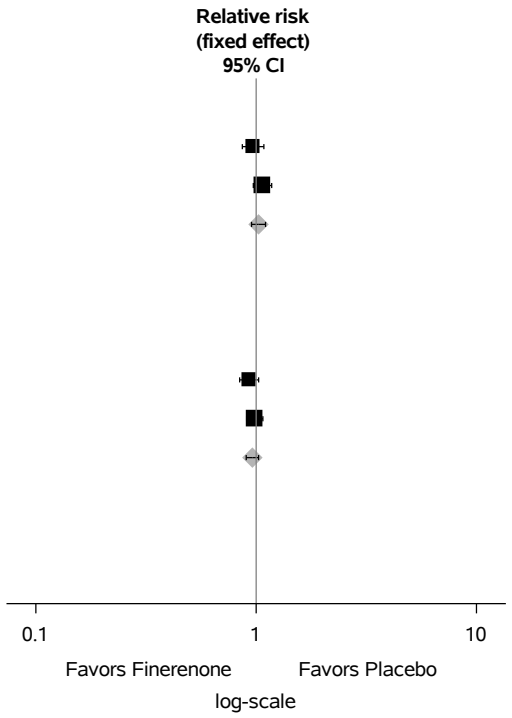
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 210	81 / 213	11.3	0.96 [0.75,1.23]	
FIGARO-DKD	634 / 1722	617 / 1705	88.7	1.02 [0.93,1.11]	
Total	711 / 1932	698 / 1918		1.01 [0.93,1.10]	Z=0.26, p=0.7925
Heterogeneity:	Q=0.16 (df=1)	p=0.6881	I^2=0.0%		
Very High					
FIDELIO-DKD	827 / 2623	877 / 2628	57.8	0.94 [0.87,1.02]	
FIGARO-DKD	634 / 1964	618 / 1961	42.2	1.02 [0.93,1.12]	
Total	1461 / 4587	1495 / 4589		0.98 [0.92,1.04]	Z=-0.75, p=0.4533
Heterogeneity:	Q=1.74 (df=1)	p=0.1877	I^2=42.4%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5157	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set

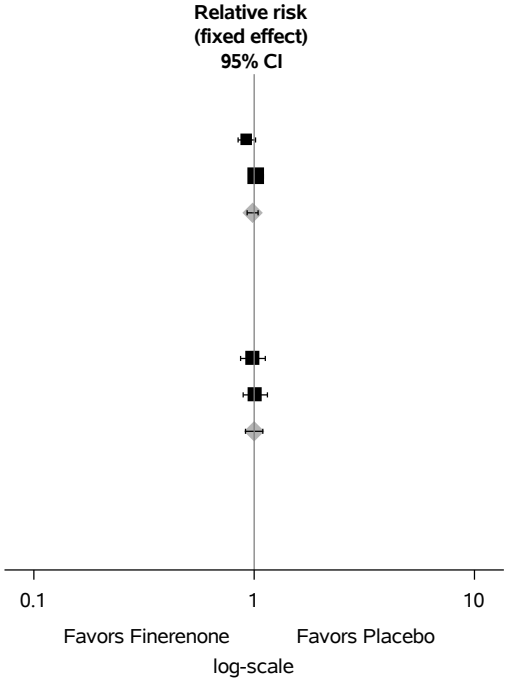
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	407 / 1303	420 / 1302	42.1	0.97 [0.87,1.08]	
FIGARO-DKD	578 / 1676	534 / 1654	57.9	1.07 [0.97,1.18]	
Total	985 / 2979	954 / 2956		1.02 [0.95,1.10]	Z=0.66, p=0.5082
Heterogeneity:	Q=1.69 (df=1)	p=0.1936	I^2=40.8%		
Absent					
FIDELIO-DKD	497 / 1530	538 / 1539	42.3	0.93 [0.84,1.03]	
FIGARO-DKD	690 / 2010	701 / 2012	57.7	0.99 [0.90,1.07]	
Total	1187 / 3540	1239 / 3551		0.96 [0.90,1.03]	Z=-1.20, p=0.2292
Heterogeneity:	Q=0.77 (df=1)	p=0.3798	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.67 (df=1)	p=0.1963	I^2=40.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

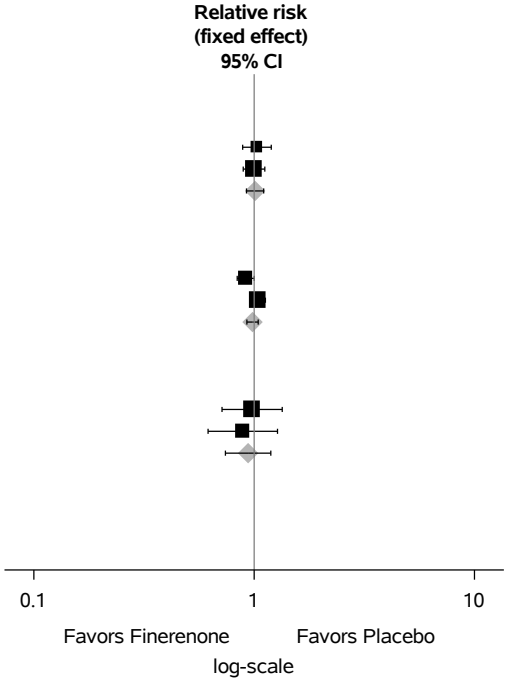
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	599 / 1881	640 / 1861	39.4	0.93 [0.85,1.01]	
FIGARO-DKD	939 / 2643	907 / 2612	60.6	1.02 [0.95,1.10]	
Total	1538 / 4524	1547 / 4473		0.98 [0.93,1.04]	Z=-0.56, p=0.5728
Heterogeneity:	Q=2.79 (df=1)	p=0.0949	I^2=64.1%		
> 4.5					
FIDELIO-DKD	305 / 951	318 / 979	49.0	0.99 [0.87,1.12]	
FIGARO-DKD	329 / 1043	328 / 1052	51.0	1.01 [0.89,1.15]	
Total	634 / 1994	646 / 2031		1.00 [0.91,1.09]	Z=-0.01, p=0.9948
Heterogeneity:	Q=0.07 (df=1)	p=0.7920	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7673	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.3.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

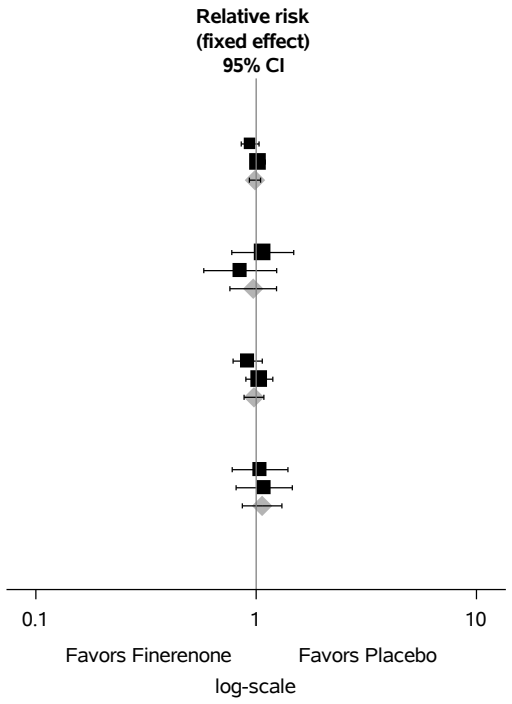
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	244 / 788	234 / 778	36.3	1.03 [0.89,1.20]	
FIGARO-DKD	399 / 1187	403 / 1197	63.7	1.00 [0.89,1.12]	
Total	643 / 1975	637 / 1975		1.01 [0.92,1.10]	Z=0.21, p=0.8355
Heterogeneity:	Q=0.10 (df=1)	p=0.7483	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	610 / 1900	674 / 1922	43.9	0.92 [0.84,1.00]	
FIGARO-DKD	834 / 2392	790 / 2355	56.1	1.04 [0.96,1.12]	
Total	1444 / 4292	1464 / 4277		0.98 [0.93,1.04]	Z=-0.57, p=0.5708
Heterogeneity:	Q=4.35 (df=1)	p=0.0370	I^2=77.0%		
>= 160					
FIDELIO-DKD	50 / 142	50 / 139	57.1	0.98 [0.71,1.34]	
FIGARO-DKD	35 / 107	42 / 114	42.9	0.89 [0.62,1.28]	
Total	85 / 249	92 / 253		0.94 [0.74,1.19]	Z=-0.52, p=0.6008
Heterogeneity:	Q=0.16 (df=1)	p=0.6904	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=2)	p=0.8075	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.3.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set

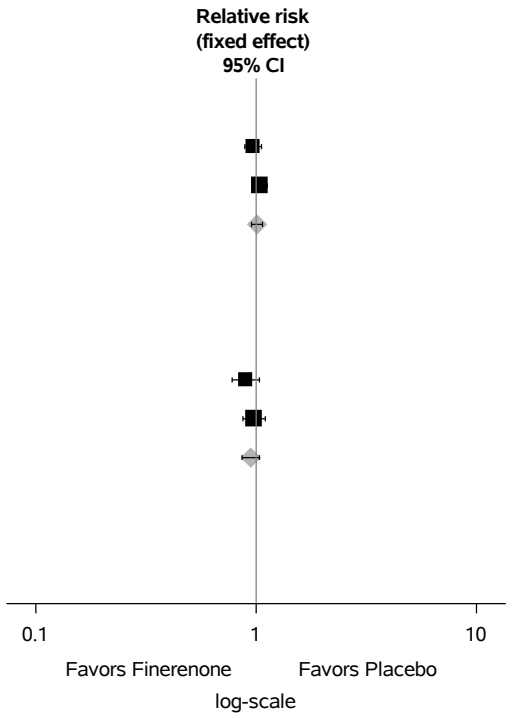
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	570 / 1777	620 / 1815	39.4	0.94 [0.86,1.03]	
FIGARO-DKD	920 / 2672	879 / 2605	60.6	1.02 [0.95,1.10]	
Total	1490 / 4449	1499 / 4420		0.99 [0.93,1.05]	Z=-0.42, p=0.6724
Heterogeneity:	Q=1.86 (df=1)	p=0.1730	I^2=46.2%		
Black					
FIDELIO-DKD	52 / 140	43 / 124	58.1	1.07 [0.77,1.48]	
FIGARO-DKD	31 / 113	47 / 145	41.9	0.85 [0.58,1.24]	
Total	83 / 253	90 / 269		0.97 [0.76,1.24]	Z=-0.25, p=0.8037
Heterogeneity:	Q=0.85 (df=1)	p=0.3559	I^2=0.0%		
Asian					
FIDELIO-DKD	216 / 717	238 / 723	46.0	0.92 [0.79,1.07]	
FIGARO-DKD	253 / 715	253 / 739	54.0	1.03 [0.90,1.19]	
Total	469 / 1432	491 / 1462		0.98 [0.88,1.08]	Z=-0.44, p=0.6625
Heterogeneity:	Q=1.32 (df=1)	p=0.2504	I^2=24.3%		
Others					
FIDELIO-DKD	66 / 199	57 / 179	50.4	1.04 [0.78,1.39]	
FIGARO-DKD	64 / 186	56 / 177	49.6	1.09 [0.81,1.46]	
Total	130 / 385	113 / 356		1.06 [0.87,1.31]	Z=0.59, p=0.5559
Heterogeneity:	Q=0.04 (df=1)	p=0.8376	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=3)	p=0.9054	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.3.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set

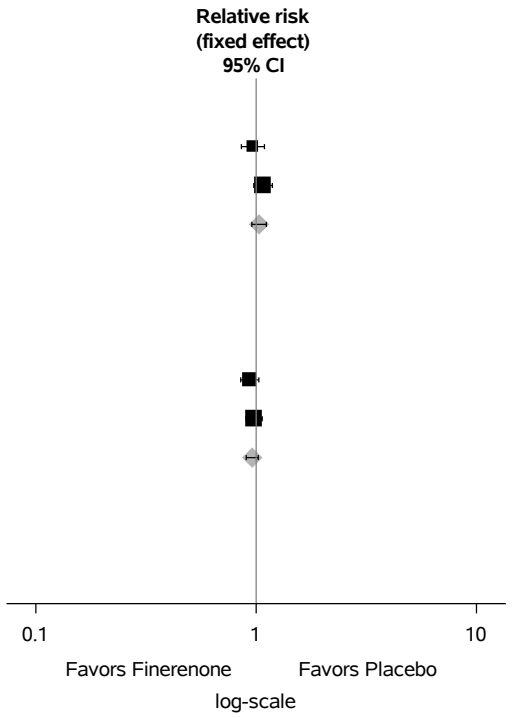
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	647 / 1953	694 / 2030	43.0	0.97 [0.89,1.06]	
FIGARO-DKD	887 / 2528	869 / 2577	57.0	1.04 [0.96,1.12]	
Total	1534 / 4481	1563 / 4607		1.01 [0.95,1.07]	Z=0.31, p=0.7553
Heterogeneity:	Q=1.46 (df=1)	p=0.2275	I^2=31.3%		
Female					
FIDELIO-DKD	257 / 880	264 / 811	40.2	0.90 [0.78,1.03]	
FIGARO-DKD	381 / 1158	366 / 1089	59.8	0.98 [0.87,1.10]	
Total	638 / 2038	630 / 1900		0.95 [0.86,1.03]	Z=-1.22, p=0.2225
Heterogeneity:	Q=0.86 (df=1)	p=0.3546	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=1)	p=0.2310	I^2=30.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.3.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set

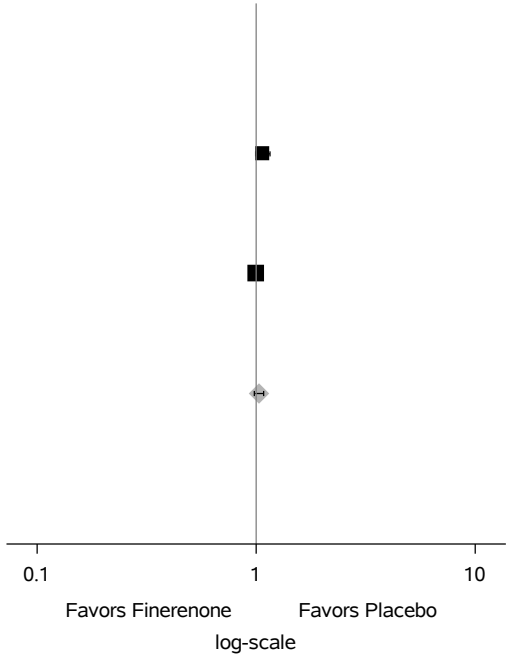
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	365 / 1205	368 / 1174	39.3	0.97 [0.86,1.09]	
FIGARO-DKD	578 / 1753	539 / 1757	60.7	1.07 [0.98,1.18]	
Total	943 / 2958	907 / 2931		1.03 [0.96,1.11]	Z=0.79, p=0.4306
Heterogeneity:	Q=1.82 (df=1)	p=0.1774	I^2=45.0%		
>= 65					
FIDELIO-DKD	539 / 1628	590 / 1667	44.1	0.94 [0.85,1.03]	
FIGARO-DKD	690 / 1933	696 / 1909	55.9	0.98 [0.90,1.07]	
Total	1229 / 3561	1286 / 3576		0.96 [0.90,1.02]	Z=-1.29, p=0.1984
Heterogeneity:	Q=0.50 (df=1)	p=0.4808	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.04 (df=1)	p=0.1531	I^2=51.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set

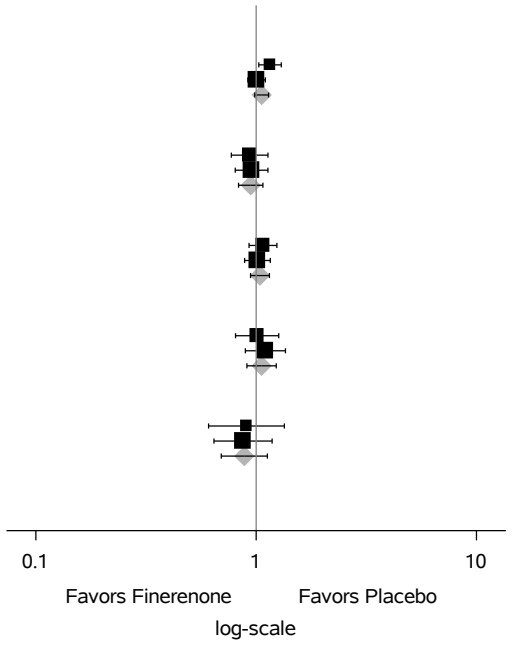
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	937 / 2833	879 / 2841	41.7	1.07 [0.99,1.16]	
FIGARO-DKD	1244 / 3686	1235 / 3666	58.3	1.00 [0.94,1.07]	
Total	2181 / 6519	2114 / 6507		1.03 [0.98,1.08]	Z=1.18, p=0.2363
Heterogeneity:	Q=1.80 (df=1)	p=0.1795	I^2=44.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.4.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set

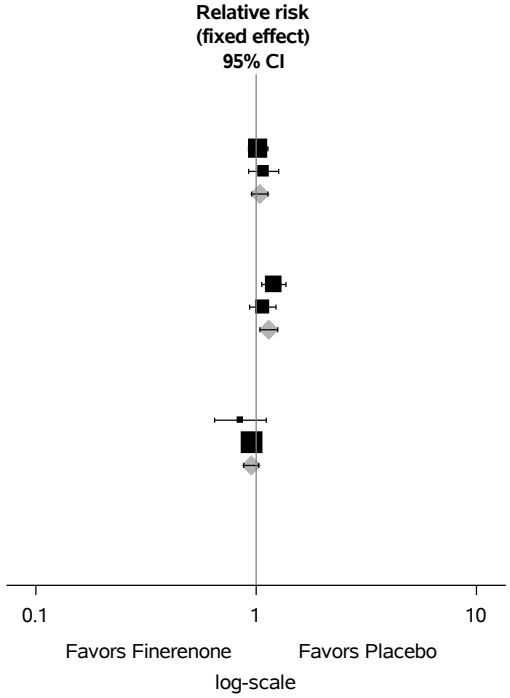
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	409 / 1182	352 / 1176	37.6	1.16 [1.03,1.30]	
FIGARO-DKD	607 / 1754	603 / 1750	62.4	1.00 [0.92,1.10]	
Total	1016 / 2936	955 / 2926		1.06 [0.99,1.14]	Z=1.56, p=0.1177
Heterogeneity:	Q=3.44 (df=1)	p=0.0637	I^2=70.9%		
North America					
FIDELIO-DKD	139 / 467	152 / 477	44.3	0.93 [0.77,1.13]	
FIGARO-DKD	176 / 559	181 / 548	55.7	0.95 [0.80,1.13]	
Total	315 / 1026	333 / 1025		0.94 [0.83,1.07]	Z=-0.88, p=0.3814
Heterogeneity:	Q=0.02 (df=1)	p=0.8765	I^2=0.0%		
Asia					
FIDELIO-DKD	258 / 790	240 / 789	45.9	1.07 [0.93,1.24]	
FIGARO-DKD	281 / 810	279 / 815	54.1	1.01 [0.89,1.16]	
Total	539 / 1600	519 / 1604		1.04 [0.94,1.15]	Z=0.79, p=0.4282
Heterogeneity:	Q=0.33 (df=1)	p=0.5672	I^2=0.0%		
Latin America					
FIDELIO-DKD	100 / 295	100 / 298	46.3	1.01 [0.81,1.27]	
FIGARO-DKD	131 / 424	117 / 417	53.7	1.10 [0.89,1.36]	
Total	231 / 719	217 / 715		1.06 [0.91,1.23]	Z=0.72, p=0.4705
Heterogeneity:	Q=0.30 (df=1)	p=0.5829	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	35 / 101	37.1	0.90 [0.61,1.34]	
FIGARO-DKD	49 / 139	55 / 136	62.9	0.87 [0.64,1.18]	
Total	80 / 238	90 / 237		0.88 [0.69,1.12]	Z=-1.01, p=0.3134
Heterogeneity:	Q=0.02 (df=1)	p=0.8877	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.06 (df=4)	p=0.3975	I^2=1.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

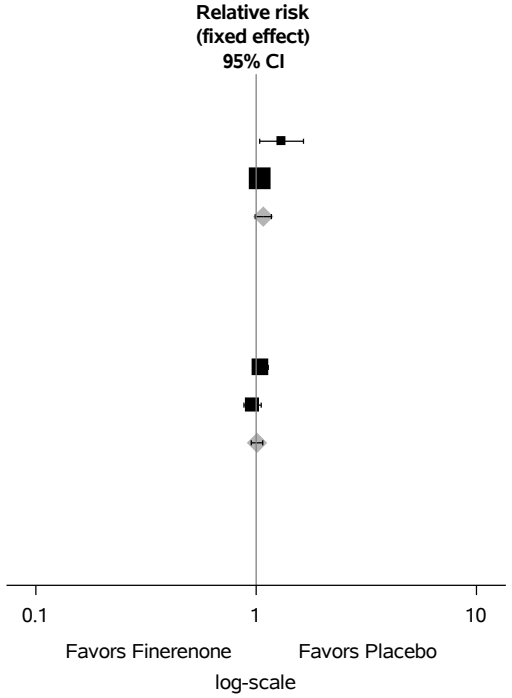
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	510 / 1559	496 / 1549	70.5	1.02 [0.92,1.13]	
FIGARO-DKD	219 / 639	200 / 631	29.5	1.08 [0.92,1.27]	
Total	729 / 2198	696 / 2180		1.04 [0.95,1.13]	Z=0.88, p=0.3803
Heterogeneity:	Q=0.35 (df=1)	p=0.5520	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	363 / 1063	304 / 1071	54.2	1.20 [1.06,1.37]	
FIGARO-DKD	267 / 720	253 / 731	45.8	1.07 [0.93,1.23]	
Total	630 / 1783	557 / 1802		1.14 [1.04,1.25]	Z=2.78, p=0.0055
Heterogeneity:	Q=1.47 (df=1)	p=0.2248	I^2=32.1%		
>= 60					
FIDELIO-DKD	64 / 211	79 / 221	8.4	0.85 [0.65,1.11]	
FIGARO-DKD	758 / 2327	782 / 2304	91.6	0.96 [0.88,1.04]	
Total	822 / 2538	861 / 2525		0.95 [0.88,1.03]	Z=-1.29, p=0.1963
Heterogeneity:	Q=0.73 (df=1)	p=0.3926	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.82 (df=2)	p=0.0121	I^2=77.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set

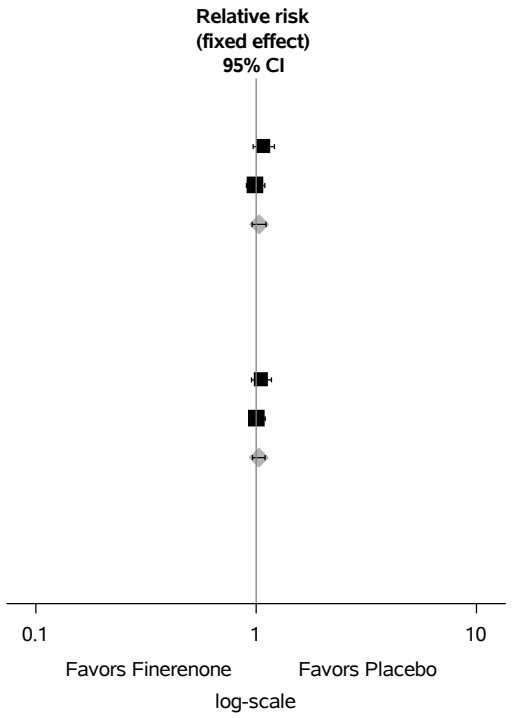
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	99 / 210	77 / 213	13.7	1.30 [1.04,1.64]	
FIGARO-DKD	617 / 1722	585 / 1705	86.3	1.04 [0.95,1.14]	
Total	716 / 1932	662 / 1918		1.08 [0.99,1.17]	Z=1.72, p=0.0850
Heterogeneity:	Q=3.13 (df=1)	p=0.0771	I^2=68.0%		
Very High					
FIDELIO-DKD	838 / 2623	802 / 2628	55.7	1.05 [0.97,1.13]	
FIGARO-DKD	627 / 1964	650 / 1961	44.3	0.96 [0.88,1.05]	
Total	1465 / 4587	1452 / 4589		1.01 [0.95,1.07]	Z=0.29, p=0.7705
Heterogeneity:	Q=1.83 (df=1)	p=0.1758	I^2=45.4%		
Subgroup Heterogeneity:	Q=1.53 (df=1)	p=0.2162	I^2=34.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set

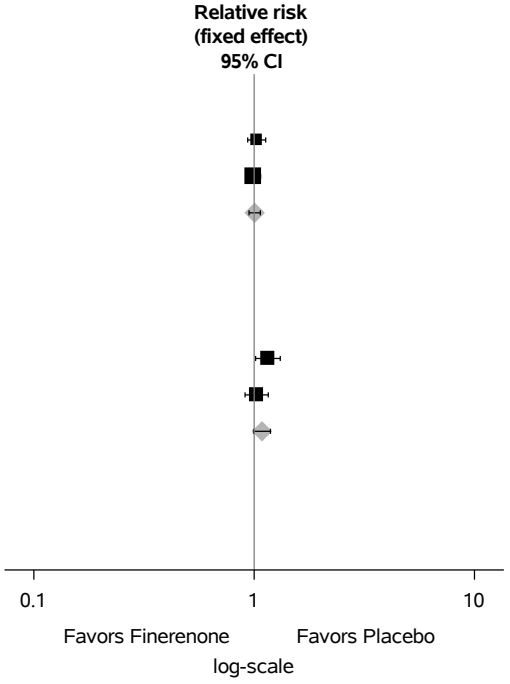
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	440 / 1303	406 / 1302	42.9	1.08 [0.97,1.21]	
FIGARO-DKD	556 / 1676	552 / 1654	57.1	0.99 [0.90,1.09]	
Total	996 / 2979	958 / 2956		1.03 [0.96,1.11]	Z=0.83, p=0.4056
Heterogeneity:	Q=1.31 (df=1)	p=0.2528	I^2=23.5%		
Absent					
FIDELIO-DKD	497 / 1530	473 / 1539	40.5	1.06 [0.95,1.17]	
FIGARO-DKD	688 / 2010	683 / 2012	59.5	1.01 [0.93,1.10]	
Total	1185 / 3540	1156 / 3551		1.03 [0.96,1.10]	Z=0.81, p=0.4183
Heterogeneity:	Q=0.47 (df=1)	p=0.4944	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9450	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

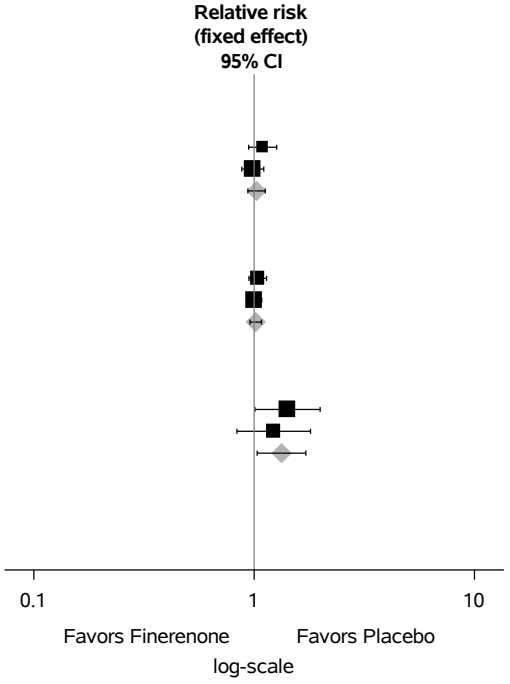
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	605 / 1881	583 / 1861	39.2	1.03 [0.93,1.13]	
FIGARO-DKD	893 / 2643	890 / 2612	60.8	0.99 [0.92,1.07]	
Total	1498 / 4524	1473 / 4473		1.01 [0.95,1.07]	Z=0.17, p=0.8624
Heterogeneity:	Q=0.32 (df=1)	p=0.5716	I^2=0.0%		
> 4.5					
FIDELIO-DKD	332 / 951	296 / 979	47.1	1.15 [1.02,1.31]	
FIGARO-DKD	351 / 1043	345 / 1052	52.9	1.03 [0.91,1.16]	
Total	683 / 1994	641 / 2031		1.08 [0.99,1.19]	Z=1.81, p=0.0706
Heterogeneity:	Q=1.71 (df=1)	p=0.1915	I^2=41.4%		
Subgroup Heterogeneity:	Q=1.98 (df=1)	p=0.1590	I^2=49.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.4.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

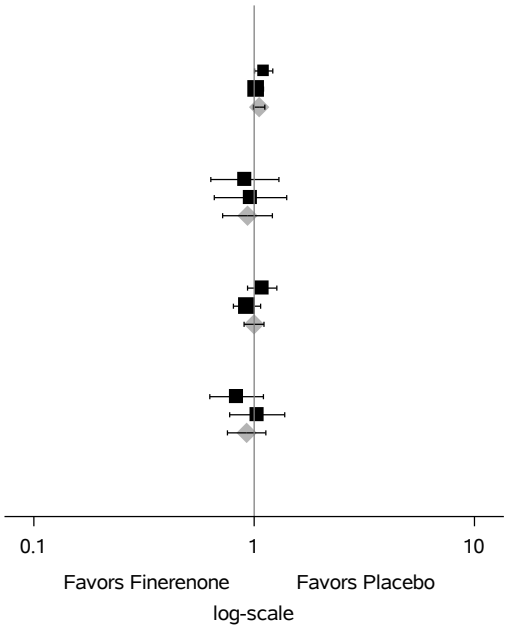
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	259 / 788	234 / 778	38.1	1.09 [0.94,1.27]	
FIGARO-DKD	387 / 1187	396 / 1197	61.9	0.99 [0.88,1.11]	
Total	646 / 1975	630 / 1975		1.03 [0.94,1.12]	Z=0.54, p=0.5903
Heterogeneity:	Q=1.18 (df=1)	p=0.2763	I^2=15.6%		
130 - < 160					
FIDELIO-DKD	623 / 1900	607 / 1922	42.3	1.04 [0.95,1.14]	
FIGARO-DKD	819 / 2392	806 / 2355	57.7	1.00 [0.92,1.08]	
Total	1442 / 4292	1413 / 4277		1.02 [0.96,1.08]	Z=0.53, p=0.5977
Heterogeneity:	Q=0.36 (df=1)	p=0.5484	I^2=0.0%		
>= 160					
FIDELIO-DKD	55 / 142	38 / 139	56.0	1.42 [1.01,1.99]	
FIGARO-DKD	38 / 107	33 / 114	44.0	1.23 [0.84,1.80]	
Total	93 / 249	71 / 253		1.33 [1.03,1.72]	Z=2.20, p=0.0278
Heterogeneity:	Q=0.30 (df=1)	p=0.5830	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.09 (df=2)	p=0.1292	I^2=51.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.4.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set

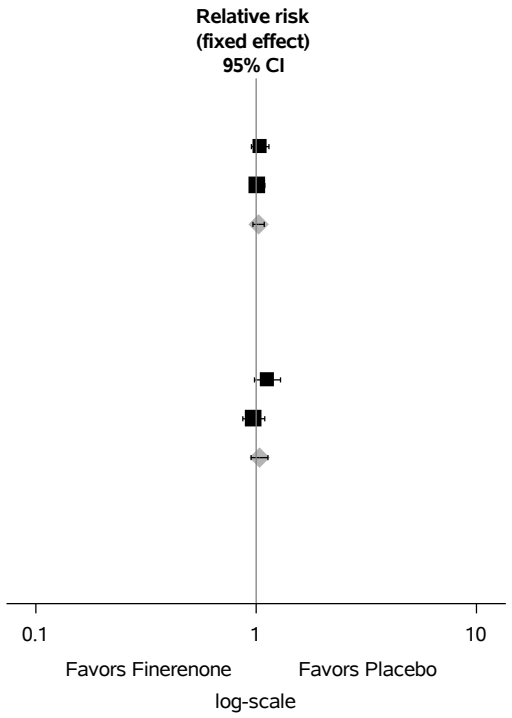
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	599 / 1777	554 / 1815	38.7	1.10 [1.00,1.21]	
FIGARO-DKD	910 / 2672	868 / 2605	61.3	1.02 [0.95,1.10]	
Total	1509 / 4449	1422 / 4420		1.05 [0.99,1.12]	Z=1.72, p=0.0863
Heterogeneity:	Q=1.55 (df=1)	p=0.2125	I^2=35.7%		
Black					
FIDELIO-DKD	42 / 140	41 / 124	53.1	0.91 [0.64,1.30]	
FIGARO-DKD	33 / 113	44 / 145	46.9	0.96 [0.66,1.41]	
Total	75 / 253	85 / 269		0.93 [0.72,1.21]	Z=-0.53, p=0.5994
Heterogeneity:	Q=0.05 (df=1)	p=0.8241	I^2=0.0%		
Asian					
FIDELIO-DKD	234 / 717	217 / 723	46.3	1.09 [0.93,1.27]	
FIGARO-DKD	237 / 715	264 / 739	53.7	0.93 [0.80,1.07]	
Total	471 / 1432	481 / 1462		1.00 [0.90,1.11]	Z=-0.03, p=0.9770
Heterogeneity:	Q=2.22 (df=1)	p=0.1367	I^2=54.9%		
Others					
FIDELIO-DKD	62 / 199	67 / 179	51.3	0.83 [0.63,1.10]	
FIGARO-DKD	64 / 186	59 / 177	48.7	1.03 [0.77,1.38]	
Total	126 / 385	126 / 356		0.92 [0.76,1.13]	Z=-0.77, p=0.4418
Heterogeneity:	Q=1.10 (df=1)	p=0.2936	I^2=9.4%		
Subgroup Heterogeneity:	Q=2.56 (df=3)	p=0.4641	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.4.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set

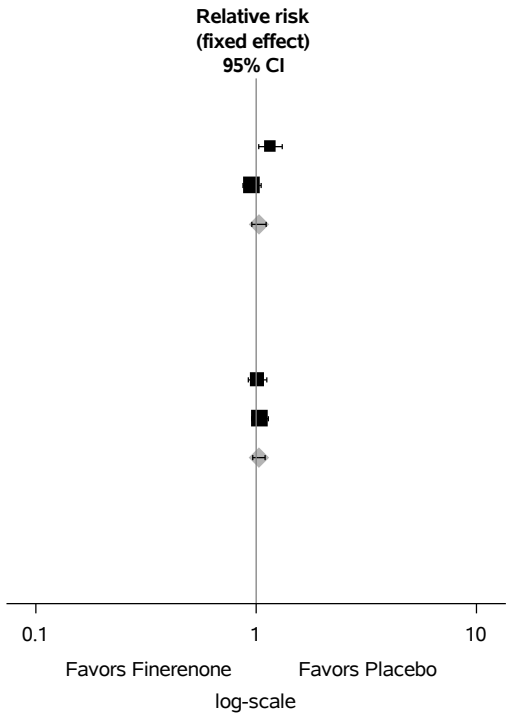
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	628 / 1953	626 / 2030	41.6	1.04 [0.95,1.14]	
FIGARO-DKD	853 / 2528	858 / 2577	58.4	1.01 [0.94,1.09]	
Total	1481 / 4481	1484 / 4607		1.03 [0.97,1.09]	Z=0.84, p=0.4030
Heterogeneity:	Q=0.22 (df=1)	p=0.6411	I^2=0.0%		
Female					
FIDELIO-DKD	309 / 880	253 / 811	41.6	1.13 [0.98,1.29]	
FIGARO-DKD	391 / 1158	377 / 1089	58.4	0.98 [0.87,1.09]	
Total	700 / 2038	630 / 1900		1.04 [0.95,1.13]	Z=0.78, p=0.4351
Heterogeneity:	Q=2.49 (df=1)	p=0.1147	I^2=59.8%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8573	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.4.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set

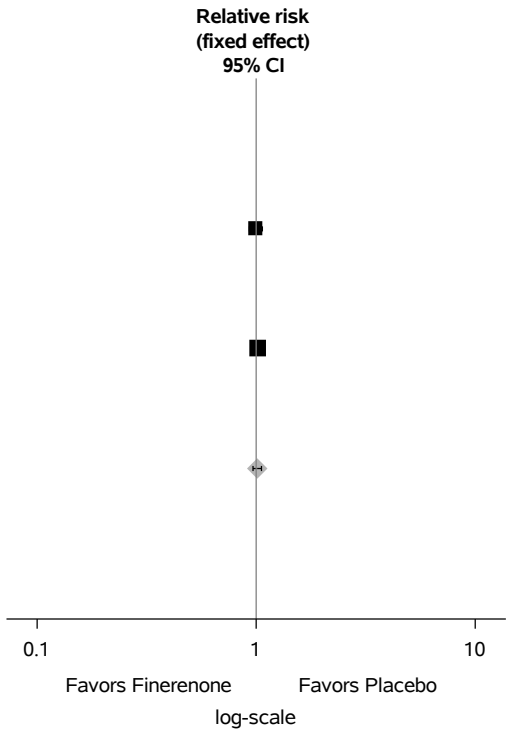
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	391 / 1205	328 / 1174	37.4	1.16 [1.03,1.31]	
FIGARO-DKD	562 / 1753	588 / 1757	62.6	0.96 [0.87,1.05]	
Total	953 / 2958	916 / 2931		1.03 [0.96,1.11]	Z=0.77, p=0.4433
Heterogeneity:	Q=5.92 (df=1)	p=0.0150	I^2=83.1%		
>= 65					
FIDELIO-DKD	546 / 1628	551 / 1667	44.8	1.01 [0.92,1.12]	
FIGARO-DKD	682 / 1933	647 / 1909	55.2	1.04 [0.95,1.14]	
Total	1228 / 3561	1198 / 3576		1.03 [0.96,1.10]	Z=0.87, p=0.3840
Heterogeneity:	Q=0.15 (df=1)	p=0.6993	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9908	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set

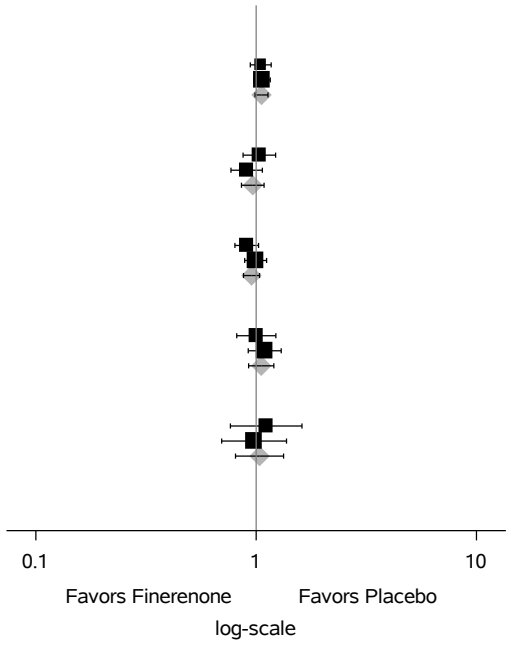
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1042 / 2833	1046 / 2841	42.6	1.00 [0.93,1.07]	
FIGARO-DKD	1404 / 3686	1365 / 3666	57.4	1.02 [0.96,1.08]	
Total	2446 / 6519	2411 / 6507		1.01 [0.97,1.06]	Z=0.49, p=0.6239
Heterogeneity:	Q=0.30 (df=1)	p=0.5839	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.5.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set

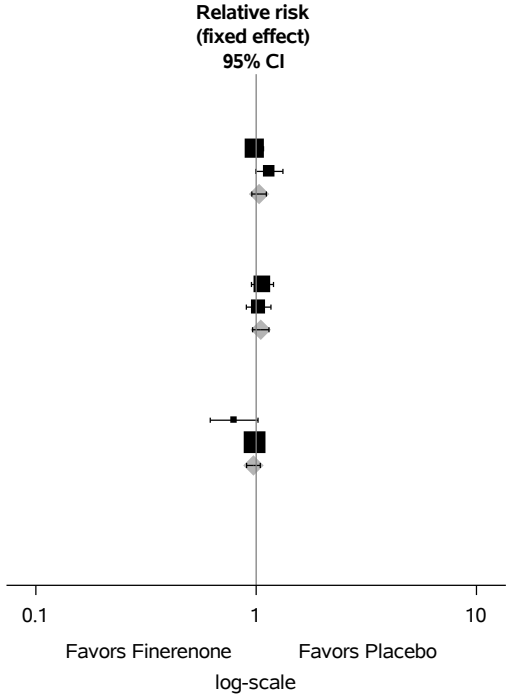
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	428 / 1182	406 / 1176	38.5	1.05 [0.94,1.17]	
FIGARO-DKD	670 / 1754	629 / 1750	61.5	1.06 [0.97,1.16]	
Total	1098 / 2936	1035 / 2926		1.06 [0.99,1.13]	Z=1.61, p=0.1064
Heterogeneity:	Q=0.03 (df=1)	p=0.8527	I^2=0.0%		
North America					
FIDELIO-DKD	171 / 467	169 / 477	48.2	1.03 [0.87,1.23]	
FIGARO-DKD	181 / 559	196 / 548	51.8	0.91 [0.77,1.07]	
Total	352 / 1026	365 / 1025		0.96 [0.86,1.09]	Z=-0.59, p=0.5535
Heterogeneity:	Q=1.21 (df=1)	p=0.2721	I^2=17.1%		
Asia					
FIDELIO-DKD	293 / 790	323 / 789	46.1	0.91 [0.80,1.03]	
FIGARO-DKD	339 / 810	343 / 815	53.9	0.99 [0.89,1.11]	
Total	632 / 1600	666 / 1604		0.95 [0.88,1.04]	Z=-1.14, p=0.2560
Heterogeneity:	Q=1.18 (df=1)	p=0.2781	I^2=15.0%		
Latin America					
FIDELIO-DKD	113 / 295	114 / 298	41.6	1.00 [0.82,1.23]	
FIGARO-DKD	169 / 424	152 / 417	58.4	1.09 [0.92,1.30]	
Total	282 / 719	266 / 715		1.05 [0.92,1.20]	Z=0.79, p=0.4319
Heterogeneity:	Q=0.42 (df=1)	p=0.5186	I^2=0.0%		
Others					
FIDELIO-DKD	37 / 99	34 / 101	45.1	1.11 [0.76,1.61]	
FIGARO-DKD	45 / 139	45 / 136	54.9	0.98 [0.70,1.37]	
Total	82 / 238	79 / 237		1.04 [0.81,1.33]	Z=0.27, p=0.7834
Heterogeneity:	Q=0.24 (df=1)	p=0.6237	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.64 (df=4)	p=0.3263	I^2=13.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

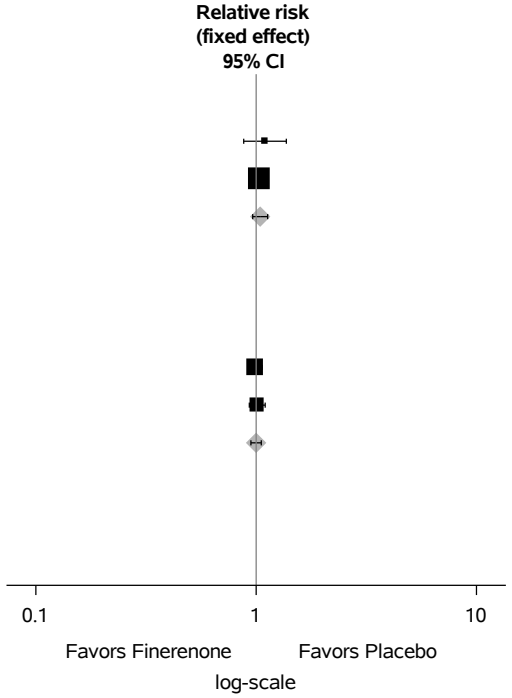
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	586 / 1559	590 / 1549	71.2	0.99 [0.90,1.08]	
FIGARO-DKD	258 / 639	222 / 631	28.8	1.15 [1.00,1.32]	
Total	844 / 2198	812 / 2180		1.03 [0.96,1.11]	Z=0.78, p=0.4327
Heterogeneity:	Q=3.10 (df=1)	p=0.0782	I^2=67.8%		
45 - < 60					
FIDELIO-DKD	387 / 1063	365 / 1071	55.5	1.07 [0.95,1.20]	
FIGARO-DKD	285 / 720	282 / 731	44.5	1.03 [0.90,1.17]	
Total	672 / 1783	647 / 1802		1.05 [0.96,1.14]	Z=1.10, p=0.2715
Heterogeneity:	Q=0.21 (df=1)	p=0.6472	I^2=0.0%		
>= 60					
FIDELIO-DKD	69 / 211	91 / 221	8.3	0.79 [0.62,1.02]	
FIGARO-DKD	861 / 2327	861 / 2304	91.7	0.99 [0.92,1.07]	
Total	930 / 2538	952 / 2525		0.97 [0.90,1.04]	Z=-0.78, p=0.4356
Heterogeneity:	Q=2.75 (df=1)	p=0.0972	I^2=63.6%		
Subgroup Heterogeneity:	Q=2.13 (df=2)	p=0.3440	I^2=6.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

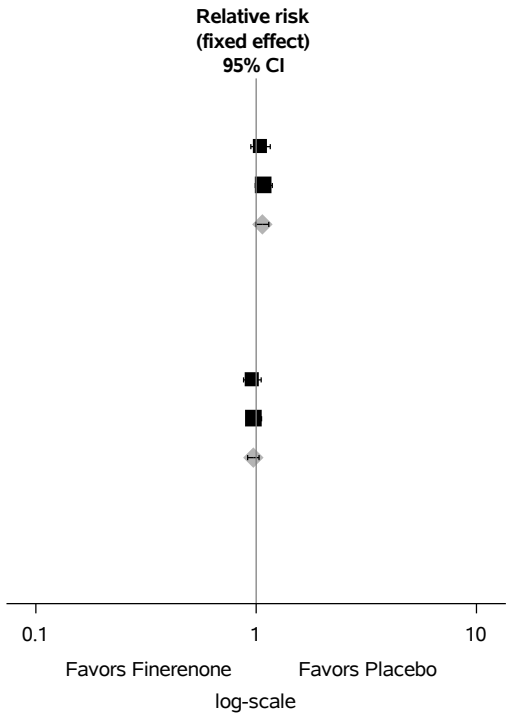
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	93 / 210	86 / 213	12.3	1.10 [0.88,1.37]	
FIGARO-DKD	687 / 1722	657 / 1705	87.7	1.04 [0.95,1.13]	
Total	780 / 1932	743 / 1918		1.04 [0.96,1.13]	Z=1.05, p=0.2938
Heterogeneity:	Q=0.23 (df=1)	p=0.6345	I^2=0.0%		
Very High					
FIDELIO-DKD	949 / 2623	960 / 2628	57.3	0.99 [0.92,1.06]	
FIGARO-DKD	717 / 1964	708 / 1961	42.7	1.01 [0.93,1.10]	
Total	1666 / 4587	1668 / 4589		1.00 [0.95,1.05]	Z=-0.03, p=0.9779
Heterogeneity:	Q=0.14 (df=1)	p=0.7107	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3797	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set

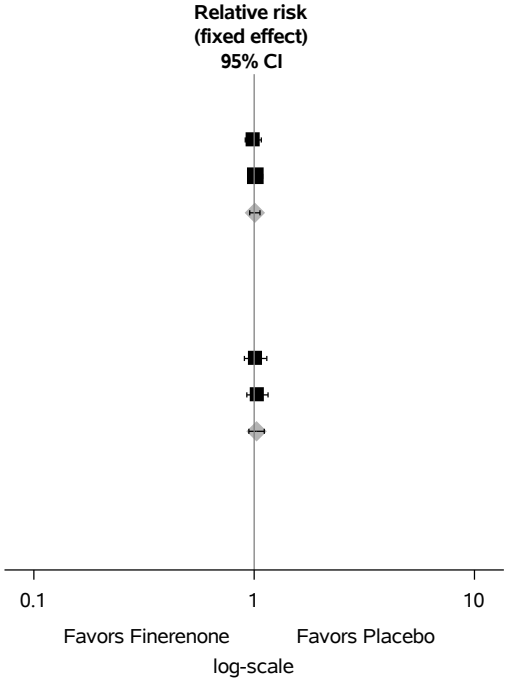
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	485 / 1303	463 / 1302	43.4	1.05 [0.95,1.16]	
FIGARO-DKD	643 / 1676	586 / 1654	56.6	1.08 [0.99,1.18]	
Total	1128 / 2979	1049 / 2956		1.07 [1.00,1.14]	Z=1.90, p=0.0574
Heterogeneity:	Q=0.24 (df=1)	p=0.6221	I^2=0.0%		
Absent					
FIDELIO-DKD	557 / 1530	583 / 1539	42.1	0.96 [0.88,1.05]	
FIGARO-DKD	761 / 2010	779 / 2012	57.9	0.98 [0.90,1.06]	
Total	1318 / 3540	1362 / 3551		0.97 [0.91,1.03]	Z=-0.97, p=0.3298
Heterogeneity:	Q=0.08 (df=1)	p=0.7784	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.27 (df=1)	p=0.0388	I^2=76.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

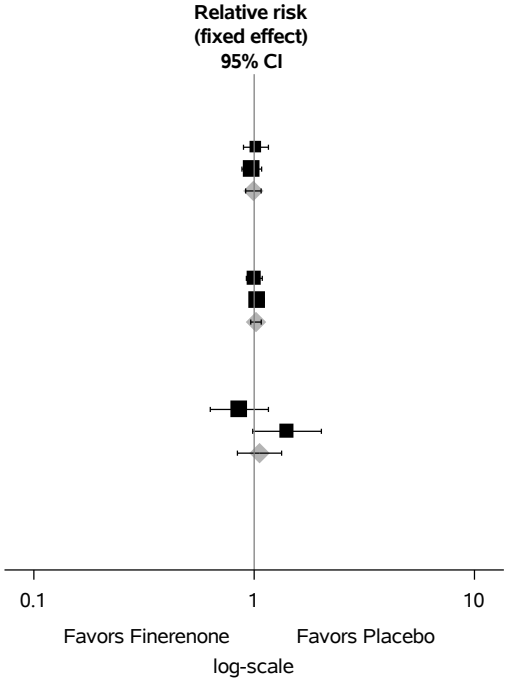
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	690 / 1881	689 / 1861	40.7	0.99 [0.91,1.08]	
FIGARO-DKD	1007 / 2643	977 / 2612	59.3	1.02 [0.95,1.09]	
Total	1697 / 4524	1666 / 4473		1.01 [0.95,1.06]	Z=0.26, p=0.7922
Heterogeneity:	Q=0.25 (df=1)	p=0.6183	I^2=0.0%		
> 4.5					
FIDELIO-DKD	352 / 951	357 / 979	47.2	1.02 [0.90,1.14]	
FIGARO-DKD	397 / 1043	387 / 1052	52.8	1.03 [0.93,1.16]	
Total	749 / 1994	744 / 2031		1.03 [0.95,1.11]	Z=0.61, p=0.5419
Heterogeneity:	Q=0.05 (df=1)	p=0.8155	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7172	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.5.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

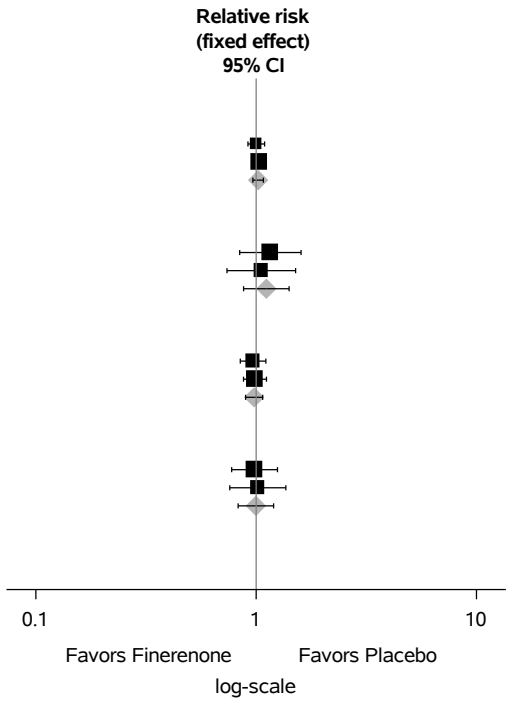
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	291 / 788	282 / 778	38.3	1.02 [0.89,1.16]	
FIGARO-DKD	444 / 1187	459 / 1197	61.7	0.98 [0.88,1.08]	
Total	735 / 1975	741 / 1975		0.99 [0.91,1.08]	Z=-0.20, p=0.8428
Heterogeneity:	Q=0.26 (df=1)	p=0.6079	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	701 / 1900	708 / 1922	43.8	1.00 [0.92,1.09]	
FIGARO-DKD	915 / 2392	872 / 2355	56.2	1.03 [0.96,1.11]	
Total	1616 / 4292	1580 / 4277		1.02 [0.96,1.08]	Z=0.68, p=0.4980
Heterogeneity:	Q=0.30 (df=1)	p=0.5834	I^2=0.0%		
>= 160					
FIDELIO-DKD	49 / 142	56 / 139	58.2	0.86 [0.63,1.16]	
FIGARO-DKD	45 / 107	34 / 114	41.8	1.41 [0.98,2.02]	
Total	94 / 249	90 / 253		1.06 [0.84,1.33]	Z=0.47, p=0.6355
Heterogeneity:	Q=4.32 (df=1)	p=0.0377	I^2=76.9%		
Subgroup Heterogeneity:	Q=0.44 (df=2)	p=0.8024	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.5.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set

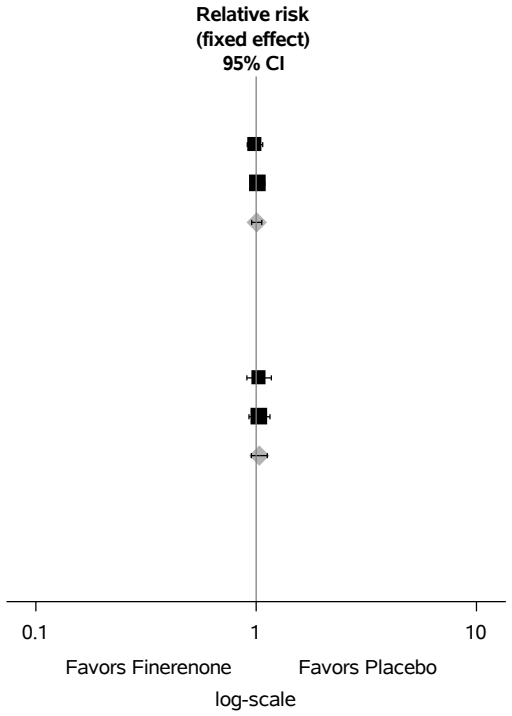
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	641 / 1777	654 / 1815	39.6	1.00 [0.92,1.09]	
FIGARO-DKD	1004 / 2672	947 / 2605	60.4	1.03 [0.96,1.11]	
Total	1645 / 4449	1601 / 4420		1.02 [0.97,1.08]	Z=0.73, p=0.4655
Heterogeneity:	Q=0.31 (df=1)	p=0.5760	I^2=0.0%		
Black					
FIDELIO-DKD	55 / 140	42 / 124	55.6	1.16 [0.84,1.60]	
FIGARO-DKD	37 / 113	45 / 145	44.4	1.06 [0.74,1.51]	
Total	92 / 253	87 / 269		1.11 [0.88,1.41]	Z=0.88, p=0.3814
Heterogeneity:	Q=0.15 (df=1)	p=0.6997	I^2=0.0%		
Asian					
FIDELIO-DKD	264 / 717	275 / 723	44.6	0.97 [0.85,1.11]	
FIGARO-DKD	301 / 715	315 / 739	55.4	0.99 [0.88,1.11]	
Total	565 / 1432	590 / 1462		0.98 [0.90,1.07]	Z=-0.47, p=0.6385
Heterogeneity:	Q=0.05 (df=1)	p=0.8268	I^2=0.0%		
Others					
FIDELIO-DKD	82 / 199	75 / 179	60.0	0.98 [0.77,1.25]	
FIGARO-DKD	62 / 186	58 / 177	40.0	1.02 [0.76,1.36]	
Total	144 / 385	133 / 356		1.00 [0.83,1.20]	Z=-0.03, p=0.9734
Heterogeneity:	Q=0.03 (df=1)	p=0.8611	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.26 (df=3)	p=0.7395	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.5.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set

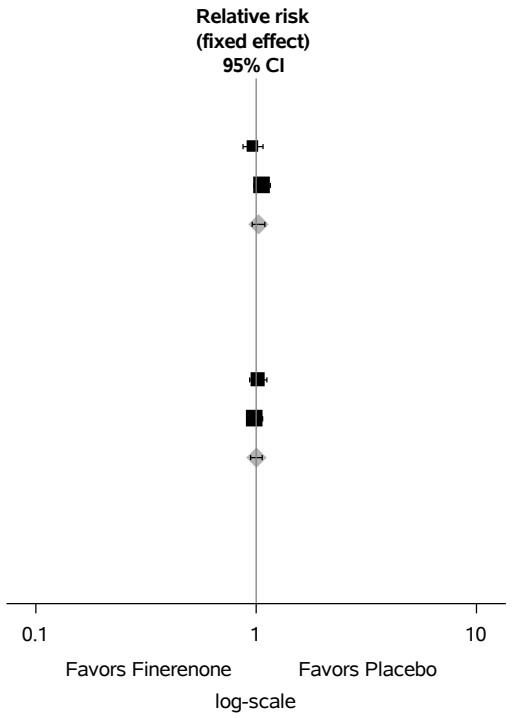
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	722 / 1953	760 / 2030	42.7	0.99 [0.91,1.07]	
FIGARO-DKD	977 / 2528	977 / 2577	57.3	1.02 [0.95,1.09]	
Total	1699 / 4481	1737 / 4607		1.01 [0.95,1.06]	Z=0.21, p=0.8349
Heterogeneity:	Q=0.34 (df=1)	p=0.5586	I^2=0.0%		
Female					
FIDELIO-DKD	320 / 880	286 / 811	42.5	1.03 [0.91,1.17]	
FIGARO-DKD	427 / 1158	388 / 1089	57.5	1.03 [0.93,1.16]	
Total	747 / 2038	674 / 1900		1.03 [0.95,1.12]	Z=0.77, p=0.4403
Heterogeneity:	Q=0.00 (df=1)	p=0.9660	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5889	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.5.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set

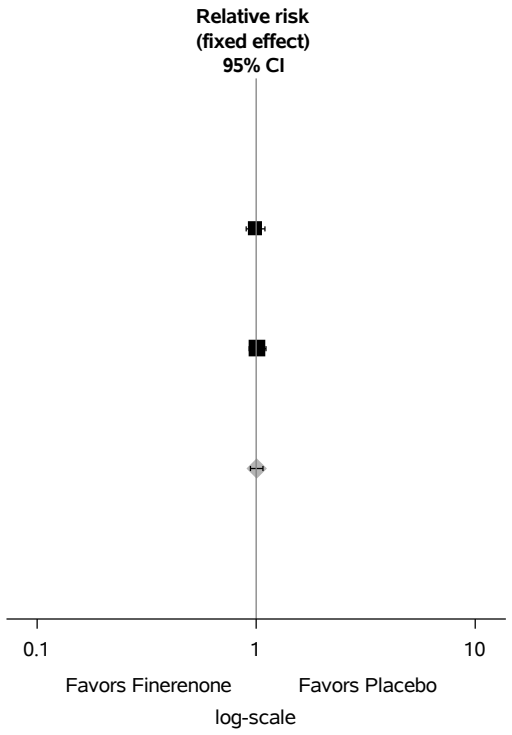
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	441 / 1205	444 / 1174	39.9	0.97 [0.87,1.07]	
FIGARO-DKD	682 / 1753	642 / 1757	60.1	1.06 [0.98,1.16]	
Total	1123 / 2958	1086 / 2931		1.02 [0.96,1.09]	Z=0.73, p=0.4643
Heterogeneity:	Q=1.93 (df=1)	p=0.1643	I^2=48.3%		
>= 65					
FIDELIO-DKD	601 / 1628	602 / 1667	45.0	1.02 [0.93,1.12]	
FIGARO-DKD	722 / 1933	723 / 1909	55.0	0.99 [0.91,1.07]	
Total	1323 / 3561	1325 / 3576		1.00 [0.94,1.06]	Z=0.07, p=0.9413
Heterogeneity:	Q=0.34 (df=1)	p=0.5624	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6242	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set

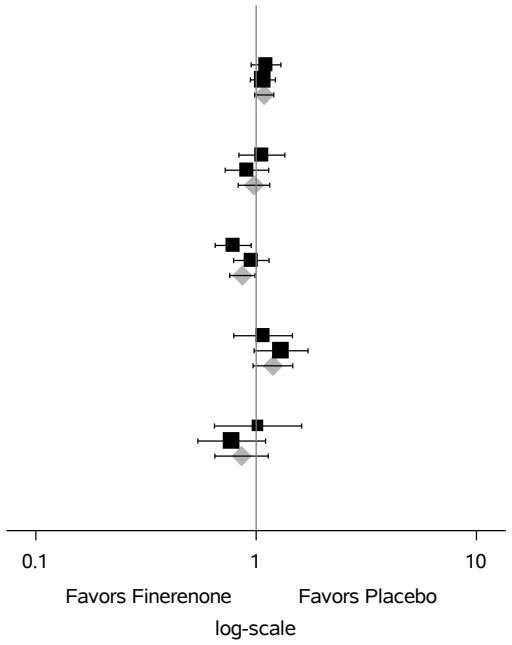
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	615 / 2833	621 / 2841	44.4	0.99 [0.90,1.10]	
FIGARO-DKD	785 / 3686	766 / 3666	55.6	1.02 [0.93,1.11]	
Total	1400 / 6519	1387 / 6507		1.01 [0.94,1.07]	Z=0.17, p=0.8669
Heterogeneity:	Q=0.10 (df=1)	p=0.7526	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.6.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set

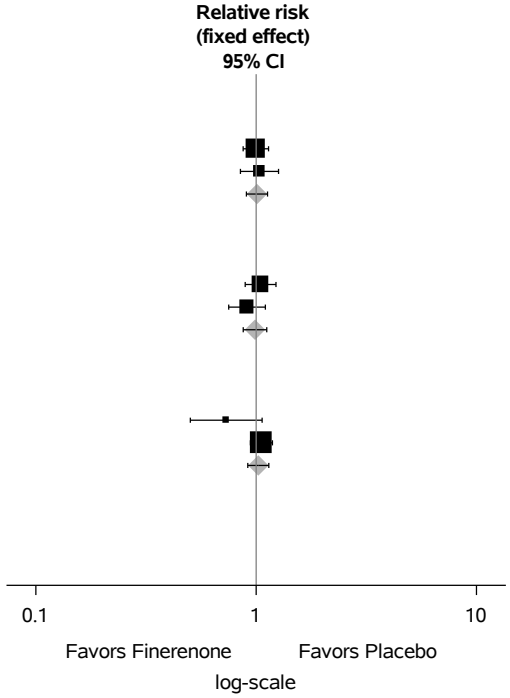
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	264 / 1182	237 / 1176	41.3	1.11 [0.95,1.29]	
FIGARO-DKD	372 / 1754	346 / 1750	58.7	1.07 [0.94,1.22]	
Total	636 / 2936	583 / 2926		1.09 [0.98,1.20]	Z=1.64, p=0.1012
Heterogeneity:	Q=0.10 (df=1)	p=0.7530	I^2=0.0%		
North America					
FIDELIO-DKD	106 / 467	102 / 477	47.2	1.06 [0.83,1.35]	
FIGARO-DKD	113 / 559	122 / 548	52.8	0.91 [0.72,1.14]	
Total	219 / 1026	224 / 1025		0.98 [0.83,1.15]	Z=-0.27, p=0.7866
Heterogeneity:	Q=0.86 (df=1)	p=0.3544	I^2=0.0%		
Asia					
FIDELIO-DKD	152 / 790	193 / 789	49.1	0.79 [0.65,0.95]	
FIGARO-DKD	171 / 810	181 / 815	50.9	0.95 [0.79,1.14]	
Total	323 / 1600	374 / 1604		0.87 [0.76,0.99]	Z=-2.15, p=0.0319
Heterogeneity:	Q=1.98 (df=1)	p=0.1596	I^2=49.4%		
Latin America					
FIDELIO-DKD	66 / 295	62 / 298	45.8	1.08 [0.79,1.46]	
FIGARO-DKD	91 / 424	69 / 417	54.2	1.30 [0.98,1.72]	
Total	157 / 719	131 / 715		1.19 [0.97,1.47]	Z=1.65, p=0.0986
Heterogeneity:	Q=0.78 (df=1)	p=0.3782	I^2=0.0%		
Others					
FIDELIO-DKD	27 / 99	27 / 101	37.6	1.02 [0.65,1.61]	
FIGARO-DKD	38 / 139	48 / 136	62.4	0.77 [0.54,1.10]	
Total	65 / 238	75 / 237		0.86 [0.65,1.13]	Z=-1.07, p=0.2827
Heterogeneity:	Q=0.88 (df=1)	p=0.3495	I^2=0.0%		
Subgroup Heterogeneity:	Q=11.22 (df=4)	p=0.0242	I^2=64.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

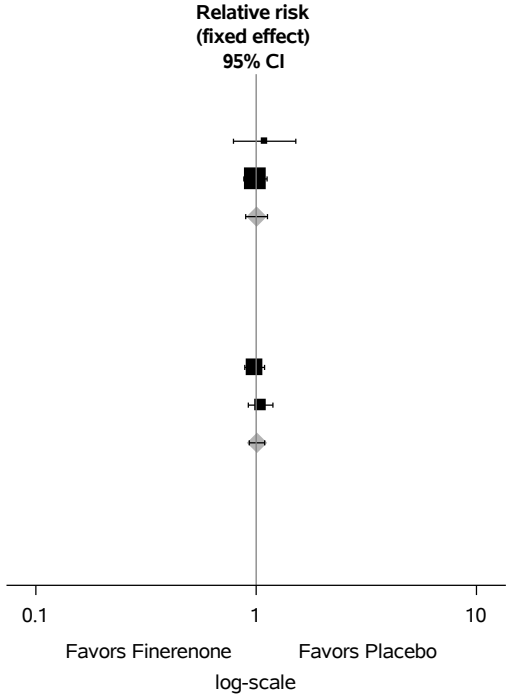
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	341 / 1559	340 / 1549	69.2	1.00 [0.87,1.14]	
FIGARO-DKD	152 / 639	145 / 631	30.8	1.04 [0.85,1.26]	
Total	493 / 2198	485 / 2180		1.01 [0.90,1.13]	Z=0.15, p=0.8842
Heterogeneity:	Q=0.10 (df=1)	p=0.7554	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	237 / 1063	228 / 1071	58.7	1.05 [0.89,1.23]	
FIGARO-DKD	154 / 720	172 / 731	41.3	0.91 [0.75,1.10]	
Total	391 / 1783	400 / 1802		0.99 [0.87,1.12]	Z=-0.20, p=0.8434
Heterogeneity:	Q=1.23 (df=1)	p=0.2671	I^2=18.8%		
>= 60					
FIDELIO-DKD	37 / 211	53 / 221	8.6	0.73 [0.50,1.06]	
FIGARO-DKD	479 / 2327	449 / 2304	91.4	1.06 [0.94,1.19]	
Total	516 / 2538	502 / 2525		1.02 [0.92,1.14]	Z=0.40, p=0.6913
Heterogeneity:	Q=3.38 (df=1)	p=0.0662	I^2=70.4%		
Subgroup Heterogeneity:	Q=0.17 (df=2)	p=0.9186	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

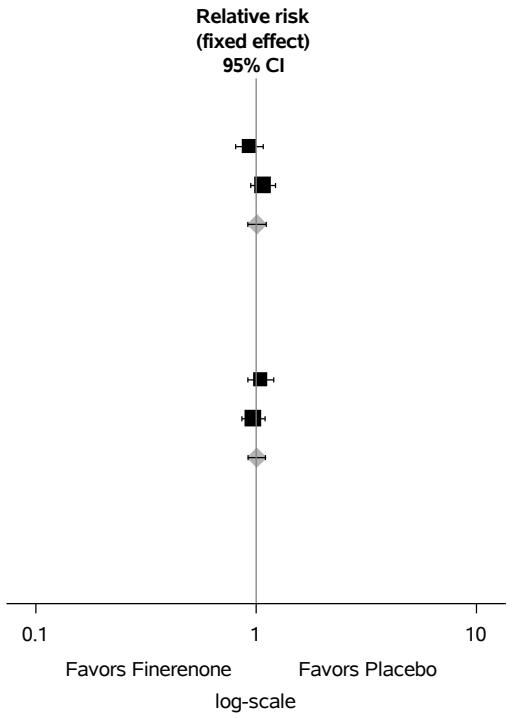
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	56 / 210	52 / 213	12.2	1.09 [0.79,1.51]	
FIGARO-DKD	400 / 1722	399 / 1705	87.8	0.99 [0.88,1.12]	
Total	456 / 1932	451 / 1918		1.00 [0.90,1.13]	Z=0.07, p=0.9413
Heterogeneity:	Q=0.29 (df=1)	p=0.5895	I^2=0.0%		
Very High					
FIDELIO-DKD	559 / 2623	569 / 2628	60.7	0.98 [0.89,1.09]	
FIGARO-DKD	385 / 1964	367 / 1961	39.3	1.05 [0.92,1.19]	
Total	944 / 4587	936 / 4589		1.01 [0.93,1.09]	Z=0.21, p=0.8341
Heterogeneity:	Q=0.55 (df=1)	p=0.4602	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9514	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set

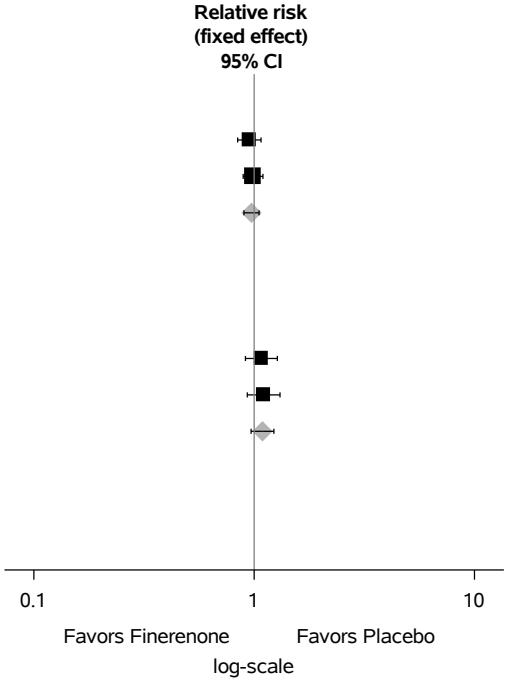
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	278 / 1303	298 / 1302	44.6	0.93 [0.81,1.08]	
FIGARO-DKD	376 / 1676	345 / 1654	55.4	1.08 [0.95,1.22]	
Total	654 / 2979	643 / 2956		1.01 [0.92,1.11]	Z=0.18, p=0.8534
Heterogeneity:	Q=2.09 (df=1)	p=0.1479	I^2=52.2%		
Absent					
FIDELIO-DKD	337 / 1530	323 / 1539	44.6	1.05 [0.92,1.20]	
FIGARO-DKD	409 / 2010	421 / 2012	55.4	0.97 [0.86,1.10]	
Total	746 / 3540	744 / 3551		1.01 [0.92,1.10]	Z=0.13, p=0.8956
Heterogeneity:	Q=0.68 (df=1)	p=0.4108	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9642	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

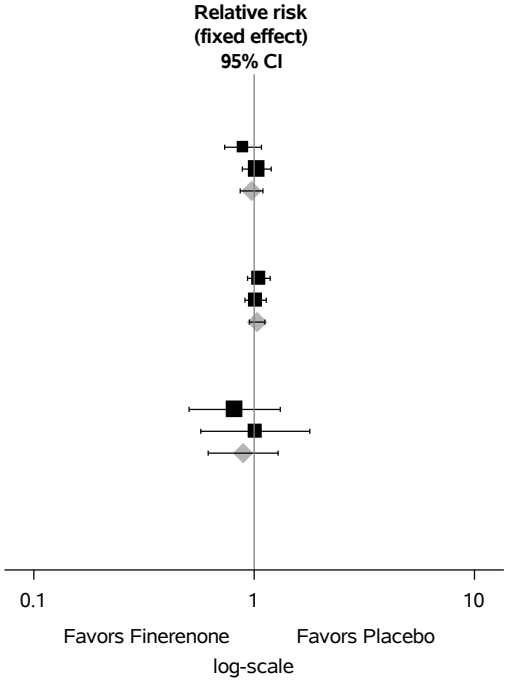
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	395 / 1881	411 / 1861	41.6	0.95 [0.84,1.07]	
FIGARO-DKD	565 / 2643	565 / 2612	58.4	0.99 [0.89,1.10]	
Total	960 / 4524	976 / 4473		0.97 [0.90,1.05]	Z=-0.69, p=0.4889
Heterogeneity:	Q=0.22 (df=1)	p=0.6366	I^2=0.0%		
> 4.5					
FIDELIO-DKD	220 / 951	210 / 979	51.3	1.08 [0.91,1.27]	
FIGARO-DKD	220 / 1043	201 / 1052	48.7	1.10 [0.93,1.31]	
Total	440 / 1994	411 / 2031		1.09 [0.97,1.23]	Z=1.43, p=0.1534
Heterogeneity:	Q=0.04 (df=1)	p=0.8479	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.47 (df=1)	p=0.1158	I^2=59.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.6.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

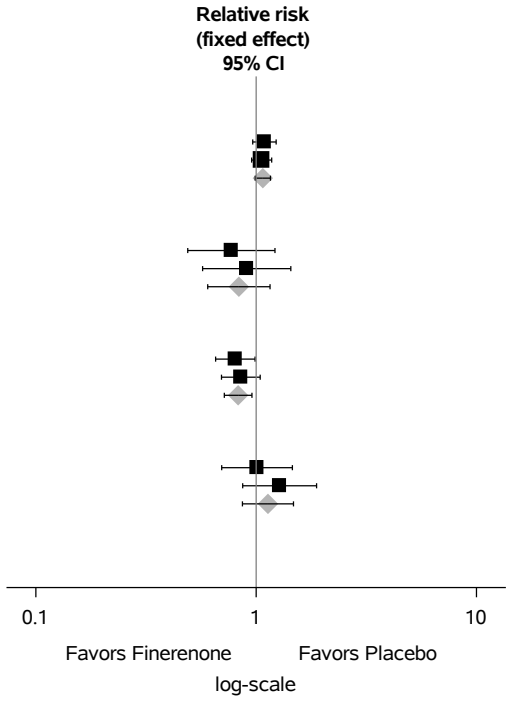
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	156 / 788	173 / 778	38.0	0.89 [0.73,1.08]	
FIGARO-DKD	266 / 1187	261 / 1197	62.0	1.03 [0.88,1.19]	
Total	422 / 1975	434 / 1975		0.97 [0.86,1.10]	Z=-0.45, p=0.6517
Heterogeneity:	Q=1.33 (df=1)	p=0.2496	I^2=24.6%		
130 - < 160					
FIDELIO-DKD	434 / 1900	418 / 1922	46.9	1.05 [0.93,1.18]	
FIGARO-DKD	500 / 2392	485 / 2355	53.1	1.01 [0.91,1.13]	
Total	934 / 4292	903 / 4277		1.03 [0.95,1.12]	Z=0.75, p=0.4549
Heterogeneity:	Q=0.17 (df=1)	p=0.6798	I^2=0.0%		
>= 160					
FIDELIO-DKD	25 / 142	30 / 139	58.8	0.82 [0.51,1.31]	
FIGARO-DKD	19 / 107	20 / 114	41.2	1.01 [0.57,1.79]	
Total	44 / 249	50 / 253		0.89 [0.62,1.28]	Z=-0.62, p=0.5360
Heterogeneity:	Q=0.32 (df=1)	p=0.5691	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.09 (df=2)	p=0.5812	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.6.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set

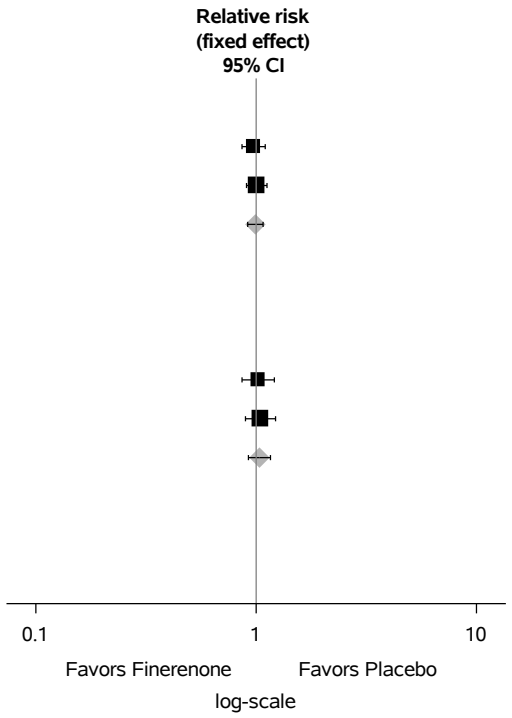
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	412 / 1777	386 / 1815	42.2	1.09 [0.96,1.23]	
FIGARO-DKD	578 / 2672	532 / 2605	57.8	1.06 [0.95,1.18]	
Total	990 / 4449	918 / 4420		1.07 [0.99,1.16]	Z=1.72, p=0.0860
Heterogeneity:	Q=0.12 (df=1)	p=0.7260	I^2=0.0%		
Black					
FIDELIO-DKD	27 / 140	31 / 124	50.6	0.77 [0.49,1.22]	
FIGARO-DKD	24 / 113	34 / 145	49.4	0.91 [0.57,1.44]	
Total	51 / 253	65 / 269		0.83 [0.60,1.16]	Z=-1.09, p=0.2766
Heterogeneity:	Q=0.24 (df=1)	p=0.6274	I^2=0.0%		
Asian					
FIDELIO-DKD	130 / 717	163 / 723	49.1	0.80 [0.65,0.99]	
FIGARO-DKD	136 / 715	165 / 739	50.9	0.85 [0.70,1.04]	
Total	266 / 1432	328 / 1462		0.83 [0.72,0.96]	Z=-2.56, p=0.0104
Heterogeneity:	Q=0.15 (df=1)	p=0.6958	I^2=0.0%		
Others					
FIDELIO-DKD	46 / 199	41 / 179	52.2	1.01 [0.70,1.46]	
FIGARO-DKD	47 / 186	35 / 177	47.8	1.28 [0.87,1.88]	
Total	93 / 385	76 / 356		1.13 [0.87,1.48]	Z=0.90, p=0.3658
Heterogeneity:	Q=0.75 (df=1)	p=0.3866	I^2=0.0%		
Subgroup Heterogeneity:	Q=11.44 (df=3)	p=0.0096	I^2=73.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.6.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set

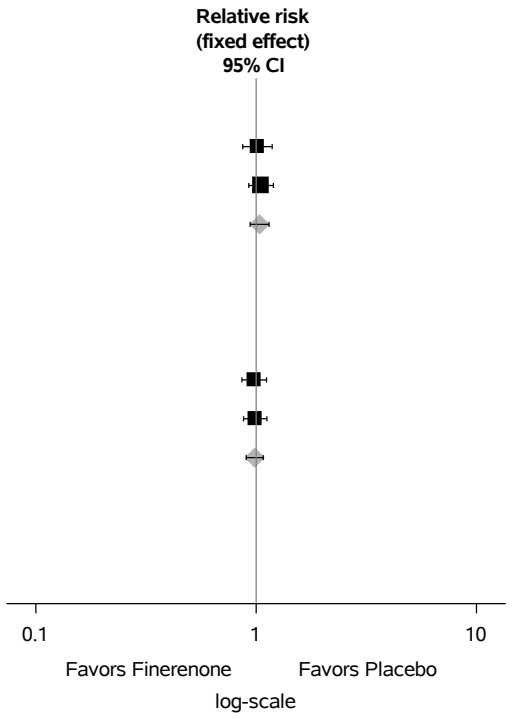
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	400 / 1953	427 / 2030	43.7	0.97 [0.86,1.10]	
FIGARO-DKD	528 / 2528	535 / 2577	56.3	1.01 [0.90,1.12]	
Total	928 / 4481	962 / 4607		0.99 [0.92,1.07]	Z=-0.20, p=0.8401
Heterogeneity:	Q=0.16 (df=1)	p=0.6923	I^2=0.0%		
Female					
FIDELIO-DKD	215 / 880	194 / 811	46.4	1.02 [0.86,1.21]	
FIGARO-DKD	257 / 1158	231 / 1089	53.6	1.05 [0.89,1.22]	
Total	472 / 2038	425 / 1900		1.03 [0.92,1.16]	Z=0.58, p=0.5622
Heterogeneity:	Q=0.04 (df=1)	p=0.8379	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5546	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.6.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set

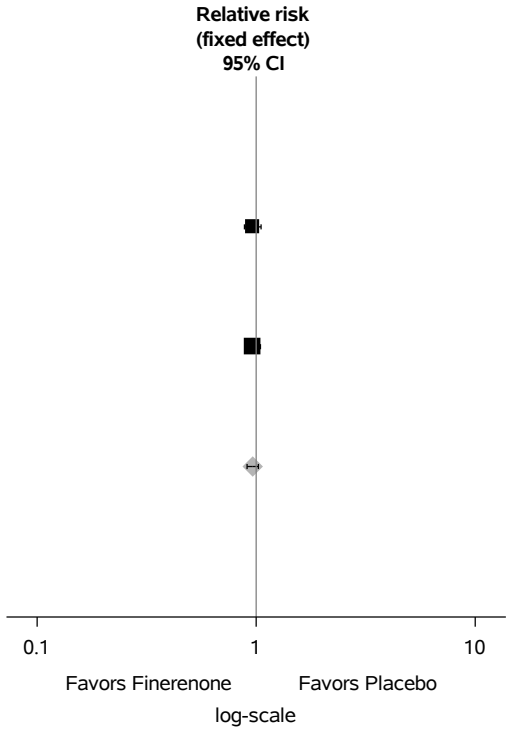
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	260 / 1205	250 / 1174	41.1	1.01 [0.87,1.18]	
FIGARO-DKD	377 / 1753	359 / 1757	58.9	1.05 [0.93,1.20]	
Total	637 / 2958	609 / 2931		1.04 [0.94,1.14]	Z=0.71, p=0.4796
Heterogeneity:	Q=0.14 (df=1)	p=0.7099	I^2=0.0%		
>= 65					
FIDELIO-DKD	355 / 1628	371 / 1667	47.4	0.98 [0.86,1.11]	
FIGARO-DKD	408 / 1933	407 / 1909	52.6	0.99 [0.88,1.12]	
Total	763 / 3561	778 / 3576		0.99 [0.90,1.08]	Z=-0.33, p=0.7403
Heterogeneity:	Q=0.01 (df=1)	p=0.9086	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4547	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set

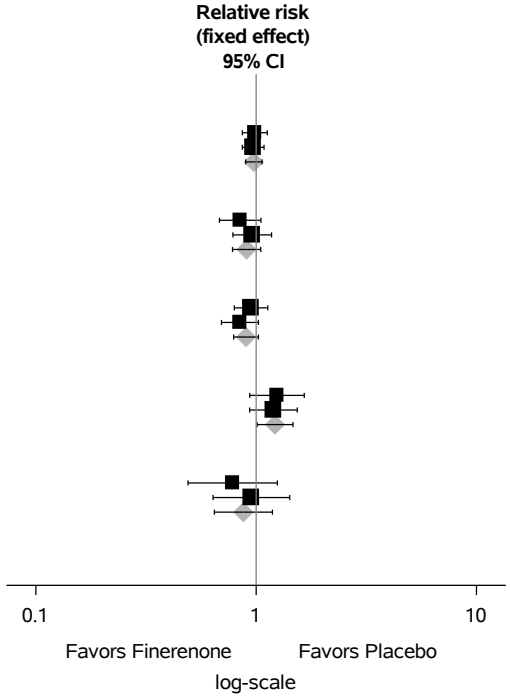
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	725 / 2833	753 / 2841	46.2	0.96 [0.88,1.05]	
FIGARO-DKD	869 / 3686	896 / 3666	53.8	0.96 [0.89,1.05]	
Total	1594 / 6519	1649 / 6507		0.96 [0.91,1.02]	Z=-1.20, p=0.2316
Heterogeneity:	Q=0.00 (df=1)	p=0.9930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.7.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set

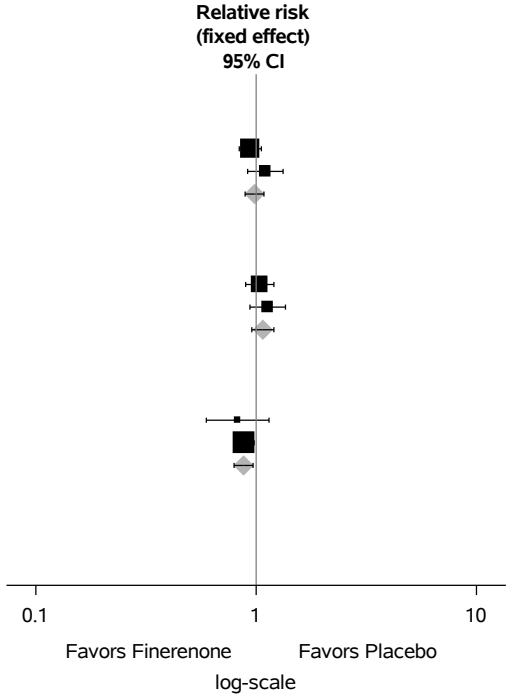
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	325 / 1182	328 / 1176	43.1	0.99 [0.87,1.12]	
FIGARO-DKD	438 / 1754	451 / 1750	56.9	0.97 [0.86,1.09]	
Total	763 / 2936	779 / 2926		0.98 [0.90,1.06]	Z=-0.55, p=0.5815
Heterogeneity:	Q=0.04 (df=1)	p=0.8450	I^2=0.0%		
North America					
FIDELIO-DKD	111 / 467	134 / 477	46.5	0.85 [0.68,1.05]	
FIGARO-DKD	139 / 559	142 / 548	53.5	0.96 [0.78,1.17]	
Total	250 / 1026	276 / 1025		0.90 [0.78,1.05]	Z=-1.33, p=0.1846
Heterogeneity:	Q=0.69 (df=1)	p=0.4050	I^2=0.0%		
Asia					
FIDELIO-DKD	186 / 790	196 / 789	55.0	0.95 [0.80,1.13]	
FIGARO-DKD	151 / 810	180 / 815	45.0	0.84 [0.70,1.02]	
Total	337 / 1600	376 / 1604		0.90 [0.79,1.02]	Z=-1.60, p=0.1090
Heterogeneity:	Q=0.76 (df=1)	p=0.3832	I^2=0.0%		
Latin America					
FIDELIO-DKD	80 / 295	65 / 298	43.3	1.24 [0.94,1.65]	
FIGARO-DKD	106 / 424	87 / 417	56.7	1.20 [0.93,1.54]	
Total	186 / 719	152 / 715		1.22 [1.01,1.47]	Z=2.06, p=0.0397
Heterogeneity:	Q=0.04 (df=1)	p=0.8486	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 99	30 / 101	42.4	0.78 [0.49,1.25]	
FIGARO-DKD	35 / 139	36 / 136	57.6	0.95 [0.64,1.42]	
Total	58 / 238	66 / 237		0.87 [0.65,1.19]	Z=-0.86, p=0.3882
Heterogeneity:	Q=0.39 (df=1)	p=0.5331	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.23 (df=4)	p=0.0835	I^2=51.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

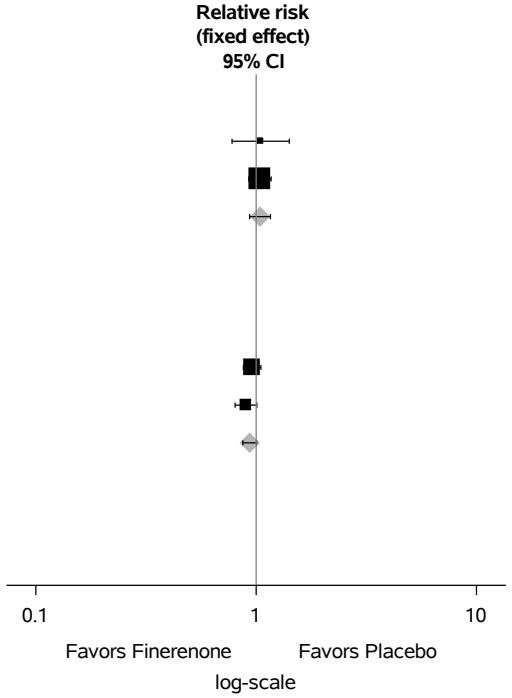
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	408 / 1559	431 / 1549	71.9	0.94 [0.84,1.06]	
FIGARO-DKD	175 / 639	157 / 631	28.1	1.10 [0.91,1.32]	
Total	583 / 2198	588 / 2180		0.98 [0.89,1.08]	Z=-0.34, p=0.7326
Heterogeneity:	Q=1.99 (df=1)	p=0.1583	I^2=49.8%		
45 - < 60					
FIDELIO-DKD	269 / 1063	261 / 1071	61.3	1.04 [0.90,1.20]	
FIGARO-DKD	180 / 720	162 / 731	38.7	1.13 [0.94,1.36]	
Total	449 / 1783	423 / 1802		1.07 [0.96,1.20]	Z=1.18, p=0.2362
Heterogeneity:	Q=0.47 (df=1)	p=0.4937	I^2=0.0%		
>= 60					
FIDELIO-DKD	48 / 211	61 / 221	9.1	0.82 [0.59,1.14]	
FIGARO-DKD	514 / 2327	577 / 2304	90.9	0.88 [0.79,0.98]	
Total	562 / 2538	638 / 2525		0.88 [0.79,0.97]	Z=-2.61, p=0.0091
Heterogeneity:	Q=0.15 (df=1)	p=0.6991	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.96 (df=2)	p=0.0309	I^2=71.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

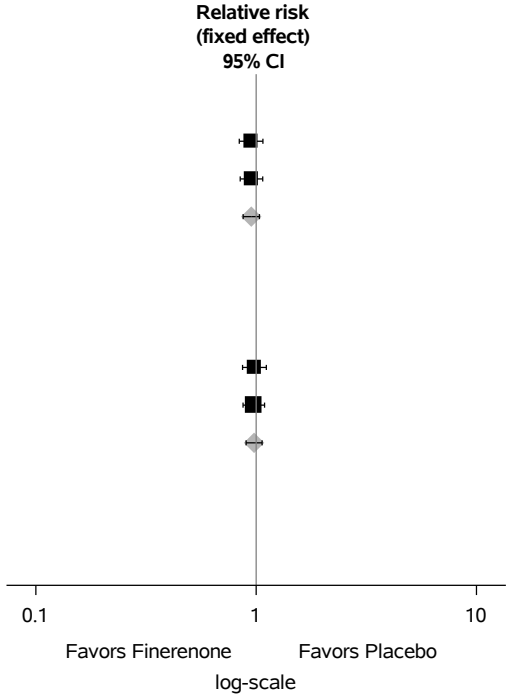
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	60 / 213	13.2	1.05 [0.78,1.41]	
FIGARO-DKD	436 / 1722	415 / 1705	86.8	1.04 [0.93,1.17]	
Total	498 / 1932	475 / 1918		1.04 [0.93,1.16]	Z=0.73, p=0.4656
Heterogeneity:	Q=0.00 (df=1)	p=0.9634	I^2=0.0%		
Very High					
FIDELIO-DKD	663 / 2623	693 / 2628	60.6	0.96 [0.87,1.05]	
FIGARO-DKD	433 / 1964	481 / 1961	39.4	0.90 [0.80,1.01]	
Total	1096 / 4587	1174 / 4589		0.93 [0.87,1.00]	Z=-1.86, p=0.0630
Heterogeneity:	Q=0.74 (df=1)	p=0.3884	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.66 (df=1)	p=0.1029	I^2=62.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set

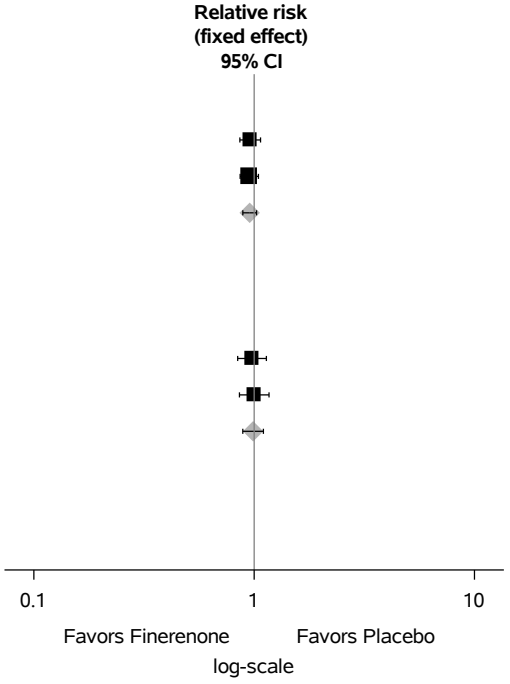
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	354 / 1303	373 / 1302	47.6	0.95 [0.84,1.07]	
FIGARO-DKD	409 / 1676	424 / 1654	52.4	0.95 [0.85,1.07]	
Total	763 / 2979	797 / 2956		0.95 [0.87,1.03]	Z=-1.17, p=0.2401
Heterogeneity:	Q=0.00 (df=1)	p=0.9650	I^2=0.0%		
Absent					
FIDELIO-DKD	371 / 1530	380 / 1539	45.0	0.98 [0.87,1.11]	
FIGARO-DKD	460 / 2010	472 / 2012	55.0	0.98 [0.87,1.09]	
Total	831 / 3540	852 / 3551		0.98 [0.90,1.06]	Z=-0.51, p=0.6093
Heterogeneity:	Q=0.01 (df=1)	p=0.9380	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6302	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

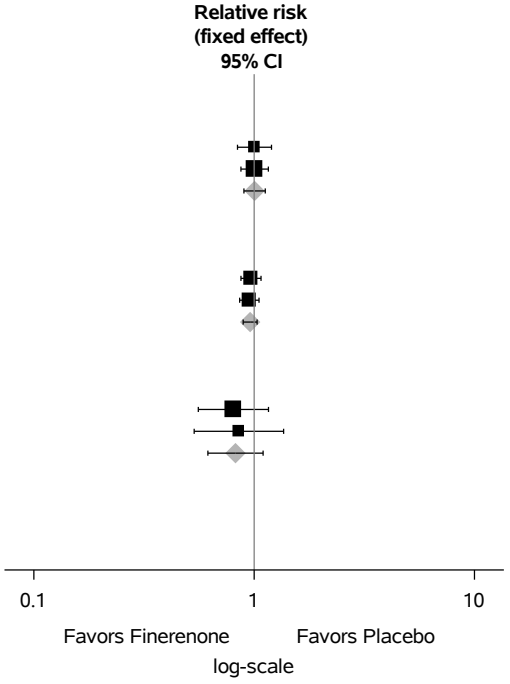
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	479 / 1881	494 / 1861	43.9	0.96 [0.86,1.07]	
FIGARO-DKD	624 / 2643	649 / 2612	56.1	0.95 [0.86,1.05]	
Total	1103 / 4524	1143 / 4473		0.95 [0.89,1.03]	Z=-1.28, p=0.1996
Heterogeneity:	Q=0.02 (df=1)	p=0.8968	I^2=0.0%		
> 4.5					
FIDELIO-DKD	246 / 951	259 / 979	51.5	0.98 [0.84,1.14]	
FIGARO-DKD	245 / 1043	247 / 1052	48.5	1.00 [0.86,1.17]	
Total	491 / 1994	506 / 2031		0.99 [0.89,1.10]	Z=-0.21, p=0.8361
Heterogeneity:	Q=0.04 (df=1)	p=0.8346	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5902	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.7.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

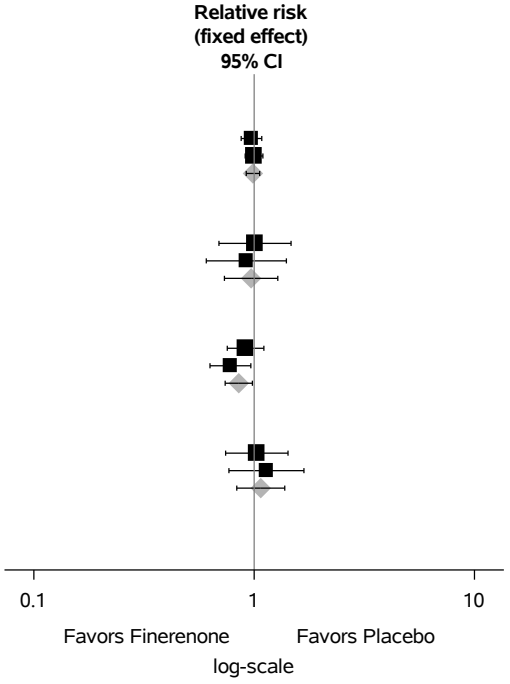
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	187 / 788	184 / 778	39.4	1.00 [0.84,1.20]	
FIGARO-DKD	284 / 1187	285 / 1197	60.6	1.00 [0.87,1.16]	
Total	471 / 1975	469 / 1975		1.00 [0.90,1.12]	Z=0.08, p=0.9399
Heterogeneity:	Q=0.00 (df=1)	p=0.9899	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	501 / 1900	524 / 1922	48.2	0.97 [0.87,1.07]	
FIGARO-DKD	561 / 2392	581 / 2355	51.8	0.95 [0.86,1.05]	
Total	1062 / 4292	1105 / 4277		0.96 [0.89,1.03]	Z=-1.14, p=0.2545
Heterogeneity:	Q=0.05 (df=1)	p=0.8164	I^2=0.0%		
>= 160					
FIDELIO-DKD	37 / 142	45 / 139	61.9	0.80 [0.56,1.16]	
FIGARO-DKD	24 / 107	30 / 114	38.1	0.85 [0.53,1.36]	
Total	61 / 249	75 / 253		0.82 [0.62,1.10]	Z=-1.33, p=0.1846
Heterogeneity:	Q=0.04 (df=1)	p=0.8500	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.70 (df=2)	p=0.4274	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.7.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set

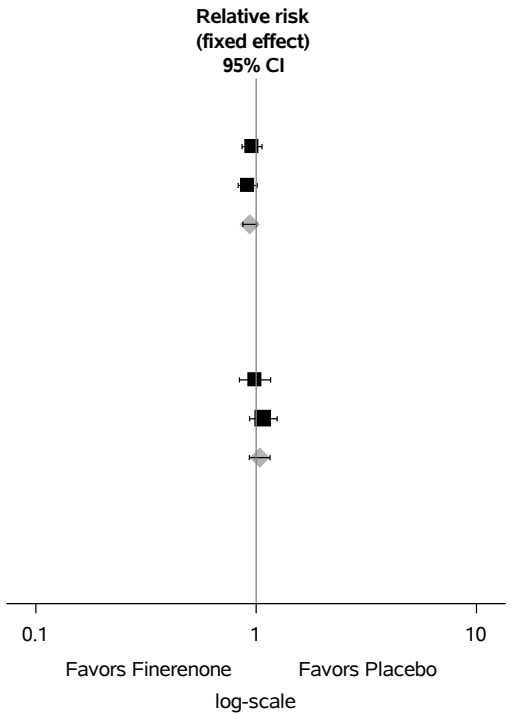
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	473 / 1777	497 / 1815	42.5	0.97 [0.87,1.08]	
FIGARO-DKD	678 / 2672	662 / 2605	57.5	1.00 [0.91,1.10]	
Total	1151 / 4449	1159 / 4420		0.99 [0.92,1.06]	Z=-0.36, p=0.7181
Heterogeneity:	Q=0.14 (df=1)	p=0.7110	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 140	36 / 124	55.2	1.01 [0.69,1.47]	
FIGARO-DKD	28 / 113	39 / 145	44.8	0.92 [0.61,1.40]	
Total	69 / 253	75 / 269		0.97 [0.73,1.28]	Z=-0.22, p=0.8221
Heterogeneity:	Q=0.10 (df=1)	p=0.7523	I^2=0.0%		
Asian					
FIDELIO-DKD	155 / 717	171 / 723	55.5	0.91 [0.75,1.11]	
FIGARO-DKD	120 / 715	159 / 739	44.5	0.78 [0.63,0.97]	
Total	275 / 1432	330 / 1462		0.85 [0.74,0.98]	Z=-2.22, p=0.0267
Heterogeneity:	Q=1.17 (df=1)	p=0.2785	I^2=14.8%		
Others					
FIDELIO-DKD	56 / 199	49 / 179	59.1	1.03 [0.74,1.42]	
FIGARO-DKD	43 / 186	36 / 177	40.9	1.14 [0.77,1.68]	
Total	99 / 385	85 / 356		1.07 [0.83,1.38]	Z=0.54, p=0.5905
Heterogeneity:	Q=0.15 (df=1)	p=0.6993	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.05 (df=3)	p=0.2564	I^2=25.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.7.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set

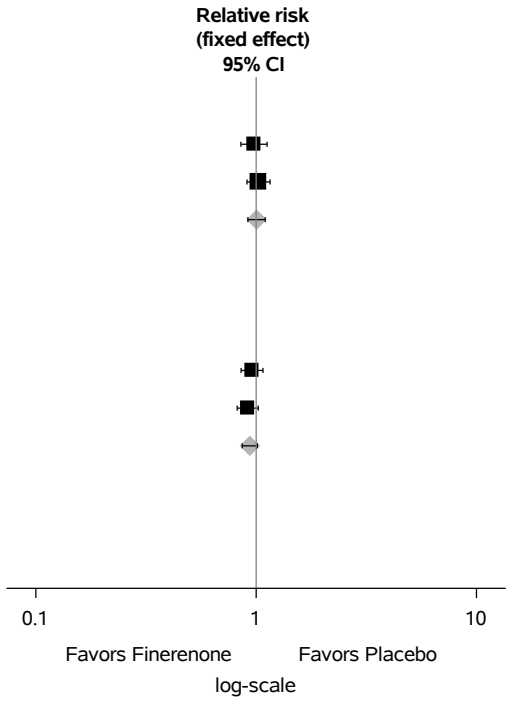
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	502 / 1953	545 / 2030	47.4	0.96 [0.86,1.06]	
FIGARO-DKD	571 / 2528	636 / 2577	52.6	0.92 [0.83,1.01]	
Total	1073 / 4481	1181 / 4607		0.93 [0.87,1.00]	Z=-1.84, p=0.0658
Heterogeneity:	Q=0.38 (df=1)	p=0.5380	I^2=0.0%		
Female					
FIDELIO-DKD	223 / 880	208 / 811	43.9	0.99 [0.84,1.16]	
FIGARO-DKD	298 / 1158	260 / 1089	56.1	1.08 [0.93,1.25]	
Total	521 / 2038	468 / 1900		1.04 [0.93,1.16]	Z=0.67, p=0.5038
Heterogeneity:	Q=0.61 (df=1)	p=0.4336	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.48 (df=1)	p=0.1155	I^2=59.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.7.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set

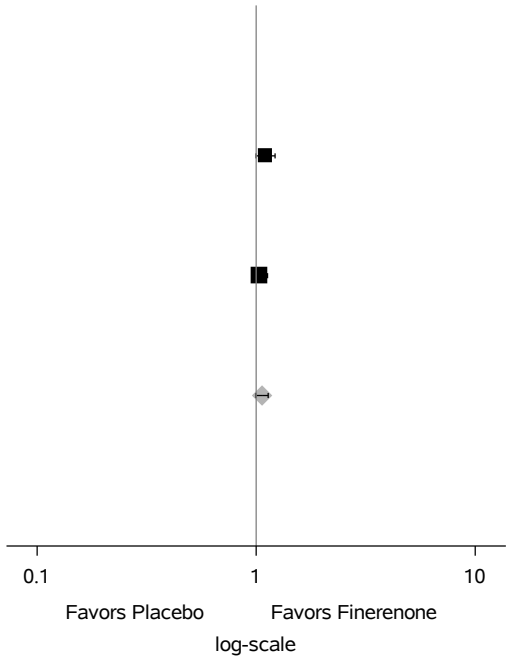
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	305 / 1205	304 / 1174	43.6	0.98 [0.85,1.12]	
FIGARO-DKD	411 / 1753	402 / 1757	56.4	1.02 [0.91,1.16]	
Total	716 / 2958	706 / 2931		1.00 [0.92,1.10]	Z=0.08, p=0.9338
Heterogeneity:	Q=0.26 (df=1)	p=0.6122	I^2=0.0%		
>= 65					
FIDELIO-DKD	420 / 1628	449 / 1667	48.3	0.96 [0.85,1.07]	
FIGARO-DKD	458 / 1933	494 / 1909	51.7	0.92 [0.82,1.02]	
Total	878 / 3561	943 / 3576		0.94 [0.86,1.01]	Z=-1.64, p=0.1008
Heterogeneity:	Q=0.31 (df=1)	p=0.5780	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.31 (df=1)	p=0.2525	I^2=23.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set

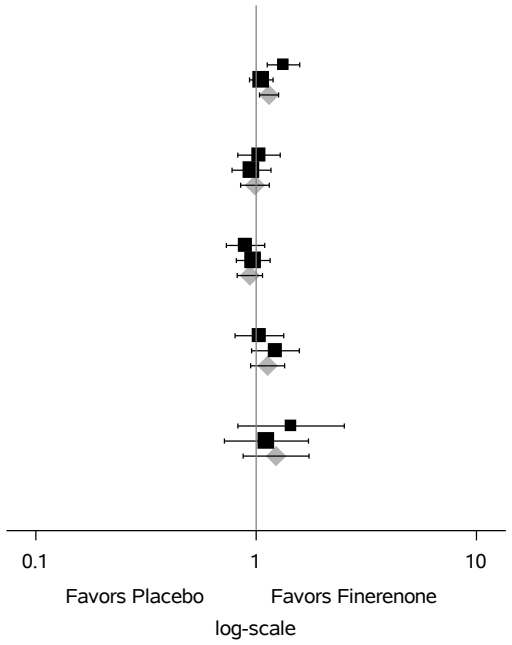
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	628 / 2833	571 / 2841	40.9	1.10 [1.00,1.22]	
FIGARO-DKD	867 / 3686	831 / 3666	59.1	1.04 [0.95,1.13]	
Total	1495 / 6519	1402 / 6507		1.06 [1.00,1.13]	Z=1.89, p=0.0586
Heterogeneity:	Q=0.88 (df=1)	p=0.3476	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.8.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set

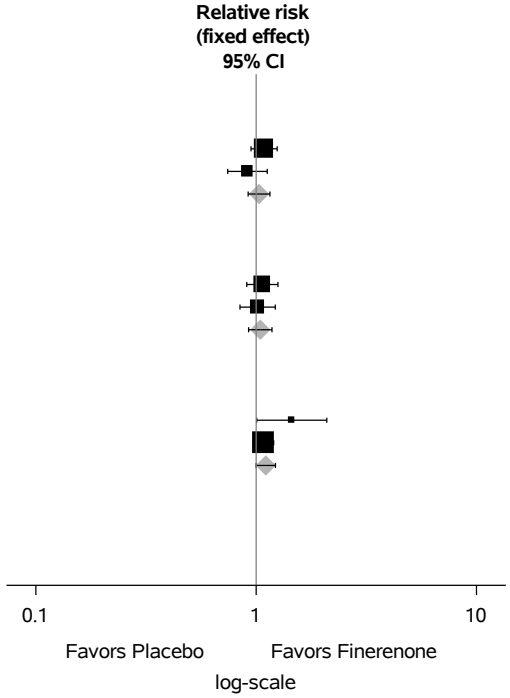
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	254 / 1182	190 / 1176	34.5	1.33 [1.12,1.58]	
FIGARO-DKD	404 / 1754	382 / 1750	65.5	1.06 [0.93,1.19]	
Total	658 / 2936	572 / 2926		1.14 [1.04,1.26]	Z=2.65, p=0.0081
Heterogeneity:	Q=4.68 (df=1)	p=0.0305	I^2=78.6%		
North America					
FIDELIO-DKD	118 / 467	117 / 477	45.7	1.03 [0.83,1.29]	
FIGARO-DKD	137 / 559	141 / 548	54.3	0.95 [0.78,1.17]	
Total	255 / 1026	258 / 1025		0.99 [0.85,1.15]	Z=-0.17, p=0.8669
Heterogeneity:	Q=0.26 (df=1)	p=0.6097	I^2=0.0%		
Asia					
FIDELIO-DKD	146 / 790	163 / 789	43.7	0.89 [0.73,1.09]	
FIGARO-DKD	186 / 810	193 / 815	56.3	0.97 [0.81,1.16]	
Total	332 / 1600	356 / 1604		0.94 [0.82,1.07]	Z=-0.98, p=0.3282
Heterogeneity:	Q=0.35 (df=1)	p=0.5539	I^2=0.0%		
Latin America					
FIDELIO-DKD	86 / 295	84 / 298	49.1	1.03 [0.80,1.33]	
FIGARO-DKD	107 / 424	86 / 417	50.9	1.22 [0.95,1.57]	
Total	193 / 719	170 / 715		1.13 [0.94,1.35]	Z=1.32, p=0.1875
Heterogeneity:	Q=0.86 (df=1)	p=0.3546	I^2=0.0%		
Others					
FIDELIO-DKD	24 / 99	17 / 101	38.4	1.44 [0.83,2.51]	
FIGARO-DKD	33 / 139	29 / 136	61.6	1.11 [0.72,1.73]	
Total	57 / 238	46 / 237		1.23 [0.87,1.74]	Z=1.18, p=0.2369
Heterogeneity:	Q=0.51 (df=1)	p=0.4764	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.67 (df=4)	p=0.1043	I^2=47.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

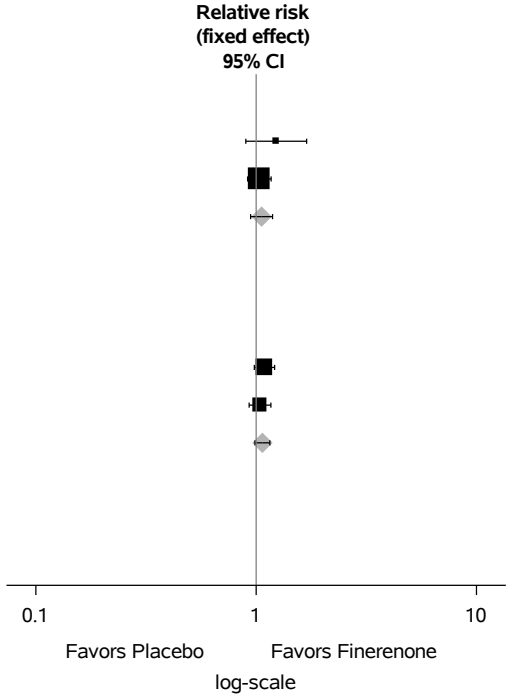
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	340 / 1559	311 / 1549	69.5	1.09 [0.95,1.25]	
FIGARO-DKD	135 / 639	146 / 631	30.5	0.91 [0.74,1.12]	
Total	475 / 2198	457 / 2180		1.03 [0.92,1.15]	Z=0.51, p=0.6083
Heterogeneity:	Q=1.89 (df=1)	p=0.1695	I^2=47.0%		
45 - < 60					
FIDELIO-DKD	234 / 1063	221 / 1071	56.2	1.07 [0.91,1.26]	
FIGARO-DKD	172 / 720	172 / 731	43.8	1.02 [0.84,1.22]	
Total	406 / 1783	393 / 1802		1.04 [0.92,1.18]	Z=0.69, p=0.4908
Heterogeneity:	Q=0.16 (df=1)	p=0.6937	I^2=0.0%		
>= 60					
FIDELIO-DKD	54 / 211	39 / 221	7.6	1.45 [1.01,2.09]	
FIGARO-DKD	560 / 2327	513 / 2304	92.4	1.08 [0.97,1.20]	
Total	614 / 2538	552 / 2525		1.11 [1.00,1.22]	Z=1.95, p=0.0507
Heterogeneity:	Q=2.29 (df=1)	p=0.1303	I^2=56.3%		
Subgroup Heterogeneity:	Q=0.96 (df=2)	p=0.6182	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set

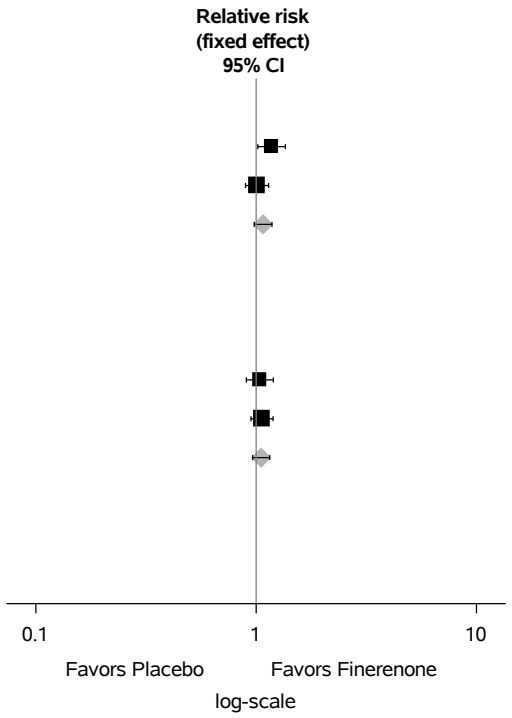
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	51 / 213	13.0	1.23 [0.90,1.69]	
FIGARO-DKD	401 / 1722	384 / 1705	87.0	1.03 [0.91,1.17]	
Total	463 / 1932	435 / 1918		1.06 [0.94,1.19]	Z=0.97, p=0.3337
Heterogeneity:	Q=1.03 (df=1)	p=0.3110	I^2=2.6%		
Very High					
FIDELIO-DKD	566 / 2623	520 / 2628	53.5	1.09 [0.98,1.21]	
FIGARO-DKD	466 / 1964	447 / 1961	46.5	1.04 [0.93,1.17]	
Total	1032 / 4587	967 / 4589		1.07 [0.99,1.15]	Z=1.64, p=0.1003
Heterogeneity:	Q=0.34 (df=1)	p=0.5571	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9040	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set

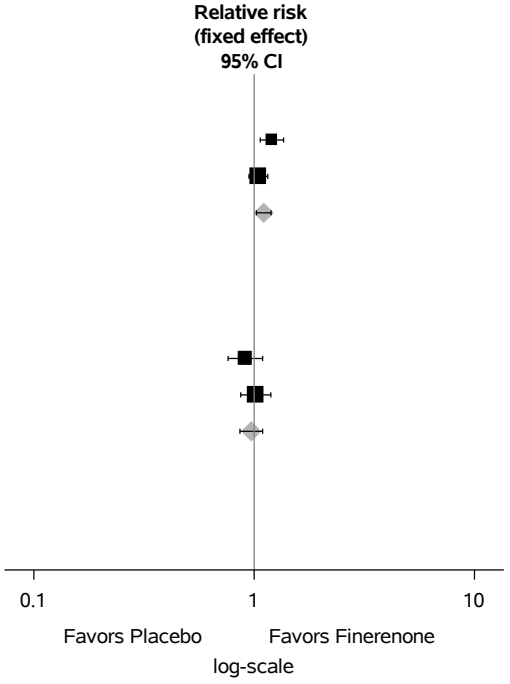
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	314 / 1303	267 / 1302	41.4	1.18 [1.02,1.36]	
FIGARO-DKD	404 / 1676	395 / 1654	58.6	1.01 [0.89,1.14]	
Total	718 / 2979	662 / 2956		1.08 [0.98,1.18]	Z=1.53, p=0.1250
Heterogeneity:	Q=2.51 (df=1)	p=0.1129	I^2=60.2%		
Absent					
FIDELIO-DKD	314 / 1530	304 / 1539	40.1	1.04 [0.90,1.20]	
FIGARO-DKD	463 / 2010	436 / 2012	59.9	1.06 [0.95,1.19]	
Total	777 / 3540	740 / 3551		1.05 [0.96,1.15]	Z=1.14, p=0.2540
Heterogeneity:	Q=0.06 (df=1)	p=0.8057	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7545	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

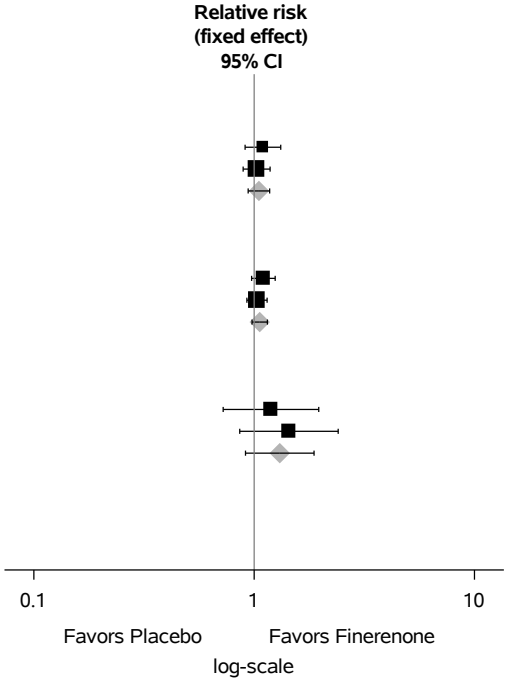
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	449 / 1881	369 / 1861	39.4	1.20 [1.07,1.36]	
FIGARO-DKD	627 / 2643	593 / 2612	60.6	1.04 [0.95,1.15]	
Total	1076 / 4524	962 / 4473		1.11 [1.02,1.19]	Z=2.56, p=0.0104
Heterogeneity:	Q=3.14 (df=1)	p=0.0765	I^2=68.1%		
> 4.5					
FIDELIO-DKD	179 / 951	202 / 979	43.3	0.91 [0.76,1.09]	
FIGARO-DKD	240 / 1043	238 / 1052	56.7	1.02 [0.87,1.19]	
Total	419 / 1994	440 / 2031		0.97 [0.86,1.09]	Z=-0.50, p=0.6175
Heterogeneity:	Q=0.79 (df=1)	p=0.3730	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.27 (df=1)	p=0.0704	I^2=69.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.8.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

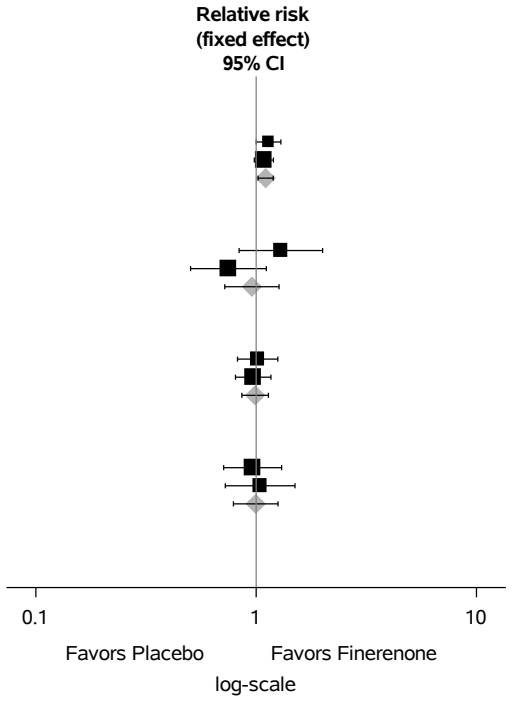
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	182 / 788	164 / 778	36.3	1.10 [0.91,1.32]	
FIGARO-DKD	295 / 1187	290 / 1197	63.7	1.03 [0.89,1.18]	
Total	477 / 1975	454 / 1975		1.05 [0.94,1.18]	Z=0.86, p=0.3881
Heterogeneity:	Q=0.31 (df=1)	p=0.5803	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	418 / 1900	384 / 1922	42.4	1.10 [0.97,1.25]	
FIGARO-DKD	545 / 2392	521 / 2355	57.6	1.03 [0.93,1.14]	
Total	963 / 4292	905 / 4277		1.06 [0.98,1.15]	Z=1.41, p=0.1575
Heterogeneity:	Q=0.65 (df=1)	p=0.4193	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 142	23 / 139	51.5	1.19 [0.72,1.96]	
FIGARO-DKD	27 / 107	20 / 114	48.5	1.44 [0.86,2.41]	
Total	55 / 249	43 / 253		1.31 [0.91,1.87]	Z=1.46, p=0.1435
Heterogeneity:	Q=0.26 (df=1)	p=0.6071	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.32 (df=2)	p=0.5166	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.8.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set

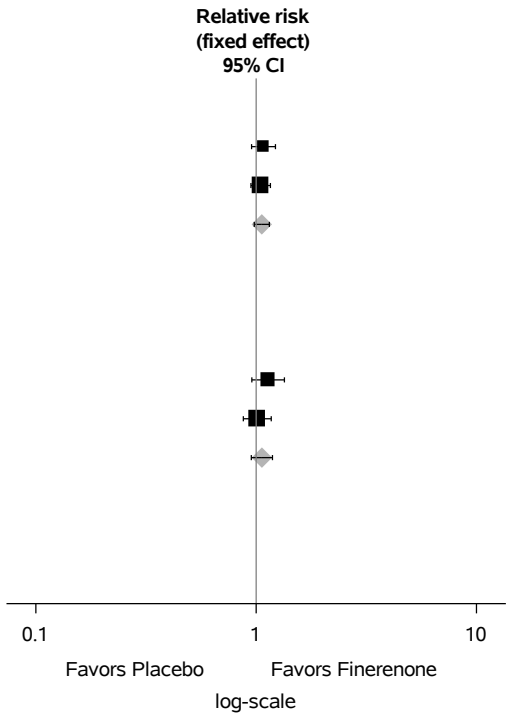
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	390 / 1777	350 / 1815	37.7	1.14 [1.00,1.29]	
FIGARO-DKD	627 / 2672	564 / 2605	62.3	1.08 [0.98,1.20]	
Total	1017 / 4449	914 / 4420		1.10 [1.02,1.19]	Z=2.45, p=0.0141
Heterogeneity:	Q=0.35 (df=1)	p=0.5568	I^2=0.0%		
Black					
FIDELIO-DKD	38 / 140	26 / 124	45.1	1.29 [0.84,2.00]	
FIGARO-DKD	28 / 113	48 / 145	54.9	0.75 [0.50,1.11]	
Total	66 / 253	74 / 269		0.96 [0.72,1.27]	Z=-0.31, p=0.7579
Heterogeneity:	Q=3.32 (df=1)	p=0.0684	I^2=69.9%		
Asian					
FIDELIO-DKD	140 / 717	139 / 723	43.6	1.02 [0.82,1.25]	
FIGARO-DKD	166 / 715	177 / 739	56.4	0.97 [0.81,1.17]	
Total	306 / 1432	316 / 1462		0.99 [0.86,1.14]	Z=-0.15, p=0.8787
Heterogeneity:	Q=0.11 (df=1)	p=0.7445	I^2=0.0%		
Others					
FIDELIO-DKD	60 / 199	56 / 179	59.1	0.96 [0.71,1.30]	
FIGARO-DKD	46 / 186	42 / 177	40.9	1.04 [0.72,1.50]	
Total	106 / 385	98 / 356		1.00 [0.79,1.26]	Z=-0.04, p=0.9676
Heterogeneity:	Q=0.10 (df=1)	p=0.7460	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=3)	p=0.4317	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.8.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set

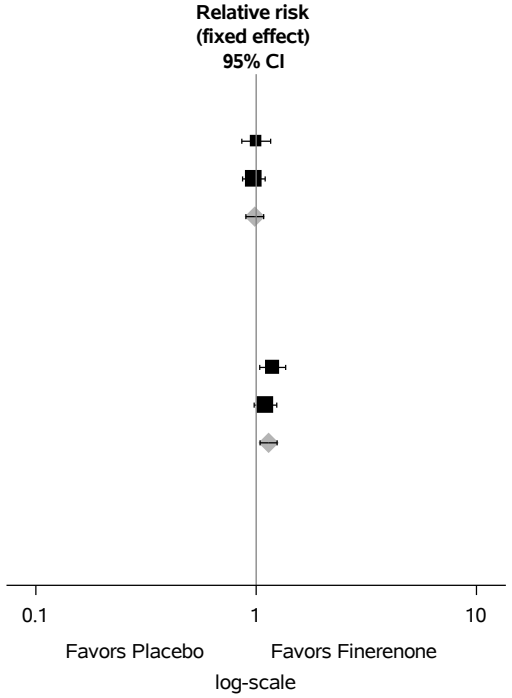
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	403 / 1953	388 / 2030	39.9	1.08 [0.95,1.22]	
FIGARO-DKD	583 / 2528	567 / 2577	60.1	1.05 [0.95,1.16]	
Total	986 / 4481	955 / 4607		1.06 [0.98,1.15]	Z=1.46, p=0.1437
Heterogeneity:	Q=0.13 (df=1)	p=0.7189	I^2=0.0%		
Female					
FIDELIO-DKD	225 / 880	183 / 811	42.3	1.13 [0.96,1.34]	
FIGARO-DKD	284 / 1158	264 / 1089	57.7	1.01 [0.87,1.17]	
Total	509 / 2038	447 / 1900		1.06 [0.95,1.19]	Z=1.06, p=0.2898
Heterogeneity:	Q=0.98 (df=1)	p=0.3213	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9897	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.8.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set

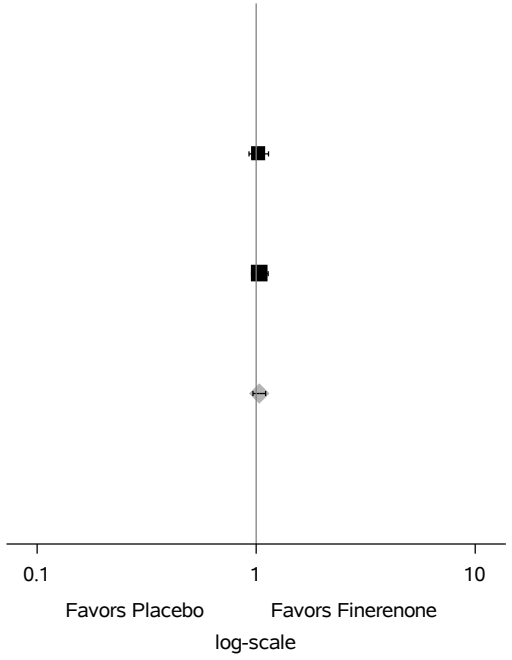
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	267 / 1205	260 / 1174	38.0	1.00 [0.86,1.16]	
FIGARO-DKD	414 / 1753	425 / 1757	62.0	0.98 [0.87,1.10]	
Total	681 / 2958	685 / 2931		0.99 [0.90,1.08]	Z=-0.31, p=0.7574
Heterogeneity:	Q=0.06 (df=1)	p=0.8023	I^2=0.0%		
>= 65					
FIDELIO-DKD	361 / 1628	311 / 1667	43.2	1.19 [1.04,1.36]	
FIGARO-DKD	453 / 1933	406 / 1909	56.8	1.10 [0.98,1.24]	
Total	814 / 3561	717 / 3576		1.14 [1.04,1.24]	Z=2.86, p=0.0042
Heterogeneity:	Q=0.68 (df=1)	p=0.4088	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.84 (df=1)	p=0.0278	I^2=79.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set

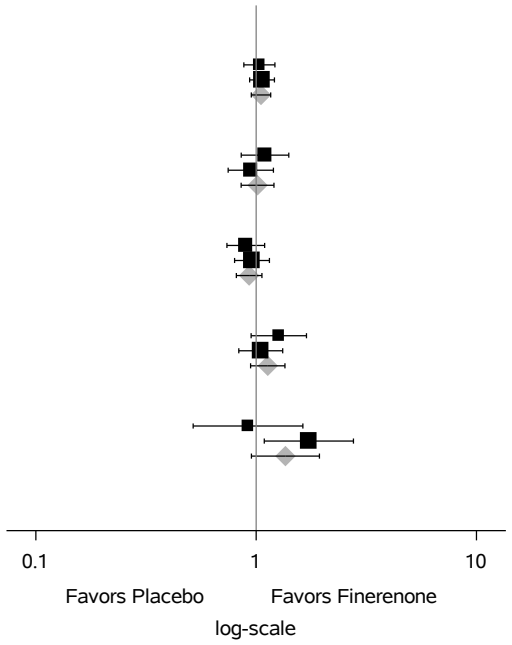
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	587 / 2833	574 / 2841	41.9	1.03 [0.93,1.14]	
FIGARO-DKD	809 / 3686	775 / 3666	58.1	1.04 [0.95,1.13]	
Total	1396 / 6519	1349 / 6507		1.03 [0.97,1.10]	Z=0.96, p=0.3363
Heterogeneity:	Q=0.03 (df=1)	p=0.8650	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.9.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set

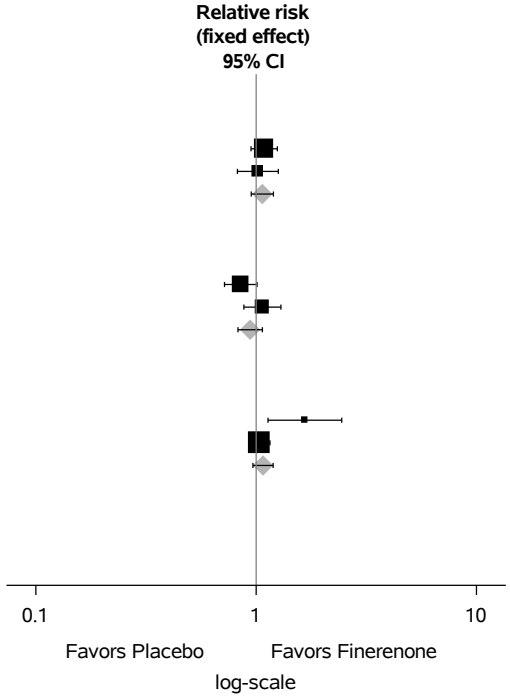
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	238 / 1182	229 / 1176	38.9	1.03 [0.88,1.22]	
FIGARO-DKD	374 / 1754	351 / 1750	61.1	1.06 [0.93,1.21]	
Total	612 / 2936	580 / 2926		1.05 [0.95,1.16]	Z=0.97, p=0.3299
Heterogeneity:	Q=0.07 (df=1)	p=0.7938	I^2=0.0%		
North America					
FIDELIO-DKD	102 / 467	95 / 477	47.5	1.10 [0.86,1.41]	
FIGARO-DKD	108 / 559	112 / 548	52.5	0.95 [0.75,1.20]	
Total	210 / 1026	207 / 1025		1.01 [0.85,1.20]	Z=0.16, p=0.8693
Heterogeneity:	Q=0.72 (df=1)	p=0.3964	I^2=0.0%		
Asia					
FIDELIO-DKD	150 / 790	167 / 789	46.0	0.90 [0.74,1.09]	
FIGARO-DKD	176 / 810	185 / 815	54.0	0.96 [0.80,1.15]	
Total	326 / 1600	352 / 1604		0.93 [0.81,1.06]	Z=-1.08, p=0.2807
Heterogeneity:	Q=0.22 (df=1)	p=0.6355	I^2=0.0%		
Latin America					
FIDELIO-DKD	79 / 295	63 / 298	38.6	1.27 [0.95,1.69]	
FIGARO-DKD	112 / 424	105 / 417	61.4	1.05 [0.83,1.32]	
Total	191 / 719	168 / 715		1.13 [0.94,1.35]	Z=1.32, p=0.1860
Heterogeneity:	Q=1.00 (df=1)	p=0.3169	I^2=0.2%		
Others					
FIDELIO-DKD	18 / 99	20 / 101	39.8	0.92 [0.52,1.63]	
FIGARO-DKD	39 / 139	22 / 136	60.2	1.73 [1.09,2.76]	
Total	57 / 238	42 / 237		1.36 [0.95,1.94]	Z=1.69, p=0.0919
Heterogeneity:	Q=2.85 (df=1)	p=0.0914	I^2=64.9%		
Subgroup Heterogeneity:	Q=5.79 (df=4)	p=0.2156	I^2=30.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

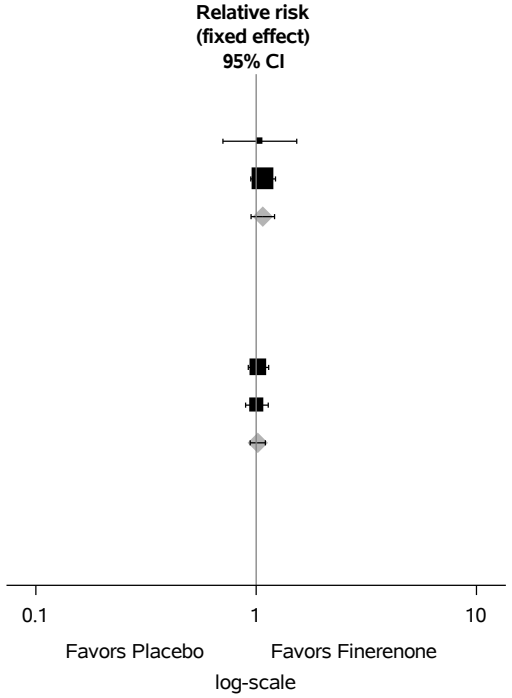
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	337 / 1559	308 / 1549	70.7	1.09 [0.95,1.25]	
FIGARO-DKD	135 / 639	131 / 631	29.3	1.02 [0.82,1.26]	
Total	472 / 2198	439 / 2180		1.07 [0.95,1.20]	Z=1.09, p=0.2766
Heterogeneity:	Q=0.26 (df=1)	p=0.6104	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	196 / 1063	232 / 1071	56.4	0.85 [0.72,1.01]	
FIGARO-DKD	164 / 720	156 / 731	43.6	1.07 [0.88,1.30]	
Total	360 / 1783	388 / 1802		0.94 [0.83,1.07]	Z=-0.96, p=0.3351
Heterogeneity:	Q=2.96 (df=1)	p=0.0852	I^2=66.2%		
>= 60					
FIDELIO-DKD	54 / 211	34 / 221	7.5	1.66 [1.13,2.45]	
FIGARO-DKD	510 / 2327	488 / 2304	92.5	1.03 [0.93,1.15]	
Total	564 / 2538	522 / 2525		1.07 [0.97,1.19]	Z=1.33, p=0.1841
Heterogeneity:	Q=5.39 (df=1)	p=0.0202	I^2=81.5%		
Subgroup Heterogeneity:	Q=2.95 (df=2)	p=0.2282	I^2=32.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set

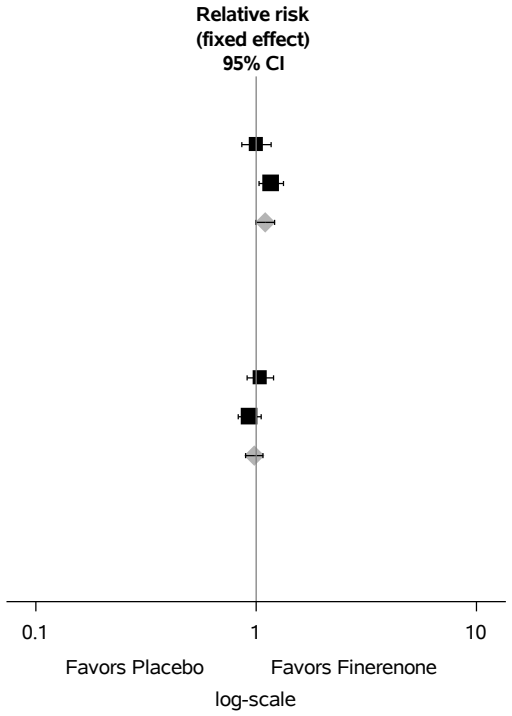
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 210	41 / 213	10.1	1.04 [0.71,1.53]	
FIGARO-DKD	378 / 1722	348 / 1705	89.9	1.08 [0.95,1.22]	
Total	420 / 1932	389 / 1918		1.07 [0.95,1.21]	Z=1.11, p=0.2679
Heterogeneity:	Q=0.03 (df=1)	p=0.8681	I^2=0.0%		
Very High					
FIDELIO-DKD	545 / 2623	533 / 2628	55.3	1.02 [0.92,1.14]	
FIGARO-DKD	431 / 1964	427 / 1961	44.7	1.01 [0.90,1.13]	
Total	976 / 4587	960 / 4589		1.02 [0.94,1.10]	Z=0.42, p=0.6765
Heterogeneity:	Q=0.04 (df=1)	p=0.8402	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4811	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set

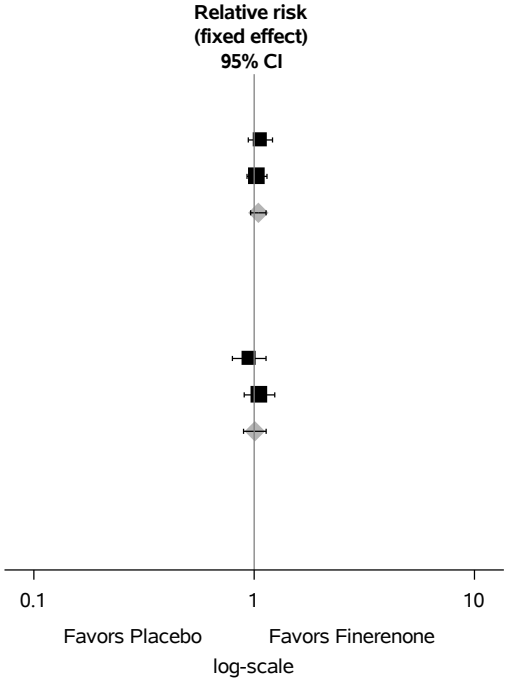
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	262 / 1303	261 / 1302	41.0	1.00 [0.86,1.17]	
FIGARO-DKD	401 / 1676	338 / 1654	59.0	1.17 [1.03,1.33]	
Total	663 / 2979	599 / 2956		1.10 [1.00,1.21]	Z=1.89, p=0.0589
Heterogeneity:	Q=2.31 (df=1)	p=0.1287	I^2=56.7%		
Absent					
FIDELIO-DKD	325 / 1530	313 / 1539	43.0	1.04 [0.91,1.20]	
FIGARO-DKD	408 / 2010	437 / 2012	57.0	0.93 [0.83,1.05]	
Total	733 / 3540	750 / 3551		0.98 [0.90,1.07]	Z=-0.43, p=0.6664
Heterogeneity:	Q=1.42 (df=1)	p=0.2337	I^2=29.5%		
Subgroup Heterogeneity:	Q=2.82 (df=1)	p=0.0930	I^2=64.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

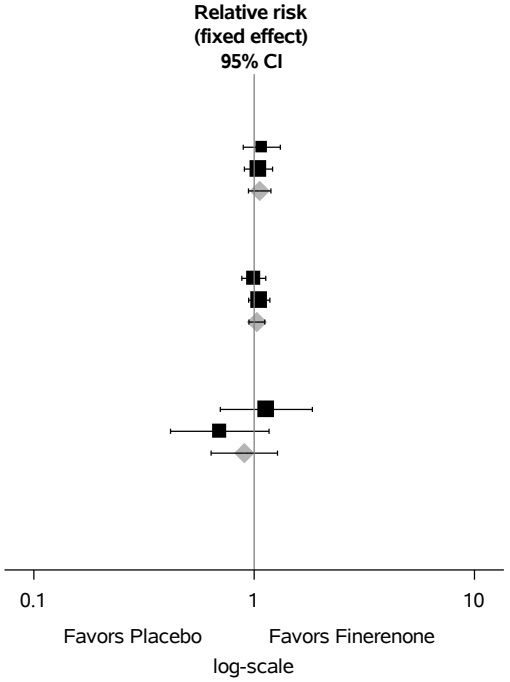
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	397 / 1881	368 / 1861	40.4	1.07 [0.94,1.21]	
FIGARO-DKD	569 / 2643	546 / 2612	59.6	1.03 [0.93,1.14]	
Total	966 / 4524	914 / 4473		1.04 [0.96,1.13]	Z=1.07, p=0.2848
Heterogeneity:	Q=0.18 (df=1)	p=0.6695	I^2=0.0%		
> 4.5					
FIDELIO-DKD	190 / 951	206 / 979	45.2	0.95 [0.80,1.13]	
FIGARO-DKD	240 / 1043	229 / 1052	54.8	1.06 [0.90,1.24]	
Total	430 / 1994	435 / 2031		1.01 [0.89,1.13]	Z=0.12, p=0.9073
Heterogeneity:	Q=0.79 (df=1)	p=0.3755	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6128	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.9.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

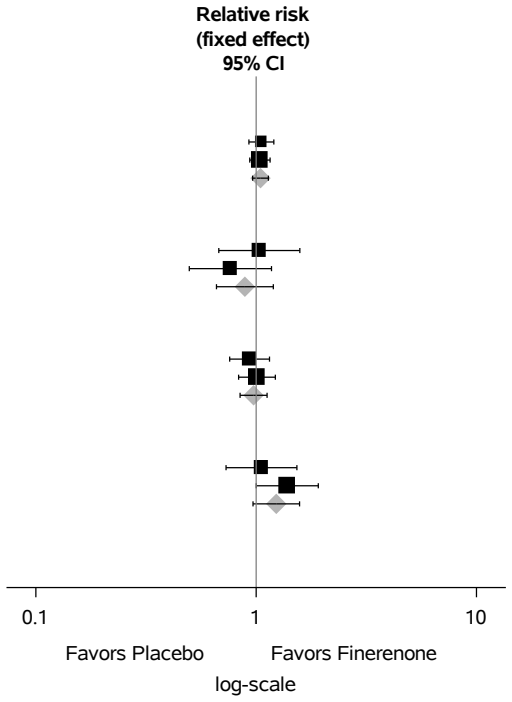
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	170 / 788	155 / 778	36.6	1.08 [0.89,1.31]	
FIGARO-DKD	278 / 1187	268 / 1197	63.4	1.05 [0.90,1.21]	
Total	448 / 1975	423 / 1975		1.06 [0.94,1.19]	Z=0.96, p=0.3350
Heterogeneity:	Q=0.08 (df=1)	p=0.7807	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	388 / 1900	394 / 1922	44.0	1.00 [0.88,1.13]	
FIGARO-DKD	512 / 2392	478 / 2355	56.0	1.05 [0.94,1.18]	
Total	900 / 4292	872 / 4277		1.03 [0.95,1.12]	Z=0.66, p=0.5075
Heterogeneity:	Q=0.45 (df=1)	p=0.5042	I^2=0.0%		
>= 160					
FIDELIO-DKD	29 / 142	25 / 139	53.4	1.14 [0.70,1.84]	
FIGARO-DKD	19 / 107	29 / 114	46.6	0.70 [0.42,1.17]	
Total	48 / 249	54 / 253		0.90 [0.64,1.28]	Z=-0.58, p=0.5605
Heterogeneity:	Q=1.83 (df=1)	p=0.1759	I^2=45.4%		
Subgroup Heterogeneity:	Q=0.77 (df=2)	p=0.6789	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.9.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set

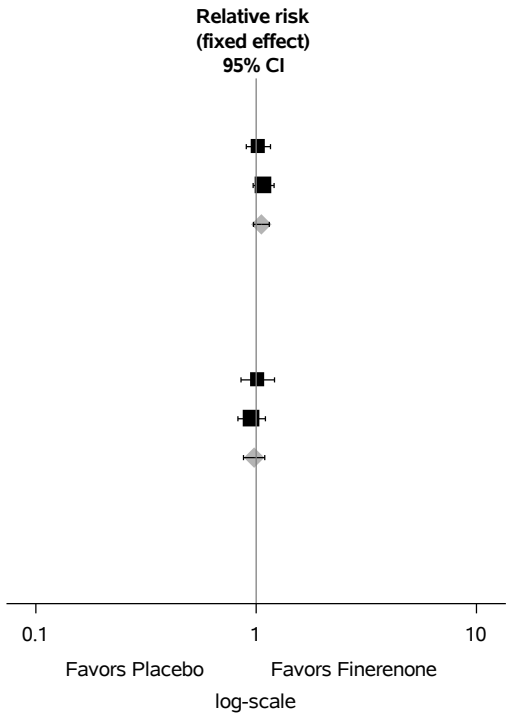
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	368 / 1777	356 / 1815	39.9	1.06 [0.93,1.20]	
FIGARO-DKD	560 / 2672	525 / 2605	60.1	1.04 [0.94,1.16]	
Total	928 / 4449	881 / 4420		1.05 [0.96,1.14]	Z=1.08, p=0.2816
Heterogeneity:	Q=0.03 (df=1)	p=0.8595	I^2=0.0%		
Black					
FIDELIO-DKD	35 / 140	30 / 124	50.7	1.03 [0.68,1.58]	
FIGARO-DKD	25 / 113	42 / 145	49.3	0.76 [0.50,1.17]	
Total	60 / 253	72 / 269		0.89 [0.66,1.20]	Z=-0.78, p=0.4366
Heterogeneity:	Q=0.96 (df=1)	p=0.3262	I^2=0.0%		
Asian					
FIDELIO-DKD	137 / 717	148 / 723	46.0	0.93 [0.76,1.15]	
FIGARO-DKD	160 / 715	164 / 739	54.0	1.01 [0.83,1.22]	
Total	297 / 1432	312 / 1462		0.97 [0.85,1.12]	Z=-0.38, p=0.7056
Heterogeneity:	Q=0.29 (df=1)	p=0.5930	I^2=0.0%		
Others					
FIDELIO-DKD	47 / 199	40 / 179	43.4	1.06 [0.73,1.53]	
FIGARO-DKD	64 / 186	44 / 177	56.6	1.38 [1.00,1.91]	
Total	111 / 385	84 / 356		1.23 [0.97,1.57]	Z=1.69, p=0.0902
Heterogeneity:	Q=1.16 (df=1)	p=0.2824	I^2=13.5%		
Subgroup Heterogeneity:	Q=3.81 (df=3)	p=0.2822	I^2=21.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.9.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set

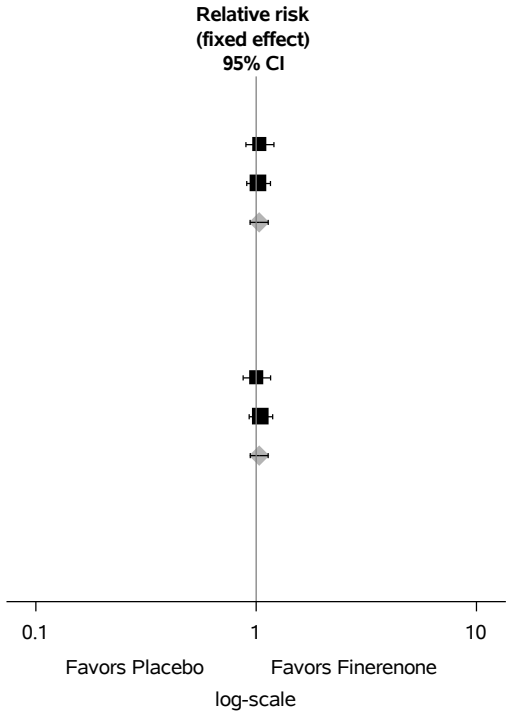
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	384 / 1953	390 / 2030	42.8	1.02 [0.90,1.16]	
FIGARO-DKD	528 / 2528	498 / 2577	57.2	1.08 [0.97,1.21]	
Total	912 / 4481	888 / 4607		1.06 [0.97,1.15]	Z=1.29, p=0.1980
Heterogeneity:	Q=0.41 (df=1)	p=0.5228	I^2=0.0%		
Female					
FIDELIO-DKD	203 / 880	184 / 811	40.3	1.02 [0.85,1.21]	
FIGARO-DKD	281 / 1158	277 / 1089	59.7	0.95 [0.83,1.10]	
Total	484 / 2038	461 / 1900		0.98 [0.88,1.09]	Z=-0.38, p=0.7057
Heterogeneity:	Q=0.30 (df=1)	p=0.5817	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.15 (df=1)	p=0.2839	I^2=12.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.9.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set

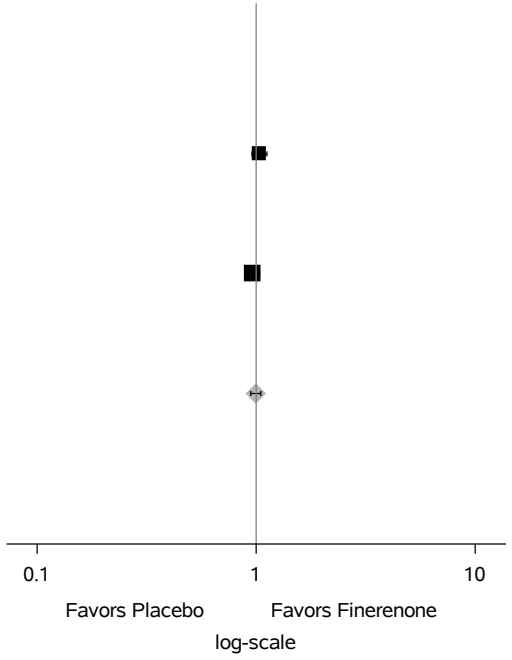
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	285 / 1205	267 / 1174	41.8	1.04 [0.90,1.20]	
FIGARO-DKD	394 / 1753	385 / 1757	58.2	1.03 [0.91,1.16]	
Total	679 / 2958	652 / 2931		1.03 [0.94,1.13]	Z=0.65, p=0.5185
Heterogeneity:	Q=0.02 (df=1)	p=0.8879	I^2=0.0%		
>= 65					
FIDELIO-DKD	302 / 1628	307 / 1667	42.3	1.01 [0.87,1.16]	
FIGARO-DKD	415 / 1933	390 / 1909	57.7	1.05 [0.93,1.19]	
Total	717 / 3561	697 / 3576		1.03 [0.94,1.13]	Z=0.67, p=0.5056
Heterogeneity:	Q=0.19 (df=1)	p=0.6601	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9936	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set

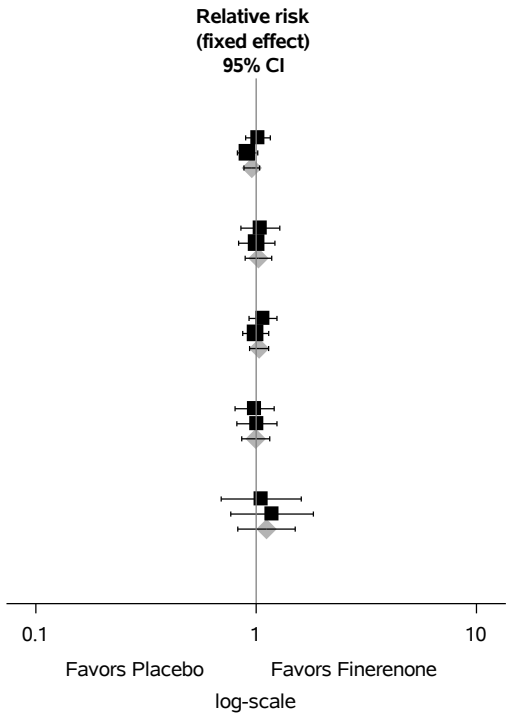
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	871 / 2833	844 / 2841	44.7	1.04 [0.96,1.12]	
FIGARO-DKD	1059 / 3686	1092 / 3666	55.3	0.97 [0.90,1.04]	
Total	1930 / 6519	1936 / 6507		1.00 [0.94,1.05]	Z=-0.14, p=0.8849
Heterogeneity:	Q=1.66 (df=1)	p=0.1975	I^2=39.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.10.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set

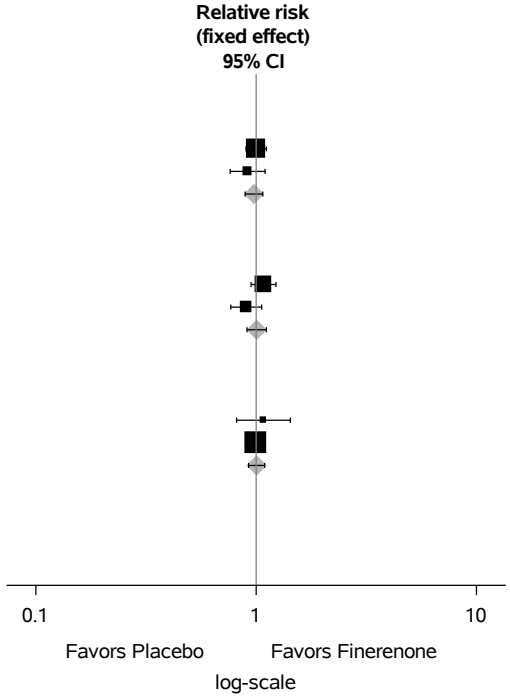
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	336 / 1182	328 / 1176	40.5	1.02 [0.90,1.16]	
FIGARO-DKD	469 / 1754	512 / 1750	59.5	0.91 [0.82,1.02]	
Total	805 / 2936	840 / 2926		0.96 [0.88,1.04]	Z=-1.10, p=0.2724
Heterogeneity:	Q=1.63 (df=1)	p=0.2011	I^2=38.8%		
North America					
FIDELIO-DKD	135 / 467	132 / 477	46.6	1.04 [0.85,1.28]	
FIGARO-DKD	156 / 559	152 / 548	53.4	1.01 [0.83,1.22]	
Total	291 / 1026	284 / 1025		1.02 [0.89,1.18]	Z=0.33, p=0.7387
Heterogeneity:	Q=0.07 (df=1)	p=0.7912	I^2=0.0%		
Asia					
FIDELIO-DKD	257 / 790	239 / 789	46.4	1.07 [0.93,1.24]	
FIGARO-DKD	274 / 810	277 / 815	53.6	1.00 [0.87,1.14]	
Total	531 / 1600	516 / 1604		1.03 [0.93,1.14]	Z=0.60, p=0.5462
Heterogeneity:	Q=0.56 (df=1)	p=0.4543	I^2=0.0%		
Latin America					
FIDELIO-DKD	112 / 295	115 / 298	51.3	0.98 [0.80,1.21]	
FIGARO-DKD	125 / 424	122 / 417	48.7	1.01 [0.82,1.24]	
Total	237 / 719	237 / 715		1.00 [0.86,1.15]	Z=-0.06, p=0.9505
Heterogeneity:	Q=0.03 (df=1)	p=0.8726	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	30 / 101	51.6	1.05 [0.69,1.60]	
FIGARO-DKD	35 / 139	29 / 136	48.4	1.18 [0.77,1.82]	
Total	66 / 238	59 / 237		1.11 [0.83,1.50]	Z=0.70, p=0.4812
Heterogeneity:	Q=0.14 (df=1)	p=0.7115	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.16 (df=4)	p=0.7072	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

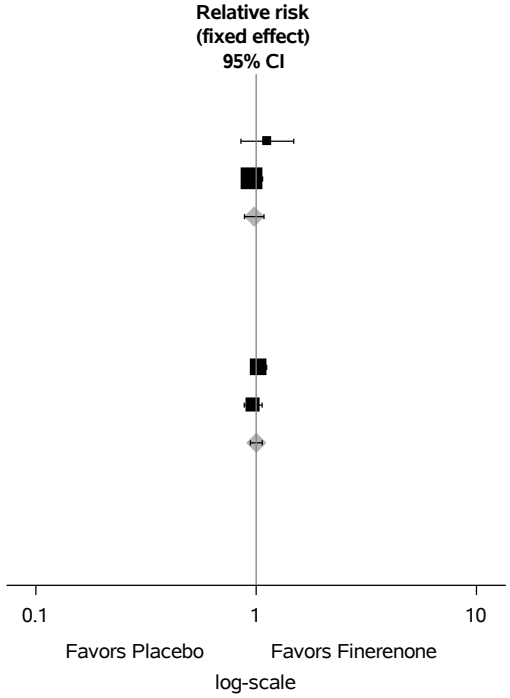
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	474 / 1559	471 / 1549	74.6	1.00 [0.90,1.11]	
FIGARO-DKD	163 / 639	176 / 631	25.4	0.91 [0.76,1.10]	
Total	637 / 2198	647 / 2180		0.98 [0.89,1.07]	Z=-0.49, p=0.6275
Heterogeneity:	Q=0.69 (df=1)	p=0.4076	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	329 / 1063	307 / 1071	60.5	1.08 [0.95,1.23]	
FIGARO-DKD	198 / 720	223 / 731	39.5	0.90 [0.77,1.06]	
Total	527 / 1783	530 / 1802		1.01 [0.91,1.11]	Z=0.10, p=0.9174
Heterogeneity:	Q=2.91 (df=1)	p=0.0882	I^2=65.6%		
>= 60					
FIDELIO-DKD	68 / 211	66 / 221	8.9	1.08 [0.81,1.43]	
FIGARO-DKD	698 / 2327	693 / 2304	91.1	1.00 [0.91,1.09]	
Total	766 / 2538	759 / 2525		1.00 [0.92,1.09]	Z=0.10, p=0.9204
Heterogeneity:	Q=0.28 (df=1)	p=0.5997	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=2)	p=0.8914	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

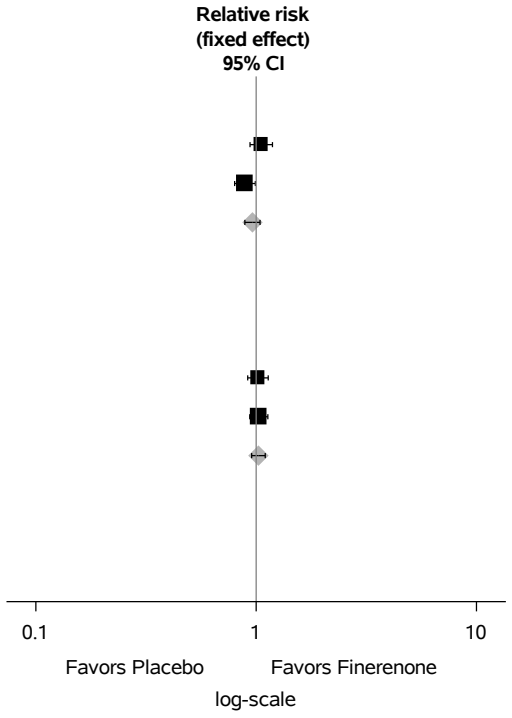
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	72 / 210	65 / 213	13.6	1.12 [0.85,1.48]	
FIGARO-DKD	460 / 1722	475 / 1705	86.4	0.96 [0.86,1.07]	
Total	532 / 1932	540 / 1918		0.98 [0.89,1.08]	Z=-0.39, p=0.6933
Heterogeneity:	Q=1.10 (df=1)	p=0.2953	I^2=8.7%		
Very High					
FIDELIO-DKD	799 / 2623	779 / 2628	56.2	1.03 [0.95,1.12]	
FIGARO-DKD	599 / 1964	617 / 1961	43.8	0.97 [0.88,1.06]	
Total	1398 / 4587	1396 / 4589		1.00 [0.94,1.07]	Z=0.05, p=0.9583
Heterogeneity:	Q=0.84 (df=1)	p=0.3586	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7158	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set

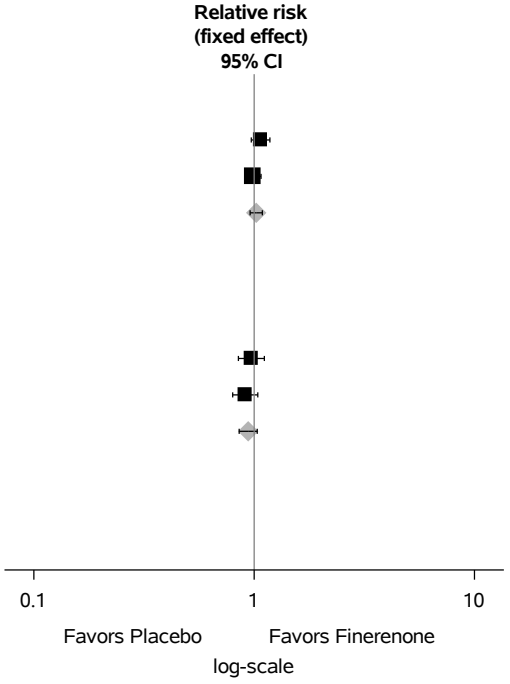
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	402 / 1303	381 / 1302	46.0	1.05 [0.94,1.19]	
FIGARO-DKD	448 / 1676	497 / 1654	54.0	0.89 [0.80,0.99]	
Total	850 / 2979	878 / 2956		0.96 [0.89,1.04]	Z=-0.96, p=0.3357
Heterogeneity:	Q=4.36 (df=1)	p=0.0368	I^2=77.1%		
Absent					
FIDELIO-DKD	469 / 1530	463 / 1539	43.7	1.02 [0.92,1.13]	
FIGARO-DKD	611 / 2010	595 / 2012	56.3	1.03 [0.94,1.13]	
Total	1080 / 3540	1058 / 3551		1.02 [0.95,1.10]	Z=0.66, p=0.5123
Heterogeneity:	Q=0.01 (df=1)	p=0.9040	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2483	I^2=25.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

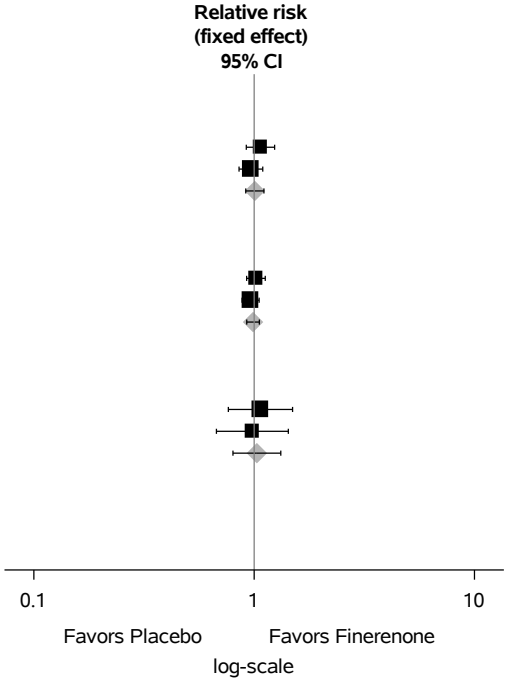
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	588 / 1881	544 / 1861	43.0	1.07 [0.97,1.18]	
FIGARO-DKD	761 / 2643	762 / 2612	57.0	0.99 [0.91,1.07]	
Total	1349 / 4524	1306 / 4473		1.02 [0.96,1.09]	Z=0.66, p=0.5109
Heterogeneity:	Q=1.48 (df=1)	p=0.2232	I^2=32.6%		
> 4.5					
FIDELIO-DKD	283 / 951	300 / 979	48.3	0.97 [0.85,1.11]	
FIGARO-DKD	298 / 1043	330 / 1052	51.7	0.91 [0.80,1.04]	
Total	581 / 1994	630 / 2031		0.94 [0.85,1.03]	Z=-1.30, p=0.1939
Heterogeneity:	Q=0.44 (df=1)	p=0.5056	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1487	I^2=52.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.10.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

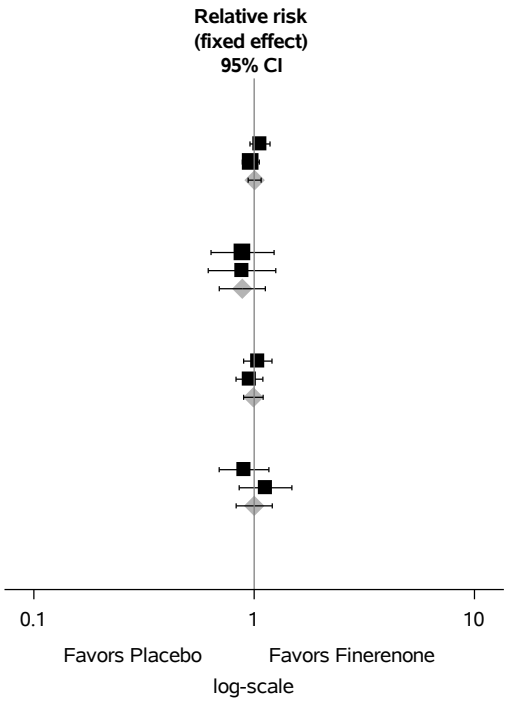
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	252 / 788	233 / 778	41.2	1.07 [0.92,1.24]	
FIGARO-DKD	345 / 1187	360 / 1197	58.8	0.97 [0.85,1.09]	
Total	597 / 1975	593 / 1975		1.01 [0.92,1.11]	Z=0.14, p=0.8856
Heterogeneity:	Q=1.03 (df=1)	p=0.3111	I^2=2.5%		
130 - < 160					
FIDELIO-DKD	571 / 1900	567 / 1922	45.6	1.02 [0.92,1.12]	
FIGARO-DKD	679 / 2392	694 / 2355	54.4	0.96 [0.88,1.05]	
Total	1250 / 4292	1261 / 4277		0.99 [0.93,1.06]	Z=-0.35, p=0.7228
Heterogeneity:	Q=0.69 (df=1)	p=0.4060	I^2=0.0%		
>= 160					
FIDELIO-DKD	48 / 142	44 / 139	55.6	1.07 [0.76,1.49]	
FIGARO-DKD	35 / 107	38 / 114	44.4	0.98 [0.67,1.43]	
Total	83 / 249	82 / 253		1.03 [0.80,1.32]	Z=0.22, p=0.8253
Heterogeneity:	Q=0.11 (df=1)	p=0.7423	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=2)	p=0.9184	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.10.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set

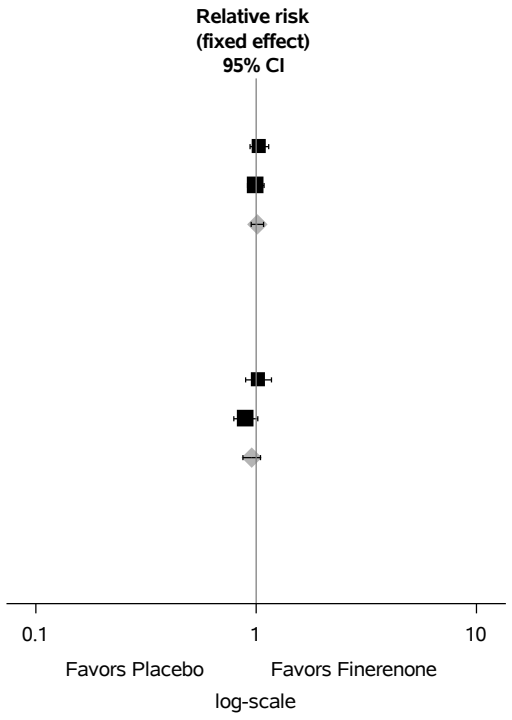
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	515 / 1777	495 / 1815	41.8	1.06 [0.96,1.18]	
FIGARO-DKD	709 / 2672	716 / 2605	58.2	0.97 [0.88,1.05]	
Total	1224 / 4449	1211 / 4420		1.00 [0.94,1.08]	Z=0.14, p=0.8859
Heterogeneity:	Q=1.88 (df=1)	p=0.1702	I^2=46.8%		
Black					
FIDELIO-DKD	46 / 140	46 / 124	53.4	0.89 [0.64,1.23]	
FIGARO-DKD	35 / 113	51 / 145	46.6	0.88 [0.62,1.25]	
Total	81 / 253	97 / 269		0.88 [0.69,1.12]	Z=-1.01, p=0.3127
Heterogeneity:	Q=0.00 (df=1)	p=0.9813	I^2=0.0%		
Asian					
FIDELIO-DKD	239 / 717	232 / 723	47.2	1.04 [0.90,1.20]	
FIGARO-DKD	244 / 715	265 / 739	52.8	0.95 [0.83,1.09]	
Total	483 / 1432	497 / 1462		0.99 [0.90,1.10]	Z=-0.16, p=0.8749
Heterogeneity:	Q=0.71 (df=1)	p=0.4000	I^2=0.0%		
Others					
FIDELIO-DKD	71 / 199	71 / 179	52.9	0.90 [0.69,1.17]	
FIGARO-DKD	71 / 186	60 / 177	47.1	1.13 [0.86,1.48]	
Total	142 / 385	131 / 356		1.00 [0.83,1.21]	Z=0.00, p=0.9963
Heterogeneity:	Q=1.35 (df=1)	p=0.2446	I^2=26.1%		
Subgroup Heterogeneity:	Q=1.03 (df=3)	p=0.7943	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.10.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set

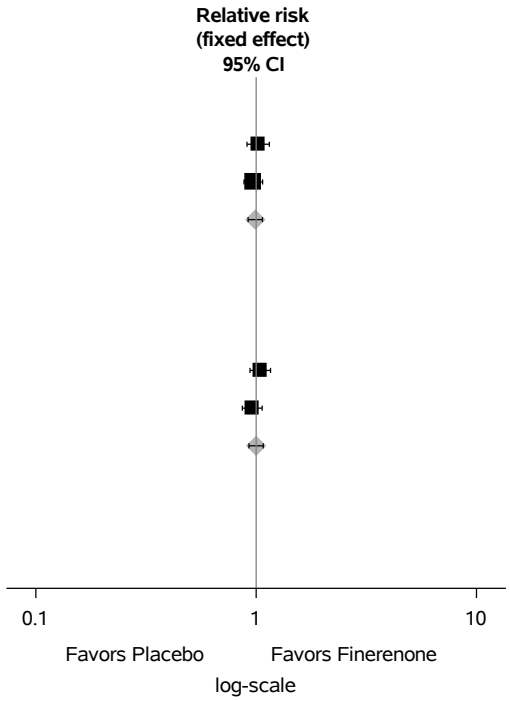
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	574 / 1953	577 / 2030	44.0	1.03 [0.94,1.14]	
FIGARO-DKD	726 / 2528	743 / 2577	56.0	1.00 [0.91,1.09]	
Total	1300 / 4481	1320 / 4607		1.01 [0.95,1.08]	Z=0.38, p=0.7045
Heterogeneity:	Q=0.32 (df=1)	p=0.5733	I^2=0.0%		
Female					
FIDELIO-DKD	297 / 880	267 / 811	46.3	1.03 [0.90,1.17]	
FIGARO-DKD	333 / 1158	349 / 1089	53.7	0.90 [0.79,1.02]	
Total	630 / 2038	616 / 1900		0.95 [0.87,1.05]	Z=-1.00, p=0.3188
Heterogeneity:	Q=2.01 (df=1)	p=0.1563	I^2=50.2%		
Subgroup Heterogeneity:	Q=1.07 (df=1)	p=0.3014	I^2=6.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.10.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set

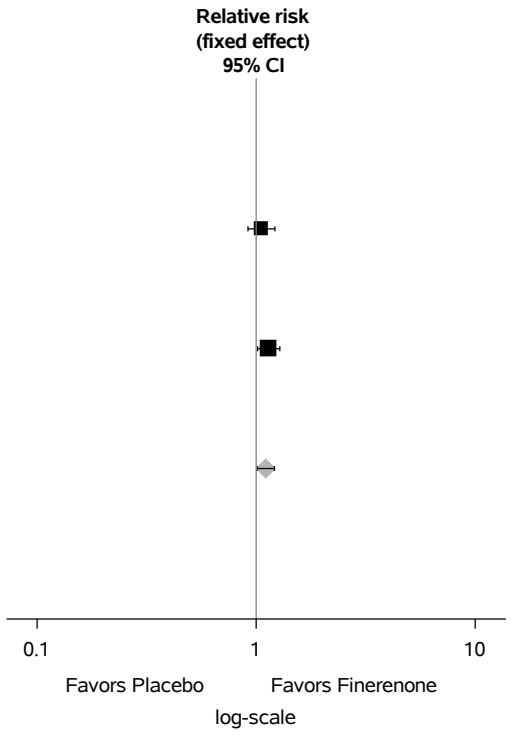
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	392 / 1205	374 / 1174	41.1	1.02 [0.91,1.15]	
FIGARO-DKD	545 / 1753	563 / 1757	58.9	0.97 [0.88,1.07]	
Total	937 / 2958	937 / 2931		0.99 [0.92,1.07]	Z=-0.24, p=0.8096
Heterogeneity:	Q=0.44 (df=1)	p=0.5095	I^2=0.0%		
>= 65					
FIDELIO-DKD	479 / 1628	470 / 1667	48.2	1.04 [0.94,1.16]	
FIGARO-DKD	514 / 1933	529 / 1909	51.8	0.96 [0.87,1.06]	
Total	993 / 3561	999 / 3576		1.00 [0.93,1.08]	Z=-0.02, p=0.9831
Heterogeneity:	Q=1.21 (df=1)	p=0.2704	I^2=17.7%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8763	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set

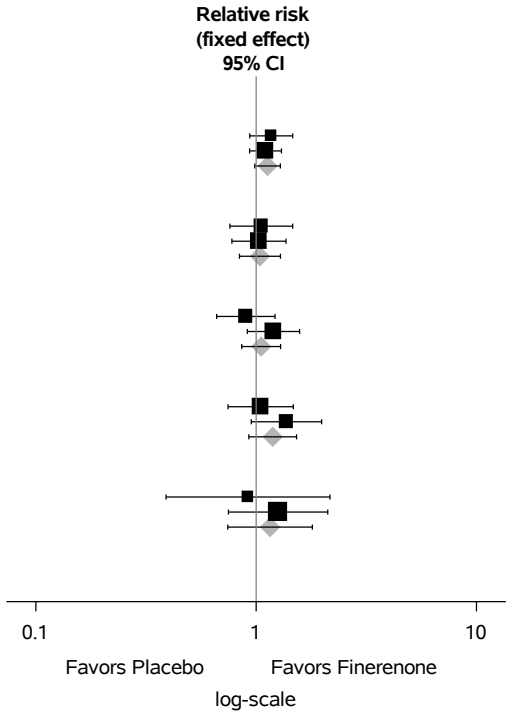
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	345 / 2833	328 / 2841	40.5	1.06 [0.92,1.22]	
FIGARO-DKD	523 / 3686	456 / 3666	59.5	1.14 [1.02,1.28]	
Total	868 / 6519	784 / 6507		1.11 [1.01,1.21]	Z=2.18, p=0.0291
Heterogeneity:	Q=0.67 (df=1)	p=0.4136	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.11.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set

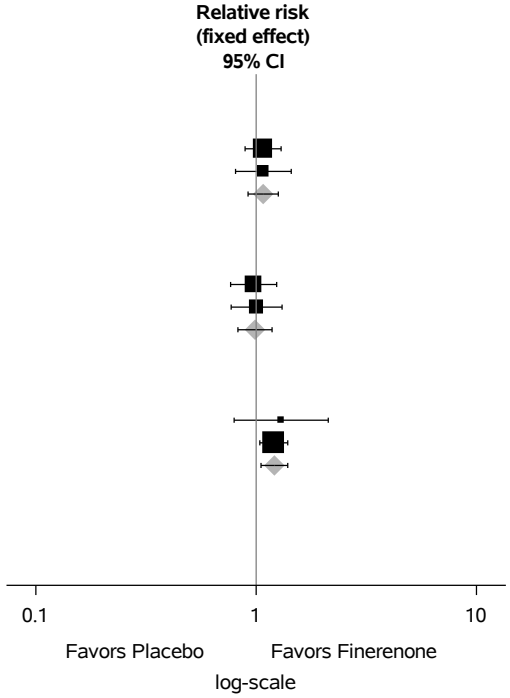
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	147 / 1182	125 / 1176	35.5	1.17 [0.93,1.46]	
FIGARO-DKD	252 / 1754	228 / 1750	64.5	1.10 [0.93,1.30]	
Total	399 / 2936	353 / 2926		1.13 [0.99,1.29]	Z=1.74, p=0.0814
Heterogeneity:	Q=0.17 (df=1)	p=0.6778	I^2=0.0%		
North America					
FIDELIO-DKD	63 / 467	61 / 477	42.6	1.05 [0.76,1.46]	
FIGARO-DKD	84 / 559	80 / 548	57.4	1.03 [0.78,1.37]	
Total	147 / 1026	141 / 1025		1.04 [0.84,1.29]	Z=0.36, p=0.7186
Heterogeneity:	Q=0.01 (df=1)	p=0.9116	I^2=0.0%		
Asia					
FIDELIO-DKD	71 / 790	79 / 789	44.5	0.90 [0.66,1.22]	
FIGARO-DKD	100 / 810	84 / 815	55.5	1.20 [0.91,1.57]	
Total	171 / 1600	163 / 1604		1.05 [0.86,1.29]	Z=0.50, p=0.6143
Heterogeneity:	Q=1.91 (df=1)	p=0.1673	I^2=47.6%		
Latin America					
FIDELIO-DKD	55 / 295	53 / 298	53.7	1.05 [0.75,1.47]	
FIGARO-DKD	60 / 424	43 / 417	46.3	1.37 [0.95,1.98]	
Total	115 / 719	96 / 715		1.19 [0.93,1.53]	Z=1.36, p=0.1741
Heterogeneity:	Q=1.11 (df=1)	p=0.2925	I^2=9.8%		
Others					
FIDELIO-DKD	9 / 99	10 / 101	26.8	0.92 [0.39,2.16]	
FIGARO-DKD	27 / 139	21 / 136	73.2	1.26 [0.75,2.11]	
Total	36 / 238	31 / 237		1.16 [0.74,1.80]	Z=0.64, p=0.5194
Heterogeneity:	Q=0.38 (df=1)	p=0.5379	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.97 (df=4)	p=0.9148	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

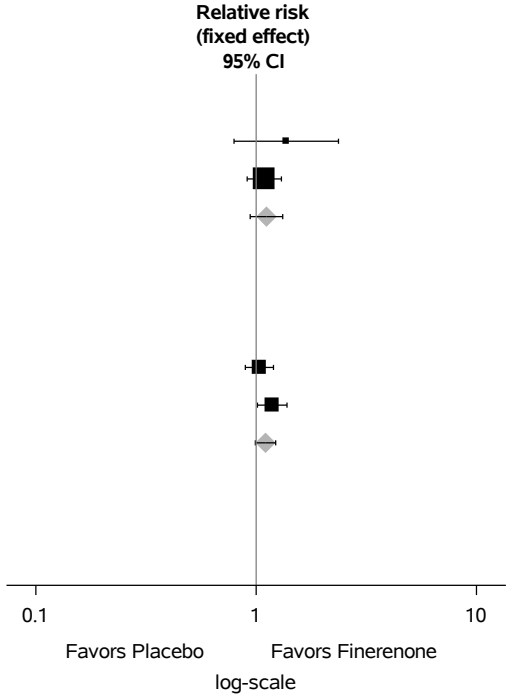
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	198 / 1559	183 / 1549	70.5	1.08 [0.89,1.30]	
FIGARO-DKD	83 / 639	76 / 631	29.5	1.08 [0.81,1.44]	
Total	281 / 2198	259 / 2180		1.08 [0.92,1.26]	Z=0.91, p=0.3636
Heterogeneity:	Q=0.00 (df=1)	p=0.9857	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	116 / 1063	120 / 1071	55.0	0.97 [0.77,1.24]	
FIGARO-DKD	94 / 720	95 / 731	45.0	1.00 [0.77,1.31]	
Total	210 / 1783	215 / 1802		0.99 [0.83,1.18]	Z=-0.14, p=0.8912
Heterogeneity:	Q=0.03 (df=1)	p=0.8655	I^2=0.0%		
>= 60					
FIDELIO-DKD	31 / 211	25 / 221	8.1	1.30 [0.79,2.12]	
FIGARO-DKD	346 / 2327	285 / 2304	91.9	1.20 [1.04,1.39]	
Total	377 / 2538	310 / 2525		1.21 [1.05,1.39]	Z=2.67, p=0.0076
Heterogeneity:	Q=0.09 (df=1)	p=0.7675	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.24 (df=2)	p=0.1981	I^2=38.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

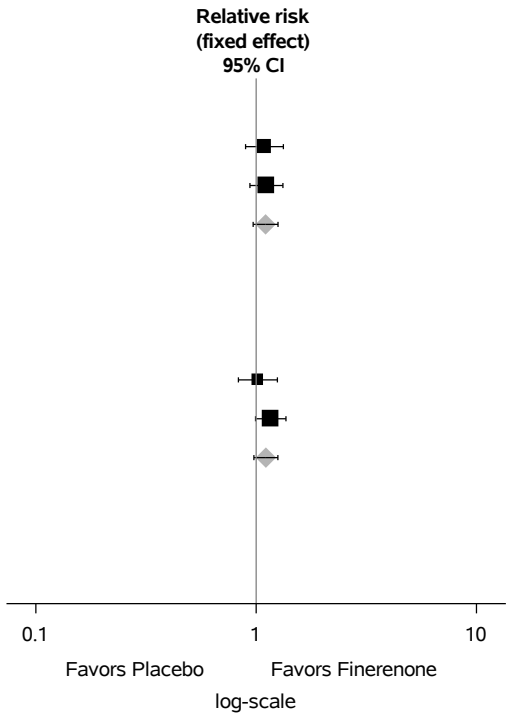
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	27 / 210	20 / 213	9.7	1.37 [0.79,2.36]	
FIGARO-DKD	221 / 1722	201 / 1705	90.3	1.09 [0.91,1.30]	
Total	248 / 1932	221 / 1918		1.11 [0.94,1.32]	Z=1.24, p=0.2151
Heterogeneity:	Q=0.61 (df=1)	p=0.4339	I^2=0.0%		
Very High					
FIDELIO-DKD	318 / 2623	308 / 2628	52.5	1.03 [0.89,1.20]	
FIGARO-DKD	302 / 1964	255 / 1961	47.5	1.18 [1.01,1.38]	
Total	620 / 4587	563 / 4589		1.10 [0.99,1.23]	Z=1.80, p=0.0723
Heterogeneity:	Q=1.51 (df=1)	p=0.2190	I^2=33.8%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9230	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set

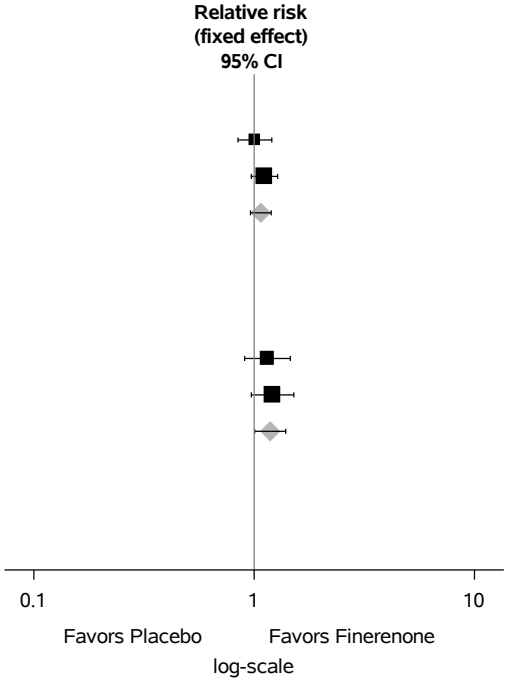
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	179 / 1303	164 / 1302	43.3	1.09 [0.90,1.33]	
FIGARO-DKD	238 / 1676	211 / 1654	56.7	1.11 [0.94,1.32]	
Total	417 / 2979	375 / 2956		1.10 [0.97,1.26]	Z=1.48, p=0.1377
Heterogeneity:	Q=0.02 (df=1)	p=0.8785	I^2=0.0%		
Absent					
FIDELIO-DKD	166 / 1530	164 / 1539	37.9	1.02 [0.83,1.25]	
FIGARO-DKD	285 / 2010	245 / 2012	62.1	1.16 [0.99,1.37]	
Total	451 / 3540	409 / 3551		1.11 [0.98,1.25]	Z=1.59, p=0.1126
Heterogeneity:	Q=1.03 (df=1)	p=0.3090	I^2=3.4%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9729	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

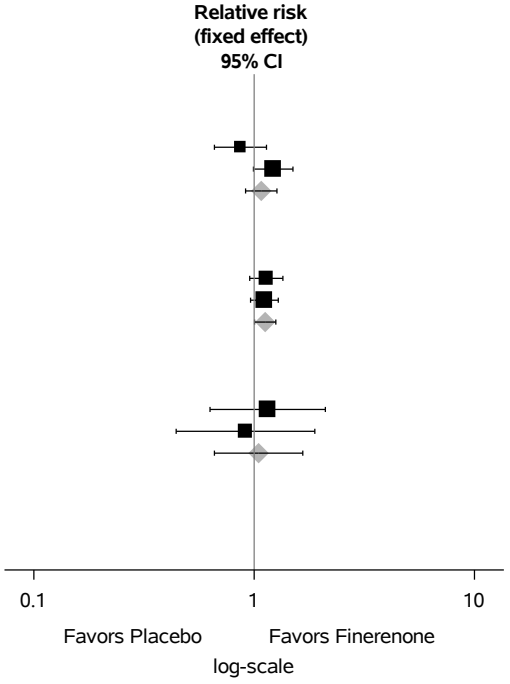
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	220 / 1881	216 / 1861	37.8	1.01 [0.84,1.20]	
FIGARO-DKD	374 / 2643	332 / 2612	62.2	1.11 [0.97,1.28]	
Total	594 / 4524	548 / 4473		1.07 [0.96,1.20]	Z=1.26, p=0.2077
Heterogeneity:	Q=0.76 (df=1)	p=0.3826	I^2=0.0%		
> 4.5					
FIDELIO-DKD	125 / 951	112 / 979	46.4	1.15 [0.90,1.46]	
FIGARO-DKD	149 / 1043	124 / 1052	53.6	1.21 [0.97,1.51]	
Total	274 / 1994	236 / 2031		1.18 [1.00,1.39]	Z=2.02, p=0.0436
Heterogeneity:	Q=0.10 (df=1)	p=0.7483	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.96 (df=1)	p=0.3270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.11.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

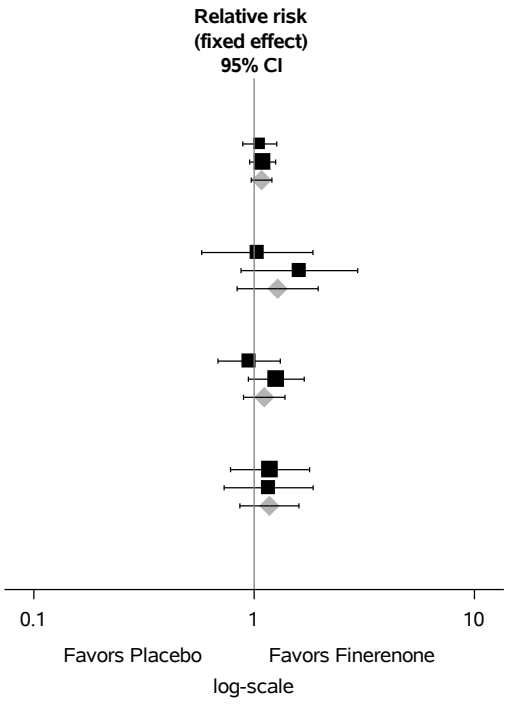
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	86 / 788	98 / 778	36.5	0.87 [0.66,1.14]	
FIGARO-DKD	173 / 1187	143 / 1197	63.5	1.22 [0.99,1.50]	
Total	259 / 1975	241 / 1975		1.08 [0.91,1.27]	Z=0.88, p=0.3762
Heterogeneity:	Q=3.86 (df=1)	p=0.0496	I^2=74.1%		
130 - < 160					
FIDELIO-DKD	239 / 1900	213 / 1922	41.1	1.14 [0.95,1.35]	
FIGARO-DKD	338 / 2392	299 / 2355	58.9	1.11 [0.96,1.29]	
Total	577 / 4292	512 / 4277		1.12 [1.00,1.25]	Z=2.03, p=0.0425
Heterogeneity:	Q=0.03 (df=1)	p=0.8645	I^2=0.0%		
>= 160					
FIDELIO-DKD	20 / 142	17 / 139	59.1	1.15 [0.63,2.10]	
FIGARO-DKD	12 / 107	14 / 114	40.9	0.91 [0.44,1.88]	
Total	32 / 249	31 / 253		1.05 [0.66,1.66]	Z=0.20, p=0.8444
Heterogeneity:	Q=0.23 (df=1)	p=0.6296	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=2)	p=0.8961	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.11.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set

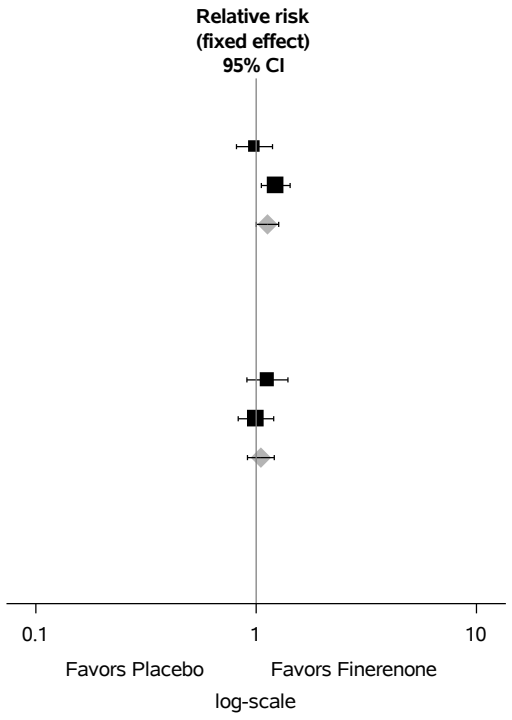
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	218 / 1777	210 / 1815	36.9	1.06 [0.89,1.27]	
FIGARO-DKD	381 / 2672	340 / 2605	63.1	1.09 [0.95,1.25]	
Total	599 / 4449	550 / 4420		1.08 [0.97,1.20]	Z=1.41, p=0.1598
Heterogeneity:	Q=0.07 (df=1)	p=0.7934	I^2=0.0%		
Black					
FIDELIO-DKD	21 / 140	18 / 124	52.4	1.03 [0.58,1.85]	
FIGARO-DKD	20 / 113	16 / 145	47.6	1.60 [0.87,2.95]	
Total	41 / 253	34 / 269		1.28 [0.84,1.95]	Z=1.13, p=0.2565
Heterogeneity:	Q=1.05 (df=1)	p=0.3062	I^2=4.5%		
Asian					
FIDELIO-DKD	64 / 717	68 / 723	44.6	0.95 [0.69,1.31]	
FIGARO-DKD	89 / 715	73 / 739	55.4	1.26 [0.94,1.69]	
Total	153 / 1432	141 / 1462		1.11 [0.89,1.38]	Z=0.95, p=0.3417
Heterogeneity:	Q=1.62 (df=1)	p=0.2037	I^2=38.1%		
Others					
FIDELIO-DKD	42 / 199	32 / 179	55.9	1.18 [0.78,1.78]	
FIGARO-DKD	33 / 186	27 / 177	44.1	1.16 [0.73,1.85]	
Total	75 / 385	59 / 356		1.17 [0.86,1.60]	Z=1.01, p=0.3117
Heterogeneity:	Q=0.00 (df=1)	p=0.9625	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=3)	p=0.8593	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.11.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set

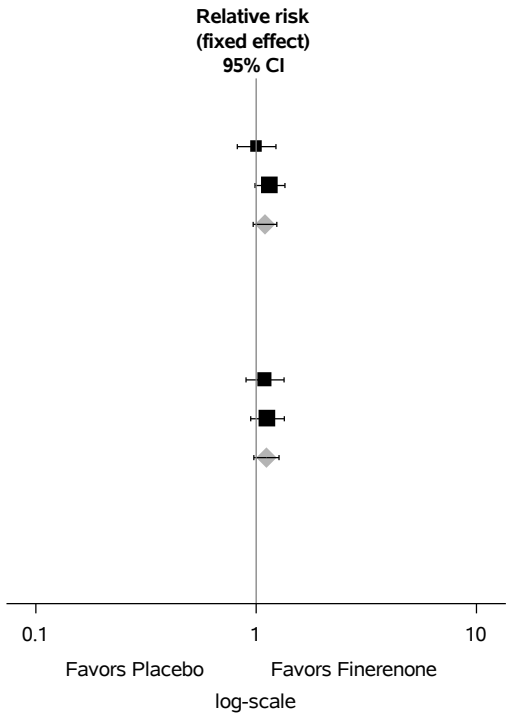
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	190 / 1953	201 / 2030	38.9	0.98 [0.81,1.19]	
FIGARO-DKD	331 / 2528	275 / 2577	61.1	1.23 [1.06,1.43]	
Total	521 / 4481	476 / 4607		1.13 [1.00,1.27]	Z=1.98, p=0.0477
Heterogeneity:	Q=3.27 (df=1)	p=0.0707	I^2=69.4%		
Female					
FIDELIO-DKD	155 / 880	127 / 811	42.8	1.12 [0.91,1.39]	
FIGARO-DKD	192 / 1158	181 / 1089	57.2	1.00 [0.83,1.20]	
Total	347 / 2038	308 / 1900		1.05 [0.91,1.21]	Z=0.69, p=0.4921
Heterogeneity:	Q=0.69 (df=1)	p=0.4065	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4574	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.11.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set

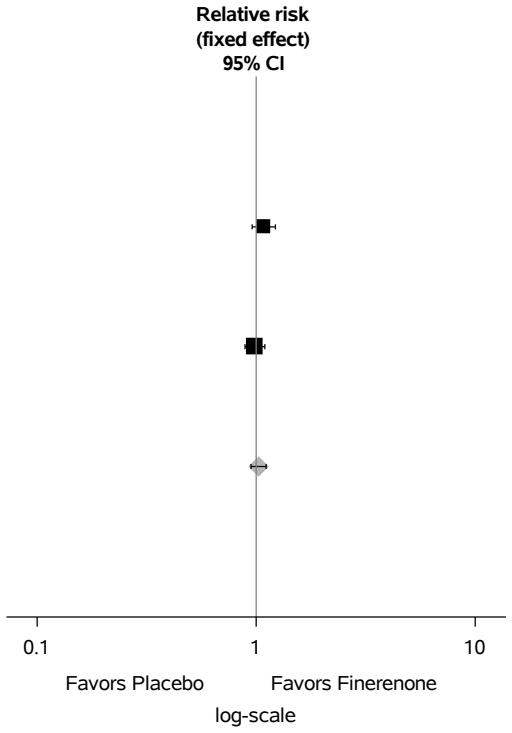
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	165 / 1205	160 / 1174	37.4	1.00 [0.82,1.23]	
FIGARO-DKD	287 / 1753	249 / 1757	62.6	1.16 [0.99,1.35]	
Total	452 / 2958	409 / 2931		1.10 [0.97,1.24]	Z=1.46, p=0.1438
Heterogeneity:	Q=1.15 (df=1)	p=0.2842	I^2=12.8%		
>= 65					
FIDELIO-DKD	180 / 1628	168 / 1667	43.8	1.10 [0.90,1.34]	
FIGARO-DKD	236 / 1933	207 / 1909	56.2	1.13 [0.94,1.34]	
Total	416 / 3561	375 / 3576		1.11 [0.98,1.27]	Z=1.60, p=0.1102
Heterogeneity:	Q=0.04 (df=1)	p=0.8479	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8700	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set

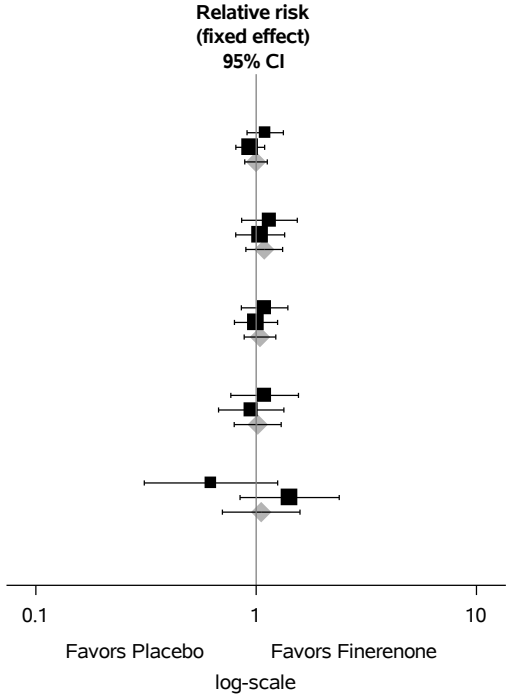
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	452 / 2833	418 / 2841	42.1	1.08 [0.96,1.22]	
FIGARO-DKD	588 / 3686	593 / 3666	57.9	0.99 [0.89,1.10]	
Total	1040 / 6519	1011 / 6507		1.03 [0.95,1.11]	Z=0.63, p=0.5287
Heterogeneity:	Q=1.29 (df=1)	p=0.2554	I^2=22.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and log as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.2.12.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set

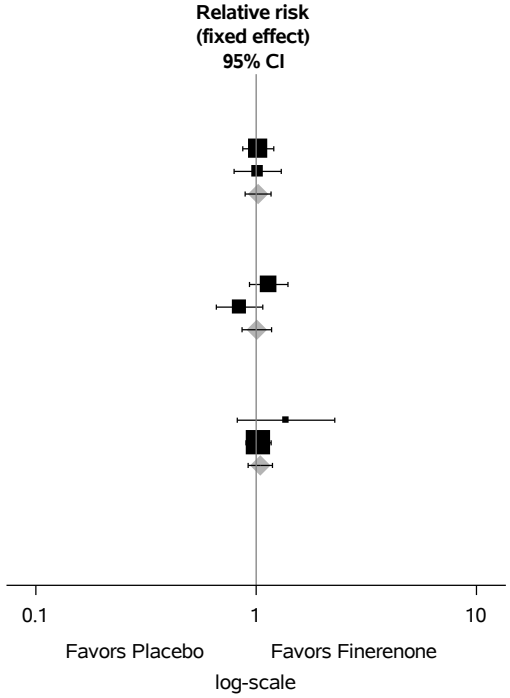
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	190 / 1182	172 / 1176	38.6	1.10 [0.91,1.33]	
FIGARO-DKD	276 / 1754	293 / 1750	61.4	0.94 [0.81,1.09]	
Total	466 / 2936	465 / 2926		1.00 [0.89,1.12]	Z=-0.03, p=0.9785
Heterogeneity:	Q=1.60 (df=1)	p=0.2054	I^2=37.6%		
North America					
FIDELIO-DKD	81 / 467	72 / 477	43.6	1.15 [0.86,1.54]	
FIGARO-DKD	100 / 559	94 / 548	56.4	1.04 [0.81,1.35]	
Total	181 / 1026	166 / 1025		1.09 [0.90,1.32]	Z=0.86, p=0.3891
Heterogeneity:	Q=0.24 (df=1)	p=0.6235	I^2=0.0%		
Asia					
FIDELIO-DKD	117 / 790	107 / 789	46.3	1.09 [0.86,1.39]	
FIGARO-DKD	127 / 810	128 / 815	53.7	1.00 [0.80,1.25]	
Total	244 / 1600	235 / 1604		1.04 [0.88,1.23]	Z=0.47, p=0.6361
Heterogeneity:	Q=0.28 (df=1)	p=0.5955	I^2=0.0%		
Latin America					
FIDELIO-DKD	53 / 295	49 / 298	48.3	1.09 [0.77,1.56]	
FIGARO-DKD	56 / 424	58 / 417	51.7	0.95 [0.67,1.34]	
Total	109 / 719	107 / 715		1.02 [0.79,1.30]	Z=0.13, p=0.8982
Heterogeneity:	Q=0.31 (df=1)	p=0.5757	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 99	18 / 101	35.6	0.62 [0.31,1.25]	
FIGARO-DKD	29 / 139	20 / 136	64.4	1.42 [0.84,2.38]	
Total	40 / 238	38 / 237		1.05 [0.70,1.58]	Z=0.25, p=0.7998
Heterogeneity:	Q=3.44 (df=1)	p=0.0635	I^2=71.0%		
Subgroup Heterogeneity:	Q=0.62 (df=4)	p=0.9613	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

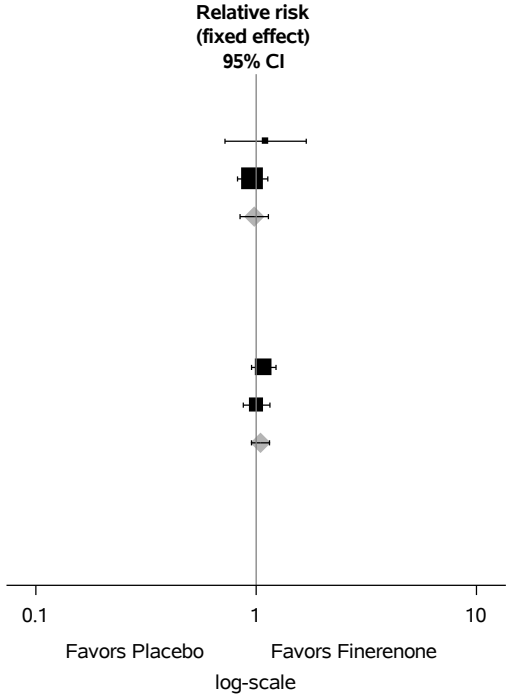
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	250 / 1559	243 / 1549	69.8	1.02 [0.87,1.20]	
FIGARO-DKD	107 / 639	104 / 631	30.2	1.02 [0.79,1.30]	
Total	357 / 2198	347 / 2180		1.02 [0.89,1.17]	Z=0.29, p=0.7708
Heterogeneity:	Q=0.00 (df=1)	p=0.9675	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	172 / 1063	152 / 1071	59.3	1.14 [0.93,1.39]	
FIGARO-DKD	101 / 720	122 / 731	40.7	0.84 [0.66,1.07]	
Total	273 / 1783	274 / 1802		1.01 [0.86,1.17]	Z=0.09, p=0.9311
Heterogeneity:	Q=3.59 (df=1)	p=0.0580	I^2=72.2%		
>= 60					
FIDELIO-DKD	30 / 211	23 / 221	6.2	1.37 [0.82,2.27]	
FIGARO-DKD	380 / 2327	367 / 2304	93.8	1.03 [0.90,1.17]	
Total	410 / 2538	390 / 2525		1.04 [0.92,1.19]	Z=0.66, p=0.5072
Heterogeneity:	Q=1.14 (df=1)	p=0.2847	I^2=12.6%		
Subgroup Heterogeneity:	Q=0.14 (df=2)	p=0.9345	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

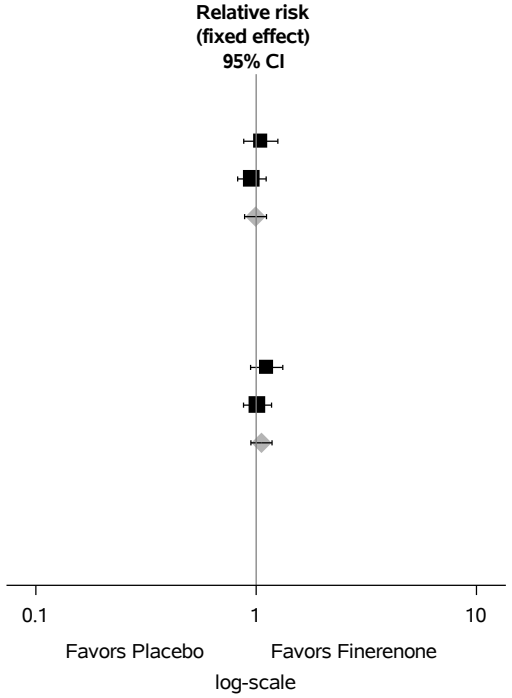
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	37 / 210	34 / 213	12.2	1.10 [0.72,1.69]	
FIGARO-DKD	257 / 1722	264 / 1705	87.8	0.96 [0.82,1.13]	
Total	294 / 1932	298 / 1918		0.98 [0.84,1.14]	Z=-0.27, p=0.7886
Heterogeneity:	Q=0.34 (df=1)	p=0.5579	I^2=0.0%		
Very High					
FIDELIO-DKD	415 / 2623	384 / 2628	54.2	1.08 [0.95,1.23]	
FIGARO-DKD	331 / 1964	329 / 1961	45.8	1.00 [0.87,1.15]	
Total	746 / 4587	713 / 4589		1.05 [0.95,1.15]	Z=0.94, p=0.3461
Heterogeneity:	Q=0.61 (df=1)	p=0.4365	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=1)	p=0.4645	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set

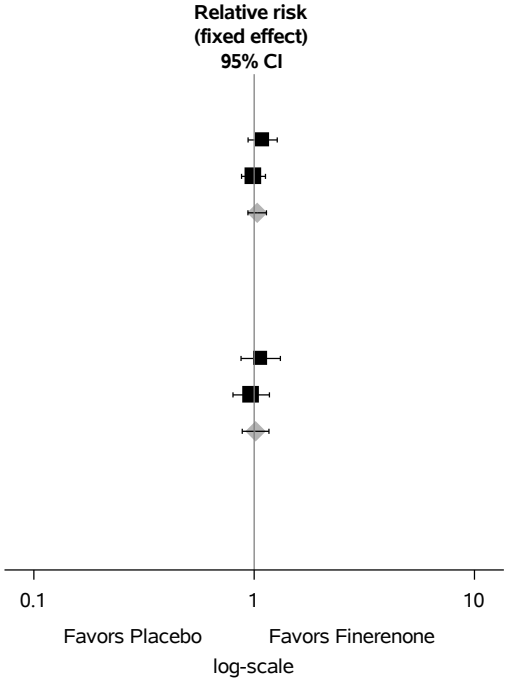
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	209 / 1303	199 / 1302	41.1	1.05 [0.88,1.25]	
FIGARO-DKD	282 / 1676	291 / 1654	58.9	0.96 [0.82,1.11]	
Total	491 / 2979	490 / 2956		0.99 [0.89,1.11]	Z=-0.11, p=0.9124
Heterogeneity:	Q=0.61 (df=1)	p=0.4333	I^2=0.0%		
Absent					
FIDELIO-DKD	243 / 1530	219 / 1539	43.1	1.12 [0.94,1.32]	
FIGARO-DKD	306 / 2010	302 / 2012	56.9	1.01 [0.88,1.17]	
Total	549 / 3540	521 / 3551		1.06 [0.95,1.18]	Z=0.98, p=0.3254
Heterogeneity:	Q=0.71 (df=1)	p=0.4006	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.58 (df=1)	p=0.4458	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

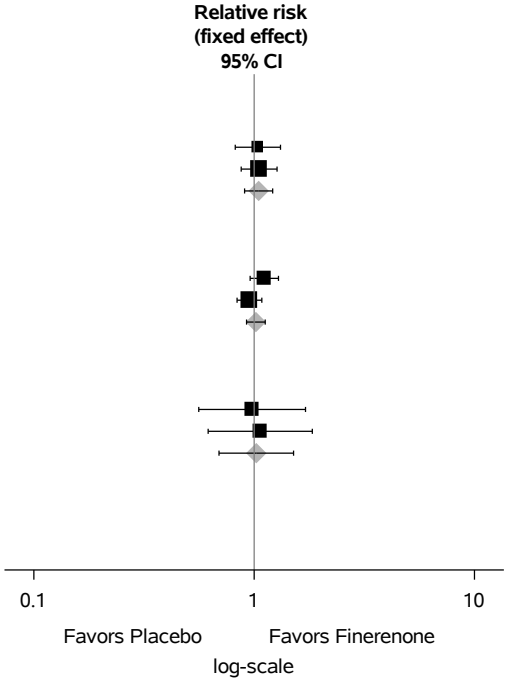
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	296 / 1881	268 / 1861	40.3	1.09 [0.94,1.27]	
FIGARO-DKD	415 / 2643	413 / 2612	59.7	0.99 [0.88,1.13]	
Total	711 / 4524	681 / 4473		1.03 [0.94,1.14]	Z=0.64, p=0.5218
Heterogeneity:	Q=0.90 (df=1)	p=0.3415	I^2=0.0%		
> 4.5					
FIDELIO-DKD	156 / 951	150 / 979	46.1	1.07 [0.87,1.32]	
FIGARO-DKD	173 / 1043	180 / 1052	53.9	0.97 [0.80,1.17]	
Total	329 / 1994	330 / 2031		1.01 [0.88,1.17]	Z=0.21, p=0.8360
Heterogeneity:	Q=0.48 (df=1)	p=0.4872	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8460	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.12.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

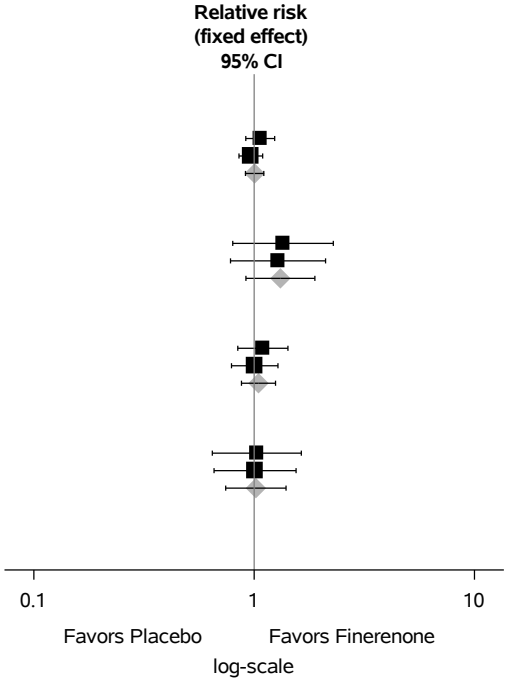
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	120 / 788	114 / 778	38.6	1.04 [0.82,1.32]	
FIGARO-DKD	189 / 1187	181 / 1197	61.4	1.05 [0.87,1.27]	
Total	309 / 1975	295 / 1975		1.05 [0.90,1.21]	Z=0.62, p=0.5341
Heterogeneity:	Q=0.01 (df=1)	p=0.9321	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	311 / 1900	283 / 1922	43.3	1.11 [0.96,1.29]	
FIGARO-DKD	378 / 2392	391 / 2355	56.7	0.95 [0.84,1.08]	
Total	689 / 4292	674 / 4277		1.02 [0.92,1.12]	Z=0.36, p=0.7181
Heterogeneity:	Q=2.40 (df=1)	p=0.1217	I^2=58.3%		
>= 160					
FIDELIO-DKD	21 / 142	21 / 139	48.8	0.98 [0.56,1.71]	
FIGARO-DKD	21 / 107	21 / 114	51.2	1.07 [0.62,1.84]	
Total	42 / 249	42 / 253		1.02 [0.69,1.51]	Z=0.11, p=0.9117
Heterogeneity:	Q=0.05 (df=1)	p=0.8313	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=2)	p=0.9503	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.12.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set

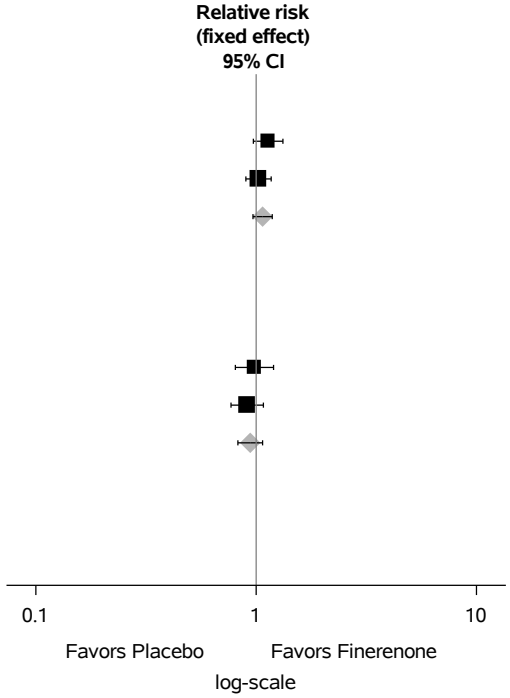
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	290 / 1777	278 / 1815	40.2	1.07 [0.92,1.24]	
FIGARO-DKD	419 / 2672	423 / 2605	59.8	0.97 [0.85,1.09]	
Total	709 / 4449	701 / 4420		1.00 [0.91,1.11]	Z=0.10, p=0.9239
Heterogeneity:	Q=0.97 (df=1)	p=0.3237	I^2=0.0%		
Black					
FIDELIO-DKD	29 / 140	19 / 124	47.2	1.35 [0.80,2.29]	
FIGARO-DKD	25 / 113	25 / 145	52.8	1.28 [0.78,2.11]	
Total	54 / 253	44 / 269		1.32 [0.92,1.89]	Z=1.49, p=0.1362
Heterogeneity:	Q=0.02 (df=1)	p=0.8876	I^2=0.0%		
Asian					
FIDELIO-DKD	101 / 717	93 / 723	46.2	1.10 [0.84,1.42]	
FIGARO-DKD	109 / 715	112 / 739	53.8	1.01 [0.79,1.28]	
Total	210 / 1432	205 / 1462		1.05 [0.88,1.25]	Z=0.50, p=0.6192
Heterogeneity:	Q=0.22 (df=1)	p=0.6410	I^2=0.0%		
Others					
FIDELIO-DKD	32 / 199	28 / 179	45.9	1.03 [0.65,1.64]	
FIGARO-DKD	35 / 186	33 / 177	54.1	1.01 [0.66,1.55]	
Total	67 / 385	61 / 356		1.02 [0.74,1.40]	Z=0.11, p=0.9125
Heterogeneity:	Q=0.00 (df=1)	p=0.9546	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.06 (df=3)	p=0.5607	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.2.12.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set

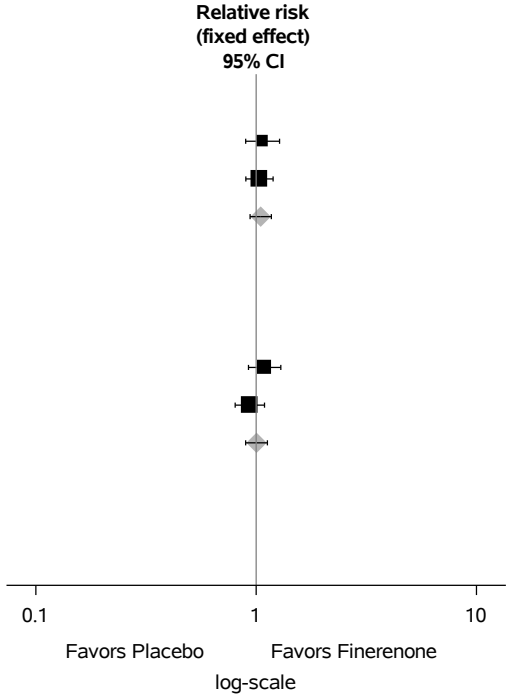
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	290 / 1953	266 / 2030	42.4	1.13 [0.97,1.32]	
FIGARO-DKD	375 / 2528	373 / 2577	57.6	1.02 [0.90,1.17]	
Total	665 / 4481	639 / 4607		1.07 [0.97,1.18]	Z=1.31, p=0.1900
Heterogeneity:	Q=0.94 (df=1)	p=0.3327	I^2=0.0%		
Female					
FIDELIO-DKD	162 / 880	152 / 811	41.8	0.98 [0.80,1.20]	
FIGARO-DKD	213 / 1158	220 / 1089	58.2	0.91 [0.77,1.08]	
Total	375 / 2038	372 / 1900		0.94 [0.83,1.07]	Z=-0.94, p=0.3460
Heterogeneity:	Q=0.32 (df=1)	p=0.5702	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.40 (df=1)	p=0.1215	I^2=58.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.2.12.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set

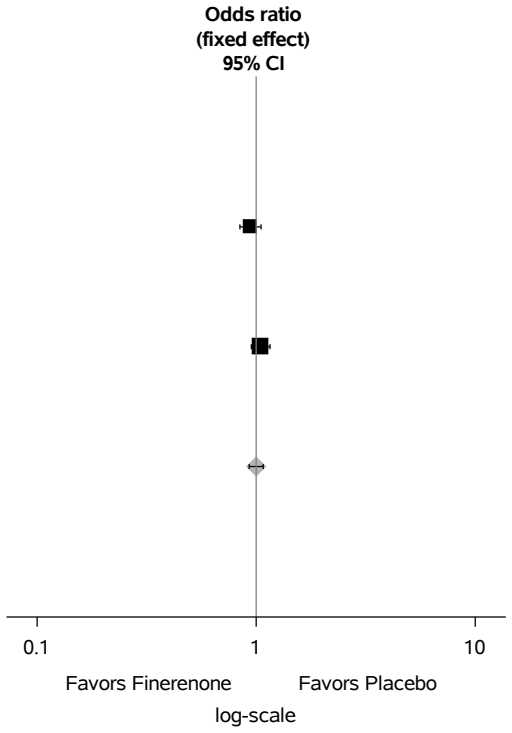
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	213 / 1205	194 / 1174	39.3	1.07 [0.90,1.28]	
FIGARO-DKD	316 / 1753	306 / 1757	60.7	1.04 [0.90,1.19]	
Total	529 / 2958	500 / 2931		1.05 [0.94,1.17]	Z=0.84, p=0.4030
Heterogeneity:	Q=0.08 (df=1)	p=0.7765	I^2=0.0%		
>= 65					
FIDELIO-DKD	239 / 1628	224 / 1667	45.2	1.09 [0.92,1.29]	
FIGARO-DKD	272 / 1933	287 / 1909	54.8	0.94 [0.80,1.09]	
Total	511 / 3561	511 / 3576		1.00 [0.90,1.12]	Z=0.06, p=0.9495
Heterogeneity:	Q=1.76 (df=1)	p=0.1840	I^2=43.3%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5894	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For single studies the RR is estimated by a GLM with factor treatment group using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set

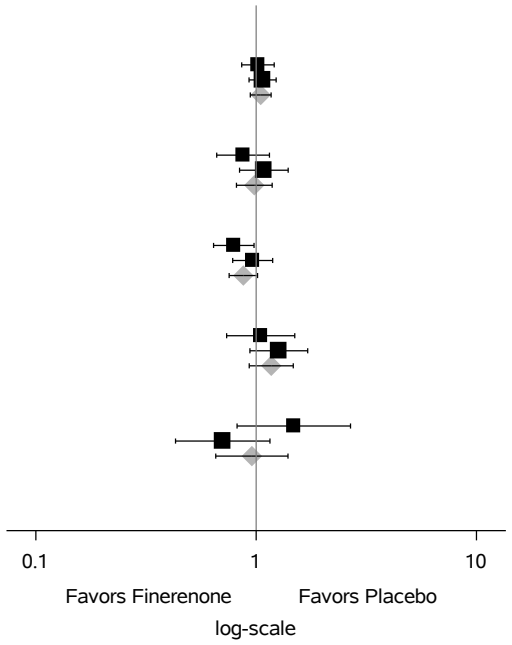
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	907 / 2833	947 / 2841	43.9	0.94 [0.84,1.05]	
FIGARO-DKD	1187 / 3686	1143 / 3666	56.1	1.05 [0.95,1.16]	
Total	2094 / 6519	2090 / 6507		1.00 [0.93,1.08]	Z=-0.00, p=0.9991
Heterogeneity:	Q=2.01 (df=1)	p=0.1568	I^2=50.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.1.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set

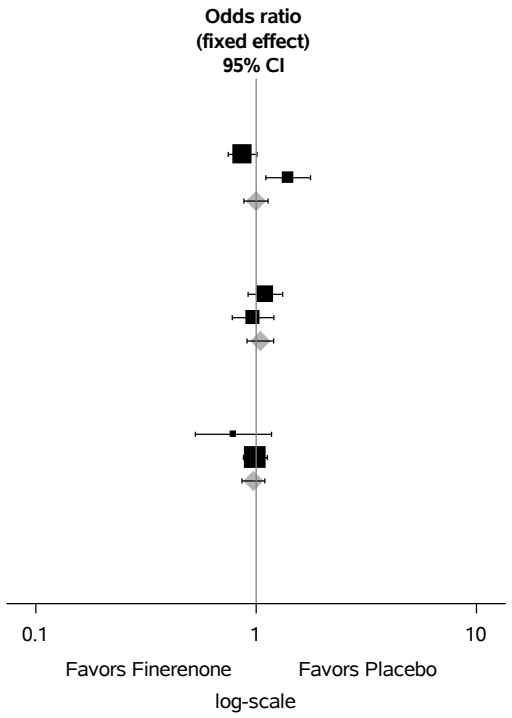
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	410 / 1182	403 / 1176	41.0	1.02 [0.86,1.21]	
FIGARO-DKD	579 / 1754	552 / 1750	59.0	1.07 [0.93,1.23]	
Total	989 / 2936	955 / 2926		1.05 [0.94,1.17]	Z=0.85, p=0.3952
Heterogeneity:	Q=0.19 (df=1)	p=0.6665	I^2=0.0%		
North America					
FIDELIO-DKD	139 / 467	156 / 477	46.0	0.87 [0.66,1.15]	
FIGARO-DKD	180 / 559	167 / 548	54.0	1.08 [0.84,1.40]	
Total	319 / 1026	323 / 1025		0.98 [0.81,1.18]	Z=-0.21, p=0.8369
Heterogeneity:	Q=1.29 (df=1)	p=0.2561	I^2=22.5%		
Asia					
FIDELIO-DKD	235 / 790	275 / 789	49.4	0.79 [0.64,0.98]	
FIGARO-DKD	254 / 810	262 / 815	50.6	0.96 [0.78,1.19]	
Total	489 / 1600	537 / 1604		0.87 [0.75,1.01]	Z=-1.77, p=0.0769
Heterogeneity:	Q=1.70 (df=1)	p=0.1928	I^2=41.0%		
Latin America					
FIDELIO-DKD	86 / 295	84 / 298	41.8	1.05 [0.73,1.50]	
FIGARO-DKD	129 / 424	107 / 417	58.2	1.27 [0.94,1.71]	
Total	215 / 719	191 / 715		1.17 [0.93,1.47]	Z=1.34, p=0.1797
Heterogeneity:	Q=0.63 (df=1)	p=0.4264	I^2=0.0%		
Others					
FIDELIO-DKD	37 / 99	29 / 101	40.9	1.48 [0.82,2.68]	
FIGARO-DKD	45 / 139	55 / 136	59.1	0.71 [0.43,1.15]	
Total	82 / 238	84 / 237		0.96 [0.66,1.39]	Z=-0.23, p=0.8149
Heterogeneity:	Q=3.56 (df=1)	p=0.0592	I^2=71.9%		
Subgroup Heterogeneity:	Q=5.75 (df=4)	p=0.2186	I^2=30.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

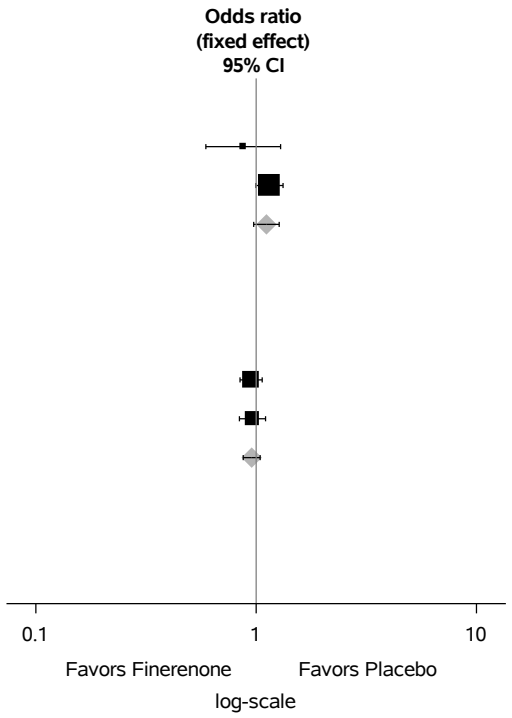
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	480 / 1559	525 / 1549	70.7	0.87 [0.75,1.01]	
FIGARO-DKD	239 / 639	189 / 631	29.3	1.40 [1.11,1.77]	
Total	719 / 2198	714 / 2180		1.00 [0.88,1.13]	Z=-0.03, p=0.9761
Heterogeneity:	Q=11.28 (df=1)	p=0.0008	I^2=91.1%		
45 - < 60					
FIDELIO-DKD	360 / 1063	340 / 1071	59.1	1.10 [0.92,1.32]	
FIGARO-DKD	241 / 720	250 / 731	40.9	0.97 [0.78,1.20]	
Total	601 / 1783	590 / 1802		1.04 [0.91,1.20]	Z=0.62, p=0.5385
Heterogeneity:	Q=0.80 (df=1)	p=0.3724	I^2=0.0%		
>= 60					
FIDELIO-DKD	67 / 211	82 / 221	9.0	0.79 [0.53,1.17]	
FIGARO-DKD	707 / 2327	704 / 2304	91.0	0.99 [0.88,1.12]	
Total	774 / 2538	786 / 2525		0.97 [0.86,1.09]	Z=-0.47, p=0.6357
Heterogeneity:	Q=1.16 (df=1)	p=0.2817	I^2=13.7%		
Subgroup Heterogeneity:	Q=0.60 (df=2)	p=0.7395	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

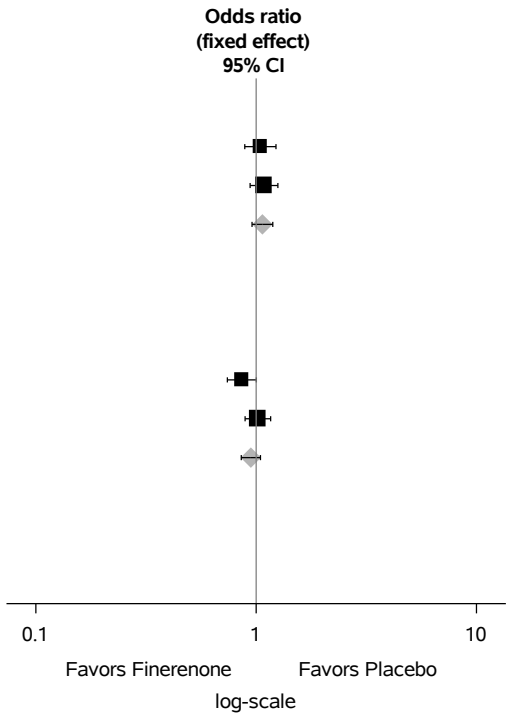
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	79 / 210	87 / 213	11.6	0.87 [0.59,1.29]	
FIGARO-DKD	607 / 1722	548 / 1705	88.4	1.15 [1.00,1.32]	
Total	686 / 1932	635 / 1918		1.11 [0.97,1.27]	Z=1.58, p=0.1147
Heterogeneity:	Q=1.68 (df=1)	p=0.1953	I^2=40.4%		
Very High					
FIDELIO-DKD	828 / 2623	860 / 2628	58.2	0.95 [0.84,1.06]	
FIGARO-DKD	580 / 1964	595 / 1961	41.8	0.96 [0.84,1.10]	
Total	1408 / 4587	1455 / 4589		0.95 [0.87,1.04]	Z=-1.04, p=0.2968
Heterogeneity:	Q=0.03 (df=1)	p=0.8744	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.58 (df=1)	p=0.0586	I^2=72.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set

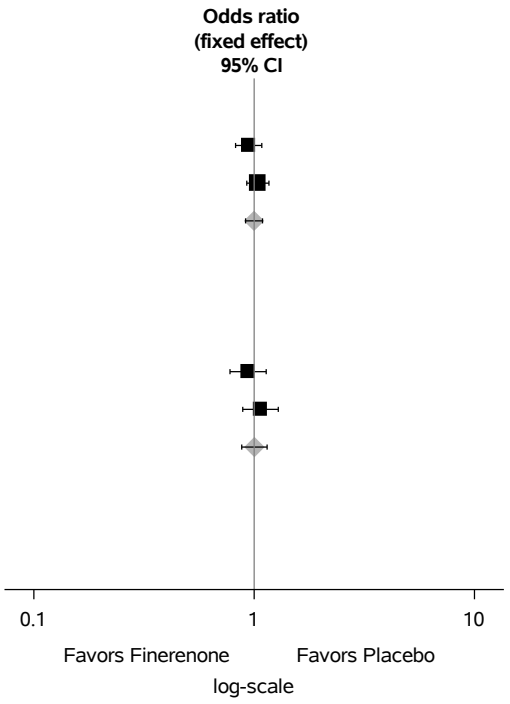
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	439 / 1303	426 / 1302	44.2	1.04 [0.89,1.23]	
FIGARO-DKD	559 / 1676	522 / 1654	55.8	1.09 [0.94,1.25]	
Total	998 / 2979	948 / 2956		1.07 [0.96,1.19]	Z=1.18, p=0.2397
Heterogeneity:	Q=0.12 (df=1)	p=0.7332	I^2=0.0%		
Absent					
FIDELIO-DKD	468 / 1530	521 / 1539	43.7	0.86 [0.74,1.00]	
FIGARO-DKD	628 / 2010	621 / 2012	56.3	1.02 [0.89,1.16]	
Total	1096 / 3540	1142 / 3551		0.95 [0.86,1.05]	Z=-1.09, p=0.2777
Heterogeneity:	Q=2.63 (df=1)	p=0.1046	I^2=62.0%		
Subgroup Heterogeneity:	Q=2.56 (df=1)	p=0.1095	I^2=61.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

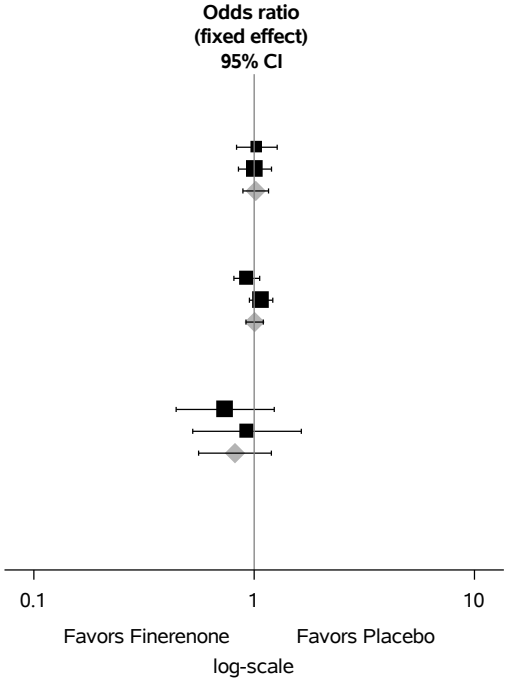
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	596 / 1881	613 / 1861	41.7	0.94 [0.82,1.08]	
FIGARO-DKD	859 / 2643	827 / 2612	58.3	1.04 [0.93,1.17]	
Total	1455 / 4524	1440 / 4473		1.00 [0.91,1.09]	Z=-0.03, p=0.9747
Heterogeneity:	Q=1.10 (df=1)	p=0.2951	I^2=8.8%		
> 4.5					
FIDELIO-DKD	311 / 951	334 / 979	49.0	0.94 [0.78,1.13]	
FIGARO-DKD	328 / 1043	316 / 1052	51.0	1.07 [0.89,1.29]	
Total	639 / 1994	650 / 2031		1.00 [0.88,1.14]	Z=0.04, p=0.9697
Heterogeneity:	Q=0.92 (df=1)	p=0.3373	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9607	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.1.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

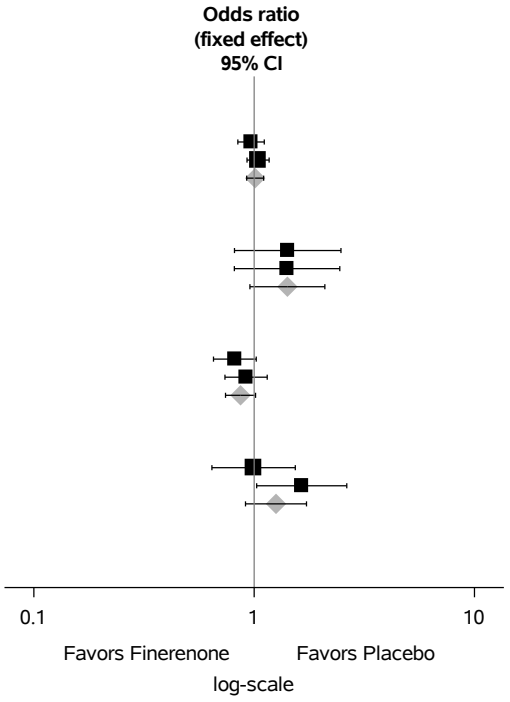
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	255 / 788	247 / 778	39.9	1.03 [0.83,1.27]	
FIGARO-DKD	375 / 1187	376 / 1197	60.1	1.01 [0.85,1.20]	
Total	630 / 1975	623 / 1975		1.02 [0.89,1.16]	Z=0.24, p=0.8123
Heterogeneity:	Q=0.02 (df=1)	p=0.8875	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	614 / 1900	654 / 1922	45.2	0.93 [0.81,1.06]	
FIGARO-DKD	779 / 2392	730 / 2355	54.8	1.08 [0.95,1.21]	
Total	1393 / 4292	1384 / 4277		1.00 [0.92,1.10]	Z=0.10, p=0.9166
Heterogeneity:	Q=2.60 (df=1)	p=0.1070	I^2=61.5%		
>= 160					
FIDELIO-DKD	38 / 142	46 / 139	55.1	0.74 [0.44,1.23]	
FIGARO-DKD	33 / 107	37 / 114	44.9	0.93 [0.53,1.64]	
Total	71 / 249	83 / 253		0.82 [0.56,1.20]	Z=-1.03, p=0.3014
Heterogeneity:	Q=0.34 (df=1)	p=0.5587	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.14 (df=2)	p=0.5669	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.1.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set

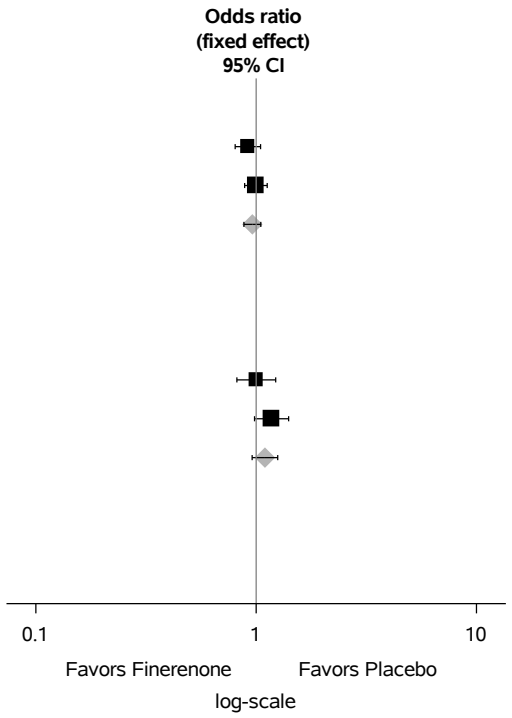
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	596 / 1777	622 / 1815	41.1	0.97 [0.84,1.11]	
FIGARO-DKD	872 / 2672	827 / 2605	58.9	1.04 [0.93,1.17]	
Total	1468 / 4449	1449 / 4420		1.01 [0.92,1.10]	Z=0.23, p=0.8156
Heterogeneity:	Q=0.64 (df=1)	p=0.4252	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 140	28 / 124	49.5	1.42 [0.81,2.48]	
FIGARO-DKD	35 / 113	35 / 145	50.5	1.41 [0.81,2.45]	
Total	76 / 253	63 / 269		1.42 [0.96,2.09]	Z=1.74, p=0.0823
Heterogeneity:	Q=0.00 (df=1)	p=0.9864	I^2=0.0%		
Asian					
FIDELIO-DKD	208 / 717	241 / 723	49.4	0.82 [0.65,1.02]	
FIGARO-DKD	221 / 715	242 / 739	50.6	0.92 [0.74,1.15]	
Total	429 / 1432	483 / 1462		0.87 [0.74,1.01]	Z=-1.78, p=0.0751
Heterogeneity:	Q=0.53 (df=1)	p=0.4652	I^2=0.0%		
Others					
FIDELIO-DKD	62 / 199	56 / 179	53.9	0.99 [0.64,1.54]	
FIGARO-DKD	59 / 186	39 / 177	46.1	1.64 [1.03,2.63]	
Total	121 / 385	95 / 356		1.26 [0.91,1.73]	Z=1.40, p=0.1609
Heterogeneity:	Q=2.36 (df=1)	p=0.1243	I^2=57.7%		
Subgroup Heterogeneity:	Q=8.21 (df=3)	p=0.0419	I^2=63.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.1.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set

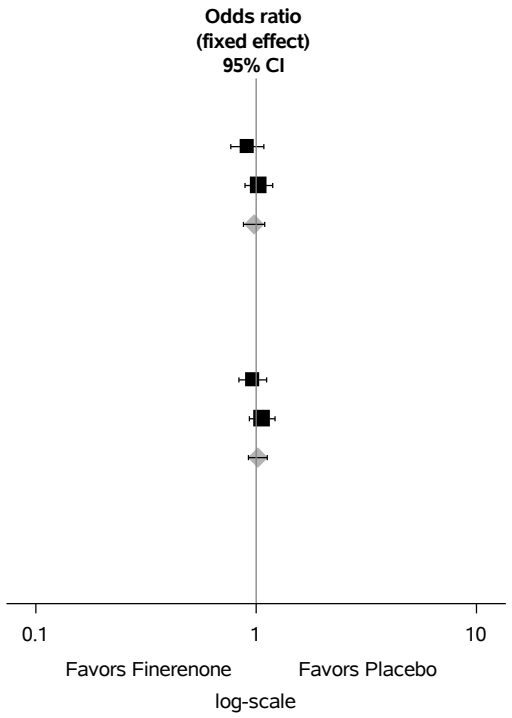
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	616 / 1953	679 / 2030	44.1	0.92 [0.80,1.05]	
FIGARO-DKD	800 / 2528	817 / 2577	55.9	1.00 [0.89,1.12]	
Total	1416 / 4481	1496 / 4607		0.96 [0.88,1.05]	Z=-0.89, p=0.3752
Heterogeneity:	Q=0.87 (df=1)	p=0.3522	I^2=0.0%		
Female					
FIDELIO-DKD	291 / 880	268 / 811	43.5	1.00 [0.82,1.23]	
FIGARO-DKD	387 / 1158	326 / 1089	56.5	1.17 [0.98,1.40]	
Total	678 / 2038	594 / 1900		1.10 [0.96,1.25]	Z=1.34, p=0.1803
Heterogeneity:	Q=1.35 (df=1)	p=0.2451	I^2=26.0%		
Subgroup Heterogeneity:	Q=2.58 (df=1)	p=0.1081	I^2=61.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.1.9: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set

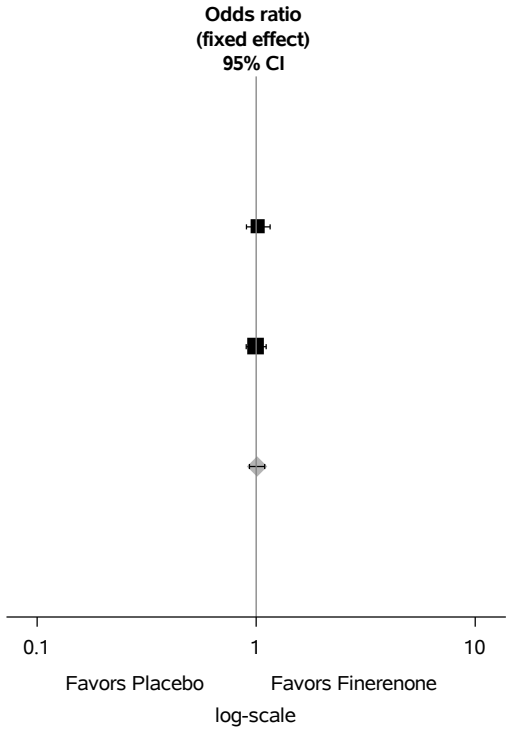
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	371 / 1205	385 / 1174	41.3	0.91 [0.77,1.08]	
FIGARO-DKD	525 / 1753	516 / 1757	58.7	1.03 [0.89,1.19]	
Total	896 / 2958	901 / 2931		0.98 [0.88,1.09]	Z=-0.39, p=0.6989
Heterogeneity:	Q=1.10 (df=1)	p=0.2953	I^2=8.7%		
>= 65					
FIDELIO-DKD	536 / 1628	562 / 1667	46.1	0.97 [0.83,1.12]	
FIGARO-DKD	662 / 1933	627 / 1909	53.9	1.06 [0.93,1.22]	
Total	1198 / 3561	1189 / 3576		1.02 [0.92,1.12]	Z=0.35, p=0.7264
Heterogeneity:	Q=0.96 (df=1)	p=0.3281	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6020	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set

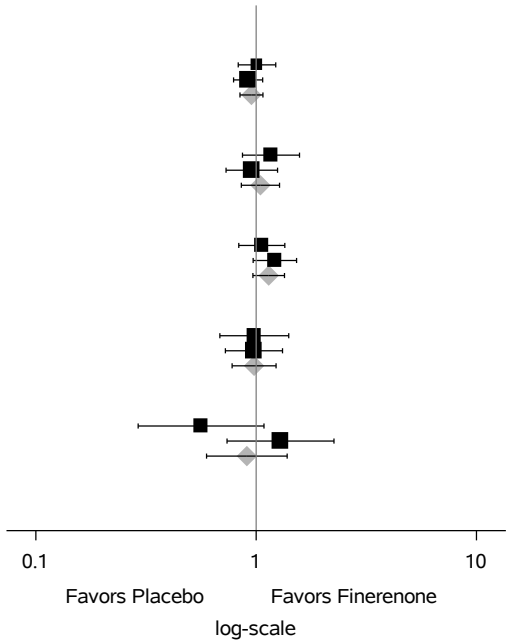
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	650 / 2833	641 / 2841	41.6	1.02 [0.90,1.16]	
FIGARO-DKD	944 / 3686	938 / 3666	58.4	1.00 [0.90,1.11]	
Total	1594 / 6519	1579 / 6507		1.01 [0.93,1.09]	Z=0.23, p=0.8190
Heterogeneity:	Q=0.07 (df=1)	p=0.7909	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.2.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set

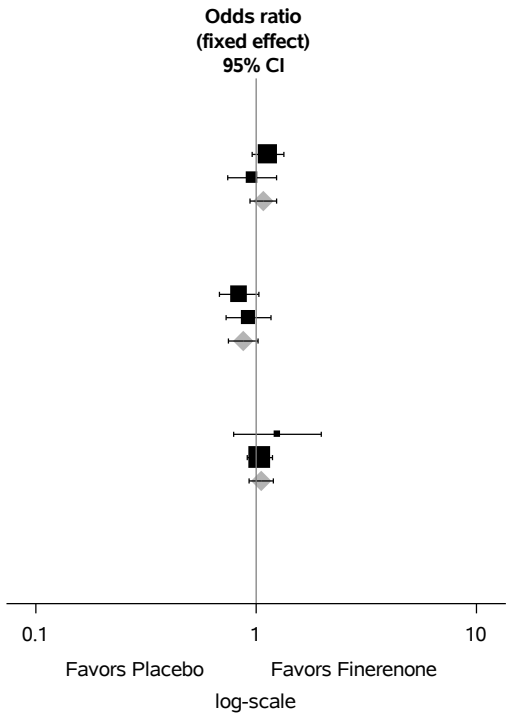
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	257 / 1182	254 / 1176	37.6	1.01 [0.83,1.23]	
FIGARO-DKD	433 / 1754	460 / 1750	62.4	0.92 [0.79,1.07]	
Total	690 / 2936	714 / 2926		0.95 [0.84,1.07]	Z=-0.81, p=0.4201
Heterogeneity:	Q=0.54 (df=1)	p=0.4636	I^2=0.0%		
North America					
FIDELIO-DKD	120 / 467	109 / 477	44.9	1.17 [0.87,1.57]	
FIGARO-DKD	142 / 559	144 / 548	55.1	0.96 [0.73,1.25]	
Total	262 / 1026	253 / 1025		1.05 [0.86,1.28]	Z=0.44, p=0.6620
Heterogeneity:	Q=0.96 (df=1)	p=0.3276	I^2=0.0%		
Asia					
FIDELIO-DKD	173 / 790	165 / 789	47.1	1.06 [0.83,1.35]	
FIGARO-DKD	212 / 810	184 / 815	52.9	1.22 [0.97,1.53]	
Total	385 / 1600	349 / 1604		1.14 [0.97,1.34]	Z=1.56, p=0.1197
Heterogeneity:	Q=0.66 (df=1)	p=0.4177	I^2=0.0%		
Latin America					
FIDELIO-DKD	81 / 295	83 / 298	40.8	0.98 [0.68,1.41]	
FIGARO-DKD	121 / 424	121 / 417	59.2	0.98 [0.72,1.32]	
Total	202 / 719	204 / 715		0.98 [0.78,1.23]	Z=-0.19, p=0.8519
Heterogeneity:	Q=0.00 (df=1)	p=0.9878	I^2=0.0%		
Others					
FIDELIO-DKD	19 / 99	30 / 101	41.9	0.56 [0.29,1.08]	
FIGARO-DKD	36 / 139	29 / 136	58.1	1.29 [0.74,2.26]	
Total	55 / 238	59 / 237		0.91 [0.60,1.38]	Z=-0.45, p=0.6504
Heterogeneity:	Q=3.56 (df=1)	p=0.0593	I^2=71.9%		
Subgroup Heterogeneity:	Q=3.44 (df=4)	p=0.4864	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

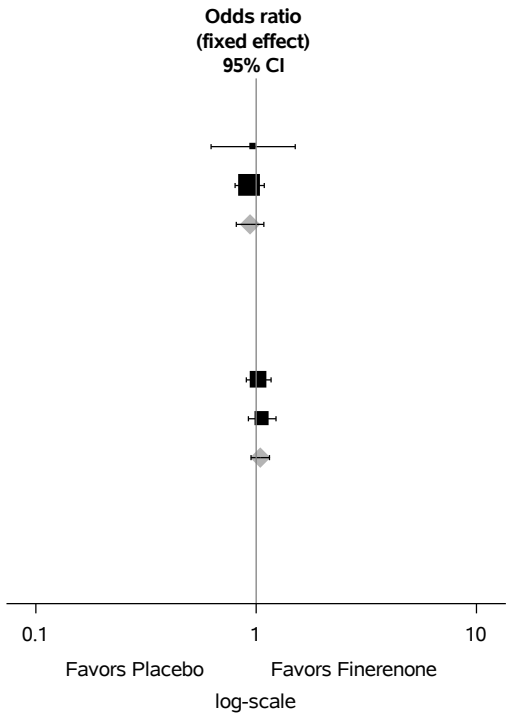
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	385 / 1559	348 / 1549	70.3	1.13 [0.96,1.34]	
FIGARO-DKD	155 / 639	158 / 631	29.7	0.96 [0.74,1.24]	
Total	540 / 2198	506 / 2180		1.08 [0.94,1.24]	Z=1.05, p=0.2930
Heterogeneity:	Q=1.14 (df=1)	p=0.2853	I^2=12.4%		
45 - < 60					
FIDELIO-DKD	215 / 1063	249 / 1071	56.4	0.84 [0.68,1.03]	
FIGARO-DKD	182 / 720	196 / 731	43.6	0.92 [0.73,1.17]	
Total	397 / 1783	445 / 1802		0.87 [0.75,1.02]	Z=-1.71, p=0.0870
Heterogeneity:	Q=0.38 (df=1)	p=0.5375	I^2=0.0%		
>= 60					
FIDELIO-DKD	50 / 211	44 / 221	7.7	1.25 [0.79,1.97]	
FIGARO-DKD	607 / 2327	584 / 2304	92.3	1.04 [0.91,1.19]	
Total	657 / 2538	628 / 2525		1.05 [0.93,1.20]	Z=0.82, p=0.4145
Heterogeneity:	Q=0.57 (df=1)	p=0.4493	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.64 (df=2)	p=0.0981	I^2=56.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

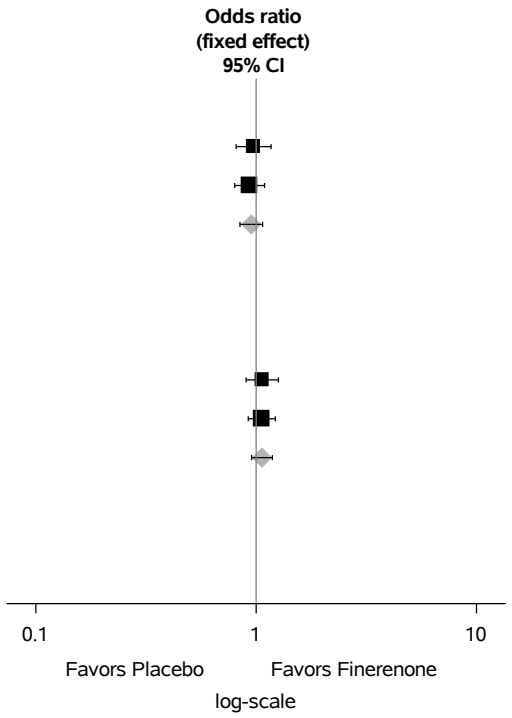
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	52 / 210	54 / 213	10.7	0.97 [0.62,1.50]	
FIGARO-DKD	439 / 1722	457 / 1705	89.3	0.93 [0.80,1.09]	
Total	491 / 1932	511 / 1918		0.94 [0.81,1.08]	Z=-0.87, p=0.3842
Heterogeneity:	Q=0.02 (df=1)	p=0.8782	I^2=0.0%		
Very High					
FIDELIO-DKD	598 / 2623	587 / 2628	55.4	1.03 [0.90,1.17]	
FIGARO-DKD	505 / 1964	481 / 1961	44.6	1.07 [0.92,1.23]	
Total	1103 / 4587	1068 / 4589		1.04 [0.95,1.15]	Z=0.87, p=0.3847
Heterogeneity:	Q=0.14 (df=1)	p=0.7117	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.46 (df=1)	p=0.2276	I^2=31.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set

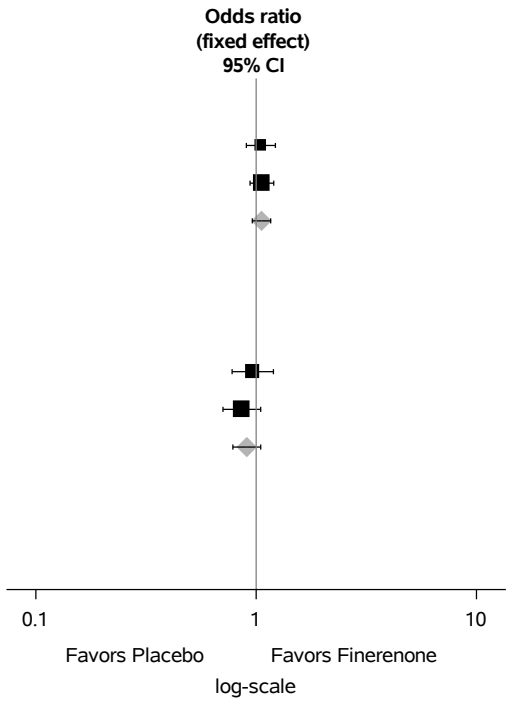
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	296 / 1303	302 / 1302	42.2	0.97 [0.81,1.17]	
FIGARO-DKD	416 / 1676	432 / 1654	57.8	0.93 [0.80,1.09]	
Total	712 / 2979	734 / 2956		0.95 [0.84,1.07]	Z=-0.84, p=0.3998
Heterogeneity:	Q=0.11 (df=1)	p=0.7359	I^2=0.0%		
Absent					
FIDELIO-DKD	354 / 1530	339 / 1539	41.1	1.07 [0.90,1.26]	
FIGARO-DKD	528 / 2010	506 / 2012	58.9	1.06 [0.92,1.22]	
Total	882 / 3540	845 / 3551		1.06 [0.95,1.18]	Z=1.09, p=0.2736
Heterogeneity:	Q=0.00 (df=1)	p=0.9654	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.85 (df=1)	p=0.1738	I^2=45.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

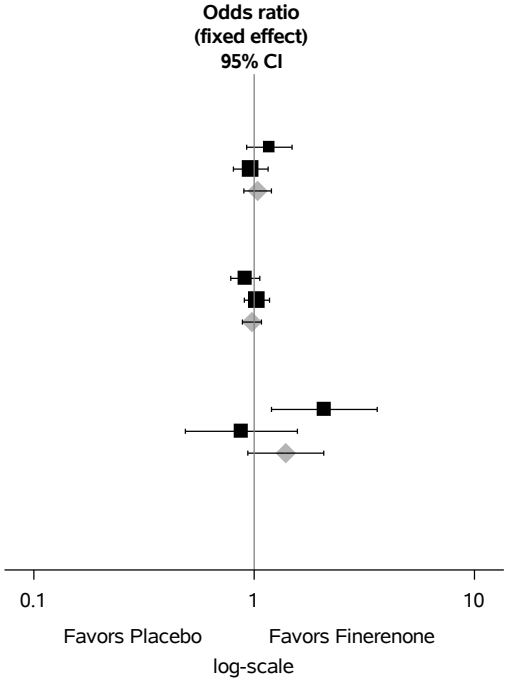
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	445 / 1881	424 / 1861	39.9	1.05 [0.90,1.22]	
FIGARO-DKD	694 / 2643	656 / 2612	60.1	1.06 [0.94,1.20]	
Total	1139 / 4524	1080 / 4473		1.06 [0.96,1.16]	Z=1.14, p=0.2564
Heterogeneity:	Q=0.01 (df=1)	p=0.9135	I^2=0.0%		
> 4.5					
FIDELIO-DKD	205 / 951	217 / 979	45.4	0.96 [0.78,1.20]	
FIGARO-DKD	250 / 1043	282 / 1052	54.6	0.86 [0.71,1.05]	
Total	455 / 1994	499 / 2031		0.91 [0.78,1.05]	Z=-1.32, p=0.1868
Heterogeneity:	Q=0.59 (df=1)	p=0.4438	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.98 (df=1)	p=0.0842	I^2=66.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.2.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

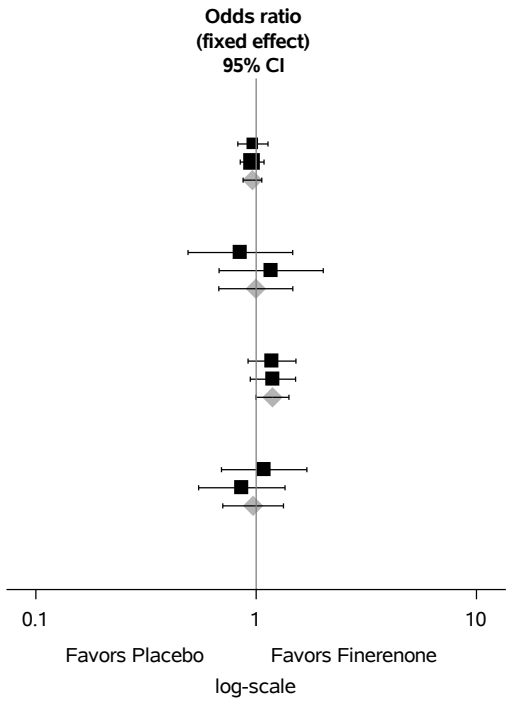
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	189 / 788	165 / 778	36.9	1.17 [0.92,1.49]	
FIGARO-DKD	313 / 1187	324 / 1197	63.1	0.96 [0.80,1.16]	
Total	502 / 1975	489 / 1975		1.04 [0.90,1.20]	Z=0.49, p=0.6222
Heterogeneity:	Q=1.63 (df=1)	p=0.2016	I^2=38.7%		
130 - < 160					
FIDELIO-DKD	414 / 1900	450 / 1922	42.9	0.91 [0.78,1.06]	
FIGARO-DKD	602 / 2392	580 / 2355	57.1	1.03 [0.90,1.17]	
Total	1016 / 4292	1030 / 4277		0.98 [0.88,1.08]	Z=-0.46, p=0.6438
Heterogeneity:	Q=1.41 (df=1)	p=0.2351	I^2=29.1%		
>= 160					
FIDELIO-DKD	46 / 142	26 / 139	52.9	2.08 [1.20,3.62]	
FIGARO-DKD	29 / 107	34 / 114	47.1	0.87 [0.49,1.57]	
Total	75 / 249	60 / 253		1.39 [0.94,2.07]	Z=1.63, p=0.1028
Heterogeneity:	Q=4.46 (df=1)	p=0.0347	I^2=77.6%		
Subgroup Heterogeneity:	Q=3.07 (df=2)	p=0.2159	I^2=34.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.2.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set

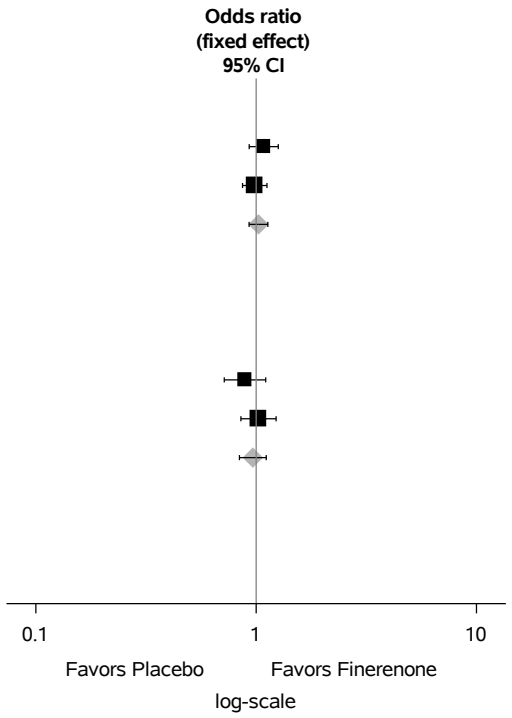
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	389 / 1777	408 / 1815	38.3	0.97 [0.83,1.13]	
FIGARO-DKD	665 / 2672	669 / 2605	61.7	0.96 [0.85,1.09]	
Total	1054 / 4449	1077 / 4420		0.96 [0.87,1.06]	Z=-0.78, p=0.4333
Heterogeneity:	Q=0.01 (df=1)	p=0.9383	I^2=0.0%		
Black					
FIDELIO-DKD	35 / 140	35 / 124	49.8	0.85 [0.49,1.46]	
FIGARO-DKD	34 / 113	39 / 145	50.2	1.17 [0.68,2.02]	
Total	69 / 253	74 / 269		1.00 [0.68,1.47]	Z=-0.02, p=0.9852
Heterogeneity:	Q=0.67 (df=1)	p=0.4133	I^2=0.0%		
Asian					
FIDELIO-DKD	167 / 717	148 / 723	47.2	1.18 [0.92,1.52]	
FIGARO-DKD	193 / 715	175 / 739	52.8	1.19 [0.94,1.51]	
Total	360 / 1432	323 / 1462		1.19 [1.00,1.41]	Z=1.94, p=0.0519
Heterogeneity:	Q=0.00 (df=1)	p=0.9544	I^2=0.0%		
Others					
FIDELIO-DKD	59 / 199	50 / 179	50.6	1.09 [0.70,1.70]	
FIGARO-DKD	52 / 186	55 / 177	49.4	0.86 [0.55,1.35]	
Total	111 / 385	105 / 356		0.97 [0.71,1.33]	Z=-0.20, p=0.8448
Heterogeneity:	Q=0.52 (df=1)	p=0.4708	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.39 (df=3)	p=0.2226	I^2=31.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.2.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set

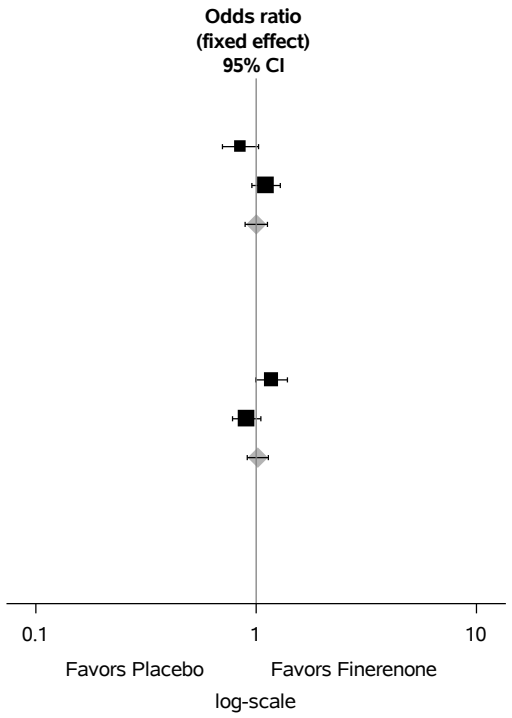
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	428 / 1953	418 / 2030	41.4	1.08 [0.93,1.26]	
FIGARO-DKD	615 / 2528	634 / 2577	58.6	0.99 [0.87,1.12]	
Total	1043 / 4481	1052 / 4607		1.02 [0.93,1.13]	Z=0.48, p=0.6297
Heterogeneity:	Q=0.86 (df=1)	p=0.3531	I^2=0.0%		
Female					
FIDELIO-DKD	222 / 880	223 / 811	41.9	0.89 [0.72,1.10]	
FIGARO-DKD	329 / 1158	304 / 1089	58.1	1.02 [0.85,1.23]	
Total	551 / 2038	527 / 1900		0.97 [0.84,1.11]	Z=-0.49, p=0.6268
Heterogeneity:	Q=0.95 (df=1)	p=0.3292	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4999	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.2.9: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set

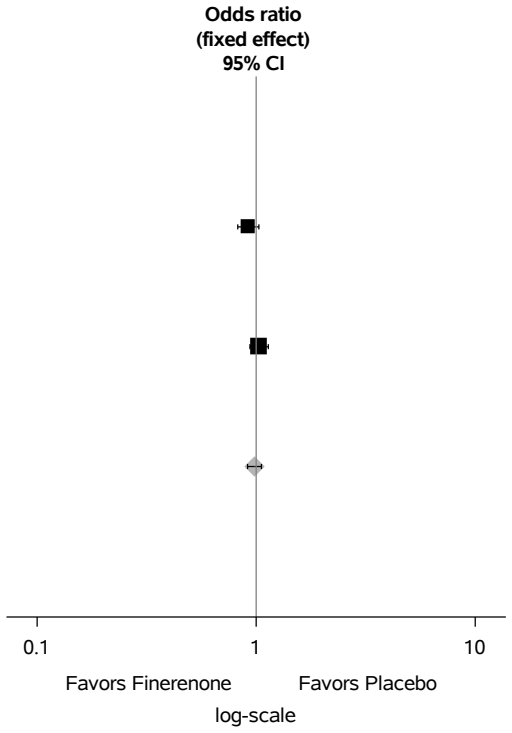
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	270 / 1205	298 / 1174	38.3	0.85 [0.70,1.03]	
FIGARO-DKD	497 / 1753	462 / 1757	61.7	1.11 [0.96,1.29]	
Total	767 / 2958	760 / 2931		1.00 [0.89,1.13]	Z=0.02, p=0.9836
Heterogeneity:	Q=4.76 (df=1)	p=0.0291	I^2=79.0%		
>= 65					
FIDELIO-DKD	380 / 1628	343 / 1667	44.6	1.18 [1.00,1.39]	
FIGARO-DKD	447 / 1933	476 / 1909	55.4	0.91 [0.78,1.05]	
Total	827 / 3561	819 / 3576		1.02 [0.91,1.14]	Z=0.30, p=0.7616
Heterogeneity:	Q=5.31 (df=1)	p=0.0213	I^2=81.2%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8467	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set

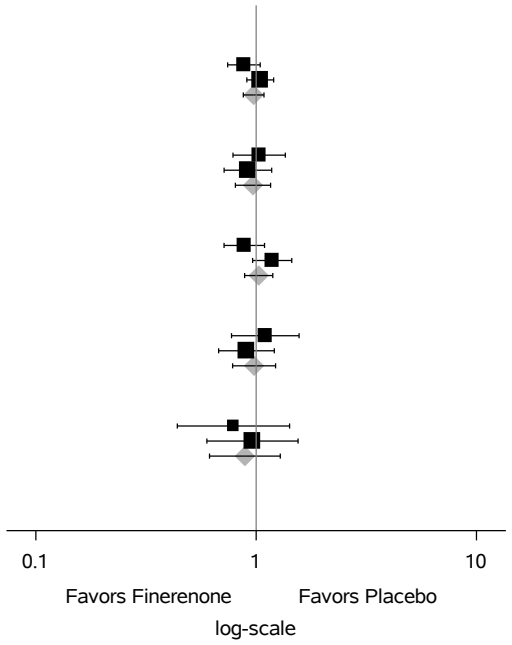
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	904 / 2833	958 / 2841	43.2	0.92 [0.82,1.03]	
FIGARO-DKD	1268 / 3686	1235 / 3666	56.8	1.03 [0.94,1.14]	
Total	2172 / 6519	2193 / 6507		0.98 [0.91,1.06]	Z=-0.47, p=0.6366
Heterogeneity:	Q=2.28 (df=1)	p=0.1312	I^2=56.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.3.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set

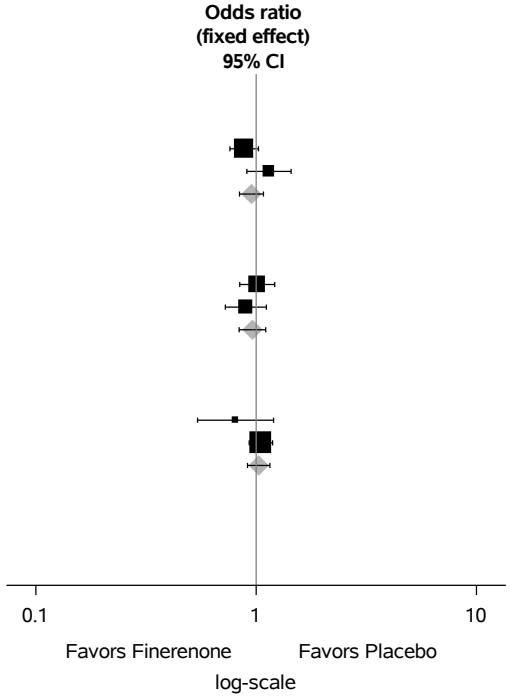
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	390 / 1182	422 / 1176	40.5	0.88 [0.74,1.04]	
FIGARO-DKD	599 / 1754	581 / 1750	59.5	1.04 [0.91,1.20]	
Total	989 / 2936	1003 / 2926		0.97 [0.87,1.09]	Z=-0.48, p=0.6311
Heterogeneity:	Q=2.30 (df=1)	p=0.1291	I^2=56.6%		
North America					
FIDELIO-DKD	151 / 467	151 / 477	45.2	1.03 [0.78,1.36]	
FIGARO-DKD	185 / 559	192 / 548	54.8	0.92 [0.72,1.18]	
Total	336 / 1026	343 / 1025		0.97 [0.80,1.16]	Z=-0.35, p=0.7232
Heterogeneity:	Q=0.39 (df=1)	p=0.5329	I^2=0.0%		
Asia					
FIDELIO-DKD	242 / 790	263 / 789	48.3	0.88 [0.71,1.09]	
FIGARO-DKD	295 / 810	266 / 815	51.7	1.18 [0.96,1.45]	
Total	537 / 1600	529 / 1604		1.03 [0.89,1.19]	Z=0.35, p=0.7242
Heterogeneity:	Q=3.77 (df=1)	p=0.0523	I^2=73.5%		
Latin America					
FIDELIO-DKD	90 / 295	85 / 298	40.5	1.10 [0.77,1.57]	
FIGARO-DKD	129 / 424	136 / 417	59.5	0.90 [0.68,1.21]	
Total	219 / 719	221 / 715		0.98 [0.78,1.22]	Z=-0.19, p=0.8492
Heterogeneity:	Q=0.71 (df=1)	p=0.3990	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	37 / 101	39.8	0.79 [0.44,1.42]	
FIGARO-DKD	60 / 139	60 / 136	60.2	0.96 [0.60,1.55]	
Total	91 / 238	97 / 237		0.89 [0.61,1.29]	Z=-0.62, p=0.5320
Heterogeneity:	Q=0.27 (df=1)	p=0.6062	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.68 (df=4)	p=0.9534	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

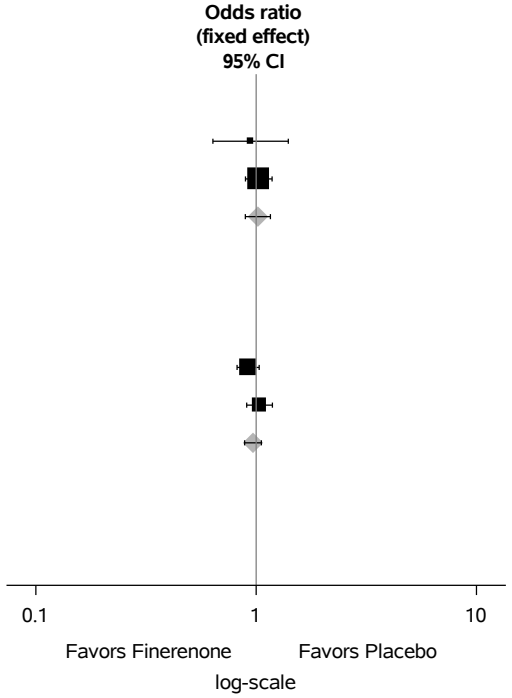
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	500 / 1559	540 / 1549	70.7	0.88 [0.76,1.02]	
FIGARO-DKD	231 / 639	209 / 631	29.3	1.14 [0.91,1.44]	
Total	731 / 2198	749 / 2180		0.95 [0.84,1.08]	Z=-0.77, p=0.4410
Heterogeneity:	Q=3.41 (df=1)	p=0.0650	I^2=70.6%		
45 - < 60					
FIDELIO-DKD	336 / 1063	336 / 1071	57.9	1.01 [0.84,1.21]	
FIGARO-DKD	251 / 720	273 / 731	42.1	0.90 [0.72,1.11]	
Total	587 / 1783	609 / 1802		0.96 [0.84,1.11]	Z=-0.55, p=0.5823
Heterogeneity:	Q=0.68 (df=1)	p=0.4088	I^2=0.0%		
>= 60					
FIDELIO-DKD	68 / 211	82 / 221	8.7	0.81 [0.54,1.20]	
FIGARO-DKD	786 / 2327	753 / 2304	91.3	1.05 [0.93,1.19]	
Total	854 / 2538	835 / 2525		1.03 [0.91,1.15]	Z=0.44, p=0.6585
Heterogeneity:	Q=1.56 (df=1)	p=0.2116	I^2=35.9%		
Subgroup Heterogeneity:	Q=0.88 (df=2)	p=0.6442	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set

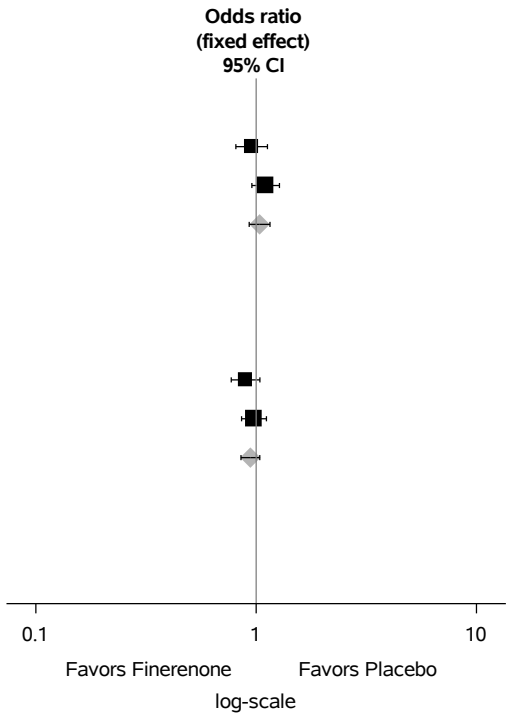
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 210	81 / 213	11.1	0.94 [0.64,1.40]	
FIGARO-DKD	634 / 1722	617 / 1705	88.9	1.03 [0.89,1.18]	
Total	711 / 1932	698 / 1918		1.02 [0.89,1.16]	Z=0.26, p=0.7912
Heterogeneity:	Q=0.16 (df=1)	p=0.6889	I^2=0.0%		
Very High					
FIDELIO-DKD	827 / 2623	877 / 2628	57.4	0.92 [0.82,1.03]	
FIGARO-DKD	634 / 1964	618 / 1961	42.6	1.04 [0.91,1.18]	
Total	1461 / 4587	1495 / 4589		0.97 [0.89,1.06]	Z=-0.74, p=0.4565
Heterogeneity:	Q=1.74 (df=1)	p=0.1866	I^2=42.7%		
Subgroup Heterogeneity:	Q=0.40 (df=1)	p=0.5262	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set

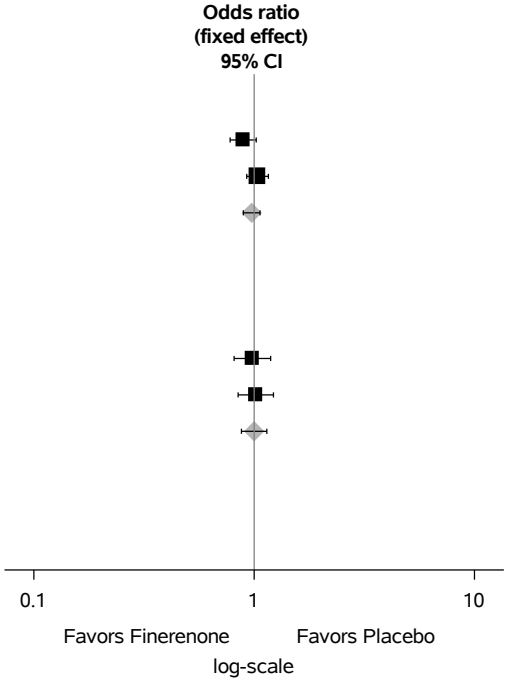
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	407 / 1303	420 / 1302	43.3	0.95 [0.81,1.13]	
FIGARO-DKD	578 / 1676	534 / 1654	56.7	1.10 [0.96,1.28]	
Total	985 / 2979	954 / 2956		1.04 [0.93,1.16]	Z=0.65, p=0.5183
Heterogeneity:	Q=1.71 (df=1)	p=0.1909	I^2=41.6%		
Absent					
FIDELIO-DKD	497 / 1530	538 / 1539	43.0	0.90 [0.77,1.04]	
FIGARO-DKD	690 / 2010	701 / 2012	57.0	0.98 [0.86,1.11]	
Total	1187 / 3540	1239 / 3551		0.94 [0.85,1.04]	Z=-1.21, p=0.2269
Heterogeneity:	Q=0.76 (df=1)	p=0.3839	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.66 (df=1)	p=0.1972	I^2=39.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

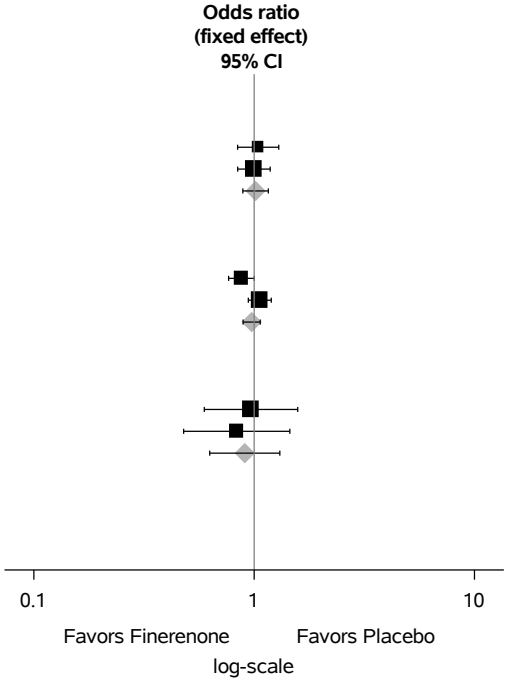
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	599 / 1881	640 / 1861	40.9	0.89 [0.78,1.02]	
FIGARO-DKD	939 / 2643	907 / 2612	59.1	1.04 [0.92,1.16]	
Total	1538 / 4524	1547 / 4473		0.97 [0.89,1.06]	Z=-0.59, p=0.5559
Heterogeneity:	Q=2.76 (df=1)	p=0.0966	I^2=63.8%		
> 4.5					
FIDELIO-DKD	305 / 951	318 / 979	48.3	0.98 [0.81,1.19]	
FIGARO-DKD	329 / 1043	328 / 1052	51.7	1.02 [0.85,1.22]	
Total	634 / 1994	646 / 2031		1.00 [0.88,1.14]	Z=-0.00, p=0.9962
Heterogeneity:	Q=0.07 (df=1)	p=0.7919	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7496	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

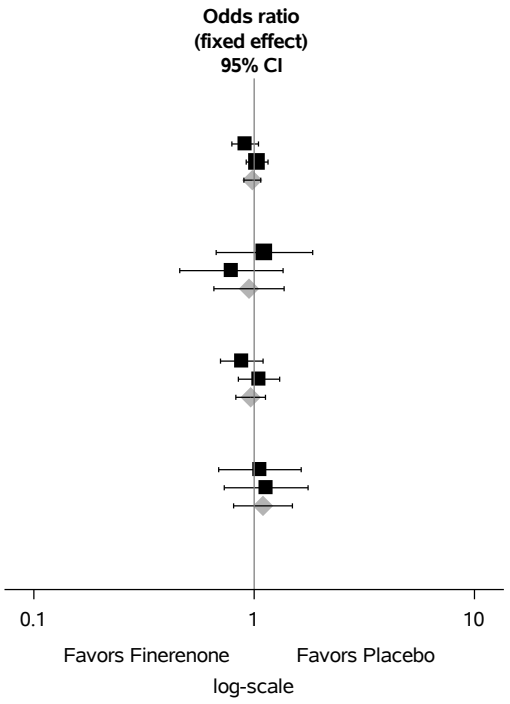
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	244 / 788	234 / 778	38.4	1.04 [0.84,1.29]	
FIGARO-DKD	399 / 1187	403 / 1197	61.6	1.00 [0.84,1.18]	
Total	643 / 1975	637 / 1975		1.01 [0.89,1.16]	Z=0.21, p=0.8300
Heterogeneity:	Q=0.10 (df=1)	p=0.7518	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	610 / 1900	674 / 1922	44.4	0.88 [0.77,1.00]	
FIGARO-DKD	834 / 2392	790 / 2355	55.6	1.06 [0.94,1.20]	
Total	1444 / 4292	1464 / 4277		0.97 [0.89,1.07]	Z=-0.58, p=0.5643
Heterogeneity:	Q=4.34 (df=1)	p=0.0371	I^2=77.0%		
>= 160					
FIDELIO-DKD	50 / 142	50 / 139	56.3	0.97 [0.59,1.58]	
FIGARO-DKD	35 / 107	42 / 114	43.7	0.83 [0.48,1.45]	
Total	85 / 249	92 / 253		0.91 [0.63,1.31]	Z=-0.53, p=0.5990
Heterogeneity:	Q=0.16 (df=1)	p=0.6925	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.45 (df=2)	p=0.7999	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set

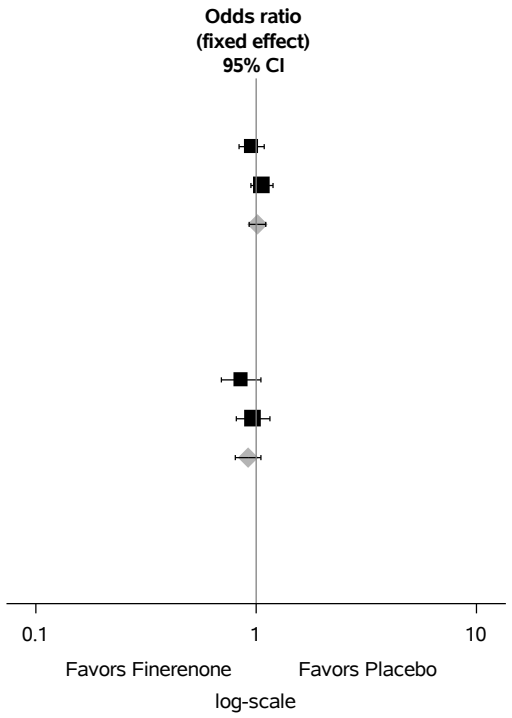
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	570 / 1777	620 / 1815	40.1	0.91 [0.79,1.05]	
FIGARO-DKD	920 / 2672	879 / 2605	59.9	1.03 [0.92,1.16]	
Total	1490 / 4449	1499 / 4420		0.98 [0.90,1.07]	Z=-0.43, p=0.6654
Heterogeneity:	Q=1.85 (df=1)	p=0.1738	I^2=45.9%		
Black					
FIDELIO-DKD	52 / 140	43 / 124	53.4	1.11 [0.67,1.84]	
FIGARO-DKD	31 / 113	47 / 145	46.6	0.79 [0.46,1.35]	
Total	83 / 253	90 / 269		0.95 [0.66,1.37]	Z=-0.29, p=0.7729
Heterogeneity:	Q=0.84 (df=1)	p=0.3600	I^2=0.0%		
Asian					
FIDELIO-DKD	216 / 717	238 / 723	48.5	0.88 [0.70,1.10]	
FIGARO-DKD	253 / 715	253 / 739	51.5	1.05 [0.85,1.31]	
Total	469 / 1432	491 / 1462		0.96 [0.83,1.13]	Z=-0.46, p=0.6423
Heterogeneity:	Q=1.30 (df=1)	p=0.2549	I^2=22.9%		
Others					
FIDELIO-DKD	66 / 199	57 / 179	50.8	1.06 [0.69,1.63]	
FIGARO-DKD	64 / 186	56 / 177	49.2	1.13 [0.73,1.76]	
Total	130 / 385	113 / 356		1.10 [0.81,1.49]	Z=0.59, p=0.5561
Heterogeneity:	Q=0.04 (df=1)	p=0.8357	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=3)	p=0.8990	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set

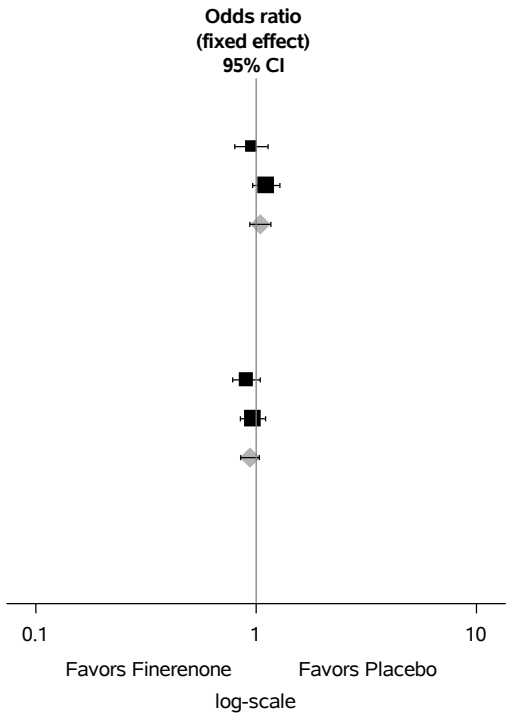
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	647 / 1953	694 / 2030	43.6	0.95 [0.84,1.09]	
FIGARO-DKD	887 / 2528	869 / 2577	56.4	1.06 [0.95,1.19]	
Total	1534 / 4481	1563 / 4607		1.01 [0.93,1.11]	Z=0.30, p=0.7604
Heterogeneity:	Q=1.46 (df=1)	p=0.2268	I^2=31.6%		
Female					
FIDELIO-DKD	257 / 880	264 / 811	41.9	0.85 [0.70,1.05]	
FIGARO-DKD	381 / 1158	366 / 1089	58.1	0.97 [0.81,1.15]	
Total	638 / 2038	630 / 1900		0.92 [0.80,1.05]	Z=-1.24, p=0.2166
Heterogeneity:	Q=0.82 (df=1)	p=0.3658	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.45 (df=1)	p=0.2291	I^2=30.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.3.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set

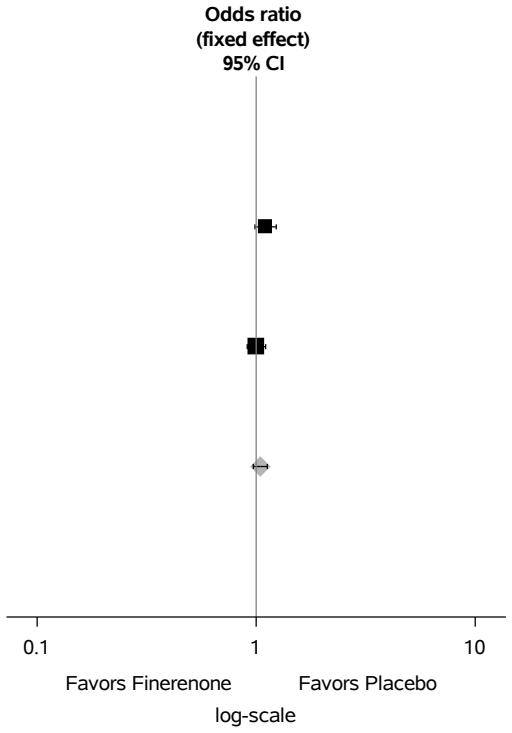
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	365 / 1205	368 / 1174	40.0	0.95 [0.80,1.13]	
FIGARO-DKD	578 / 1753	539 / 1757	60.0	1.11 [0.96,1.28]	
Total	943 / 2958	907 / 2931		1.04 [0.94,1.17]	Z=0.78, p=0.4364
Heterogeneity:	Q=1.83 (df=1)	p=0.1756	I^2=45.5%		
>= 65					
FIDELIO-DKD	539 / 1628	590 / 1667	45.6	0.90 [0.78,1.04]	
FIGARO-DKD	690 / 1933	696 / 1909	54.4	0.97 [0.85,1.10]	
Total	1229 / 3561	1286 / 3576		0.94 [0.85,1.03]	Z=-1.30, p=0.1950
Heterogeneity:	Q=0.47 (df=1)	p=0.4921	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.08 (df=1)	p=0.1495	I^2=51.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set

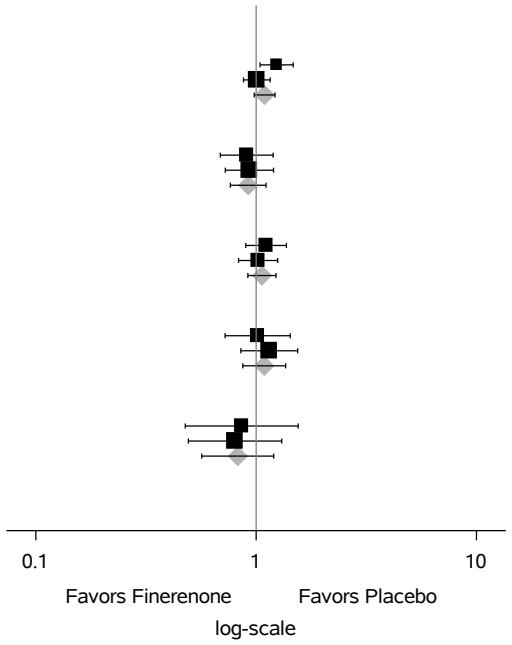
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	937 / 2833	879 / 2841	42.9	1.10 [0.99,1.23]	
FIGARO-DKD	1244 / 3686	1235 / 3666	57.1	1.00 [0.91,1.10]	
Total	2181 / 6519	2114 / 6507		1.04 [0.97,1.12]	Z=1.17, p=0.2433
Heterogeneity:	Q=1.62 (df=1)	p=0.2030	I^2=38.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.4.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set

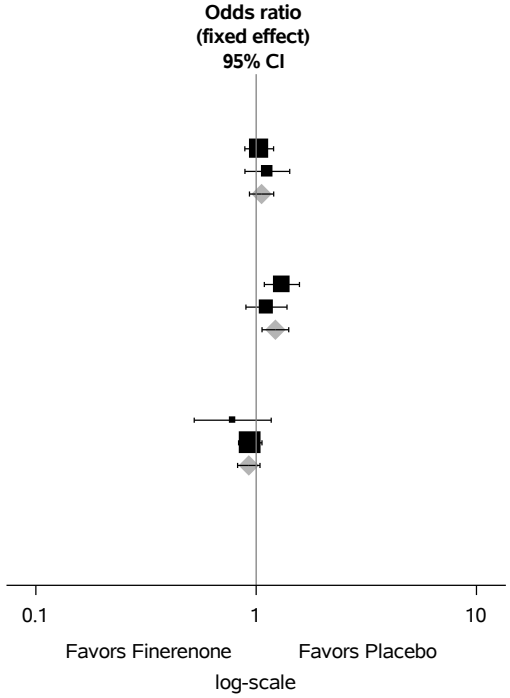
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	409 / 1182	352 / 1176	39.3	1.24 [1.04,1.47]	
FIGARO-DKD	607 / 1754	603 / 1750	60.7	1.01 [0.88,1.16]	
Total	1016 / 2936	955 / 2926		1.09 [0.98,1.22]	Z=1.60, p=0.1107
Heterogeneity:	Q=3.35 (df=1)	p=0.0673	I^2=70.1%		
North America					
FIDELIO-DKD	139 / 467	152 / 477	45.4	0.91 [0.69,1.19]	
FIGARO-DKD	176 / 559	181 / 548	54.6	0.93 [0.72,1.20]	
Total	315 / 1026	333 / 1025		0.92 [0.76,1.11]	Z=-0.88, p=0.3804
Heterogeneity:	Q=0.02 (df=1)	p=0.8838	I^2=0.0%		
Asia					
FIDELIO-DKD	258 / 790	240 / 789	48.1	1.11 [0.90,1.37]	
FIGARO-DKD	281 / 810	279 / 815	51.9	1.02 [0.83,1.25]	
Total	539 / 1600	519 / 1604		1.06 [0.92,1.23]	Z=0.80, p=0.4211
Heterogeneity:	Q=0.31 (df=1)	p=0.5790	I^2=0.0%		
Latin America					
FIDELIO-DKD	100 / 295	100 / 298	43.2	1.02 [0.72,1.43]	
FIGARO-DKD	131 / 424	117 / 417	56.8	1.15 [0.85,1.54]	
Total	231 / 719	217 / 715		1.09 [0.87,1.36]	Z=0.74, p=0.4603
Heterogeneity:	Q=0.28 (df=1)	p=0.5984	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	35 / 101	40.6	0.86 [0.48,1.55]	
FIGARO-DKD	49 / 139	55 / 136	59.4	0.80 [0.49,1.31]	
Total	80 / 238	90 / 237		0.82 [0.57,1.20]	Z=-1.00, p=0.3157
Heterogeneity:	Q=0.03 (df=1)	p=0.8585	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.13 (df=4)	p=0.3891	I^2=3.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

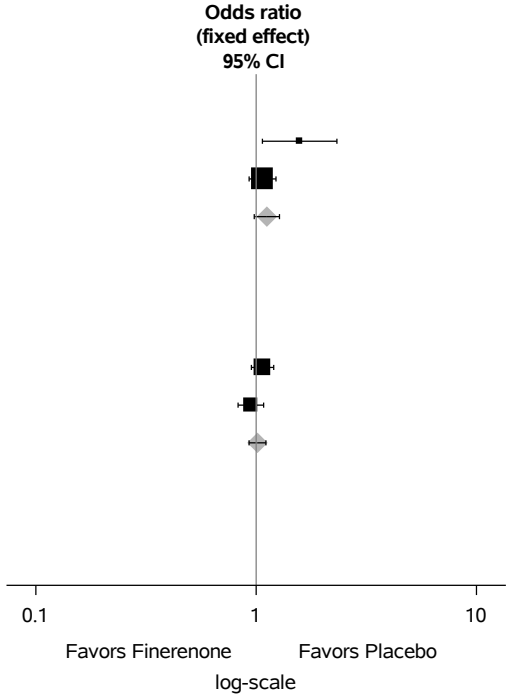
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	510 / 1559	496 / 1549	70.8	1.03 [0.89,1.20]	
FIGARO-DKD	219 / 639	200 / 631	29.2	1.12 [0.89,1.42]	
Total	729 / 2198	696 / 2180		1.06 [0.93,1.20]	Z=0.87, p=0.3816
Heterogeneity:	Q=0.36 (df=1)	p=0.5494	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	363 / 1063	304 / 1071	57.8	1.31 [1.09,1.57]	
FIGARO-DKD	267 / 720	253 / 731	42.2	1.11 [0.90,1.38]	
Total	630 / 1783	557 / 1802		1.22 [1.06,1.41]	Z=2.82, p=0.0048
Heterogeneity:	Q=1.25 (df=1)	p=0.2634	I^2=20.1%		
>= 60					
FIDELIO-DKD	64 / 211	79 / 221	8.5	0.78 [0.52,1.17]	
FIGARO-DKD	758 / 2327	782 / 2304	91.5	0.94 [0.83,1.06]	
Total	822 / 2538	861 / 2525		0.93 [0.82,1.04]	Z=-1.29, p=0.1961
Heterogeneity:	Q=0.73 (df=1)	p=0.3921	I^2=0.0%		
Subgroup Heterogeneity:	Q=9.01 (df=2)	p=0.0110	I^2=77.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set

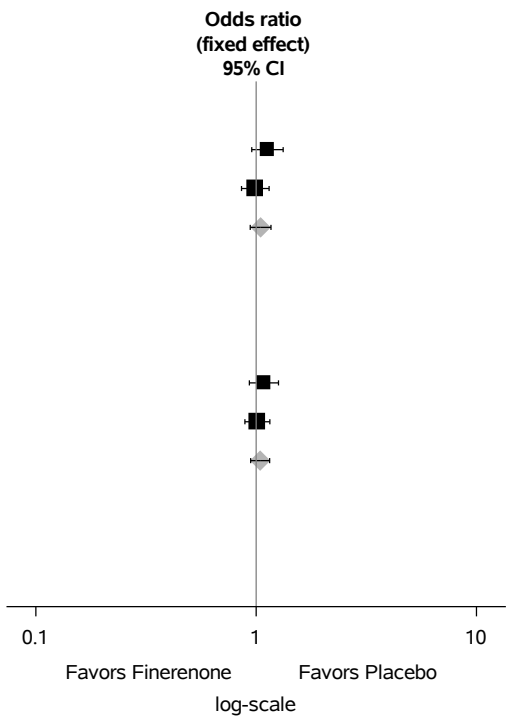
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	99 / 210	77 / 213	11.5	1.58 [1.07,2.33]	
FIGARO-DKD	617 / 1722	585 / 1705	88.5	1.07 [0.93,1.23]	
Total	716 / 1932	662 / 1918		1.12 [0.98,1.28]	Z=1.66, p=0.0973
Heterogeneity:	Q=3.37 (df=1)	p=0.0663	I^2=70.3%		
Very High					
FIDELIO-DKD	838 / 2623	802 / 2628	56.7	1.07 [0.95,1.20]	
FIGARO-DKD	627 / 1964	650 / 1961	43.3	0.95 [0.83,1.08]	
Total	1465 / 4587	1452 / 4589		1.01 [0.93,1.11]	Z=0.30, p=0.7607
Heterogeneity:	Q=1.83 (df=1)	p=0.1767	I^2=45.2%		
Subgroup Heterogeneity:	Q=1.47 (df=1)	p=0.2258	I^2=31.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set

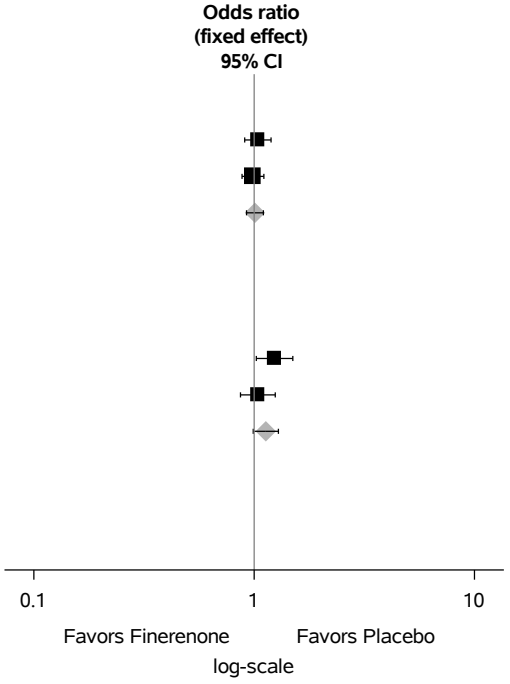
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	440 / 1303	406 / 1302	43.6	1.13 [0.95,1.33]	
FIGARO-DKD	556 / 1676	552 / 1654	56.4	0.99 [0.86,1.14]	
Total	996 / 2979	958 / 2956		1.05 [0.94,1.17]	Z=0.84, p=0.4018
Heterogeneity:	Q=1.30 (df=1)	p=0.2547	I^2=22.9%		
Absent					
FIDELIO-DKD	497 / 1530	473 / 1539	42.3	1.08 [0.93,1.26]	
FIGARO-DKD	688 / 2010	683 / 2012	57.7	1.01 [0.89,1.15]	
Total	1185 / 3540	1156 / 3551		1.04 [0.94,1.15]	Z=0.82, p=0.4113
Heterogeneity:	Q=0.45 (df=1)	p=0.5038	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9487	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

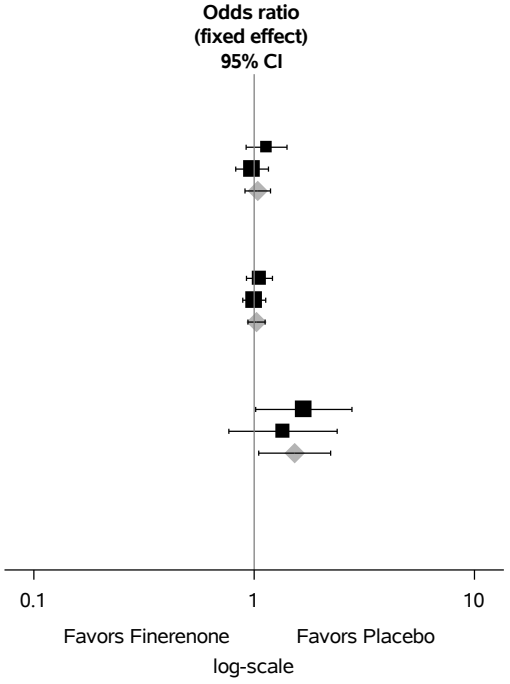
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	605 / 1881	583 / 1861	40.8	1.04 [0.91,1.19]	
FIGARO-DKD	893 / 2643	890 / 2612	59.2	0.99 [0.88,1.11]	
Total	1498 / 4524	1473 / 4473		1.01 [0.92,1.10]	Z=0.18, p=0.8553
Heterogeneity:	Q=0.32 (df=1)	p=0.5735	I^2=0.0%		
> 4.5					
FIDELIO-DKD	332 / 951	296 / 979	47.6	1.24 [1.02,1.50]	
FIGARO-DKD	351 / 1043	345 / 1052	52.4	1.04 [0.87,1.25]	
Total	683 / 1994	641 / 2031		1.13 [0.99,1.29]	Z=1.81, p=0.0696
Heterogeneity:	Q=1.68 (df=1)	p=0.1944	I^2=40.6%		
Subgroup Heterogeneity:	Q=1.98 (df=1)	p=0.1592	I^2=49.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.4.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

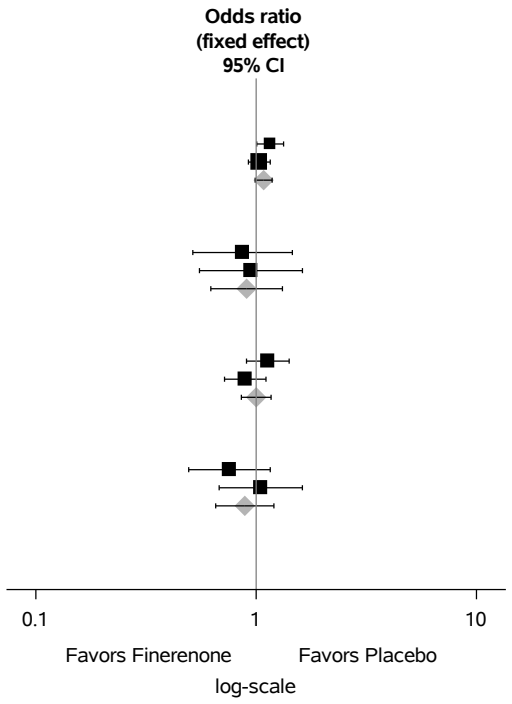
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	259 / 788	234 / 778	39.1	1.14 [0.92,1.41]	
FIGARO-DKD	387 / 1187	396 / 1197	60.9	0.98 [0.82,1.16]	
Total	646 / 1975	630 / 1975		1.04 [0.91,1.19]	Z=0.55, p=0.5829
Heterogeneity:	Q=1.17 (df=1)	p=0.2785	I^2=14.8%		
130 - < 160					
FIDELIO-DKD	623 / 1900	607 / 1922	43.8	1.06 [0.92,1.21]	
FIGARO-DKD	819 / 2392	806 / 2355	56.2	1.00 [0.89,1.13]	
Total	1442 / 4292	1413 / 4277		1.02 [0.94,1.12]	Z=0.54, p=0.5914
Heterogeneity:	Q=0.35 (df=1)	p=0.5538	I^2=0.0%		
>= 160					
FIDELIO-DKD	55 / 142	38 / 139	55.9	1.68 [1.02,2.78]	
FIGARO-DKD	38 / 107	33 / 114	44.1	1.35 [0.77,2.38]	
Total	93 / 249	71 / 253		1.53 [1.05,2.22]	Z=2.21, p=0.0272
Heterogeneity:	Q=0.32 (df=1)	p=0.5735	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.10 (df=2)	p=0.1285	I^2=51.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.4.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set

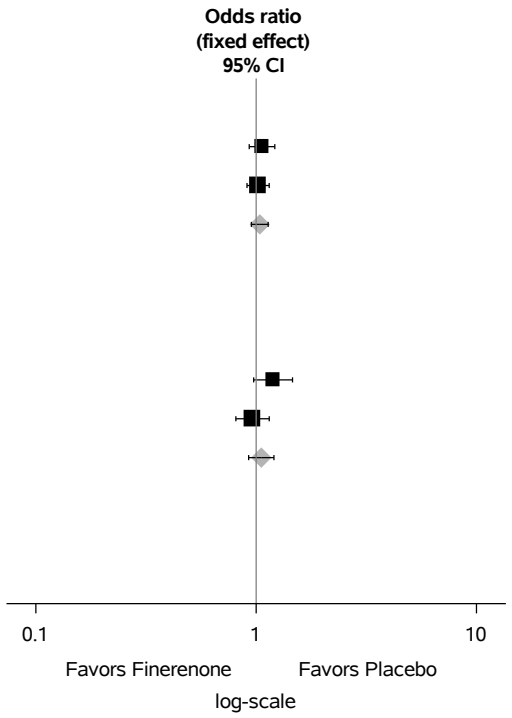
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	599 / 1777	554 / 1815	39.9	1.16 [1.01,1.33]	
FIGARO-DKD	910 / 2672	868 / 2605	60.1	1.03 [0.92,1.16]	
Total	1509 / 4449	1422 / 4420		1.08 [0.99,1.18]	Z=1.73, p=0.0836
Heterogeneity:	Q=1.51 (df=1)	p=0.2197	I^2=33.6%		
Black					
FIDELIO-DKD	42 / 140	41 / 124	51.7	0.87 [0.52,1.46]	
FIGARO-DKD	33 / 113	44 / 145	48.3	0.95 [0.55,1.62]	
Total	75 / 253	85 / 269		0.90 [0.62,1.32]	Z=-0.52, p=0.6012
Heterogeneity:	Q=0.05 (df=1)	p=0.8189	I^2=0.0%		
Asian					
FIDELIO-DKD	234 / 717	217 / 723	48.6	1.13 [0.90,1.41]	
FIGARO-DKD	237 / 715	264 / 739	51.4	0.89 [0.72,1.11]	
Total	471 / 1432	481 / 1462		1.00 [0.86,1.17]	Z=0.01, p=0.9953
Heterogeneity:	Q=2.22 (df=1)	p=0.1364	I^2=54.9%		
Others					
FIDELIO-DKD	62 / 199	67 / 179	51.0	0.76 [0.49,1.16]	
FIGARO-DKD	64 / 186	59 / 177	49.0	1.05 [0.68,1.62]	
Total	126 / 385	126 / 356		0.89 [0.66,1.20]	Z=-0.77, p=0.4435
Heterogeneity:	Q=1.11 (df=1)	p=0.2925	I^2=9.8%		
Subgroup Heterogeneity:	Q=2.54 (df=3)	p=0.4678	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.4.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set

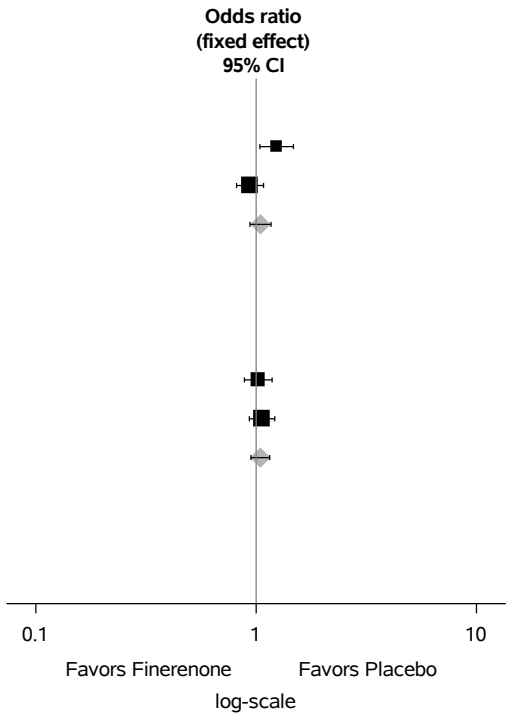
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	628 / 1953	626 / 2030	43.0	1.06 [0.93,1.22]	
FIGARO-DKD	853 / 2528	858 / 2577	57.0	1.02 [0.91,1.15]	
Total	1481 / 4481	1484 / 4607		1.04 [0.95,1.13]	Z=0.84, p=0.3992
Heterogeneity:	Q=0.21 (df=1)	p=0.6500	I^2=0.0%		
Female					
FIDELIO-DKD	309 / 880	253 / 811	42.5	1.19 [0.97,1.46]	
FIGARO-DKD	391 / 1158	377 / 1089	57.5	0.96 [0.81,1.15]	
Total	700 / 2038	630 / 1900		1.05 [0.92,1.20]	Z=0.79, p=0.4285
Heterogeneity:	Q=2.48 (df=1)	p=0.1156	I^2=59.6%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8464	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.4.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set

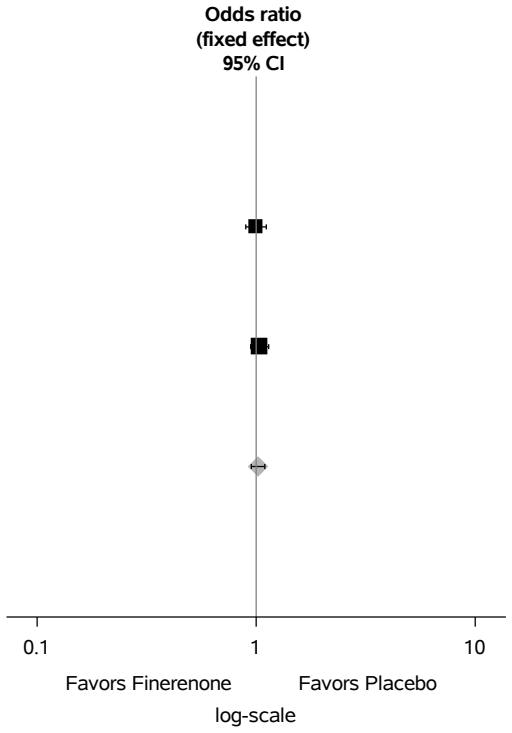
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	391 / 1205	328 / 1174	39.2	1.24 [1.04,1.48]	
FIGARO-DKD	562 / 1753	588 / 1757	60.8	0.94 [0.81,1.08]	
Total	953 / 2958	916 / 2931		1.05 [0.94,1.17]	Z=0.81, p=0.4176
Heterogeneity:	Q=5.86 (df=1)	p=0.0155	I^2=82.9%		
>= 65					
FIDELIO-DKD	546 / 1628	551 / 1667	45.7	1.02 [0.88,1.18]	
FIGARO-DKD	682 / 1933	647 / 1909	54.3	1.06 [0.93,1.21]	
Total	1228 / 3561	1198 / 3576		1.04 [0.95,1.15]	Z=0.87, p=0.3861
Heterogeneity:	Q=0.16 (df=1)	p=0.6930	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9779	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set

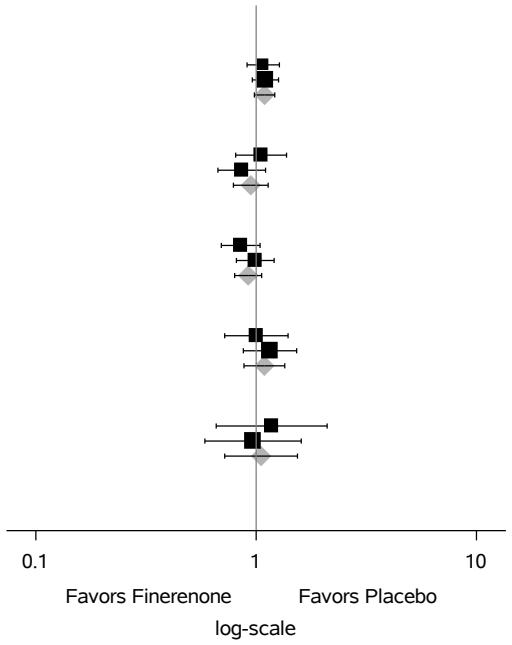
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1042 / 2833	1046 / 2841	43.4	1.00 [0.90,1.11]	
FIGARO-DKD	1404 / 3686	1365 / 3666	56.6	1.04 [0.94,1.14]	
Total	2446 / 6519	2411 / 6507		1.02 [0.95,1.10]	Z=0.55, p=0.5831
Heterogeneity:	Q=0.28 (df=1)	p=0.5989	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.5.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set

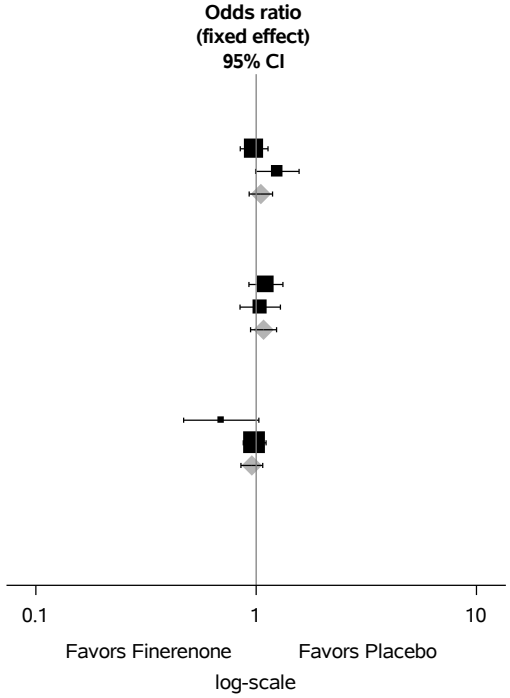
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	428 / 1182	406 / 1176	39.7	1.08 [0.91,1.27]	
FIGARO-DKD	670 / 1754	629 / 1750	60.3	1.10 [0.96,1.26]	
Total	1098 / 2936	1035 / 2926		1.09 [0.98,1.21]	Z=1.61, p=0.1068
Heterogeneity:	Q=0.04 (df=1)	p=0.8363	I^2=0.0%		
North America					
FIDELIO-DKD	171 / 467	169 / 477	46.7	1.05 [0.81,1.37]	
FIGARO-DKD	181 / 559	196 / 548	53.3	0.86 [0.67,1.10]	
Total	352 / 1026	365 / 1025		0.95 [0.79,1.13]	Z=-0.61, p=0.5426
Heterogeneity:	Q=1.19 (df=1)	p=0.2759	I^2=15.8%		
Asia					
FIDELIO-DKD	293 / 790	323 / 789	48.7	0.85 [0.69,1.04]	
FIGARO-DKD	339 / 810	343 / 815	51.3	0.99 [0.81,1.21]	
Total	632 / 1600	666 / 1604		0.92 [0.80,1.06]	Z=-1.16, p=0.2450
Heterogeneity:	Q=1.12 (df=1)	p=0.2907	I^2=10.4%		
Latin America					
FIDELIO-DKD	113 / 295	114 / 298	41.4	1.00 [0.72,1.40]	
FIGARO-DKD	169 / 424	152 / 417	58.6	1.16 [0.87,1.53]	
Total	282 / 719	266 / 715		1.09 [0.88,1.35]	Z=0.79, p=0.4315
Heterogeneity:	Q=0.42 (df=1)	p=0.5190	I^2=0.0%		
Others					
FIDELIO-DKD	37 / 99	34 / 101	43.0	1.18 [0.66,2.10]	
FIGARO-DKD	45 / 139	45 / 136	57.0	0.97 [0.58,1.60]	
Total	82 / 238	79 / 237		1.05 [0.72,1.54]	Z=0.26, p=0.7913
Heterogeneity:	Q=0.25 (df=1)	p=0.6196	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.69 (df=4)	p=0.3204	I^2=14.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

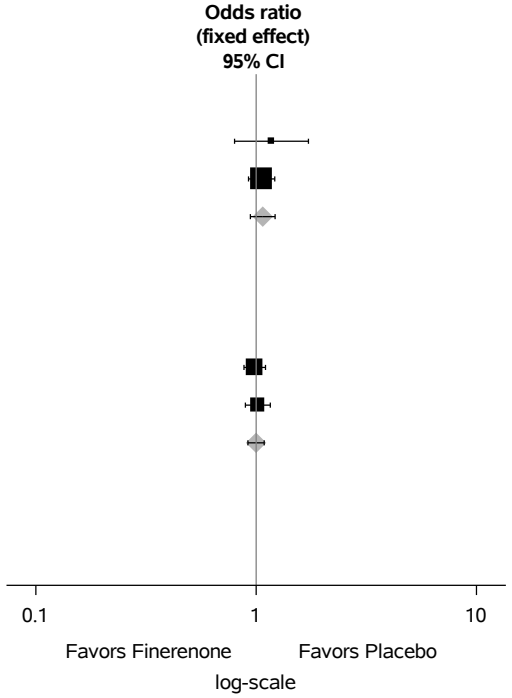
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	586 / 1559	590 / 1549	71.1	0.98 [0.85,1.13]	
FIGARO-DKD	258 / 639	222 / 631	28.9	1.25 [0.99,1.57]	
Total	844 / 2198	812 / 2180		1.05 [0.93,1.19]	Z=0.79, p=0.4324
Heterogeneity:	Q=3.11 (df=1)	p=0.0779	I^2=67.8%		
45 - < 60					
FIDELIO-DKD	387 / 1063	365 / 1071	58.5	1.11 [0.93,1.32]	
FIGARO-DKD	285 / 720	282 / 731	41.5	1.04 [0.84,1.29]	
Total	672 / 1783	647 / 1802		1.08 [0.94,1.24]	Z=1.11, p=0.2657
Heterogeneity:	Q=0.18 (df=1)	p=0.6714	I^2=0.0%		
>= 60					
FIDELIO-DKD	69 / 211	91 / 221	8.4	0.69 [0.47,1.03]	
FIGARO-DKD	861 / 2327	861 / 2304	91.6	0.98 [0.87,1.11]	
Total	930 / 2538	952 / 2525		0.96 [0.85,1.07]	Z=-0.78, p=0.4349
Heterogeneity:	Q=2.78 (df=1)	p=0.0956	I^2=64.0%		
Subgroup Heterogeneity:	Q=2.16 (df=2)	p=0.3395	I^2=7.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

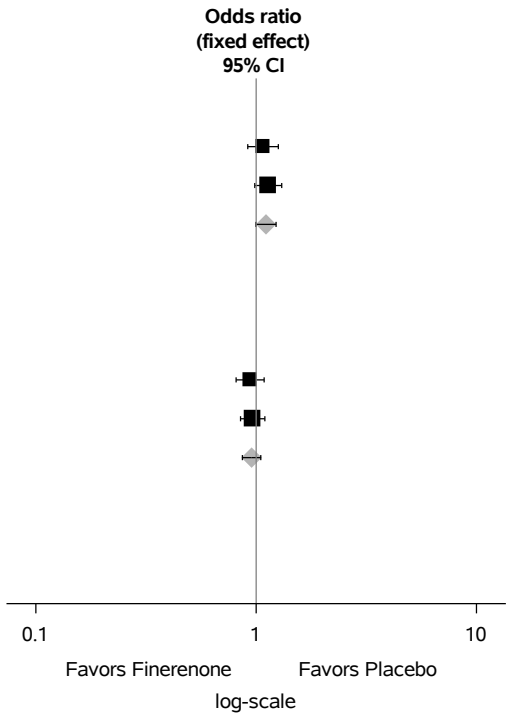
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	93 / 210	86 / 213	11.2	1.17 [0.80,1.73]	
FIGARO-DKD	687 / 1722	657 / 1705	88.8	1.06 [0.92,1.21]	
Total	780 / 1932	743 / 1918		1.07 [0.94,1.22]	Z=1.04, p=0.2975
Heterogeneity:	Q=0.24 (df=1)	p=0.6218	I^2=0.0%		
Very High					
FIDELIO-DKD	949 / 2623	960 / 2628	57.2	0.98 [0.88,1.10]	
FIGARO-DKD	717 / 1964	708 / 1961	42.8	1.02 [0.89,1.16]	
Total	1666 / 4587	1668 / 4589		1.00 [0.92,1.09]	Z=-0.03, p=0.9780
Heterogeneity:	Q=0.14 (df=1)	p=0.7107	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.78 (df=1)	p=0.3760	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set

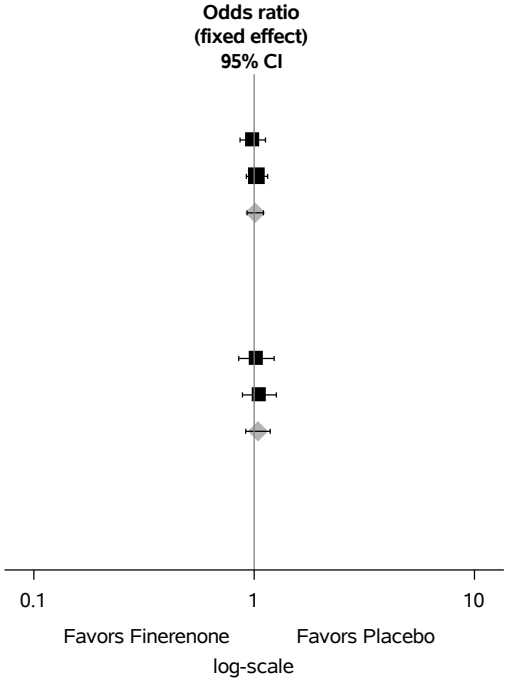
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	485 / 1303	463 / 1302	43.8	1.07 [0.92,1.26]	
FIGARO-DKD	643 / 1676	586 / 1654	56.2	1.13 [0.99,1.31]	
Total	1128 / 2979	1049 / 2956		1.11 [1.00,1.23]	Z=1.90, p=0.0576
Heterogeneity:	Q=0.25 (df=1)	p=0.6167	I^2=0.0%		
Absent					
FIDELIO-DKD	557 / 1530	583 / 1539	43.0	0.94 [0.81,1.09]	
FIGARO-DKD	761 / 2010	779 / 2012	57.0	0.96 [0.85,1.10]	
Total	1318 / 3540	1362 / 3551		0.95 [0.87,1.05]	Z=-0.98, p=0.3285
Heterogeneity:	Q=0.07 (df=1)	p=0.7852	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.25 (df=1)	p=0.0392	I^2=76.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

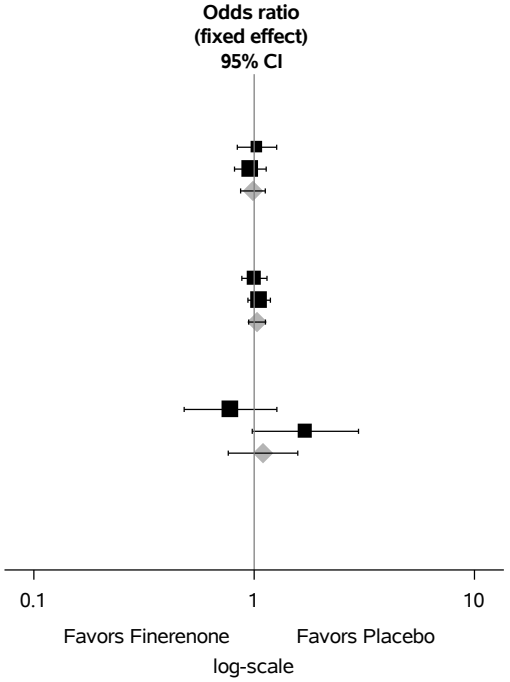
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	690 / 1881	689 / 1861	41.4	0.99 [0.86,1.13]	
FIGARO-DKD	1007 / 2643	977 / 2612	58.6	1.03 [0.92,1.15]	
Total	1697 / 4524	1666 / 4473		1.01 [0.93,1.10]	Z=0.26, p=0.7950
Heterogeneity:	Q=0.25 (df=1)	p=0.6170	I^2=0.0%		
> 4.5					
FIDELIO-DKD	352 / 951	357 / 979	47.8	1.02 [0.85,1.23]	
FIGARO-DKD	397 / 1043	387 / 1052	52.2	1.06 [0.88,1.26]	
Total	749 / 1994	744 / 2031		1.04 [0.92,1.18]	Z=0.61, p=0.5427
Heterogeneity:	Q=0.06 (df=1)	p=0.8129	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7174	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.5.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

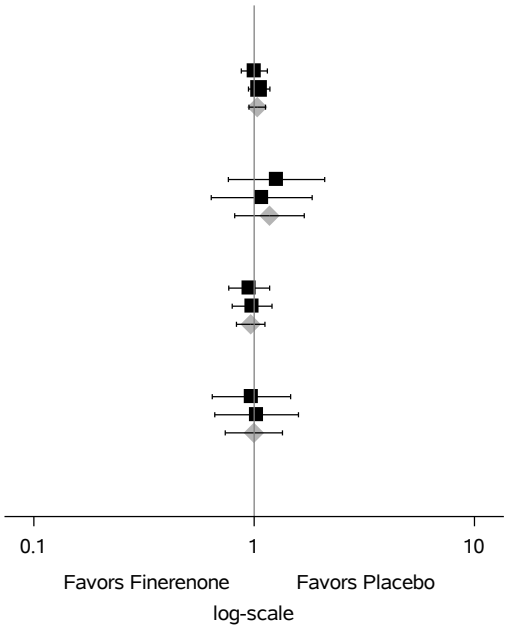
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	291 / 788	282 / 778	39.3	1.03 [0.84,1.26]	
FIGARO-DKD	444 / 1187	459 / 1197	60.7	0.96 [0.81,1.13]	
Total	735 / 1975	741 / 1975		0.99 [0.87,1.12]	Z=-0.19, p=0.8469
Heterogeneity:	Q=0.27 (df=1)	p=0.6065	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	701 / 1900	708 / 1922	44.4	1.00 [0.88,1.14]	
FIGARO-DKD	915 / 2392	872 / 2355	55.6	1.05 [0.94,1.18]	
Total	1616 / 4292	1580 / 4277		1.03 [0.94,1.12]	Z=0.67, p=0.5002
Heterogeneity:	Q=0.31 (df=1)	p=0.5806	I^2=0.0%		
>= 160					
FIDELIO-DKD	49 / 142	56 / 139	56.8	0.78 [0.48,1.27]	
FIGARO-DKD	45 / 107	34 / 114	43.2	1.71 [0.98,2.98]	
Total	94 / 249	90 / 253		1.10 [0.76,1.58]	Z=0.50, p=0.6181
Heterogeneity:	Q=4.33 (df=1)	p=0.0374	I^2=76.9%		
Subgroup Heterogeneity:	Q=0.45 (df=2)	p=0.7981	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.5.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set

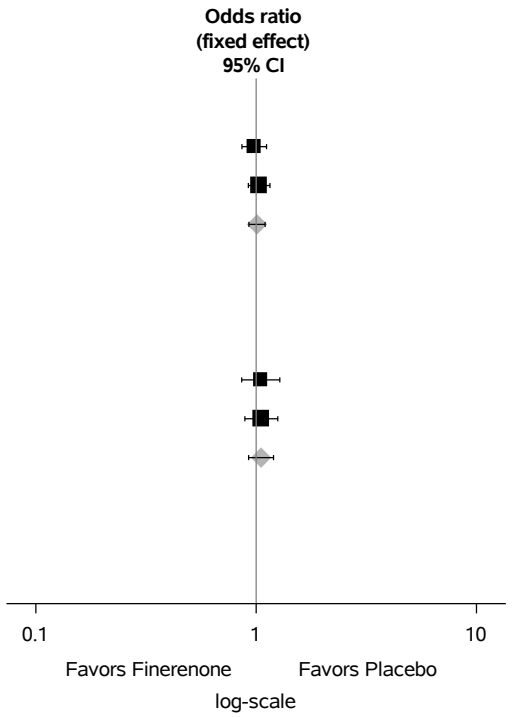
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	641 / 1777	654 / 1815	40.3	1.00 [0.87,1.15]	
FIGARO-DKD	1004 / 2672	947 / 2605	59.7	1.05 [0.94,1.18]	
Total	1645 / 4449	1601 / 4420		1.03 [0.95,1.13]	Z=0.73, p=0.4679
Heterogeneity:	Q=0.32 (df=1)	p=0.5725	I^2=0.0%		
Black					
FIDELIO-DKD	55 / 140	42 / 124	52.3	1.26 [0.76,2.09]	
FIGARO-DKD	37 / 113	45 / 145	47.7	1.08 [0.64,1.83]	
Total	92 / 253	87 / 269		1.17 [0.82,1.69]	Z=0.86, p=0.3889
Heterogeneity:	Q=0.17 (df=1)	p=0.6768	I^2=0.0%		
Asian					
FIDELIO-DKD	264 / 717	275 / 723	48.7	0.95 [0.77,1.18]	
FIGARO-DKD	301 / 715	315 / 739	51.3	0.98 [0.79,1.21]	
Total	565 / 1432	590 / 1462		0.96 [0.83,1.12]	Z=-0.48, p=0.6324
Heterogeneity:	Q=0.04 (df=1)	p=0.8420	I^2=0.0%		
Others					
FIDELIO-DKD	82 / 199	75 / 179	53.3	0.97 [0.65,1.46]	
FIGARO-DKD	62 / 186	58 / 177	46.7	1.03 [0.66,1.59]	
Total	144 / 385	133 / 356		1.00 [0.74,1.34]	Z=-0.02, p=0.9828
Heterogeneity:	Q=0.03 (df=1)	p=0.8596	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.22 (df=3)	p=0.7494	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.5.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set

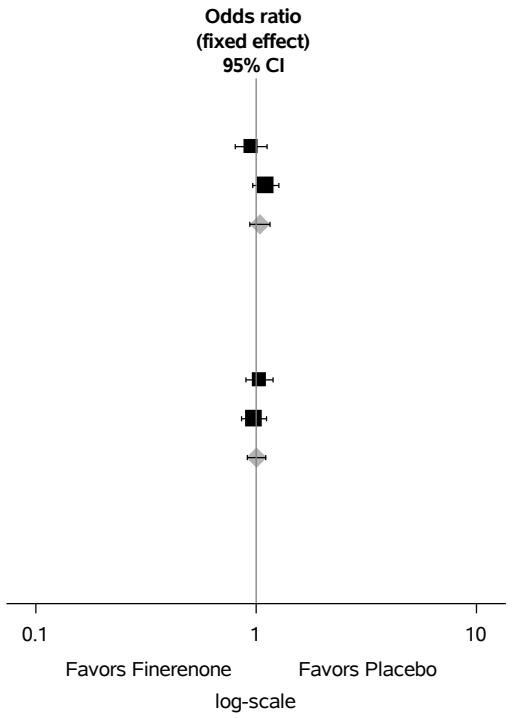
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	722 / 1953	760 / 2030	43.5	0.98 [0.86,1.11]	
FIGARO-DKD	977 / 2528	977 / 2577	56.5	1.03 [0.92,1.15]	
Total	1699 / 4481	1737 / 4607		1.01 [0.93,1.10]	Z=0.20, p=0.8387
Heterogeneity:	Q=0.34 (df=1)	p=0.5574	I^2=0.0%		
Female					
FIDELIO-DKD	320 / 880	286 / 811	42.8	1.05 [0.86,1.28]	
FIGARO-DKD	427 / 1158	388 / 1089	57.2	1.06 [0.89,1.25]	
Total	747 / 2038	674 / 1900		1.05 [0.92,1.20]	Z=0.77, p=0.4402
Heterogeneity:	Q=0.00 (df=1)	p=0.9639	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5922	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.5.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set

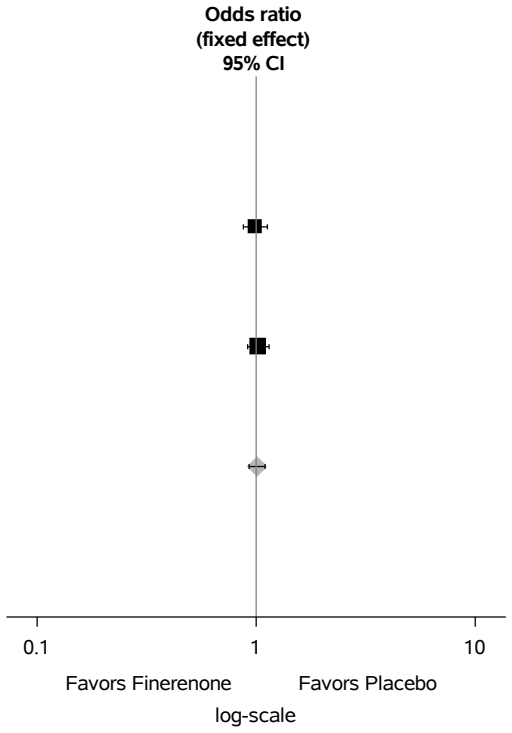
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	441 / 1205	444 / 1174	40.3	0.95 [0.80,1.12]	
FIGARO-DKD	682 / 1753	642 / 1757	59.7	1.11 [0.96,1.27]	
Total	1123 / 2958	1086 / 2931		1.04 [0.94,1.16]	Z=0.73, p=0.4678
Heterogeneity:	Q=1.94 (df=1)	p=0.1634	I^2=48.5%		
>= 65					
FIDELIO-DKD	601 / 1628	602 / 1667	45.9	1.04 [0.90,1.19]	
FIGARO-DKD	722 / 1933	723 / 1909	54.1	0.98 [0.86,1.11]	
Total	1323 / 3561	1325 / 3576		1.00 [0.91,1.11]	Z=0.08, p=0.9373
Heterogeneity:	Q=0.33 (df=1)	p=0.5628	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6284	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set

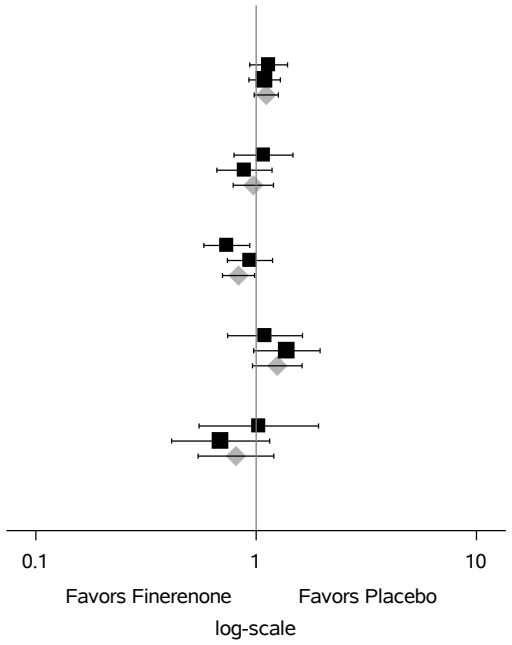
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	615 / 2833	621 / 2841	44.2	0.99 [0.87,1.12]	
FIGARO-DKD	785 / 3686	766 / 3666	55.8	1.02 [0.91,1.14]	
Total	1400 / 6519	1387 / 6507		1.01 [0.93,1.10]	Z=0.22, p=0.8281
Heterogeneity:	Q=0.13 (df=1)	p=0.7171	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.6.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set

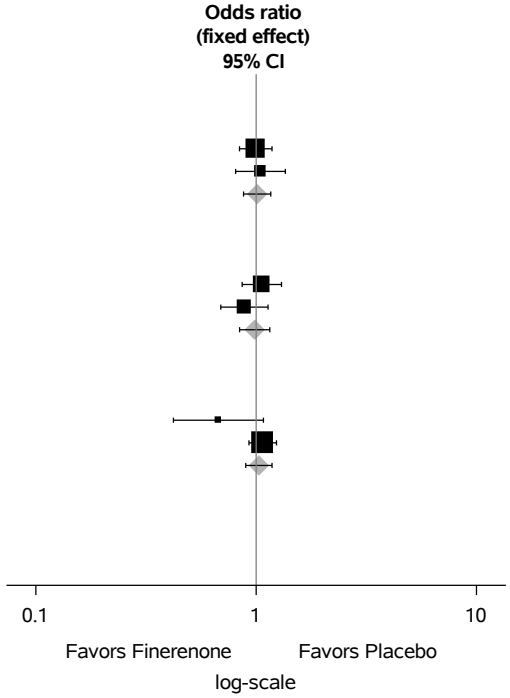
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	264 / 1182	237 / 1176	40.8	1.14 [0.94,1.39]	
FIGARO-DKD	372 / 1754	346 / 1750	59.2	1.09 [0.93,1.29]	
Total	636 / 2936	583 / 2926		1.11 [0.98,1.26]	Z=1.64, p=0.1014
Heterogeneity:	Q=0.10 (df=1)	p=0.7471	I^2=0.0%		
North America					
FIDELIO-DKD	106 / 467	102 / 477	46.7	1.08 [0.79,1.47]	
FIGARO-DKD	113 / 559	122 / 548	53.3	0.88 [0.66,1.18]	
Total	219 / 1026	224 / 1025		0.97 [0.79,1.20]	Z=-0.28, p=0.7830
Heterogeneity:	Q=0.86 (df=1)	p=0.3550	I^2=0.0%		
Asia					
FIDELIO-DKD	152 / 790	193 / 789	49.2	0.74 [0.58,0.94]	
FIGARO-DKD	171 / 810	181 / 815	50.8	0.94 [0.74,1.19]	
Total	323 / 1600	374 / 1604		0.83 [0.70,0.98]	Z=-2.15, p=0.0319
Heterogeneity:	Q=1.99 (df=1)	p=0.1586	I^2=49.7%		
Latin America					
FIDELIO-DKD	66 / 295	62 / 298	44.0	1.10 [0.74,1.62]	
FIGARO-DKD	91 / 424	69 / 417	56.0	1.38 [0.97,1.95]	
Total	157 / 719	131 / 715		1.25 [0.96,1.62]	Z=1.67, p=0.0954
Heterogeneity:	Q=0.73 (df=1)	p=0.3926	I^2=0.0%		
Others					
FIDELIO-DKD	27 / 99	27 / 101	40.3	1.03 [0.55,1.92]	
FIGARO-DKD	38 / 139	48 / 136	59.7	0.69 [0.41,1.15]	
Total	65 / 238	75 / 237		0.81 [0.54,1.20]	Z=-1.05, p=0.2951
Heterogeneity:	Q=0.94 (df=1)	p=0.3333	I^2=0.0%		
Subgroup Heterogeneity:	Q=11.19 (df=4)	p=0.0245	I^2=64.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

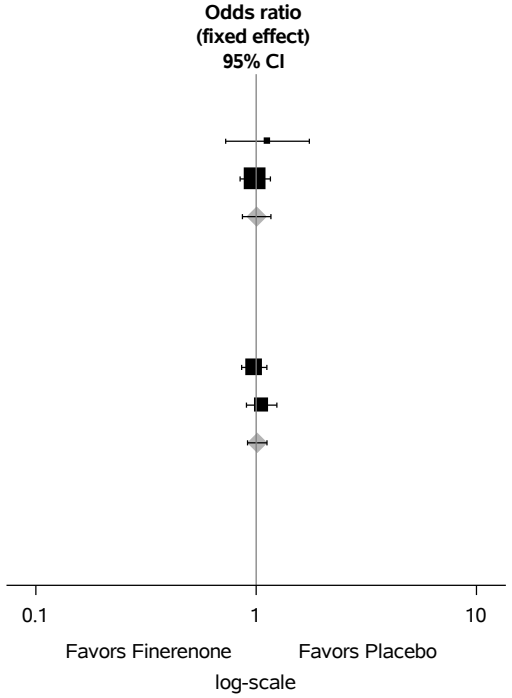
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	341 / 1559	340 / 1549	70.0	1.00 [0.84,1.18]	
FIGARO-DKD	152 / 639	145 / 631	30.0	1.05 [0.81,1.36]	
Total	493 / 2198	485 / 2180		1.01 [0.88,1.16]	Z=0.14, p=0.8864
Heterogeneity:	Q=0.10 (df=1)	p=0.7544	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	237 / 1063	228 / 1071	59.0	1.06 [0.86,1.30]	
FIGARO-DKD	154 / 720	172 / 731	41.0	0.88 [0.69,1.13]	
Total	391 / 1783	400 / 1802		0.98 [0.84,1.15]	Z=-0.19, p=0.8472
Heterogeneity:	Q=1.23 (df=1)	p=0.2666	I^2=19.0%		
>= 60					
FIDELIO-DKD	37 / 211	53 / 221	8.6	0.67 [0.42,1.08]	
FIGARO-DKD	479 / 2327	449 / 2304	91.4	1.07 [0.93,1.24]	
Total	516 / 2538	502 / 2525		1.03 [0.90,1.18]	Z=0.40, p=0.6874
Heterogeneity:	Q=3.40 (df=1)	p=0.0651	I^2=70.6%		
Subgroup Heterogeneity:	Q=0.17 (df=2)	p=0.9195	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

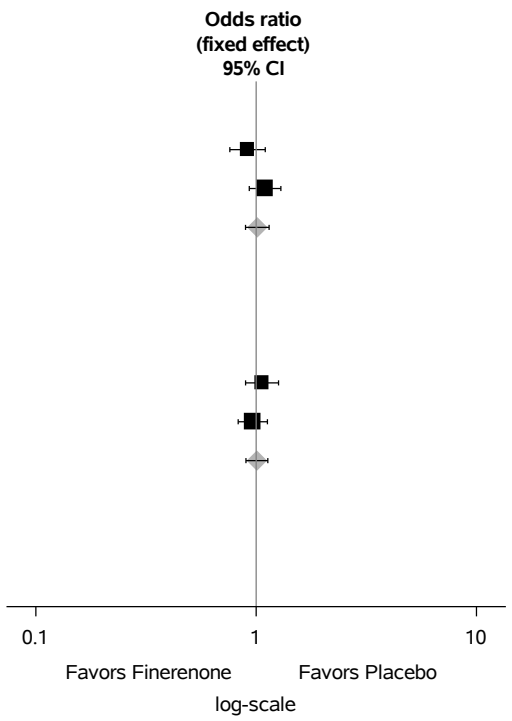
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	56 / 210	52 / 213	11.6	1.13 [0.73,1.74]	
FIGARO-DKD	400 / 1722	399 / 1705	88.4	0.99 [0.85,1.16]	
Total	456 / 1932	451 / 1918		1.01 [0.87,1.17]	Z=0.07, p=0.9454
Heterogeneity:	Q=0.29 (df=1)	p=0.5890	I^2=0.0%		
Very High					
FIDELIO-DKD	559 / 2623	569 / 2628	59.3	0.98 [0.86,1.12]	
FIGARO-DKD	385 / 1964	367 / 1961	40.7	1.06 [0.90,1.24]	
Total	944 / 4587	936 / 4589		1.01 [0.91,1.12]	Z=0.22, p=0.8259
Heterogeneity:	Q=0.54 (df=1)	p=0.4620	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9464	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set

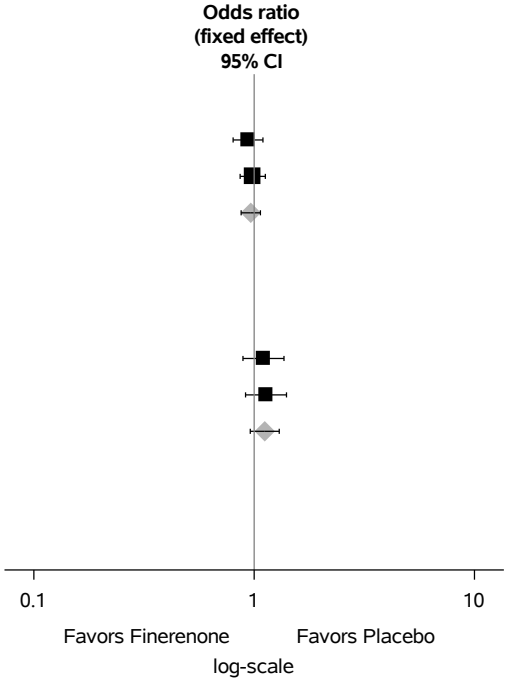
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	278 / 1303	298 / 1302	44.3	0.91 [0.76,1.10]	
FIGARO-DKD	376 / 1676	345 / 1654	55.7	1.10 [0.93,1.29]	
Total	654 / 2979	643 / 2956		1.01 [0.89,1.14]	Z=0.19, p=0.8501
Heterogeneity:	Q=2.09 (df=1)	p=0.1479	I^2=52.2%		
Absent					
FIDELIO-DKD	337 / 1530	323 / 1539	44.0	1.06 [0.90,1.26]	
FIGARO-DKD	409 / 2010	421 / 2012	56.0	0.97 [0.83,1.12]	
Total	746 / 3540	744 / 3551		1.01 [0.90,1.13]	Z=0.13, p=0.8991
Heterogeneity:	Q=0.68 (df=1)	p=0.4103	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9583	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

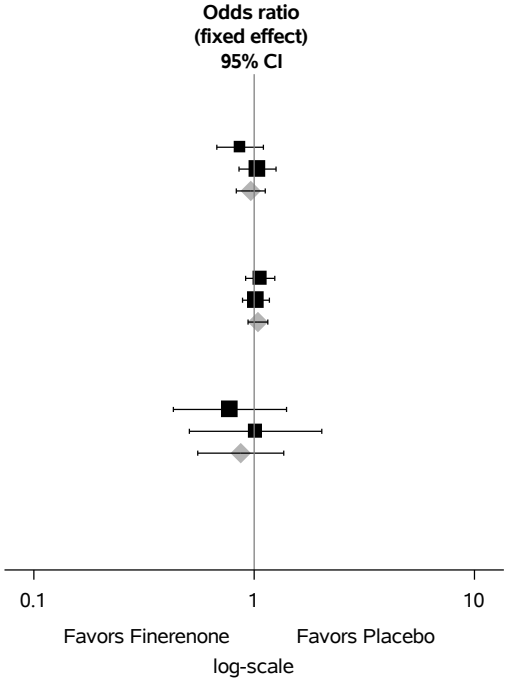
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	395 / 1881	411 / 1861	41.6	0.94 [0.80,1.10]	
FIGARO-DKD	565 / 2643	565 / 2612	58.4	0.99 [0.86,1.12]	
Total	960 / 4524	976 / 4473		0.97 [0.87,1.07]	Z=-0.69, p=0.4889
Heterogeneity:	Q=0.22 (df=1)	p=0.6365	I^2=0.0%		
> 4.5					
FIDELIO-DKD	220 / 951	210 / 979	49.9	1.10 [0.89,1.37]	
FIGARO-DKD	220 / 1043	201 / 1052	50.1	1.13 [0.91,1.40]	
Total	440 / 1994	411 / 2031		1.12 [0.96,1.30]	Z=1.43, p=0.1526
Heterogeneity:	Q=0.03 (df=1)	p=0.8635	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.48 (df=1)	p=0.1154	I^2=59.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.6.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

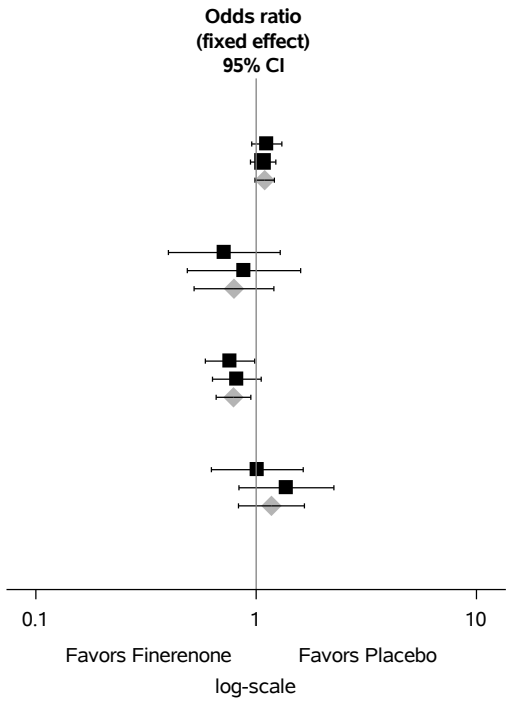
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	156 / 788	173 / 778	38.7	0.86 [0.68,1.10]	
FIGARO-DKD	266 / 1187	261 / 1197	61.3	1.04 [0.85,1.26]	
Total	422 / 1975	434 / 1975		0.97 [0.83,1.12]	Z=-0.46, p=0.6461
Heterogeneity:	Q=1.32 (df=1)	p=0.2507	I^2=24.2%		
130 - < 160					
FIDELIO-DKD	434 / 1900	418 / 1922	45.9	1.07 [0.91,1.24]	
FIGARO-DKD	500 / 2392	485 / 2355	54.1	1.02 [0.89,1.17]	
Total	934 / 4292	903 / 4277		1.04 [0.94,1.15]	Z=0.74, p=0.4574
Heterogeneity:	Q=0.18 (df=1)	p=0.6745	I^2=0.0%		
>= 160					
FIDELIO-DKD	25 / 142	30 / 139	57.8	0.78 [0.43,1.40]	
FIGARO-DKD	19 / 107	20 / 114	42.2	1.01 [0.51,2.03]	
Total	44 / 249	50 / 253		0.87 [0.55,1.36]	Z=-0.61, p=0.5403
Heterogeneity:	Q=0.33 (df=1)	p=0.5642	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=2)	p=0.5819	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.6.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set

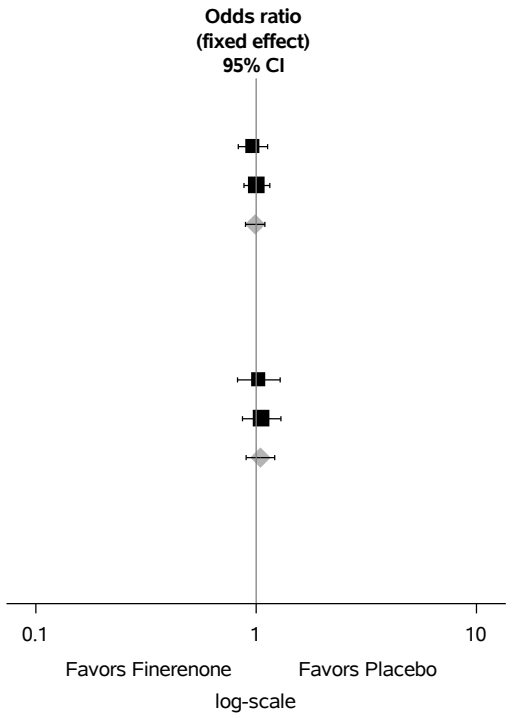
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	412 / 1777	386 / 1815	41.5	1.12 [0.95,1.31]	
FIGARO-DKD	578 / 2672	532 / 2605	58.5	1.08 [0.94,1.23]	
Total	990 / 4449	918 / 4420		1.09 [0.99,1.21]	Z=1.71, p=0.0864
Heterogeneity:	Q=0.13 (df=1)	p=0.7163	I^2=0.0%		
Black					
FIDELIO-DKD	27 / 140	31 / 124	50.7	0.72 [0.40,1.29]	
FIGARO-DKD	24 / 113	34 / 145	49.3	0.88 [0.49,1.59]	
Total	51 / 253	65 / 269		0.79 [0.52,1.20]	Z=-1.09, p=0.2754
Heterogeneity:	Q=0.23 (df=1)	p=0.6283	I^2=0.0%		
Asian					
FIDELIO-DKD	130 / 717	163 / 723	49.4	0.76 [0.59,0.98]	
FIGARO-DKD	136 / 715	165 / 739	50.6	0.82 [0.63,1.05]	
Total	266 / 1432	328 / 1462		0.79 [0.66,0.95]	Z=-2.57, p=0.0103
Heterogeneity:	Q=0.15 (df=1)	p=0.6997	I^2=0.0%		
Others					
FIDELIO-DKD	46 / 199	41 / 179	51.7	1.01 [0.63,1.63]	
FIGARO-DKD	47 / 186	35 / 177	48.3	1.37 [0.84,2.25]	
Total	93 / 385	76 / 356		1.17 [0.83,1.66]	Z=0.91, p=0.3640
Heterogeneity:	Q=0.75 (df=1)	p=0.3875	I^2=0.0%		
Subgroup Heterogeneity:	Q=11.48 (df=3)	p=0.0094	I^2=73.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.6.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set

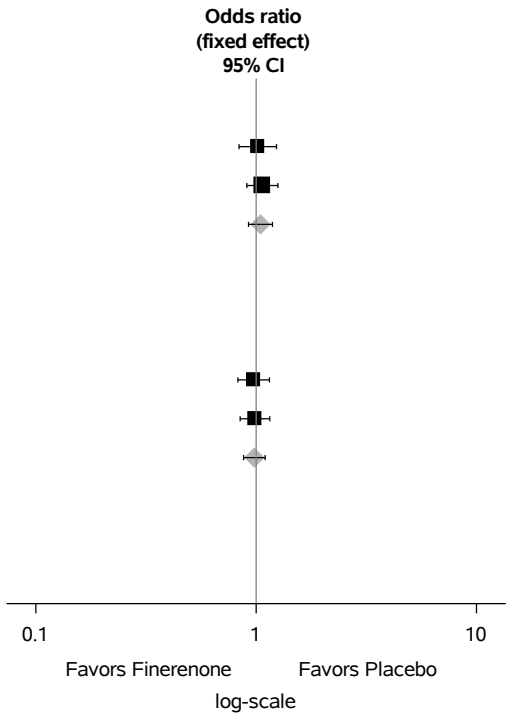
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	400 / 1953	427 / 2030	43.8	0.97 [0.83,1.13]	
FIGARO-DKD	528 / 2528	535 / 2577	56.2	1.01 [0.88,1.15]	
Total	928 / 4481	962 / 4607		0.99 [0.89,1.10]	Z=-0.20, p=0.8400
Heterogeneity:	Q=0.16 (df=1)	p=0.6923	I^2=0.0%		
Female					
FIDELIO-DKD	215 / 880	194 / 811	44.8	1.03 [0.82,1.28]	
FIGARO-DKD	257 / 1158	231 / 1089	55.2	1.06 [0.87,1.30]	
Total	472 / 2038	425 / 1900		1.05 [0.90,1.21]	Z=0.58, p=0.5600
Heterogeneity:	Q=0.04 (df=1)	p=0.8451	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5514	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.6.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set

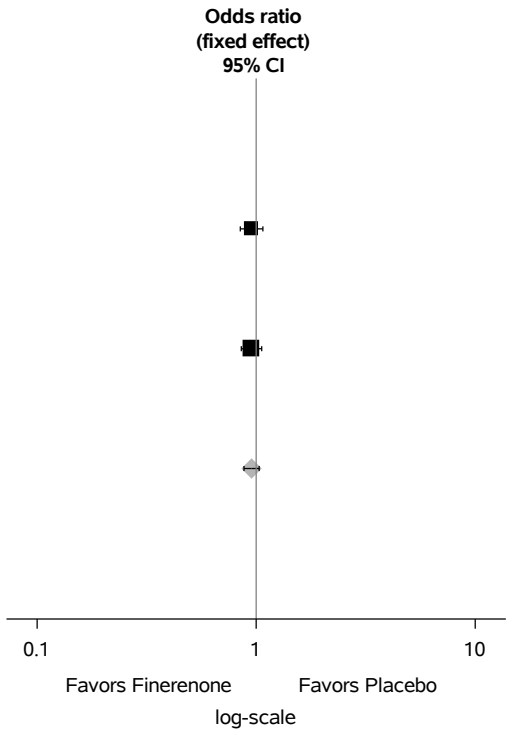
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	260 / 1205	250 / 1174	40.8	1.02 [0.84,1.24]	
FIGARO-DKD	377 / 1753	359 / 1757	59.2	1.07 [0.91,1.26]	
Total	637 / 2958	609 / 2931		1.05 [0.92,1.19]	Z=0.71, p=0.4789
Heterogeneity:	Q=0.14 (df=1)	p=0.7115	I^2=0.0%		
>= 65					
FIDELIO-DKD	355 / 1628	371 / 1667	46.8	0.97 [0.83,1.15]	
FIGARO-DKD	408 / 1933	407 / 1909	53.2	0.99 [0.85,1.15]	
Total	763 / 3561	778 / 3576		0.98 [0.88,1.10]	Z=-0.33, p=0.7408
Heterogeneity:	Q=0.01 (df=1)	p=0.9073	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4548	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set

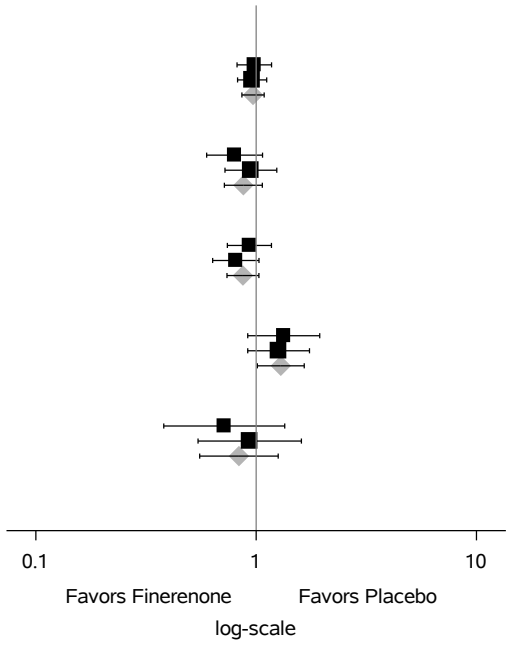
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	725 / 2833	753 / 2841	44.9	0.95 [0.85,1.07]	
FIGARO-DKD	869 / 3686	896 / 3666	55.1	0.95 [0.86,1.06]	
Total	1594 / 6519	1649 / 6507		0.95 [0.88,1.03]	Z=-1.19, p=0.2332
Heterogeneity:	Q=0.00 (df=1)	p=0.9912	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.7.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set

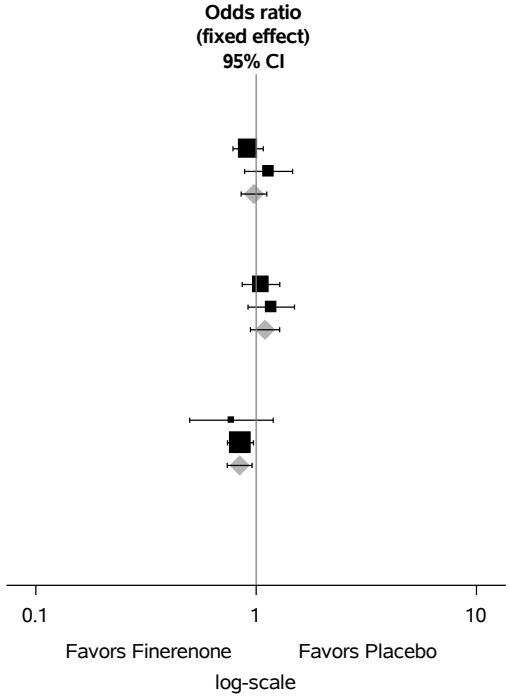
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	325 / 1182	328 / 1176	41.6	0.98 [0.82,1.17]	
FIGARO-DKD	438 / 1754	451 / 1750	58.4	0.96 [0.82,1.12]	
Total	763 / 2936	779 / 2926		0.97 [0.86,1.09]	Z=-0.55, p=0.5794
Heterogeneity:	Q=0.03 (df=1)	p=0.8518	I^2=0.0%		
North America					
FIDELIO-DKD	111 / 467	134 / 477	46.2	0.80 [0.60,1.07]	
FIGARO-DKD	139 / 559	142 / 548	53.8	0.95 [0.72,1.24]	
Total	250 / 1026	276 / 1025		0.87 [0.72,1.07]	Z=-1.32, p=0.1854
Heterogeneity:	Q=0.70 (df=1)	p=0.4020	I^2=0.0%		
Asia					
FIDELIO-DKD	186 / 790	196 / 789	52.5	0.93 [0.74,1.17]	
FIGARO-DKD	151 / 810	180 / 815	47.5	0.81 [0.63,1.03]	
Total	337 / 1600	376 / 1604		0.87 [0.74,1.03]	Z=-1.62, p=0.1043
Heterogeneity:	Q=0.69 (df=1)	p=0.4050	I^2=0.0%		
Latin America					
FIDELIO-DKD	80 / 295	65 / 298	42.4	1.33 [0.92,1.94]	
FIGARO-DKD	106 / 424	87 / 417	57.6	1.26 [0.92,1.75]	
Total	186 / 719	152 / 715		1.29 [1.01,1.65]	Z=2.06, p=0.0395
Heterogeneity:	Q=0.04 (df=1)	p=0.8325	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 99	30 / 101	42.2	0.72 [0.38,1.35]	
FIGARO-DKD	35 / 139	36 / 136	57.8	0.93 [0.54,1.60]	
Total	58 / 238	66 / 237		0.84 [0.55,1.26]	Z=-0.86, p=0.3893
Heterogeneity:	Q=0.39 (df=1)	p=0.5301	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.28 (df=4)	p=0.0819	I^2=51.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

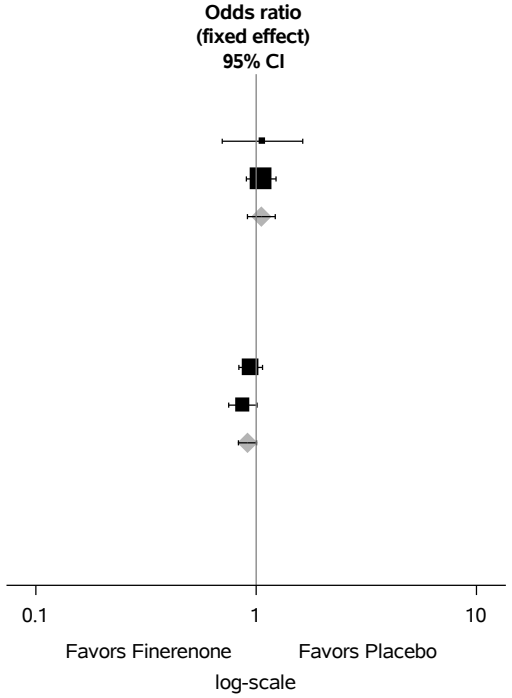
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	408 / 1559	431 / 1549	71.4	0.92 [0.78,1.08]	
FIGARO-DKD	175 / 639	157 / 631	28.6	1.14 [0.89,1.46]	
Total	583 / 2198	588 / 2180		0.98 [0.85,1.12]	Z=-0.33, p=0.7381
Heterogeneity:	Q=2.00 (df=1)	p=0.1576	I^2=49.9%		
45 - < 60					
FIDELIO-DKD	269 / 1063	261 / 1071	60.4	1.05 [0.86,1.28]	
FIGARO-DKD	180 / 720	162 / 731	39.6	1.17 [0.92,1.49]	
Total	449 / 1783	423 / 1802		1.10 [0.94,1.28]	Z=1.19, p=0.2339
Heterogeneity:	Q=0.46 (df=1)	p=0.4997	I^2=0.0%		
>= 60					
FIDELIO-DKD	48 / 211	61 / 221	8.8	0.77 [0.50,1.20]	
FIGARO-DKD	514 / 2327	577 / 2304	91.2	0.85 [0.74,0.97]	
Total	562 / 2538	638 / 2525		0.84 [0.74,0.96]	Z=-2.61, p=0.0092
Heterogeneity:	Q=0.16 (df=1)	p=0.6869	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.94 (df=2)	p=0.0311	I^2=71.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

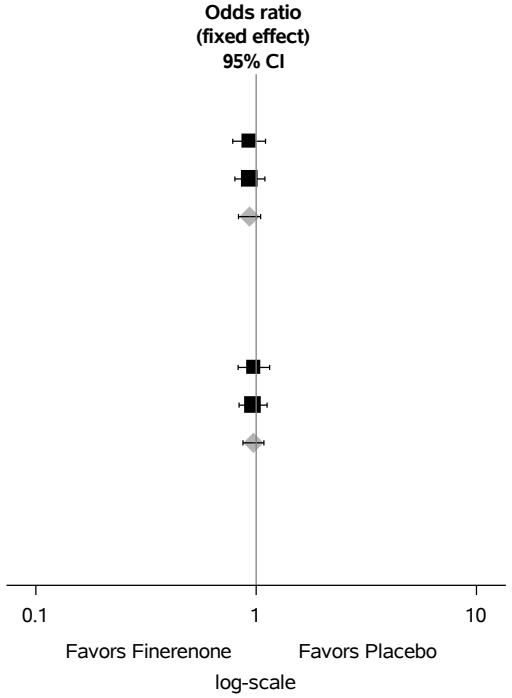
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	60 / 213	12.0	1.07 [0.70,1.63]	
FIGARO-DKD	436 / 1722	415 / 1705	88.0	1.05 [0.90,1.23]	
Total	498 / 1932	475 / 1918		1.06 [0.91,1.22]	Z=0.73, p=0.4661
Heterogeneity:	Q=0.00 (df=1)	p=0.9528	I^2=0.0%		
Very High					
FIDELIO-DKD	663 / 2623	693 / 2628	59.0	0.94 [0.83,1.07]	
FIGARO-DKD	433 / 1964	481 / 1961	41.0	0.87 [0.75,1.01]	
Total	1096 / 4587	1174 / 4589		0.91 [0.83,1.00]	Z=-1.87, p=0.0610
Heterogeneity:	Q=0.69 (df=1)	p=0.4055	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.67 (df=1)	p=0.1023	I^2=62.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set

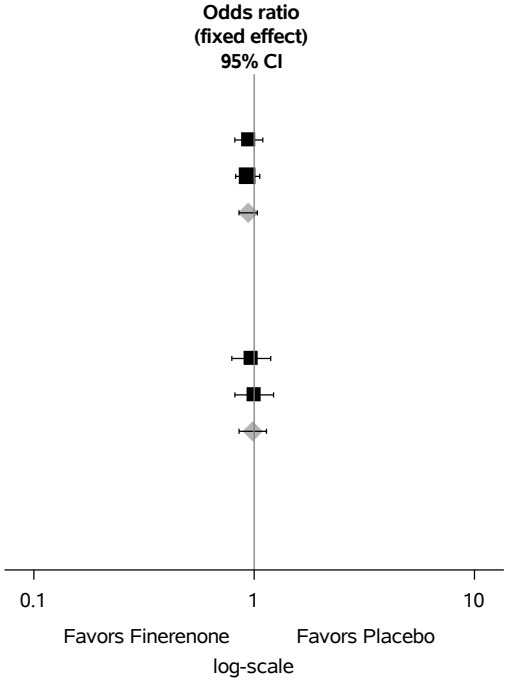
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	354 / 1303	373 / 1302	45.6	0.93 [0.78,1.10]	
FIGARO-DKD	409 / 1676	424 / 1654	54.4	0.94 [0.80,1.10]	
Total	763 / 2979	797 / 2956		0.93 [0.83,1.05]	Z=-1.17, p=0.2405
Heterogeneity:	Q=0.00 (df=1)	p=0.9467	I^2=0.0%		
Absent					
FIDELIO-DKD	371 / 1530	380 / 1539	44.2	0.98 [0.83,1.15]	
FIGARO-DKD	460 / 2010	472 / 2012	55.8	0.97 [0.84,1.12]	
Total	831 / 3540	852 / 3551		0.97 [0.87,1.08]	Z=-0.51, p=0.6088
Heterogeneity:	Q=0.01 (df=1)	p=0.9415	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6164	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

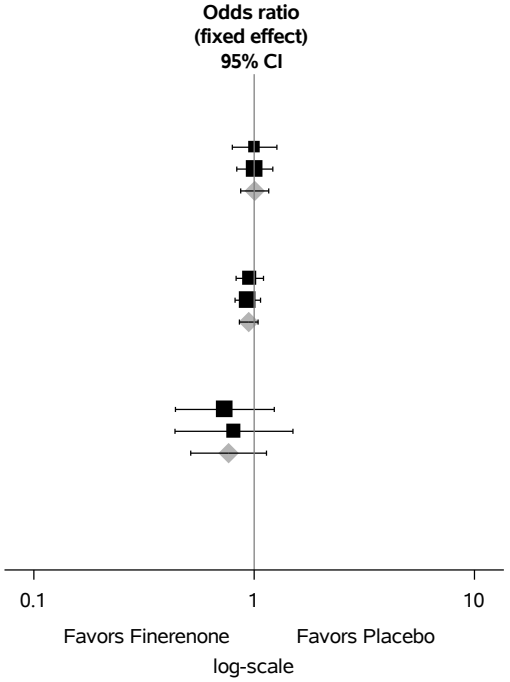
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	479 / 1881	494 / 1861	42.7	0.95 [0.82,1.09]	
FIGARO-DKD	624 / 2643	649 / 2612	57.3	0.93 [0.82,1.06]	
Total	1103 / 4524	1143 / 4473		0.94 [0.85,1.03]	Z=-1.28, p=0.1991
Heterogeneity:	Q=0.01 (df=1)	p=0.9087	I^2=0.0%		
> 4.5					
FIDELIO-DKD	246 / 951	259 / 979	49.7	0.97 [0.79,1.19]	
FIGARO-DKD	245 / 1043	247 / 1052	50.3	1.00 [0.82,1.22]	
Total	491 / 1994	506 / 2031		0.99 [0.85,1.14]	Z=-0.20, p=0.8390
Heterogeneity:	Q=0.05 (df=1)	p=0.8318	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5868	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.7.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

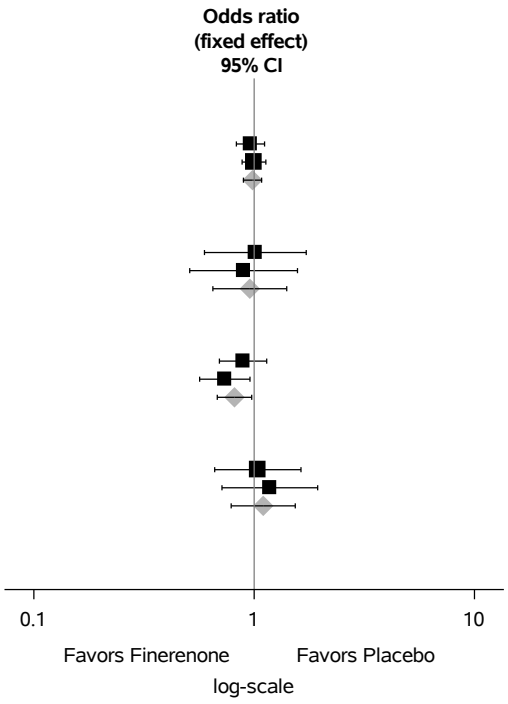
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	187 / 788	184 / 778	39.5	1.00 [0.80,1.27]	
FIGARO-DKD	284 / 1187	285 / 1197	60.5	1.01 [0.83,1.21]	
Total	471 / 1975	469 / 1975		1.01 [0.87,1.16]	Z=0.08, p=0.9399
Heterogeneity:	Q=0.00 (df=1)	p=0.9898	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	501 / 1900	524 / 1922	46.4	0.96 [0.83,1.10]	
FIGARO-DKD	561 / 2392	581 / 2355	53.6	0.94 [0.82,1.07]	
Total	1062 / 4292	1105 / 4277		0.94 [0.86,1.04]	Z=-1.14, p=0.2527
Heterogeneity:	Q=0.04 (df=1)	p=0.8328	I^2=0.0%		
>= 160					
FIDELIO-DKD	37 / 142	45 / 139	58.8	0.74 [0.44,1.23]	
FIGARO-DKD	24 / 107	30 / 114	41.2	0.81 [0.44,1.50]	
Total	61 / 249	75 / 253		0.77 [0.52,1.14]	Z=-1.32, p=0.1859
Heterogeneity:	Q=0.05 (df=1)	p=0.8164	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.72 (df=2)	p=0.4224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.7.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set

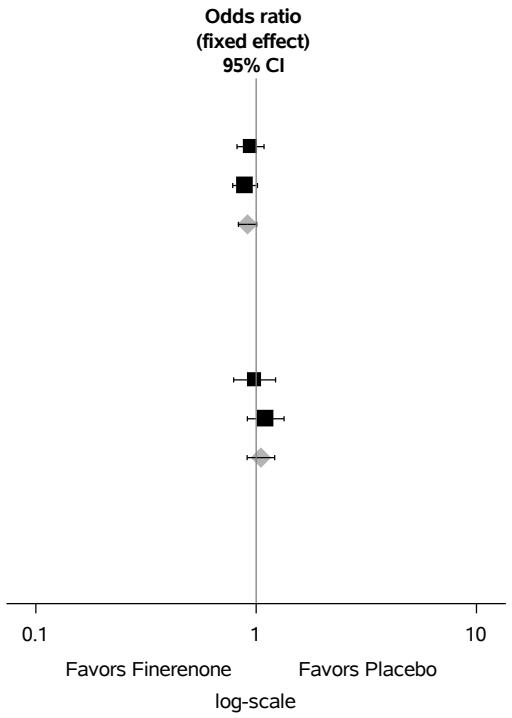
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	473 / 1777	497 / 1815	41.5	0.96 [0.83,1.11]	
FIGARO-DKD	678 / 2672	662 / 2605	58.5	1.00 [0.88,1.13]	
Total	1151 / 4449	1159 / 4420		0.98 [0.89,1.08]	Z=-0.36, p=0.7211
Heterogeneity:	Q=0.14 (df=1)	p=0.7081	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 140	36 / 124	52.9	1.01 [0.59,1.72]	
FIGARO-DKD	28 / 113	39 / 145	47.1	0.90 [0.51,1.57]	
Total	69 / 253	75 / 269		0.96 [0.65,1.41]	Z=-0.23, p=0.8165
Heterogeneity:	Q=0.10 (df=1)	p=0.7559	I^2=0.0%		
Asian					
FIDELIO-DKD	155 / 717	171 / 723	53.2	0.89 [0.70,1.14]	
FIGARO-DKD	120 / 715	159 / 739	46.8	0.74 [0.57,0.96]	
Total	275 / 1432	330 / 1462		0.81 [0.68,0.97]	Z=-2.24, p=0.0250
Heterogeneity:	Q=1.07 (df=1)	p=0.3003	I^2=6.8%		
Others					
FIDELIO-DKD	56 / 199	49 / 179	55.2	1.04 [0.66,1.63]	
FIGARO-DKD	43 / 186	36 / 177	44.8	1.18 [0.71,1.94]	
Total	99 / 385	85 / 356		1.10 [0.79,1.54]	Z=0.55, p=0.5801
Heterogeneity:	Q=0.13 (df=1)	p=0.7152	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.05 (df=3)	p=0.2558	I^2=26.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.7.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set

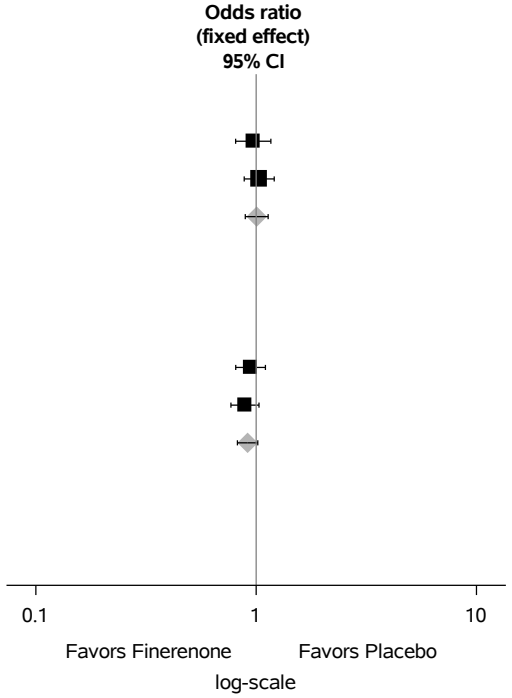
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	502 / 1953	545 / 2030	45.6	0.94 [0.82,1.09]	
FIGARO-DKD	571 / 2528	636 / 2577	54.4	0.89 [0.78,1.01]	
Total	1073 / 4481	1181 / 4607		0.91 [0.83,1.01]	Z=-1.85, p=0.0642
Heterogeneity:	Q=0.34 (df=1)	p=0.5595	I^2=0.0%		
Female					
FIDELIO-DKD	223 / 880	208 / 811	43.4	0.98 [0.79,1.22]	
FIGARO-DKD	298 / 1158	260 / 1089	56.6	1.10 [0.91,1.34]	
Total	521 / 2038	468 / 1900		1.05 [0.91,1.21]	Z=0.67, p=0.5015
Heterogeneity:	Q=0.61 (df=1)	p=0.4353	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.50 (df=1)	p=0.1138	I^2=60.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.7.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set

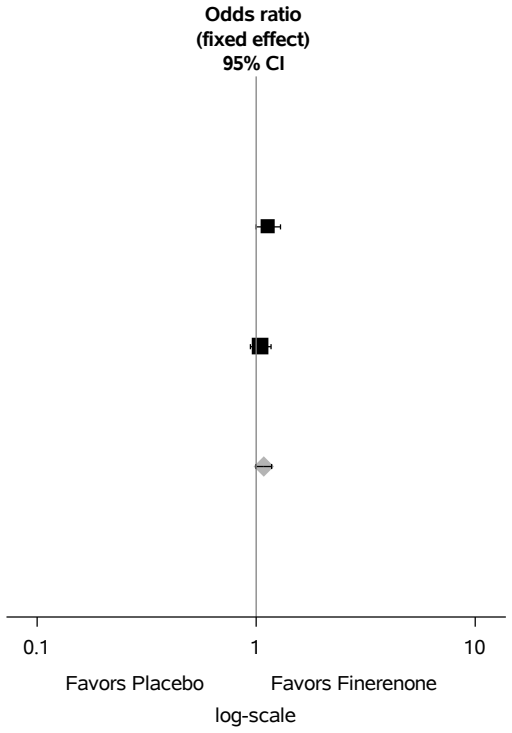
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	305 / 1205	304 / 1174	42.0	0.97 [0.81,1.17]	
FIGARO-DKD	411 / 1753	402 / 1757	58.0	1.03 [0.88,1.21]	
Total	716 / 2958	706 / 2931		1.01 [0.89,1.13]	Z=0.09, p=0.9274
Heterogeneity:	Q=0.26 (df=1)	p=0.6131	I^2=0.0%		
>= 65					
FIDELIO-DKD	420 / 1628	449 / 1667	47.2	0.94 [0.81,1.10]	
FIGARO-DKD	458 / 1933	494 / 1909	52.8	0.89 [0.77,1.03]	
Total	878 / 3561	943 / 3576		0.91 [0.82,1.02]	Z=-1.65, p=0.0995
Heterogeneity:	Q=0.29 (df=1)	p=0.5899	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.36 (df=1)	p=0.2442	I^2=26.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set

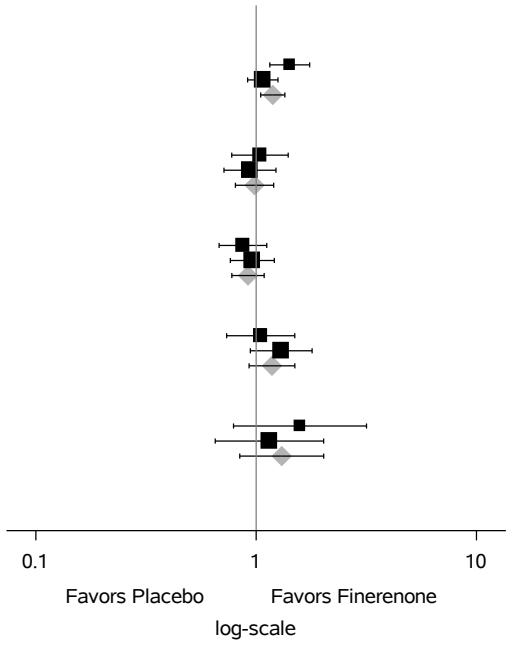
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	628 / 2833	571 / 2841	41.8	1.14 [1.00,1.29]	
FIGARO-DKD	867 / 3686	831 / 3666	58.2	1.05 [0.94,1.17]	
Total	1495 / 6519	1402 / 6507		1.08 [1.00,1.18]	Z=1.89, p=0.0582
Heterogeneity:	Q=0.86 (df=1)	p=0.3524	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.8.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set

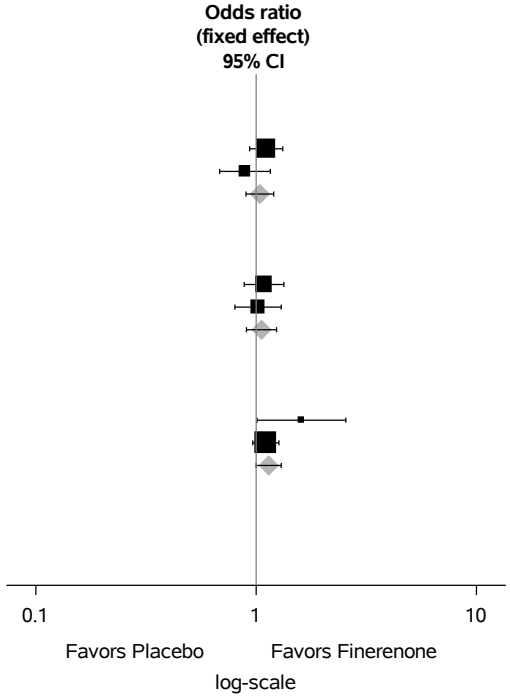
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	254 / 1182	190 / 1176	36.8	1.42 [1.15,1.75]	
FIGARO-DKD	404 / 1754	382 / 1750	63.2	1.07 [0.91,1.26]	
Total	658 / 2936	572 / 2926		1.19 [1.05,1.35]	Z=2.69, p=0.0071
Heterogeneity:	Q=4.44 (df=1)	p=0.0350	I^2=77.5%		
North America					
FIDELIO-DKD	118 / 467	117 / 477	45.9	1.04 [0.77,1.40]	
FIGARO-DKD	137 / 559	141 / 548	54.1	0.94 [0.71,1.23]	
Total	255 / 1026	258 / 1025		0.98 [0.81,1.20]	Z=-0.17, p=0.8675
Heterogeneity:	Q=0.26 (df=1)	p=0.6096	I^2=0.0%		
Asia					
FIDELIO-DKD	146 / 790	163 / 789	46.0	0.87 [0.68,1.12]	
FIGARO-DKD	186 / 810	193 / 815	54.0	0.96 [0.76,1.21]	
Total	332 / 1600	356 / 1604		0.92 [0.78,1.09]	Z=-0.99, p=0.3214
Heterogeneity:	Q=0.32 (df=1)	p=0.5696	I^2=0.0%		
Latin America					
FIDELIO-DKD	86 / 295	84 / 298	45.1	1.05 [0.73,1.50]	
FIGARO-DKD	107 / 424	86 / 417	54.9	1.30 [0.94,1.79]	
Total	193 / 719	170 / 715		1.18 [0.93,1.50]	Z=1.35, p=0.1758
Heterogeneity:	Q=0.77 (df=1)	p=0.3817	I^2=0.0%		
Others					
FIDELIO-DKD	24 / 99	17 / 101	39.9	1.58 [0.79,3.17]	
FIGARO-DKD	33 / 139	29 / 136	60.1	1.15 [0.65,2.02]	
Total	57 / 238	46 / 237		1.31 [0.84,2.03]	Z=1.19, p=0.2326
Heterogeneity:	Q=0.49 (df=1)	p=0.4848	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.88 (df=4)	p=0.0960	I^2=49.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

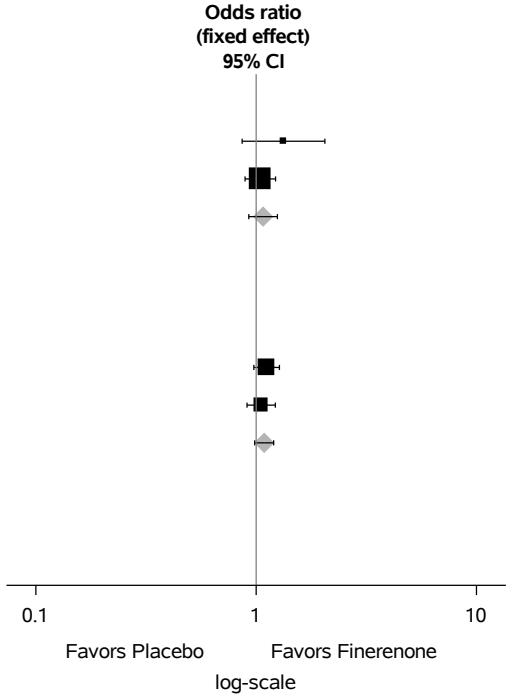
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	340 / 1559	311 / 1549	70.2	1.11 [0.93,1.32]	
FIGARO-DKD	135 / 639	146 / 631	29.8	0.89 [0.68,1.16]	
Total	475 / 2198	457 / 2180		1.04 [0.90,1.20]	Z=0.52, p=0.6017
Heterogeneity:	Q=1.88 (df=1)	p=0.1705	I^2=46.8%		
45 - < 60					
FIDELIO-DKD	234 / 1063	221 / 1071	57.7	1.09 [0.88,1.34]	
FIGARO-DKD	172 / 720	172 / 731	42.3	1.02 [0.80,1.30]	
Total	406 / 1783	393 / 1802		1.06 [0.90,1.24]	Z=0.70, p=0.4870
Heterogeneity:	Q=0.15 (df=1)	p=0.7015	I^2=0.0%		
>= 60					
FIDELIO-DKD	54 / 211	39 / 221	8.0	1.61 [1.01,2.55]	
FIGARO-DKD	560 / 2327	513 / 2304	92.0	1.11 [0.97,1.27]	
Total	614 / 2538	552 / 2525		1.14 [1.00,1.30]	Z=1.96, p=0.0496
Heterogeneity:	Q=2.27 (df=1)	p=0.1316	I^2=56.0%		
Subgroup Heterogeneity:	Q=0.99 (df=2)	p=0.6088	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set

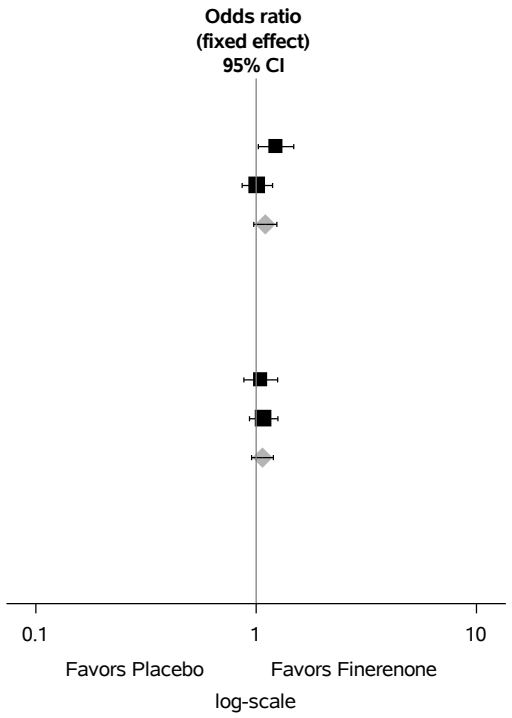
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	51 / 213	12.0	1.33 [0.86,2.05]	
FIGARO-DKD	401 / 1722	384 / 1705	88.0	1.04 [0.89,1.22]	
Total	463 / 1932	435 / 1918		1.08 [0.93,1.25]	Z=0.95, p=0.3424
Heterogeneity:	Q=1.06 (df=1)	p=0.3026	I^2=5.9%		
Very High					
FIDELIO-DKD	566 / 2623	520 / 2628	55.1	1.12 [0.98,1.27]	
FIGARO-DKD	466 / 1964	447 / 1961	44.9	1.05 [0.91,1.22]	
Total	1032 / 4587	967 / 4589		1.09 [0.98,1.20]	Z=1.65, p=0.0984
Heterogeneity:	Q=0.31 (df=1)	p=0.5755	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.9022	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set

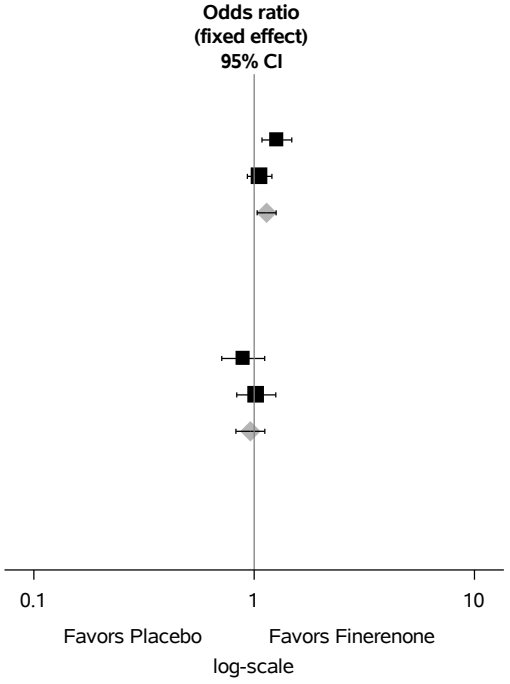
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	314 / 1303	267 / 1302	42.5	1.23 [1.02,1.48]	
FIGARO-DKD	404 / 1676	395 / 1654	57.5	1.01 [0.86,1.19]	
Total	718 / 2979	662 / 2956		1.10 [0.98,1.24]	Z=1.55, p=0.1207
Heterogeneity:	Q=2.46 (df=1)	p=0.1166	I^2=59.4%		
Absent					
FIDELIO-DKD	314 / 1530	304 / 1539	41.4	1.05 [0.88,1.25]	
FIGARO-DKD	463 / 2010	436 / 2012	58.6	1.08 [0.93,1.25]	
Total	777 / 3540	740 / 3551		1.07 [0.95,1.20]	Z=1.14, p=0.2555
Heterogeneity:	Q=0.07 (df=1)	p=0.7936	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7267	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

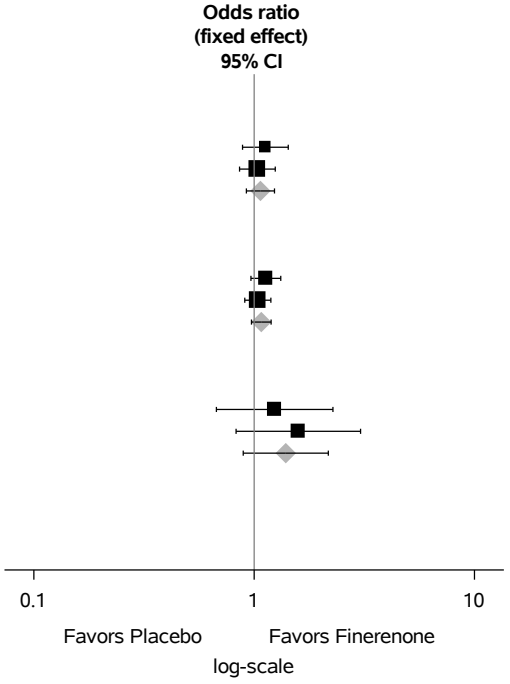
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	449 / 1881	369 / 1861	40.4	1.27 [1.09,1.48]	
FIGARO-DKD	627 / 2643	593 / 2612	59.6	1.06 [0.93,1.20]	
Total	1076 / 4524	962 / 4473		1.14 [1.03,1.26]	Z=2.58, p=0.0099
Heterogeneity:	Q=3.06 (df=1)	p=0.0800	I^2=67.4%		
> 4.5					
FIDELIO-DKD	179 / 951	202 / 979	45.2	0.89 [0.71,1.12]	
FIGARO-DKD	240 / 1043	238 / 1052	54.8	1.02 [0.83,1.25]	
Total	419 / 1994	440 / 2031		0.96 [0.83,1.12]	Z=-0.52, p=0.6054
Heterogeneity:	Q=0.78 (df=1)	p=0.3782	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.41 (df=1)	p=0.0650	I^2=70.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.8.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

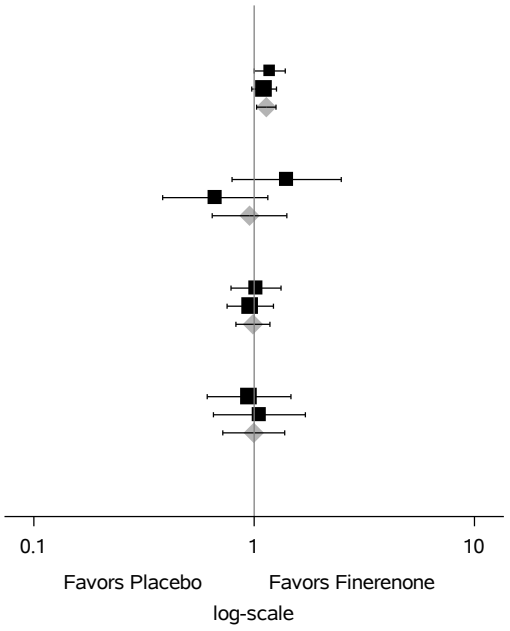
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	182 / 788	164 / 778	37.9	1.12 [0.89,1.43]	
FIGARO-DKD	295 / 1187	290 / 1197	62.1	1.03 [0.86,1.25]	
Total	477 / 1975	454 / 1975		1.07 [0.92,1.24]	Z=0.87, p=0.3834
Heterogeneity:	Q=0.29 (df=1)	p=0.5894	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	418 / 1900	384 / 1922	43.4	1.13 [0.97,1.32]	
FIGARO-DKD	545 / 2392	521 / 2355	56.6	1.04 [0.91,1.19]	
Total	963 / 4292	905 / 4277		1.08 [0.97,1.19]	Z=1.42, p=0.1553
Heterogeneity:	Q=0.63 (df=1)	p=0.4268	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 142	23 / 139	53.3	1.24 [0.67,2.28]	
FIGARO-DKD	27 / 107	20 / 114	46.7	1.59 [0.83,3.04]	
Total	55 / 249	43 / 253		1.39 [0.89,2.17]	Z=1.46, p=0.1455
Heterogeneity:	Q=0.30 (df=1)	p=0.5866	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.27 (df=2)	p=0.5311	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.8.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set

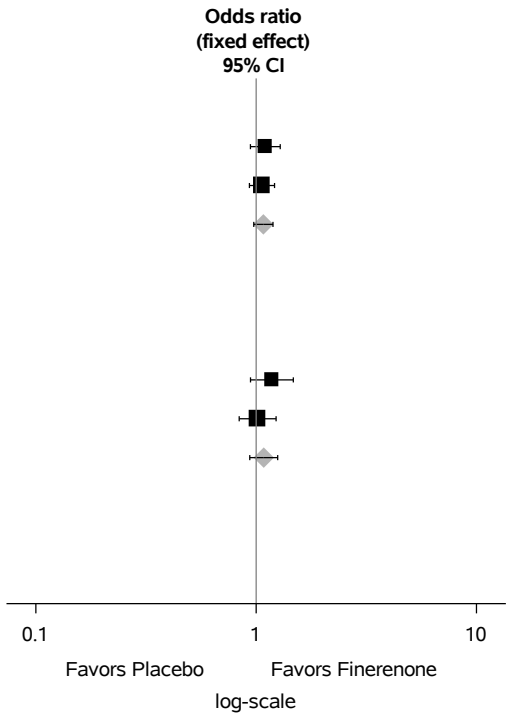
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	390 / 1777	350 / 1815	38.9	1.18 [1.00,1.38]	
FIGARO-DKD	627 / 2672	564 / 2605	61.1	1.11 [0.98,1.26]	
Total	1017 / 4449	914 / 4420		1.14 [1.03,1.26]	Z=2.46, p=0.0138
Heterogeneity:	Q=0.31 (df=1)	p=0.5768	I^2=0.0%		
Black					
FIDELIO-DKD	38 / 140	26 / 124	48.1	1.40 [0.79,2.48]	
FIGARO-DKD	28 / 113	48 / 145	51.9	0.67 [0.38,1.15]	
Total	66 / 253	74 / 269		0.95 [0.64,1.41]	Z=-0.24, p=0.8073
Heterogeneity:	Q=3.41 (df=1)	p=0.0648	I^2=70.7%		
Asian					
FIDELIO-DKD	140 / 717	139 / 723	46.2	1.02 [0.78,1.32]	
FIGARO-DKD	166 / 715	177 / 739	53.8	0.96 [0.75,1.22]	
Total	306 / 1432	316 / 1462		0.99 [0.83,1.18]	Z=-0.14, p=0.8856
Heterogeneity:	Q=0.11 (df=1)	p=0.7415	I^2=0.0%		
Others					
FIDELIO-DKD	60 / 199	56 / 179	54.7	0.95 [0.61,1.47]	
FIGARO-DKD	46 / 186	42 / 177	45.3	1.06 [0.65,1.71]	
Total	106 / 385	98 / 356		1.00 [0.72,1.38]	Z=-0.03, p=0.9790
Heterogeneity:	Q=0.11 (df=1)	p=0.7449	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.56 (df=3)	p=0.4645	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.8.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set

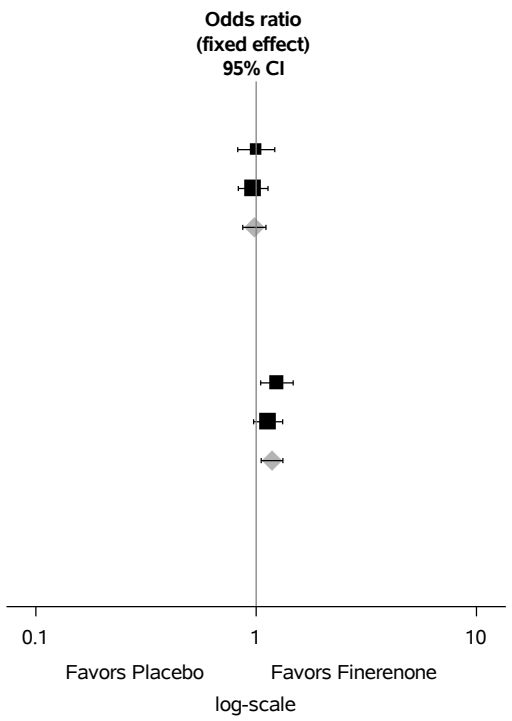
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	403 / 1953	388 / 2030	41.6	1.10 [0.94,1.29]	
FIGARO-DKD	583 / 2528	567 / 2577	58.4	1.06 [0.93,1.21]	
Total	986 / 4481	955 / 4607		1.08 [0.98,1.19]	Z=1.47, p=0.1421
Heterogeneity:	Q=0.11 (df=1)	p=0.7371	I^2=0.0%		
Female					
FIDELIO-DKD	225 / 880	183 / 811	42.6	1.18 [0.94,1.47]	
FIGARO-DKD	284 / 1158	264 / 1089	57.4	1.02 [0.84,1.23]	
Total	509 / 2038	447 / 1900		1.08 [0.94,1.25]	Z=1.06, p=0.2888
Heterogeneity:	Q=0.98 (df=1)	p=0.3220	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9667	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.8.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set

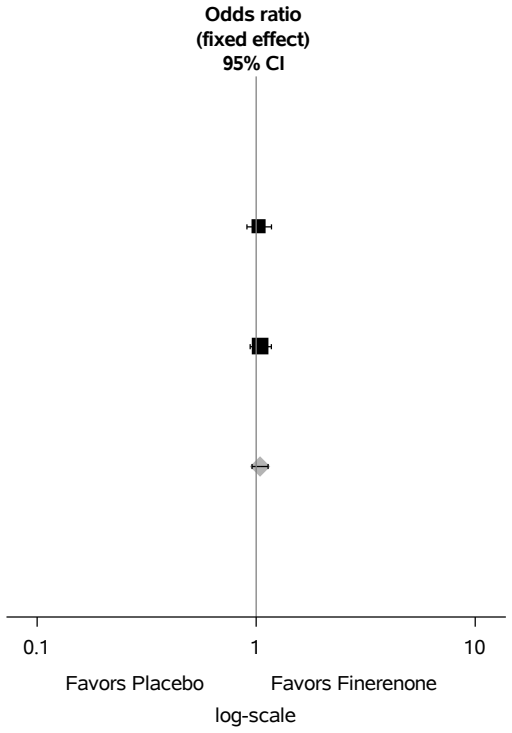
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	267 / 1205	260 / 1174	39.1	1.00 [0.82,1.21]	
FIGARO-DKD	414 / 1753	425 / 1757	60.9	0.97 [0.83,1.13]	
Total	681 / 2958	685 / 2931		0.98 [0.87,1.11]	Z=-0.31, p=0.7596
Heterogeneity:	Q=0.06 (df=1)	p=0.7997	I^2=0.0%		
>= 65					
FIDELIO-DKD	361 / 1628	311 / 1667	44.5	1.24 [1.05,1.47]	
FIGARO-DKD	453 / 1933	406 / 1909	55.5	1.13 [0.97,1.32]	
Total	814 / 3561	717 / 3576		1.18 [1.05,1.32]	Z=2.87, p=0.0041
Heterogeneity:	Q=0.63 (df=1)	p=0.4288	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.77 (df=1)	p=0.0289	I^2=79.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set

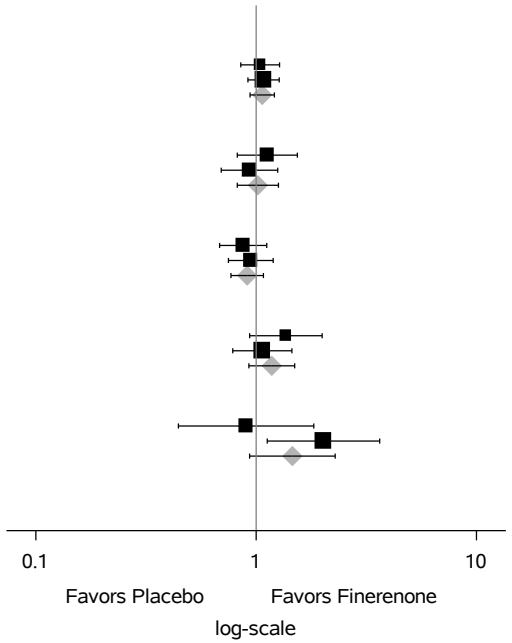
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	587 / 2833	574 / 2841	42.7	1.03 [0.91,1.17]	
FIGARO-DKD	809 / 3686	775 / 3666	57.3	1.05 [0.94,1.17]	
Total	1396 / 6519	1349 / 6507		1.04 [0.96,1.13]	Z=0.95, p=0.3415
Heterogeneity:	Q=0.04 (df=1)	p=0.8504	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.9.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set

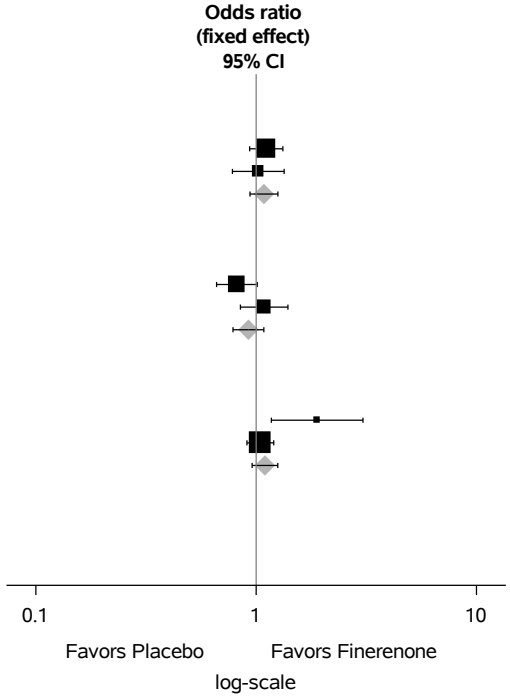
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	238 / 1182	229 / 1176	39.5	1.04 [0.85,1.28]	
FIGARO-DKD	374 / 1754	351 / 1750	60.5	1.08 [0.92,1.27]	
Total	612 / 2936	580 / 2926		1.07 [0.94,1.21]	Z=0.97, p=0.3306
Heterogeneity:	Q=0.07 (df=1)	p=0.7897	I^2=0.0%		
North America					
FIDELIO-DKD	102 / 467	95 / 477	46.9	1.12 [0.82,1.54]	
FIGARO-DKD	108 / 559	112 / 548	53.1	0.93 [0.69,1.25]	
Total	210 / 1026	207 / 1025		1.02 [0.82,1.26]	Z=0.16, p=0.8735
Heterogeneity:	Q=0.72 (df=1)	p=0.3957	I^2=0.0%		
Asia					
FIDELIO-DKD	150 / 790	167 / 789	47.4	0.87 [0.68,1.12]	
FIGARO-DKD	176 / 810	185 / 815	52.6	0.95 [0.75,1.19]	
Total	326 / 1600	352 / 1604		0.91 [0.77,1.08]	Z=-1.09, p=0.2778
Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		
Latin America					
FIDELIO-DKD	79 / 295	63 / 298	39.9	1.36 [0.93,1.99]	
FIGARO-DKD	112 / 424	105 / 417	60.1	1.07 [0.78,1.45]	
Total	191 / 719	168 / 715		1.18 [0.93,1.50]	Z=1.34, p=0.1818
Heterogeneity:	Q=0.97 (df=1)	p=0.3241	I^2=0.0%		
Others					
FIDELIO-DKD	18 / 99	20 / 101	40.8	0.90 [0.44,1.83]	
FIGARO-DKD	39 / 139	22 / 136	59.2	2.02 [1.12,3.64]	
Total	57 / 238	42 / 237		1.46 [0.93,2.28]	Z=1.66, p=0.0972
Heterogeneity:	Q=2.97 (df=1)	p=0.0847	I^2=66.4%		
Subgroup Heterogeneity:	Q=5.78 (df=4)	p=0.2163	I^2=30.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

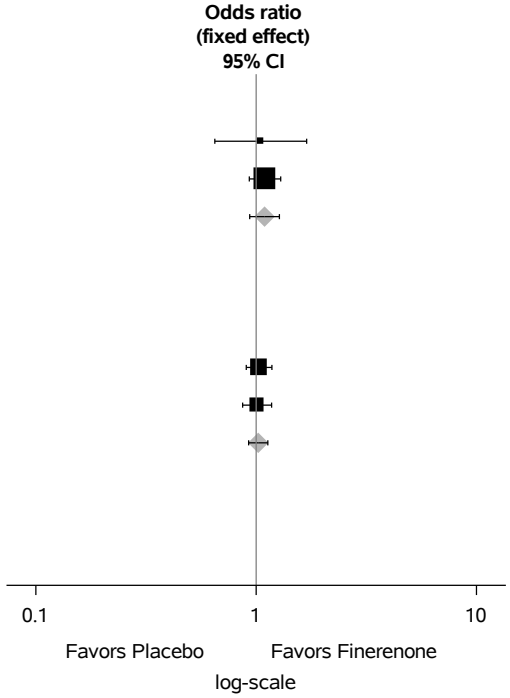
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	337 / 1559	308 / 1549	70.8	1.11 [0.93,1.32]	
FIGARO-DKD	135 / 639	131 / 631	29.2	1.02 [0.78,1.34]	
Total	472 / 2198	439 / 2180		1.08 [0.94,1.26]	Z=1.09, p=0.2762
Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	196 / 1063	232 / 1071	57.7	0.82 [0.66,1.01]	
FIGARO-DKD	164 / 720	156 / 731	42.3	1.09 [0.85,1.39]	
Total	360 / 1783	388 / 1802		0.92 [0.78,1.08]	Z=-0.99, p=0.3244
Heterogeneity:	Q=2.92 (df=1)	p=0.0873	I^2=65.8%		
>= 60					
FIDELIO-DKD	54 / 211	34 / 221	7.9	1.89 [1.17,3.05]	
FIGARO-DKD	510 / 2327	488 / 2304	92.1	1.04 [0.91,1.20]	
Total	564 / 2538	522 / 2525		1.10 [0.96,1.25]	Z=1.34, p=0.1809
Heterogeneity:	Q=5.45 (df=1)	p=0.0196	I^2=81.6%		
Subgroup Heterogeneity:	Q=3.04 (df=2)	p=0.2189	I^2=34.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set

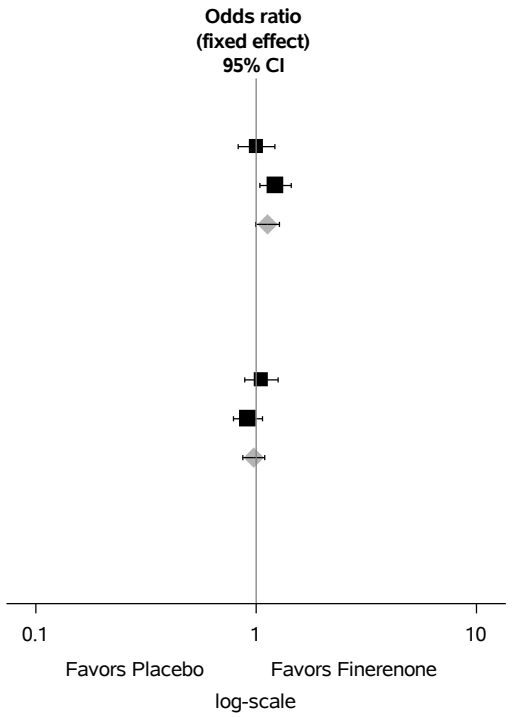
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 210	41 / 213	10.5	1.05 [0.65,1.69]	
FIGARO-DKD	378 / 1722	348 / 1705	89.5	1.10 [0.93,1.29]	
Total	420 / 1932	389 / 1918		1.09 [0.93,1.27]	Z=1.11, p=0.2683
Heterogeneity:	Q=0.03 (df=1)	p=0.8629	I^2=0.0%		
Very High					
FIDELIO-DKD	545 / 2623	533 / 2628	56.1	1.03 [0.90,1.18]	
FIGARO-DKD	431 / 1964	427 / 1961	43.9	1.01 [0.87,1.18]	
Total	976 / 4587	960 / 4589		1.02 [0.92,1.13]	Z=0.42, p=0.6753
Heterogeneity:	Q=0.04 (df=1)	p=0.8429	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.49 (df=1)	p=0.4825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set

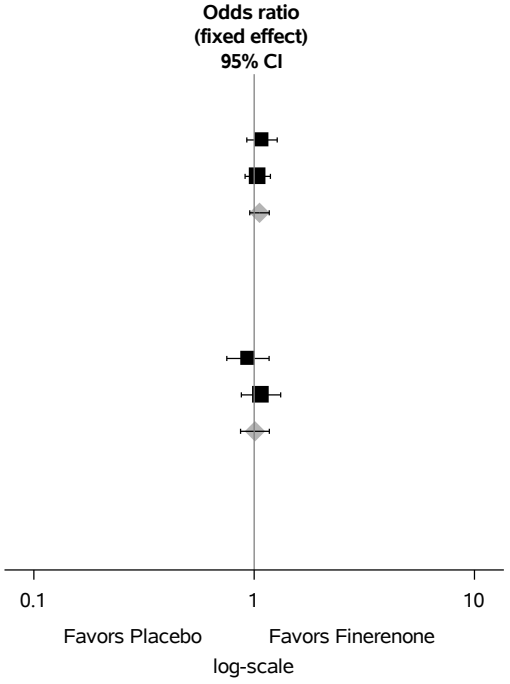
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	262 / 1303	261 / 1302	42.2	1.00 [0.83,1.22]	
FIGARO-DKD	401 / 1676	338 / 1654	57.8	1.22 [1.04,1.44]	
Total	663 / 2979	599 / 2956		1.13 [0.99,1.28]	Z=1.87, p=0.0616
Heterogeneity:	Q=2.38 (df=1)	p=0.1226	I^2=58.1%		
Absent					
FIDELIO-DKD	325 / 1530	313 / 1539	43.1	1.06 [0.89,1.26]	
FIGARO-DKD	408 / 2010	437 / 2012	56.9	0.92 [0.79,1.07]	
Total	733 / 3540	750 / 3551		0.98 [0.87,1.09]	Z=-0.43, p=0.6676
Heterogeneity:	Q=1.42 (df=1)	p=0.2334	I^2=29.6%		
Subgroup Heterogeneity:	Q=2.78 (df=1)	p=0.0956	I^2=64.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

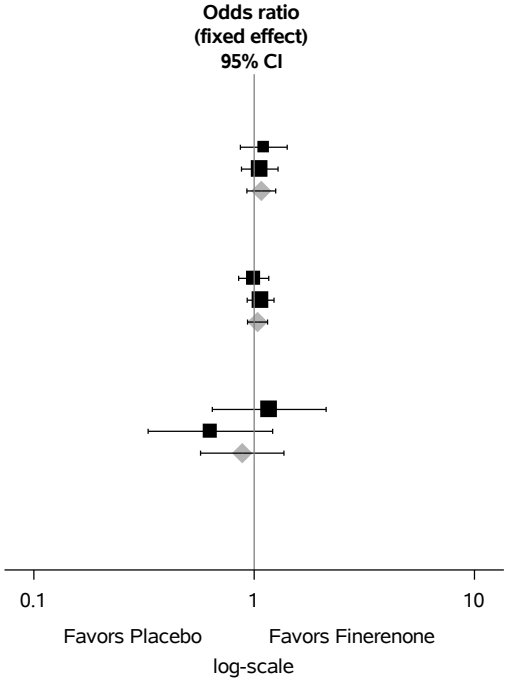
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	397 / 1881	368 / 1861	40.9	1.09 [0.93,1.27]	
FIGARO-DKD	569 / 2643	546 / 2612	59.1	1.04 [0.91,1.18]	
Total	966 / 4524	914 / 4473		1.06 [0.95,1.17]	Z=1.07, p=0.2838
Heterogeneity:	Q=0.18 (df=1)	p=0.6732	I^2=0.0%		
> 4.5					
FIDELIO-DKD	190 / 951	206 / 979	46.4	0.94 [0.75,1.17]	
FIGARO-DKD	240 / 1043	229 / 1052	53.6	1.07 [0.87,1.32]	
Total	430 / 1994	435 / 2031		1.01 [0.87,1.17]	Z=0.11, p=0.9156
Heterogeneity:	Q=0.79 (df=1)	p=0.3747	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6084	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.9.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

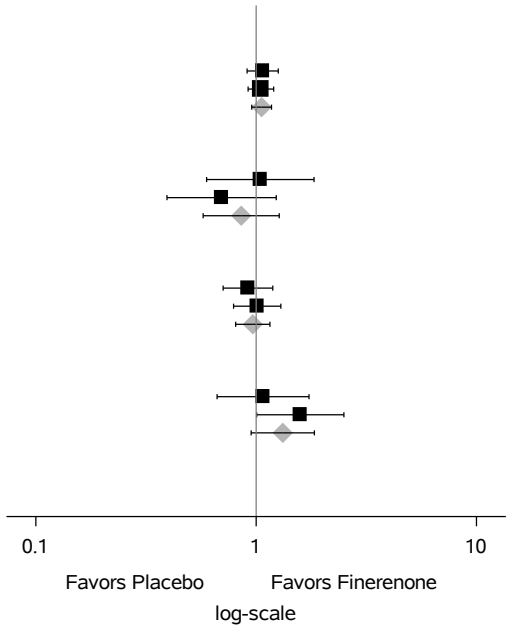
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	170 / 788	155 / 778	37.9	1.11 [0.87,1.41]	
FIGARO-DKD	278 / 1187	268 / 1197	62.1	1.06 [0.88,1.28]	
Total	448 / 1975	423 / 1975		1.08 [0.93,1.25]	Z=0.97, p=0.3331
Heterogeneity:	Q=0.07 (df=1)	p=0.7906	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	388 / 1900	394 / 1922	44.3	1.00 [0.85,1.16]	
FIGARO-DKD	512 / 2392	478 / 2355	55.7	1.07 [0.93,1.23]	
Total	900 / 4292	872 / 4277		1.04 [0.93,1.15]	Z=0.66, p=0.5086
Heterogeneity:	Q=0.45 (df=1)	p=0.5031	I^2=0.0%		
>= 160					
FIDELIO-DKD	29 / 142	25 / 139	54.5	1.17 [0.65,2.12]	
FIGARO-DKD	19 / 107	29 / 114	45.5	0.63 [0.33,1.21]	
Total	48 / 249	54 / 253		0.88 [0.57,1.36]	Z=-0.56, p=0.5748
Heterogeneity:	Q=1.87 (df=1)	p=0.1717	I^2=46.5%		
Subgroup Heterogeneity:	Q=0.76 (df=2)	p=0.6854	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.9.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set

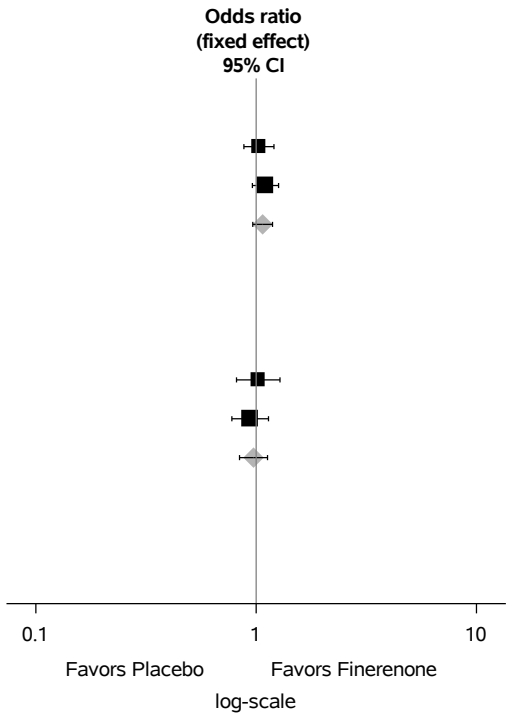
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	368 / 1777	356 / 1815	40.2	1.07 [0.91,1.26]	
FIGARO-DKD	560 / 2672	525 / 2605	59.8	1.05 [0.92,1.20]	
Total	928 / 4449	881 / 4420		1.06 [0.95,1.17]	Z=1.08, p=0.2813
Heterogeneity:	Q=0.03 (df=1)	p=0.8616	I^2=0.0%		
Black					
FIDELIO-DKD	35 / 140	30 / 124	50.8	1.04 [0.60,1.83]	
FIGARO-DKD	25 / 113	42 / 145	49.2	0.70 [0.39,1.23]	
Total	60 / 253	72 / 269		0.86 [0.57,1.27]	Z=-0.77, p=0.4403
Heterogeneity:	Q=0.98 (df=1)	p=0.3217	I^2=0.0%		
Asian					
FIDELIO-DKD	137 / 717	148 / 723	47.6	0.92 [0.71,1.19]	
FIGARO-DKD	160 / 715	164 / 739	52.4	1.01 [0.79,1.29]	
Total	297 / 1432	312 / 1462		0.97 [0.81,1.15]	Z=-0.39, p=0.6993
Heterogeneity:	Q=0.28 (df=1)	p=0.5972	I^2=0.0%		
Others					
FIDELIO-DKD	47 / 199	40 / 179	47.4	1.07 [0.66,1.74]	
FIGARO-DKD	64 / 186	44 / 177	52.6	1.59 [1.01,2.50]	
Total	111 / 385	84 / 356		1.32 [0.95,1.84]	Z=1.65, p=0.0991
Heterogeneity:	Q=1.33 (df=1)	p=0.2493	I^2=24.7%		
Subgroup Heterogeneity:	Q=3.71 (df=3)	p=0.2943	I^2=19.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.9.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set

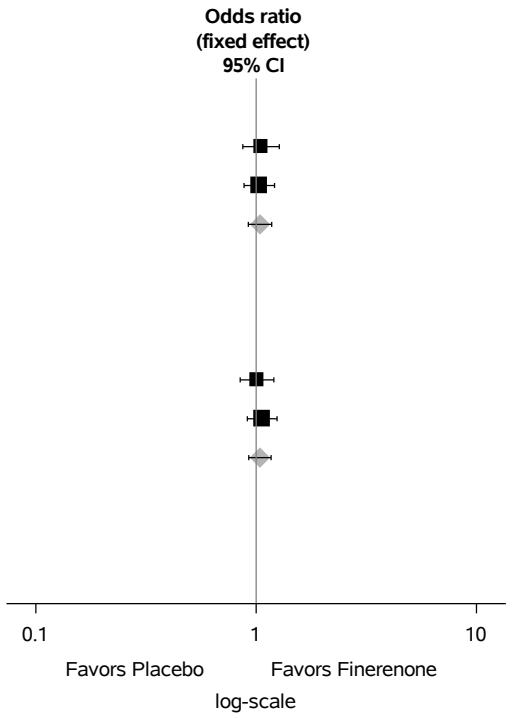
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	384 / 1953	390 / 2030	43.2	1.03 [0.88,1.20]	
FIGARO-DKD	528 / 2528	498 / 2577	56.8	1.10 [0.96,1.26]	
Total	912 / 4481	888 / 4607		1.07 [0.97,1.19]	Z=1.28, p=0.1989
Heterogeneity:	Q=0.42 (df=1)	p=0.5194	I^2=0.0%		
Female					
FIDELIO-DKD	203 / 880	184 / 811	41.5	1.02 [0.81,1.28]	
FIGARO-DKD	281 / 1158	277 / 1089	58.5	0.94 [0.78,1.14]	
Total	484 / 2038	461 / 1900		0.97 [0.84,1.13]	Z=-0.37, p=0.7109
Heterogeneity:	Q=0.31 (df=1)	p=0.5785	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.09 (df=1)	p=0.2968	I^2=8.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.9.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set

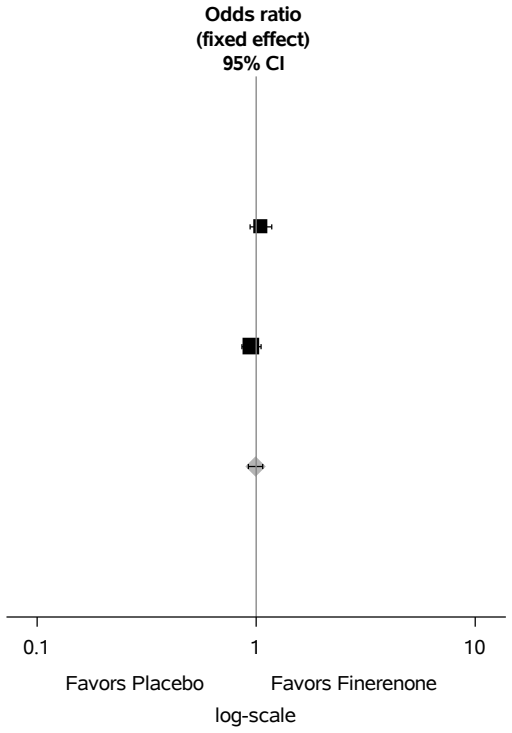
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	285 / 1205	267 / 1174	41.1	1.05 [0.87,1.27]	
FIGARO-DKD	394 / 1753	385 / 1757	58.9	1.03 [0.88,1.21]	
Total	679 / 2958	652 / 2931		1.04 [0.92,1.18]	Z=0.64, p=0.5190
Heterogeneity:	Q=0.02 (df=1)	p=0.8846	I^2=0.0%		
>= 65					
FIDELIO-DKD	302 / 1628	307 / 1667	43.8	1.01 [0.85,1.20]	
FIGARO-DKD	415 / 1933	390 / 1909	56.2	1.06 [0.91,1.24]	
Total	717 / 3561	697 / 3576		1.04 [0.93,1.17]	Z=0.66, p=0.5099
Heterogeneity:	Q=0.20 (df=1)	p=0.6528	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9905	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set

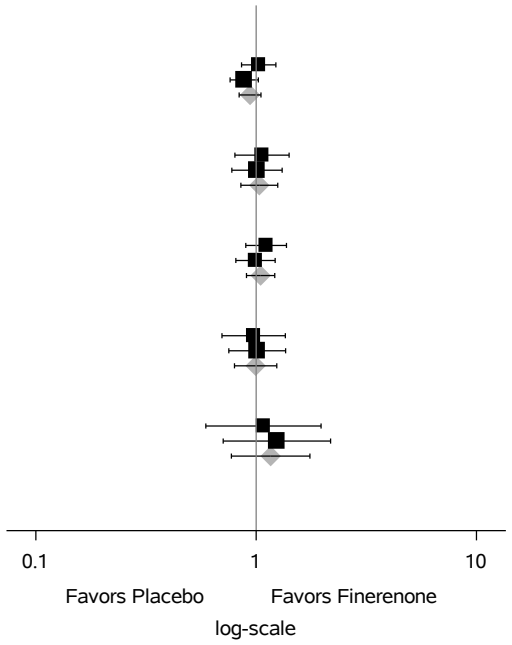
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	871 / 2833	844 / 2841	44.0	1.05 [0.94,1.18]	
FIGARO-DKD	1059 / 3686	1092 / 3666	56.0	0.95 [0.86,1.05]	
Total	1930 / 6519	1936 / 6507		0.99 [0.92,1.07]	Z=-0.17, p=0.8626
Heterogeneity:	Q=1.64 (df=1)	p=0.2005	I^2=39.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.10.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set

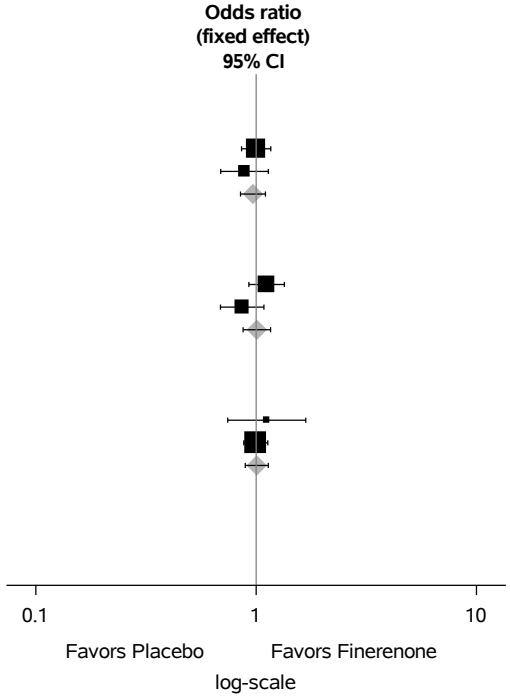
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	336 / 1182	328 / 1176	40.3	1.03 [0.86,1.23]	
FIGARO-DKD	469 / 1754	512 / 1750	59.7	0.88 [0.76,1.02]	
Total	805 / 2936	840 / 2926		0.94 [0.84,1.05]	Z=-1.10, p=0.2718
Heterogeneity:	Q=1.63 (df=1)	p=0.2015	I^2=38.7%		
North America					
FIDELIO-DKD	135 / 467	132 / 477	46.3	1.06 [0.80,1.41]	
FIGARO-DKD	156 / 559	152 / 548	53.7	1.01 [0.78,1.31]	
Total	291 / 1026	284 / 1025		1.03 [0.85,1.25]	Z=0.33, p=0.7393
Heterogeneity:	Q=0.07 (df=1)	p=0.7903	I^2=0.0%		
Asia					
FIDELIO-DKD	257 / 790	239 / 789	48.3	1.11 [0.90,1.37]	
FIGARO-DKD	274 / 810	277 / 815	51.7	0.99 [0.81,1.22]	
Total	531 / 1600	516 / 1604		1.05 [0.90,1.21]	Z=0.62, p=0.5371
Heterogeneity:	Q=0.54 (df=1)	p=0.4611	I^2=0.0%		
Latin America					
FIDELIO-DKD	112 / 295	115 / 298	44.5	0.97 [0.70,1.36]	
FIGARO-DKD	125 / 424	122 / 417	55.5	1.01 [0.75,1.36]	
Total	237 / 719	237 / 715		0.99 [0.80,1.24]	Z=-0.05, p=0.9592
Heterogeneity:	Q=0.03 (df=1)	p=0.8696	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 99	30 / 101	46.5	1.08 [0.59,1.97]	
FIGARO-DKD	35 / 139	29 / 136	53.5	1.24 [0.71,2.18]	
Total	66 / 238	59 / 237		1.16 [0.77,1.75]	Z=0.72, p=0.4701
Heterogeneity:	Q=0.11 (df=1)	p=0.7379	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.20 (df=4)	p=0.6997	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

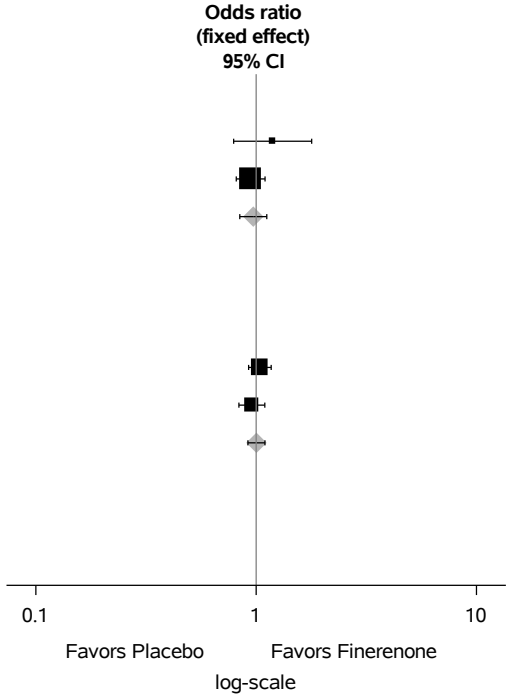
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	474 / 1559	471 / 1549	72.6	1.00 [0.86,1.17]	
FIGARO-DKD	163 / 639	176 / 631	27.4	0.89 [0.69,1.14]	
Total	637 / 2198	647 / 2180		0.97 [0.85,1.10]	Z=-0.50, p=0.6142
Heterogeneity:	Q=0.67 (df=1)	p=0.4139	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	329 / 1063	307 / 1071	59.9	1.12 [0.93,1.34]	
FIGARO-DKD	198 / 720	223 / 731	40.1	0.86 [0.69,1.08]	
Total	527 / 1783	530 / 1802		1.01 [0.87,1.16]	Z=0.09, p=0.9248
Heterogeneity:	Q=2.91 (df=1)	p=0.0879	I^2=65.7%		
>= 60					
FIDELIO-DKD	68 / 211	66 / 221	8.7	1.12 [0.74,1.68]	
FIGARO-DKD	698 / 2327	693 / 2304	91.3	1.00 [0.88,1.13]	
Total	766 / 2538	759 / 2525		1.01 [0.89,1.13]	Z=0.10, p=0.9221
Heterogeneity:	Q=0.28 (df=1)	p=0.5995	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=2)	p=0.8869	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

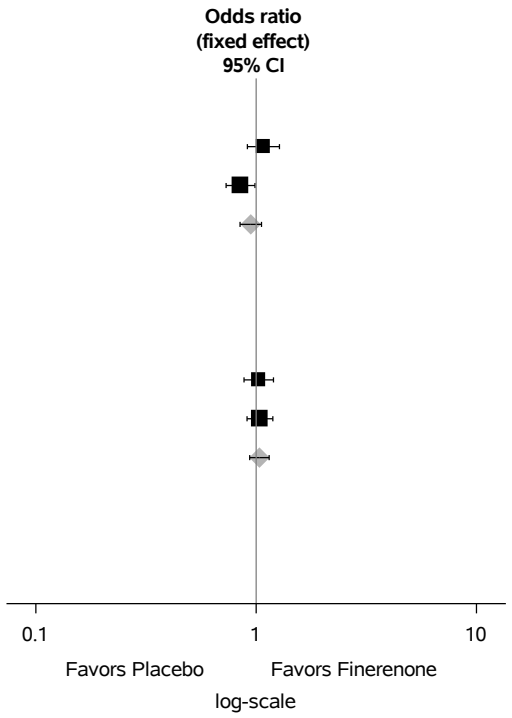
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	72 / 210	65 / 213	12.0	1.19 [0.79,1.79]	
FIGARO-DKD	460 / 1722	475 / 1705	88.0	0.94 [0.81,1.10]	
Total	532 / 1932	540 / 1918		0.97 [0.84,1.12]	Z=-0.42, p=0.6747
Heterogeneity:	Q=1.08 (df=1)	p=0.2996	I^2=7.1%		
Very High					
FIDELIO-DKD	799 / 2623	779 / 2628	56.8	1.04 [0.92,1.17]	
FIGARO-DKD	599 / 1964	617 / 1961	43.2	0.96 [0.83,1.09]	
Total	1398 / 4587	1396 / 4589		1.00 [0.92,1.10]	Z=0.06, p=0.9535
Heterogeneity:	Q=0.84 (df=1)	p=0.3587	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.6994	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set

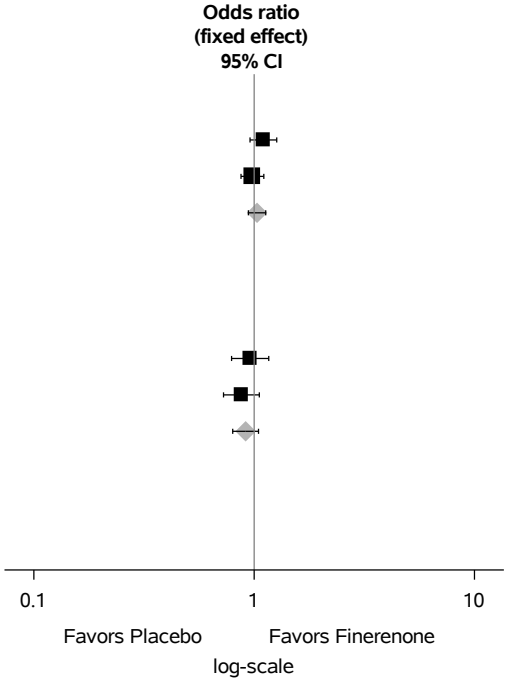
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	402 / 1303	381 / 1302	44.8	1.08 [0.91,1.28]	
FIGARO-DKD	448 / 1676	497 / 1654	55.2	0.85 [0.73,0.99]	
Total	850 / 2979	878 / 2956		0.95 [0.84,1.06]	Z=-0.99, p=0.3236
Heterogeneity:	Q=4.32 (df=1)	p=0.0378	I^2=76.8%		
Absent					
FIDELIO-DKD	469 / 1530	463 / 1539	43.5	1.03 [0.88,1.20]	
FIGARO-DKD	611 / 2010	595 / 2012	56.5	1.04 [0.91,1.19]	
Total	1080 / 3540	1058 / 3551		1.03 [0.93,1.14]	Z=0.66, p=0.5121
Heterogeneity:	Q=0.01 (df=1)	p=0.9054	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2413	I^2=27.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

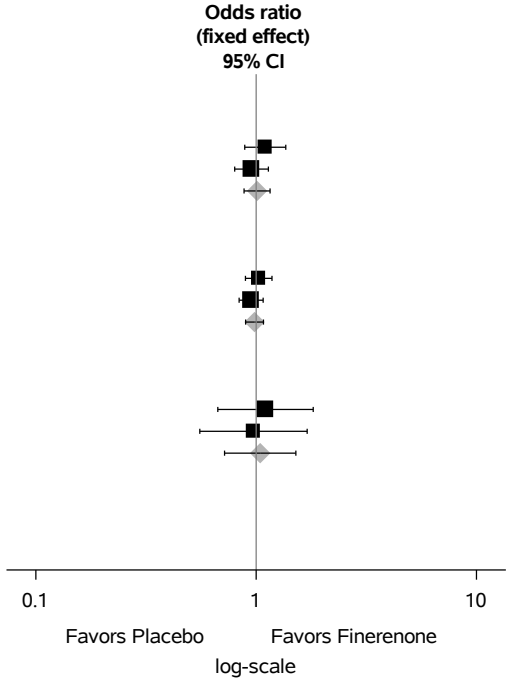
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	588 / 1881	544 / 1861	42.2	1.10 [0.96,1.27]	
FIGARO-DKD	761 / 2643	762 / 2612	57.8	0.98 [0.87,1.11]	
Total	1349 / 4524	1306 / 4473		1.03 [0.94,1.13]	Z=0.65, p=0.5180
Heterogeneity:	Q=1.50 (df=1)	p=0.2209	I^2=33.3%		
> 4.5					
FIDELIO-DKD	283 / 951	300 / 979	48.1	0.96 [0.79,1.16]	
FIGARO-DKD	298 / 1043	330 / 1052	51.9	0.88 [0.73,1.06]	
Total	581 / 1994	630 / 2031		0.91 [0.80,1.05]	Z=-1.30, p=0.1934
Heterogeneity:	Q=0.44 (df=1)	p=0.5069	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.07 (df=1)	p=0.1499	I^2=51.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.10.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

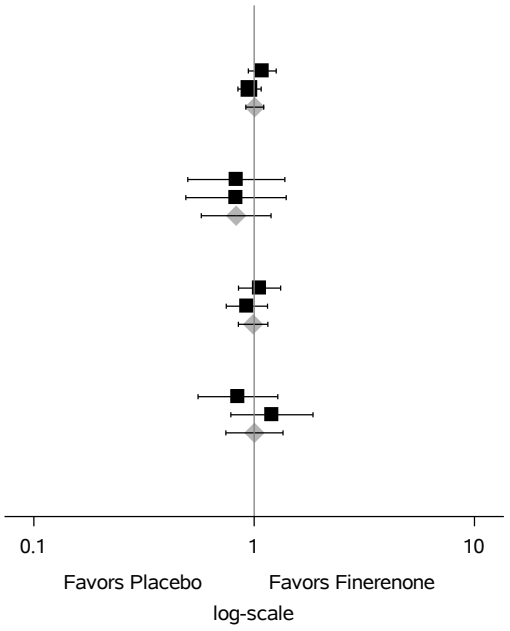
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	252 / 788	233 / 778	40.3	1.10 [0.89,1.36]	
FIGARO-DKD	345 / 1187	360 / 1197	59.7	0.95 [0.80,1.14]	
Total	597 / 1975	593 / 1975		1.01 [0.88,1.16]	Z=0.13, p=0.8935
Heterogeneity:	Q=1.03 (df=1)	p=0.3103	I^2=2.9%		
130 - < 160					
FIDELIO-DKD	571 / 1900	567 / 1922	45.0	1.03 [0.89,1.18]	
FIGARO-DKD	679 / 2392	694 / 2355	55.0	0.95 [0.84,1.08]	
Total	1250 / 4292	1261 / 4277		0.98 [0.90,1.08]	Z=-0.36, p=0.7191
Heterogeneity:	Q=0.69 (df=1)	p=0.4072	I^2=0.0%		
>= 160					
FIDELIO-DKD	48 / 142	44 / 139	55.9	1.10 [0.67,1.82]	
FIGARO-DKD	35 / 107	38 / 114	44.1	0.97 [0.55,1.70]	
Total	83 / 249	82 / 253		1.04 [0.72,1.51]	Z=0.22, p=0.8248
Heterogeneity:	Q=0.11 (df=1)	p=0.7426	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=2)	p=0.9200	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.10.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set

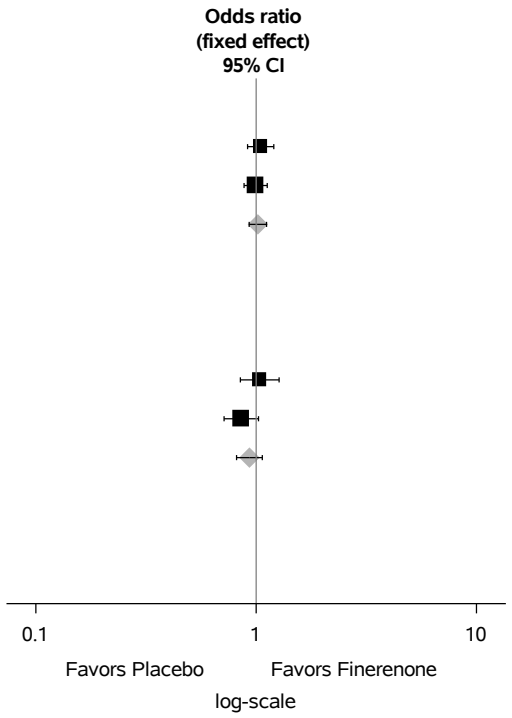
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	515 / 1777	495 / 1815	41.1	1.09 [0.94,1.26]	
FIGARO-DKD	709 / 2672	716 / 2605	58.9	0.95 [0.84,1.08]	
Total	1224 / 4449	1211 / 4420		1.01 [0.92,1.10]	Z=0.13, p=0.8941
Heterogeneity:	Q=1.88 (df=1)	p=0.1698	I^2=46.9%		
Black					
FIDELIO-DKD	46 / 140	46 / 124	51.7	0.83 [0.50,1.38]	
FIGARO-DKD	35 / 113	51 / 145	48.3	0.83 [0.49,1.40]	
Total	81 / 253	97 / 269		0.83 [0.58,1.19]	Z=-1.01, p=0.3117
Heterogeneity:	Q=0.00 (df=1)	p=0.9929	I^2=0.0%		
Asian					
FIDELIO-DKD	239 / 717	232 / 723	49.0	1.06 [0.85,1.32]	
FIGARO-DKD	244 / 715	265 / 739	51.0	0.93 [0.75,1.15]	
Total	483 / 1432	497 / 1462		0.99 [0.85,1.15]	Z=-0.14, p=0.8864
Heterogeneity:	Q=0.71 (df=1)	p=0.3985	I^2=0.0%		
Others					
FIDELIO-DKD	71 / 199	71 / 179	51.5	0.84 [0.56,1.28]	
FIGARO-DKD	71 / 186	60 / 177	48.5	1.20 [0.78,1.85]	
Total	142 / 385	131 / 356		1.00 [0.74,1.35]	Z=0.02, p=0.9855
Heterogeneity:	Q=1.36 (df=1)	p=0.2443	I^2=26.2%		
Subgroup Heterogeneity:	Q=1.03 (df=3)	p=0.7930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.10.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set

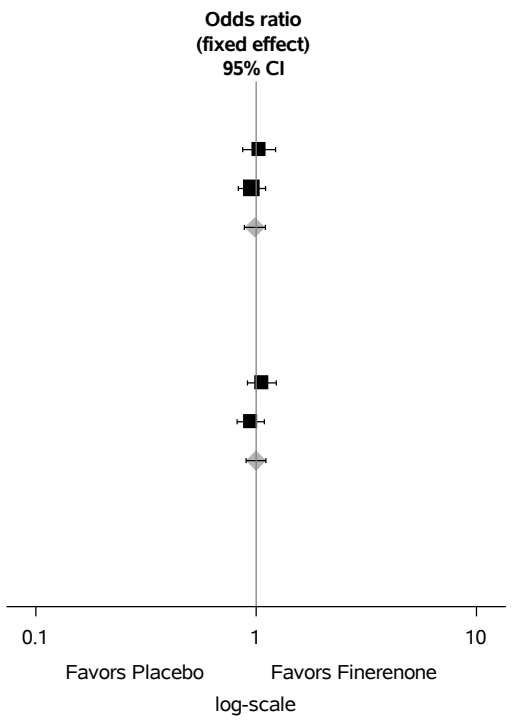
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	574 / 1953	577 / 2030	43.9	1.05 [0.91,1.20]	
FIGARO-DKD	726 / 2528	743 / 2577	56.1	0.99 [0.88,1.12]	
Total	1300 / 4481	1320 / 4607		1.02 [0.93,1.11]	Z=0.38, p=0.7049
Heterogeneity:	Q=0.32 (df=1)	p=0.5730	I^2=0.0%		
Female					
FIDELIO-DKD	297 / 880	267 / 811	44.2	1.04 [0.85,1.27]	
FIGARO-DKD	333 / 1158	349 / 1089	55.8	0.86 [0.71,1.02]	
Total	630 / 2038	616 / 1900		0.93 [0.81,1.07]	Z=-1.03, p=0.3042
Heterogeneity:	Q=1.95 (df=1)	p=0.1627	I^2=48.7%		
Subgroup Heterogeneity:	Q=1.13 (df=1)	p=0.2876	I^2=11.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.10.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set

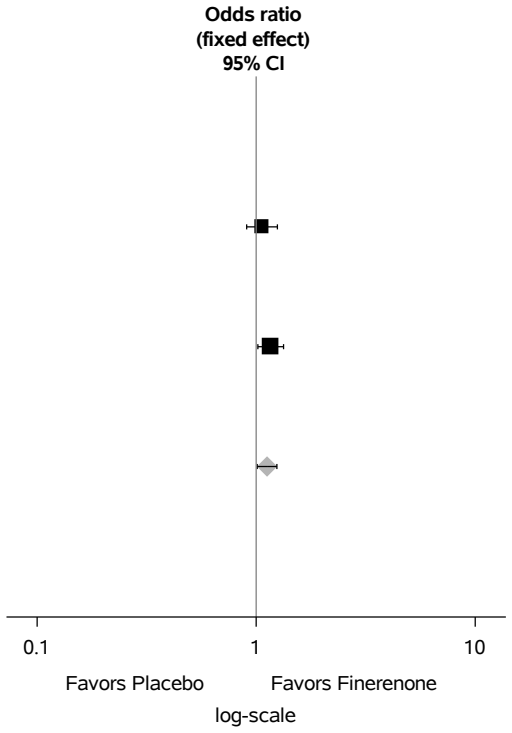
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	392 / 1205	374 / 1174	40.6	1.03 [0.87,1.22]	
FIGARO-DKD	545 / 1753	563 / 1757	59.4	0.96 [0.83,1.10]	
Total	937 / 2958	937 / 2931		0.99 [0.88,1.10]	Z=-0.24, p=0.8073
Heterogeneity:	Q=0.43 (df=1)	p=0.5102	I^2=0.0%		
>= 65					
FIDELIO-DKD	479 / 1628	470 / 1667	47.1	1.06 [0.91,1.23]	
FIGARO-DKD	514 / 1933	529 / 1909	52.9	0.94 [0.82,1.09]	
Total	993 / 3561	999 / 3576		1.00 [0.90,1.11]	Z=-0.03, p=0.9730
Heterogeneity:	Q=1.21 (df=1)	p=0.2706	I^2=17.6%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8775	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set

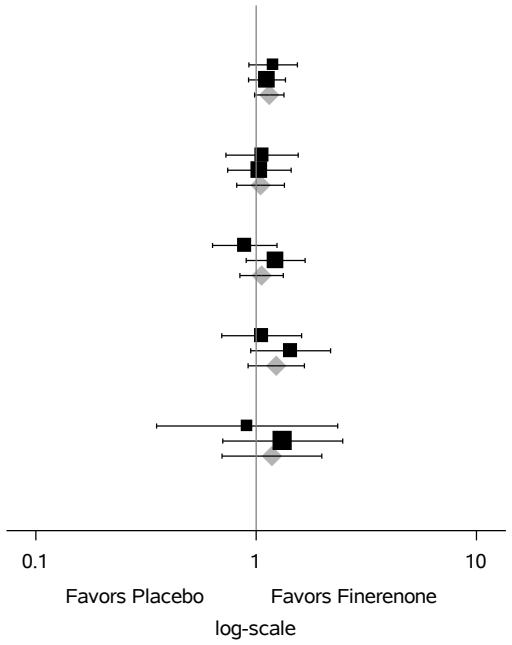
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	345 / 2833	328 / 2841	41.1	1.06 [0.90,1.25]	
FIGARO-DKD	523 / 3686	456 / 3666	58.9	1.17 [1.02,1.33]	
Total	868 / 6519	784 / 6507		1.12 [1.01,1.24]	Z=2.16, p=0.0306
Heterogeneity:	Q=0.72 (df=1)	p=0.3959	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.11.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set

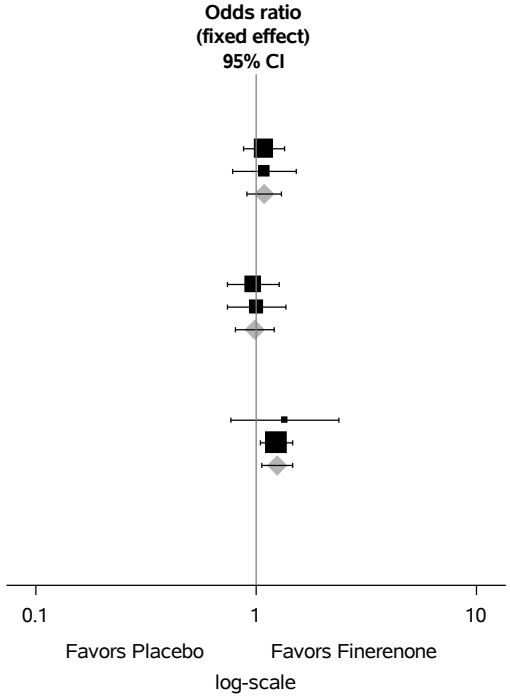
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	147 / 1182	125 / 1176	36.7	1.19 [0.93,1.54]	
FIGARO-DKD	252 / 1754	228 / 1750	63.3	1.12 [0.92,1.36]	
Total	399 / 2936	353 / 2926		1.15 [0.98,1.34]	Z=1.75, p=0.0804
Heterogeneity:	Q=0.16 (df=1)	p=0.6930	I^2=0.0%		
North America					
FIDELIO-DKD	63 / 467	61 / 477	43.5	1.06 [0.73,1.55]	
FIGARO-DKD	84 / 559	80 / 548	56.5	1.03 [0.74,1.44]	
Total	147 / 1026	141 / 1025		1.05 [0.82,1.34]	Z=0.36, p=0.7178
Heterogeneity:	Q=0.01 (df=1)	p=0.9143	I^2=0.0%		
Asia					
FIDELIO-DKD	71 / 790	79 / 789	45.5	0.89 [0.63,1.24]	
FIGARO-DKD	100 / 810	84 / 815	54.5	1.23 [0.90,1.67]	
Total	171 / 1600	163 / 1604		1.06 [0.84,1.33]	Z=0.49, p=0.6242
Heterogeneity:	Q=1.92 (df=1)	p=0.1656	I^2=48.0%		
Latin America					
FIDELIO-DKD	55 / 295	53 / 298	50.0	1.06 [0.70,1.61]	
FIGARO-DKD	60 / 424	43 / 417	50.0	1.43 [0.94,2.18]	
Total	115 / 719	96 / 715		1.23 [0.92,1.66]	Z=1.40, p=0.1626
Heterogeneity:	Q=1.01 (df=1)	p=0.3149	I^2=1.0%		
Others					
FIDELIO-DKD	9 / 99	10 / 101	30.5	0.91 [0.35,2.34]	
FIGARO-DKD	27 / 139	21 / 136	69.5	1.32 [0.71,2.47]	
Total	36 / 238	31 / 237		1.18 [0.70,1.99]	Z=0.62, p=0.5361
Heterogeneity:	Q=0.41 (df=1)	p=0.5206	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.06 (df=4)	p=0.9008	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

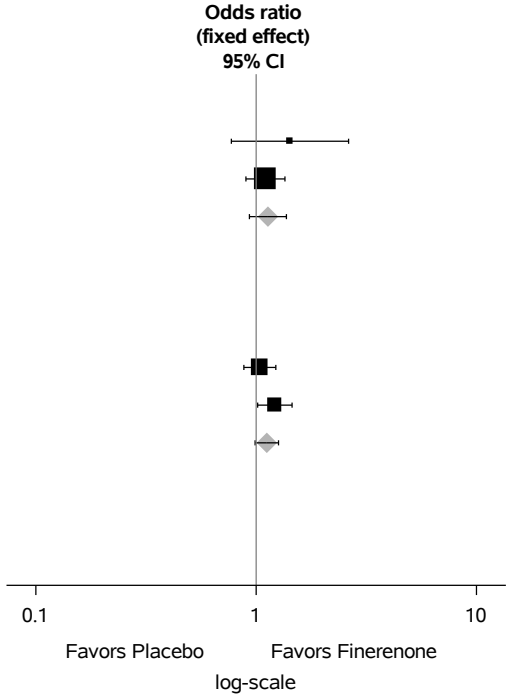
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	198 / 1559	183 / 1549	70.6	1.09 [0.88,1.35]	
FIGARO-DKD	83 / 639	76 / 631	29.4	1.09 [0.78,1.52]	
Total	281 / 2198	259 / 2180		1.09 [0.91,1.30]	Z=0.91, p=0.3636
Heterogeneity:	Q=0.00 (df=1)	p=0.9848	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	116 / 1063	120 / 1071	56.1	0.97 [0.74,1.27]	
FIGARO-DKD	94 / 720	95 / 731	43.9	1.01 [0.74,1.36]	
Total	210 / 1783	215 / 1802		0.99 [0.80,1.21]	Z=-0.14, p=0.8897
Heterogeneity:	Q=0.03 (df=1)	p=0.8668	I^2=0.0%		
>= 60					
FIDELIO-DKD	31 / 211	25 / 221	8.2	1.35 [0.77,2.37]	
FIGARO-DKD	346 / 2327	285 / 2304	91.8	1.24 [1.05,1.46]	
Total	377 / 2538	310 / 2525		1.25 [1.06,1.46]	Z=2.67, p=0.0076
Heterogeneity:	Q=0.08 (df=1)	p=0.7714	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.31 (df=2)	p=0.1913	I^2=39.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

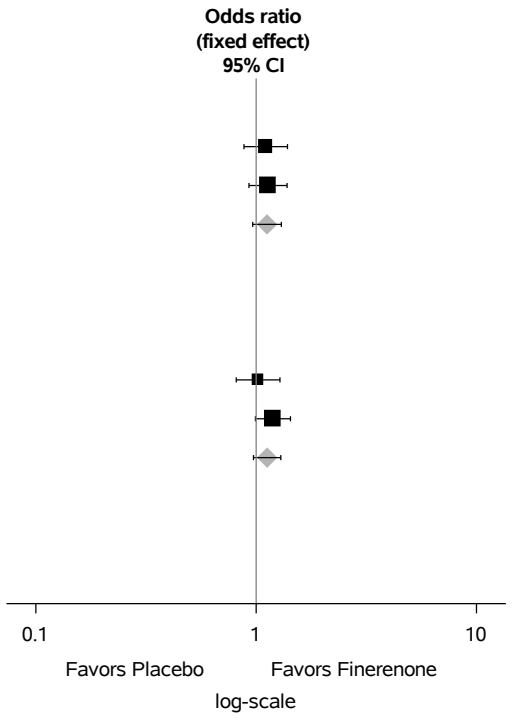
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	27 / 210	20 / 213	10.0	1.42 [0.77,2.63]	
FIGARO-DKD	221 / 1722	201 / 1705	90.0	1.10 [0.90,1.35]	
Total	248 / 1932	221 / 1918		1.13 [0.93,1.37]	Z=1.24, p=0.2138
Heterogeneity:	Q=0.61 (df=1)	p=0.4363	I^2=0.0%		
Very High					
FIDELIO-DKD	318 / 2623	308 / 2628	53.7	1.04 [0.88,1.23]	
FIGARO-DKD	302 / 1964	255 / 1961	46.3	1.22 [1.02,1.46]	
Total	620 / 4587	563 / 4589		1.12 [0.99,1.26]	Z=1.78, p=0.0749
Heterogeneity:	Q=1.57 (df=1)	p=0.2103	I^2=36.3%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9212	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set

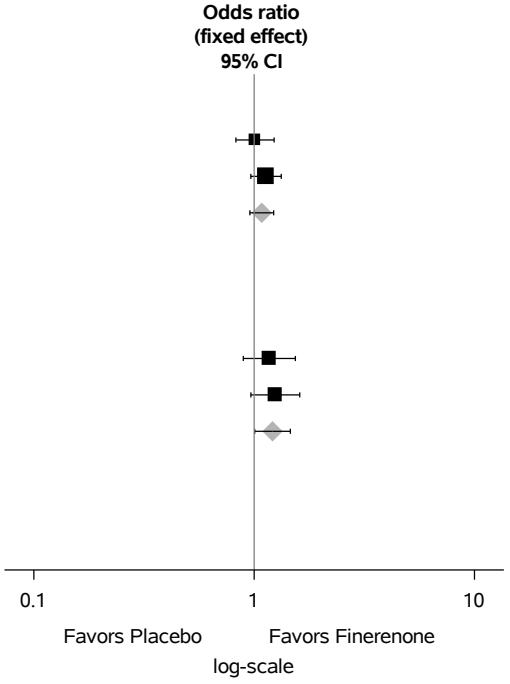
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	179 / 1303	164 / 1302	43.4	1.11 [0.88,1.39]	
FIGARO-DKD	238 / 1676	211 / 1654	56.6	1.13 [0.93,1.38]	
Total	417 / 2979	375 / 2956		1.12 [0.96,1.30]	Z=1.48, p=0.1377
Heterogeneity:	Q=0.02 (df=1)	p=0.8764	I^2=0.0%		
Absent					
FIDELIO-DKD	166 / 1530	164 / 1539	39.1	1.02 [0.81,1.28]	
FIGARO-DKD	285 / 2010	245 / 2012	60.9	1.19 [0.99,1.43]	
Total	451 / 3540	409 / 3551		1.12 [0.97,1.29]	Z=1.57, p=0.1157
Heterogeneity:	Q=1.08 (df=1)	p=0.2991	I^2=7.3%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9911	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

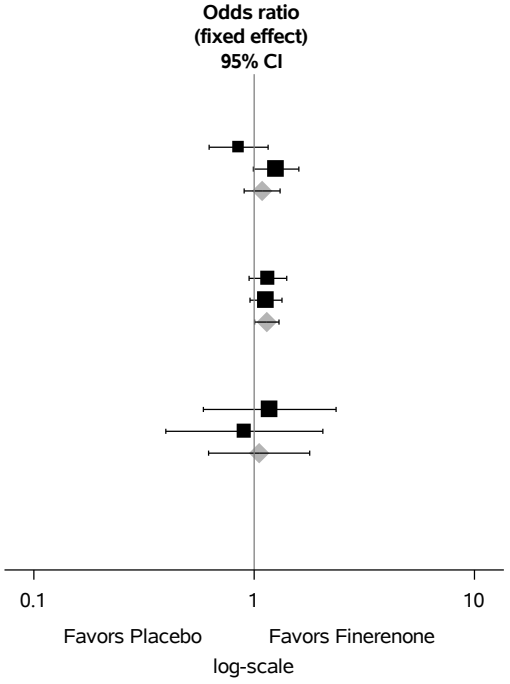
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	220 / 1881	216 / 1861	38.7	1.01 [0.83,1.23]	
FIGARO-DKD	374 / 2643	332 / 2612	61.3	1.13 [0.97,1.33]	
Total	594 / 4524	548 / 4473		1.08 [0.96,1.23]	Z=1.25, p=0.2108
Heterogeneity:	Q=0.78 (df=1)	p=0.3759	I^2=0.0%		
> 4.5					
FIDELIO-DKD	125 / 951	112 / 979	46.8	1.17 [0.89,1.54]	
FIGARO-DKD	149 / 1043	124 / 1052	53.2	1.25 [0.97,1.61]	
Total	274 / 1994	236 / 2031		1.21 [1.01,1.46]	Z=2.02, p=0.0437
Heterogeneity:	Q=0.11 (df=1)	p=0.7418	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.97 (df=1)	p=0.3255	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.11.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

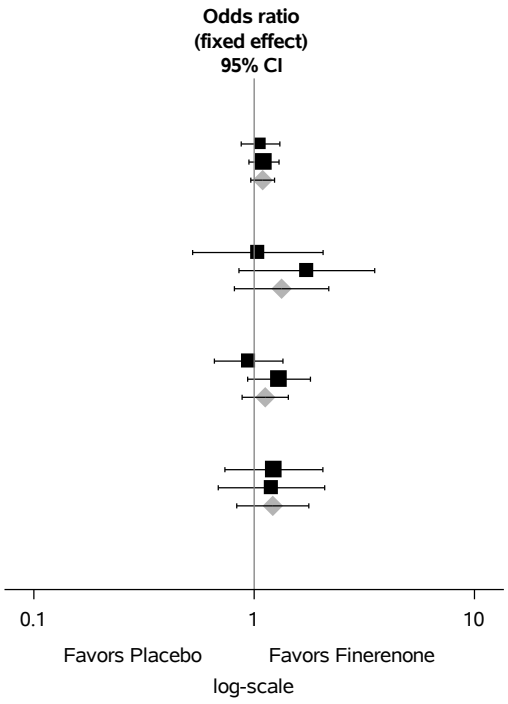
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	86 / 788	98 / 778	37.3	0.85 [0.62,1.16]	
FIGARO-DKD	173 / 1187	143 / 1197	62.7	1.26 [0.99,1.59]	
Total	259 / 1975	241 / 1975		1.09 [0.90,1.31]	Z=0.87, p=0.3851
Heterogeneity:	Q=3.89 (df=1)	p=0.0486	I^2=74.3%		
130 - < 160					
FIDELIO-DKD	239 / 1900	213 / 1922	42.0	1.15 [0.95,1.41]	
FIGARO-DKD	338 / 2392	299 / 2355	58.0	1.13 [0.96,1.34]	
Total	577 / 4292	512 / 4277		1.14 [1.00,1.30]	Z=2.03, p=0.0422
Heterogeneity:	Q=0.02 (df=1)	p=0.8788	I^2=0.0%		
>= 160					
FIDELIO-DKD	20 / 142	17 / 139	58.3	1.18 [0.59,2.35]	
FIGARO-DKD	12 / 107	14 / 114	41.7	0.90 [0.40,2.05]	
Total	32 / 249	31 / 253		1.05 [0.62,1.79]	Z=0.19, p=0.8473
Heterogeneity:	Q=0.23 (df=1)	p=0.6283	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=2)	p=0.8899	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.11.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set

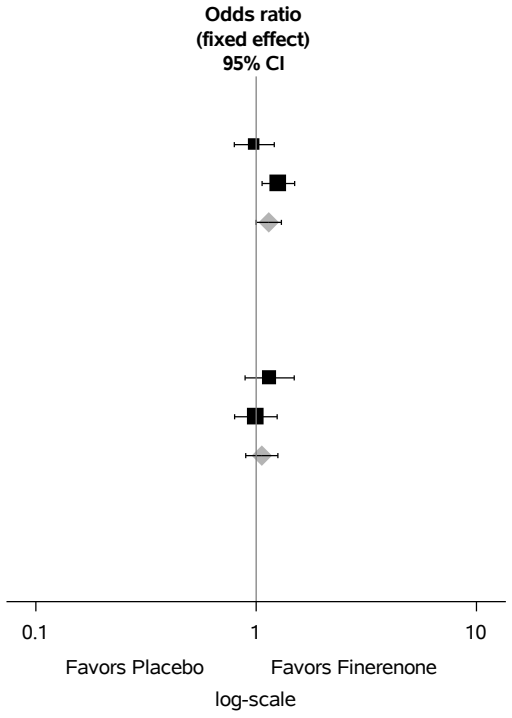
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	218 / 1777	210 / 1815	37.8	1.07 [0.87,1.31]	
FIGARO-DKD	381 / 2672	340 / 2605	62.2	1.11 [0.95,1.30]	
Total	599 / 4449	550 / 4420		1.09 [0.97,1.24]	Z=1.40, p=0.1605
Heterogeneity:	Q=0.08 (df=1)	p=0.7830	I^2=0.0%		
Black					
FIDELIO-DKD	21 / 140	18 / 124	52.0	1.04 [0.53,2.05]	
FIGARO-DKD	20 / 113	16 / 145	48.0	1.73 [0.85,3.52]	
Total	41 / 253	34 / 269		1.33 [0.81,2.18]	Z=1.14, p=0.2548
Heterogeneity:	Q=1.04 (df=1)	p=0.3079	I^2=3.8%		
Asian					
FIDELIO-DKD	64 / 717	68 / 723	45.6	0.94 [0.66,1.35]	
FIGARO-DKD	89 / 715	73 / 739	54.4	1.30 [0.93,1.80]	
Total	153 / 1432	141 / 1462		1.12 [0.88,1.43]	Z=0.94, p=0.3488
Heterogeneity:	Q=1.64 (df=1)	p=0.1999	I^2=39.1%		
Others					
FIDELIO-DKD	42 / 199	32 / 179	54.1	1.23 [0.74,2.05]	
FIGARO-DKD	33 / 186	27 / 177	45.9	1.20 [0.69,2.09]	
Total	75 / 385	59 / 356		1.21 [0.83,1.77]	Z=1.01, p=0.3114
Heterogeneity:	Q=0.00 (df=1)	p=0.9478	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.80 (df=3)	p=0.8497	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.11.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set

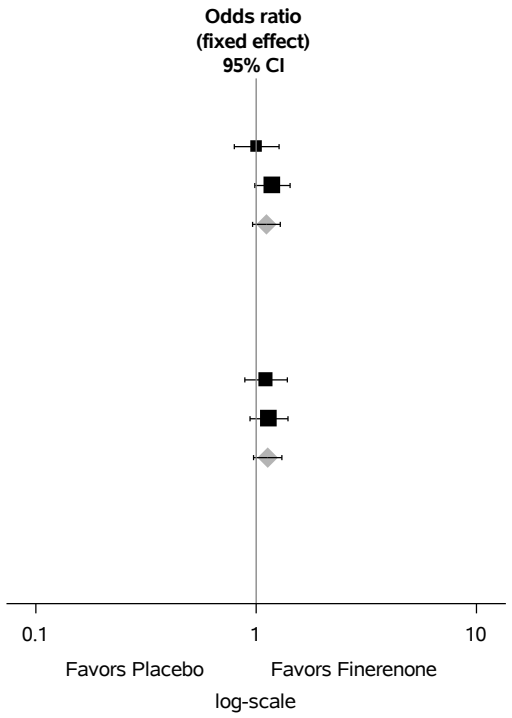
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	190 / 1953	201 / 2030	39.9	0.98 [0.80,1.21]	
FIGARO-DKD	331 / 2528	275 / 2577	60.1	1.26 [1.06,1.50]	
Total	521 / 4481	476 / 4607		1.14 [1.00,1.30]	Z=1.96, p=0.0500
Heterogeneity:	Q=3.35 (df=1)	p=0.0673	I^2=70.1%		
Female					
FIDELIO-DKD	155 / 880	127 / 811	42.8	1.15 [0.89,1.49]	
FIGARO-DKD	192 / 1158	181 / 1089	57.2	1.00 [0.80,1.25]	
Total	347 / 2038	308 / 1900		1.06 [0.90,1.25]	Z=0.69, p=0.4922
Heterogeneity:	Q=0.69 (df=1)	p=0.4062	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.45 (df=1)	p=0.5036	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.11.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set

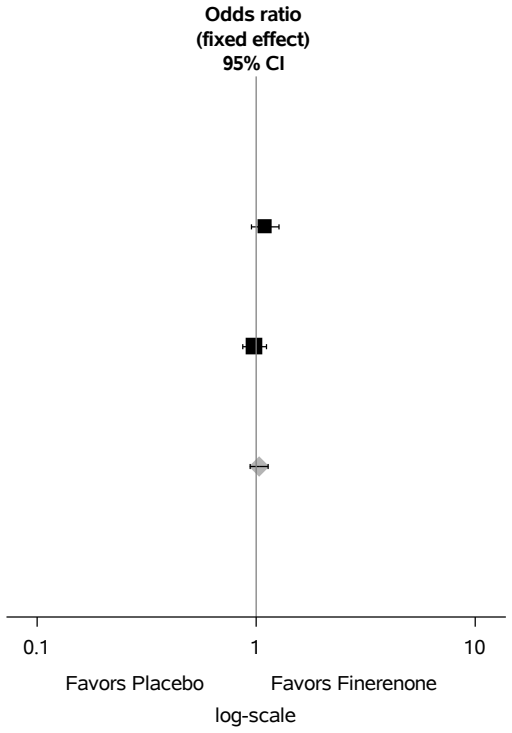
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	165 / 1205	160 / 1174	38.3	1.01 [0.80,1.27]	
FIGARO-DKD	287 / 1753	249 / 1757	61.7	1.19 [0.99,1.43]	
Total	452 / 2958	409 / 2931		1.11 [0.96,1.29]	Z=1.45, p=0.1464
Heterogeneity:	Q=1.18 (df=1)	p=0.2782	I^2=15.0%		
>= 65					
FIDELIO-DKD	180 / 1628	168 / 1667	44.3	1.11 [0.89,1.39]	
FIGARO-DKD	236 / 1933	207 / 1909	55.7	1.14 [0.94,1.39]	
Total	416 / 3561	375 / 3576		1.13 [0.97,1.31]	Z=1.60, p=0.1104
Heterogeneity:	Q=0.04 (df=1)	p=0.8413	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8999	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set

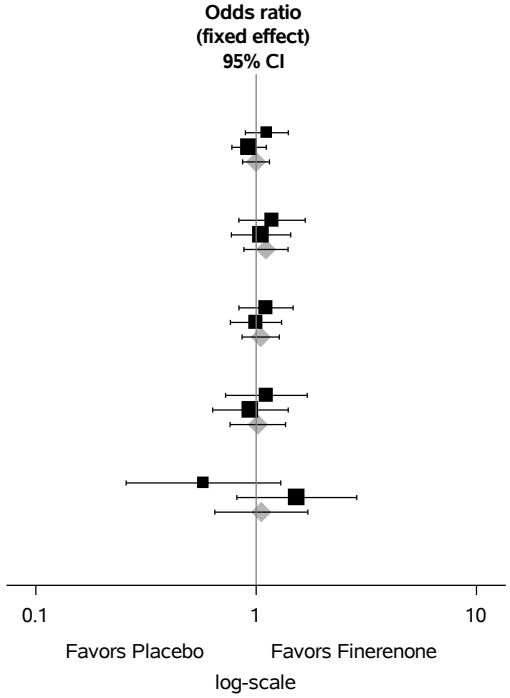
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	452 / 2833	418 / 2841	42.6	1.10 [0.95,1.27]	
FIGARO-DKD	588 / 3686	593 / 3666	57.4	0.98 [0.87,1.11]	
Total	1040 / 6519	1011 / 6507		1.03 [0.94,1.13]	Z=0.64, p=0.5191
Heterogeneity:	Q=1.31 (df=1)	p=0.2525	I^2=23.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history using a binomial distribution and logit as link function. For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 3.3.12.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set

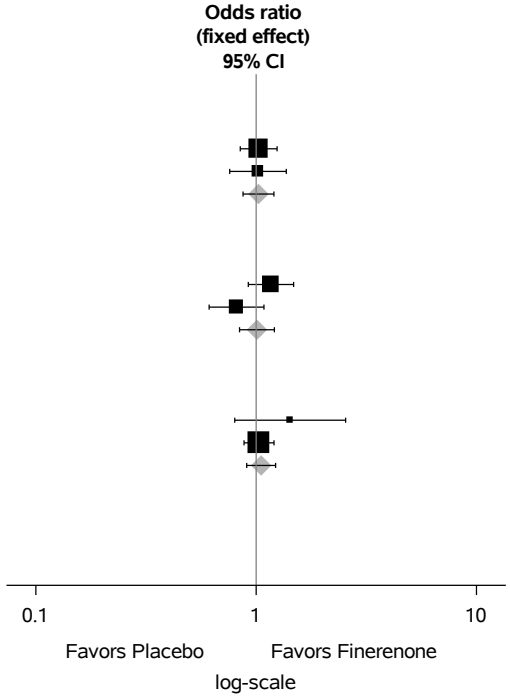
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	190 / 1182	172 / 1176	39.1	1.12 [0.89,1.40]	
FIGARO-DKD	276 / 1754	293 / 1750	60.9	0.93 [0.78,1.11]	
Total	466 / 2936	465 / 2926		1.00 [0.87,1.15]	Z=-0.02, p=0.9837
Heterogeneity:	Q=1.60 (df=1)	p=0.2053	I^2=37.7%		
North America					
FIDELIO-DKD	81 / 467	72 / 477	44.4	1.18 [0.83,1.67]	
FIGARO-DKD	100 / 559	94 / 548	55.6	1.05 [0.77,1.43]	
Total	181 / 1026	166 / 1025		1.11 [0.88,1.40]	Z=0.87, p=0.3869
Heterogeneity:	Q=0.23 (df=1)	p=0.6282	I^2=0.0%		
Asia					
FIDELIO-DKD	117 / 790	107 / 789	47.2	1.11 [0.83,1.47]	
FIGARO-DKD	127 / 810	128 / 815	52.8	1.00 [0.76,1.30]	
Total	244 / 1600	235 / 1604		1.05 [0.86,1.27]	Z=0.48, p=0.6328
Heterogeneity:	Q=0.28 (df=1)	p=0.5983	I^2=0.0%		
Latin America					
FIDELIO-DKD	53 / 295	49 / 298	46.1	1.11 [0.73,1.71]	
FIGARO-DKD	56 / 424	58 / 417	53.9	0.94 [0.63,1.40]	
Total	109 / 719	107 / 715		1.02 [0.76,1.36]	Z=0.12, p=0.9078
Heterogeneity:	Q=0.32 (df=1)	p=0.5739	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 99	18 / 101	37.6	0.58 [0.26,1.29]	
FIGARO-DKD	29 / 139	20 / 136	62.4	1.53 [0.82,2.86]	
Total	40 / 238	38 / 237		1.06 [0.65,1.72]	Z=0.22, p=0.8277
Heterogeneity:	Q=3.50 (df=1)	p=0.0614	I^2=71.4%		
Subgroup Heterogeneity:	Q=0.61 (df=4)	p=0.9615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set

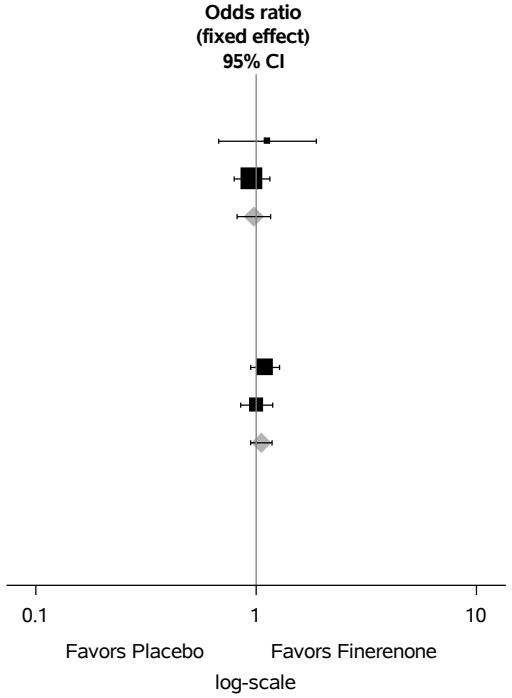
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	250 / 1559	243 / 1549	70.2	1.03 [0.85,1.24]	
FIGARO-DKD	107 / 639	104 / 631	29.8	1.02 [0.76,1.37]	
Total	357 / 2198	347 / 2180		1.02 [0.87,1.20]	Z=0.29, p=0.7707
Heterogeneity:	Q=0.00 (df=1)	p=0.9685	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	172 / 1063	152 / 1071	59.4	1.17 [0.92,1.48]	
FIGARO-DKD	101 / 720	122 / 731	40.6	0.81 [0.61,1.08]	
Total	273 / 1783	274 / 1802		1.01 [0.84,1.21]	Z=0.09, p=0.9295
Heterogeneity:	Q=3.60 (df=1)	p=0.0578	I^2=72.2%		
>= 60					
FIDELIO-DKD	30 / 211	23 / 221	6.8	1.43 [0.80,2.55]	
FIGARO-DKD	380 / 2327	367 / 2304	93.2	1.03 [0.88,1.20]	
Total	410 / 2538	390 / 2525		1.05 [0.91,1.23]	Z=0.68, p=0.4996
Heterogeneity:	Q=1.13 (df=1)	p=0.2873	I^2=11.7%		
Subgroup Heterogeneity:	Q=0.14 (df=2)	p=0.9315	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set

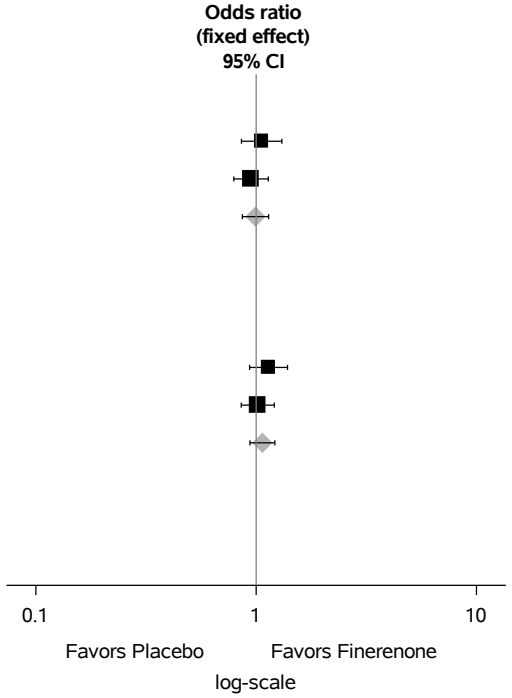
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	37 / 210	34 / 213	11.8	1.13 [0.68,1.88]	
FIGARO-DKD	257 / 1722	264 / 1705	88.2	0.96 [0.79,1.15]	
Total	294 / 1932	298 / 1918		0.98 [0.82,1.16]	Z=-0.27, p=0.7858
Heterogeneity:	Q=0.34 (df=1)	p=0.5589	I^2=0.0%		
Very High					
FIDELIO-DKD	415 / 2623	384 / 2628	55.2	1.10 [0.94,1.28]	
FIGARO-DKD	331 / 1964	329 / 1961	44.8	1.01 [0.85,1.19]	
Total	746 / 4587	713 / 4589		1.06 [0.94,1.18]	Z=0.95, p=0.3423
Heterogeneity:	Q=0.59 (df=1)	p=0.4418	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4591	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set

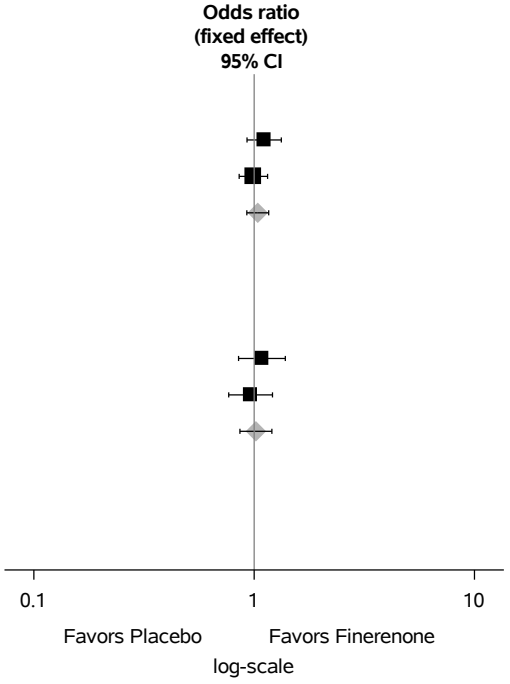
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	209 / 1303	199 / 1302	42.0	1.06 [0.86,1.31]	
FIGARO-DKD	282 / 1676	291 / 1654	58.0	0.95 [0.79,1.13]	
Total	491 / 2979	490 / 2956		0.99 [0.87,1.14]	Z=-0.10, p=0.9181
Heterogeneity:	Q=0.62 (df=1)	p=0.4327	I^2=0.0%		
Absent					
FIDELIO-DKD	243 / 1530	219 / 1539	43.1	1.14 [0.93,1.39]	
FIGARO-DKD	306 / 2010	302 / 2012	56.9	1.02 [0.86,1.21]	
Total	549 / 3540	521 / 3551		1.07 [0.94,1.22]	Z=0.98, p=0.3252
Heterogeneity:	Q=0.71 (df=1)	p=0.4007	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4521	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set

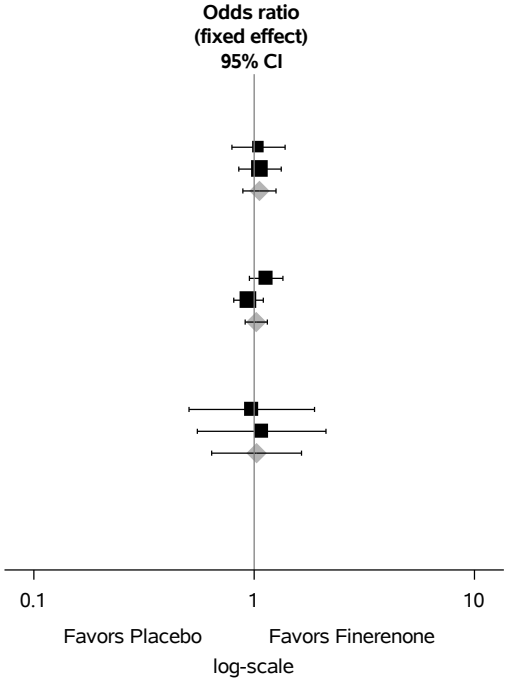
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	296 / 1881	268 / 1861	40.7	1.11 [0.93,1.33]	
FIGARO-DKD	415 / 2643	413 / 2612	59.3	0.99 [0.85,1.15]	
Total	711 / 4524	681 / 4473		1.04 [0.93,1.16]	Z=0.64, p=0.5194
Heterogeneity:	Q=0.90 (df=1)	p=0.3427	I^2=0.0%		
> 4.5					
FIDELIO-DKD	156 / 951	150 / 979	46.7	1.08 [0.85,1.38]	
FIGARO-DKD	173 / 1043	180 / 1052	53.3	0.96 [0.77,1.21]	
Total	329 / 1994	330 / 2031		1.02 [0.86,1.20]	Z=0.21, p=0.8328
Heterogeneity:	Q=0.48 (df=1)	p=0.4879	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8495	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.12.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set

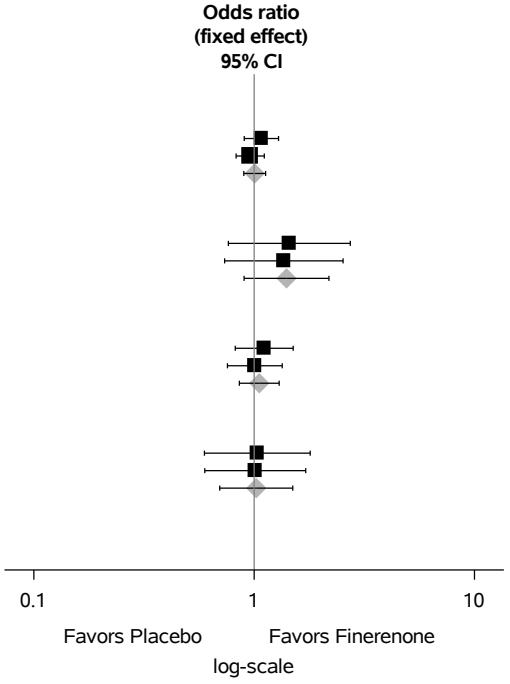
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	120 / 788	114 / 778	38.9	1.05 [0.79,1.38]	
FIGARO-DKD	189 / 1187	181 / 1197	61.1	1.06 [0.85,1.33]	
Total	309 / 1975	295 / 1975		1.06 [0.89,1.26]	Z=0.62, p=0.5343
Heterogeneity:	Q=0.01 (df=1)	p=0.9304	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	311 / 1900	283 / 1922	43.7	1.13 [0.95,1.35]	
FIGARO-DKD	378 / 2392	391 / 2355	56.3	0.94 [0.81,1.10]	
Total	689 / 4292	674 / 4277		1.02 [0.91,1.15]	Z=0.37, p=0.7136
Heterogeneity:	Q=2.39 (df=1)	p=0.1220	I^2=58.2%		
>= 160					
FIDELIO-DKD	21 / 142	21 / 139	51.2	0.98 [0.51,1.88]	
FIGARO-DKD	21 / 107	21 / 114	48.8	1.08 [0.55,2.12]	
Total	42 / 249	42 / 253		1.03 [0.64,1.64]	Z=0.11, p=0.9159
Heterogeneity:	Q=0.05 (df=1)	p=0.8292	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=2)	p=0.9519	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.12.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set

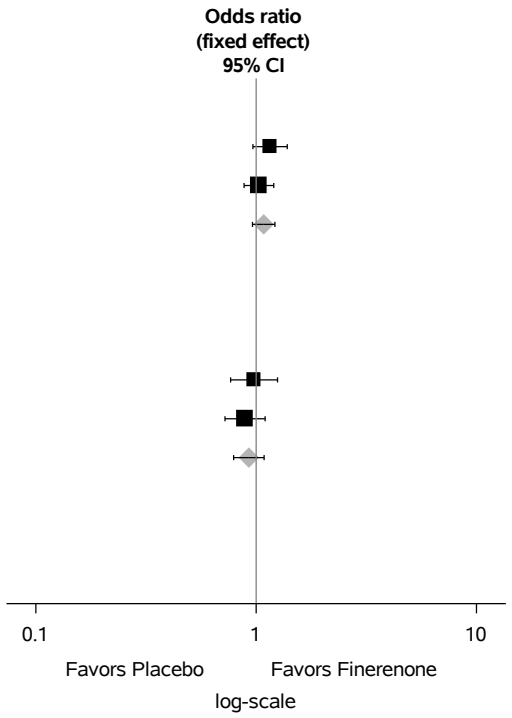
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	290 / 1777	278 / 1815	40.3	1.08 [0.90,1.29]	
FIGARO-DKD	419 / 2672	423 / 2605	59.7	0.96 [0.83,1.11]	
Total	709 / 4449	701 / 4420		1.01 [0.90,1.13]	Z=0.10, p=0.9232
Heterogeneity:	Q=0.97 (df=1)	p=0.3237	I^2=0.0%		
Black					
FIDELIO-DKD	29 / 140	19 / 124	48.6	1.44 [0.76,2.73]	
FIGARO-DKD	25 / 113	25 / 145	51.4	1.36 [0.73,2.53]	
Total	54 / 253	44 / 269		1.40 [0.90,2.18]	Z=1.49, p=0.1353
Heterogeneity:	Q=0.02 (df=1)	p=0.8997	I^2=0.0%		
Asian					
FIDELIO-DKD	101 / 717	93 / 723	47.2	1.11 [0.82,1.50]	
FIGARO-DKD	109 / 715	112 / 739	52.8	1.01 [0.76,1.34]	
Total	210 / 1432	205 / 1462		1.05 [0.86,1.30]	Z=0.50, p=0.6159
Heterogeneity:	Q=0.21 (df=1)	p=0.6446	I^2=0.0%		
Others					
FIDELIO-DKD	32 / 199	28 / 179	47.7	1.03 [0.59,1.80]	
FIGARO-DKD	35 / 186	33 / 177	52.3	1.01 [0.60,1.71]	
Total	67 / 385	61 / 356		1.02 [0.70,1.50]	Z=0.11, p=0.9117
Heterogeneity:	Q=0.00 (df=1)	p=0.9561	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.08 (df=3)	p=0.5565	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 3.3.12.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set

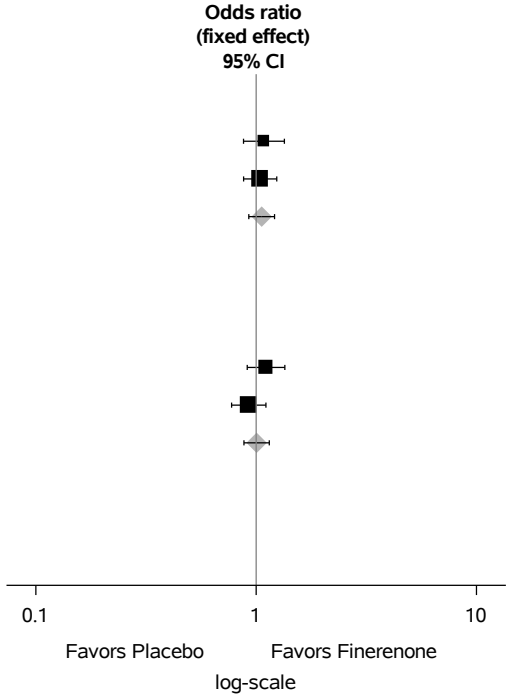
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	290 / 1953	266 / 2030	42.8	1.16 [0.97,1.38]	
FIGARO-DKD	375 / 2528	373 / 2577	57.2	1.03 [0.88,1.20]	
Total	665 / 4481	639 / 4607		1.08 [0.96,1.22]	Z=1.31, p=0.1887
Heterogeneity:	Q=0.93 (df=1)	p=0.3353	I^2=0.0%		
Female					
FIDELIO-DKD	162 / 880	152 / 811	42.2	0.98 [0.77,1.25]	
FIGARO-DKD	213 / 1158	220 / 1089	57.8	0.89 [0.72,1.10]	
Total	375 / 2038	372 / 1900		0.93 [0.79,1.09]	Z=-0.94, p=0.3473
Heterogeneity:	Q=0.33 (df=1)	p=0.5675	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.36 (df=1)	p=0.1245	I^2=57.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 3.3.12.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	213 / 1205	194 / 1174	39.7	1.08 [0.88,1.34]	
FIGARO-DKD	316 / 1753	306 / 1757	60.3	1.04 [0.88,1.24]	
Total	529 / 2958	500 / 2931		1.06 [0.93,1.21]	Z=0.84, p=0.4023
Heterogeneity:	Q=0.08 (df=1)	p=0.7788	I^2=0.0%		
>= 65					
FIDELIO-DKD	239 / 1628	224 / 1667	45.4	1.11 [0.91,1.35]	
FIGARO-DKD	272 / 1933	287 / 1909	54.6	0.93 [0.77,1.11]	
Total	511 / 3561	511 / 3576		1.00 [0.88,1.15]	Z=0.07, p=0.9464
Heterogeneity:	Q=1.76 (df=1)	p=0.1840	I^2=43.3%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For single studies the OR is estimated by a GLM with factor treatment group using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Any TEAE	5602(86.1%)	5607(86.4%)
Infections And Infestations	2864(44.0%)	2911(44.9%)
Nasopharyngitis	559(8.6%)	577(8.9%)
Urinary tract infection	431(6.6%)	432(6.7%)
Upper respiratory tract infection	407(6.3%)	394(6.1%)
Bronchitis	328(5.0%)	332(5.1%)
Pneumonia	271(4.2%)	387(6.0%)
Influenza	257(3.9%)	269(4.1%)
Cellulitis	174(2.7%)	144(2.2%)
Gastroenteritis	124(1.9%)	136(2.1%)
Respiratory tract infection	117(1.8%)	96(1.5%)
Conjunctivitis	101(1.6%)	98(1.5%)
Herpes zoster	87(1.3%)	88(1.4%)
Pharyngitis	84(1.3%)	85(1.3%)
Sinusitis	73(1.1%)	78(1.2%)
Cystitis	65(1.0%)	65(1.0%)
Localised infection	57(0.9%)	43(0.7%)
Periodontitis	50(0.8%)	53(0.8%)
Erysipelas	46(0.7%)	63(1.0%)
Viral infection	44(0.7%)	54(0.8%)
Lower respiratory tract infection	41(0.6%)	46(0.7%)
Osteomyelitis	40(0.6%)	40(0.6%)
Sepsis	40(0.6%)	40(0.6%)
COVID-19	37(0.6%)	57(0.9%)
Tooth abscess	37(0.6%)	21(0.3%)
Rhinitis	36(0.6%)	40(0.6%)
Wound infection	35(0.5%)	24(0.4%)
Onychomycosis	34(0.5%)	41(0.6%)
Otitis externa	34(0.5%)	30(0.5%)
Abscess limb	30(0.5%)	21(0.3%)
Respiratory tract infection viral	28(0.4%)	41(0.6%)
Ear infection	28(0.4%)	23(0.4%)
Helicobacter infection	28(0.4%)	19(0.3%)
Skin infection	27(0.4%)	28(0.4%)
Gingivitis	26(0.4%)	33(0.5%)
Tooth infection	26(0.4%)	32(0.5%)
Fungal skin infection	26(0.4%)	21(0.3%)
Tonsillitis	25(0.4%)	31(0.5%)
Otitis media	24(0.4%)	23(0.4%)
Gastroenteritis viral	24(0.4%)	21(0.3%)
Pyelonephritis	24(0.4%)	18(0.3%)
Tinea pedis	23(0.4%)	39(0.6%)
Subcutaneous abscess	23(0.4%)	14(0.2%)
Acute sinusitis	22(0.3%)	19(0.3%)
Diverticulitis	20(0.3%)	22(0.3%)
Paronychia	20(0.3%)	21(0.3%)
Postoperative wound infection	20(0.3%)	12(0.2%)
Folliculitis	18(0.3%)	14(0.2%)
Pyelonephritis chronic	18(0.3%)	12(0.2%)
Urosepsis	17(0.3%)	21(0.3%)
Laryngitis	17(0.3%)	11(0.2%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Infected skin ulcer	16(0.2%)	13(0.2%)
Pulpitis dental	15(0.2%)	7(0.1%)
Dermatophytosis of nail	14(0.2%)	6(0.1%)
Diabetic foot infection	13(0.2%)	19(0.3%)
Gangrene	13(0.2%)	13(0.2%)
Pyelonephritis acute	13(0.2%)	8(0.1%)
Oral herpes	13(0.2%)	6(0.1%)
Viral upper respiratory tract infection	12(0.2%)	21(0.3%)
Hordeolum	11(0.2%)	9(0.1%)
Epididymitis	11(0.2%)	8(0.1%)
Acarodermatitis	10(0.2%)	16(0.2%)
COVID-19 pneumonia	10(0.2%)	11(0.2%)
Tracheobronchitis	10(0.2%)	10(0.2%)
Pharyngotonsillitis	10(0.2%)	7(0.1%)
Infected bite	10(0.2%)	6(0.1%)
Eye infection	9(0.1%)	13(0.2%)
Septic shock	9(0.1%)	11(0.2%)
Fungal infection	9(0.1%)	9(0.1%)
Soft tissue infection	9(0.1%)	8(0.1%)
Chronic sinusitis	9(0.1%)	7(0.1%)
Infected dermal cyst	9(0.1%)	7(0.1%)
Asymptomatic bacteriuria	9(0.1%)	6(0.1%)
Orchitis	9(0.1%)	6(0.1%)
Vaginal infection	9(0.1%)	2(0.0%)
Febrile infection	9(0.1%)	1(0.0%)
Infection	8(0.1%)	16(0.2%)
Oral candidiasis	8(0.1%)	12(0.2%)
Appendicitis	8(0.1%)	10(0.2%)
Labyrinthitis	8(0.1%)	10(0.2%)
Urinary tract infection bacterial	8(0.1%)	9(0.1%)
Tracheitis	8(0.1%)	7(0.1%)
Abscess	8(0.1%)	6(0.1%)
Oral fungal infection	8(0.1%)	3(0.0%)
Tinea cruris	7(0.1%)	6(0.1%)
Herpes dermatitis	7(0.1%)	3(0.0%)
Furuncle	6(0.1%)	19(0.3%)
Vulvovaginal candidiasis	6(0.1%)	9(0.1%)
Escherichia urinary tract infection	6(0.1%)	8(0.1%)
Pulmonary tuberculosis	6(0.1%)	7(0.1%)
Pulmonary sepsis	6(0.1%)	4(0.1%)
Hepatitis C	6(0.1%)	3(0.0%)
Pneumonia bacterial	5(0.1%)	14(0.2%)
Helicobacter gastritis	5(0.1%)	9(0.1%)
Anal abscess	5(0.1%)	6(0.1%)
Body tinea	5(0.1%)	6(0.1%)
Oesophageal candidiasis	5(0.1%)	6(0.1%)
Bacteraemia	5(0.1%)	5(0.1%)
Vulvovaginal mycotic infection	5(0.1%)	5(0.1%)
Groin abscess	5(0.1%)	4(0.1%)
Osteomyelitis chronic	5(0.1%)	3(0.0%)
Enteritis infectious	5(0.1%)	2(0.0%)
Arthritis bacterial	5(0.1%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Tinea infection	4(0.1%)	8(0.1%)
Herpes ophthalmic	4(0.1%)	6(0.1%)
Herpes simplex	4(0.1%)	6(0.1%)
Liver abscess	4(0.1%)	6(0.1%)
Otitis media chronic	4(0.1%)	6(0.1%)
Groin infection	4(0.1%)	5(0.1%)
Otitis media acute	4(0.1%)	5(0.1%)
Gingival abscess	4(0.1%)	4(0.1%)
Candida infection	4(0.1%)	3(0.0%)
Genitourinary tract infection	4(0.1%)	3(0.0%)
Sialoadenitis	4(0.1%)	3(0.0%)
Suspected COVID-19	4(0.1%)	3(0.0%)
Abdominal abscess	4(0.1%)	2(0.0%)
Dengue fever	4(0.1%)	2(0.0%)
Conjunctivitis bacterial	3(0.0%)	6(0.1%)
Urethritis	3(0.0%)	6(0.1%)
Pneumonia viral	3(0.0%)	5(0.1%)
Carbuncle	3(0.0%)	4(0.1%)
Gastrointestinal viral infection	3(0.0%)	4(0.1%)
Mastoiditis	3(0.0%)	4(0.1%)
Post procedural infection	3(0.0%)	4(0.1%)
Bacteriuria	3(0.0%)	2(0.0%)
Bronchitis bacterial	3(0.0%)	2(0.0%)
Conjunctivitis viral	3(0.0%)	2(0.0%)
Genital candidiasis	3(0.0%)	2(0.0%)
Impetigo	3(0.0%)	2(0.0%)
Parotitis	3(0.0%)	2(0.0%)
Pustule	3(0.0%)	2(0.0%)
Pyuria	3(0.0%)	2(0.0%)
Staphylococcal infection	3(0.0%)	2(0.0%)
Staphylococcal sepsis	3(0.0%)	2(0.0%)
Tuberculosis	3(0.0%)	2(0.0%)
Viral diarrhoea	3(0.0%)	2(0.0%)
Viral rhinitis	3(0.0%)	2(0.0%)
Abdominal wall abscess	3(0.0%)	1(0.0%)
Bacterial infection	3(0.0%)	1(0.0%)
Pharyngitis streptococcal	3(0.0%)	1(0.0%)
Pyoderma	3(0.0%)	1(0.0%)
Staphylococcal bacteraemia	3(0.0%)	1(0.0%)
Tinea versicolour	3(0.0%)	1(0.0%)
Infected cyst	3(0.0%)	0
Pneumonia streptococcal	3(0.0%)	0
Atypical pneumonia	2(0.0%)	8(0.1%)
Genital infection fungal	2(0.0%)	5(0.1%)
Intervertebral discitis	2(0.0%)	5(0.1%)
Nail infection	2(0.0%)	5(0.1%)
Penile infection	2(0.0%)	5(0.1%)
Ear infection fungal	2(0.0%)	4(0.1%)
Infective exacerbation of chronic obstructive airways disease	2(0.0%)	4(0.1%)
Bronchitis viral	2(0.0%)	3(0.0%)
Clostridium difficile infection	2(0.0%)	3(0.0%)
Dacryocystitis	2(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Diarrhoea infectious	2(0.0%)	3(0.0%)
Gastrointestinal infection	2(0.0%)	3(0.0%)
Genital infection	2(0.0%)	3(0.0%)
Pharyngitis bacterial	2(0.0%)	3(0.0%)
Abscess oral	2(0.0%)	2(0.0%)
Diabetic gangrene	2(0.0%)	2(0.0%)
Endocarditis	2(0.0%)	2(0.0%)
Meningitis	2(0.0%)	2(0.0%)
Scrotal abscess	2(0.0%)	2(0.0%)
Abscess neck	2(0.0%)	1(0.0%)
Bacterial vaginosis	2(0.0%)	1(0.0%)
Chest wall abscess	2(0.0%)	1(0.0%)
Eyelid infection	2(0.0%)	1(0.0%)
Gastritis viral	2(0.0%)	1(0.0%)
Genital herpes	2(0.0%)	1(0.0%)
Herpes virus infection	2(0.0%)	1(0.0%)
Kidney infection	2(0.0%)	1(0.0%)
Oral infection	2(0.0%)	1(0.0%)
Urinary tract infection fungal	2(0.0%)	1(0.0%)
Varicella zoster virus infection	2(0.0%)	1(0.0%)
Abdominal infection	2(0.0%)	0
Appendicitis perforated	2(0.0%)	0
Ascariasis	2(0.0%)	0
Aspergilloma	2(0.0%)	0
Borrelia infection	2(0.0%)	0
Emphysematous pyelonephritis	2(0.0%)	0
Endophthalmitis	2(0.0%)	0
Enterocolitis viral	2(0.0%)	0
Eye infection viral	2(0.0%)	0
Otitis externa fungal	2(0.0%)	0
Otosalpingitis	2(0.0%)	0
Peritonitis bacterial	2(0.0%)	0
Prostatic abscess	2(0.0%)	0
Pyelocystitis	2(0.0%)	0
Sinusitis bacterial	2(0.0%)	0
Stoma site infection	2(0.0%)	0
Tongue fungal infection	2(0.0%)	0
Vulvovaginitis	2(0.0%)	0
Wound infection bacterial	2(0.0%)	0
Infective exacerbation of bronchiectasis	1(0.0%)	5(0.1%)
Large intestine infection	1(0.0%)	4(0.1%)
Myringitis	1(0.0%)	4(0.1%)
Arthritis infective	1(0.0%)	3(0.0%)
Gastroenteritis salmonella	1(0.0%)	3(0.0%)
Alveolar osteitis	1(0.0%)	2(0.0%)
Bronchiolitis	1(0.0%)	2(0.0%)
Cholecystitis infective	1(0.0%)	2(0.0%)
Clostridium difficile colitis	1(0.0%)	2(0.0%)
Erythema migrans	1(0.0%)	2(0.0%)
Fungal pharyngitis	1(0.0%)	2(0.0%)
Gastroenteritis norovirus	1(0.0%)	2(0.0%)
Haematoma infection	1(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Hepatitis B	1(0.0%)	2(0.0%)
Injection site infection	1(0.0%)	2(0.0%)
Lymphangitis	1(0.0%)	2(0.0%)
Necrotising fasciitis	1(0.0%)	2(0.0%)
Ophthalmic herpes simplex	1(0.0%)	2(0.0%)
Perineal abscess	1(0.0%)	2(0.0%)
Peritonitis	1(0.0%)	2(0.0%)
Urinary tract infection enterococcal	1(0.0%)	2(0.0%)
Vestibular neuronitis	1(0.0%)	2(0.0%)
Asymptomatic COVID-19	1(0.0%)	1(0.0%)
Bacterial disease carrier	1(0.0%)	1(0.0%)
Bacterial sepsis	1(0.0%)	1(0.0%)
Blister infected	1(0.0%)	1(0.0%)
Burn infection	1(0.0%)	1(0.0%)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Cellulitis staphylococcal	1(0.0%)	1(0.0%)
Cystitis bacterial	1(0.0%)	1(0.0%)
Device related infection	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Fungal oesophagitis	1(0.0%)	1(0.0%)
HIV infection	1(0.0%)	1(0.0%)
Herpes zoster infection neurological	1(0.0%)	1(0.0%)
Incision site abscess	1(0.0%)	1(0.0%)
Infective spondylitis	1(0.0%)	1(0.0%)
Latent tuberculosis	1(0.0%)	1(0.0%)
Lower respiratory tract infection viral	1(0.0%)	1(0.0%)
Lyme disease	1(0.0%)	1(0.0%)
Mastitis	1(0.0%)	1(0.0%)
Medical device site infection	1(0.0%)	1(0.0%)
Osteomyelitis acute	1(0.0%)	1(0.0%)
Pericoronitis	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Pseudomonas infection	1(0.0%)	1(0.0%)
Respiratory syncytial virus infection	1(0.0%)	1(0.0%)
Skin candida	1(0.0%)	1(0.0%)
Tinea blanca	1(0.0%)	1(0.0%)
Urogenital infection fungal	1(0.0%)	1(0.0%)
Viral pericarditis	1(0.0%)	1(0.0%)
Viral pharyngitis	1(0.0%)	1(0.0%)
Bladder diverticulitis	1(0.0%)	0
Bone abscess	1(0.0%)	0
Cervicitis	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Dacryocanaliculitis	1(0.0%)	0
Dermatitis infected	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Ear infection staphylococcal	1(0.0%)	0
Encephalitis viral	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Escherichia bacteraemia	1(0.0%)	0
External ear cellulitis	1(0.0%)	0
Eye infection bacterial	1(0.0%)	0
Eyelid folliculitis	1(0.0%)	0
Fascioliasis	1(0.0%)	0
Gastroenteritis bacterial	1(0.0%)	0
Gastroenteritis rotavirus	1(0.0%)	0
Gastrointestinal candidiasis	1(0.0%)	0
Hand-foot-and-mouth disease	1(0.0%)	0
Helminthic infection	1(0.0%)	0
Hepatic infection	1(0.0%)	0
Hepatitis E	1(0.0%)	0
Herpangina	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Infectious pleural effusion	1(0.0%)	0
Infective myositis	1(0.0%)	0
Infective tenosynovitis	1(0.0%)	0
Infusion site infection	1(0.0%)	0
Injection site cellulitis	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Keratitis bacterial	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Ludwig angina	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Mastitis bacterial	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oropharyngitis fungal	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pharyngeal abscess	1(0.0%)	0
Pilonidal cyst	1(0.0%)	0
Pneumococcal infection	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Prostate infection	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Purulent discharge	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Q fever	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Respiratory tract infection bacterial	1(0.0%)	0
Scrotal cellulitis	1(0.0%)	0
Septic rash	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Sputum purulent	1(0.0%)	0
Stitch abscess	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Tracheobronchitis bacterial	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Viraemia	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Viral labyrinthitis	1(0.0%)	0
Viral sinusitis	1(0.0%)	0
Vulval abscess	1(0.0%)	0
Vulvitis	1(0.0%)	0
Chronic hepatitis C	0	4(0.1%)
Root canal infection	0	4(0.1%)
Acute hepatitis B	0	3(0.0%)
Bacterial vulvovaginitis	0	3(0.0%)
Tonsillitis bacterial	0	3(0.0%)
Balanitis candida	0	2(0.0%)
Breast abscess	0	2(0.0%)
Bullous erysipelas	0	2(0.0%)
Chronic hepatitis B	0	2(0.0%)
Dermatophytosis	0	2(0.0%)
Dysentery	0	2(0.0%)
Eczema infected	0	2(0.0%)
Enterococcal bacteraemia	0	2(0.0%)
Fungal balanitis	0	2(0.0%)
Genital infection female	0	2(0.0%)
Infected seroma	0	2(0.0%)
Medical device site joint infection	0	2(0.0%)
Nail bed infection	0	2(0.0%)
Ophthalmic herpes zoster	0	2(0.0%)
Periorbital cellulitis	0	2(0.0%)
Salmonellosis	0	2(0.0%)
Skin bacterial infection	0	2(0.0%)
Trichomoniasis	0	2(0.0%)
Urinary tract candidiasis	0	2(0.0%)
Abdominal sepsis	0	1(0.0%)
Abscess jaw	0	1(0.0%)
Abscess of eyelid	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)
Adenoviral conjunctivitis	0	1(0.0%)
American trypanosomiasis	0	1(0.0%)
Anal fistula infection	0	1(0.0%)
Anorectal cellulitis	0	1(0.0%)
Anorectal infection bacterial	0	1(0.0%)
Arteriosclerotic gangrene	0	1(0.0%)
Arthropod-borne disease	0	1(0.0%)
Bacterial rhinitis	0	1(0.0%)
Bacterial tracheitis	0	1(0.0%)
Balanoposthitis infective	0	1(0.0%)
Bartholinitis	0	1(0.0%)
Beta haemolytic streptococcal infection	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Chikungunya virus infection	0	1(0.0%)
Chronic tonsillitis	0	1(0.0%)
Clostridium colitis	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Cryptococcosis	0	1(0.0%)
Dental fistula	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Dermo-hypodermitis	0	1(0.0%)
Eczema herpeticum	0	1(0.0%)
Eczema impetiginous	0	1(0.0%)
Enterococcal infection	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Epstein-Barr virus infection	0	1(0.0%)
Escherichia sepsis	0	1(0.0%)
Eye abscess	0	1(0.0%)
Gastrointestinal fungal infection	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
Haemophilus infection	0	1(0.0%)
Hepatitis A	0	1(0.0%)
Hepatitis viral	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Herpes zoster oticus	0	1(0.0%)
Herpes zoster reactivation	0	1(0.0%)
Infected varicose vein	0	1(0.0%)
Joint abscess	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Klebsiella infection	0	1(0.0%)
Laryngitis viral	0	1(0.0%)
Leprosy	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Muscle abscess	0	1(0.0%)
Mycoplasma infection	0	1(0.0%)
Nasal herpes	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Omphalitis	0	1(0.0%)
Parasitic gastroenteritis	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pertussis	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Prostatitis Escherichia coli	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Pyelitis	0	1(0.0%)
Rash pustular	0	1(0.0%)
Renal abscess	0	1(0.0%)
Retinitis	0	1(0.0%)
Retroperitoneal abscess	0	1(0.0%)
Rocky mountain spotted fever	0	1(0.0%)
Rotavirus infection	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Streptococcal bacteraemia	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Subacute endocarditis	0	1(0.0%)
Sweat gland infection	0	1(0.0%)
Testicular abscess	0	1(0.0%)
Tinea manuum	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Upper respiratory tract infection bacterial	0	1(0.0%)
Varicella	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Vulvovaginitis trichomonal	0	1(0.0%)
Metabolism And Nutrition Disorders	2263(34.8%)	2018(31.1%)
Hyperkalaemia	781(12.0%)	382(5.9%)
Hypoglycaemia	340(5.2%)	375(5.8%)
Hyperuricaemia	292(4.5%)	220(3.4%)
Hyperglycaemia	180(2.8%)	162(2.5%)
Gout	169(2.6%)	167(2.6%)
Diabetes mellitus inadequate control	160(2.5%)	157(2.4%)
Diabetes mellitus	154(2.4%)	200(3.1%)
Vitamin D deficiency	116(1.8%)	116(1.8%)
Type 2 diabetes mellitus	110(1.7%)	111(1.7%)
Hypertriglyceridaemia	85(1.3%)	70(1.1%)
Hyponatraemia	75(1.2%)	45(0.7%)
Dehydration	72(1.1%)	64(1.0%)
Hypokalaemia	70(1.1%)	149(2.3%)
Dyslipidaemia	70(1.1%)	72(1.1%)
Hyperlipidaemia	67(1.0%)	66(1.0%)
Decreased appetite	62(1.0%)	62(1.0%)
Diabetic metabolic decompensation	57(0.9%)	61(0.9%)
Metabolic acidosis	50(0.8%)	33(0.5%)
Hypomagnesaemia	37(0.6%)	32(0.5%)
Iron deficiency	35(0.5%)	43(0.7%)
Vitamin B12 deficiency	32(0.5%)	18(0.3%)
Obesity	20(0.3%)	23(0.4%)
Fluid overload	19(0.3%)	22(0.3%)
Hypercholesterolaemia	19(0.3%)	18(0.3%)
Hypocalcaemia	18(0.3%)	29(0.4%)
Hyperphosphataemia	17(0.3%)	16(0.2%)
Hypercalcaemia	17(0.3%)	11(0.2%)
Folate deficiency	16(0.2%)	15(0.2%)
Diabetic ketoacidosis	14(0.2%)	16(0.2%)
Hypovolaemia	13(0.2%)	4(0.1%)
Hypoproteinaemia	12(0.2%)	16(0.2%)
Metabolic disorder	9(0.1%)	16(0.2%)
Acidosis	9(0.1%)	6(0.1%)
Hypoalbuminaemia	6(0.1%)	9(0.1%)
Fluid retention	6(0.1%)	6(0.1%)
Overweight	6(0.1%)	1(0.0%)
Hypervolaemia	5(0.1%)	5(0.1%)
Hypernatraemia	4(0.1%)	10(0.2%)
Hyperglycaemic hyperosmolar nonketotic syndrome	4(0.1%)	8(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Malnutrition	4(0.1%)	4(0.1%)
Vitamin B complex deficiency	4(0.1%)	3(0.0%)
Abnormal loss of weight	3(0.0%)	5(0.1%)
Hypophosphataemia	3(0.0%)	2(0.0%)
Lipid metabolism disorder	3(0.0%)	2(0.0%)
Metabolic syndrome	3(0.0%)	2(0.0%)
Ketoacidosis	3(0.0%)	1(0.0%)
Ketosis	3(0.0%)	0
Hyperhomocysteinaemia	2(0.0%)	6(0.1%)
Hypochloraemia	2(0.0%)	5(0.1%)
Magnesium deficiency	2(0.0%)	4(0.1%)
Diabetic complication	2(0.0%)	2(0.0%)
Hypovitaminosis	2(0.0%)	2(0.0%)
Hypoglycaemia unawareness	2(0.0%)	1(0.0%)
Polydipsia	2(0.0%)	1(0.0%)
Food aversion	2(0.0%)	0
Increased appetite	1(0.0%)	5(0.1%)
Cachexia	1(0.0%)	4(0.1%)
Electrolyte imbalance	1(0.0%)	3(0.0%)
Hyperchloraemia	1(0.0%)	2(0.0%)
Diabetic ketosis	1(0.0%)	1(0.0%)
Lactic acidosis	1(0.0%)	1(0.0%)
Lactose intolerance	1(0.0%)	1(0.0%)
Acidosis hyperchloraemic	1(0.0%)	0
Alkalosis	1(0.0%)	0
Calciphylaxis	1(0.0%)	0
Calcium metabolism disorder	1(0.0%)	0
Decreased insulin requirement	1(0.0%)	0
Hyperferritinaemia	1(0.0%)	0
Hyperlipasaemia	1(0.0%)	0
Hyperphagia	1(0.0%)	0
Hypervitaminosis D	1(0.0%)	0
Hypocholesterolaemia	1(0.0%)	0
Hypometabolism	1(0.0%)	0
Mineral deficiency	1(0.0%)	0
Phosphorus metabolism disorder	1(0.0%)	0
Shock hypoglycaemic	1(0.0%)	0
Vitamin B1 deficiency	1(0.0%)	0
Metabolic alkalosis	0	3(0.0%)
Hypermagnesaemia	0	2(0.0%)
Periarthritis calcarea	0	2(0.0%)
Tumour lysis syndrome	0	2(0.0%)
Abnormal weight gain	0	1(0.0%)
Acid-base balance disorder mixed	0	1(0.0%)
Calcium deficiency	0	1(0.0%)
Central obesity	0	1(0.0%)
Food intolerance	0	1(0.0%)
Hyperalbuminaemia	0	1(0.0%)
Hyperlactacidaemia	0	1(0.0%)
Hyperosmolar state	0	1(0.0%)
Hyperproteinaemia	0	1(0.0%)
Hypervitaminosis B12	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Hypozincaemia	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Pancreatogenous diabetes	0	1(0.0%)
Protein deficiency	0	1(0.0%)
Pseudohyponatraemia	0	1(0.0%)
Weight loss poor	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	1838(28.2%)	1858(28.6%)
Arthralgia	496(7.6%)	459(7.1%)
Back pain	436(6.7%)	428(6.6%)
Pain in extremity	252(3.9%)	248(3.8%)
Muscle spasms	226(3.5%)	210(3.2%)
Osteoarthritis	182(2.8%)	202(3.1%)
Myalgia	125(1.9%)	111(1.7%)
Spinal osteoarthritis	74(1.1%)	97(1.5%)
Neck pain	71(1.1%)	77(1.2%)
Arthritis	65(1.0%)	56(0.9%)
Intervertebral disc protrusion	52(0.8%)	72(1.1%)
Rotator cuff syndrome	46(0.7%)	53(0.8%)
Periarthritis	40(0.6%)	34(0.5%)
Gouty arthritis	35(0.5%)	36(0.6%)
Flank pain	34(0.5%)	33(0.5%)
Osteoporosis	33(0.5%)	29(0.4%)
Bursitis	32(0.5%)	46(0.7%)
Muscular weakness	31(0.5%)	30(0.5%)
Lumbar spinal stenosis	30(0.5%)	30(0.5%)
Trigger finger	30(0.5%)	28(0.4%)
Tendonitis	29(0.4%)	30(0.5%)
Joint swelling	26(0.4%)	36(0.6%)
Musculoskeletal chest pain	26(0.4%)	26(0.4%)
Tenosynovitis	23(0.4%)	14(0.2%)
Plantar fasciitis	19(0.3%)	29(0.4%)
Intervertebral disc disorder	18(0.3%)	16(0.2%)
Spinal pain	18(0.3%)	14(0.2%)
Musculoskeletal pain	17(0.3%)	23(0.4%)
Exostosis	17(0.3%)	16(0.2%)
Tendon disorder	17(0.3%)	16(0.2%)
Musculoskeletal stiffness	17(0.3%)	13(0.2%)
Spinal stenosis	15(0.2%)	17(0.3%)
Synovial cyst	14(0.2%)	11(0.2%)
Intervertebral disc degeneration	13(0.2%)	12(0.2%)
Rhabdomyolysis	13(0.2%)	8(0.1%)
Osteopenia	11(0.2%)	10(0.2%)
Foot deformity	11(0.2%)	6(0.1%)
Spondylolisthesis	10(0.2%)	7(0.1%)
Rheumatoid arthritis	10(0.2%)	5(0.1%)
Neuropathic arthropathy	9(0.1%)	12(0.2%)
Tenosynovitis stenosans	8(0.1%)	7(0.1%)
Scoliosis	8(0.1%)	6(0.1%)
Dupuytren's contracture	7(0.1%)	10(0.2%)
Osteochondrosis	7(0.1%)	9(0.1%)
Polymyalgia rheumatica	7(0.1%)	9(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Arthropathy	7(0.1%)	5(0.1%)
Joint effusion	6(0.1%)	6(0.1%)
Limb discomfort	6(0.1%)	5(0.1%)
Polyarthritis	5(0.1%)	5(0.1%)
Limb mass	5(0.1%)	3(0.0%)
Synovitis	5(0.1%)	2(0.0%)
Osteitis	4(0.1%)	11(0.2%)
Costochondritis	4(0.1%)	10(0.2%)
Bone pain	4(0.1%)	9(0.1%)
Groin pain	4(0.1%)	9(0.1%)
Cervical spinal stenosis	4(0.1%)	6(0.1%)
Muscle fatigue	4(0.1%)	6(0.1%)
Chondrocalcinosis pyrophosphate	4(0.1%)	5(0.1%)
Mobility decreased	4(0.1%)	3(0.0%)
Myopathy	4(0.1%)	3(0.0%)
Muscle atrophy	4(0.1%)	2(0.0%)
Facet joint syndrome	4(0.1%)	0
Sacroiliitis	4(0.1%)	0
Muscle contracture	3(0.0%)	8(0.1%)
Myositis	3(0.0%)	5(0.1%)
Spondylitis	3(0.0%)	5(0.1%)
Coccydynia	3(0.0%)	4(0.1%)
Joint stiffness	3(0.0%)	3(0.0%)
Osteolysis	3(0.0%)	3(0.0%)
Chondropathy	3(0.0%)	2(0.0%)
Muscle twitching	3(0.0%)	2(0.0%)
Musculoskeletal disorder	3(0.0%)	2(0.0%)
Pain in jaw	3(0.0%)	2(0.0%)
Tendon pain	3(0.0%)	2(0.0%)
Kyphosis	3(0.0%)	1(0.0%)
Musculoskeletal discomfort	2(0.0%)	6(0.1%)
Vertebral foraminal stenosis	2(0.0%)	5(0.1%)
Chondrocalcinosis	2(0.0%)	4(0.1%)
Fibromyalgia	2(0.0%)	4(0.1%)
Joint range of motion decreased	2(0.0%)	4(0.1%)
Back disorder	2(0.0%)	2(0.0%)
Fasciitis	2(0.0%)	2(0.0%)
Metatarsalgia	2(0.0%)	2(0.0%)
Myalgia intercostal	2(0.0%)	2(0.0%)
Osteosclerosis	2(0.0%)	2(0.0%)
Fracture pain	2(0.0%)	1(0.0%)
Haematoma muscle	2(0.0%)	1(0.0%)
Meniscal degeneration	2(0.0%)	1(0.0%)
Muscle rigidity	2(0.0%)	1(0.0%)
Myofascial pain syndrome	2(0.0%)	1(0.0%)
Osteonecrosis	2(0.0%)	1(0.0%)
Bone swelling	2(0.0%)	0
Clubbing	2(0.0%)	0
Enthesopathy	2(0.0%)	0
Periostitis	2(0.0%)	0
Soft tissue swelling	2(0.0%)	0
Diastasis recti abdominis	1(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Joint contracture	1(0.0%)	3(0.0%)
Spinal ligament ossification	1(0.0%)	3(0.0%)
Arthritis reactive	1(0.0%)	2(0.0%)
Haemarthrosis	1(0.0%)	2(0.0%)
Osteochondritis	1(0.0%)	2(0.0%)
Temporomandibular joint syndrome	1(0.0%)	2(0.0%)
Tendon calcification	1(0.0%)	2(0.0%)
Chronic kidney disease-mineral and bone disorder	1(0.0%)	1(0.0%)
Degenerative bone disease	1(0.0%)	1(0.0%)
Fistula	1(0.0%)	1(0.0%)
Gouty tophus	1(0.0%)	1(0.0%)
Immobilisation syndrome	1(0.0%)	1(0.0%)
Muscle disorder	1(0.0%)	1(0.0%)
Rheumatic disorder	1(0.0%)	1(0.0%)
Spinal disorder	1(0.0%)	1(0.0%)
Torticollis	1(0.0%)	1(0.0%)
Vertebral osteophyte	1(0.0%)	1(0.0%)
Chest wall mass	1(0.0%)	0
Connective tissue inflammation	1(0.0%)	0
Enostosis	1(0.0%)	0
Exostosis of jaw	1(0.0%)	0
Femoroacetabular impingement	1(0.0%)	0
Finger deformity	1(0.0%)	0
Fracture nonunion	1(0.0%)	0
Hypercreatinaemia	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Joint noise	1(0.0%)	0
Knee deformity	1(0.0%)	0
Ligament pain	1(0.0%)	0
Ligamentitis	1(0.0%)	0
Mandibular mass	1(0.0%)	0
Muscle discomfort	1(0.0%)	0
Neuropathic muscular atrophy	1(0.0%)	0
Palindromic rheumatism	1(0.0%)	0
Polymyositis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Spinal deformity	1(0.0%)	0
Spinal flattening	1(0.0%)	0
Spinal synovial cyst	1(0.0%)	0
Tendon discomfort	1(0.0%)	0
Vertebral lateral recess stenosis	1(0.0%)	0
Spondyloarthropathy	0	5(0.1%)
Bone formation increased	0	4(0.1%)
Osteoarthropathy	0	4(0.1%)
Psoriatic arthropathy	0	4(0.1%)
Patellofemoral pain syndrome	0	3(0.0%)
Sjogren's syndrome	0	3(0.0%)
Chondromalacia	0	2(0.0%)
Crystal arthropathy	0	2(0.0%)
Muscle haemorrhage	0	2(0.0%)
Spinal instability	0	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Systemic lupus erythematosus	0	2(0.0%)
Amyotrophy	0	1(0.0%)
Ankylosing spondylitis	0	1(0.0%)
Articular calcification	0	1(0.0%)
Axillary mass	0	1(0.0%)
Bone callus excessive	0	1(0.0%)
Bursa disorder	0	1(0.0%)
Chest wall cyst	0	1(0.0%)
Chest wall haematoma	0	1(0.0%)
Chondritis	0	1(0.0%)
Connective tissue disorder	0	1(0.0%)
Intervertebral disc calcification	0	1(0.0%)
Jaw cyst	0	1(0.0%)
Kyphoscoliosis	0	1(0.0%)
Ligament calcification	0	1(0.0%)
Loose body in joint	0	1(0.0%)
Muscle swelling	0	1(0.0%)
Muscle tightness	0	1(0.0%)
Neck mass	0	1(0.0%)
Nodal osteoarthritis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Osteoporotic fracture	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Plantar fascial fibromatosis	0	1(0.0%)
Rheumatoid nodule	0	1(0.0%)
Soft tissue disorder	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Soft tissue mass	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal fusion acquired	0	1(0.0%)
Systemic scleroderma	0	1(0.0%)
Trismus	0	1(0.0%)
Undifferentiated connective tissue disease	0	1(0.0%)
Vertebral lesion	0	1(0.0%)
Gastrointestinal Disorders	1770(27.2%)	1720(26.5%)
Diarrhoea	423(6.5%)	411(6.3%)
Constipation	317(4.9%)	334(5.1%)
Nausea	192(2.9%)	176(2.7%)
Vomiting	146(2.2%)	138(2.1%)
Gastrooesophageal reflux disease	117(1.8%)	138(2.1%)
Abdominal pain	113(1.7%)	128(2.0%)
Gastritis	112(1.7%)	90(1.4%)
Abdominal pain upper	110(1.7%)	103(1.6%)
Dyspepsia	91(1.4%)	79(1.2%)
Haemorrhoids	89(1.4%)	68(1.0%)
Large intestine polyp	77(1.2%)	114(1.8%)
Chronic gastritis	65(1.0%)	54(0.8%)
Toothache	53(0.8%)	59(0.9%)
Diverticulum intestinal	39(0.6%)	33(0.5%)
Dental caries	36(0.6%)	29(0.4%)
Abdominal distension	35(0.5%)	30(0.5%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Gastritis erosive	33(0.5%)	30(0.5%)
Abdominal discomfort	31(0.5%)	30(0.5%)
Hiatus hernia	26(0.4%)	41(0.6%)
Gastric ulcer	26(0.4%)	23(0.4%)
Gastrointestinal haemorrhage	26(0.4%)	23(0.4%)
Umbilical hernia	22(0.3%)	22(0.3%)
Inguinal hernia	20(0.3%)	31(0.5%)
Gastric polyps	20(0.3%)	17(0.3%)
Duodenal ulcer	20(0.3%)	16(0.2%)
Flatulence	19(0.3%)	24(0.4%)
Pancreatitis acute	19(0.3%)	13(0.2%)
Dysphagia	18(0.3%)	21(0.3%)
Periodontal disease	18(0.3%)	13(0.2%)
Haematochezia	17(0.3%)	20(0.3%)
Abdominal pain lower	17(0.3%)	18(0.3%)
Colitis	17(0.3%)	14(0.2%)
Rectal haemorrhage	17(0.3%)	13(0.2%)
Dry mouth	15(0.2%)	15(0.2%)
Pancreatitis chronic	14(0.2%)	18(0.3%)
Irritable bowel syndrome	14(0.2%)	17(0.3%)
Diverticulum	13(0.2%)	22(0.3%)
Melaena	12(0.2%)	8(0.1%)
Oesophagitis	11(0.2%)	17(0.3%)
Duodenitis	11(0.2%)	15(0.2%)
Enteritis	11(0.2%)	8(0.1%)
Lower gastrointestinal haemorrhage	11(0.2%)	5(0.1%)
Gastrointestinal disorder	10(0.2%)	11(0.2%)
Ascites	10(0.2%)	9(0.1%)
Upper gastrointestinal haemorrhage	9(0.1%)	13(0.2%)
Peptic ulcer	9(0.1%)	11(0.2%)
Rectal polyp	9(0.1%)	10(0.2%)
Pancreatitis	9(0.1%)	6(0.1%)
Haemorrhoidal haemorrhage	9(0.1%)	5(0.1%)
Enterocolitis	9(0.1%)	4(0.1%)
Haematemesis	9(0.1%)	3(0.0%)
Food poisoning	8(0.1%)	8(0.1%)
Pancreatic cyst	8(0.1%)	7(0.1%)
Mouth ulceration	8(0.1%)	5(0.1%)
Tooth disorder	6(0.1%)	9(0.1%)
Abdominal hernia	6(0.1%)	8(0.1%)
Varices oesophageal	6(0.1%)	5(0.1%)
Intestinal obstruction	5(0.1%)	10(0.2%)
Anal fissure	5(0.1%)	6(0.1%)
Gastrointestinal motility disorder	5(0.1%)	4(0.1%)
Ileus	5(0.1%)	3(0.0%)
Angular cheilitis	5(0.1%)	2(0.0%)
Gastric disorder	5(0.1%)	1(0.0%)
Gastric haemorrhage	5(0.1%)	1(0.0%)
Gingival bleeding	5(0.1%)	1(0.0%)
Gingival pain	4(0.1%)	7(0.1%)
Small intestinal obstruction	4(0.1%)	6(0.1%)
Anal incontinence	4(0.1%)	5(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Gastrointestinal angiodysplasia	4(0.1%)	5(0.1%)
Gingival swelling	4(0.1%)	5(0.1%)
Abnormal faeces	4(0.1%)	3(0.0%)
Epigastric discomfort	4(0.1%)	3(0.0%)
Duodenal polyp	4(0.1%)	2(0.0%)
Gastritis haemorrhagic	4(0.1%)	2(0.0%)
Aphthous ulcer	4(0.1%)	0
Intestinal haemorrhage	4(0.1%)	0
Proctalgia	4(0.1%)	0
Stomatitis	3(0.0%)	13(0.2%)
Barrett's oesophagus	3(0.0%)	6(0.1%)
Eructation	3(0.0%)	5(0.1%)
Faecaloma	3(0.0%)	5(0.1%)
Change of bowel habit	3(0.0%)	4(0.1%)
Intestinal metaplasia	3(0.0%)	4(0.1%)
Colitis ischaemic	3(0.0%)	3(0.0%)
Faeces soft	3(0.0%)	2(0.0%)
Gastric ulcer haemorrhage	3(0.0%)	2(0.0%)
Functional gastrointestinal disorder	3(0.0%)	1(0.0%)
Gastroduodenal ulcer	3(0.0%)	1(0.0%)
Incarcerated umbilical hernia	3(0.0%)	1(0.0%)
Pancreatic steatosis	3(0.0%)	1(0.0%)
Parotid gland enlargement	3(0.0%)	1(0.0%)
Portal hypertensive gastropathy	3(0.0%)	1(0.0%)
Proctitis	3(0.0%)	1(0.0%)
Abdominal symptom	3(0.0%)	0
Swollen tongue	3(0.0%)	0
Tongue ulceration	3(0.0%)	0
Colon dysplasia	2(0.0%)	5(0.1%)
Intestinal polyp	2(0.0%)	5(0.1%)
Duodenal ulcer haemorrhage	2(0.0%)	4(0.1%)
Oral pain	2(0.0%)	4(0.1%)
Anal fistula	2(0.0%)	3(0.0%)
Odynophagia	2(0.0%)	3(0.0%)
Colitis microscopic	2(0.0%)	2(0.0%)
Faeces discoloured	2(0.0%)	2(0.0%)
Lip swelling	2(0.0%)	2(0.0%)
Lumbar hernia	2(0.0%)	2(0.0%)
Reflux gastritis	2(0.0%)	2(0.0%)
Diarrhoea haemorrhagic	2(0.0%)	1(0.0%)
Diverticulum intestinal haemorrhagic	2(0.0%)	1(0.0%)
Gastric mucosal lesion	2(0.0%)	1(0.0%)
Loose tooth	2(0.0%)	1(0.0%)
Mechanical ileus	2(0.0%)	1(0.0%)
Oesophageal obstruction	2(0.0%)	1(0.0%)
Oesophageal ulcer	2(0.0%)	1(0.0%)
Pancreatic disorder	2(0.0%)	1(0.0%)
Tooth loss	2(0.0%)	1(0.0%)
Coeliac artery stenosis	2(0.0%)	0
Defaecation urgency	2(0.0%)	0
Duodenogastric reflux	2(0.0%)	0
Dyschezia	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Gastrointestinal polyp	2(0.0%)	0
Glossitis	2(0.0%)	0
Haemorrhagic erosive gastritis	2(0.0%)	0
Lip disorder	2(0.0%)	0
Mouth cyst	2(0.0%)	0
Oedematous pancreatitis	2(0.0%)	0
Small intestinal haemorrhage	2(0.0%)	0
Frequent bowel movements	1(0.0%)	7(0.1%)
Erosive duodenitis	1(0.0%)	5(0.1%)
Anal haemorrhage	1(0.0%)	4(0.1%)
Intestinal mass	1(0.0%)	4(0.1%)
Abdominal adhesions	1(0.0%)	3(0.0%)
Diaphragmatic hernia	1(0.0%)	3(0.0%)
Gastric mucosa erythema	1(0.0%)	3(0.0%)
Mesenteric panniculitis	1(0.0%)	3(0.0%)
Pancreatolithiasis	1(0.0%)	3(0.0%)
Salivary gland calculus	1(0.0%)	3(0.0%)
Subileus	1(0.0%)	3(0.0%)
Acquired oesophageal web	1(0.0%)	2(0.0%)
Faeces hard	1(0.0%)	2(0.0%)
Glossodynia	1(0.0%)	2(0.0%)
Noninfective gingivitis	1(0.0%)	2(0.0%)
Oesophageal polyp	1(0.0%)	2(0.0%)
Peptic ulcer haemorrhage	1(0.0%)	2(0.0%)
Rectal prolapse	1(0.0%)	2(0.0%)
Abdominal mass	1(0.0%)	1(0.0%)
Anal pruritus	1(0.0%)	1(0.0%)
Diabetic gastroparesis	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Gastrointestinal dysplasia	1(0.0%)	1(0.0%)
Gastrointestinal hypermotility	1(0.0%)	1(0.0%)
Gastrointestinal oedema	1(0.0%)	1(0.0%)
Hypoaesthesia oral	1(0.0%)	1(0.0%)
Ileal ulcer	1(0.0%)	1(0.0%)
Intestinal ischaemia	1(0.0%)	1(0.0%)
Mouth haemorrhage	1(0.0%)	1(0.0%)
Oesophageal mass	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Oral discomfort	1(0.0%)	1(0.0%)
Pancreatic duct stenosis	1(0.0%)	1(0.0%)
Peritoneal adhesions	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Abdominal rigidity	1(0.0%)	0
Acid peptic disease	1(0.0%)	0
Aerophagia	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Anal polyp	1(0.0%)	0
Anorectal swelling	1(0.0%)	0
Apical granuloma	1(0.0%)	0
Aptyalism	1(0.0%)	0
Bile acid malabsorption	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Defaecation disorder	1(0.0%)	0
Dental alveolar anomaly	1(0.0%)	0
Dental attrition	1(0.0%)	0
Dental cyst	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Dysbiosis	1(0.0%)	0
Epulis	1(0.0%)	0
Gastric dilatation	1(0.0%)	0
Gastric xanthoma	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal ulcer	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Haemorrhoids thrombosed	1(0.0%)	0
Hyperaesthesia teeth	1(0.0%)	0
Infrequent bowel movements	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Intra-abdominal fluid collection	1(0.0%)	0
Large intestinal stenosis	1(0.0%)	0
Large intestinal ulcer	1(0.0%)	0
Lip pain	1(0.0%)	0
Lip pruritus	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Oesophageal pain	1(0.0%)	0
Oesophageal ulcer haemorrhage	1(0.0%)	0
Oesophagitis ulcerative	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Paraesthesia oral	1(0.0%)	0
Precancerous lesion of digestive tract	1(0.0%)	0
Pyloric sphincter insufficiency	1(0.0%)	0
Rectal ulcer	1(0.0%)	0
Retching	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Salivary gland mass	1(0.0%)	0
Salivary hypersecretion	1(0.0%)	0
Splenic artery aneurysm	1(0.0%)	0
Stress ulcer	1(0.0%)	0
Submaxillary gland enlargement	1(0.0%)	0
Tongue haemorrhage	1(0.0%)	0
Tooth ankylosis	1(0.0%)	0
Tooth development disorder	1(0.0%)	0
Tooth impacted	1(0.0%)	0
Ulcerative duodenitis	1(0.0%)	0
Volvulus	1(0.0%)	0
Impaired gastric emptying	0	7(0.1%)
Colitis ulcerative	0	4(0.1%)
Bowel movement irregularity	0	3(0.0%)
Erosive oesophagitis	0	3(0.0%)
Gastrointestinal inflammation	0	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Abdominal wall haematoma	0	2(0.0%)
Breath odour	0	2(0.0%)
Coeliac disease	0	2(0.0%)
Duodenal ulcer perforation	0	2(0.0%)
Enterovesical fistula	0	2(0.0%)
Gastrointestinal tract mucosal pigmentation	0	2(0.0%)
Gingival hypertrophy	0	2(0.0%)
Hernial eventration	0	2(0.0%)
Lip oedema	0	2(0.0%)
Oesophageal disorder	0	2(0.0%)
Oesophageal dysplasia	0	2(0.0%)
Pancreatic failure	0	2(0.0%)
Retroperitoneal haematoma	0	2(0.0%)
Abdominal strangulated hernia	0	1(0.0%)
Abdominal tenderness	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal inflammation	0	1(0.0%)
Anal rash	0	1(0.0%)
Anal skin tags	0	1(0.0%)
Brunner's gland hyperplasia	0	1(0.0%)
Chapped lips	0	1(0.0%)
Cheilitis	0	1(0.0%)
Crohn's disease	0	1(0.0%)
Diabetic gastroenteropathy	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Ectopic gastric mucosa	0	1(0.0%)
Gastric antral vascular ectasia	0	1(0.0%)
Gastric dysplasia	0	1(0.0%)
Gastric mucosal hypertrophy	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastrointestinal hypomotility	0	1(0.0%)
Gastrointestinal mucosa hyperaemia	0	1(0.0%)
Gastrointestinal obstruction	0	1(0.0%)
Gastrointestinal pain	0	1(0.0%)
Gastrointestinal scarring	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Gastrooesophageal sphincter insufficiency	0	1(0.0%)
Glycogenic acanthosis	0	1(0.0%)
Hyperchlorhydria	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Internal hernia	0	1(0.0%)
Lip blister	0	1(0.0%)
Lip ulceration	0	1(0.0%)
Lymphangiectasia intestinal	0	1(0.0%)
Malabsorption	0	1(0.0%)
Mesenteric artery stenosis	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Oesophageal stenosis	0	1(0.0%)
Omental infarction	0	1(0.0%)
Oral disorder	0	1(0.0%)
Oral mucosa erosion	0	1(0.0%)
Palatal disorder	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Palatal polyp	0	1(0.0%)
Pancreatic mass	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Periodontal inflammation	0	1(0.0%)
Pneumoperitoneum	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Rectal dysplasia	0	1(0.0%)
Rectal ulcer haemorrhage	0	1(0.0%)
Salivary gland cyst	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Small intestinal perforation	0	1(0.0%)
Small intestine ulcer	0	1(0.0%)
Steatorrhoea	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Terminal ileitis	0	1(0.0%)
Tooth deposit	0	1(0.0%)
Uvulitis	0	1(0.0%)
Investigations	1494(22.9%)	1495(23.0%)
Glomerular filtration rate decreased	348(5.3%)	274(4.2%)
Blood creatinine increased	170(2.6%)	151(2.3%)
Blood creatine phosphokinase increased	169(2.6%)	223(3.4%)
C-reactive protein increased	164(2.5%)	172(2.7%)
Blood potassium increased	151(2.3%)	75(1.2%)
Blood pressure increased	110(1.7%)	136(2.1%)
Glycosylated haemoglobin increased	88(1.4%)	73(1.1%)
Gamma-glutamyltransferase increased	72(1.1%)	69(1.1%)
Weight decreased	65(1.0%)	74(1.1%)
Blood glucose increased	48(0.7%)	52(0.8%)
Blood uric acid increased	42(0.6%)	37(0.6%)
Blood triglycerides increased	37(0.6%)	28(0.4%)
Blood urea increased	36(0.6%)	19(0.3%)
Alanine aminotransferase increased	31(0.5%)	36(0.6%)
Weight increased	29(0.4%)	42(0.6%)
Aspartate aminotransferase increased	28(0.4%)	22(0.3%)
Haemoglobin decreased	24(0.4%)	34(0.5%)
Blood pressure decreased	19(0.3%)	15(0.2%)
Liver function test increased	18(0.3%)	16(0.2%)
Blood potassium decreased	16(0.2%)	12(0.2%)
Prostatic specific antigen increased	15(0.2%)	22(0.3%)
Blood alkaline phosphatase increased	15(0.2%)	14(0.2%)
Hepatic enzyme increased	14(0.2%)	26(0.4%)
White blood cell count increased	14(0.2%)	7(0.1%)
Cardiac murmur	13(0.2%)	15(0.2%)
Heart rate increased	13(0.2%)	11(0.2%)
Helicobacter test positive	12(0.2%)	12(0.2%)
Occult blood positive	12(0.2%)	12(0.2%)
Blood lactate dehydrogenase increased	10(0.2%)	9(0.1%)
Blood sodium decreased	9(0.1%)	2(0.0%)
Colonoscopy	8(0.1%)	8(0.1%)
Vitamin D decreased	8(0.1%)	5(0.1%)
Blood glucose decreased	8(0.1%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Blood urine present	8(0.1%)	2(0.0%)
Electrocardiogram QT prolonged	7(0.1%)	8(0.1%)
Transaminases increased	6(0.1%)	9(0.1%)
Angiocardiogram	6(0.1%)	8(0.1%)
Blood bicarbonate decreased	6(0.1%)	7(0.1%)
Blood cholesterol increased	6(0.1%)	5(0.1%)
Ejection fraction decreased	6(0.1%)	5(0.1%)
Troponin T increased	6(0.1%)	3(0.0%)
Troponin increased	5(0.1%)	17(0.3%)
Electrocardiogram T wave inversion	5(0.1%)	9(0.1%)
Platelet count decreased	5(0.1%)	5(0.1%)
Blood glucose fluctuation	5(0.1%)	2(0.0%)
Low density lipoprotein increased	5(0.1%)	1(0.0%)
N-terminal prohormone brain natriuretic peptide increased	4(0.1%)	16(0.2%)
Blood magnesium decreased	4(0.1%)	8(0.1%)
Polymerase chain reaction positive	4(0.1%)	6(0.1%)
Low density lipoprotein decreased	4(0.1%)	5(0.1%)
Liver function test abnormal	4(0.1%)	4(0.1%)
Blood calcium increased	4(0.1%)	3(0.0%)
Haemoglobin increased	4(0.1%)	3(0.0%)
Blood cholesterol decreased	4(0.1%)	2(0.0%)
Electrocardiogram T wave amplitude decreased	4(0.1%)	1(0.0%)
Catheterisation cardiac	4(0.1%)	0
Intraocular pressure increased	3(0.0%)	10(0.2%)
Urine albumin/creatinine ratio increased	3(0.0%)	10(0.2%)
Influenza A virus test positive	3(0.0%)	9(0.1%)
Electrocardiogram ST segment depression	3(0.0%)	8(0.1%)
Electrocardiogram abnormal	3(0.0%)	5(0.1%)
Protein urine present	3(0.0%)	5(0.1%)
Vitamin B12 decreased	3(0.0%)	4(0.1%)
Amylase increased	3(0.0%)	3(0.0%)
Biopsy kidney	3(0.0%)	3(0.0%)
Biopsy prostate	3(0.0%)	3(0.0%)
Carcinoembryonic antigen increased	3(0.0%)	3(0.0%)
Haematocrit decreased	3(0.0%)	3(0.0%)
Lipase increased	3(0.0%)	3(0.0%)
Red blood cell count decreased	3(0.0%)	3(0.0%)
Blood iron decreased	3(0.0%)	2(0.0%)
Bone density decreased	3(0.0%)	2(0.0%)
Blood parathyroid hormone increased	3(0.0%)	1(0.0%)
International normalised ratio increased	3(0.0%)	1(0.0%)
Lipids increased	3(0.0%)	1(0.0%)
Urine output decreased	3(0.0%)	1(0.0%)
Arthroscopy	2(0.0%)	4(0.1%)
Electrocardiogram T wave abnormal	2(0.0%)	4(0.1%)
High density lipoprotein decreased	2(0.0%)	4(0.1%)
Inflammatory marker increased	2(0.0%)	4(0.1%)
SARS-CoV-2 test positive	2(0.0%)	4(0.1%)
Blood folate decreased	2(0.0%)	3(0.0%)
Blood pressure diastolic decreased	2(0.0%)	3(0.0%)
Brain natriuretic peptide increased	2(0.0%)	3(0.0%)
ECG signs of myocardial ischaemia	2(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Blood albumin decreased	2(0.0%)	2(0.0%)
Blood thyroid stimulating hormone increased	2(0.0%)	2(0.0%)
Haematocrit increased	2(0.0%)	2(0.0%)
Scan myocardial perfusion abnormal	2(0.0%)	2(0.0%)
Bacterial test positive	2(0.0%)	1(0.0%)
Biopsy liver	2(0.0%)	1(0.0%)
Blood lactic acid increased	2(0.0%)	1(0.0%)
Blood testosterone decreased	2(0.0%)	1(0.0%)
Electrocardiogram Q wave abnormal	2(0.0%)	1(0.0%)
Electrocardiogram QRS complex abnormal	2(0.0%)	1(0.0%)
Electrocardiogram repolarisation abnormality	2(0.0%)	1(0.0%)
Glycosylated haemoglobin abnormal	2(0.0%)	1(0.0%)
White blood cell count decreased	2(0.0%)	1(0.0%)
Biopsy artery	2(0.0%)	0
Blood chloride decreased	2(0.0%)	0
Electrocardiogram change	2(0.0%)	0
Endoscopy	2(0.0%)	0
Escherichia test positive	2(0.0%)	0
Pulmonary arterial pressure increased	2(0.0%)	0
Transaminases abnormal	2(0.0%)	0
Waist circumference increased	2(0.0%)	0
Heart rate decreased	1(0.0%)	7(0.1%)
QRS axis abnormal	1(0.0%)	6(0.1%)
Anticoagulation drug level above therapeutic	1(0.0%)	4(0.1%)
Blood phosphorus increased	1(0.0%)	3(0.0%)
Fibrin D dimer increased	1(0.0%)	3(0.0%)
Biopsy skin	1(0.0%)	2(0.0%)
Blood calcium decreased	1(0.0%)	2(0.0%)
Blood creatine phosphokinase MB increased	1(0.0%)	2(0.0%)
Chest X-ray abnormal	1(0.0%)	2(0.0%)
Electrocardiogram ST segment elevation	1(0.0%)	2(0.0%)
Glomerular filtration rate increased	1(0.0%)	2(0.0%)
Oxygen consumption increased	1(0.0%)	2(0.0%)
Transferrin saturation decreased	1(0.0%)	2(0.0%)
Aspiration pleural cavity	1(0.0%)	1(0.0%)
Blood bilirubin increased	1(0.0%)	1(0.0%)
Blood pressure systolic increased	1(0.0%)	1(0.0%)
Blood sodium increased	1(0.0%)	1(0.0%)
Clostridium test positive	1(0.0%)	1(0.0%)
Haematology test abnormal	1(0.0%)	1(0.0%)
Imaging procedure abnormal	1(0.0%)	1(0.0%)
Mean cell volume increased	1(0.0%)	1(0.0%)
Proteus test positive	1(0.0%)	1(0.0%)
Pulmonary imaging procedure abnormal	1(0.0%)	1(0.0%)
Renal function test abnormal	1(0.0%)	1(0.0%)
Respiratory syncytial virus test positive	1(0.0%)	1(0.0%)
Vascular resistance systemic increased	1(0.0%)	1(0.0%)
White blood cells urine positive	1(0.0%)	1(0.0%)
Albumin urine present	1(0.0%)	0
Angiogram	1(0.0%)	0
Angiogram peripheral	1(0.0%)	0
Angiogram retina	1(0.0%)	0

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Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Antinuclear antibody positive	1(0.0%)	0
Arteriogram	1(0.0%)	0
Arteriogram carotid abnormal	1(0.0%)	0
Aspiration joint	1(0.0%)	0
Biopsy bladder	1(0.0%)	0
Blood albumin abnormal	1(0.0%)	0
Blood albumin increased	1(0.0%)	0
Blood alkaline phosphatase abnormal	1(0.0%)	0
Blood growth hormone decreased	1(0.0%)	0
Blood osmolarity decreased	1(0.0%)	0
Blood phosphorus decreased	1(0.0%)	0
Blood pressure abnormal	1(0.0%)	0
Blood pressure diastolic increased	1(0.0%)	0
Blood pressure orthostatic decreased	1(0.0%)	0
Breath sounds abnormal	1(0.0%)	0
Brucella test positive	1(0.0%)	0
C-reactive protein abnormal	1(0.0%)	0
Cancer staging	1(0.0%)	0
Carbohydrate antigen 125 increased	1(0.0%)	0
Cardiac function test abnormal	1(0.0%)	0
Cardiac imaging procedure abnormal	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0
Cardiac stress test abnormal	1(0.0%)	0
Colonoscopy abnormal	1(0.0%)	0
Colonoscopy normal	1(0.0%)	0
Computerised tomogram	1(0.0%)	0
Cystoscopy	1(0.0%)	0
Electrocardiogram P wave abnormal	1(0.0%)	0
Electrocardiogram PR prolongation	1(0.0%)	0
Electrocardiogram ST-T segment depression	1(0.0%)	0
Endoscopy upper gastrointestinal tract	1(0.0%)	0
False positive investigation result	1(0.0%)	0
Hepatic enzyme abnormal	1(0.0%)	0
Hepatitis B core antibody positive	1(0.0%)	0
Hepatitis B surface antibody positive	1(0.0%)	0
Human chorionic gonadotropin increased	1(0.0%)	0
Intestinal transit time decreased	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Investigation	1(0.0%)	0
Klebsiella test positive	1(0.0%)	0
Legionella test positive	1(0.0%)	0
Lipids abnormal	1(0.0%)	0
Mean cell haemoglobin concentration decreased	1(0.0%)	0
Myoglobin blood increased	1(0.0%)	0
Neurone-specific enolase increased	1(0.0%)	0
Nitrite urine present	1(0.0%)	0
Optic nerve cup/disc ratio increased	1(0.0%)	0
Protein S decreased	1(0.0%)	0
Protein total increased	1(0.0%)	0
Prothrombin time prolonged	1(0.0%)	0
Pulse abnormal	1(0.0%)	0
Pulse absent	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Red blood cell sedimentation rate decreased	1(0.0%)	0
Rheumatoid factor increased	1(0.0%)	0
Serratia test positive	1(0.0%)	0
Serum ferritin increased	1(0.0%)	0
Sleep study	1(0.0%)	0
Sputum abnormal	1(0.0%)	0
Tumour marker increased	1(0.0%)	0
Urine alcohol test positive	1(0.0%)	0
Urinary occult blood positive	0	5(0.1%)
Carotid bruit	0	4(0.1%)
Electrocardiogram ST segment abnormal	0	4(0.1%)
Platelet count increased	0	4(0.1%)
Serum ferritin decreased	0	4(0.1%)
Quality of life decreased	0	3(0.0%)
Red blood cell sedimentation rate increased	0	3(0.0%)
Ultrasound kidney abnormal	0	3(0.0%)
Angiogram cerebral	0	2(0.0%)
Blood magnesium increased	0	2(0.0%)
Body temperature increased	0	2(0.0%)
Carbohydrate antigen 19-9 increased	0	2(0.0%)
Endoscopy small intestine	0	2(0.0%)
Eosinophil count increased	0	2(0.0%)
Gastric pH decreased	0	2(0.0%)
Influenza B virus test positive	0	2(0.0%)
Left ventricular end-diastolic pressure increased	0	2(0.0%)
Light chain analysis increased	0	2(0.0%)
Myocardial necrosis marker increased	0	2(0.0%)
Neutrophil count increased	0	2(0.0%)
Peripheral arteriogram	0	2(0.0%)
Troponin I increased	0	2(0.0%)
Ultrasound Doppler abnormal	0	2(0.0%)
Alpha 1 foetoprotein increased	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Anticoagulation drug level increased	0	1(0.0%)
Biopsy	0	1(0.0%)
Biopsy breast	0	1(0.0%)
Biopsy thyroid gland	0	1(0.0%)
Blood chromium decreased	0	1(0.0%)
Blood chromogranin A increased	0	1(0.0%)
Blood creatine phosphokinase abnormal	0	1(0.0%)
Blood thyroid stimulating hormone decreased	0	1(0.0%)
Brain scan abnormal	0	1(0.0%)
Carbohydrate antigen 50 increased	0	1(0.0%)
Cardiac index decreased	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)
Coagulation time prolonged	0	1(0.0%)
Computerised tomogram abdomen	0	1(0.0%)
Cytogenetic analysis abnormal	0	1(0.0%)
Electrocardiogram QRS complex prolonged	0	1(0.0%)
Electrocardiogram QT interval abnormal	0	1(0.0%)
Electrocardiogram ST-T segment abnormal	0	1(0.0%)
Electroencephalogram abnormal	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Endobronchial ultrasound	0	1(0.0%)
Face and mouth X-ray abnormal	0	1(0.0%)
Gastrin-releasing peptide precursor increased	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Haematocrit abnormal	0	1(0.0%)
Haemoglobin abnormal	0	1(0.0%)
Heart rate irregular	0	1(0.0%)
Hepatitis C virus test positive	0	1(0.0%)
Herpes simplex test positive	0	1(0.0%)
Human rhinovirus test positive	0	1(0.0%)
Laboratory test abnormal	0	1(0.0%)
Magnetic resonance imaging brain abnormal	0	1(0.0%)
Mean cell volume decreased	0	1(0.0%)
Muscle enzyme increased	0	1(0.0%)
Mycobacterium tuberculosis complex test positive	0	1(0.0%)
Oral soft tissue biopsy	0	1(0.0%)
Oxygen saturation decreased	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Pulmonary function test decreased	0	1(0.0%)
Red blood cell count increased	0	1(0.0%)
Red blood cells urine positive	0	1(0.0%)
Reticulocyte count increased	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
Scan adrenal gland abnormal	0	1(0.0%)
Staphylococcus test positive	0	1(0.0%)
Stool analysis abnormal	0	1(0.0%)
Thyroid hormones increased	0	1(0.0%)
Treponema test positive	0	1(0.0%)
Ultrasound liver abnormal	0	1(0.0%)
Ultrasound thyroid abnormal	0	1(0.0%)
Urine analysis abnormal	0	1(0.0%)
Urine output increased	0	1(0.0%)
Urine protein/creatinine ratio increased	0	1(0.0%)
Vitamin B12 increased	0	1(0.0%)
White blood cell analysis abnormal	0	1(0.0%)
Nervous System Disorders	1362(20.9%)	1387(21.4%)
Dizziness	341(5.2%)	322(5.0%)
Headache	209(3.2%)	210(3.2%)
Diabetic neuropathy	135(2.1%)	137(2.1%)
Syncope	76(1.2%)	111(1.7%)
Hypoaesthesia	72(1.1%)	74(1.1%)
Sciatica	60(0.9%)	71(1.1%)
Neuropathy peripheral	52(0.8%)	44(0.7%)
Carpal tunnel syndrome	47(0.7%)	42(0.6%)
Paraesthesia	39(0.6%)	45(0.7%)
Carotid artery stenosis	38(0.6%)	42(0.6%)
Carotid arteriosclerosis	37(0.6%)	42(0.6%)
Dizziness postural	25(0.4%)	16(0.2%)
Presyncope	25(0.4%)	12(0.2%)
Cognitive disorder	24(0.4%)	24(0.4%)
Tremor	23(0.4%)	26(0.4%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Facial paralysis	20(0.3%)	21(0.3%)
Loss of consciousness	19(0.3%)	7(0.1%)
Neuralgia	18(0.3%)	24(0.4%)
Memory impairment	18(0.3%)	16(0.2%)
Lacunar infarction	18(0.3%)	11(0.2%)
Polyneuropathy	17(0.3%)	20(0.3%)
Transient ischaemic attack	16(0.2%)	19(0.3%)
Cerebral ischaemia	15(0.2%)	14(0.2%)
Lethargy	15(0.2%)	10(0.2%)
Dementia	14(0.2%)	19(0.3%)
Somnolence	13(0.2%)	21(0.3%)
Cerebrovascular disorder	13(0.2%)	12(0.2%)
Restless legs syndrome	13(0.2%)	7(0.1%)
Parkinson's disease	12(0.2%)	16(0.2%)
Cerebral infarction	12(0.2%)	13(0.2%)
Hemiparesis	12(0.2%)	9(0.1%)
Seizure	11(0.2%)	9(0.1%)
Tension headache	11(0.2%)	4(0.1%)
Amnesia	10(0.2%)	19(0.3%)
Cervicobrachial syndrome	10(0.2%)	10(0.2%)
Cerebral atrophy	10(0.2%)	9(0.1%)
Radiculopathy	9(0.1%)	9(0.1%)
Cerebral arteriosclerosis	8(0.1%)	12(0.2%)
Dysarthria	8(0.1%)	7(0.1%)
Balance disorder	7(0.1%)	15(0.2%)
Cervical radiculopathy	7(0.1%)	9(0.1%)
Dysgeusia	7(0.1%)	8(0.1%)
Lumbar radiculopathy	7(0.1%)	7(0.1%)
Subarachnoid haemorrhage	7(0.1%)	7(0.1%)
Vascular encephalopathy	7(0.1%)	7(0.1%)
Epilepsy	7(0.1%)	5(0.1%)
Poor quality sleep	7(0.1%)	2(0.0%)
Migraine	6(0.1%)	14(0.2%)
Dementia Alzheimer's type	6(0.1%)	8(0.1%)
Parkinsonism	6(0.1%)	6(0.1%)
Post herpetic neuralgia	6(0.1%)	6(0.1%)
Peripheral sensorimotor neuropathy	6(0.1%)	5(0.1%)
Nerve compression	6(0.1%)	3(0.0%)
Encephalopathy	5(0.1%)	13(0.2%)
Cerebral microangiopathy	5(0.1%)	3(0.0%)
Hemianaesthesia	5(0.1%)	3(0.0%)
Normal pressure hydrocephalus	5(0.1%)	2(0.0%)
Orthostatic intolerance	5(0.1%)	2(0.0%)
Burning sensation	4(0.1%)	6(0.1%)
Aphasia	4(0.1%)	4(0.1%)
Carotid artery disease	4(0.1%)	4(0.1%)
Metabolic encephalopathy	4(0.1%)	4(0.1%)
Myelopathy	4(0.1%)	4(0.1%)
Cerebral small vessel ischaemic disease	4(0.1%)	2(0.0%)
Leukoencephalopathy	4(0.1%)	2(0.0%)
Altered state of consciousness	4(0.1%)	1(0.0%)
Cerebral haemorrhage	4(0.1%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vertebral artery occlusion	4(0.1%)	1(0.0%)
Sensory disturbance	3(0.0%)	8(0.1%)
Essential tremor	3(0.0%)	7(0.1%)
Facial paresis	3(0.0%)	5(0.1%)
IIIrd nerve paralysis	3(0.0%)	5(0.1%)
Carotid artery occlusion	3(0.0%)	4(0.1%)
Lumbosacral radiculopathy	3(0.0%)	4(0.1%)
Phantom limb syndrome	3(0.0%)	4(0.1%)
Cerebrovascular accident	3(0.0%)	3(0.0%)
Intercostal neuralgia	3(0.0%)	3(0.0%)
Visual field defect	3(0.0%)	3(0.0%)
Cubital tunnel syndrome	3(0.0%)	2(0.0%)
Dysaesthesia	3(0.0%)	2(0.0%)
Vocal cord paralysis	3(0.0%)	2(0.0%)
Autonomic neuropathy	3(0.0%)	0
IVth nerve paralysis	3(0.0%)	0
Motor dysfunction	3(0.0%)	0
Cerebral artery stenosis	2(0.0%)	7(0.1%)
Intracranial aneurysm	2(0.0%)	4(0.1%)
Peripheral sensory neuropathy	2(0.0%)	4(0.1%)
Hemiparaesthesia	2(0.0%)	3(0.0%)
Vertebral artery stenosis	2(0.0%)	3(0.0%)
Ageusia	2(0.0%)	2(0.0%)
Decreased vibratory sense	2(0.0%)	2(0.0%)
Myoclonus	2(0.0%)	2(0.0%)
Trigeminal neuralgia	2(0.0%)	2(0.0%)
Ataxia	2(0.0%)	1(0.0%)
Cerebellar stroke	2(0.0%)	1(0.0%)
Cerebral circulatory failure	2(0.0%)	1(0.0%)
Cerebrovascular insufficiency	2(0.0%)	1(0.0%)
Demyelination	2(0.0%)	1(0.0%)
Head discomfort	2(0.0%)	1(0.0%)
Hyporeflexia	2(0.0%)	1(0.0%)
Ischaemic stroke	2(0.0%)	1(0.0%)
Meralgia paraesthetica	2(0.0%)	1(0.0%)
Parosmia	2(0.0%)	1(0.0%)
Partial seizures	2(0.0%)	1(0.0%)
Amputation stump pain	2(0.0%)	0
Cerebral artery occlusion	2(0.0%)	0
Coordination abnormal	2(0.0%)	0
Dyskinesia	2(0.0%)	0
Hepatic encephalopathy	2(0.0%)	0
Migraine without aura	2(0.0%)	0
Sinus headache	2(0.0%)	0
Spinal claudication	2(0.0%)	0
Transient global amnesia	2(0.0%)	0
VIth nerve paralysis	2(0.0%)	0
Vascular headache	2(0.0%)	0
Vascular parkinsonism	2(0.0%)	0
Vocal cord paresis	2(0.0%)	0
White matter lesion	2(0.0%)	0
Anosmia	1(0.0%)	4(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vascular dementia	1(0.0%)	4(0.1%)
Hydrocephalus	1(0.0%)	3(0.0%)
Neurodegenerative disorder	1(0.0%)	3(0.0%)
Brain oedema	1(0.0%)	2(0.0%)
Central nervous system lesion	1(0.0%)	2(0.0%)
Facial nerve disorder	1(0.0%)	2(0.0%)
Hypersomnia	1(0.0%)	2(0.0%)
Mixed dementia	1(0.0%)	2(0.0%)
Monoparesis	1(0.0%)	2(0.0%)
Muscle contractions involuntary	1(0.0%)	2(0.0%)
Paraparesis	1(0.0%)	2(0.0%)
Senile dementia	1(0.0%)	2(0.0%)
Vertebrobasilar insufficiency	1(0.0%)	2(0.0%)
Cerebellar infarction	1(0.0%)	1(0.0%)
Cerebral calcification	1(0.0%)	1(0.0%)
Cervicogenic headache	1(0.0%)	1(0.0%)
Dementia with Lewy bodies	1(0.0%)	1(0.0%)
Dizziness exertional	1(0.0%)	1(0.0%)
Focal dyscognitive seizures	1(0.0%)	1(0.0%)
Generalised tonic-clonic seizure	1(0.0%)	1(0.0%)
Hemianopia	1(0.0%)	1(0.0%)
Hypogeusia	1(0.0%)	1(0.0%)
Hypoglycaemic unconsciousness	1(0.0%)	1(0.0%)
Mononeuropathy	1(0.0%)	1(0.0%)
Nervous system disorder	1(0.0%)	1(0.0%)
Neuritis	1(0.0%)	1(0.0%)
Peroneal nerve palsy	1(0.0%)	1(0.0%)
Spinal cord compression	1(0.0%)	1(0.0%)
Subdural effusion	1(0.0%)	1(0.0%)
Allodynia	1(0.0%)	0
Angiopathic neuropathy	1(0.0%)	0
Basilar artery occlusion	1(0.0%)	0
Basilar artery stenosis	1(0.0%)	0
Brachial plexopathy	1(0.0%)	0
Brain injury	1(0.0%)	0
Bulbar palsy	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral hypoperfusion	1(0.0%)	0
Cerebral microhaemorrhage	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Cerebrospinal fluid leakage	1(0.0%)	0
Cerebrovascular stenosis	1(0.0%)	0
Complex regional pain syndrome	1(0.0%)	0
Demyelinating polyneuropathy	1(0.0%)	0
Drop attacks	1(0.0%)	0
Dysmetria	1(0.0%)	0
Frontotemporal dementia	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianopia homonymous	1(0.0%)	0
Intention tremor	1(0.0%)	0
Intracranial hypotension	1(0.0%)	0
Lacunar stroke	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Monoplegia	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Neuromuscular blockade	1(0.0%)	0
Peripheral motor neuropathy	1(0.0%)	0
Peripheral nerve lesion	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Post-traumatic headache	1(0.0%)	0
Resting tremor	1(0.0%)	0
Sleep deficit	1(0.0%)	0
Slow speech	1(0.0%)	0
Speech disorder	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
Unresponsive to stimuli	1(0.0%)	0
Vertebrobasilar dolichoectasia	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
Radicular pain	0	4(0.1%)
Hypoxic-ischaemic encephalopathy	0	3(0.0%)
Anaesthesia	0	2(0.0%)
Arachnoid cyst	0	2(0.0%)
Axonal neuropathy	0	2(0.0%)
Carotid artery aneurysm	0	2(0.0%)
Cerebellar atrophy	0	2(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	2(0.0%)
Coma	0	2(0.0%)
Diabetic hyperosmolar coma	0	2(0.0%)
Disturbance in attention	0	2(0.0%)
Dysstasia	0	2(0.0%)
Hemiplegia	0	2(0.0%)
Hypoglycaemic coma	0	2(0.0%)
Postural tremor	0	2(0.0%)
Spondylitic myelopathy	0	2(0.0%)
Toxic neuropathy	0	2(0.0%)
Vertigo CNS origin	0	2(0.0%)
Alcohol induced persisting dementia	0	1(0.0%)
Amnestic disorder	0	1(0.0%)
Basal ganglia haemorrhage	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Brain stem infarction	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery thrombosis	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebral vascular occlusion	0	1(0.0%)
Cerebrovascular pseudoaneurysm	0	1(0.0%)
Clonus	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Epidural lipomatosis	0	1(0.0%)
Facial neuralgia	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Facial spasm	0	1(0.0%)
Gliosis	0	1(0.0%)
Head titubation	0	1(0.0%)
Hyperglycaemic unconsciousness	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypotonia	0	1(0.0%)
IVth nerve paresis	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Ischaemic neuropathy	0	1(0.0%)
Mental impairment	0	1(0.0%)
Migraine with aura	0	1(0.0%)
Mononeuropathy multiplex	0	1(0.0%)
Multiple sclerosis	0	1(0.0%)
Multiple sclerosis relapse	0	1(0.0%)
Multiple system atrophy	0	1(0.0%)
Muscle tone disorder	0	1(0.0%)
Myasthenia gravis	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Myelomalacia	0	1(0.0%)
Neuralgic amyotrophy	0	1(0.0%)
Neurological symptom	0	1(0.0%)
Neuromyopathy	0	1(0.0%)
Nystagmus	0	1(0.0%)
Occipital neuralgia	0	1(0.0%)
Optic neuritis	0	1(0.0%)
Paraplegia	0	1(0.0%)
Peripheral nerve paresis	0	1(0.0%)
Piriformis syndrome	0	1(0.0%)
Posthaemorrhagic hydrocephalus	0	1(0.0%)
Precerebral arteriosclerosis	0	1(0.0%)
Pronator teres syndrome	0	1(0.0%)
Radiculitis brachial	0	1(0.0%)
Sacral radiculopathy	0	1(0.0%)
Sciatic nerve neuropathy	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Spinal cord haematoma	0	1(0.0%)
Subdural hygroma	0	1(0.0%)
Tarsal tunnel syndrome	0	1(0.0%)
Taste disorder	0	1(0.0%)
Thalamic infarction	0	1(0.0%)
Thalamus haemorrhage	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Ulnar nerve palsy	0	1(0.0%)
Ulnar tunnel syndrome	0	1(0.0%)
VIth nerve paresis	0	1(0.0%)
Vertebral artery arteriosclerosis	0	1(0.0%)
Vascular Disorders	1153(17.7%)	1183(18.2%)
Hypertension	419(6.4%)	581(9.0%)
Hypotension	282(4.3%)	177(2.7%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Peripheral arterial occlusive disease	95(1.5%)	103(1.6%)
Hypertensive crisis	51(0.8%)	54(0.8%)
Orthostatic hypotension	46(0.7%)	39(0.6%)
Intermittent claudication	37(0.6%)	31(0.5%)
Peripheral venous disease	34(0.5%)	29(0.4%)
Aortic stenosis	30(0.5%)	25(0.4%)
Varicose vein	27(0.4%)	21(0.3%)
Aortic arteriosclerosis	24(0.4%)	34(0.5%)
Deep vein thrombosis	23(0.4%)	18(0.3%)
Arteriosclerosis	20(0.3%)	16(0.2%)
Peripheral artery occlusion	19(0.3%)	8(0.1%)
Peripheral artery stenosis	18(0.3%)	19(0.3%)
Peripheral vascular disorder	17(0.3%)	26(0.4%)
Haematoma	17(0.3%)	19(0.3%)
Peripheral ischaemia	14(0.2%)	9(0.1%)
Aortic aneurysm	13(0.2%)	20(0.3%)
Diabetic vascular disorder	12(0.2%)	15(0.2%)
Blood pressure inadequately controlled	11(0.2%)	19(0.3%)
Hypertensive urgency	11(0.2%)	11(0.2%)
Extremity necrosis	10(0.2%)	3(0.0%)
Lymphoedema	9(0.1%)	8(0.1%)
Hypertensive emergency	7(0.1%)	9(0.1%)
Thrombophlebitis	7(0.1%)	6(0.1%)
Phlebitis	6(0.1%)	9(0.1%)
Hot flush	5(0.1%)	10(0.2%)
Circulatory collapse	5(0.1%)	6(0.1%)
Brachiocephalic arteriosclerosis	5(0.1%)	1(0.0%)
Thrombophlebitis superficial	5(0.1%)	1(0.0%)
Aortic dilatation	4(0.1%)	9(0.1%)
Peripheral coldness	4(0.1%)	6(0.1%)
Iliac artery stenosis	4(0.1%)	2(0.0%)
Thrombosis	4(0.1%)	2(0.0%)
Peripheral embolism	4(0.1%)	0
Phlebitis superficial	4(0.1%)	0
Blood pressure fluctuation	3(0.0%)	5(0.1%)
Peripheral artery aneurysm	3(0.0%)	3(0.0%)
Peripheral artery thrombosis	3(0.0%)	3(0.0%)
Giant cell arteritis	3(0.0%)	2(0.0%)
Arterial occlusive disease	3(0.0%)	1(0.0%)
Labile hypertension	3(0.0%)	1(0.0%)
Lymphostasis	3(0.0%)	1(0.0%)
Macroangiopathy	3(0.0%)	1(0.0%)
Aortic dissection	3(0.0%)	0
Labile blood pressure	3(0.0%)	0
Raynaud's phenomenon	3(0.0%)	0
Arterial disorder	2(0.0%)	1(0.0%)
Dry gangrene	2(0.0%)	1(0.0%)
Post thrombotic syndrome	2(0.0%)	1(0.0%)
Cyanosis	2(0.0%)	0
Diastolic hypotension	2(0.0%)	0
Essential hypertension	1(0.0%)	6(0.1%)
Microangiopathy	1(0.0%)	4(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Diabetic macroangiopathy	1(0.0%)	3(0.0%)
Poor peripheral circulation	1(0.0%)	3(0.0%)
Venous thrombosis limb	1(0.0%)	3(0.0%)
Arterial stenosis	1(0.0%)	2(0.0%)
Hypovolaemic shock	1(0.0%)	2(0.0%)
Subclavian artery stenosis	1(0.0%)	2(0.0%)
Aortic occlusion	1(0.0%)	1(0.0%)
Arteriosclerosis Moenckeberg-type	1(0.0%)	1(0.0%)
Arteriovenous fistula	1(0.0%)	1(0.0%)
Embolism venous	1(0.0%)	1(0.0%)
Internal haemorrhage	1(0.0%)	1(0.0%)
Ischaemia	1(0.0%)	1(0.0%)
Neovascularisation	1(0.0%)	1(0.0%)
Subclavian steal syndrome	1(0.0%)	1(0.0%)
Vasculitis	1(0.0%)	1(0.0%)
Vein disorder	1(0.0%)	1(0.0%)
Vein rupture	1(0.0%)	1(0.0%)
Angiodysplasia	1(0.0%)	0
Aortitis	1(0.0%)	0
Artery dissection	1(0.0%)	0
Collateral circulation	1(0.0%)	0
Dialysis hypotension	1(0.0%)	0
Haematocoele	1(0.0%)	0
Iliac artery occlusion	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Lymphocele	1(0.0%)	0
Lymphorrhoea	1(0.0%)	0
Penetrating aortic ulcer	1(0.0%)	0
Phlebosclerosis	1(0.0%)	0
Subclavian artery dissection	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Vascular wall hypertrophy	1(0.0%)	0
Vasodilatation	1(0.0%)	0
Venous occlusion	1(0.0%)	0
White coat hypertension	1(0.0%)	0
Accelerated hypertension	0	4(0.1%)
Aortic disorder	0	3(0.0%)
Flushing	0	3(0.0%)
Hypertensive angiopathy	0	3(0.0%)
Systolic hypertension	0	3(0.0%)
Angiosclerosis	0	2(0.0%)
Aortic thrombosis	0	2(0.0%)
Arteritis	0	2(0.0%)
Hyperaemia	0	2(0.0%)
Malignant hypertension	0	2(0.0%)
Angiopathy	0	1(0.0%)
Aortic aneurysm rupture	0	1(0.0%)
Arterial thrombosis	0	1(0.0%)
Brachiocephalic artery stenosis	0	1(0.0%)
Inferior vena cava syndrome	0	1(0.0%)
Leriche syndrome	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Orthostatic hypertension	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Phlebolith	0	1(0.0%)
Renovascular hypertension	0	1(0.0%)
Shock	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Supra-aortic trunk stenosis	0	1(0.0%)
Thromboangiitis obliterans	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	1122(17.2%)	1170(18.0%)
Cough	284(4.4%)	300(4.6%)
Dyspnoea	201(3.1%)	219(3.4%)
Chronic obstructive pulmonary disease	106(1.6%)	95(1.5%)
Oropharyngeal pain	62(1.0%)	51(0.8%)
Sleep apnoea syndrome	61(0.9%)	75(1.2%)
Dyspnoea exertional	59(0.9%)	60(0.9%)
Epistaxis	48(0.7%)	45(0.7%)
Rhinitis allergic	46(0.7%)	37(0.6%)
Pulmonary mass	41(0.6%)	29(0.4%)
Pleural effusion	40(0.6%)	37(0.6%)
Asthma	38(0.6%)	51(0.8%)
Bronchitis chronic	33(0.5%)	22(0.3%)
Respiratory disorder	30(0.5%)	17(0.3%)
Rhinorrhoea	26(0.4%)	27(0.4%)
Respiratory failure	23(0.4%)	28(0.4%)
Acute respiratory failure	23(0.4%)	27(0.4%)
Productive cough	22(0.3%)	36(0.6%)
Upper respiratory tract inflammation	18(0.3%)	15(0.2%)
Pulmonary embolism	16(0.2%)	17(0.3%)
Interstitial lung disease	16(0.2%)	13(0.2%)
Catarrh	16(0.2%)	11(0.2%)
Pulmonary hypertension	15(0.2%)	23(0.4%)
Emphysema	13(0.2%)	11(0.2%)
Nasal congestion	12(0.2%)	13(0.2%)
Atelectasis	10(0.2%)	11(0.2%)
Pulmonary fibrosis	10(0.2%)	10(0.2%)
Hypoxia	9(0.1%)	9(0.1%)
Sinus congestion	8(0.1%)	5(0.1%)
Acute pulmonary oedema	7(0.1%)	10(0.2%)
Hiccups	7(0.1%)	5(0.1%)
Obstructive airways disorder	7(0.1%)	2(0.0%)
Pulmonary congestion	6(0.1%)	13(0.2%)
Bronchospasm	6(0.1%)	11(0.2%)
Pneumonia aspiration	6(0.1%)	7(0.1%)
Bronchiectasis	6(0.1%)	4(0.1%)
Pleurisy	6(0.1%)	3(0.0%)
Pulmonary oedema	5(0.1%)	23(0.4%)
Dysphonia	5(0.1%)	11(0.2%)
Haemoptysis	5(0.1%)	8(0.1%)
Upper-airway cough syndrome	5(0.1%)	5(0.1%)
Restrictive pulmonary disease	5(0.1%)	4(0.1%)
Dyspnoea paroxysmal nocturnal	4(0.1%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Pneumothorax	4(0.1%)	3(0.0%)
Nasal septum deviation	4(0.1%)	2(0.0%)
Sneezing	4(0.1%)	1(0.0%)
Pneumonitis	3(0.0%)	7(0.1%)
Rales	3(0.0%)	7(0.1%)
Wheezing	3(0.0%)	7(0.1%)
Nasal obstruction	3(0.0%)	6(0.1%)
Orthopnoea	3(0.0%)	4(0.1%)
Lung disorder	3(0.0%)	3(0.0%)
Respiratory tract congestion	3(0.0%)	3(0.0%)
Chronic respiratory failure	3(0.0%)	2(0.0%)
Laryngeal oedema	3(0.0%)	1(0.0%)
Lung opacity	3(0.0%)	1(0.0%)
Hyperventilation	3(0.0%)	0
Oropharyngeal discomfort	3(0.0%)	0
Pulmonary arterial hypertension	2(0.0%)	4(0.1%)
Aphonia	2(0.0%)	2(0.0%)
Cystic lung disease	2(0.0%)	2(0.0%)
Nasal turbinate hypertrophy	2(0.0%)	2(0.0%)
Laryngeal mass	2(0.0%)	1(0.0%)
Lower respiratory tract inflammation	2(0.0%)	1(0.0%)
Paranasal cyst	2(0.0%)	1(0.0%)
Vasomotor rhinitis	2(0.0%)	1(0.0%)
Asthmatic crisis	2(0.0%)	0
Choking sensation	2(0.0%)	0
Lung consolidation	2(0.0%)	0
Lung infiltration	2(0.0%)	0
Nasal crusting	2(0.0%)	0
Nasal disorder	2(0.0%)	0
Pharyngeal erythema	2(0.0%)	0
Pleuritic pain	2(0.0%)	0
Cough variant asthma	1(0.0%)	6(0.1%)
Bronchial hyperreactivity	1(0.0%)	3(0.0%)
Hydrothorax	1(0.0%)	3(0.0%)
Idiopathic pulmonary fibrosis	1(0.0%)	3(0.0%)
Respiratory acidosis	1(0.0%)	3(0.0%)
Throat irritation	1(0.0%)	3(0.0%)
Dry throat	1(0.0%)	2(0.0%)
Dyspnoea at rest	1(0.0%)	2(0.0%)
Hypercapnia	1(0.0%)	2(0.0%)
Paranasal sinus hypersecretion	1(0.0%)	2(0.0%)
Pharyngeal inflammation	1(0.0%)	2(0.0%)
Respiratory distress	1(0.0%)	2(0.0%)
Rhonchi	1(0.0%)	2(0.0%)
Sinus disorder	1(0.0%)	2(0.0%)
Vocal cord polyp	1(0.0%)	2(0.0%)
Increased bronchial secretion	1(0.0%)	1(0.0%)
Nasal dryness	1(0.0%)	1(0.0%)
Nasal polyps	1(0.0%)	1(0.0%)
Paranasal sinus inflammation	1(0.0%)	1(0.0%)
Respiratory tract inflammation	1(0.0%)	1(0.0%)
Small airways disease	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Tonsillar hypertrophy	1(0.0%)	1(0.0%)
Allergic bronchitis	1(0.0%)	0
Alveolar lung disease	1(0.0%)	0
Asphyxia	1(0.0%)	0
Bronchial disorder	1(0.0%)	0
Combined pulmonary fibrosis and emphysema	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Laryngeal cyst	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Laryngeal polyp	1(0.0%)	0
Laryngitis allergic	1(0.0%)	0
Lung hyperinflation	1(0.0%)	0
Nasal mucosal disorder	1(0.0%)	0
Nasal mucosal erosion	1(0.0%)	0
Nasal pruritus	1(0.0%)	0
Oropharyngeal dysplasia	1(0.0%)	0
Pharyngeal disorder	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pharyngeal paraesthesia	1(0.0%)	0
Pleural fibrosis	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Reversible airways obstruction	1(0.0%)	0
Rhinitis hypertrophic	1(0.0%)	0
Sputum discoloured	1(0.0%)	0
Stridor	1(0.0%)	0
Tonsillar cyst	1(0.0%)	0
Tonsillar inflammation	1(0.0%)	0
Tracheal squamous cell metaplasia	1(0.0%)	0
Tracheal stenosis	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Vocal cord inflammation	1(0.0%)	0
Upper respiratory tract congestion	0	4(0.1%)
Aspiration	0	3(0.0%)
Lung cyst	0	3(0.0%)
Haemothorax	0	2(0.0%)
Paranasal sinus discomfort	0	2(0.0%)
Pickwickian syndrome	0	2(0.0%)
Pulmonary granuloma	0	2(0.0%)
Reflux laryngitis	0	2(0.0%)
Respiration abnormal	0	2(0.0%)
Sinus pain	0	2(0.0%)
Sinus polyp	0	2(0.0%)
Snoring	0	2(0.0%)
Acute respiratory distress syndrome	0	1(0.0%)
Allergic cough	0	1(0.0%)
Allergic respiratory disease	0	1(0.0%)
Allergic sinusitis	0	1(0.0%)
Apnoea	0	1(0.0%)
Atopic cough	0	1(0.0%)
Bronchial secretion retention	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Bronchopneumopathy	0	1(0.0%)
Choking	0	1(0.0%)
Chronic respiratory disease	0	1(0.0%)
Diaphragmatic abnormal relaxation	0	1(0.0%)
Epiglottic oedema	0	1(0.0%)
Hepatic hydrothorax	0	1(0.0%)
Hypersensitivity pneumonitis	0	1(0.0%)
Hypopnoea	0	1(0.0%)
Laryngeal disorder	0	1(0.0%)
Laryngeal inflammation	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Laryngospasm	0	1(0.0%)
Lung hypoinflation	0	1(0.0%)
Lung perforation	0	1(0.0%)
Nasal varices	0	1(0.0%)
Nocturnal dyspnoea	0	1(0.0%)
Paranasal sinus mucosal hypertrophy	0	1(0.0%)
Pharyngeal stenosis	0	1(0.0%)
Pleural thickening	0	1(0.0%)
Pulmonary calcification	0	1(0.0%)
Pulmonary haematoma	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Rhinitis perennial	0	1(0.0%)
Sputum increased	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Throat tightness	0	1(0.0%)
Vocal cord disorder	0	1(0.0%)
Vocal cord leukoplakia	0	1(0.0%)
General Disorders And Administration Site Conditions	1107(17.0%)	1329(20.5%)
Oedema peripheral	384(5.9%)	584(9.0%)
Chest pain	169(2.6%)	190(2.9%)
Fatigue	140(2.2%)	133(2.0%)
Pyrexia	98(1.5%)	93(1.4%)
Asthenia	90(1.4%)	113(1.7%)
Oedema	69(1.1%)	93(1.4%)
Peripheral swelling	67(1.0%)	84(1.3%)
Chest discomfort	40(0.6%)	37(0.6%)
Influenza like illness	36(0.6%)	37(0.6%)
Malaise	28(0.4%)	25(0.4%)
Pain	26(0.4%)	27(0.4%)
Inflammation	19(0.3%)	26(0.4%)
Gait disturbance	12(0.2%)	21(0.3%)
Chills	11(0.2%)	9(0.1%)
Generalised oedema	10(0.2%)	13(0.2%)
Death	10(0.2%)	10(0.2%)
Non-cardiac chest pain	9(0.1%)	13(0.2%)
General physical health deterioration	9(0.1%)	11(0.2%)
Impaired healing	9(0.1%)	3(0.0%)
Face oedema	7(0.1%)	8(0.1%)
Cyst	6(0.1%)	9(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Feeling cold	6(0.1%)	6(0.1%)
Mass	6(0.1%)	6(0.1%)
Illness	6(0.1%)	5(0.1%)
Drug intolerance	5(0.1%)	6(0.1%)
Feeling abnormal	5(0.1%)	4(0.1%)
Nodule	5(0.1%)	4(0.1%)
Hernia	5(0.1%)	0
Unevaluable event	5(0.1%)	0
Polyp	4(0.1%)	9(0.1%)
Oedema due to renal disease	4(0.1%)	3(0.0%)
Swelling face	4(0.1%)	3(0.0%)
Hyperthermia	4(0.1%)	1(0.0%)
Exercise tolerance decreased	4(0.1%)	0
Gravitational oedema	3(0.0%)	3(0.0%)
Multiple organ dysfunction syndrome	3(0.0%)	3(0.0%)
Discomfort	3(0.0%)	2(0.0%)
Localised oedema	2(0.0%)	4(0.1%)
Thirst	2(0.0%)	3(0.0%)
Vascular stent stenosis	2(0.0%)	2(0.0%)
Granuloma	2(0.0%)	1(0.0%)
Medical device site reaction	2(0.0%)	0
Stent-graft endoleak	2(0.0%)	0
Feeling hot	1(0.0%)	2(0.0%)
Hunger	1(0.0%)	2(0.0%)
Suprapubic pain	1(0.0%)	2(0.0%)
Swelling	1(0.0%)	2(0.0%)
Xerosis	1(0.0%)	2(0.0%)
Adverse drug reaction	1(0.0%)	1(0.0%)
Axillary pain	1(0.0%)	1(0.0%)
Calcinosis	1(0.0%)	1(0.0%)
Early satiety	1(0.0%)	1(0.0%)
Hernia pain	1(0.0%)	1(0.0%)
Hypothermia	1(0.0%)	1(0.0%)
Injection site atrophy	1(0.0%)	1(0.0%)
Injection site pain	1(0.0%)	1(0.0%)
Injection site pruritus	1(0.0%)	1(0.0%)
Medical device site pain	1(0.0%)	1(0.0%)
Sensation of foreign body	1(0.0%)	1(0.0%)
Soft tissue inflammation	1(0.0%)	1(0.0%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Adverse event	1(0.0%)	0
Application site reaction	1(0.0%)	0
Catheter site inflammation	1(0.0%)	0
Catheter site pain	1(0.0%)	0
Chronic fatigue syndrome	1(0.0%)	0
Complication associated with device	1(0.0%)	0
Crepitations	1(0.0%)	0
Cyst rupture	1(0.0%)	0
Hanging	1(0.0%)	0
Implant site erosion	1(0.0%)	0
Injection site erosion	1(0.0%)	0
Injection site extravasation	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Injection site nodule	1(0.0%)	0
Medical device pain	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Physical deconditioning	1(0.0%)	0
Precancerous condition	1(0.0%)	0
Pseudocyst	1(0.0%)	0
Pseudopolyp	1(0.0%)	0
Puncture site swelling	1(0.0%)	0
Facial pain	0	3(0.0%)
Induration	0	2(0.0%)
Medical device site ulcer	0	2(0.0%)
Puncture site pain	0	2(0.0%)
Secretion discharge	0	2(0.0%)
Temperature intolerance	0	2(0.0%)
Vessel puncture site bruise	0	2(0.0%)
Adhesion	0	1(0.0%)
Catheter site discharge	0	1(0.0%)
Catheter site erythema	0	1(0.0%)
Device intolerance	0	1(0.0%)
Drug ineffective	0	1(0.0%)
Facial discomfort	0	1(0.0%)
Haemorrhagic cyst	0	1(0.0%)
Hyperpyrexia	0	1(0.0%)
Injection site erythema	0	1(0.0%)
Injection site swelling	0	1(0.0%)
Medical device site nerve damage	0	1(0.0%)
Medical device site pruritus	0	1(0.0%)
Non-pitting oedema	0	1(0.0%)
Pacemaker generated arrhythmia	0	1(0.0%)
Performance status decreased	0	1(0.0%)
Sense of oppression	0	1(0.0%)
Sudden death	0	1(0.0%)
Vascular stent thrombosis	0	1(0.0%)
Vessel puncture site haematoma	0	1(0.0%)
Vessel puncture site haemorrhage	0	1(0.0%)
Injury, Poisoning And Procedural Complications	1081(16.6%)	1065(16.4%)
Limb injury	165(2.5%)	137(2.1%)
Contusion	130(2.0%)	128(2.0%)
Fall	119(1.8%)	133(2.0%)
Ligament sprain	72(1.1%)	65(1.0%)
Skin abrasion	49(0.8%)	45(0.7%)
Rib fracture	39(0.6%)	42(0.6%)
Thermal burn	37(0.6%)	31(0.5%)
Foot fracture	35(0.5%)	31(0.5%)
Joint injury	34(0.5%)	22(0.3%)
Head injury	31(0.5%)	35(0.5%)
Skin laceration	30(0.5%)	34(0.5%)
Post-traumatic pain	27(0.4%)	14(0.2%)
Procedural pain	26(0.4%)	20(0.3%)
Ankle fracture	24(0.4%)	26(0.4%)
Radius fracture	22(0.3%)	20(0.3%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Muscle strain	21(0.3%)	27(0.4%)
Accident	20(0.3%)	15(0.2%)
Bone contusion	17(0.3%)	11(0.2%)
Meniscus injury	16(0.2%)	21(0.3%)
Upper limb fracture	16(0.2%)	13(0.2%)
Hand fracture	16(0.2%)	12(0.2%)
Tibia fracture	15(0.2%)	5(0.1%)
Femur fracture	14(0.2%)	19(0.3%)
Skin wound	13(0.2%)	13(0.2%)
Road traffic accident	13(0.2%)	11(0.2%)
Humerus fracture	12(0.2%)	28(0.4%)
Arthropod bite	12(0.2%)	11(0.2%)
Tooth fracture	12(0.2%)	11(0.2%)
Hip fracture	12(0.2%)	7(0.1%)
Heat illness	12(0.2%)	5(0.1%)
Scratch	12(0.2%)	5(0.1%)
Joint dislocation	11(0.2%)	14(0.2%)
Chest injury	11(0.2%)	7(0.1%)
Femoral neck fracture	11(0.2%)	3(0.0%)
Epicondylitis	10(0.2%)	14(0.2%)
Spinal compression fracture	10(0.2%)	12(0.2%)
Tendon rupture	10(0.2%)	12(0.2%)
Wound	10(0.2%)	9(0.1%)
Subdural haematoma	9(0.1%)	14(0.2%)
Soft tissue injury	9(0.1%)	9(0.1%)
Fibula fracture	9(0.1%)	7(0.1%)
Muscle rupture	9(0.1%)	7(0.1%)
Arthropod sting	9(0.1%)	5(0.1%)
Lower limb fracture	9(0.1%)	4(0.1%)
Wrist fracture	8(0.1%)	13(0.2%)
Lumbar vertebral fracture	8(0.1%)	11(0.2%)
Subcutaneous haematoma	8(0.1%)	11(0.2%)
Animal bite	8(0.1%)	9(0.1%)
Patella fracture	8(0.1%)	5(0.1%)
Clavicle fracture	8(0.1%)	2(0.0%)
Face injury	7(0.1%)	6(0.1%)
Muscle injury	7(0.1%)	3(0.0%)
Concussion	6(0.1%)	6(0.1%)
Craniocerebral injury	6(0.1%)	6(0.1%)
Traumatic haematoma	6(0.1%)	5(0.1%)
Eye injury	6(0.1%)	4(0.1%)
Ulna fracture	6(0.1%)	4(0.1%)
Ligament rupture	6(0.1%)	3(0.0%)
Foreign body in eye	6(0.1%)	1(0.0%)
Facial bones fracture	5(0.1%)	13(0.2%)
Injury	5(0.1%)	11(0.2%)
Burns second degree	5(0.1%)	6(0.1%)
Fractured coccyx	5(0.1%)	5(0.1%)
Back injury	5(0.1%)	4(0.1%)
Toxicity to various agents	5(0.1%)	4(0.1%)
Inflammation of wound	5(0.1%)	0
Accidental overdose	4(0.1%)	6(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Heat stroke	4(0.1%)	4(0.1%)
Subdural haemorrhage	4(0.1%)	4(0.1%)
Chillblains	4(0.1%)	1(0.0%)
Ligament injury	4(0.1%)	1(0.0%)
Scar	4(0.1%)	1(0.0%)
Tendon injury	4(0.1%)	1(0.0%)
Foreign body	4(0.1%)	0
Scapula fracture	4(0.1%)	0
Overdose	3(0.0%)	9(0.1%)
Traumatic fracture	3(0.0%)	6(0.1%)
Incisional hernia	3(0.0%)	4(0.1%)
Post procedural complication	3(0.0%)	4(0.1%)
Spinal column injury	3(0.0%)	4(0.1%)
Anaemia postoperative	3(0.0%)	3(0.0%)
Corneal abrasion	3(0.0%)	3(0.0%)
Cervical vertebral fracture	3(0.0%)	2(0.0%)
Multiple fractures	3(0.0%)	2(0.0%)
Wound complication	3(0.0%)	2(0.0%)
Foreign body in throat	3(0.0%)	1(0.0%)
Nail avulsion	3(0.0%)	1(0.0%)
Postoperative wound complication	3(0.0%)	1(0.0%)
Skin injury	2(0.0%)	6(0.1%)
Incision site pain	2(0.0%)	5(0.1%)
Post procedural haemorrhage	2(0.0%)	4(0.1%)
Hyphaema	2(0.0%)	3(0.0%)
Lip injury	2(0.0%)	3(0.0%)
Procedural haemorrhage	2(0.0%)	3(0.0%)
Injury corneal	2(0.0%)	2(0.0%)
Wound dehiscence	2(0.0%)	2(0.0%)
Limb crushing injury	2(0.0%)	1(0.0%)
Mallet finger	2(0.0%)	1(0.0%)
Mouth injury	2(0.0%)	1(0.0%)
Nerve injury	2(0.0%)	1(0.0%)
Post procedural haematoma	2(0.0%)	1(0.0%)
Tongue injury	2(0.0%)	1(0.0%)
Foreign body in ear	2(0.0%)	0
Ocular procedural complication	2(0.0%)	0
Poisoning	2(0.0%)	0
Postoperative delirium	2(0.0%)	0
Radiation proctitis	2(0.0%)	0
Skeletal injury	2(0.0%)	0
Splenic rupture	2(0.0%)	0
Traumatic arthritis	2(0.0%)	0
Vascular injury	2(0.0%)	0
Wound necrosis	2(0.0%)	0
Wound secretion	2(0.0%)	0
Spinal fracture	1(0.0%)	6(0.1%)
Nasal injury	1(0.0%)	5(0.1%)
Seroma	1(0.0%)	5(0.1%)
Thoracic vertebral fracture	1(0.0%)	5(0.1%)
Eye contusion	1(0.0%)	4(0.1%)
Arteriovenous fistula site complication	1(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Brain contusion	1(0.0%)	3(0.0%)
Cartilage injury	1(0.0%)	3(0.0%)
Nail injury	1(0.0%)	3(0.0%)
Vascular pseudoaneurysm	1(0.0%)	3(0.0%)
Abdominal injury	1(0.0%)	2(0.0%)
Alcohol poisoning	1(0.0%)	2(0.0%)
Cataract operation complication	1(0.0%)	2(0.0%)
Dental restoration failure	1(0.0%)	2(0.0%)
Exposure to communicable disease	1(0.0%)	2(0.0%)
Fracture	1(0.0%)	2(0.0%)
Pelvic fracture	1(0.0%)	2(0.0%)
Post procedural hypothyroidism	1(0.0%)	2(0.0%)
Post procedural inflammation	1(0.0%)	2(0.0%)
Post-traumatic neck syndrome	1(0.0%)	2(0.0%)
Reactive gastropathy	1(0.0%)	2(0.0%)
Skull fracture	1(0.0%)	2(0.0%)
Spinal cord injury cervical	1(0.0%)	2(0.0%)
Stomal hernia	1(0.0%)	2(0.0%)
Wound haemorrhage	1(0.0%)	2(0.0%)
Acetabulum fracture	1(0.0%)	1(0.0%)
Burns third degree	1(0.0%)	1(0.0%)
Cardiac procedure complication	1(0.0%)	1(0.0%)
Dislocation of vertebra	1(0.0%)	1(0.0%)
Ear canal injury	1(0.0%)	1(0.0%)
Ear injury	1(0.0%)	1(0.0%)
Incision site haematoma	1(0.0%)	1(0.0%)
Multiple injuries	1(0.0%)	1(0.0%)
Muscle contusion	1(0.0%)	1(0.0%)
Peripheral nerve injury	1(0.0%)	1(0.0%)
Radiation skin injury	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Superficial injury of eye	1(0.0%)	1(0.0%)
Synovial rupture	1(0.0%)	1(0.0%)
Urinary retention postoperative	1(0.0%)	1(0.0%)
Abdominal wound dehiscence	1(0.0%)	0
Arterial bypass occlusion	1(0.0%)	0
Arterial bypass stenosis	1(0.0%)	0
Asbestosis	1(0.0%)	0
Avulsion fracture	1(0.0%)	0
Barotitis media	1(0.0%)	0
Barotrauma	1(0.0%)	0
Bladder injury	1(0.0%)	0
Buttock injury	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Closed globe injury	1(0.0%)	0
Colon injury	1(0.0%)	0
Device placement issue	1(0.0%)	0
Extradural haematoma	1(0.0%)	0
Foreign body aspiration	1(0.0%)	0
Foreign body in gastrointestinal tract	1(0.0%)	0
Gun shot wound	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Incision site complication	1(0.0%)	0
Incision site inflammation	1(0.0%)	0
Injury of conjunctiva	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Limb traumatic amputation	1(0.0%)	0
Musculoskeletal injury	1(0.0%)	0
Nerve root injury lumbar	1(0.0%)	0
Periorbital haematoma	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Post procedural discomfort	1(0.0%)	0
Post procedural haematuria	1(0.0%)	0
Post procedural hypotension	1(0.0%)	0
Radial head dislocation	1(0.0%)	0
Radiation proctopathy	1(0.0%)	0
Sciatic nerve injury	1(0.0%)	0
Scrotal injury	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Snake bite	1(0.0%)	0
Splenic injury	1(0.0%)	0
Testicular injury	1(0.0%)	0
Tooth injury	1(0.0%)	0
Traumatic haemorrhage	1(0.0%)	0
Urostomy complication	1(0.0%)	0
Vaccination complication	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Vascular access site haematoma	1(0.0%)	0
Vascular access site thrombosis	1(0.0%)	0
Vascular access steal syndrome	1(0.0%)	0
Wound contamination	1(0.0%)	0
Traumatic ulcer	0	7(0.1%)
Burns first degree	0	3(0.0%)
Procedural nausea	0	3(0.0%)
Sunburn	0	3(0.0%)
Animal scratch	0	2(0.0%)
Exposure to SARS-CoV-2	0	2(0.0%)
Fractured sacrum	0	2(0.0%)
Procedural vomiting	0	2(0.0%)
Auricular haematoma	0	1(0.0%)
Bite	0	1(0.0%)
Bone fissure	0	1(0.0%)
Brachial plexus injury	0	1(0.0%)
Burn oral cavity	0	1(0.0%)
Chemical burns of eye	0	1(0.0%)
Cold burn	0	1(0.0%)
Compression fracture	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Eschar	0	1(0.0%)
Extra-axial haemorrhage	0	1(0.0%)
Eyelid injury	0	1(0.0%)
Forearm fracture	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Gastroenteritis radiation	0	1(0.0%)
Iliotibial band syndrome	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Incorrect dose administered	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Limb fracture	0	1(0.0%)
Neck injury	0	1(0.0%)
Open globe injury	0	1(0.0%)
Pelvic bone injury	0	1(0.0%)
Pelvic organ injury	0	1(0.0%)
Penis injury	0	1(0.0%)
Periprosthetic fracture	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural constipation	0	1(0.0%)
Post procedural fever	0	1(0.0%)
Post procedural hypoparathyroidism	0	1(0.0%)
Post procedural oedema	0	1(0.0%)
Postoperative ileus	0	1(0.0%)
Procedural complication	0	1(0.0%)
Procedural hypertension	0	1(0.0%)
Procedural intestinal perforation	0	1(0.0%)
Radiation associated pain	0	1(0.0%)
Reproductive tract procedural complication	0	1(0.0%)
Retinal injury	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Stab wound	0	1(0.0%)
Stress fracture	0	1(0.0%)
Tooth dislocation	0	1(0.0%)
Tracheal deviation	0	1(0.0%)
Transfusion reaction	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Trunk injury	0	1(0.0%)
Ulnar nerve injury	0	1(0.0%)
Urethral injury	0	1(0.0%)
VIIIth nerve injury	0	1(0.0%)
Vascular anastomosis aneurysm	0	1(0.0%)
Vascular graft occlusion	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	1028(15.8%)	1007(15.5%)
Pruritus	191(2.9%)	146(2.2%)
Skin ulcer	147(2.3%)	154(2.4%)
Eczema	104(1.6%)	92(1.4%)
Rash	89(1.4%)	84(1.3%)
Diabetic foot	79(1.2%)	76(1.2%)
Dermatitis	45(0.7%)	46(0.7%)
Dry skin	45(0.7%)	45(0.7%)
Urticaria	42(0.6%)	30(0.5%)
Hyperkeratosis	30(0.5%)	24(0.4%)
Dermatitis allergic	28(0.4%)	19(0.3%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Skin lesion	27(0.4%)	33(0.5%)
Erythema	22(0.3%)	35(0.5%)
Actinic keratosis	20(0.3%)	27(0.4%)
Dermatitis contact	20(0.3%)	22(0.3%)
Psoriasis	18(0.3%)	17(0.3%)
Decubitus ulcer	18(0.3%)	15(0.2%)
Blister	17(0.3%)	30(0.5%)
Hyperhidrosis	17(0.3%)	12(0.2%)
Eczema asteatotic	17(0.3%)	10(0.2%)
Skin disorder	16(0.2%)	0
Dermal cyst	15(0.2%)	20(0.3%)
Alopecia	15(0.2%)	14(0.2%)
Stasis dermatitis	15(0.2%)	9(0.1%)
Ingrowing nail	14(0.2%)	17(0.3%)
Dermatitis atopic	12(0.2%)	10(0.2%)
Angioedema	10(0.2%)	7(0.1%)
Skin exfoliation	10(0.2%)	5(0.1%)
Seborrhoeic dermatitis	8(0.1%)	13(0.2%)
Hand dermatitis	8(0.1%)	6(0.1%)
Palmoplantar keratoderma	8(0.1%)	5(0.1%)
Xeroderma	8(0.1%)	4(0.1%)
Neurodermatitis	8(0.1%)	3(0.0%)
Drug eruption	7(0.1%)	10(0.2%)
Acne	7(0.1%)	8(0.1%)
Rosacea	6(0.1%)	7(0.1%)
Skin fissures	6(0.1%)	5(0.1%)
Hidradenitis	6(0.1%)	4(0.1%)
Skin discolouration	5(0.1%)	7(0.1%)
Eczema nummular	5(0.1%)	4(0.1%)
Ecchymosis	4(0.1%)	9(0.1%)
Rash pruritic	4(0.1%)	8(0.1%)
Pemphigoid	4(0.1%)	6(0.1%)
Rash macular	4(0.1%)	4(0.1%)
Rash papular	4(0.1%)	4(0.1%)
Dyshidrotic eczema	4(0.1%)	2(0.0%)
Night sweats	4(0.1%)	2(0.0%)
Nail dystrophy	4(0.1%)	1(0.0%)
Skin necrosis	4(0.1%)	1(0.0%)
Diabetic ulcer	3(0.0%)	6(0.1%)
Dermatitis bullous	3(0.0%)	5(0.1%)
Intertrigo	3(0.0%)	5(0.1%)
Prurigo	3(0.0%)	5(0.1%)
Asteatosis	3(0.0%)	3(0.0%)
Pigmentation disorder	3(0.0%)	3(0.0%)
Rash maculo-papular	3(0.0%)	3(0.0%)
Onychoclasis	3(0.0%)	2(0.0%)
Petechiae	3(0.0%)	2(0.0%)
Onycholysis	3(0.0%)	1(0.0%)
Papule	3(0.0%)	1(0.0%)
Skin hypertrophy	3(0.0%)	1(0.0%)
Erythema nodosum	3(0.0%)	0
Skin reaction	3(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Skin hyperpigmentation	2(0.0%)	5(0.1%)
Skin mass	2(0.0%)	4(0.1%)
Miliaria	2(0.0%)	3(0.0%)
Haemorrhage subcutaneous	2(0.0%)	2(0.0%)
Pruritus allergic	2(0.0%)	2(0.0%)
Vitiligo	2(0.0%)	2(0.0%)
Itching scar	2(0.0%)	1(0.0%)
Nail disorder	2(0.0%)	1(0.0%)
Neuropathic ulcer	2(0.0%)	1(0.0%)
Scab	2(0.0%)	1(0.0%)
Toxic skin eruption	2(0.0%)	1(0.0%)
Androgenetic alopecia	2(0.0%)	0
Angiodermatitis	2(0.0%)	0
Blood blister	2(0.0%)	0
Diabetic bullosis	2(0.0%)	0
Diffuse alopecia	2(0.0%)	0
Exfoliative rash	2(0.0%)	0
Solar lentigo	2(0.0%)	0
Skin irritation	1(0.0%)	6(0.1%)
Lipodystrophy acquired	1(0.0%)	3(0.0%)
Rash erythematous	1(0.0%)	3(0.0%)
Dermatosis	1(0.0%)	2(0.0%)
Purpura	1(0.0%)	2(0.0%)
Skin haemorrhage	1(0.0%)	2(0.0%)
Alopecia areata	1(0.0%)	1(0.0%)
Angiokeratoma	1(0.0%)	1(0.0%)
Dandruff	1(0.0%)	1(0.0%)
Dermatitis psoriasiform	1(0.0%)	1(0.0%)
Lichen planopilaris	1(0.0%)	1(0.0%)
Lichen sclerosus	1(0.0%)	1(0.0%)
Nail bed inflammation	1(0.0%)	1(0.0%)
Necrobiosis lipoidica diabeticorum	1(0.0%)	1(0.0%)
Pain of skin	1(0.0%)	1(0.0%)
Pustular psoriasis	1(0.0%)	1(0.0%)
Reactive perforating collagenosis	1(0.0%)	1(0.0%)
Skin dystrophy	1(0.0%)	1(0.0%)
Skin erosion	1(0.0%)	1(0.0%)
Acanthosis nigricans	1(0.0%)	0
Alopecia scarring	1(0.0%)	0
Autoimmune dermatitis	1(0.0%)	0
Brow ptosis	1(0.0%)	0
Chronic pigmented purpura	1(0.0%)	0
Chronic spontaneous urticaria	1(0.0%)	0
Cold sweat	1(0.0%)	0
Dermatitis exfoliative	1(0.0%)	0
Dermatitis herpetiformis	1(0.0%)	0
Erythema ab igne	1(0.0%)	0
Erythematotelangiectatic rosacea	1(0.0%)	0
Fixed eruption	1(0.0%)	0
Granuloma annulare	1(0.0%)	0
Lichen planus	1(0.0%)	0
Lichenoid keratosis	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Macule	1(0.0%)	0
Myxoid cyst	1(0.0%)	0
Nail fold inflammation	1(0.0%)	0
Nail hypertrophy	1(0.0%)	0
Onychomadesis	1(0.0%)	0
Pemphigus	1(0.0%)	0
Photosensitivity reaction	1(0.0%)	0
Post inflammatory pigmentation change	1(0.0%)	0
Rhinophyma	1(0.0%)	0
Scar pain	1(0.0%)	0
Sebaceous adenitis	1(0.0%)	0
Seborrhoea	1(0.0%)	0
Senile xerosis	1(0.0%)	0
Skin burning sensation	1(0.0%)	0
Skin discomfort	1(0.0%)	0
Skin fibrosis	1(0.0%)	0
Urticaria chronic	1(0.0%)	0
Urticarial dermatitis	1(0.0%)	0
Lipohypertrophy	0	7(0.1%)
Ischaemic skin ulcer	0	3(0.0%)
Diabetic dermopathy	0	2(0.0%)
Erythema multiforme	0	2(0.0%)
Nail discolouration	0	2(0.0%)
Palmoplantar pustulosis	0	2(0.0%)
Parapsoriasis	0	2(0.0%)
Skin induration	0	2(0.0%)
Skin oedema	0	2(0.0%)
Blister rupture	0	1(0.0%)
Circumoral oedema	0	1(0.0%)
Cutaneous amyloidosis	0	1(0.0%)
Dermatomyositis	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Erythema annulare	0	1(0.0%)
Excessive skin	0	1(0.0%)
Fracture blisters	0	1(0.0%)
Granuloma skin	0	1(0.0%)
Hangnail	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Hypertrophic scar	0	1(0.0%)
Hypotrichosis	0	1(0.0%)
Ingrown hair	0	1(0.0%)
Lentigo	0	1(0.0%)
Leukoderma	0	1(0.0%)
Leukoplakia	0	1(0.0%)
Nail bed bleeding	0	1(0.0%)
Penile ulceration	0	1(0.0%)
Pityriasis rosea	0	1(0.0%)
Skin depigmentation	0	1(0.0%)
Skin weeping	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Trichorrhexis	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Renal And Urinary Disorders	1019(15.7%)	1100(17.0%)
Acute kidney injury	220(3.4%)	234(3.6%)
Renal impairment	177(2.7%)	159(2.5%)
Renal cyst	87(1.3%)	98(1.5%)
Nephrolithiasis	84(1.3%)	93(1.4%)
Haematuria	68(1.0%)	93(1.4%)
Chronic kidney disease	67(1.0%)	85(1.3%)
Urinary incontinence	51(0.8%)	38(0.6%)
Diabetic nephropathy	48(0.7%)	52(0.8%)
Urinary retention	46(0.7%)	48(0.7%)
Renal failure	42(0.6%)	36(0.6%)
Dysuria	41(0.6%)	59(0.9%)
Pollakiuria	27(0.4%)	46(0.7%)
Nocturia	24(0.4%)	37(0.6%)
Proteinuria	16(0.2%)	29(0.4%)
Ureterolithiasis	15(0.2%)	15(0.2%)
Renal colic	14(0.2%)	17(0.3%)
Polyuria	14(0.2%)	11(0.2%)
Hydronephrosis	13(0.2%)	26(0.4%)
Nephropathy	12(0.2%)	16(0.2%)
Micturition urgency	11(0.2%)	9(0.1%)
Nephrotic syndrome	8(0.1%)	23(0.4%)
Calculus urinary	8(0.1%)	13(0.2%)
Urinary tract obstruction	8(0.1%)	5(0.1%)
Hypertonic bladder	7(0.1%)	20(0.3%)
Albuminuria	7(0.1%)	10(0.2%)
Urethral stenosis	7(0.1%)	8(0.1%)
Neurogenic bladder	7(0.1%)	6(0.1%)
Lower urinary tract symptoms	6(0.1%)	11(0.2%)
End stage renal disease	6(0.1%)	7(0.1%)
Urge incontinence	6(0.1%)	6(0.1%)
Calculus bladder	5(0.1%)	8(0.1%)
Azotaemia	5(0.1%)	5(0.1%)
Oliguria	5(0.1%)	2(0.0%)
Urinary hesitation	5(0.1%)	2(0.0%)
Urine flow decreased	5(0.1%)	2(0.0%)
Acquired cystic kidney disease	4(0.1%)	4(0.1%)
Renal artery stenosis	4(0.1%)	4(0.1%)
Renal atrophy	4(0.1%)	4(0.1%)
Urinary tract disorder	4(0.1%)	3(0.0%)
Nephropathy toxic	4(0.1%)	1(0.0%)
Bladder irritation	4(0.1%)	0
Renal disorder	3(0.0%)	6(0.1%)
Perinephritis	3(0.0%)	4(0.1%)
Stress urinary incontinence	3(0.0%)	3(0.0%)
Bladder spasm	3(0.0%)	2(0.0%)
Microalbuminuria	3(0.0%)	1(0.0%)
Micturition disorder	3(0.0%)	1(0.0%)
Renal mass	2(0.0%)	11(0.2%)
Bladder hypertrophy	2(0.0%)	4(0.1%)
Nephrosclerosis	2(0.0%)	4(0.1%)
Bladder diverticulum	2(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Pyelocaliectasis	2(0.0%)	3(0.0%)
Renal injury	2(0.0%)	3(0.0%)
Bladder outlet obstruction	2(0.0%)	2(0.0%)
Nephroangiosclerosis	2(0.0%)	2(0.0%)
Urinary bladder polyp	2(0.0%)	2(0.0%)
Chromaturia	2(0.0%)	1(0.0%)
Strangury	2(0.0%)	1(0.0%)
Ureteric obstruction	2(0.0%)	1(0.0%)
Bladder disorder	2(0.0%)	0
Bladder pain	2(0.0%)	0
Focal segmental glomerulosclerosis	2(0.0%)	0
Subacute kidney injury	2(0.0%)	0
Urate nephropathy	2(0.0%)	0
Renal pain	1(0.0%)	5(0.1%)
Tubulointerstitial nephritis	1(0.0%)	4(0.1%)
Urine odour abnormal	1(0.0%)	4(0.1%)
Incontinence	1(0.0%)	3(0.0%)
Hypertensive nephropathy	1(0.0%)	2(0.0%)
Nephrocalcinosis	1(0.0%)	2(0.0%)
Renal aneurysm	1(0.0%)	2(0.0%)
Renal hypertrophy	1(0.0%)	2(0.0%)
Haemorrhage urinary tract	1(0.0%)	1(0.0%)
Hydroureter	1(0.0%)	1(0.0%)
Nephroptosis	1(0.0%)	1(0.0%)
Prerenal failure	1(0.0%)	1(0.0%)
Renal hypertension	1(0.0%)	1(0.0%)
Bladder cyst	1(0.0%)	0
Bladder dilatation	1(0.0%)	0
Bladder dysfunction	1(0.0%)	0
Bladder hyperaemia	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Bladder obstruction	1(0.0%)	0
Bladder perforation	1(0.0%)	0
Cystitis haemorrhagic	1(0.0%)	0
Cystitis noninfective	1(0.0%)	0
Hydrocalyx	1(0.0%)	0
Hypocitraturia	1(0.0%)	0
Hyponatriuria	1(0.0%)	0
Hypotonic urinary bladder	1(0.0%)	0
Renal cyst haemorrhage	1(0.0%)	0
Renal infarct	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Renal tubular necrosis	1(0.0%)	0
Renal vessel disorder	1(0.0%)	0
Urethral pain	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0
Glomerulonephritis chronic	0	4(0.1%)
Intercapillary glomerulosclerosis	0	4(0.1%)
Renal artery arteriosclerosis	0	3(0.0%)
Urine abnormality	0	3(0.0%)
Anuria	0	2(0.0%)
Glomerulonephritis membranous	0	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Renal haemorrhage	0	2(0.0%)
Sterile pyuria	0	2(0.0%)
Subcapsular renal haematoma	0	2(0.0%)
Ureteric stenosis	0	2(0.0%)
Bladder mass	0	1(0.0%)
Bladder neck obstruction	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Glycosuria	0	1(0.0%)
Hyperuricosuria	0	1(0.0%)
Kidney enlargement	0	1(0.0%)
Kidney fibrosis	0	1(0.0%)
Nephritic syndrome	0	1(0.0%)
Nephritis	0	1(0.0%)
Pelvi-ureteric obstruction	0	1(0.0%)
Perinephric collection	0	1(0.0%)
Post micturition dribble	0	1(0.0%)
Renal haematoma	0	1(0.0%)
Ureteric dilatation	0	1(0.0%)
Urethral meatus stenosis	0	1(0.0%)
Urinary tract inflammation	0	1(0.0%)
Vesical fistula	0	1(0.0%)
Eye Disorders	800(12.3%)	845(13.0%)
Cataract	279(4.3%)	285(4.4%)
Diabetic retinopathy	145(2.2%)	168(2.6%)
Vitreous haemorrhage	68(1.0%)	57(0.9%)
Glaucoma	44(0.7%)	45(0.7%)
Dry eye	44(0.7%)	40(0.6%)
Macular oedema	32(0.5%)	32(0.5%)
Visual impairment	30(0.5%)	33(0.5%)
Vision blurred	28(0.4%)	27(0.4%)
Retinal haemorrhage	23(0.4%)	33(0.5%)
Blepharitis	19(0.3%)	18(0.3%)
Diabetic retinal oedema	18(0.3%)	16(0.2%)
Conjunctivitis allergic	16(0.2%)	17(0.3%)
Conjunctival haemorrhage	14(0.2%)	11(0.2%)
Retinal detachment	13(0.2%)	12(0.2%)
Retinopathy	12(0.2%)	10(0.2%)
Macular fibrosis	11(0.2%)	12(0.2%)
Eye haemorrhage	11(0.2%)	4(0.1%)
Macular degeneration	10(0.2%)	12(0.2%)
Retinopathy hypertensive	10(0.2%)	12(0.2%)
Ocular hypertension	10(0.2%)	7(0.1%)
Asthenopia	10(0.2%)	1(0.0%)
Diplopia	8(0.1%)	6(0.1%)
Eye pain	7(0.1%)	10(0.2%)
Posterior capsule opacification	7(0.1%)	9(0.1%)
Vitreous opacities	7(0.1%)	6(0.1%)
Maculopathy	7(0.1%)	4(0.1%)
Visual acuity reduced	7(0.1%)	4(0.1%)
Eye pruritus	6(0.1%)	11(0.2%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vitreous floaters	6(0.1%)	8(0.1%)
Keratitis	6(0.1%)	7(0.1%)
Blindness unilateral	6(0.1%)	6(0.1%)
Age-related macular degeneration	6(0.1%)	3(0.0%)
Chalazion	6(0.1%)	3(0.0%)
Astigmatism	6(0.1%)	1(0.0%)
Retinal vein occlusion	5(0.1%)	6(0.1%)
Lacrimation increased	5(0.1%)	5(0.1%)
Tractional retinal detachment	5(0.1%)	5(0.1%)
Eye inflammation	5(0.1%)	3(0.0%)
Open angle glaucoma	5(0.1%)	3(0.0%)
Ocular hyperaemia	5(0.1%)	2(0.0%)
Eyelid ptosis	4(0.1%)	6(0.1%)
Vitreous detachment	4(0.1%)	5(0.1%)
Pterygium	4(0.1%)	4(0.1%)
Retinopathy proliferative	4(0.1%)	4(0.1%)
Ulcerative keratitis	4(0.1%)	4(0.1%)
Periorbital oedema	4(0.1%)	3(0.0%)
Refraction disorder	4(0.1%)	3(0.0%)
Retinal vascular disorder	4(0.1%)	2(0.0%)
Meibomian gland dysfunction	4(0.1%)	1(0.0%)
Presbyopia	3(0.0%)	6(0.1%)
Ocular discomfort	3(0.0%)	4(0.1%)
Cataract nuclear	3(0.0%)	3(0.0%)
Eye irritation	3(0.0%)	3(0.0%)
Periorbital swelling	3(0.0%)	3(0.0%)
Iritis	3(0.0%)	2(0.0%)
Vitreoretinal traction syndrome	3(0.0%)	2(0.0%)
Entropion	3(0.0%)	1(0.0%)
Strabismus	3(0.0%)	1(0.0%)
Sudden visual loss	3(0.0%)	0
Eyelid oedema	2(0.0%)	7(0.1%)
Retinal tear	2(0.0%)	4(0.1%)
Blindness	2(0.0%)	3(0.0%)
Non-proliferative retinopathy	2(0.0%)	3(0.0%)
Optic atrophy	2(0.0%)	3(0.0%)
Retinal degeneration	2(0.0%)	3(0.0%)
Retinal oedema	2(0.0%)	3(0.0%)
Cataract subcapsular	2(0.0%)	2(0.0%)
Dermatochalasis	2(0.0%)	2(0.0%)
Dry age-related macular degeneration	2(0.0%)	2(0.0%)
Photophobia	2(0.0%)	2(0.0%)
Retinal aneurysm	2(0.0%)	2(0.0%)
Conjunctival hyperaemia	2(0.0%)	1(0.0%)
Hypermetropia	2(0.0%)	1(0.0%)
Lens dislocation	2(0.0%)	1(0.0%)
Myopia	2(0.0%)	1(0.0%)
Punctate keratitis	2(0.0%)	1(0.0%)
Retinal neovascularisation	2(0.0%)	1(0.0%)
Rhegmatogenous retinal detachment	2(0.0%)	1(0.0%)
Swelling of eyelid	2(0.0%)	1(0.0%)
Conjunctival deposit	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Conjunctival oedema	2(0.0%)	0
Diabetic eye disease	2(0.0%)	0
Eye disorder	2(0.0%)	0
Polypoidal choroidal vasculopathy	2(0.0%)	0
Dacryostenosis acquired	1(0.0%)	6(0.1%)
Corneal erosion	1(0.0%)	5(0.1%)
Eye discharge	1(0.0%)	5(0.1%)
Uveitis	1(0.0%)	5(0.1%)
Xerophthalmia	1(0.0%)	5(0.1%)
Arteriosclerotic retinopathy	1(0.0%)	4(0.1%)
Cystoid macular oedema	1(0.0%)	4(0.1%)
Macular hole	1(0.0%)	4(0.1%)
Ectropion	1(0.0%)	3(0.0%)
Eyelid cyst	1(0.0%)	3(0.0%)
Retinal artery occlusion	1(0.0%)	3(0.0%)
Cataract diabetic	1(0.0%)	2(0.0%)
Eye allergy	1(0.0%)	2(0.0%)
Photopsia	1(0.0%)	2(0.0%)
Vitreous degeneration	1(0.0%)	2(0.0%)
Choroidal neovascularisation	1(0.0%)	1(0.0%)
Corneal disorder	1(0.0%)	1(0.0%)
Corneal leukoma	1(0.0%)	1(0.0%)
Corneal oedema	1(0.0%)	1(0.0%)
Eczema eyelids	1(0.0%)	1(0.0%)
Extraocular muscle paresis	1(0.0%)	1(0.0%)
Foreign body sensation in eyes	1(0.0%)	1(0.0%)
Keratopathy	1(0.0%)	1(0.0%)
Macular cyst	1(0.0%)	1(0.0%)
Optic disc haemorrhage	1(0.0%)	1(0.0%)
Papilloedema	1(0.0%)	1(0.0%)
Retinal vein thrombosis	1(0.0%)	1(0.0%)
Scleral haemorrhage	1(0.0%)	1(0.0%)
Scleritis	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Atrophy of globe	1(0.0%)	0
Blepharochalasis	1(0.0%)	0
Chorioretinopathy	1(0.0%)	0
Conjunctival disorder	1(0.0%)	0
Corneal epithelium defect	1(0.0%)	0
Deformity of orbit	1(0.0%)	0
Diabetic glaucoma	1(0.0%)	0
Erythema of eyelid	1(0.0%)	0
Exposure keratitis	1(0.0%)	0
Eye haematoma	1(0.0%)	0
Eye ulcer	1(0.0%)	0
Eyelid skin dryness	1(0.0%)	0
Lacrimation decreased	1(0.0%)	0
Noninfective retinitis	1(0.0%)	0
Normal tension glaucoma	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0
Ocular myasthenia	1(0.0%)	0
Optic nerve cupping	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Orbit atrophy	1(0.0%)	0
Pathologic myopia	1(0.0%)	0
Pupils unequal	1(0.0%)	0
Retinal artery spasm	1(0.0%)	0
Retinal deposits	1(0.0%)	0
Retinal disorder	1(0.0%)	0
Retinal exudates	1(0.0%)	0
Staphyloma	1(0.0%)	0
Trichiasis	1(0.0%)	0
Vernal keratoconjunctivitis	1(0.0%)	0
Amaurosis fugax	0	3(0.0%)
Cataract cortical	0	3(0.0%)
Iridocyclitis	0	3(0.0%)
Meibomianitis	0	3(0.0%)
Angle closure glaucoma	0	2(0.0%)
Blepharitis allergic	0	2(0.0%)
Eye swelling	0	2(0.0%)
Keratoconus	0	2(0.0%)
Lenticular opacities	0	2(0.0%)
Optic ischaemic neuropathy	0	2(0.0%)
Abnormal sensation in eye	0	1(0.0%)
Amblyopia	0	1(0.0%)
Aphakia	0	1(0.0%)
Borderline glaucoma	0	1(0.0%)
Cholesterolosis bulbi	0	1(0.0%)
Chorioretinal atrophy	0	1(0.0%)
Corneal infiltrates	0	1(0.0%)
Endocrine ophthalmopathy	0	1(0.0%)
Episcleritis	0	1(0.0%)
Eye oedema	0	1(0.0%)
Eyelid retraction	0	1(0.0%)
Glaucomatous optic disc atrophy	0	1(0.0%)
Halo vision	0	1(0.0%)
Hyalosis asteroid	0	1(0.0%)
Iris disorder	0	1(0.0%)
Lacrimal disorder	0	1(0.0%)
Lacrimal passage granuloma	0	1(0.0%)
Lens disorder	0	1(0.0%)
Macular rupture	0	1(0.0%)
Metamorphopsia	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Optic disc disorder	0	1(0.0%)
Orbital oedema	0	1(0.0%)
Retinal artery embolism	0	1(0.0%)
Retinal pigmentation	0	1(0.0%)
Retinal vascular occlusion	0	1(0.0%)
Retinoschisis	0	1(0.0%)
Visual acuity reduced transiently	0	1(0.0%)
Vitreous prolapse	0	1(0.0%)
Cardiac Disorders	788(12.1%)	906(14.0%)
Cardiac failure	73(1.1%)	128(2.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Angina pectoris	70(1.1%)	83(1.3%)
Coronary artery disease	58(0.9%)	71(1.1%)
Atrial fibrillation	49(0.8%)	47(0.7%)
Myocardial ischaemia	48(0.7%)	62(1.0%)
Bradycardia	46(0.7%)	54(0.8%)
Ventricular extrasystoles	45(0.7%)	46(0.7%)
Palpitations	44(0.7%)	47(0.7%)
Mitral valve incompetence	40(0.6%)	45(0.7%)
Cardiac failure chronic	36(0.6%)	59(0.9%)
Sinus bradycardia	36(0.6%)	25(0.4%)
Atrioventricular block first degree	34(0.5%)	31(0.5%)
Bundle branch block right	31(0.5%)	23(0.4%)
Cardiac failure congestive	30(0.5%)	47(0.7%)
Bundle branch block left	29(0.4%)	29(0.4%)
Left ventricular hypertrophy	27(0.4%)	30(0.5%)
Arteriosclerosis coronary artery	26(0.4%)	19(0.3%)
Supraventricular extrasystoles	24(0.4%)	20(0.3%)
Tricuspid valve incompetence	23(0.4%)	27(0.4%)
Tachycardia	21(0.3%)	27(0.4%)
Atrioventricular block second degree	20(0.3%)	17(0.3%)
Angina unstable	16(0.2%)	22(0.3%)
Aortic valve stenosis	15(0.2%)	24(0.4%)
Coronary artery stenosis	15(0.2%)	20(0.3%)
Aortic valve incompetence	14(0.2%)	19(0.3%)
Left ventricular dysfunction	14(0.2%)	8(0.1%)
Hypertensive heart disease	14(0.2%)	5(0.1%)
Diastolic dysfunction	13(0.2%)	16(0.2%)
Atrial flutter	13(0.2%)	8(0.1%)
Sinus tachycardia	12(0.2%)	18(0.3%)
Arrhythmia	10(0.2%)	17(0.3%)
Cardiomegaly	8(0.1%)	12(0.2%)
Pericardial effusion	8(0.1%)	12(0.2%)
Left ventricular failure	8(0.1%)	6(0.1%)
Ischaemic cardiomyopathy	7(0.1%)	9(0.1%)
Ventricular tachycardia	7(0.1%)	9(0.1%)
Left atrial enlargement	7(0.1%)	7(0.1%)
Congestive cardiomyopathy	7(0.1%)	4(0.1%)
Ventricular hypokinesia	7(0.1%)	4(0.1%)
Supraventricular tachycardia	6(0.1%)	13(0.2%)
Sinus node dysfunction	6(0.1%)	6(0.1%)
Cardiac failure acute	6(0.1%)	5(0.1%)
Extrasystoles	5(0.1%)	10(0.2%)
Sinus arrhythmia	5(0.1%)	6(0.1%)
Myocardial infarction	5(0.1%)	2(0.0%)
Left atrial dilatation	4(0.1%)	8(0.1%)
Aortic valve sclerosis	4(0.1%)	6(0.1%)
Atrioventricular block	4(0.1%)	6(0.1%)
Aortic valve calcification	4(0.1%)	4(0.1%)
Myocardial fibrosis	4(0.1%)	3(0.0%)
Pericarditis	4(0.1%)	2(0.0%)
Acute coronary syndrome	3(0.0%)	7(0.1%)
Aortic valve disease mixed	3(0.0%)	4(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Cardiac valve disease	3(0.0%)	4(0.1%)
Cardiomyopathy	3(0.0%)	4(0.1%)
Acute left ventricular failure	3(0.0%)	3(0.0%)
Mitral valve sclerosis	3(0.0%)	3(0.0%)
Mitral valve stenosis	3(0.0%)	3(0.0%)
Mitral valve calcification	3(0.0%)	2(0.0%)
Arrhythmia supraventricular	3(0.0%)	1(0.0%)
Chronic left ventricular failure	3(0.0%)	1(0.0%)
Degenerative aortic valve disease	3(0.0%)	1(0.0%)
Ventricular hypertrophy	3(0.0%)	0
Left ventricular dilatation	2(0.0%)	3(0.0%)
Pulmonary valve incompetence	2(0.0%)	3(0.0%)
Atrial thrombosis	2(0.0%)	2(0.0%)
Mitral valve disease	2(0.0%)	2(0.0%)
Atrial tachycardia	2(0.0%)	1(0.0%)
Cardiac hypertrophy	2(0.0%)	1(0.0%)
Cardio-respiratory arrest	2(0.0%)	1(0.0%)
Degenerative mitral valve disease	2(0.0%)	1(0.0%)
Cardiac discomfort	2(0.0%)	0
Defect conduction intraventricular	2(0.0%)	0
Ventricular fibrillation	2(0.0%)	0
Atrioventricular block complete	1(0.0%)	6(0.1%)
Cardiac arrest	1(0.0%)	5(0.1%)
Conduction disorder	1(0.0%)	4(0.1%)
Cardiac asthma	1(0.0%)	3(0.0%)
Systolic dysfunction	1(0.0%)	3(0.0%)
Aortic valve disease	1(0.0%)	2(0.0%)
Bifascicular block	1(0.0%)	2(0.0%)
Cardiac aneurysm	1(0.0%)	2(0.0%)
Coronary artery occlusion	1(0.0%)	2(0.0%)
Metabolic cardiomyopathy	1(0.0%)	2(0.0%)
Wandering pacemaker	1(0.0%)	2(0.0%)
Cardiac disorder	1(0.0%)	1(0.0%)
Cardiac septal hypertrophy	1(0.0%)	1(0.0%)
Cardiovascular insufficiency	1(0.0%)	1(0.0%)
Diabetic cardiomyopathy	1(0.0%)	1(0.0%)
Tachyarrhythmia	1(0.0%)	1(0.0%)
Atrial enlargement	1(0.0%)	0
Bundle branch block bilateral	1(0.0%)	0
Cor pulmonale	1(0.0%)	0
Coronary ostial stenosis	1(0.0%)	0
Degenerative multivalvular disease	1(0.0%)	0
Dilatation atrial	1(0.0%)	0
Intracardiac mass	1(0.0%)	0
Myocarditis	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis adhesive	1(0.0%)	0
Pulseless electrical activity	1(0.0%)	0
Rheumatic heart disease	1(0.0%)	0
Rhythm idioventricular	1(0.0%)	0
Right atrial dilatation	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Sigmoid-shaped ventricular septum	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Tachycardia paroxysmal	1(0.0%)	0
Ventricular tachyarrhythmia	1(0.0%)	0
Wellens' syndrome	1(0.0%)	0
Cardiogenic shock	0	4(0.1%)
Acute myocardial infarction	0	3(0.0%)
Cardiac dysfunction	0	3(0.0%)
Cardiovascular disorder	0	3(0.0%)
Coronary artery insufficiency	0	3(0.0%)
Ventricular arrhythmia	0	3(0.0%)
Cor pulmonale chronic	0	2(0.0%)
Hypertensive cardiomyopathy	0	2(0.0%)
Mitral valve prolapse	0	2(0.0%)
Right ventricular dilatation	0	2(0.0%)
Sinoatrial block	0	2(0.0%)
Atrial conduction time prolongation	0	1(0.0%)
Bradyarrhythmia	0	1(0.0%)
Bundle branch block	0	1(0.0%)
Cardiac amyloidosis	0	1(0.0%)
Cardiac tamponade	0	1(0.0%)
Cardiac valve sclerosis	0	1(0.0%)
Cardiac valve thickening	0	1(0.0%)
Cardiomyopathy acute	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Coronary artery perforation	0	1(0.0%)
Heart valve incompetence	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Left atrial hypertrophy	0	1(0.0%)
Long QT syndrome	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Nodal rhythm	0	1(0.0%)
Paroxysmal arrhythmia	0	1(0.0%)
Pericardial disease	0	1(0.0%)
Prinzmetal angina	0	1(0.0%)
Right atrial enlargement	0	1(0.0%)
Right ventricular failure	0	1(0.0%)
Ventricular dysfunction	0	1(0.0%)
Ventricular remodelling	0	1(0.0%)
Blood And Lymphatic System Disorders	649(10.0%)	634(9.8%)
Anaemia	425(6.5%)	397(6.1%)
Iron deficiency anaemia	63(1.0%)	69(1.1%)
Nephrogenic anaemia	42(0.6%)	34(0.5%)
Thrombocytopenia	36(0.6%)	34(0.5%)
Lymphadenopathy	16(0.2%)	19(0.3%)
Leukocytosis	13(0.2%)	19(0.3%)
Normocytic anaemia	13(0.2%)	8(0.1%)
Blood loss anaemia	12(0.2%)	8(0.1%)
Microcytic anaemia	10(0.2%)	10(0.2%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Splenomegaly	9(0.1%)	13(0.2%)
Polycythaemia	9(0.1%)	9(0.1%)
Thrombocytosis	7(0.1%)	9(0.1%)
Hypochromic anaemia	5(0.1%)	8(0.1%)
Lymphadenopathy mediastinal	5(0.1%)	4(0.1%)
Leukopenia	5(0.1%)	3(0.0%)
Abdominal lymphadenopathy	4(0.1%)	3(0.0%)
Macrocytosis	4(0.1%)	2(0.0%)
Normochromic normocytic anaemia	3(0.0%)	8(0.1%)
Lymphadenitis	3(0.0%)	4(0.1%)
Anaemia of chronic disease	3(0.0%)	1(0.0%)
Pancytopenia	2(0.0%)	7(0.1%)
Eosinophilia	2(0.0%)	4(0.1%)
Anaemia macrocytic	2(0.0%)	1(0.0%)
Coagulopathy	2(0.0%)	1(0.0%)
Immune thrombocytopenia	2(0.0%)	0
Neutrophilia	2(0.0%)	0
Spontaneous haematoma	2(0.0%)	0
Anaemia folate deficiency	1(0.0%)	1(0.0%)
Hypocoagulable state	1(0.0%)	1(0.0%)
Normochromic anaemia	1(0.0%)	1(0.0%)
Anaemia vitamin B12 deficiency	1(0.0%)	0
Bone marrow failure	1(0.0%)	0
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Lymph node calcification	1(0.0%)	0
Lymph node pain	1(0.0%)	0
Lymphocytic infiltration	1(0.0%)	0
Lymphocytosis	1(0.0%)	0
Lymphopenia	1(0.0%)	0
Pseudolymphoma	1(0.0%)	0
Retroperitoneal lymphadenopathy	1(0.0%)	0
Splenic granuloma	1(0.0%)	0
Febrile neutropenia	0	2(0.0%)
Neutropenia	0	2(0.0%)
Acquired haemophilia	0	1(0.0%)
Anaemia megaloblastic	0	1(0.0%)
Anaemia of malignant disease	0	1(0.0%)
Antiphospholipid syndrome	0	1(0.0%)
B-lymphocyte abnormalities	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Bone marrow oedema	0	1(0.0%)
Haemoconcentration	0	1(0.0%)
Haemoglobinaemia	0	1(0.0%)
Haemorrhagic diathesis	0	1(0.0%)
Hypercoagulation	0	1(0.0%)
Hyperglobulinaemia	0	1(0.0%)
Hyperviscosity syndrome	0	1(0.0%)
Increased tendency to bruise	0	1(0.0%)
Spleen disorder	0	1(0.0%)
Splenic calcification	0	1(0.0%)
Splenic embolism	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Splenic lesion	0	1(0.0%)
Splenic vein thrombosis	0	1(0.0%)
Spontaneous haemorrhage	0	1(0.0%)
White blood cell disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	499(7.7%)	510(7.9%)
Basal cell carcinoma	42(0.6%)	46(0.7%)
Prostate cancer	38(0.6%)	42(0.6%)
Skin papilloma	20(0.3%)	20(0.3%)
Colon cancer	19(0.3%)	13(0.2%)
Colon adenoma	18(0.3%)	21(0.3%)
Lung neoplasm malignant	18(0.3%)	15(0.2%)
Bladder cancer	16(0.2%)	11(0.2%)
Lipoma	14(0.2%)	18(0.3%)
Squamous cell carcinoma of skin	14(0.2%)	12(0.2%)
Seborrhoeic keratosis	11(0.2%)	10(0.2%)
Renal neoplasm	11(0.2%)	7(0.1%)
Uterine leiomyoma	10(0.2%)	7(0.1%)
Breast cancer	9(0.1%)	9(0.1%)
Haemangioma of liver	9(0.1%)	7(0.1%)
Adrenal adenoma	7(0.1%)	12(0.2%)
Pancreatic carcinoma	7(0.1%)	8(0.1%)
Adenoma benign	7(0.1%)	6(0.1%)
Hepatocellular carcinoma	7(0.1%)	6(0.1%)
Bladder cancer recurrent	7(0.1%)	1(0.0%)
Bladder neoplasm	6(0.1%)	5(0.1%)
Squamous cell carcinoma	6(0.1%)	4(0.1%)
Renal cell carcinoma	6(0.1%)	1(0.0%)
Melanocytic naevus	5(0.1%)	9(0.1%)
Plasma cell myeloma	5(0.1%)	5(0.1%)
Prostatic adenoma	5(0.1%)	5(0.1%)
Hepatic cancer	5(0.1%)	4(0.1%)
Meningioma	5(0.1%)	4(0.1%)
Neoplasm	5(0.1%)	4(0.1%)
Metastases to lung	5(0.1%)	3(0.0%)
Transitional cell carcinoma	5(0.1%)	3(0.0%)
Clear cell renal cell carcinoma	5(0.1%)	1(0.0%)
Malignant melanoma	4(0.1%)	10(0.2%)
Adenocarcinoma of colon	4(0.1%)	6(0.1%)
Metastases to liver	4(0.1%)	6(0.1%)
Lung adenocarcinoma	4(0.1%)	5(0.1%)
Bladder transitional cell carcinoma	4(0.1%)	4(0.1%)
Metastases to lymph nodes	4(0.1%)	4(0.1%)
Pancreatic neoplasm	4(0.1%)	2(0.0%)
Prostate cancer recurrent	4(0.1%)	2(0.0%)
Chronic lymphocytic leukaemia	4(0.1%)	1(0.0%)
Oesophageal adenocarcinoma	4(0.1%)	0
Lung neoplasm	3(0.0%)	8(0.1%)
Large intestine benign neoplasm	3(0.0%)	4(0.1%)
Neoplasm skin	3(0.0%)	4(0.1%)
Skin cancer	3(0.0%)	4(0.1%)
Adenocarcinoma	3(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Anogenital warts	3(0.0%)	3(0.0%)
Hypergammaglobulinaemia benign monoclonal	3(0.0%)	3(0.0%)
Pancreatic carcinoma metastatic	3(0.0%)	3(0.0%)
Metastases to bone	3(0.0%)	2(0.0%)
Rectal adenocarcinoma	3(0.0%)	2(0.0%)
Metastases to central nervous system	3(0.0%)	1(0.0%)
Metastases to spine	3(0.0%)	1(0.0%)
Benign renal neoplasm	3(0.0%)	0
Intraductal papillary mucinous neoplasm	3(0.0%)	0
Renal cancer	2(0.0%)	7(0.1%)
Gastric cancer	2(0.0%)	5(0.1%)
Oesophageal carcinoma	2(0.0%)	5(0.1%)
Acrochordon	2(0.0%)	4(0.1%)
Colorectal cancer	2(0.0%)	4(0.1%)
Renal hamartoma	2(0.0%)	4(0.1%)
Small cell lung cancer	2(0.0%)	4(0.1%)
Adrenal neoplasm	2(0.0%)	3(0.0%)
Monoclonal gammopathy	2(0.0%)	3(0.0%)
Benign lung neoplasm	2(0.0%)	2(0.0%)
Benign neoplasm of thyroid gland	2(0.0%)	2(0.0%)
Cholangiocarcinoma	2(0.0%)	2(0.0%)
Endometrial cancer	2(0.0%)	2(0.0%)
Squamous cell carcinoma of lung	2(0.0%)	2(0.0%)
Thyroid cancer	2(0.0%)	2(0.0%)
Endometrial adenocarcinoma	2(0.0%)	1(0.0%)
Gastrointestinal carcinoma	2(0.0%)	1(0.0%)
Haemangioma	2(0.0%)	1(0.0%)
Keratoacanthoma	2(0.0%)	1(0.0%)
Lung cancer metastatic	2(0.0%)	1(0.0%)
Lymphoma	2(0.0%)	1(0.0%)
Metastatic malignant melanoma	2(0.0%)	1(0.0%)
Myelodysplastic syndrome	2(0.0%)	1(0.0%)
Oral papilloma	2(0.0%)	1(0.0%)
Prostate cancer metastatic	2(0.0%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.0%)	1(0.0%)
Benign bone neoplasm	2(0.0%)	0
Benign breast neoplasm	2(0.0%)	0
Benign neoplasm of skin	2(0.0%)	0
Brain neoplasm malignant	2(0.0%)	0
Breast cancer metastatic	2(0.0%)	0
Cancer pain	2(0.0%)	0
Cerebral haemangioma	2(0.0%)	0
Fibroma	2(0.0%)	0
Gastrointestinal stromal tumour	2(0.0%)	0
Invasive ductal breast carcinoma	2(0.0%)	0
Neuroendocrine tumour	2(0.0%)	0
Squamous cell carcinoma of the tongue	2(0.0%)	0
Bowen's disease	1(0.0%)	4(0.1%)
Adenocarcinoma gastric	1(0.0%)	3(0.0%)
Blepharal papilloma	1(0.0%)	3(0.0%)
Breast neoplasm	1(0.0%)	3(0.0%)
Eye naevus	1(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Pituitary tumour benign	1(0.0%)	3(0.0%)
Salivary gland neoplasm	1(0.0%)	3(0.0%)
Acute myeloid leukaemia	1(0.0%)	2(0.0%)
B-cell lymphoma	1(0.0%)	2(0.0%)
Benign hepatic neoplasm	1(0.0%)	2(0.0%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.0%)
Enchondromatosis	1(0.0%)	2(0.0%)
Haemangioma of bone	1(0.0%)	2(0.0%)
Lip squamous cell carcinoma	1(0.0%)	2(0.0%)
Papillary renal cell carcinoma	1(0.0%)	2(0.0%)
Papillary thyroid cancer	1(0.0%)	2(0.0%)
Papilloma	1(0.0%)	2(0.0%)
Pituitary tumour	1(0.0%)	2(0.0%)
Rectal adenoma	1(0.0%)	2(0.0%)
Bladder transitional cell carcinoma recurrent	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Epithelioid mesothelioma	1(0.0%)	1(0.0%)
Fibroadenoma of breast	1(0.0%)	1(0.0%)
Gastric adenoma	1(0.0%)	1(0.0%)
Gastrointestinal tract adenoma	1(0.0%)	1(0.0%)
Hepatic neoplasm	1(0.0%)	1(0.0%)
Infected neoplasm	1(0.0%)	1(0.0%)
Laryngeal squamous cell carcinoma	1(0.0%)	1(0.0%)
Lipofibroma	1(0.0%)	1(0.0%)
Malignant pleural effusion	1(0.0%)	1(0.0%)
Neoplasm malignant	1(0.0%)	1(0.0%)
Oesophageal neoplasm	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Pyogenic granuloma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)
Retroperitoneal neoplasm	1(0.0%)	1(0.0%)
Sarcoma	1(0.0%)	1(0.0%)
Schwannoma	1(0.0%)	1(0.0%)
Soft tissue neoplasm	1(0.0%)	1(0.0%)
Tonsil cancer	1(0.0%)	1(0.0%)
Angiomyofibroblastoma	1(0.0%)	0
Angiomyolipoma	1(0.0%)	0
Atypical fibroxanthoma	1(0.0%)	0
Benign gastric neoplasm	1(0.0%)	0
Benign mediastinal neoplasm	1(0.0%)	0
Benign neoplasm	1(0.0%)	0
Benign neoplasm of conjunctiva	1(0.0%)	0
Benign ovarian tumour	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Choroid neoplasm	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Dermatofibrosarcoma protuberans	1(0.0%)	0
Fallopian tube leiomyoma	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal submucosal tumour	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Hepatobiliary cancer	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0
Inflammatory carcinoma of the breast	1(0.0%)	0
Intraocular melanoma	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Langerhans' cell histiocytosis	1(0.0%)	0
Light chain disease	1(0.0%)	0
Lip and/or oral cavity cancer stage 0	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0
Muscle neoplasm	1(0.0%)	0
Nervous system neoplasm benign	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Ocular neoplasm	1(0.0%)	0
Oral fibroma	1(0.0%)	0
Oral neoplasm	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Osteochondroma	1(0.0%)	0
Pancreatic neuroendocrine tumour	1(0.0%)	0
Paraneoplastic syndrome	1(0.0%)	0
Pharyngeal neoplasm	1(0.0%)	0
Polycythaemia vera	1(0.0%)	0
Rectal cancer metastatic	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm benign	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Tumour ulceration	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Uterine cancer	1(0.0%)	0
Brain neoplasm	0	3(0.0%)
Cholesteatoma	0	3(0.0%)
Malignant melanoma in situ	0	3(0.0%)
Adenocarcinoma pancreas	0	2(0.0%)
Benign neoplasm of bladder	0	2(0.0%)
Benign pancreatic neoplasm	0	2(0.0%)
Colon neoplasm	0	2(0.0%)
Colorectal adenocarcinoma	0	2(0.0%)
Intraductal papilloma of breast	0	2(0.0%)
Lentigo maligna	0	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Malignant neoplasm of unknown primary site	0	2(0.0%)
Neoplasm prostate	0	2(0.0%)
Papillary cystadenoma lymphomatosum	0	2(0.0%)
Thyroid neoplasm	0	2(0.0%)
Acoustic neuroma	0	1(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
Anal cancer	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign anorectal neoplasm	0	1(0.0%)
Benign gastrointestinal neoplasm	0	1(0.0%)
Benign neoplasm of eyelid	0	1(0.0%)
Benign neoplasm of prostate	0	1(0.0%)
Bladder papilloma	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Carcinoma in situ of skin	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Dysplastic naevus	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Eyelid tumour	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Ganglioneuroma	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Haemangioblastoma	0	1(0.0%)
Hepatic cancer metastatic	0	1(0.0%)
Intraductal papillary-mucinous carcinoma of pancreas	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Kaposi's sarcoma	0	1(0.0%)
Lymphocytic leukaemia	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Mesenteric neoplasm	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Metastasis	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Ovarian neoplasm	0	1(0.0%)
Paraproteinaemia	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pleomorphic adenoma	0	1(0.0%)
Prostate cancer stage IV	0	1(0.0%)
Renal adenoma	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Sarcomatoid carcinoma of the lung	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Seminoma	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Sweat gland tumour	0	1(0.0%)
Testis cancer	0	1(0.0%)
Thymoma	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Vulvovaginal warts	0	1(0.0%)
Waldenstrom's macroglobulinaemia	0	1(0.0%)
Surgical And Medical Procedures	435(6.7%)	406(6.3%)
Cataract operation	89(1.4%)	99(1.5%)
Tooth extraction	41(0.6%)	35(0.5%)
Toe amputation	16(0.2%)	12(0.2%)
Knee arthroplasty	14(0.2%)	18(0.3%)
Skin neoplasm excision	13(0.2%)	7(0.1%)
Large intestinal polypectomy	12(0.2%)	11(0.2%)
Intraocular lens implant	12(0.2%)	10(0.2%)
Vitrectomy	9(0.1%)	13(0.2%)
Hip arthroplasty	8(0.1%)	9(0.1%)
Polypectomy	8(0.1%)	8(0.1%)
Dental implantation	7(0.1%)	8(0.1%)
Carpal tunnel decompression	7(0.1%)	7(0.1%)
Skin lesion removal	7(0.1%)	4(0.1%)
Arteriovenous fistula operation	7(0.1%)	3(0.0%)
Leg amputation	6(0.1%)	5(0.1%)
Tendon sheath incision	6(0.1%)	5(0.1%)
Diabetes mellitus management	6(0.1%)	1(0.0%)
Cholecystectomy	5(0.1%)	13(0.2%)
Gastric bypass	5(0.1%)	2(0.0%)
Eye operation	5(0.1%)	0
Cardiac pacemaker insertion	4(0.1%)	3(0.0%)
Colectomy	4(0.1%)	1(0.0%)
Endodontic procedure	4(0.1%)	1(0.0%)
Hysterectomy	4(0.1%)	1(0.0%)
Eye laser surgery	3(0.0%)	5(0.1%)
Intervertebral disc operation	3(0.0%)	5(0.1%)
Foot amputation	3(0.0%)	4(0.1%)
Circumcision	3(0.0%)	1(0.0%)
Metabolic surgery	3(0.0%)	1(0.0%)
Parathyroidectomy	3(0.0%)	1(0.0%)
Peripheral artery angioplasty	3(0.0%)	1(0.0%)
Retinal laser coagulation	3(0.0%)	1(0.0%)
Spinal laminectomy	3(0.0%)	1(0.0%)
Foot operation	3(0.0%)	0
Removal of internal fixation	3(0.0%)	0
Roux loop conversion	3(0.0%)	0
Skin graft	3(0.0%)	0
Spinal decompression	3(0.0%)	0
Lens extraction	2(0.0%)	8(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Umbilical hernia repair	2(0.0%)	6(0.1%)
Transurethral prostatectomy	2(0.0%)	5(0.1%)
Coronary angioplasty	2(0.0%)	3(0.0%)
Gastrectomy	2(0.0%)	3(0.0%)
Haemodialysis	2(0.0%)	3(0.0%)
Coronary artery bypass	2(0.0%)	2(0.0%)
Debridement	2(0.0%)	2(0.0%)
Inguinal hernia repair	2(0.0%)	2(0.0%)
Prostatectomy	2(0.0%)	2(0.0%)
Spinal operation	2(0.0%)	2(0.0%)
Transurethral bladder resection	2(0.0%)	2(0.0%)
Aortic valve replacement	2(0.0%)	1(0.0%)
Blepharoplasty	2(0.0%)	1(0.0%)
Cardioversion	2(0.0%)	1(0.0%)
Coronary revascularisation	2(0.0%)	1(0.0%)
Dental operation	2(0.0%)	1(0.0%)
Peripheral artery bypass	2(0.0%)	1(0.0%)
Chemotherapy	2(0.0%)	0
Dental care	2(0.0%)	0
Dialysis	2(0.0%)	0
Finger amputation	2(0.0%)	0
Internal fixation of fracture	2(0.0%)	0
Lens capsulotomy	2(0.0%)	0
Lithotripsy	2(0.0%)	0
Metatarsal excision	2(0.0%)	0
Nail operation	2(0.0%)	0
Ostectomy	2(0.0%)	0
Parotidectomy	2(0.0%)	0
Rehabilitation therapy	2(0.0%)	0
Renal stone removal	2(0.0%)	0
Shoulder arthroplasty	2(0.0%)	0
Shoulder operation	2(0.0%)	0
Spinal fusion surgery	2(0.0%)	0
Tooth repair	2(0.0%)	0
Vasectomy	2(0.0%)	0
Abscess drainage	1(0.0%)	3(0.0%)
Percutaneous coronary intervention	1(0.0%)	3(0.0%)
Dialysis device insertion	1(0.0%)	2(0.0%)
Dupuytren's contracture operation	1(0.0%)	2(0.0%)
Intestinal polypectomy	1(0.0%)	2(0.0%)
Intra-ocular injection	1(0.0%)	2(0.0%)
Knee operation	1(0.0%)	2(0.0%)
Retinal operation	1(0.0%)	2(0.0%)
Aortic aneurysm repair	1(0.0%)	1(0.0%)
Cardiac ablation	1(0.0%)	1(0.0%)
Central venous catheterisation	1(0.0%)	1(0.0%)
Coronary arterial stent insertion	1(0.0%)	1(0.0%)
Drug delivery device placement	1(0.0%)	1(0.0%)
Eyelid operation	1(0.0%)	1(0.0%)
Glaucoma drainage device placement	1(0.0%)	1(0.0%)
Glaucoma surgery	1(0.0%)	1(0.0%)
Implantable defibrillator insertion	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Joint injection	1(0.0%)	1(0.0%)
Laser therapy	1(0.0%)	1(0.0%)
Meniscus operation	1(0.0%)	1(0.0%)
Papilloma excision	1(0.0%)	1(0.0%)
Peripheral artery stent insertion	1(0.0%)	1(0.0%)
Preoperative care	1(0.0%)	1(0.0%)
Pterygium operation	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Tenotomy	1(0.0%)	1(0.0%)
Thyroidectomy	1(0.0%)	1(0.0%)
Uterine polypectomy	1(0.0%)	1(0.0%)
Abdominal hernia repair	1(0.0%)	0
Acrochordon excision	1(0.0%)	0
Aneurysm repair	1(0.0%)	0
Ankle operation	1(0.0%)	0
Atrial appendage closure	1(0.0%)	0
Benign tumour excision	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Biliary catheter removal	1(0.0%)	0
Bladder calculus removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Brachytherapy	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Breast prosthesis removal	1(0.0%)	0
Cancer surgery	1(0.0%)	0
Canthoplasty	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Cerumen removal	1(0.0%)	0
Drug therapy	1(0.0%)	0
Epidural injection	1(0.0%)	0
Fasciotomy	1(0.0%)	0
Femoral hernia repair	1(0.0%)	0
Finger repair operation	1(0.0%)	0
Fistula repair	1(0.0%)	0
Gastric polypectomy	1(0.0%)	0
Gingival operation	1(0.0%)	0
Hernia repair	1(0.0%)	0
Infiltration anaesthesia	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Large intestine operation	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Mass excision	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Medical device removal	1(0.0%)	0
Micrographic skin surgery	1(0.0%)	0
Mole excision	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Nerve block	1(0.0%)	0
Neurolysis	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Ocular stem cell transplant	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Oophorectomy bilateral	1(0.0%)	0
Oral surgery	1(0.0%)	0
Orthopaedic procedure	1(0.0%)	0
Pancreatic stent placement	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0
Platelet rich plasma therapy	1(0.0%)	0
Proctocolectomy	1(0.0%)	0
Ptosis repair	1(0.0%)	0
Radical hysterectomy	1(0.0%)	0
Radical mastectomy	1(0.0%)	0
Removal of foreign body from eye	1(0.0%)	0
Scar excision	1(0.0%)	0
Sequestrectomy	1(0.0%)	0
Small intestinal polypectomy	1(0.0%)	0
Suture insertion	1(0.0%)	0
Synovectomy	1(0.0%)	0
Tenolysis	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Tumour excision	1(0.0%)	0
Ureteric calculus removal	1(0.0%)	0
Urethral bulking agent injection	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Wound treatment	1(0.0%)	0
Insertion of ambulatory peritoneal catheter	0	4(0.1%)
Limb operation	0	4(0.1%)
Lipoma excision	0	4(0.1%)
Stent placement	0	4(0.1%)
Hydrocele operation	0	3(0.0%)
Retinopexy	0	3(0.0%)
Sebaceous cyst excision	0	3(0.0%)
Varicose vein operation	0	3(0.0%)
Amputation	0	2(0.0%)
Angioplasty	0	2(0.0%)
Cardiac pacemaker replacement	0	2(0.0%)
Haemorrhoid operation	0	2(0.0%)
Skin ulcer excision	0	2(0.0%)
Antitussive therapy	0	1(0.0%)
Aortic surgery	0	1(0.0%)
Appendicectomy	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Artificial crown procedure	0	1(0.0%)
Astringent therapy	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder neck resection	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Bone operation	0	1(0.0%)
Bunion operation	0	1(0.0%)
Caecum operation	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac rehabilitation therapy	0	1(0.0%)
Central venous catheter removal	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Colon operation	0	1(0.0%)
Colostomy	0	1(0.0%)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Cyst removal	0	1(0.0%)
Cystostomy	0	1(0.0%)
Dermal filler injection	0	1(0.0%)
Ear tube insertion	0	1(0.0%)
Eye excision	0	1(0.0%)
Facial lesion excision	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Gastric electrical stimulation	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Intensive care	0	1(0.0%)
Intraocular lens repositioning	0	1(0.0%)
Intravitreal implant	0	1(0.0%)
Iridotomy	0	1(0.0%)
Keratomileusis	0	1(0.0%)
Ligament operation	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Matrixectomy	0	1(0.0%)
Mitral valve repair	0	1(0.0%)
Nasal operation	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Neurosurgery	0	1(0.0%)
Peripheral nerve operation	0	1(0.0%)
Pharyngeal polypectomy	0	1(0.0%)
Phlebotomy	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Posterior lens capsulotomy	0	1(0.0%)
Radioactive iodine therapy	0	1(0.0%)
Rectocele repair	0	1(0.0%)
Removal of foreign body from larynx	0	1(0.0%)
Renal cyst excision	0	1(0.0%)
Renal disorder prophylaxis	0	1(0.0%)
Sclerotherapy	0	1(0.0%)
Sinus operation	0	1(0.0%)
Toe operation	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Urinary cystectomy	0	1(0.0%)
Vascular catheterisation	0	1(0.0%)
Vascular graft	0	1(0.0%)
Wisdom teeth removal	0	1(0.0%)
Zonulolysis	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Psychiatric Disorders	378(5.8%)	449(6.9%)
Insomnia	142(2.2%)	145(2.2%)
Depression	92(1.4%)	117(1.8%)
Anxiety	51(0.8%)	74(1.1%)
Sleep disorder	25(0.4%)	23(0.4%)
Confusional state	14(0.2%)	14(0.2%)
Stress	7(0.1%)	5(0.1%)
Depressed mood	6(0.1%)	16(0.2%)
Delirium	6(0.1%)	11(0.2%)
Major depression	6(0.1%)	5(0.1%)
Mixed anxiety and depressive disorder	6(0.1%)	3(0.0%)
Mental status changes	5(0.1%)	7(0.1%)
Hallucination	5(0.1%)	6(0.1%)
Nervousness	4(0.1%)	3(0.0%)
Bipolar disorder	4(0.1%)	0
Anxiety disorder	3(0.0%)	5(0.1%)
Restlessness	3(0.0%)	4(0.1%)
Aggression	3(0.0%)	2(0.0%)
Disorientation	3(0.0%)	2(0.0%)
Nightmare	3(0.0%)	1(0.0%)
Apathy	2(0.0%)	3(0.0%)
Middle insomnia	2(0.0%)	1(0.0%)
Nicotine dependence	2(0.0%)	1(0.0%)
Tension	2(0.0%)	1(0.0%)
Affective disorder	2(0.0%)	0
Completed suicide	2(0.0%)	0
Personality change due to a general medical condition	2(0.0%)	0
Tic	2(0.0%)	0
Adjustment disorder with depressed mood	1(0.0%)	6(0.1%)
Suicidal ideation	1(0.0%)	3(0.0%)
Abulia	1(0.0%)	2(0.0%)
Alcohol abuse	1(0.0%)	2(0.0%)
Libido decreased	1(0.0%)	2(0.0%)
Drug use disorder	1(0.0%)	1(0.0%)
Enuresis	1(0.0%)	1(0.0%)
Generalised anxiety disorder	1(0.0%)	1(0.0%)
Grief reaction	1(0.0%)	1(0.0%)
Initial insomnia	1(0.0%)	1(0.0%)
Irritability	1(0.0%)	1(0.0%)
Mental disorder due to a general medical condition	1(0.0%)	1(0.0%)
Neurosis	1(0.0%)	1(0.0%)
Psychotic disorder	1(0.0%)	1(0.0%)
Abnormal behaviour	1(0.0%)	0
Agitation	1(0.0%)	0
Alcohol withdrawal syndrome	1(0.0%)	0
Attention deficit hyperactivity disorder	1(0.0%)	0
Autism spectrum disorder	1(0.0%)	0
Drug dependence	1(0.0%)	0
Mania	1(0.0%)	0
Mental disorder	1(0.0%)	0
Panic attack	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Persistent depressive disorder	1(0.0%)	0
Phonophobia	1(0.0%)	0
Schizophrenia	1(0.0%)	0
Schizophreniform disorder	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Post-traumatic stress disorder	0	5(0.1%)
Adjustment disorder	0	3(0.0%)
Panic disorder	0	3(0.0%)
Drug abuse	0	2(0.0%)
Mood altered	0	2(0.0%)
Abnormal dreams	0	1(0.0%)
Acute stress disorder	0	1(0.0%)
Affect lability	0	1(0.0%)
Alcoholism	0	1(0.0%)
Anorgasmia	0	1(0.0%)
Behaviour disorder	0	1(0.0%)
Claustrophobia	0	1(0.0%)
Daydreaming	0	1(0.0%)
Delusional disorder, unspecified type	0	1(0.0%)
Dysphemia	0	1(0.0%)
Dyssomnia	0	1(0.0%)
Executive dysfunction	0	1(0.0%)
Impulse-control disorder	0	1(0.0%)
Parasomnia	0	1(0.0%)
Personality change	0	1(0.0%)
Polydipsia psychogenic	0	1(0.0%)
Social avoidant behaviour	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Tearfulness	0	1(0.0%)
Tobacco abuse	0	1(0.0%)
Reproductive System And Breast Disorders	362(5.6%)	361(5.6%)
Benign prostatic hyperplasia	159(2.4%)	153(2.4%)
Erectile dysfunction	42(0.6%)	45(0.7%)
Prostatomegaly	22(0.3%)	24(0.4%)
Prostatitis	17(0.3%)	19(0.3%)
Breast pain	10(0.2%)	5(0.1%)
Pelvic pain	9(0.1%)	5(0.1%)
Gynaecomastia	8(0.1%)	11(0.2%)
Balanoposthitis	8(0.1%)	9(0.1%)
Prostatism	7(0.1%)	6(0.1%)
Atrophic vulvovaginitis	6(0.1%)	2(0.0%)
Vulvovaginal pruritus	6(0.1%)	2(0.0%)
Prostatic calcification	5(0.1%)	8(0.1%)
Vaginal haemorrhage	5(0.1%)	4(0.1%)
Uterine haemorrhage	5(0.1%)	2(0.0%)
Postmenopausal haemorrhage	5(0.1%)	1(0.0%)
Pruritus genital	4(0.1%)	3(0.0%)
Sexual dysfunction	4(0.1%)	2(0.0%)
Breast mass	3(0.0%)	5(0.1%)
Uterine polyp	3(0.0%)	5(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Testicular pain	3(0.0%)	3(0.0%)
Prostatic mass	3(0.0%)	1(0.0%)
Ovarian cyst	2(0.0%)	10(0.2%)
Prostatic disorder	2(0.0%)	6(0.1%)
Cervical dysplasia	2(0.0%)	3(0.0%)
Endometrial hyperplasia	2(0.0%)	3(0.0%)
Metrorrhagia	2(0.0%)	3(0.0%)
Nipple pain	2(0.0%)	2(0.0%)
Breast disorder	2(0.0%)	1(0.0%)
Cervical polyp	2(0.0%)	1(0.0%)
Penile pain	2(0.0%)	1(0.0%)
Vaginal disorder	2(0.0%)	1(0.0%)
Menstruation irregular	2(0.0%)	0
Vulvovaginal dryness	2(0.0%)	0
Fibrocystic breast disease	1(0.0%)	2(0.0%)
Genital lesion	1(0.0%)	2(0.0%)
Breast calcifications	1(0.0%)	1(0.0%)
Breast cyst	1(0.0%)	1(0.0%)
Breast dysplasia	1(0.0%)	1(0.0%)
Cystocele	1(0.0%)	1(0.0%)
Menopausal symptoms	1(0.0%)	1(0.0%)
Pelvic fluid collection	1(0.0%)	1(0.0%)
Penile erythema	1(0.0%)	1(0.0%)
Perineal pain	1(0.0%)	1(0.0%)
Scrotal dermatitis	1(0.0%)	1(0.0%)
Uterine prolapse	1(0.0%)	1(0.0%)
Amenorrhoea	1(0.0%)	0
Breast discharge	1(0.0%)	0
Breast necrosis	1(0.0%)	0
Breast tenderness	1(0.0%)	0
Dysmenorrhoea	1(0.0%)	0
Ectropion of cervix	1(0.0%)	0
Endometriosis	1(0.0%)	0
Fallopian tube cyst	1(0.0%)	0
Ovarian mass	1(0.0%)	0
Pelvic adhesions	1(0.0%)	0
Pelvic haematoma	1(0.0%)	0
Peyronie's disease	1(0.0%)	0
Prostatic dysplasia	1(0.0%)	0
Prostatovesiculitis	1(0.0%)	0
Scrotal disorder	1(0.0%)	0
Testicular perforation	1(0.0%)	0
Uterine disorder	1(0.0%)	0
Breast hyperplasia	0	5(0.1%)
Menorrhagia	0	3(0.0%)
Varicocele	0	3(0.0%)
Vulvovaginal pain	0	3(0.0%)
Prostatic cyst	0	2(0.0%)
Scrotal pain	0	2(0.0%)
Adnexa uteri cyst	0	1(0.0%)
Adnexa uteri mass	0	1(0.0%)
Breast inflammation	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Calculus prostatic	0	1(0.0%)
Cervical cyst	0	1(0.0%)
Dysfunctional uterine bleeding	0	1(0.0%)
Ejaculation disorder	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Epididymal enlargement	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Galactorrhoea	0	1(0.0%)
Genital atrophy	0	1(0.0%)
Genital discomfort	0	1(0.0%)
Genital hypoaesthesia	0	1(0.0%)
Genital tract inflammation	0	1(0.0%)
Haematospermia	0	1(0.0%)
Hydrometra	0	1(0.0%)
Nipple exudate bloody	0	1(0.0%)
Nipple inflammation	0	1(0.0%)
Ovarian enlargement	0	1(0.0%)
Ovarian failure	0	1(0.0%)
Pelvic cyst	0	1(0.0%)
Pelvic discomfort	0	1(0.0%)
Penile vascular disorder	0	1(0.0%)
Rectocele	0	1(0.0%)
Scrotal oedema	0	1(0.0%)
Scrotal swelling	0	1(0.0%)
Testicular mass	0	1(0.0%)
Testicular swelling	0	1(0.0%)
Uterine inflammation	0	1(0.0%)
Uterine mass	0	1(0.0%)
Vaginal oedema	0	1(0.0%)
Vulval eczema	0	1(0.0%)
Hepatobiliary Disorders	343(5.3%)	335(5.2%)
Hepatic steatosis	101(1.6%)	111(1.7%)
Cholelithiasis	88(1.4%)	82(1.3%)
Hepatic function abnormal	32(0.5%)	26(0.4%)
Hepatic cirrhosis	21(0.3%)	20(0.3%)
Gallbladder polyp	20(0.3%)	12(0.2%)
Cholecystitis	19(0.3%)	17(0.3%)
Cholecystitis acute	13(0.2%)	18(0.3%)
Hepatomegaly	12(0.2%)	6(0.1%)
Hepatic cyst	10(0.2%)	8(0.1%)
Cholecystitis chronic	9(0.1%)	13(0.2%)
Bile duct stone	9(0.1%)	8(0.1%)
Biliary colic	9(0.1%)	6(0.1%)
Cholestasis	7(0.1%)	8(0.1%)
Hepatic lesion	5(0.1%)	4(0.1%)
Liver disorder	5(0.1%)	3(0.0%)
Cholangitis	4(0.1%)	8(0.1%)
Non-alcoholic steatohepatitis	4(0.1%)	5(0.1%)
Nonalcoholic fatty liver disease	4(0.1%)	4(0.1%)
Hepatitis	4(0.1%)	1(0.0%)
Hepatocellular injury	3(0.0%)	3(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Drug-induced liver injury	3(0.0%)	2(0.0%)
Hepatic calcification	3(0.0%)	1(0.0%)
Biliary dyskinesia	3(0.0%)	0
Chronic hepatitis	3(0.0%)	0
Hepatosplenomegaly	2(0.0%)	3(0.0%)
Jaundice cholestatic	2(0.0%)	3(0.0%)
Portal hypertension	2(0.0%)	3(0.0%)
Biliary dilatation	2(0.0%)	2(0.0%)
Hyperplastic cholecystopathy	2(0.0%)	2(0.0%)
Gallbladder disorder	2(0.0%)	1(0.0%)
Hepatic failure	2(0.0%)	1(0.0%)
Hepatitis acute	2(0.0%)	1(0.0%)
Hypertransaminasaemia	2(0.0%)	1(0.0%)
Biliary obstruction	2(0.0%)	0
Hepatic fibrosis	2(0.0%)	0
Ocular icterus	2(0.0%)	0
Cholangitis acute	1(0.0%)	5(0.1%)
Hepatic mass	1(0.0%)	5(0.1%)
Alcoholic liver disease	1(0.0%)	2(0.0%)
Gallbladder cholesterolosis	1(0.0%)	2(0.0%)
Steatohepatitis	1(0.0%)	2(0.0%)
Biliary tract disorder	1(0.0%)	1(0.0%)
Gallbladder enlargement	1(0.0%)	1(0.0%)
Hepatic pain	1(0.0%)	1(0.0%)
Hyperbilirubinaemia	1(0.0%)	1(0.0%)
Jaundice	1(0.0%)	1(0.0%)
Porcelain gallbladder	1(0.0%)	1(0.0%)
Bile duct stenosis	1(0.0%)	0
Cholangiectasis acquired	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Gallbladder fistula	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Hepatotoxicity	1(0.0%)	0
Congestive hepatopathy	0	2(0.0%)
Hepatitis alcoholic	0	2(0.0%)
Hydrocholecystis	0	2(0.0%)
Biliary fistula	0	1(0.0%)
Cardiac cirrhosis	0	1(0.0%)
Cholecystocholangitis	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Granulomatous liver disease	0	1(0.0%)
Hepatic vascular thrombosis	0	1(0.0%)
Hepatitis toxic	0	1(0.0%)
Hepatobiliary disease	0	1(0.0%)
Liver injury	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Ear And Labyrinth Disorders	290(4.5%)	268(4.1%)
Vertigo	129(2.0%)	115(1.8%)
Tinnitus	35(0.5%)	41(0.6%)
Ear pain	19(0.3%)	19(0.3%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vertigo positional	16(0.2%)	12(0.2%)
Hypoacusis	16(0.2%)	8(0.1%)
Cerumen impaction	11(0.2%)	13(0.2%)
Deafness neurosensory	11(0.2%)	9(0.1%)
Deafness	10(0.2%)	11(0.2%)
Sudden hearing loss	9(0.1%)	11(0.2%)
Vestibular disorder	7(0.1%)	8(0.1%)
Presbyacusis	7(0.1%)	2(0.0%)
Excessive cerumen production	6(0.1%)	11(0.2%)
Ear pruritus	6(0.1%)	2(0.0%)
Deafness unilateral	4(0.1%)	4(0.1%)
Meniere's disease	4(0.1%)	1(0.0%)
Tympanic membrane perforation	3(0.0%)	4(0.1%)
Ear discomfort	3(0.0%)	1(0.0%)
Motion sickness	2(0.0%)	2(0.0%)
Auricular pseudocyst	2(0.0%)	0
Inner ear disorder	2(0.0%)	0
Auditory disorder	1(0.0%)	1(0.0%)
Middle ear inflammation	1(0.0%)	1(0.0%)
Mixed deafness	1(0.0%)	1(0.0%)
Acute vestibular syndrome	1(0.0%)	0
Aural polyp	1(0.0%)	0
Conductive deafness	1(0.0%)	0
Otolithiasis	1(0.0%)	0
Deafness bilateral	0	9(0.1%)
Ear congestion	0	1(0.0%)
Ear disorder	0	1(0.0%)
Ear swelling	0	1(0.0%)
Eustachian tube dysfunction	0	1(0.0%)
Eustachian tube patulous	0	1(0.0%)
External ear inflammation	0	1(0.0%)
Neurosensory hypoacusis	0	1(0.0%)
Tympanic membrane hyperaemia	0	1(0.0%)
Vestibular ataxia	0	1(0.0%)
Endocrine Disorders	173(2.7%)	183(2.8%)
Hypothyroidism	60(0.9%)	55(0.8%)
Hyperparathyroidism secondary	26(0.4%)	22(0.3%)
Thyroid mass	25(0.4%)	23(0.4%)
Goitre	12(0.2%)	16(0.2%)
Hyperthyroidism	12(0.2%)	16(0.2%)
Hyperparathyroidism	10(0.2%)	17(0.3%)
Adrenal mass	5(0.1%)	5(0.1%)
Autoimmune thyroiditis	3(0.0%)	2(0.0%)
Adrenomegaly	3(0.0%)	0
Thyroid disorder	3(0.0%)	0
Hypogonadism	2(0.0%)	5(0.1%)
Thyroid cyst	2(0.0%)	5(0.1%)
Basedow's disease	2(0.0%)	2(0.0%)
Euthyroid sick syndrome	2(0.0%)	2(0.0%)
Primary hypothyroidism	2(0.0%)	1(0.0%)
Androgen deficiency	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Empty sella syndrome	2(0.0%)	0
Hypoparathyroidism	1(0.0%)	2(0.0%)
Primary hyperaldosteronism	1(0.0%)	2(0.0%)
Hyperparathyroidism primary	1(0.0%)	1(0.0%)
Hyperprolactinaemia	1(0.0%)	1(0.0%)
Autoimmune thyroid disorder	1(0.0%)	0
Cushing's syndrome	1(0.0%)	0
Hyperandrogenism	1(0.0%)	0
Hyperpituitarism	1(0.0%)	0
Hypopituitarism	1(0.0%)	0
Primary adrenal insufficiency	1(0.0%)	0
Thyroiditis subacute	1(0.0%)	0
Toxic nodular goitre	1(0.0%)	0
Adrenal cyst	0	3(0.0%)
Adrenal disorder	0	3(0.0%)
Hyperplasia adrenal	0	3(0.0%)
Pituitary-dependent Cushing's syndrome	0	2(0.0%)
Adrenal insufficiency	0	1(0.0%)
Secondary hyperthyroidism	0	1(0.0%)
Testicular failure	0	1(0.0%)
Thyroiditis	0	1(0.0%)
Immune System Disorders	76(1.2%)	60(0.9%)
Seasonal allergy	30(0.5%)	24(0.4%)
Drug hypersensitivity	16(0.2%)	7(0.1%)
Hypersensitivity	15(0.2%)	18(0.3%)
Anaphylactic reaction	2(0.0%)	3(0.0%)
Allergy to arthropod sting	2(0.0%)	1(0.0%)
Allergy to animal	2(0.0%)	0
Allergy to arthropod bite	2(0.0%)	0
Amyloidosis	2(0.0%)	0
Anaphylactic shock	1(0.0%)	2(0.0%)
Food allergy	1(0.0%)	2(0.0%)
Sarcoidosis	1(0.0%)	2(0.0%)
Dust allergy	1(0.0%)	0
Multiple allergies	1(0.0%)	0
Selective IgM immunodeficiency	1(0.0%)	0
Allergy to vaccine	0	1(0.0%)
Contrast media allergy	0	1(0.0%)
Mite allergy	0	1(0.0%)
Congenital, Familial And Genetic Disorders	35(0.5%)	43(0.7%)
Phimosis	6(0.1%)	10(0.2%)
Hydrocele	4(0.1%)	7(0.1%)
Congenital cystic kidney disease	4(0.1%)	1(0.0%)
Hypertrophic cardiomyopathy	3(0.0%)	1(0.0%)
Adenomatous polyposis coli	2(0.0%)	2(0.0%)
Type V hyperlipidaemia	2(0.0%)	2(0.0%)
Congenital renal cyst	2(0.0%)	1(0.0%)
Arteriovenous malformation	2(0.0%)	0
Thalassaemia	1(0.0%)	1(0.0%)
Accessory spleen	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Arnold-Chiari malformation	1(0.0%)	0
Bicuspid aortic valve	1(0.0%)	0
Factor VIII deficiency	1(0.0%)	0
Factor XII deficiency	1(0.0%)	0
Keratosis follicular	1(0.0%)	0
Limb malformation	1(0.0%)	0
Thalassaemia alpha	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Ventricular septal defect	1(0.0%)	0
Atrial septal defect	0	2(0.0%)
Anomaly of middle ear congenital	0	1(0.0%)
Birth mark	0	1(0.0%)
Cone dystrophy	0	1(0.0%)
Congenital aortic anomaly	0	1(0.0%)
Congenital poikiloderma	0	1(0.0%)
Dermoid cyst	0	1(0.0%)
Distichiasis	0	1(0.0%)
Ectrodactyly	0	1(0.0%)
Epidermolysis bullosa	0	1(0.0%)
Familial tremor	0	1(0.0%)
Haemophilia	0	1(0.0%)
Hereditary palmoplantar keratoderma	0	1(0.0%)
Hypospadias	0	1(0.0%)
Kidney duplex	0	1(0.0%)
Left-to-right cardiac shunt	0	1(0.0%)
Rathke's cleft cyst	0	1(0.0%)
Tornwaldt cyst	0	1(0.0%)
Product Issues	8(0.1%)	11(0.2%)
Device loosening	2(0.0%)	1(0.0%)
Lead dislodgement	2(0.0%)	0
Device malfunction	1(0.0%)	3(0.0%)
Device leakage	1(0.0%)	1(0.0%)
Device capturing issue	1(0.0%)	0
Device expulsion	1(0.0%)	0
Device lead damage	1(0.0%)	0
Device dislocation	0	3(0.0%)
Device breakage	0	2(0.0%)
Patient-device incompatibility	0	1(0.0%)
Social Circumstances	2(0.0%)	4(0.1%)
Social stay hospitalisation	1(0.0%)	0
Substance use	1(0.0%)	0
Walking disability	0	2(0.0%)
Menopause	0	1(0.0%)
Pregnancy of partner	0	1(0.0%)
Pregnancy, Puerperium And Perinatal Conditions	0	1(0.0%)
Umbilical granuloma	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Any TEAE	2060(31.6%)	2186(33.7%)
Infections And Infestations	623(9.6%)	680(10.5%)
Pneumonia	143(2.2%)	216(3.3%)
Cellulitis	66(1.0%)	50(0.8%)
Urinary tract infection	49(0.8%)	62(1.0%)
Sepsis	31(0.5%)	37(0.6%)
Osteomyelitis	26(0.4%)	25(0.4%)
Erysipelas	21(0.3%)	29(0.4%)
Gastroenteritis	20(0.3%)	28(0.4%)
COVID-19	17(0.3%)	22(0.3%)
Urosepsis	17(0.3%)	20(0.3%)
Bronchitis	16(0.2%)	22(0.3%)
Localised infection	16(0.2%)	8(0.1%)
Pyelonephritis	16(0.2%)	8(0.1%)
Influenza	12(0.2%)	9(0.1%)
Abscess limb	12(0.2%)	6(0.1%)
Diabetic foot infection	11(0.2%)	10(0.2%)
Gangrene	10(0.2%)	11(0.2%)
COVID-19 pneumonia	9(0.1%)	11(0.2%)
Respiratory tract infection	9(0.1%)	8(0.1%)
Pyelonephritis acute	9(0.1%)	3(0.0%)
Postoperative wound infection	8(0.1%)	2(0.0%)
Septic shock	7(0.1%)	10(0.2%)
Diverticulitis	7(0.1%)	9(0.1%)
Appendicitis	7(0.1%)	8(0.1%)
Lower respiratory tract infection	6(0.1%)	10(0.2%)
Wound infection	6(0.1%)	7(0.1%)
Infected skin ulcer	6(0.1%)	4(0.1%)
Gastroenteritis viral	6(0.1%)	0
Pulmonary sepsis	5(0.1%)	3(0.0%)
Herpes zoster	5(0.1%)	2(0.0%)
Subcutaneous abscess	5(0.1%)	0
Upper respiratory tract infection	4(0.1%)	10(0.2%)
Cystitis	4(0.1%)	5(0.1%)
Osteomyelitis chronic	4(0.1%)	2(0.0%)
Arthritis bacterial	4(0.1%)	1(0.0%)
Bacteraemia	4(0.1%)	1(0.0%)
Pneumonia bacterial	3(0.0%)	9(0.1%)
Anal abscess	3(0.0%)	5(0.1%)
Infection	3(0.0%)	5(0.1%)
Pulmonary tuberculosis	3(0.0%)	4(0.1%)
Staphylococcal sepsis	3(0.0%)	2(0.0%)
Pneumonia streptococcal	3(0.0%)	0
Intervertebral discitis	2(0.0%)	5(0.1%)
Liver abscess	2(0.0%)	5(0.1%)
Soft tissue infection	2(0.0%)	4(0.1%)
Orchitis	2(0.0%)	2(0.0%)
Pyelonephritis chronic	2(0.0%)	2(0.0%)
Tracheobronchitis	2(0.0%)	2(0.0%)
Viral infection	2(0.0%)	2(0.0%)
Abdominal abscess	2(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Clostridium difficile infection	2(0.0%)	1(0.0%)
Febrile infection	2(0.0%)	1(0.0%)
Otitis externa	2(0.0%)	1(0.0%)
Otitis media	2(0.0%)	1(0.0%)
Pneumonia viral	2(0.0%)	1(0.0%)
Appendicitis perforated	2(0.0%)	0
Aspergilloma	2(0.0%)	0
Bacterial infection	2(0.0%)	0
Bronchitis bacterial	2(0.0%)	0
Chronic sinusitis	2(0.0%)	0
Dengue fever	2(0.0%)	0
Emphysematous pyelonephritis	2(0.0%)	0
Groin abscess	2(0.0%)	0
Prostatic abscess	2(0.0%)	0
Pyelocystitis	2(0.0%)	0
Epididymitis	1(0.0%)	4(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	3(0.0%)
Cholecystitis infective	1(0.0%)	2(0.0%)
Diabetic gangrene	1(0.0%)	2(0.0%)
Escherichia urinary tract infection	1(0.0%)	2(0.0%)
Labyrinthitis	1(0.0%)	2(0.0%)
Large intestine infection	1(0.0%)	2(0.0%)
Necrotising fasciitis	1(0.0%)	2(0.0%)
Abdominal wall abscess	1(0.0%)	1(0.0%)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Endocarditis	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Gastroenteritis norovirus	1(0.0%)	1(0.0%)
Gastroenteritis salmonella	1(0.0%)	1(0.0%)
Infected bite	1(0.0%)	1(0.0%)
Mastoiditis	1(0.0%)	1(0.0%)
Paronychia	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Pneumonia influenzal	1(0.0%)	1(0.0%)
Tuberculosis	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Abscess neck	1(0.0%)	0
Acute sinusitis	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Bacterial sepsis	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Endophthalmitis	1(0.0%)	0
Enteritis infectious	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Escherichia bacteraemia	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Gastroenteritis rotavirus	1(0.0%)	0
Genitourinary tract infection	1(0.0%)	0
HIV infection	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Infectious pleural effusion	1(0.0%)	0
Infective myositis	1(0.0%)	0
Infective spondylitis	1(0.0%)	0
Infective tenosynovitis	1(0.0%)	0
Intestinal sepsis	1(0.0%)	0
Kidney infection	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Lymphadenitis bacterial	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Meningitis	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oral infection	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pharyngitis	1(0.0%)	0
Pharyngitis streptococcal	1(0.0%)	0
Pilonidal cyst	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Sialoadenitis	1(0.0%)	0
Sinusitis	1(0.0%)	0
Spinal cord abscess	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Urinary tract infection fungal	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Wound infection bacterial	1(0.0%)	0
Infective exacerbation of bronchiectasis	0	5(0.1%)
Atypical pneumonia	0	4(0.1%)
Skin infection	0	4(0.1%)
Acute hepatitis B	0	3(0.0%)
Abscess	0	2(0.0%)
Periodontitis	0	2(0.0%)
Post procedural infection	0	2(0.0%)
Vestibular neuronitis	0	2(0.0%)
Abdominal sepsis	0	1(0.0%)
Abscess soft tissue	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Anorectal cellulitis	0	1(0.0%)
Arteriosclerotic gangrene	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Catheter site infection	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Cystitis bacterial	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Device related infection	0	1(0.0%)
Ear infection	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Escherichia sepsis	0	1(0.0%)
Eye infection	0	1(0.0%)
Furuncle	0	1(0.0%)
Gastritis viral	0	1(0.0%)
Gastrointestinal viral infection	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
Hepatitis B	0	1(0.0%)
Hepatitis viral	0	1(0.0%)
Herpes zoster meningoencephalitis	0	1(0.0%)
Infected seroma	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Medical device site joint infection	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Oesophageal candidiasis	0	1(0.0%)
Pelvic inflammatory disease	0	1(0.0%)
Periorbital cellulitis	0	1(0.0%)
Perirectal abscess	0	1(0.0%)
Peritonsillar abscess	0	1(0.0%)
Pneumonia haemophilus	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Pneumonia pneumococcal	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Pyelitis	0	1(0.0%)
Renal abscess	0	1(0.0%)
Respiratory syncytial virus infection	0	1(0.0%)
Salpingitis	0	1(0.0%)
Sinobronchitis	0	1(0.0%)
Staphylococcal bacteraemia	0	1(0.0%)
Staphylococcal infection	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Subacute endocarditis	0	1(0.0%)
Tooth abscess	0	1(0.0%)
Tooth infection	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)
Urethritis	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Urinary tract infection bacterial	0	1(0.0%)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	343(5.3%)	323(5.0%)
Hyperkalaemia	65(1.0%)	16(0.2%)
Type 2 diabetes mellitus	47(0.7%)	47(0.7%)
Hyperglycaemia	40(0.6%)	34(0.5%)
Diabetes mellitus inadequate control	39(0.6%)	36(0.6%)
Hypoglycaemia	38(0.6%)	59(0.9%)
Diabetes mellitus	30(0.5%)	41(0.6%)
Diabetic metabolic decompensation	30(0.5%)	27(0.4%)
Dehydration	15(0.2%)	15(0.2%)
Hyponatraemia	14(0.2%)	8(0.1%)
Diabetic ketoacidosis	10(0.2%)	15(0.2%)
Fluid overload	7(0.1%)	9(0.1%)
Hypovolaemia	5(0.1%)	2(0.0%)
Hypercalcaemia	5(0.1%)	0
Hyperglycaemic hyperosmolar nonketotic syndrome	4(0.1%)	7(0.1%)
Obesity	4(0.1%)	3(0.0%)
Hypokalaemia	3(0.0%)	11(0.2%)
Gout	3(0.0%)	9(0.1%)
Metabolic acidosis	3(0.0%)	4(0.1%)
Diabetic complication	2(0.0%)	2(0.0%)
Fluid retention	2(0.0%)	2(0.0%)
Hypomagnesaemia	2(0.0%)	1(0.0%)
Hypervolaemia	2(0.0%)	0
Hypocalcaemia	1(0.0%)	2(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Electrolyte imbalance	1(0.0%)	0
Hypoglycaemia unawareness	1(0.0%)	0
Malnutrition	1(0.0%)	0
Metabolic syndrome	1(0.0%)	0
Cachexia	0	2(0.0%)
Decreased appetite	0	2(0.0%)
Hypoproteinaemia	0	2(0.0%)
Metabolic disorder	0	2(0.0%)
Hyperosmolar state	0	1(0.0%)
Mineral metabolism disorder	0	1(0.0%)
Periarthritis calcarea	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	246(3.8%)	256(3.9%)
Prostate cancer	23(0.4%)	29(0.4%)
Colon cancer	18(0.3%)	13(0.2%)
Lung neoplasm malignant	16(0.2%)	12(0.2%)
Bladder cancer	13(0.2%)	9(0.1%)
Pancreatic carcinoma	7(0.1%)	7(0.1%)
Hepatocellular carcinoma	6(0.1%)	5(0.1%)
Breast cancer	5(0.1%)	9(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Renal neoplasm	5(0.1%)	5(0.1%)
Hepatic cancer	5(0.1%)	4(0.1%)
Plasma cell myeloma	5(0.1%)	2(0.0%)
Renal cell carcinoma	5(0.1%)	1(0.0%)
Bladder cancer recurrent	5(0.1%)	0
Colon adenoma	5(0.1%)	0
Basal cell carcinoma	4(0.1%)	5(0.1%)
Lung adenocarcinoma	4(0.1%)	5(0.1%)
Bladder transitional cell carcinoma	4(0.1%)	4(0.1%)
Clear cell renal cell carcinoma	4(0.1%)	1(0.0%)
Oesophageal adenocarcinoma	4(0.1%)	0
Adenocarcinoma of colon	3(0.0%)	6(0.1%)
Metastases to liver	3(0.0%)	5(0.1%)
Bladder neoplasm	3(0.0%)	4(0.1%)
Metastases to lymph nodes	3(0.0%)	4(0.1%)
Pancreatic carcinoma metastatic	3(0.0%)	3(0.0%)
Adenocarcinoma	3(0.0%)	2(0.0%)
Metastases to lung	3(0.0%)	2(0.0%)
Transitional cell carcinoma	3(0.0%)	2(0.0%)
Metastases to central nervous system	3(0.0%)	1(0.0%)
Squamous cell carcinoma of skin	3(0.0%)	1(0.0%)
Malignant melanoma	2(0.0%)	5(0.1%)
Oesophageal carcinoma	2(0.0%)	5(0.1%)
Renal cancer	2(0.0%)	5(0.1%)
Gastric cancer	2(0.0%)	4(0.1%)
Small cell lung cancer	2(0.0%)	4(0.1%)
Colorectal cancer	2(0.0%)	3(0.0%)
Cholangiocarcinoma	2(0.0%)	2(0.0%)
Metastases to bone	2(0.0%)	2(0.0%)
Pancreatic neoplasm	2(0.0%)	2(0.0%)
Rectal adenocarcinoma	2(0.0%)	2(0.0%)
Squamous cell carcinoma of lung	2(0.0%)	2(0.0%)
Gastrointestinal carcinoma	2(0.0%)	1(0.0%)
Lipoma	2(0.0%)	1(0.0%)
Lung cancer metastatic	2(0.0%)	1(0.0%)
Neoplasm	2(0.0%)	1(0.0%)
Prostate cancer metastatic	2(0.0%)	1(0.0%)
Prostate cancer recurrent	2(0.0%)	1(0.0%)
Squamous cell carcinoma	2(0.0%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.0%)	1(0.0%)
Breast cancer metastatic	2(0.0%)	0
Endometrial adenocarcinoma	2(0.0%)	0
Metastases to spine	2(0.0%)	0
Metastatic malignant melanoma	2(0.0%)	0
Squamous cell carcinoma of the tongue	2(0.0%)	0
Lung neoplasm	1(0.0%)	6(0.1%)
Adenocarcinoma gastric	1(0.0%)	3(0.0%)
Acute myeloid leukaemia	1(0.0%)	2(0.0%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.0%)
Endometrial cancer	1(0.0%)	2(0.0%)
Papillary renal cell carcinoma	1(0.0%)	2(0.0%)
Thyroid cancer	1(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
B-cell lymphoma	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma recurrent	1(0.0%)	1(0.0%)
Breast neoplasm	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Chronic lymphocytic leukaemia	1(0.0%)	1(0.0%)
Epithelioid mesothelioma	1(0.0%)	1(0.0%)
Hypergammaglobulinaemia benign monoclonal	1(0.0%)	1(0.0%)
Laryngeal squamous cell carcinoma	1(0.0%)	1(0.0%)
Lymphoma	1(0.0%)	1(0.0%)
Myelodysplastic syndrome	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Retroperitoneal neoplasm	1(0.0%)	1(0.0%)
Sarcoma	1(0.0%)	1(0.0%)
Tonsil cancer	1(0.0%)	1(0.0%)
Adenoma benign	1(0.0%)	0
Angiomyofibroblastoma	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Cancer pain	1(0.0%)	0
Choroid neoplasm	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Enchondromatosis	1(0.0%)	0
Female reproductive neoplasm	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal stromal tumour	1(0.0%)	0
Haemangioma	1(0.0%)	0
Haemangioma of spleen	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Hypopharyngeal cancer	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Prostatic adenoma	1(0.0%)	0
Rectal cancer metastatic	1(0.0%)	0
Rectal neoplasm	1(0.0%)	0
Respiratory papilloma	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Skin cancer	1(0.0%)	0
Skin papilloma	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Thyroid adenoma	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour invasion	1(0.0%)	0
Tumour rupture	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Tumour ulceration	1(0.0%)	0
Uterine cancer	1(0.0%)	0
Uterine leiomyoma	1(0.0%)	0
Brain neoplasm	0	3(0.0%)
Adenocarcinoma pancreas	0	2(0.0%)
Adrenal adenoma	0	2(0.0%)
Benign pancreatic neoplasm	0	2(0.0%)
Colorectal adenocarcinoma	0	2(0.0%)
Malignant neoplasm of unknown primary site	0	2(0.0%)
Neoplasm prostate	0	2(0.0%)
Papillary thyroid cancer	0	2(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
Adrenal neoplasm	0	1(0.0%)
Anal cancer	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign anorectal neoplasm	0	1(0.0%)
Benign gastrointestinal neoplasm	0	1(0.0%)
Benign neoplasm of bladder	0	1(0.0%)
Benign neoplasm of prostate	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Bowen's disease	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Colon neoplasm	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Ear neoplasm malignant	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Haemangioblastoma	0	1(0.0%)
Hepatic cancer metastatic	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Metastasis	0	1(0.0%)
Monoclonal gammopathy	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neoplasm malignant	0	1(0.0%)
Neoplasm skin	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oesophageal neoplasm	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Ovarian neoplasm	0	1(0.0%)
Papillary cystadenoma lymphomatosum	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Papilloma	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Salivary gland adenoma	0	1(0.0%)
Salivary gland neoplasm	0	1(0.0%)
Seminoma	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Testis cancer	0	1(0.0%)
Thymoma	0	1(0.0%)
Triple negative breast cancer	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Renal And Urinary Disorders	236(3.6%)	270(4.2%)
Acute kidney injury	94(1.4%)	97(1.5%)
Diabetic nephropathy	28(0.4%)	41(0.6%)
Nephrolithiasis	18(0.3%)	9(0.1%)
Chronic kidney disease	14(0.2%)	28(0.4%)
Renal failure	11(0.2%)	9(0.1%)
Urinary retention	11(0.2%)	8(0.1%)
Renal impairment	10(0.2%)	12(0.2%)
Haematuria	8(0.1%)	10(0.2%)
Ureterolithiasis	7(0.1%)	8(0.1%)
End stage renal disease	5(0.1%)	6(0.1%)
Urinary tract obstruction	5(0.1%)	3(0.0%)
Hydronephrosis	4(0.1%)	5(0.1%)
Renal colic	4(0.1%)	3(0.0%)
Urinary incontinence	4(0.1%)	0
Nephrotic syndrome	3(0.0%)	11(0.2%)
Nephropathy	3(0.0%)	4(0.1%)
Calculus bladder	3(0.0%)	3(0.0%)
Urethral stenosis	3(0.0%)	2(0.0%)
Calculus urinary	2(0.0%)	4(0.1%)
Bladder outlet obstruction	2(0.0%)	1(0.0%)
Dysuria	1(0.0%)	2(0.0%)
Tubulointerstitial nephritis	1(0.0%)	2(0.0%)
Renal artery stenosis	1(0.0%)	1(0.0%)
Renal cyst	1(0.0%)	1(0.0%)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Albuminuria	1(0.0%)	0
Bladder cyst	1(0.0%)	0
Bladder neck sclerosis	1(0.0%)	0
Chromaturia	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0
Nocturia	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Subacute kidney injury	1(0.0%)	0
Ureteric obstruction	1(0.0%)	0
Urinary hesitation	1(0.0%)	0
Vesicoureteric reflux	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Proteinuria	0	4(0.1%)
Azotaemia	0	2(0.0%)
Intercapillary glomerulosclerosis	0	2(0.0%)
Renal haemorrhage	0	2(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Glomerulonephritis membranous	0	1(0.0%)
Hypertensive nephropathy	0	1(0.0%)
Lower urinary tract symptoms	0	1(0.0%)
Nephrosclerosis	0	1(0.0%)
Perinephritis	0	1(0.0%)
Renal mass	0	1(0.0%)
Stress urinary incontinence	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Urinary tract disorder	0	1(0.0%)
Gastrointestinal Disorders	236(3.6%)	214(3.3%)
Gastrointestinal haemorrhage	20(0.3%)	16(0.2%)
Large intestine polyp	19(0.3%)	18(0.3%)
Pancreatitis acute	19(0.3%)	12(0.2%)
Diarrhoea	14(0.2%)	10(0.2%)
Abdominal pain	11(0.2%)	11(0.2%)
Rectal haemorrhage	9(0.1%)	4(0.1%)
Vomiting	8(0.1%)	5(0.1%)
Lower gastrointestinal haemorrhage	8(0.1%)	1(0.0%)
Upper gastrointestinal haemorrhage	6(0.1%)	11(0.2%)
Abdominal pain upper	6(0.1%)	8(0.1%)
Duodenal ulcer	6(0.1%)	4(0.1%)
Pancreatitis	6(0.1%)	4(0.1%)
Haemorrhoids	6(0.1%)	1(0.0%)
Constipation	5(0.1%)	4(0.1%)
Intestinal obstruction	4(0.1%)	9(0.1%)
Gastritis	4(0.1%)	5(0.1%)
Nausea	4(0.1%)	2(0.0%)
Colitis	4(0.1%)	0
Inguinal hernia	3(0.0%)	13(0.2%)
Small intestinal obstruction	3(0.0%)	6(0.1%)
Gastrooesophageal reflux disease	3(0.0%)	4(0.1%)
Pancreatitis chronic	3(0.0%)	4(0.1%)
Umbilical hernia	3(0.0%)	4(0.1%)
Gastric ulcer haemorrhage	3(0.0%)	2(0.0%)
Dyspepsia	3(0.0%)	1(0.0%)
Gastritis haemorrhagic	3(0.0%)	1(0.0%)
Gastric haemorrhage	3(0.0%)	0
Gastroduodenal ulcer	3(0.0%)	0
Duodenal ulcer haemorrhage	2(0.0%)	4(0.1%)
Chronic gastritis	2(0.0%)	3(0.0%)
Colitis ischaemic	2(0.0%)	3(0.0%)
Gastritis erosive	2(0.0%)	2(0.0%)
Haematemesis	2(0.0%)	2(0.0%)
Haematochezia	2(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Melaena	2(0.0%)	2(0.0%)
Gastric ulcer	2(0.0%)	1(0.0%)
Ileus	2(0.0%)	1(0.0%)
Incarcerated umbilical hernia	2(0.0%)	1(0.0%)
Mechanical ileus	2(0.0%)	1(0.0%)
Varices oesophageal	2(0.0%)	1(0.0%)
Diverticulum intestinal haemorrhagic	2(0.0%)	0
Functional gastrointestinal disorder	2(0.0%)	0
Haemorrhagic erosive gastritis	2(0.0%)	0
Haemorrhoidal haemorrhage	2(0.0%)	0
Oedematous pancreatitis	2(0.0%)	0
Peptic ulcer	2(0.0%)	0
Small intestinal haemorrhage	2(0.0%)	0
Ascites	1(0.0%)	5(0.1%)
Abdominal hernia	1(0.0%)	2(0.0%)
Gastric polyps	1(0.0%)	2(0.0%)
Anal fistula	1(0.0%)	1(0.0%)
Dental caries	1(0.0%)	1(0.0%)
Diverticulum intestinal	1(0.0%)	1(0.0%)
Food poisoning	1(0.0%)	1(0.0%)
Gastric mucosal lesion	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Intestinal ischaemia	1(0.0%)	1(0.0%)
Oesophageal varices haemorrhage	1(0.0%)	1(0.0%)
Oesophagitis	1(0.0%)	1(0.0%)
Pancreatic cyst	1(0.0%)	1(0.0%)
Pancreatic duct stenosis	1(0.0%)	1(0.0%)
Subileus	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Abdominal symptom	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0
Dental cyst	1(0.0%)	0
Diarrhoea haemorrhagic	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenal polyp	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Enteritis	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Gastrointestinal disorder	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal oedema	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Intra-abdominal fluid collection	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oesophageal haemorrhage	1(0.0%)	0
Oesophageal obstruction	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Oesophageal ulcer haemorrhage	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Parotid gland enlargement	1(0.0%)	0
Proctitis	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Volvulus	1(0.0%)	0
Impaired gastric emptying	0	3(0.0%)
Abdominal pain lower	0	2(0.0%)
Abdominal wall haematoma	0	2(0.0%)
Anal haemorrhage	0	2(0.0%)
Diverticulum	0	2(0.0%)
Duodenal ulcer perforation	0	2(0.0%)
Peptic ulcer haemorrhage	0	2(0.0%)
Rectal polyp	0	2(0.0%)
Abdominal adhesions	0	1(0.0%)
Abdominal mass	0	1(0.0%)
Abdominal strangulated hernia	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Barrett's oesophagus	0	1(0.0%)
Change of bowel habit	0	1(0.0%)
Colitis ulcerative	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Faecaloma	0	1(0.0%)
Gastric dysplasia	0	1(0.0%)
Gastric varices haemorrhage	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal motility disorder	0	1(0.0%)
Gastrointestinal pain	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Internal hernia	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Oesophageal polyp	0	1(0.0%)
Omental infarction	0	1(0.0%)
Pancreatic mass	0	1(0.0%)
Pancreatitis relapsing	0	1(0.0%)
Rectal discharge	0	1(0.0%)
Reflux gastritis	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland calculus	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Small intestinal perforation	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Injury, Poisoning And Procedural Complications	202(3.1%)	179(2.8%)
Femur fracture	14(0.2%)	17(0.3%)
Ankle fracture	13(0.2%)	11(0.2%)
Hip fracture	11(0.2%)	5(0.1%)
Femoral neck fracture	10(0.2%)	3(0.0%)
Rib fracture	9(0.1%)	8(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Subdural haematoma	7(0.1%)	10(0.2%)
Tibia fracture	7(0.1%)	3(0.0%)
Fall	6(0.1%)	11(0.2%)
Limb injury	6(0.1%)	4(0.1%)
Contusion	6(0.1%)	2(0.0%)
Radius fracture	5(0.1%)	6(0.1%)
Meniscus injury	5(0.1%)	4(0.1%)
Humerus fracture	4(0.1%)	11(0.2%)
Craniocerebral injury	4(0.1%)	3(0.0%)
Foot fracture	4(0.1%)	3(0.0%)
Road traffic accident	4(0.1%)	3(0.0%)
Lower limb fracture	4(0.1%)	1(0.0%)
Clavicle fracture	4(0.1%)	0
Joint injury	4(0.1%)	0
Head injury	3(0.0%)	4(0.1%)
Subdural haemorrhage	3(0.0%)	4(0.1%)
Toxicity to various agents	3(0.0%)	3(0.0%)
Accidental overdose	3(0.0%)	2(0.0%)
Tendon rupture	3(0.0%)	2(0.0%)
Chest injury	3(0.0%)	0
Lumbar vertebral fracture	2(0.0%)	3(0.0%)
Post procedural haemorrhage	2(0.0%)	3(0.0%)
Thermal burn	2(0.0%)	3(0.0%)
Traumatic fracture	2(0.0%)	3(0.0%)
Fibula fracture	2(0.0%)	2(0.0%)
Incisional hernia	2(0.0%)	2(0.0%)
Spinal compression fracture	2(0.0%)	2(0.0%)
Ulna fracture	2(0.0%)	2(0.0%)
Accident	2(0.0%)	1(0.0%)
Facial bones fracture	2(0.0%)	1(0.0%)
Injury	2(0.0%)	1(0.0%)
Multiple fractures	2(0.0%)	1(0.0%)
Skin laceration	2(0.0%)	1(0.0%)
Upper limb fracture	2(0.0%)	1(0.0%)
Cervical vertebral fracture	2(0.0%)	0
Ocular procedural complication	2(0.0%)	0
Patella fracture	2(0.0%)	0
Postoperative wound complication	2(0.0%)	0
Radiation proctitis	2(0.0%)	0
Scapula fracture	2(0.0%)	0
Vascular injury	2(0.0%)	0
Spinal fracture	1(0.0%)	3(0.0%)
Brain contusion	1(0.0%)	2(0.0%)
Joint dislocation	1(0.0%)	2(0.0%)
Pelvic fracture	1(0.0%)	2(0.0%)
Acetabulum fracture	1(0.0%)	1(0.0%)
Concussion	1(0.0%)	1(0.0%)
Spinal cord injury cervical	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Tendon injury	1(0.0%)	1(0.0%)
Thoracic vertebral fracture	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Abdominal wound dehiscence	1(0.0%)	0
Animal bite	1(0.0%)	0
Back injury	1(0.0%)	0
Bone contusion	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Cartilage injury	1(0.0%)	0
Cerebral hyperperfusion syndrome	1(0.0%)	0
Foreign body aspiration	1(0.0%)	0
Gun shot wound	1(0.0%)	0
Incision site haematoma	1(0.0%)	0
Inflammation of wound	1(0.0%)	0
Injury corneal	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Intervertebral disc injury	1(0.0%)	0
Ligament injury	1(0.0%)	0
Ligament rupture	1(0.0%)	0
Muscle strain	1(0.0%)	0
Poisoning	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Skin abrasion	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Soft tissue injury	1(0.0%)	0
Splenic injury	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Wound contamination	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Wrist fracture	1(0.0%)	0
Overdose	0	3(0.0%)
Hand fracture	0	2(0.0%)
Heat illness	0	2(0.0%)
Skull fracture	0	2(0.0%)
Alcohol poisoning	0	1(0.0%)
Anaemia postoperative	0	1(0.0%)
Arteriovenous fistula site complication	0	1(0.0%)
Burns second degree	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Dislocation of vertebra	0	1(0.0%)
Eye contusion	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Heat stroke	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Multiple injuries	0	1(0.0%)
Muscle rupture	0	1(0.0%)
Periprosthetic fracture	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural haematoma	0	1(0.0%)
Post procedural inflammation	0	1(0.0%)
Procedural complication	0	1(0.0%)
Procedural haemorrhage	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Procedural intestinal perforation	0	1(0.0%)
Reproductive tract procedural complication	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Skin injury	0	1(0.0%)
Skin wound	0	1(0.0%)
Stomal hernia	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Traumatic ulcer	0	1(0.0%)
Vascular anastomosis aneurysm	0	1(0.0%)
Vascular pseudoaneurysm	0	1(0.0%)
Nervous System Disorders	173(2.7%)	185(2.9%)
Syncope	26(0.4%)	38(0.6%)
Diabetic neuropathy	17(0.3%)	10(0.2%)
Dizziness	13(0.2%)	18(0.3%)
Subarachnoid haemorrhage	7(0.1%)	6(0.1%)
Presyncope	7(0.1%)	4(0.1%)
Seizure	6(0.1%)	4(0.1%)
Facial paralysis	6(0.1%)	3(0.0%)
Loss of consciousness	5(0.1%)	3(0.0%)
Cerebrovascular disorder	5(0.1%)	2(0.0%)
Carotid artery stenosis	4(0.1%)	6(0.1%)
Headache	4(0.1%)	3(0.0%)
Transient ischaemic attack	3(0.0%)	3(0.0%)
Sciatica	3(0.0%)	2(0.0%)
Balance disorder	3(0.0%)	1(0.0%)
Cerebral haemorrhage	3(0.0%)	1(0.0%)
Cerebral ischaemia	3(0.0%)	1(0.0%)
Myelopathy	3(0.0%)	1(0.0%)
Dysarthria	3(0.0%)	0
Normal pressure hydrocephalus	3(0.0%)	0
Hemiparesis	2(0.0%)	4(0.1%)
Epilepsy	2(0.0%)	3(0.0%)
Lacunar infarction	2(0.0%)	3(0.0%)
Cerebral infarction	2(0.0%)	2(0.0%)
Radiculopathy	2(0.0%)	2(0.0%)
IIIrd nerve paralysis	2(0.0%)	1(0.0%)
Ischaemic stroke	2(0.0%)	1(0.0%)
Polyneuropathy	2(0.0%)	1(0.0%)
Vascular encephalopathy	2(0.0%)	1(0.0%)
Hepatic encephalopathy	2(0.0%)	0
Metabolic encephalopathy	2(0.0%)	0
Vascular headache	2(0.0%)	0
Cervicobrachial syndrome	1(0.0%)	3(0.0%)
Neuralgia	1(0.0%)	3(0.0%)
Aphasia	1(0.0%)	2(0.0%)
Lumbar radiculopathy	1(0.0%)	2(0.0%)
Altered state of consciousness	1(0.0%)	1(0.0%)
Brain oedema	1(0.0%)	1(0.0%)
Cognitive disorder	1(0.0%)	1(0.0%)
Dementia Alzheimer's type	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Dizziness postural	1(0.0%)	1(0.0%)
Generalised tonic-clonic seizure	1(0.0%)	1(0.0%)
Hypoglycaemic unconsciousness	1(0.0%)	1(0.0%)
Lethargy	1(0.0%)	1(0.0%)
Mononeuropathy	1(0.0%)	1(0.0%)
Sensory disturbance	1(0.0%)	1(0.0%)
Spinal cord compression	1(0.0%)	1(0.0%)
Amnesia	1(0.0%)	0
Amputation stump pain	1(0.0%)	0
Angiopathic neuropathy	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Cerebrospinal fluid leakage	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Drop attacks	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
Memory impairment	1(0.0%)	0
Moyamoya disease	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Partial seizures	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Tension headache	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Ulnar neuritis	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Vertebrobasilar insufficiency	1(0.0%)	0
Facial paresis	0	5(0.1%)
Cervical radiculopathy	0	3(0.0%)
Carpal tunnel syndrome	0	2(0.0%)
Cerebrovascular accident	0	2(0.0%)
Coma	0	2(0.0%)
Encephalopathy	0	2(0.0%)
Hypoxic-ischaemic encephalopathy	0	2(0.0%)
Migraine	0	2(0.0%)
Neuropathy peripheral	0	2(0.0%)
Spondylitic myelopathy	0	2(0.0%)
Alcohol induced persisting dementia	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Ataxia	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid arteriosclerosis	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebral microangiopathy	0	1(0.0%)
Cerebral vascular occlusion	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Cerebrovascular insufficiency	0	1(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Dementia	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Facial nerve disorder	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hyperglycaemic unconsciousness	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Intracranial aneurysm	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Lumbosacral radiculopathy	0	1(0.0%)
Meralgia paraesthetica	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Paraesthesia	0	1(0.0%)
Parkinson's disease	0	1(0.0%)
Peripheral nerve paresis	0	1(0.0%)
Post herpetic neuralgia	0	1(0.0%)
Posthaemorrhagic hydrocephalus	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Somnolence	0	1(0.0%)
Vertigo CNS origin	0	1(0.0%)
Surgical And Medical Procedures	160(2.5%)	155(2.4%)
Knee arthroplasty	12(0.2%)	15(0.2%)
Cataract operation	11(0.2%)	15(0.2%)
Toe amputation	8(0.1%)	7(0.1%)
Hip arthroplasty	7(0.1%)	8(0.1%)
Arteriovenous fistula operation	5(0.1%)	3(0.0%)
Diabetes mellitus management	5(0.1%)	0
Vitrectomy	4(0.1%)	6(0.1%)
Leg amputation	4(0.1%)	5(0.1%)
Gastric bypass	4(0.1%)	2(0.0%)
Colectomy	4(0.1%)	1(0.0%)
Hysterectomy	4(0.1%)	1(0.0%)
Cholecystectomy	3(0.0%)	10(0.2%)
Metabolic surgery	3(0.0%)	1(0.0%)
Spinal laminectomy	3(0.0%)	1(0.0%)
Roux loop conversion	3(0.0%)	0
Spinal decompression	3(0.0%)	0
Intervertebral disc operation	2(0.0%)	5(0.1%)
Transurethral prostatectomy	2(0.0%)	5(0.1%)
Polypectomy	2(0.0%)	4(0.1%)
Foot amputation	2(0.0%)	3(0.0%)
Gastrectomy	2(0.0%)	3(0.0%)
Prostatectomy	2(0.0%)	2(0.0%)
Skin neoplasm excision	2(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Aortic valve replacement	2(0.0%)	1(0.0%)
Coronary artery bypass	2(0.0%)	1(0.0%)
Parathyroidectomy	2(0.0%)	1(0.0%)
Peripheral artery angioplasty	2(0.0%)	1(0.0%)
Peripheral artery bypass	2(0.0%)	1(0.0%)
Cardiac pacemaker insertion	2(0.0%)	0
Chemotherapy	2(0.0%)	0
Eye operation	2(0.0%)	0
Intraocular lens implant	2(0.0%)	0
Removal of internal fixation	2(0.0%)	0
Renal stone removal	2(0.0%)	0
Skin graft	2(0.0%)	0
Spinal operation	1(0.0%)	2(0.0%)
Transurethral bladder resection	1(0.0%)	2(0.0%)
Aortic aneurysm repair	1(0.0%)	1(0.0%)
Dialysis device insertion	1(0.0%)	1(0.0%)
Haemodialysis	1(0.0%)	1(0.0%)
Implantable defibrillator insertion	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Thyroidectomy	1(0.0%)	1(0.0%)
Aneurysm repair	1(0.0%)	0
Atrial appendage closure	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Biliary catheter removal	1(0.0%)	0
Bladder calculus removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Brachytherapy	1(0.0%)	0
Breast conserving surgery	1(0.0%)	0
Cardiac ablation	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Circumcision	1(0.0%)	0
Coronary angioplasty	1(0.0%)	0
Drug therapy	1(0.0%)	0
Eyelid operation	1(0.0%)	0
Finger amputation	1(0.0%)	0
Foot operation	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Lithotripsy	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nail operation	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Neurolysis	1(0.0%)	0
Ocular stem cell transplant	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Pancreatic stent placement	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Parotidectomy	1(0.0%)	0
Percutaneous coronary intervention	1(0.0%)	0
Peripheral nerve decompression	1(0.0%)	0
Proctocolectomy	1(0.0%)	0
Radical hysterectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0
Retinal operation	1(0.0%)	0
Scar excision	1(0.0%)	0
Shoulder arthroplasty	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Tenotomy	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Vascular stent insertion	1(0.0%)	0
Wound treatment	1(0.0%)	0
Abscess drainage	0	3(0.0%)
Insertion of ambulatory peritoneal catheter	0	3(0.0%)
Umbilical hernia repair	0	3(0.0%)
Hydrocele operation	0	2(0.0%)
Inguinal hernia repair	0	2(0.0%)
Large intestinal polypectomy	0	2(0.0%)
Amputation	0	1(0.0%)
Aortic surgery	0	1(0.0%)
Appendicectomy	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder neck resection	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Bone operation	0	1(0.0%)
Caecum operation	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cardiac rehabilitation therapy	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Colon operation	0	1(0.0%)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Coronary revascularisation	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Incisional hernia repair	0	1(0.0%)
Intensive care	0	1(0.0%)
Knee operation	0	1(0.0%)
Limb operation	0	1(0.0%)
Lipoma excision	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Meniscus operation	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Neurosurgery	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Preoperative care	0	1(0.0%)
Pterygium operation	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Radioactive iodine therapy	0	1(0.0%)
Rectocele repair	0	1(0.0%)
Removal of foreign body from larynx	0	1(0.0%)
Renal cyst excision	0	1(0.0%)
Renal disorder prophylaxis	0	1(0.0%)
Retinopexy	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Tooth extraction	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Uterine polypectomy	0	1(0.0%)
Varicose vein operation	0	1(0.0%)
Vascular graft	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	153(2.4%)	177(2.7%)
Chronic obstructive pulmonary disease	36(0.6%)	28(0.4%)
Acute respiratory failure	18(0.3%)	24(0.4%)
Dyspnoea	17(0.3%)	16(0.2%)
Pulmonary embolism	14(0.2%)	15(0.2%)
Respiratory failure	11(0.2%)	16(0.2%)
Pleural effusion	9(0.1%)	9(0.1%)
Sleep apnoea syndrome	7(0.1%)	6(0.1%)
Pulmonary mass	6(0.1%)	0
Asthma	5(0.1%)	11(0.2%)
Acute pulmonary oedema	4(0.1%)	6(0.1%)
Epistaxis	4(0.1%)	2(0.0%)
Pulmonary oedema	3(0.0%)	9(0.1%)
Interstitial lung disease	3(0.0%)	5(0.1%)
Pneumonia aspiration	3(0.0%)	4(0.1%)
Pneumothorax	3(0.0%)	3(0.0%)
Hypoxia	3(0.0%)	2(0.0%)
Dyspnoea exertional	2(0.0%)	3(0.0%)
Chronic respiratory failure	2(0.0%)	2(0.0%)
Cough	2(0.0%)	2(0.0%)
Laryngeal oedema	2(0.0%)	0
Pulmonary congestion	1(0.0%)	4(0.1%)
Nasal septum deviation	1(0.0%)	1(0.0%)
Obstructive airways disorder	1(0.0%)	1(0.0%)
Respiratory distress	1(0.0%)	1(0.0%)
Alveolar lung disease	1(0.0%)	0
Asphyxia	1(0.0%)	0
Asthmatic crisis	1(0.0%)	0
Dyspnoea at rest	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Laryngeal mass	1(0.0%)	0
Lung disorder	1(0.0%)	0
Pharyngeal mass	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Restrictive pulmonary disease	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Bronchitis chronic	0	3(0.0%)
Aspiration	0	2(0.0%)
Bronchiectasis	0	2(0.0%)
Bronchospasm	0	2(0.0%)
Haemoptysis	0	2(0.0%)
Idiopathic pulmonary fibrosis	0	2(0.0%)
Pneumonitis	0	2(0.0%)
Pulmonary hypertension	0	2(0.0%)
Bronchial hyperreactivity	0	1(0.0%)
Bronchopneumopathy	0	1(0.0%)
Dysphonia	0	1(0.0%)
Emphysema	0	1(0.0%)
Hepatic hydrothorax	0	1(0.0%)
Hiccups	0	1(0.0%)
Hypercapnia	0	1(0.0%)
Laryngeal disorder	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Lung perforation	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)
Respiratory acidosis	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Small airways disease	0	1(0.0%)
Vocal cord polyp	0	1(0.0%)
Wheezing	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	128(2.0%)	145(2.2%)
Osteoarthritis	33(0.5%)	17(0.3%)
Intervertebral disc protrusion	15(0.2%)	22(0.3%)
Back pain	11(0.2%)	8(0.1%)
Lumbar spinal stenosis	7(0.1%)	8(0.1%)
Arthralgia	6(0.1%)	12(0.2%)
Spinal osteoarthritis	5(0.1%)	6(0.1%)
Gouty arthritis	5(0.1%)	4(0.1%)
Spinal stenosis	4(0.1%)	3(0.0%)
Spondylolisthesis	4(0.1%)	1(0.0%)
Arthritis	3(0.0%)	6(0.1%)
Pain in extremity	3(0.0%)	4(0.1%)
Rotator cuff syndrome	3(0.0%)	4(0.1%)
Rhabdomyolysis	3(0.0%)	2(0.0%)
Muscular weakness	2(0.0%)	2(0.0%)
Intervertebral disc disorder	2(0.0%)	1(0.0%)
Myalgia	2(0.0%)	0
Osteitis	2(0.0%)	0
Bursitis	1(0.0%)	5(0.1%)
Foot deformity	1(0.0%)	3(0.0%)
Intervertebral disc degeneration	1(0.0%)	3(0.0%)
Neuropathic arthropathy	1(0.0%)	2(0.0%)
Periarthritis	1(0.0%)	2(0.0%)
Polymyalgia rheumatica	1(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vertebral foraminal stenosis	1(0.0%)	2(0.0%)
Cervical spinal stenosis	1(0.0%)	1(0.0%)
Osteonecrosis	1(0.0%)	1(0.0%)
Synovial cyst	1(0.0%)	1(0.0%)
Connective tissue inflammation	1(0.0%)	0
Dupuytren's contracture	1(0.0%)	0
Facet joint syndrome	1(0.0%)	0
Fasciitis	1(0.0%)	0
Flank pain	1(0.0%)	0
Groin pain	1(0.0%)	0
Haematoma muscle	1(0.0%)	0
Immobilisation syndrome	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Muscle spasms	1(0.0%)	0
Myositis	1(0.0%)	0
Osteoporosis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Spondylitis	1(0.0%)	0
Tendon discomfort	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Tenosynovitis stenosans	1(0.0%)	0
Vertebral lateral recess stenosis	1(0.0%)	0
Neck pain	0	6(0.1%)
Costochondritis	0	4(0.1%)
Spinal pain	0	3(0.0%)
Musculoskeletal chest pain	0	2(0.0%)
Ankylosing spondylitis	0	1(0.0%)
Arthritis reactive	0	1(0.0%)
Arthropathy	0	1(0.0%)
Back disorder	0	1(0.0%)
Chondromalacia	0	1(0.0%)
Diastasis recti abdominis	0	1(0.0%)
Exostosis	0	1(0.0%)
Haemarthrosis	0	1(0.0%)
Limb mass	0	1(0.0%)
Muscle haemorrhage	0	1(0.0%)
Musculoskeletal discomfort	0	1(0.0%)
Musculoskeletal disorder	0	1(0.0%)
Osteoarthropathy	0	1(0.0%)
Osteolysis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Plantar fascial fibromatosis	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Rheumatoid arthritis	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Spinal ligament ossification	0	1(0.0%)
Spondyloarthropathy	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vascular Disorders	119(1.8%)	142(2.2%)
Hypertension	27(0.4%)	45(0.7%)
Hypotension	9(0.1%)	8(0.1%)
Deep vein thrombosis	7(0.1%)	5(0.1%)
Hypertensive crisis	6(0.1%)	13(0.2%)
Aortic stenosis	6(0.1%)	3(0.0%)
Hypertensive urgency	5(0.1%)	5(0.1%)
Aortic aneurysm	5(0.1%)	3(0.0%)
Orthostatic hypotension	5(0.1%)	3(0.0%)
Extremity necrosis	5(0.1%)	2(0.0%)
Hypertensive emergency	4(0.1%)	7(0.1%)
Peripheral ischaemia	3(0.0%)	6(0.1%)
Circulatory collapse	3(0.0%)	2(0.0%)
Peripheral artery occlusion	3(0.0%)	2(0.0%)
Diabetic vascular disorder	3(0.0%)	1(0.0%)
Peripheral arterial occlusive disease	2(0.0%)	12(0.2%)
Peripheral vascular disorder	2(0.0%)	3(0.0%)
Giant cell arteritis	2(0.0%)	2(0.0%)
Peripheral artery stenosis	2(0.0%)	2(0.0%)
Thrombophlebitis	2(0.0%)	2(0.0%)
Thrombosis	2(0.0%)	2(0.0%)
Dry gangrene	2(0.0%)	1(0.0%)
Aortic dissection	2(0.0%)	0
Peripheral embolism	2(0.0%)	0
Haematoma	1(0.0%)	2(0.0%)
Peripheral artery thrombosis	1(0.0%)	2(0.0%)
Hypovolaemic shock	1(0.0%)	1(0.0%)
Peripheral artery aneurysm	1(0.0%)	1(0.0%)
Aortitis	1(0.0%)	0
Arteriovenous fistula	1(0.0%)	0
Intermittent claudication	1(0.0%)	0
Phlebitis	1(0.0%)	0
Post thrombotic syndrome	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Thrombophlebitis superficial	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Varicose vein	1(0.0%)	0
Vasculitis	1(0.0%)	0
Venous occlusion	1(0.0%)	0
Essential hypertension	0	2(0.0%)
Malignant hypertension	0	2(0.0%)
Arterial thrombosis	0	1(0.0%)
Blood pressure fluctuation	0	1(0.0%)
Embolism venous	0	1(0.0%)
Labile hypertension	0	1(0.0%)
Lymphoedema	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Shock	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
Systolic hypertension	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Thromboangiitis obliterans	0	1(0.0%)
Eye Disorders	98(1.5%)	87(1.3%)
Cataract	34(0.5%)	23(0.4%)
Vitreous haemorrhage	22(0.3%)	14(0.2%)
Diabetic retinopathy	14(0.2%)	14(0.2%)
Glaucoma	10(0.2%)	4(0.1%)
Retinal detachment	6(0.1%)	5(0.1%)
Macular fibrosis	4(0.1%)	3(0.0%)
Retinal haemorrhage	3(0.0%)	4(0.1%)
Eye haemorrhage	3(0.0%)	1(0.0%)
Visual impairment	2(0.0%)	1(0.0%)
Macular oedema	1(0.0%)	4(0.1%)
Cataract diabetic	1(0.0%)	2(0.0%)
Ulcerative keratitis	1(0.0%)	2(0.0%)
Lens dislocation	1(0.0%)	1(0.0%)
Retinopathy	1(0.0%)	1(0.0%)
Retinopathy proliferative	1(0.0%)	1(0.0%)
Rhegmatogenous retinal detachment	1(0.0%)	1(0.0%)
Tractional retinal detachment	1(0.0%)	1(0.0%)
Age-related macular degeneration	1(0.0%)	0
Cataract subcapsular	1(0.0%)	0
Diabetic eye disease	1(0.0%)	0
Diabetic retinal oedema	1(0.0%)	0
Diplopia	1(0.0%)	0
Extraocular muscle paresis	1(0.0%)	0
Eye disorder	1(0.0%)	0
Ocular ischaemic syndrome	1(0.0%)	0
Vision blurred	1(0.0%)	0
Macular hole	0	3(0.0%)
Cataract nuclear	0	2(0.0%)
Pterygium	0	2(0.0%)
Retinal artery occlusion	0	2(0.0%)
Blindness	0	1(0.0%)
Dermatochalasis	0	1(0.0%)
Ectropion	0	1(0.0%)
Eyelid cyst	0	1(0.0%)
Open angle glaucoma	0	1(0.0%)
Ophthalmoplegia	0	1(0.0%)
Optic disc haemorrhage	0	1(0.0%)
Optic ischaemic neuropathy	0	1(0.0%)
Papilloedema	0	1(0.0%)
General Disorders And Administration Site Conditions	89(1.4%)	118(1.8%)
Chest pain	31(0.5%)	38(0.6%)
Death	10(0.2%)	10(0.2%)
Pyrexia	10(0.2%)	7(0.1%)
Oedema peripheral	9(0.1%)	16(0.2%)
Oedema	6(0.1%)	3(0.0%)
Asthenia	5(0.1%)	3(0.0%)
General physical health deterioration	3(0.0%)	8(0.1%)
Multiple organ dysfunction syndrome	3(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Malaise	2(0.0%)	3(0.0%)
Peripheral swelling	2(0.0%)	3(0.0%)
Fatigue	2(0.0%)	2(0.0%)
Generalised oedema	1(0.0%)	4(0.1%)
Non-cardiac chest pain	1(0.0%)	4(0.1%)
Gait disturbance	1(0.0%)	2(0.0%)
Polyp	1(0.0%)	1(0.0%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Complication associated with device	1(0.0%)	0
Drug intolerance	1(0.0%)	0
Hanging	1(0.0%)	0
Impaired healing	1(0.0%)	0
Mass	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Swelling face	1(0.0%)	0
Chest discomfort	0	2(0.0%)
Oedema due to renal disease	0	2(0.0%)
Pain	0	2(0.0%)
Adhesion	0	1(0.0%)
Device intolerance	0	1(0.0%)
Haemorrhagic cyst	0	1(0.0%)
Hernia pain	0	1(0.0%)
Hypothermia	0	1(0.0%)
Inflammation	0	1(0.0%)
Soft tissue inflammation	0	1(0.0%)
Sudden death	0	1(0.0%)
Vascular stent stenosis	0	1(0.0%)
Cardiac Disorders	80(1.2%)	106(1.6%)
Coronary artery disease	13(0.2%)	11(0.2%)
Cardiac failure	6(0.1%)	20(0.3%)
Bradycardia	5(0.1%)	5(0.1%)
Arteriosclerosis coronary artery	5(0.1%)	1(0.0%)
Cardiac failure acute	5(0.1%)	1(0.0%)
Angina unstable	4(0.1%)	6(0.1%)
Angina pectoris	4(0.1%)	4(0.1%)
Myocardial ischaemia	3(0.0%)	7(0.1%)
Aortic valve stenosis	3(0.0%)	5(0.1%)
Atrial fibrillation	3(0.0%)	4(0.1%)
Cardiac failure chronic	3(0.0%)	4(0.1%)
Sinus node dysfunction	3(0.0%)	2(0.0%)
Aortic valve disease mixed	3(0.0%)	0
Acute coronary syndrome	2(0.0%)	3(0.0%)
Coronary artery stenosis	2(0.0%)	2(0.0%)
Acute left ventricular failure	2(0.0%)	1(0.0%)
Arrhythmia	2(0.0%)	1(0.0%)
Cardio-respiratory arrest	2(0.0%)	1(0.0%)
Pericarditis	2(0.0%)	0
Ventricular fibrillation	2(0.0%)	0
Cardiac arrest	1(0.0%)	4(0.1%)
Atrial flutter	1(0.0%)	2(0.0%)
Cardiomyopathy	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Palpitations	1(0.0%)	1(0.0%)
Aortic valve calcification	1(0.0%)	0
Atrioventricular block second degree	1(0.0%)	0
Bifascicular block	1(0.0%)	0
Extrasystoles	1(0.0%)	0
Hypertensive heart disease	1(0.0%)	0
Left ventricular dysfunction	1(0.0%)	0
Left ventricular failure	1(0.0%)	0
Mitral valve disease	1(0.0%)	0
Paroxysmal atrioventricular block	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pulseless electrical activity	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular hypokinesia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Cardiac failure congestive	0	9(0.1%)
Acute myocardial infarction	0	2(0.0%)
Atrial thrombosis	0	2(0.0%)
Atrioventricular block complete	0	2(0.0%)
Bundle branch block left	0	2(0.0%)
Cardiogenic shock	0	2(0.0%)
Aortic valve incompetence	0	1(0.0%)
Atrioventricular block	0	1(0.0%)
Cardiac asthma	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac valve disease	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Coronary artery occlusion	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Left ventricular hypertrophy	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Tachycardia	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	73(1.1%)	91(1.4%)
Diabetic foot	36(0.6%)	36(0.6%)
Skin ulcer	21(0.3%)	31(0.5%)
Angioedema	5(0.1%)	2(0.0%)
Pemphigoid	2(0.0%)	2(0.0%)
Rash	2(0.0%)	1(0.0%)
Skin necrosis	2(0.0%)	0
Blister	1(0.0%)	2(0.0%)
Decubitus ulcer	1(0.0%)	2(0.0%)
Dermatitis	1(0.0%)	1(0.0%)
Ingrowing nail	1(0.0%)	1(0.0%)
Neuropathic ulcer	1(0.0%)	1(0.0%)
Angiokeratoma	1(0.0%)	0
Dermatitis herpetiformis	1(0.0%)	0
Diabetic ulcer	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Drug eruption	1(0.0%)	0
Hidradenitis	1(0.0%)	0
Palmoplantar keratoderma	1(0.0%)	0
Skin disorder	1(0.0%)	0
Stasis dermatitis	1(0.0%)	0
Toxic skin eruption	1(0.0%)	0
Dermatitis allergic	0	2(0.0%)
Actinic keratosis	0	1(0.0%)
Dermal cyst	0	1(0.0%)
Dermatitis bullous	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Ecchymosis	0	1(0.0%)
Eczema	0	1(0.0%)
Hyperkeratosis	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Purpura	0	1(0.0%)
Reactive perforating collagenosis	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Hepatobiliary Disorders	65(1.0%)	64(1.0%)
Cholelithiasis	17(0.3%)	8(0.1%)
Cholecystitis acute	11(0.2%)	16(0.2%)
Cholecystitis	11(0.2%)	8(0.1%)
Bile duct stone	7(0.1%)	3(0.0%)
Cholangitis	4(0.1%)	7(0.1%)
Biliary colic	3(0.0%)	2(0.0%)
Cholecystitis chronic	3(0.0%)	1(0.0%)
Hepatic cirrhosis	2(0.0%)	7(0.1%)
Hepatitis acute	2(0.0%)	1(0.0%)
Biliary dyskinesia	2(0.0%)	0
Biliary obstruction	2(0.0%)	0
Hepatic function abnormal	2(0.0%)	0
Cholangitis acute	1(0.0%)	4(0.1%)
Jaundice cholestatic	1(0.0%)	3(0.0%)
Liver disorder	1(0.0%)	1(0.0%)
Chronic hepatitis	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Hepatic lesion	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0
Biliary dilatation	0	1(0.0%)
Biliary fistula	0	1(0.0%)
Cholecystocholangitis	0	1(0.0%)
Cholestasis	0	1(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Drug-induced liver injury	0	1(0.0%)
Gallbladder polyp	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Hepatitis alcoholic	0	1(0.0%)
Jaundice	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Portal hypertension	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Primary biliary cholangitis	0	1(0.0%)
Investigations	57(0.9%)	80(1.2%)
Glomerular filtration rate decreased	9(0.1%)	5(0.1%)
Blood glucose increased	6(0.1%)	6(0.1%)
Colonoscopy	6(0.1%)	4(0.1%)
Blood potassium increased	4(0.1%)	0
Blood creatinine increased	3(0.0%)	7(0.1%)
Weight decreased	3(0.0%)	4(0.1%)
Biopsy kidney	2(0.0%)	3(0.0%)
Angiocardiogram	2(0.0%)	2(0.0%)
Endoscopy	2(0.0%)	0
Blood pressure increased	1(0.0%)	4(0.1%)
Influenza A virus test positive	1(0.0%)	4(0.1%)
Glycosylated haemoglobin increased	1(0.0%)	3(0.0%)
C-reactive protein increased	1(0.0%)	1(0.0%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Electrocardiogram abnormal	1(0.0%)	1(0.0%)
Alanine aminotransferase increased	1(0.0%)	0
Angiogram	1(0.0%)	0
Arteriogram	1(0.0%)	0
Aspartate aminotransferase increased	1(0.0%)	0
Biopsy bladder	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood potassium decreased	1(0.0%)	0
Blood pressure orthostatic decreased	1(0.0%)	0
Cancer staging	1(0.0%)	0
Cardiac function test abnormal	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0
Cardiac stress test abnormal	1(0.0%)	0
Colonoscopy normal	1(0.0%)	0
Computerised tomogram	1(0.0%)	0
Gamma-glutamyltransferase increased	1(0.0%)	0
Haematocrit decreased	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Investigation	1(0.0%)	0
Sleep study	1(0.0%)	0
Blood creatine phosphokinase increased	0	4(0.1%)
Arthroscopy	0	3(0.0%)
Hepatic enzyme increased	0	3(0.0%)
Liver function test increased	0	3(0.0%)
Angiogram cerebral	0	1(0.0%)
Anticoagulation drug level above therapeutic	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Biopsy liver	0	1(0.0%)
Biopsy prostate	0	1(0.0%)
Blood creatine phosphokinase MB increased	0	1(0.0%)
Blood magnesium decreased	0	1(0.0%)
Blood urine present	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Computerised tomogram abdomen	0	1(0.0%)
Endobronchial ultrasound	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Gastrointestinal stoma output increased	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Inflammatory marker increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Protein urine present	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
SARS-CoV-2 test negative	0	1(0.0%)
SARS-CoV-2 test positive	0	1(0.0%)
Troponin T increased	0	1(0.0%)
Troponin increased	0	1(0.0%)
Blood And Lymphatic System Disorders	51(0.8%)	60(0.9%)
Anaemia	32(0.5%)	34(0.5%)
Iron deficiency anaemia	6(0.1%)	7(0.1%)
Blood loss anaemia	4(0.1%)	2(0.0%)
Microcytic anaemia	2(0.0%)	1(0.0%)
Lymphadenopathy	2(0.0%)	0
Lymphadenopathy mediastinal	1(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	1(0.0%)
Coagulopathy	1(0.0%)	0
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Hypocoagulable state	1(0.0%)	0
Immune thrombocytopenia	1(0.0%)	0
Nephrogenic anaemia	0	5(0.1%)
Febrile neutropenia	0	2(0.0%)
Neutropenia	0	2(0.0%)
Thrombocytopenia	0	2(0.0%)
Acquired haemophilia	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Leukocytosis	0	1(0.0%)
Normochromic normocytic anaemia	0	1(0.0%)
Normocytic anaemia	0	1(0.0%)
Reproductive System And Breast Disorders	33(0.5%)	36(0.6%)
Benign prostatic hyperplasia	17(0.3%)	20(0.3%)
Prostatomegaly	2(0.0%)	3(0.0%)
Endometrial hyperplasia	2(0.0%)	0
Prostatism	2(0.0%)	0
Ovarian cyst	1(0.0%)	4(0.1%)
Prostatitis	1(0.0%)	3(0.0%)
Uterine polyp	1(0.0%)	1(0.0%)
Balanoposthitis	1(0.0%)	0
Breast mass	1(0.0%)	0
Breast necrosis	1(0.0%)	0
Metrorrhagia	1(0.0%)	0
Prostatic disorder	1(0.0%)	0
Scrotal dermatitis	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vaginal haemorrhage	1(0.0%)	0
Dysfunctional uterine bleeding	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Erectile dysfunction	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine haemorrhage	0	1(0.0%)
Ear And Labyrinth Disorders	22(0.3%)	26(0.4%)
Vertigo	10(0.2%)	10(0.2%)
Sudden hearing loss	4(0.1%)	6(0.1%)
Vestibular disorder	2(0.0%)	3(0.0%)
Tympanic membrane perforation	2(0.0%)	1(0.0%)
Vertigo positional	2(0.0%)	1(0.0%)
Acute vestibular syndrome	1(0.0%)	0
Deafness neurosensory	1(0.0%)	0
Deafness	0	1(0.0%)
Deafness unilateral	0	1(0.0%)
Ear pain	0	1(0.0%)
Tinnitus	0	1(0.0%)
Vestibular ataxia	0	1(0.0%)
Psychiatric Disorders	22(0.3%)	16(0.2%)
Anxiety	4(0.1%)	0
Depression	3(0.0%)	5(0.1%)
Mental status changes	3(0.0%)	5(0.1%)
Confusional state	3(0.0%)	2(0.0%)
Major depression	2(0.0%)	1(0.0%)
Bipolar disorder	2(0.0%)	0
Completed suicide	2(0.0%)	0
Alcohol abuse	1(0.0%)	0
Insomnia	1(0.0%)	0
Mania	1(0.0%)	0
Mental disorder due to a general medical condition	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Delusional disorder, unspecified type	0	1(0.0%)
Drug abuse	0	1(0.0%)
Suicide threat	0	1(0.0%)
Endocrine Disorders	6(0.1%)	7(0.1%)
Goitre	2(0.0%)	2(0.0%)
Hyperparathyroidism	1(0.0%)	0
Hypothyroidism	1(0.0%)	0
Primary hyperaldosteronism	1(0.0%)	0
Toxic nodular goitre	1(0.0%)	0
Thyroid mass	0	2(0.0%)
Hyperthyroidism	0	1(0.0%)
Pituitary-dependent Cushing's syndrome	0	1(0.0%)
Thyroiditis	0	1(0.0%)
Congenital, Familial And Genetic Disorders	6(0.1%)	3(0.0%)
Phimosis	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Adenomatous polyposis coli	1(0.0%)	0
Arnold-Chiari malformation	1(0.0%)	0
Factor VIII deficiency	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Anomaly of middle ear congenital	0	1(0.0%)
Dermoid cyst	0	1(0.0%)
Hypospadias	0	1(0.0%)
Immune System Disorders	3(0.0%)	1(0.0%)
Drug hypersensitivity	2(0.0%)	0
Anaphylactic shock	1(0.0%)	1(0.0%)
Anaphylactic reaction	0	1(0.0%)
Product Issues	1(0.0%)	4(0.1%)
Device malfunction	1(0.0%)	1(0.0%)
Device dislocation	0	2(0.0%)
Device loosening	0	1(0.0%)
Social Circumstances	1(0.0%)	0
Social stay hospitalisation	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Any TEAE	1140(17.5%)	1261(19.4%)
Infections And Infestations	306(4.7%)	348(5.4%)
Pneumonia	60(0.9%)	100(1.5%)
Cellulitis	23(0.4%)	30(0.5%)
Sepsis	21(0.3%)	30(0.5%)
COVID-19	16(0.2%)	18(0.3%)
Urinary tract infection	13(0.2%)	21(0.3%)
Osteomyelitis	11(0.2%)	18(0.3%)
Urosepsis	11(0.2%)	9(0.1%)
Localised infection	11(0.2%)	7(0.1%)
Septic shock	8(0.1%)	9(0.1%)
Erysipelas	8(0.1%)	6(0.1%)
Gastroenteritis	7(0.1%)	11(0.2%)
Influenza	7(0.1%)	8(0.1%)
Bronchitis	7(0.1%)	5(0.1%)
Respiratory tract infection	7(0.1%)	3(0.0%)
COVID-19 pneumonia	6(0.1%)	7(0.1%)
Pyelonephritis	6(0.1%)	4(0.1%)
Abscess limb	6(0.1%)	3(0.0%)
Diabetic foot infection	5(0.1%)	7(0.1%)
Gangrene	4(0.1%)	10(0.2%)
Herpes zoster	4(0.1%)	4(0.1%)
Pulmonary sepsis	4(0.1%)	2(0.0%)
Infected skin ulcer	4(0.1%)	1(0.0%)
Postoperative wound infection	4(0.1%)	1(0.0%)
Appendicitis	3(0.0%)	4(0.1%)
Pyelonephritis acute	3(0.0%)	2(0.0%)
Bacteraemia	3(0.0%)	0
Lower respiratory tract infection	2(0.0%)	6(0.1%)
Intervertebral discitis	2(0.0%)	3(0.0%)
Pulmonary tuberculosis	2(0.0%)	3(0.0%)
Wound infection	2(0.0%)	3(0.0%)
Nasopharyngitis	2(0.0%)	2(0.0%)
Pneumonia bacterial	2(0.0%)	2(0.0%)
Staphylococcal sepsis	2(0.0%)	2(0.0%)
Cystitis	2(0.0%)	1(0.0%)
Meningitis	2(0.0%)	1(0.0%)
Viral infection	2(0.0%)	1(0.0%)
Appendicitis perforated	2(0.0%)	0
Emphysematous pyelonephritis	2(0.0%)	0
Groin abscess	2(0.0%)	0
Subcutaneous abscess	2(0.0%)	0
Anal abscess	1(0.0%)	4(0.1%)
Skin infection	1(0.0%)	4(0.1%)
Upper respiratory tract infection	1(0.0%)	4(0.1%)
Diverticulitis	1(0.0%)	3(0.0%)
Liver abscess	1(0.0%)	3(0.0%)
Soft tissue infection	1(0.0%)	3(0.0%)
Endocarditis	1(0.0%)	2(0.0%)
Arthritis bacterial	1(0.0%)	1(0.0%)
Bacterial sepsis	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Epididymitis	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	1(0.0%)
Necrotising fasciitis	1(0.0%)	1(0.0%)
Osteomyelitis chronic	1(0.0%)	1(0.0%)
Otitis media	1(0.0%)	1(0.0%)
Paronychia	1(0.0%)	1(0.0%)
Peritonitis	1(0.0%)	1(0.0%)
Pharyngitis	1(0.0%)	1(0.0%)
Pneumonia viral	1(0.0%)	1(0.0%)
Staphylococcal bacteraemia	1(0.0%)	1(0.0%)
Abdominal abscess	1(0.0%)	0
Abdominal infection	1(0.0%)	0
Acute sinusitis	1(0.0%)	0
Arthritis infective	1(0.0%)	0
Bacterial infection	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Cholecystitis infective	1(0.0%)	0
Corneal abscess	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Diverticulitis intestinal haemorrhagic	1(0.0%)	0
Encephalitis viral	1(0.0%)	0
Enterocolitis bacterial	1(0.0%)	0
Eye infection	1(0.0%)	0
Genital candidiasis	1(0.0%)	0
HIV infection	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infected bite	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Kidney infection	1(0.0%)	0
Large intestine infection	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Necrotising soft tissue infection	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Onychomycosis	1(0.0%)	0
Oral infection	1(0.0%)	0
Orchitis	1(0.0%)	0
Osteomyelitis acute	1(0.0%)	0
Otitis externa bacterial	1(0.0%)	0
Parotitis	1(0.0%)	0
Periodontitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pneumocystis jirovecii pneumonia	1(0.0%)	0
Pneumonia influenzal	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Pseudomonas infection	1(0.0%)	0
Pulmonary mycosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Splenic abscess	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Viral upper respiratory tract infection	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Wound infection bacterial	1(0.0%)	0
Atypical pneumonia	0	4(0.1%)
Infection	0	4(0.1%)
Diabetic gangrene	0	2(0.0%)
Enterococcal bacteraemia	0	2(0.0%)
Mastoiditis	0	2(0.0%)
Medical device site joint infection	0	2(0.0%)
Oral candidiasis	0	2(0.0%)
Otitis externa	0	2(0.0%)
Post procedural infection	0	2(0.0%)
Tooth infection	0	2(0.0%)
Urinary tract infection bacterial	0	2(0.0%)
Acute hepatitis B	0	1(0.0%)
Anorectal infection bacterial	0	1(0.0%)
Arteriosclerotic gangrene	0	1(0.0%)
Bacterial rhinitis	0	1(0.0%)
Bacterial tracheitis	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Cellulitis gangrenous	0	1(0.0%)
Cellulitis staphylococcal	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Conjunctivitis	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Ear infection	0	1(0.0%)
Enterococcal infection	0	1(0.0%)
Escherichia sepsis	0	1(0.0%)
Escherichia urinary tract infection	0	1(0.0%)
Gastritis viral	0	1(0.0%)
Gastroenteritis norovirus	0	1(0.0%)
Gastroenteritis salmonella	0	1(0.0%)
Infected seroma	0	1(0.0%)
Infective exacerbation of bronchiectasis	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Medical device site abscess	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Ophthalmic herpes zoster	0	1(0.0%)
Peritonsillitis	0	1(0.0%)
Pharyngitis bacterial	0	1(0.0%)
Pneumonia legionella	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Stenotrophomonas sepsis	0	1(0.0%)
Subacute endocarditis	0	1(0.0%)
Tracheobronchitis viral	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Vascular device infection	0	1(0.0%)
Vascular graft infection	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	179(2.7%)	162(2.5%)
Hyperkalaemia	53(0.8%)	13(0.2%)
Hypoglycaemia	41(0.6%)	48(0.7%)
Hyperglycaemia	13(0.2%)	15(0.2%)
Dehydration	12(0.2%)	9(0.1%)
Diabetes mellitus	11(0.2%)	10(0.2%)
Diabetes mellitus inadequate control	7(0.1%)	14(0.2%)
Hyponatraemia	7(0.1%)	3(0.0%)
Type 2 diabetes mellitus	5(0.1%)	8(0.1%)
Gout	5(0.1%)	7(0.1%)
Diabetic ketoacidosis	5(0.1%)	6(0.1%)
Fluid overload	3(0.0%)	7(0.1%)
Hypertriglyceridaemia	3(0.0%)	3(0.0%)
Metabolic acidosis	3(0.0%)	3(0.0%)
Hypercalcaemia	3(0.0%)	0
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.0%)	5(0.1%)
Vitamin D deficiency	2(0.0%)	5(0.1%)
Hypokalaemia	2(0.0%)	4(0.1%)
Hyperlipidaemia	2(0.0%)	1(0.0%)
Hypovolaemia	2(0.0%)	1(0.0%)
Obesity	2(0.0%)	1(0.0%)
Hypoproteinaemia	1(0.0%)	4(0.1%)
Decreased appetite	1(0.0%)	3(0.0%)
Hypocalcaemia	1(0.0%)	3(0.0%)
Diabetic metabolic decompensation	1(0.0%)	2(0.0%)
Fluid retention	1(0.0%)	1(0.0%)
Hypomagnesaemia	1(0.0%)	1(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Hypercholesterolaemia	1(0.0%)	0
Lactic acidosis	1(0.0%)	0
Cachexia	0	2(0.0%)
Diabetic complication	0	1(0.0%)
Electrolyte imbalance	0	1(0.0%)
Hyperphosphataemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	141(2.2%)	157(2.4%)
Prostate cancer	11(0.2%)	16(0.2%)
Colon cancer	11(0.2%)	8(0.1%)
Lung neoplasm malignant	9(0.1%)	7(0.1%)
Renal neoplasm	6(0.1%)	5(0.1%)
Pancreatic carcinoma	5(0.1%)	7(0.1%)
Bladder cancer	5(0.1%)	5(0.1%)
Hepatic cancer	5(0.1%)	3(0.0%)
Hepatocellular carcinoma	4(0.1%)	3(0.0%)
Adenocarcinoma of colon	3(0.0%)	4(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Bladder transitional cell carcinoma	3(0.0%)	3(0.0%)
Metastases to liver	3(0.0%)	3(0.0%)
Pancreatic carcinoma metastatic	3(0.0%)	2(0.0%)
Transitional cell carcinoma	3(0.0%)	2(0.0%)
Pancreatic neoplasm	3(0.0%)	1(0.0%)
Renal cell carcinoma	3(0.0%)	1(0.0%)
Colon adenoma	3(0.0%)	0
Metastases to central nervous system	3(0.0%)	0
Metastases to lymph nodes	3(0.0%)	0
Oesophageal adenocarcinoma	3(0.0%)	0
Breast cancer	2(0.0%)	5(0.1%)
Lung adenocarcinoma	2(0.0%)	4(0.1%)
Oesophageal carcinoma	2(0.0%)	4(0.1%)
Small cell lung cancer	2(0.0%)	3(0.0%)
Metastases to bone	2(0.0%)	2(0.0%)
Plasma cell myeloma	2(0.0%)	2(0.0%)
Endometrial cancer	2(0.0%)	1(0.0%)
Lung cancer metastatic	2(0.0%)	1(0.0%)
Metastases to spine	2(0.0%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.0%)	1(0.0%)
Bladder cancer recurrent	2(0.0%)	0
Metastases to lung	2(0.0%)	0
Prostate cancer recurrent	2(0.0%)	0
Squamous cell carcinoma of lung	2(0.0%)	0
Lung neoplasm	1(0.0%)	4(0.1%)
Malignant melanoma	1(0.0%)	3(0.0%)
Cholangiocarcinoma	1(0.0%)	2(0.0%)
Diffuse large B-cell lymphoma	1(0.0%)	2(0.0%)
Thyroid cancer	1(0.0%)	2(0.0%)
Acute myeloid leukaemia	1(0.0%)	1(0.0%)
Basal cell carcinoma	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Clear cell renal cell carcinoma	1(0.0%)	1(0.0%)
Colorectal cancer	1(0.0%)	1(0.0%)
Epithelioid mesothelioma	1(0.0%)	1(0.0%)
Gastrointestinal carcinoma	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Prostate cancer metastatic	1(0.0%)	1(0.0%)
Rectal adenocarcinoma	1(0.0%)	1(0.0%)
Rectal neoplasm	1(0.0%)	1(0.0%)
Sarcoma	1(0.0%)	1(0.0%)
Adenocarcinoma	1(0.0%)	0
Breast neoplasm	1(0.0%)	0
Chronic lymphocytic leukaemia	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Endometrial adenocarcinoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Meningioma	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Myelodysplastic syndrome	1(0.0%)	0
Neoplasm malignant	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Tonsil cancer	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Brain neoplasm	0	3(0.0%)
Renal cancer	0	3(0.0%)
Adenocarcinoma gastric	0	2(0.0%)
Adenocarcinoma pancreas	0	2(0.0%)
Adrenal adenoma	0	2(0.0%)
B-cell lymphoma	0	2(0.0%)
Colorectal adenocarcinoma	0	2(0.0%)
Malignant neoplasm of unknown primary site	0	2(0.0%)
Papillary renal cell carcinoma	0	2(0.0%)
Pituitary tumour benign	0	2(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Bowen's disease	0	1(0.0%)
Colon neoplasm	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Gastric cancer	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Glioblastoma	0	1(0.0%)
Hepatic cancer metastatic	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Meningioma benign	0	1(0.0%)
Metastasis	0	1(0.0%)
Neuroendocrine carcinoma	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oropharyngeal cancer	0	1(0.0%)
Papilloma	0	1(0.0%)
Penile cancer	0	1(0.0%)
Prostate cancer stage IV	0	1(0.0%)
Retroperitoneal neoplasm	0	1(0.0%)
Seminoma	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Skin cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Squamous cell carcinoma	0	1(0.0%)
Squamous cell carcinoma of skin	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Renal And Urinary Disorders	118(1.8%)	145(2.2%)
Acute kidney injury	52(0.8%)	68(1.0%)
Renal failure	11(0.2%)	9(0.1%)
Renal impairment	8(0.1%)	7(0.1%)
Nephrolithiasis	7(0.1%)	5(0.1%)
Chronic kidney disease	6(0.1%)	16(0.2%)
Urinary retention	5(0.1%)	2(0.0%)
End stage renal disease	4(0.1%)	4(0.1%)
Diabetic nephropathy	3(0.0%)	7(0.1%)
Urinary tract obstruction	3(0.0%)	2(0.0%)
Nephropathy	2(0.0%)	6(0.1%)
Hydronephrosis	2(0.0%)	5(0.1%)
Urethral stenosis	2(0.0%)	0
Nephrotic syndrome	1(0.0%)	4(0.1%)
Haematuria	1(0.0%)	3(0.0%)
Ureterolithiasis	1(0.0%)	3(0.0%)
Bladder outlet obstruction	1(0.0%)	1(0.0%)
Pollakiuria	1(0.0%)	1(0.0%)
Urinary incontinence	1(0.0%)	1(0.0%)
Bladder perforation	1(0.0%)	0
Dysuria	1(0.0%)	0
Micturition disorder	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0
Oliguria	1(0.0%)	0
Renal artery stenosis	1(0.0%)	0
Renal cyst	1(0.0%)	0
Renal mass	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Ureteric obstruction	1(0.0%)	0
Calculus urinary	0	2(0.0%)
Proteinuria	0	2(0.0%)
Azotaemia	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerulonephritis chronic	0	1(0.0%)
Hypertonic bladder	0	1(0.0%)
Pelvi-ureteric obstruction	0	1(0.0%)
Polyuria	0	1(0.0%)
Renal colic	0	1(0.0%)
Renal haemorrhage	0	1(0.0%)
Urinary bladder polyp	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	115(1.8%)	118(1.8%)
Chronic obstructive pulmonary disease	22(0.3%)	16(0.2%)
Acute respiratory failure	17(0.3%)	23(0.4%)
Respiratory failure	15(0.2%)	13(0.2%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Dyspnoea	13(0.2%)	11(0.2%)
Pulmonary embolism	12(0.2%)	10(0.2%)
Sleep apnoea syndrome	7(0.1%)	9(0.1%)
Acute pulmonary oedema	6(0.1%)	6(0.1%)
Pulmonary mass	5(0.1%)	0
Hypoxia	4(0.1%)	2(0.0%)
Pulmonary oedema	3(0.0%)	9(0.1%)
Pleural effusion	3(0.0%)	8(0.1%)
Pulmonary hypertension	3(0.0%)	3(0.0%)
Asthma	3(0.0%)	2(0.0%)
Pneumothorax	3(0.0%)	1(0.0%)
Pneumonia aspiration	2(0.0%)	3(0.0%)
Chronic respiratory failure	2(0.0%)	0
Cough	1(0.0%)	3(0.0%)
Pneumonitis	1(0.0%)	2(0.0%)
Dyspnoea exertional	1(0.0%)	1(0.0%)
Interstitial lung disease	1(0.0%)	1(0.0%)
Obstructive airways disorder	1(0.0%)	1(0.0%)
Respiratory acidosis	1(0.0%)	1(0.0%)
Alveolar lung disease	1(0.0%)	0
Asphyxia	1(0.0%)	0
Atelectasis	1(0.0%)	0
Bronchitis chronic	1(0.0%)	0
Haemoptysis	1(0.0%)	0
Hypercapnia	1(0.0%)	0
Laryngeal oedema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Pulmonary fibrosis	1(0.0%)	0
Pulmonary infarction	1(0.0%)	0
Respiratory distress	1(0.0%)	0
Restrictive pulmonary disease	1(0.0%)	0
Haemothorax	0	2(0.0%)
Apnoea	0	1(0.0%)
Aspiration	0	1(0.0%)
Bronchiectasis	0	1(0.0%)
Bronchospasm	0	1(0.0%)
Emphysema	0	1(0.0%)
Epistaxis	0	1(0.0%)
Idiopathic pulmonary fibrosis	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Productive cough	0	1(0.0%)
Pulmonary congestion	0	1(0.0%)
Rales	0	1(0.0%)
Respiratory arrest	0	1(0.0%)
Respiratory disorder	0	1(0.0%)
Small airways disease	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Wheezing	0	1(0.0%)
Gastrointestinal Disorders	93(1.4%)	100(1.5%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Diarrhoea	9(0.1%)	5(0.1%)
Gastrointestinal haemorrhage	8(0.1%)	8(0.1%)
Pancreatitis acute	8(0.1%)	6(0.1%)
Vomiting	7(0.1%)	1(0.0%)
Abdominal pain	5(0.1%)	8(0.1%)
Rectal haemorrhage	3(0.0%)	2(0.0%)
Pancreatitis	3(0.0%)	1(0.0%)
Upper gastrointestinal haemorrhage	2(0.0%)	10(0.2%)
Intestinal obstruction	2(0.0%)	7(0.1%)
Small intestinal obstruction	2(0.0%)	5(0.1%)
Chronic gastritis	2(0.0%)	1(0.0%)
Dyspepsia	2(0.0%)	1(0.0%)
Lower gastrointestinal haemorrhage	2(0.0%)	1(0.0%)
Mechanical ileus	2(0.0%)	1(0.0%)
Functional gastrointestinal disorder	2(0.0%)	0
Gastric ulcer haemorrhage	2(0.0%)	0
Haemorrhagic erosive gastritis	2(0.0%)	0
Haemorrhoids	2(0.0%)	0
Constipation	1(0.0%)	4(0.1%)
Gastritis	1(0.0%)	3(0.0%)
Haematochezia	1(0.0%)	3(0.0%)
Nausea	1(0.0%)	3(0.0%)
Abdominal pain upper	1(0.0%)	2(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	2(0.0%)
Abdominal discomfort	1(0.0%)	1(0.0%)
Colitis ischaemic	1(0.0%)	1(0.0%)
Duodenal ulcer	1(0.0%)	1(0.0%)
Pancreatitis chronic	1(0.0%)	1(0.0%)
Abdominal hernia perforation	1(0.0%)	0
Abdominal mass	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Diarrhoea haemorrhagic	1(0.0%)	0
Diverticulum intestinal haemorrhagic	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenal polyp	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Faecaloma	1(0.0%)	0
Gastritis haemorrhagic	1(0.0%)	0
Gastrointestinal polyp	1(0.0%)	0
Gastrointestinal ulcer	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Glossitis	1(0.0%)	0
Haematemesis	1(0.0%)	0
Ileus	1(0.0%)	0
Incarcerated umbilical hernia	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Mesenteric vein thrombosis	1(0.0%)	0
Mouth haemorrhage	1(0.0%)	0
Pancreatitis necrotising	1(0.0%)	0
Peptic ulcer	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Retroperitoneal mass	1(0.0%)	0
Toothache	1(0.0%)	0
Volvulus	1(0.0%)	0
Ascites	0	4(0.1%)
Large intestine polyp	0	4(0.1%)
Inguinal hernia	0	3(0.0%)
Abdominal wall haematoma	0	2(0.0%)
Duodenal ulcer perforation	0	2(0.0%)
Dysphagia	0	2(0.0%)
Varices oesophageal	0	2(0.0%)
Abdominal adhesions	0	1(0.0%)
Abdominal pain lower	0	1(0.0%)
Abdominal wall haemorrhage	0	1(0.0%)
Anal fistula	0	1(0.0%)
Colitis	0	1(0.0%)
Colitis ulcerative	0	1(0.0%)
Colon dysplasia	0	1(0.0%)
Dental caries	0	1(0.0%)
Diverticular perforation	0	1(0.0%)
Diverticulum	0	1(0.0%)
Enteritis	0	1(0.0%)
Food poisoning	0	1(0.0%)
Gastric mucosal hypertrophy	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Ileus paralytic	0	1(0.0%)
Intestinal ischaemia	0	1(0.0%)
Melaena	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Omental infarction	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland disorder	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Subileus	0	1(0.0%)
Vascular Disorders	93(1.4%)	100(1.5%)
Hypertension	15(0.2%)	37(0.6%)
Hypotension	15(0.2%)	4(0.1%)
Aortic stenosis	9(0.1%)	2(0.0%)
Peripheral ischaemia	5(0.1%)	6(0.1%)
Hypertensive emergency	5(0.1%)	5(0.1%)
Peripheral arterial occlusive disease	4(0.1%)	9(0.1%)
Deep vein thrombosis	4(0.1%)	1(0.0%)
Orthostatic hypotension	4(0.1%)	0
Hypertensive crisis	3(0.0%)	6(0.1%)
Hypertensive urgency	3(0.0%)	5(0.1%)
Peripheral artery stenosis	3(0.0%)	5(0.1%)
Extremity necrosis	3(0.0%)	2(0.0%)
Peripheral artery occlusion	3(0.0%)	1(0.0%)
Giant cell arteritis	2(0.0%)	2(0.0%)
Aortic dissection	2(0.0%)	0
Dry gangrene	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Aortic aneurysm	1(0.0%)	2(0.0%)
Haematoma	1(0.0%)	2(0.0%)
Hypovolaemic shock	1(0.0%)	2(0.0%)
Peripheral vascular disorder	1(0.0%)	2(0.0%)
Circulatory collapse	1(0.0%)	1(0.0%)
Intermittent claudication	1(0.0%)	1(0.0%)
Lymphoedema	1(0.0%)	1(0.0%)
Peripheral artery aneurysm	1(0.0%)	1(0.0%)
Thrombosis	1(0.0%)	1(0.0%)
Aortic occlusion	1(0.0%)	0
Aortitis	1(0.0%)	0
Brachiocephalic arteriosclerosis	1(0.0%)	0
Diabetic vascular disorder	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Subclavian artery occlusion	1(0.0%)	0
Thrombophlebitis	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Vasculitis	1(0.0%)	0
Aortic aneurysm rupture	0	1(0.0%)
Arterial stenosis	0	1(0.0%)
Arterial thrombosis	0	1(0.0%)
Arteriosclerosis	0	1(0.0%)
Blood pressure inadequately controlled	0	1(0.0%)
Iliac artery stenosis	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Peripheral venous disease	0	1(0.0%)
Phlebitis	0	1(0.0%)
Shock	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Subclavian steal syndrome	0	1(0.0%)
Systolic hypertension	0	1(0.0%)
Injury, Poisoning And Procedural Complications	92(1.4%)	85(1.3%)
Hip fracture	9(0.1%)	4(0.1%)
Femoral neck fracture	9(0.1%)	0
Femur fracture	8(0.1%)	7(0.1%)
Fall	6(0.1%)	6(0.1%)
Ankle fracture	4(0.1%)	3(0.0%)
Road traffic accident	4(0.1%)	3(0.0%)
Rib fracture	3(0.0%)	6(0.1%)
Procedural pain	3(0.0%)	2(0.0%)
Radius fracture	2(0.0%)	5(0.1%)
Humerus fracture	2(0.0%)	3(0.0%)
Spinal compression fracture	2(0.0%)	3(0.0%)
Craniocerebral injury	2(0.0%)	2(0.0%)
Skin laceration	2(0.0%)	2(0.0%)
Foot fracture	2(0.0%)	1(0.0%)
Cervical vertebral fracture	2(0.0%)	0
Joint injury	2(0.0%)	0
Patella fracture	2(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Toxicity to various agents	2(0.0%)	0
Brain contusion	1(0.0%)	2(0.0%)
Contusion	1(0.0%)	2(0.0%)
Head injury	1(0.0%)	2(0.0%)
Limb injury	1(0.0%)	2(0.0%)
Lumbar vertebral fracture	1(0.0%)	2(0.0%)
Post procedural haemorrhage	1(0.0%)	2(0.0%)
Subdural haemorrhage	1(0.0%)	2(0.0%)
Thoracic vertebral fracture	1(0.0%)	2(0.0%)
Traumatic fracture	1(0.0%)	2(0.0%)
Spinal fracture	1(0.0%)	1(0.0%)
Thermal burn	1(0.0%)	1(0.0%)
Tibia fracture	1(0.0%)	1(0.0%)
Ulna fracture	1(0.0%)	1(0.0%)
Abdominal injury	1(0.0%)	0
Accidental overdose	1(0.0%)	0
Back injury	1(0.0%)	0
Cardiac procedure complication	1(0.0%)	0
Chest injury	1(0.0%)	0
Clavicle fracture	1(0.0%)	0
Fibula fracture	1(0.0%)	0
Gun shot wound	1(0.0%)	0
Hand fracture	1(0.0%)	0
Incision site pain	1(0.0%)	0
Ligament rupture	1(0.0%)	0
Lower limb fracture	1(0.0%)	0
Muscle injury	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Poisoning	1(0.0%)	0
Post procedural haematoma	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Spinal cord injury cervical	1(0.0%)	0
Splenic injury	1(0.0%)	0
Sternal fracture	1(0.0%)	0
Tendon rupture	1(0.0%)	0
Traumatic haematoma	1(0.0%)	0
Upper limb fracture	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Subdural haematoma	0	6(0.1%)
Skull fracture	0	2(0.0%)
Acetabulum fracture	0	1(0.0%)
Alcohol poisoning	0	1(0.0%)
Burns third degree	0	1(0.0%)
Cold burn	0	1(0.0%)
Cystitis radiation	0	1(0.0%)
Epicondylitis	0	1(0.0%)
Eye contusion	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Heat illness	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Heat stroke	0	1(0.0%)
Hyphaema	0	1(0.0%)
Injury	0	1(0.0%)
Joint dislocation	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Ligament sprain	0	1(0.0%)
Multiple fractures	0	1(0.0%)
Multiple injuries	0	1(0.0%)
Nasal injury	0	1(0.0%)
Overdose	0	1(0.0%)
Pelvic fracture	0	1(0.0%)
Pneumocephalus	0	1(0.0%)
Post-traumatic pain	0	1(0.0%)
Procedural haemorrhage	0	1(0.0%)
Tooth fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Traumatic intracranial haemorrhage	0	1(0.0%)
Nervous System Disorders	91(1.4%)	106(1.6%)
Syncope	11(0.2%)	16(0.2%)
Dizziness	6(0.1%)	6(0.1%)
Diabetic neuropathy	5(0.1%)	4(0.1%)
Seizure	5(0.1%)	4(0.1%)
Loss of consciousness	5(0.1%)	1(0.0%)
Subarachnoid haemorrhage	4(0.1%)	4(0.1%)
Carotid artery stenosis	3(0.0%)	7(0.1%)
Sciatica	3(0.0%)	3(0.0%)
Facial paralysis	3(0.0%)	1(0.0%)
Headache	3(0.0%)	0
Carpal tunnel syndrome	2(0.0%)	5(0.1%)
Cognitive disorder	2(0.0%)	2(0.0%)
Hemiparesis	2(0.0%)	2(0.0%)
Presyncope	2(0.0%)	2(0.0%)
Cerebrovascular disorder	2(0.0%)	1(0.0%)
Cerebral haemorrhage	2(0.0%)	0
Hepatic encephalopathy	2(0.0%)	0
Hypoaesthesia	2(0.0%)	0
Myelopathy	2(0.0%)	0
Partial seizures	2(0.0%)	0
Vertebral artery occlusion	2(0.0%)	0
Epilepsy	1(0.0%)	4(0.1%)
Encephalopathy	1(0.0%)	3(0.0%)
Transient ischaemic attack	1(0.0%)	2(0.0%)
Altered state of consciousness	1(0.0%)	1(0.0%)
Brain oedema	1(0.0%)	1(0.0%)
Cerebrovascular accident	1(0.0%)	1(0.0%)
Facial paresis	1(0.0%)	1(0.0%)
Generalised tonic-clonic seizure	1(0.0%)	1(0.0%)
Hypoglycaemic unconsciousness	1(0.0%)	1(0.0%)
Metabolic encephalopathy	1(0.0%)	1(0.0%)
Paraparesis	1(0.0%)	1(0.0%)
Parkinson's disease	1(0.0%)	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Brain injury	1(0.0%)	0
Carotid arteriosclerosis	1(0.0%)	0
Central nervous system vasculitis	1(0.0%)	0
Cerebral ischaemia	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Dizziness postural	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
IIIrd nerve paralysis	1(0.0%)	0
IVth nerve paralysis	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Normal pressure hydrocephalus	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Tension headache	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Unresponsive to stimuli	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
Cervical radiculopathy	0	2(0.0%)
Coma	0	2(0.0%)
Migraine	0	2(0.0%)
Spondylitic myelopathy	0	2(0.0%)
Aphasia	0	1(0.0%)
Brain stem haemorrhage	0	1(0.0%)
Brain stem infarction	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Cauda equina syndrome	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cervicobrachial syndrome	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Dementia	0	1(0.0%)
Dementia Alzheimer's type	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Diabetic ketoacidotic hyperglycaemic coma	0	1(0.0%)
Hydrocephalus	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypoglycaemic coma	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Intensive care unit acquired weakness	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Lacunar infarction	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Myelitis transverse	0	1(0.0%)
Myelomalacia	0	1(0.0%)
Neuralgia	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Paraplegia	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Spinal cord haematoma	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Thalamic infarction	0	1(0.0%)
Thalamus haemorrhage	0	1(0.0%)
Transverse sinus thrombosis	0	1(0.0%)
Vascular encephalopathy	0	1(0.0%)
Vertebral artery stenosis	0	1(0.0%)
Vertigo CNS origin	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	82(1.3%)	92(1.4%)
Osteoarthritis	16(0.2%)	10(0.2%)
Back pain	11(0.2%)	11(0.2%)
Arthralgia	7(0.1%)	11(0.2%)
Pain in extremity	6(0.1%)	6(0.1%)
Intervertebral disc protrusion	5(0.1%)	6(0.1%)
Spinal osteoarthritis	4(0.1%)	4(0.1%)
Gouty arthritis	3(0.0%)	2(0.0%)
Rhabdomyolysis	3(0.0%)	2(0.0%)
Rotator cuff syndrome	2(0.0%)	6(0.1%)
Muscle spasms	2(0.0%)	4(0.1%)
Arthritis	2(0.0%)	2(0.0%)
Lumbar spinal stenosis	2(0.0%)	2(0.0%)
Osteitis	2(0.0%)	1(0.0%)
Musculoskeletal pain	2(0.0%)	0
Myalgia	1(0.0%)	4(0.1%)
Cervical spinal stenosis	1(0.0%)	2(0.0%)
Intervertebral disc degeneration	1(0.0%)	2(0.0%)
Muscular weakness	1(0.0%)	1(0.0%)
Polymyalgia rheumatica	1(0.0%)	1(0.0%)
Facet joint syndrome	1(0.0%)	0
Groin pain	1(0.0%)	0
Immobilisation syndrome	1(0.0%)	0
Inclusion body myositis	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Kyphosis	1(0.0%)	0
Musculoskeletal chest pain	1(0.0%)	0
Myositis	1(0.0%)	0
Osteochondrosis	1(0.0%)	0
Osteoporosis	1(0.0%)	0
Resorption bone increased	1(0.0%)	0
Rheumatoid arthritis	1(0.0%)	0
Spinal synovial cyst	1(0.0%)	0
Spondylitis	1(0.0%)	0
Tendonitis	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Torticollis	1(0.0%)	0
Trigger finger	1(0.0%)	0
Bursitis	0	3(0.0%)
Neuropathic arthropathy	0	3(0.0%)
Costochondritis	0	2(0.0%)
Osteolysis	0	2(0.0%)
Spinal stenosis	0	2(0.0%)
Back disorder	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Chondrocalcinosis pyrophosphate	0	1(0.0%)
Flank pain	0	1(0.0%)
Foot deformity	0	1(0.0%)
Intervertebral disc disorder	0	1(0.0%)
Limb discomfort	0	1(0.0%)
Neck pain	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Osteopenia	0	1(0.0%)
Pathological fracture	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Soft tissue haemorrhage	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Spondylolisthesis	0	1(0.0%)
Cardiac Disorders	77(1.2%)	99(1.5%)
Coronary artery disease	16(0.2%)	9(0.1%)
Cardiac failure	6(0.1%)	23(0.4%)
Cardiac failure acute	6(0.1%)	1(0.0%)
Cardiac failure congestive	5(0.1%)	8(0.1%)
Bradycardia	5(0.1%)	4(0.1%)
Aortic valve stenosis	4(0.1%)	6(0.1%)
Angina unstable	4(0.1%)	5(0.1%)
Angina pectoris	3(0.0%)	2(0.0%)
Ischaemic cardiomyopathy	2(0.0%)	3(0.0%)
Acute coronary syndrome	2(0.0%)	2(0.0%)
Aortic valve disease mixed	2(0.0%)	1(0.0%)
Cardio-respiratory arrest	2(0.0%)	1(0.0%)
Acute left ventricular failure	2(0.0%)	0
Left ventricular dysfunction	2(0.0%)	0
Sinus node dysfunction	2(0.0%)	0
Ventricular fibrillation	2(0.0%)	0
Cardiac failure chronic	1(0.0%)	5(0.1%)
Cardiac arrest	1(0.0%)	4(0.1%)
Atrioventricular block second degree	1(0.0%)	2(0.0%)
Aortic valve incompetence	1(0.0%)	1(0.0%)
Coronary artery stenosis	1(0.0%)	1(0.0%)
Mitral valve incompetence	1(0.0%)	1(0.0%)
Aortic valve calcification	1(0.0%)	0
Arrhythmia	1(0.0%)	0
Arrhythmia supraventricular	1(0.0%)	0
Atrial enlargement	1(0.0%)	0
Atrioventricular block	1(0.0%)	0
Cardiac disorder	1(0.0%)	0
Cardiovascular insufficiency	1(0.0%)	0
Congestive cardiomyopathy	1(0.0%)	0
Mitral valve calcification	1(0.0%)	0
Mitral valve disease	1(0.0%)	0
Myocardial ischaemia	1(0.0%)	0
Myocarditis	1(0.0%)	0
Pericardial haemorrhage	1(0.0%)	0
Pericarditis	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Pulseless electrical activity	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Supraventricular tachyarrhythmia	1(0.0%)	0
Ventricular hypokinesia	1(0.0%)	0
Ventricular tachycardia	1(0.0%)	0
Atrial fibrillation	0	5(0.1%)
Cardiogenic shock	0	3(0.0%)
Atrial flutter	0	2(0.0%)
Cardiomyopathy	0	2(0.0%)
Left atrial dilatation	0	2(0.0%)
Left ventricular hypertrophy	0	2(0.0%)
Arteriosclerosis coronary artery	0	1(0.0%)
Atrial thrombosis	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac dysfunction	0	1(0.0%)
Cardiac tamponade	0	1(0.0%)
Cardiomegaly	0	1(0.0%)
Cardiopulmonary failure	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Conduction disorder	0	1(0.0%)
Cor pulmonale chronic	0	1(0.0%)
Coronary artery perforation	0	1(0.0%)
Diastolic dysfunction	0	1(0.0%)
Ischaemic mitral regurgitation	0	1(0.0%)
Left ventricular failure	0	1(0.0%)
Mitral valve prolapse	0	1(0.0%)
Nodal arrhythmia	0	1(0.0%)
Palpitations	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Supraventricular tachycardia	0	1(0.0%)
Tricuspid valve incompetence	0	1(0.0%)
Wandering pacemaker	0	1(0.0%)
General Disorders And Administration Site Conditions	55(0.8%)	68(1.0%)
Death	10(0.2%)	10(0.2%)
Chest pain	9(0.1%)	16(0.2%)
Oedema peripheral	8(0.1%)	6(0.1%)
General physical health deterioration	4(0.1%)	5(0.1%)
Fatigue	4(0.1%)	4(0.1%)
Pyrexia	4(0.1%)	2(0.0%)
Multiple organ dysfunction syndrome	3(0.0%)	3(0.0%)
Peripheral swelling	2(0.0%)	3(0.0%)
Oedema	2(0.0%)	1(0.0%)
Malaise	2(0.0%)	0
Asthenia	1(0.0%)	8(0.1%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Feeling abnormal	1(0.0%)	0
Hanging	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Pain	1(0.0%)	0
Swelling face	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Generalised oedema	0	3(0.0%)
Gait disturbance	0	2(0.0%)
Non-cardiac chest pain	0	2(0.0%)
Adhesion	0	1(0.0%)
Chest discomfort	0	1(0.0%)
Discomfort	0	1(0.0%)
Polyp	0	1(0.0%)
Sudden death	0	1(0.0%)
Investigations	55(0.8%)	56(0.9%)
Glomerular filtration rate decreased	20(0.3%)	18(0.3%)
Blood potassium increased	4(0.1%)	1(0.0%)
Blood creatinine increased	3(0.0%)	4(0.1%)
Weight decreased	2(0.0%)	3(0.0%)
Blood pressure increased	2(0.0%)	2(0.0%)
Blood triglycerides increased	2(0.0%)	1(0.0%)
Gamma-glutamyltransferase increased	2(0.0%)	0
Glycosylated haemoglobin increased	2(0.0%)	0
Haemoglobin decreased	2(0.0%)	0
International normalised ratio increased	2(0.0%)	0
Blood creatine phosphokinase increased	1(0.0%)	4(0.1%)
Influenza A virus test positive	1(0.0%)	3(0.0%)
C-reactive protein increased	1(0.0%)	1(0.0%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Anticoagulation drug level above therapeutic	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood calcium decreased	1(0.0%)	0
Blood sodium decreased	1(0.0%)	0
Blood testosterone decreased	1(0.0%)	0
Catheterisation cardiac	1(0.0%)	0
Intracardiac pressure increased	1(0.0%)	0
Low density lipoprotein decreased	1(0.0%)	0
Oxygen consumption increased	1(0.0%)	0
Prostatic specific antigen increased	1(0.0%)	0
Sleep study	1(0.0%)	0
Liver function test increased	0	2(0.0%)
Angiocardiogram	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Biopsy kidney	0	1(0.0%)
Biopsy prostate	0	1(0.0%)
Blood magnesium decreased	0	1(0.0%)
Blood urine present	0	1(0.0%)
Colonoscopy	0	1(0.0%)
Electrocardiogram T wave inversion	0	1(0.0%)
Haematology test abnormal	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
N-terminal prohormone brain natriuretic peptide increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Protein total decreased	0	1(0.0%)
Respiratory syncytial virus test positive	0	1(0.0%)
Troponin increased	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Urine albumin/creatinine ratio increased	0	1(0.0%)
White blood cell count increased	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	46(0.7%)	52(0.8%)
Diabetic foot	20(0.3%)	20(0.3%)
Skin ulcer	7(0.1%)	13(0.2%)
Angioedema	4(0.1%)	0
Skin necrosis	3(0.0%)	0
Decubitus ulcer	2(0.0%)	2(0.0%)
Pemphigoid	2(0.0%)	2(0.0%)
Skin lesion	2(0.0%)	1(0.0%)
Dry skin	2(0.0%)	0
Pruritus	1(0.0%)	2(0.0%)
Blister	1(0.0%)	1(0.0%)
Hidradenitis	1(0.0%)	1(0.0%)
Ingrowing nail	1(0.0%)	1(0.0%)
Dermatitis allergic	1(0.0%)	0
Diabetic bullosis	1(0.0%)	0
Drug eruption	1(0.0%)	0
Palmoplantar keratoderma	1(0.0%)	0
Actinic keratosis	0	1(0.0%)
Dermatitis	0	1(0.0%)
Dermatitis bullous	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Necrobiosis lipoidica diabeticorum	0	1(0.0%)
Psoriasis	0	1(0.0%)
Rash	0	1(0.0%)
Rash pruritic	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Surgical And Medical Procedures	44(0.7%)	48(0.7%)
Toe amputation	4(0.1%)	9(0.1%)
Cataract operation	4(0.1%)	3(0.0%)
Leg amputation	4(0.1%)	3(0.0%)
Hip arthroplasty	4(0.1%)	1(0.0%)
Foot amputation	2(0.0%)	2(0.0%)
Gastric bypass	2(0.0%)	1(0.0%)
Vitrectomy	2(0.0%)	1(0.0%)
Colectomy	2(0.0%)	0
Hysterectomy	2(0.0%)	0
Intervertebral disc operation	1(0.0%)	3(0.0%)
Knee arthroplasty	1(0.0%)	3(0.0%)
Prostatectomy	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Bladder calculus removal	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Coronary angioplasty	1(0.0%)	0
Coronary artery bypass	1(0.0%)	0
Finger amputation	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Lymphadenectomy	1(0.0%)	0
Metabolic surgery	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Neurolysis	1(0.0%)	0
Parotidectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0
Roux loop conversion	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Gastrectomy	0	2(0.0%)
Haemodialysis	0	2(0.0%)
Abscess drainage	0	1(0.0%)
Amputation	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Cardiac pacemaker insertion	0	1(0.0%)
Cardiac pacemaker removal	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Cholecystectomy	0	1(0.0%)
Drug delivery device placement	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Insertion of ambulatory peritoneal catheter	0	1(0.0%)
Intensive care	0	1(0.0%)
Lens extraction	0	1(0.0%)
Lung lobectomy	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Radioactive iodine therapy	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Spinal operation	0	1(0.0%)
Stent placement	0	1(0.0%)
Transcatheter aortic valve implantation	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Umbilical hernia repair	0	1(0.0%)
Ureteral stent insertion	0	1(0.0%)
Blood And Lymphatic System Disorders	35(0.5%)	42(0.6%)
Anaemia	20(0.3%)	27(0.4%)
Iron deficiency anaemia	4(0.1%)	5(0.1%)
Blood loss anaemia	4(0.1%)	1(0.0%)
Lymphadenopathy mediastinal	2(0.0%)	1(0.0%)
Thrombocytopenia	1(0.0%)	2(0.0%)
Normocytic anaemia	1(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	1(0.0%)
Abdominal lymphadenopathy	1(0.0%)	0
Coagulopathy	1(0.0%)	0
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Immune thrombocytopenia	1(0.0%)	0
Lymphadenopathy	1(0.0%)	0
Splenomegaly	1(0.0%)	0
Febrile neutropenia	0	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Acquired haemophilia	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Leukocytosis	0	1(0.0%)
Microcytic anaemia	0	1(0.0%)
Nephrogenic anaemia	0	1(0.0%)
Splenic embolism	0	1(0.0%)
Eye Disorders	34(0.5%)	38(0.6%)
Cataract	10(0.2%)	8(0.1%)
Diabetic retinopathy	10(0.2%)	7(0.1%)
Vitreous haemorrhage	5(0.1%)	8(0.1%)
Retinal detachment	3(0.0%)	3(0.0%)
Glaucoma	3(0.0%)	2(0.0%)
Retinal vein occlusion	2(0.0%)	2(0.0%)
Visual impairment	2(0.0%)	2(0.0%)
Macular fibrosis	2(0.0%)	1(0.0%)
Eye haemorrhage	2(0.0%)	0
Sudden visual loss	2(0.0%)	0
Blindness	1(0.0%)	2(0.0%)
Retinal haemorrhage	1(0.0%)	1(0.0%)
Tractional retinal detachment	1(0.0%)	1(0.0%)
Amaurosis	1(0.0%)	0
Diabetic eye disease	1(0.0%)	0
Eye disorder	1(0.0%)	0
Blindness unilateral	0	3(0.0%)
Dermatochalasis	0	1(0.0%)
Diabetic retinal oedema	0	1(0.0%)
Diplopia	0	1(0.0%)
Macular oedema	0	1(0.0%)
Retinopathy	0	1(0.0%)
Retinopathy proliferative	0	1(0.0%)
Rhegmatogenous retinal detachment	0	1(0.0%)
Hepatobiliary Disorders	28(0.4%)	33(0.5%)
Cholecystitis	5(0.1%)	4(0.1%)
Cholelithiasis	5(0.1%)	3(0.0%)
Cholecystitis acute	3(0.0%)	7(0.1%)
Cholangitis	3(0.0%)	5(0.1%)
Bile duct stone	2(0.0%)	0
Biliary colic	2(0.0%)	0
Cholecystitis chronic	2(0.0%)	0
Hepatic cirrhosis	1(0.0%)	4(0.1%)
Cholangitis acute	1(0.0%)	2(0.0%)
Liver disorder	1(0.0%)	1(0.0%)
Biliary dyskinesia	1(0.0%)	0
Fatty liver alcoholic	1(0.0%)	0
Gallbladder fistula	1(0.0%)	0
Hepatic steatosis	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatomegaly	1(0.0%)	0
Hepatorenal syndrome	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Jaundice cholestatic	0	3(0.0%)
Cirrhosis alcoholic	0	1(0.0%)
Hepatic failure	0	1(0.0%)
Hepatic lesion	0	1(0.0%)
Hepatic mass	0	1(0.0%)
Portal hypertension	0	1(0.0%)
Portal vein thrombosis	0	1(0.0%)
Reproductive System And Breast Disorders	14(0.2%)	12(0.2%)
Benign prostatic hyperplasia	4(0.1%)	6(0.1%)
Uterine haemorrhage	2(0.0%)	1(0.0%)
Prostatomegaly	2(0.0%)	0
Vaginal haemorrhage	2(0.0%)	0
Prostatitis	1(0.0%)	2(0.0%)
Endometrial hyperplasia	1(0.0%)	1(0.0%)
Breast necrosis	1(0.0%)	0
Prostatism	1(0.0%)	0
Uterine prolapse	1(0.0%)	0
Dysfunctional uterine bleeding	0	1(0.0%)
Female genital tract fistula	0	1(0.0%)
Ovarian cyst	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine mass	0	1(0.0%)
Psychiatric Disorders	11(0.2%)	20(0.3%)
Anxiety	3(0.0%)	1(0.0%)
Depression	2(0.0%)	6(0.1%)
Completed suicide	2(0.0%)	0
Mental status changes	1(0.0%)	3(0.0%)
Confusional state	1(0.0%)	1(0.0%)
Aggression	1(0.0%)	0
Alcohol withdrawal syndrome	1(0.0%)	0
Disorientation	1(0.0%)	0
Major depression	1(0.0%)	0
Delirium	0	2(0.0%)
Insomnia	0	2(0.0%)
Delusional disorder, unspecified type	0	1(0.0%)
Depressed mood	0	1(0.0%)
Drug abuse	0	1(0.0%)
Hallucination	0	1(0.0%)
Substance-induced psychotic disorder	0	1(0.0%)
Suicide threat	0	1(0.0%)
Ear And Labyrinth Disorders	4(0.1%)	7(0.1%)
Vertigo	2(0.0%)	3(0.0%)
Tympanic membrane perforation	1(0.0%)	0
Vertigo positional	1(0.0%)	0
Sudden hearing loss	0	2(0.0%)
Deafness	0	1(0.0%)
Vestibular disorder	0	1(0.0%)
Immune System Disorders	2(0.0%)	2(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Anaphylactic shock	1(0.0%)	2(0.0%)
Drug hypersensitivity	1(0.0%)	0
Endocrine Disorders	2(0.0%)	1(0.0%)
Hypothyroidism	1(0.0%)	0
Primary hyperaldosteronism	1(0.0%)	0
Thyroiditis	0	1(0.0%)
Congenital, Familial And Genetic Disorders	1(0.0%)	1(0.0%)
Truncus arteriosus persistent	1(0.0%)	0
Type V hyperlipidaemia	0	1(0.0%)
Product Issues	0	4(0.1%)
Device dislocation	0	1(0.0%)
Device leakage	0	1(0.0%)
Device loosening	0	1(0.0%)
Device malfunction	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Any TEAE	414(6.4%)	351(5.4%)
Metabolism And Nutrition Disorders	95(1.5%)	42(0.6%)
Hyperkalaemia	87(1.3%)	31(0.5%)
Hyponatraemia	5(0.1%)	1(0.0%)
Decreased appetite	1(0.0%)	1(0.0%)
Diabetes mellitus	1(0.0%)	0
Hypercalcaemia	1(0.0%)	0
Cachexia	0	1(0.0%)
Diabetic ketoacidosis	0	1(0.0%)
Fluid overload	0	1(0.0%)
Fluid retention	0	1(0.0%)
Gout	0	1(0.0%)
Hyperglycaemia	0	1(0.0%)
Hypoglycaemia	0	1(0.0%)
Hypokalaemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	51(0.8%)	65(1.0%)
Lung neoplasm malignant	6(0.1%)	2(0.0%)
Colon cancer	4(0.1%)	4(0.1%)
Transitional cell carcinoma	3(0.0%)	1(0.0%)
Renal neoplasm	2(0.0%)	3(0.0%)
Small cell lung cancer	2(0.0%)	3(0.0%)
Pancreatic carcinoma metastatic	2(0.0%)	2(0.0%)
Oesophageal adenocarcinoma	2(0.0%)	0
Prostate cancer	2(0.0%)	0
Lung adenocarcinoma	1(0.0%)	3(0.0%)
Pancreatic carcinoma	1(0.0%)	3(0.0%)
Breast cancer	1(0.0%)	2(0.0%)
Cholangiocarcinoma	1(0.0%)	2(0.0%)
Metastases to lymph nodes	1(0.0%)	2(0.0%)
Pancreatic neoplasm	1(0.0%)	2(0.0%)
Adenocarcinoma gastric	1(0.0%)	1(0.0%)
Lung cancer metastatic	1(0.0%)	1(0.0%)
Metastases to liver	1(0.0%)	1(0.0%)
Plasma cell myeloma	1(0.0%)	1(0.0%)
Benign salivary gland neoplasm	1(0.0%)	0
Brain neoplasm malignant	1(0.0%)	0
Clear cell renal cell carcinoma	1(0.0%)	0
Diffuse large B-cell lymphoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastric cancer	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Lymphoma	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Meningioma	1(0.0%)	0
Metastases to lung	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Myelodysplastic syndrome	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Pancreatic carcinoma stage IV	1(0.0%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Prostate cancer metastatic	1(0.0%)	0
Rectal adenocarcinoma	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Hepatocellular carcinoma	0	3(0.0%)
Adenocarcinoma pancreas	0	2(0.0%)
Adrenal adenoma	0	2(0.0%)
Bladder cancer	0	2(0.0%)
Brain neoplasm	0	2(0.0%)
Colon neoplasm	0	2(0.0%)
Lung neoplasm	0	2(0.0%)
Acoustic neuroma	0	1(0.0%)
Acute myeloid leukaemia	0	1(0.0%)
Adenocarcinoma of colon	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Endometrial adenocarcinoma	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Hepatic cancer	0	1(0.0%)
Invasive breast carcinoma	0	1(0.0%)
Malignant neoplasm of unknown primary site	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oesophageal carcinoma	0	1(0.0%)
Ovarian cancer	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Renal cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Tonsil cancer	0	1(0.0%)
Investigations	50(0.8%)	30(0.5%)
Blood potassium increased	23(0.4%)	7(0.1%)
Glomerular filtration rate decreased	16(0.2%)	12(0.2%)
Blood creatinine increased	7(0.1%)	6(0.1%)
Blood pressure increased	1(0.0%)	1(0.0%)
Protein urine present	1(0.0%)	1(0.0%)
Blood urea increased	1(0.0%)	0
Gamma-glutamyltransferase increased	1(0.0%)	0
Liver function test increased	1(0.0%)	0
Weight decreased	1(0.0%)	0
Amylase increased	0	1(0.0%)
Blood glucose increased	0	1(0.0%)
Hepatic enzyme increased	0	1(0.0%)
Lipase increased	0	1(0.0%)
Occult blood positive	0	1(0.0%)
Renal And Urinary Disorders	42(0.6%)	44(0.7%)
Acute kidney injury	14(0.2%)	10(0.2%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Renal impairment	10(0.2%)	10(0.2%)
Renal failure	5(0.1%)	5(0.1%)
Chronic kidney disease	2(0.0%)	8(0.1%)
Proteinuria	2(0.0%)	2(0.0%)
Diabetic nephropathy	2(0.0%)	1(0.0%)
Urinary retention	2(0.0%)	0
End stage renal disease	1(0.0%)	1(0.0%)
Nephropathy	1(0.0%)	1(0.0%)
Nephrolithiasis	1(0.0%)	0
Nephrotic syndrome	1(0.0%)	0
Subacute kidney injury	1(0.0%)	0
Tubulointerstitial nephritis	0	3(0.0%)
Renal mass	0	2(0.0%)
Glomerulonephritis membranous	0	1(0.0%)
Perinephritis	0	1(0.0%)
Pollakiuria	0	1(0.0%)
Renal colic	0	1(0.0%)
Renal pain	0	1(0.0%)
Gastrointestinal Disorders	38(0.6%)	42(0.6%)
Diarrhoea	14(0.2%)	13(0.2%)
Nausea	5(0.1%)	14(0.2%)
Vomiting	4(0.1%)	5(0.1%)
Constipation	3(0.0%)	6(0.1%)
Ascites	1(0.0%)	3(0.0%)
Abdominal pain	1(0.0%)	2(0.0%)
Abdominal discomfort	1(0.0%)	1(0.0%)
Dyspepsia	1(0.0%)	1(0.0%)
Chronic gastritis	1(0.0%)	0
Gastric haemorrhage	1(0.0%)	0
Gastrointestinal haemorrhage	1(0.0%)	0
Gastrointestinal motility disorder	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Mechanical ileus	1(0.0%)	0
Pancreatic cyst	1(0.0%)	0
Pancreatitis	1(0.0%)	0
Pancreatitis acute	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Abdominal pain upper	0	4(0.1%)
Abdominal distension	0	1(0.0%)
Anal fistula	0	1(0.0%)
Diabetic gastroenteropathy	0	1(0.0%)
Faeces discoloured	0	1(0.0%)
Gastrooesophageal reflux disease	0	1(0.0%)
Oesophageal varices haemorrhage	0	1(0.0%)
Oesophagitis	0	1(0.0%)
Nervous System Disorders	27(0.4%)	38(0.6%)
Dizziness	6(0.1%)	7(0.1%)
Dementia	4(0.1%)	7(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Cognitive disorder	4(0.1%)	4(0.1%)
Headache	3(0.0%)	1(0.0%)
Somnolence	1(0.0%)	3(0.0%)
Subarachnoid haemorrhage	1(0.0%)	2(0.0%)
Syncope	1(0.0%)	2(0.0%)
Dementia Alzheimer's type	1(0.0%)	1(0.0%)
Memory impairment	1(0.0%)	1(0.0%)
Presyncope	1(0.0%)	1(0.0%)
Dementia with Lewy bodies	1(0.0%)	0
Hemiparesis	1(0.0%)	0
Seizure	1(0.0%)	0
Tremor	1(0.0%)	0
Amnestic disorder	0	1(0.0%)
Carotid artery stenosis	0	1(0.0%)
Cerebral atrophy	0	1(0.0%)
Disturbance in attention	0	1(0.0%)
Dizziness postural	0	1(0.0%)
Epilepsy	0	1(0.0%)
Loss of consciousness	0	1(0.0%)
Mixed dementia	0	1(0.0%)
Paraesthesia	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Transient ischaemic attack	0	1(0.0%)
Trigeminal neuralgia	0	1(0.0%)
Vocal cord paralysis	0	1(0.0%)
Infections And Infestations	24(0.4%)	19(0.3%)
Sepsis	3(0.0%)	3(0.0%)
Pneumonia	2(0.0%)	6(0.1%)
COVID-19	1(0.0%)	2(0.0%)
COVID-19 pneumonia	1(0.0%)	1(0.0%)
Cellulitis	1(0.0%)	1(0.0%)
Localised infection	1(0.0%)	1(0.0%)
Osteomyelitis	1(0.0%)	1(0.0%)
Acarodermatitis	1(0.0%)	0
Dengue fever	1(0.0%)	0
HIV infection	1(0.0%)	0
Helicobacter infection	1(0.0%)	0
Influenza	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Necrotising fasciitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pulmonary sepsis	1(0.0%)	0
Pulmonary tuberculosis	1(0.0%)	0
Soft tissue infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Tuberculosis	1(0.0%)	0
Urinary tract infection	1(0.0%)	0
Diabetic foot infection	0	1(0.0%)
Onychomycosis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Upper respiratory tract infection	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Urosepsis	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	20(0.3%)	19(0.3%)
Rash	8(0.1%)	5(0.1%)
Pruritus	5(0.1%)	3(0.0%)
Dermatitis allergic	2(0.0%)	2(0.0%)
Rash papular	2(0.0%)	0
Eczema	1(0.0%)	3(0.0%)
Decubitus ulcer	1(0.0%)	0
Diabetic foot	1(0.0%)	0
Psoriasis	1(0.0%)	0
Blister	0	1(0.0%)
Dermatitis psoriasiform	0	1(0.0%)
Hyperhidrosis	0	1(0.0%)
Hypersensitivity vasculitis	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Urticaria	0	1(0.0%)
General Disorders And Administration Site Conditions	13(0.2%)	17(0.3%)
Fatigue	4(0.1%)	1(0.0%)
Malaise	3(0.0%)	1(0.0%)
Asthenia	2(0.0%)	2(0.0%)
General physical health deterioration	1(0.0%)	2(0.0%)
Peripheral swelling	1(0.0%)	2(0.0%)
Chest pain	1(0.0%)	1(0.0%)
Pain	1(0.0%)	1(0.0%)
Oedema	1(0.0%)	0
Oedema peripheral	0	3(0.0%)
Chills	0	1(0.0%)
Generalised oedema	0	1(0.0%)
Multiple organ dysfunction syndrome	0	1(0.0%)
Pyrexia	0	1(0.0%)
Swelling	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	13(0.2%)	7(0.1%)
Myalgia	2(0.0%)	1(0.0%)
Arthralgia	2(0.0%)	0
Muscle spasms	2(0.0%)	0
Musculoskeletal pain	1(0.0%)	1(0.0%)
Pain in extremity	1(0.0%)	1(0.0%)
Connective tissue inflammation	1(0.0%)	0
Flank pain	1(0.0%)	0
Muscle rigidity	1(0.0%)	0
Polymyalgia rheumatica	1(0.0%)	0
Rhabdomyolysis	1(0.0%)	0
Fibromyalgia	0	1(0.0%)
Intervertebral disc protrusion	0	1(0.0%)
Joint swelling	0	1(0.0%)
Rotator cuff syndrome	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	13(0.2%)	7(0.1%)
Respiratory failure	4(0.1%)	0

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Dyspnoea	2(0.0%)	3(0.0%)
Dyspnoea exertional	1(0.0%)	1(0.0%)
Interstitial lung disease	1(0.0%)	1(0.0%)
Lung disorder	1(0.0%)	0
Oropharyngeal pain	1(0.0%)	0
Pleural effusion	1(0.0%)	0
Productive cough	1(0.0%)	0
Pulmonary mass	1(0.0%)	0
Acute respiratory failure	0	2(0.0%)
Vascular Disorders	9(0.1%)	9(0.1%)
Hypotension	3(0.0%)	0
Hypertension	2(0.0%)	2(0.0%)
Hypertensive crisis	1(0.0%)	1(0.0%)
Deep vein thrombosis	1(0.0%)	0
Hypertensive urgency	1(0.0%)	0
Peripheral ischaemia	1(0.0%)	0
Arterial thrombosis	0	1(0.0%)
Flushing	0	1(0.0%)
Inferior vena cava syndrome	0	1(0.0%)
Orthostatic hypotension	0	1(0.0%)
Peripheral arterial occlusive disease	0	1(0.0%)
Vein disorder	0	1(0.0%)
Hepatobiliary Disorders	9(0.1%)	8(0.1%)
Hepatic cirrhosis	4(0.1%)	1(0.0%)
Liver disorder	2(0.0%)	2(0.0%)
Cholecystitis	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0
Nonalcoholic fatty liver disease	1(0.0%)	0
Hepatic function abnormal	0	1(0.0%)
Hepatic mass	0	1(0.0%)
Hepatic pain	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver injury	0	1(0.0%)
Cardiac Disorders	7(0.1%)	14(0.2%)
Cardiac failure	1(0.0%)	5(0.1%)
Palpitations	1(0.0%)	2(0.0%)
Atrioventricular block	1(0.0%)	0
Cardiac failure acute	1(0.0%)	0
Cardiac failure congestive	1(0.0%)	0
Ischaemic cardiomyopathy	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Aortic valve stenosis	0	1(0.0%)
Atrial fibrillation	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Bradycardia	0	1(0.0%)
Myocardial ischaemia	0	1(0.0%)
Pericardial effusion	0	1(0.0%)
Tachycardia	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Psychiatric Disorders	5(0.1%)	8(0.1%)
Depression	1(0.0%)	1(0.0%)
Alcohol abuse	1(0.0%)	0
Anxiety	1(0.0%)	0
Bipolar disorder	1(0.0%)	0
Mental status changes	1(0.0%)	0
Confusional state	0	2(0.0%)
Anorgasmia	0	1(0.0%)
Behaviour disorder	0	1(0.0%)
Depressed mood	0	1(0.0%)
Nervousness	0	1(0.0%)
Suicidal ideation	0	1(0.0%)
Injury, Poisoning And Procedural Complications	5(0.1%)	6(0.1%)
Craniocerebral injury	1(0.0%)	1(0.0%)
Road traffic accident	1(0.0%)	1(0.0%)
Femoral neck fracture	1(0.0%)	0
Hip fracture	1(0.0%)	0
Subdural haemorrhage	1(0.0%)	0
Brain contusion	0	1(0.0%)
Concussion	0	1(0.0%)
Fall	0	1(0.0%)
Femur fracture	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Lumbar vertebral fracture	0	1(0.0%)
Radius fracture	0	1(0.0%)
Rib fracture	0	1(0.0%)
Skull fracture	0	1(0.0%)
Subdural haematoma	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Surgical And Medical Procedures	4(0.1%)	0
Dialysis	1(0.0%)	0
Leg amputation	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Blood And Lymphatic System Disorders	3(0.0%)	4(0.1%)
Anaemia	2(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	0
Blood loss anaemia	0	2(0.0%)
Iron deficiency anaemia	0	1(0.0%)
Immune System Disorders	3(0.0%)	1(0.0%)
Hypersensitivity	2(0.0%)	1(0.0%)
Drug hypersensitivity	1(0.0%)	0
Eye Disorders	1(0.0%)	2(0.0%)
Scleritis	1(0.0%)	0
Optic ischaemic neuropathy	0	1(0.0%)
Periorbital swelling	0	1(0.0%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

Table 2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set

MedDRA SOC and PT	Finerenone (N=6510)	Placebo (N=6489)
Reproductive System And Breast Disorders	1(0.0%)	1(0.0%)
Erectile dysfunction	1(0.0%)	1(0.0%)
Ear And Labyrinth Disorders	0	5(0.1%)
Vertigo	0	5(0.1%)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; N=number of subjects; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

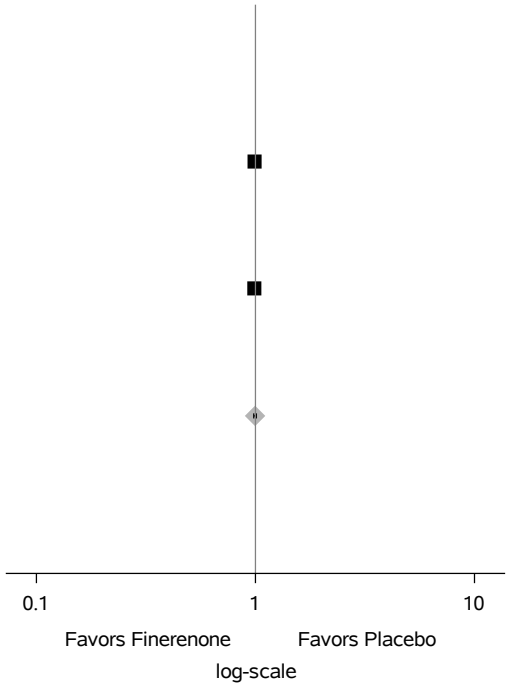
Table 2.0.5: Summary of Treatment Duration - Safety Analysis Set

	Finerenone (N=6510)	Placebo (N=6489)	Total (N=12999
Treatment duration (months)			
n	6510	6489	12999
Mean	31.6	31.8	31.7
SD	14.42	14.18	14.30
Median	31.7	31.7	31.7
Q1-Q3	22.3 - 43.0	22.8 - 43.2	22.6 - 43.1
Range	0.03 - 61.01	0.03 - 61.37	0.03 - 61.37

Abbreviations: N=number of subjects, n=number of subjects with non-missing values in category, Q1=first quartile, Q3=third quartile, SD=standard deviation.
Note: Treatment duration is defined as the time from start of study drug to permanent stop of study drug (in months).

Figure 2.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs
Safety Analysis Set

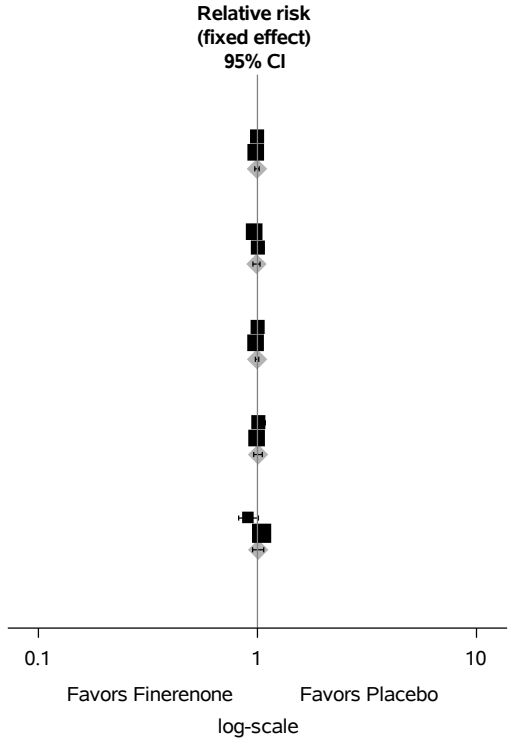
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2468 / 2827	2478 / 2831	48.0	1.00 [0.98,1.02]	
FIGARO-DKD	3134 / 3683	3129 / 3658	52.0	0.99 [0.98,1.01]	
Total	5602 / 6510	5607 / 6489		1.00 [0.98,1.01]	Z=-0.57, p=0.5694
Heterogeneity:	Q=0.03 (df=1)	p=0.8534	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Region
Safety Analysis Set

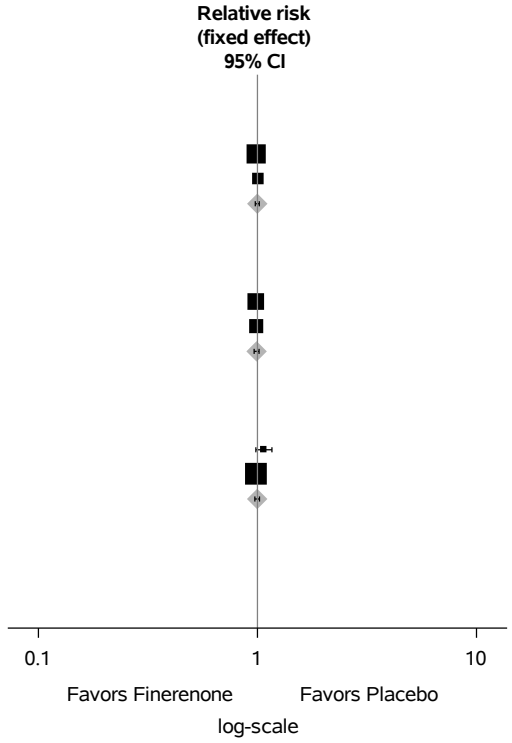
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	997 / 1178	991 / 1174	44.4	1.00 [0.97,1.04]	
FIGARO-DKD	1431 / 1752	1443 / 1747	55.6	0.99 [0.96,1.02]	
Total	2428 / 2930	2434 / 2921		0.99 [0.97,1.02]	Z=-0.43, p=0.6667
Heterogeneity:	Q=0.34 (df=1)	p=0.5586	I^2=0.0%		
North America					
FIDELIO-DKD	397 / 466	417 / 476	54.8	0.97 [0.92,1.02]	
FIGARO-DKD	459 / 559	445 / 548	45.2	1.01 [0.96,1.07]	
Total	856 / 1025	862 / 1024		0.99 [0.95,1.03]	Z=-0.54, p=0.5900
Heterogeneity:	Q=1.03 (df=1)	p=0.3108	I^2=2.6%		
Asia					
FIDELIO-DKD	738 / 790	728 / 786	42.6	1.01 [0.98,1.04]	
FIGARO-DKD	762 / 811	774 / 813	57.4	0.99 [0.96,1.01]	
Total	1500 / 1601	1502 / 1599		1.00 [0.98,1.01]	Z=-0.44, p=0.6625
Heterogeneity:	Q=1.42 (df=1)	p=0.2329	I^2=29.7%		
Latin America					
FIDELIO-DKD	253 / 294	249 / 294	45.3	1.02 [0.95,1.09]	
FIGARO-DKD	352 / 424	347 / 417	54.7	1.00 [0.94,1.06]	
Total	605 / 718	596 / 711		1.01 [0.96,1.05]	Z=0.26, p=0.7959
Heterogeneity:	Q=0.16 (df=1)	p=0.6922	I^2=0.0%		
Others					
FIDELIO-DKD	83 / 99	93 / 101	30.1	0.91 [0.82,1.01]	
FIGARO-DKD	130 / 137	120 / 133	69.9	1.05 [0.98,1.13]	
Total	213 / 236	213 / 234		1.01 [0.95,1.07]	Z=0.25, p=0.8051
Heterogeneity:	Q=5.19 (df=1)	p=0.0227	I^2=80.7%		
Subgroup Heterogeneity:	Q=0.45 (df=4)	p=0.9784	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

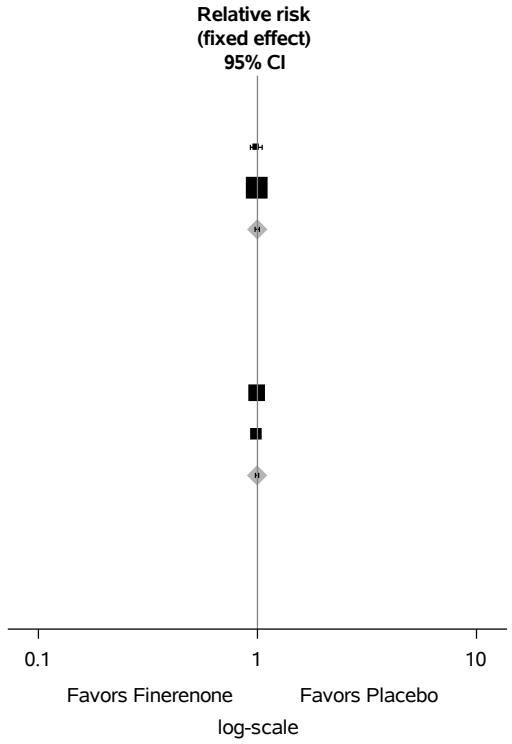
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	1381 / 1556	1377 / 1541	72.1	0.99 [0.97,1.02]	
FIGARO-DKD	567 / 637	552 / 627	27.9	1.01 [0.97,1.05]	
Total	1948 / 2193	1929 / 2168		1.00 [0.98,1.02]	Z=-0.17, p=0.8644
Heterogeneity:	Q=0.56 (df=1)	p=0.4563	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	906 / 1061	923 / 1069	56.0	0.99 [0.96,1.02]	
FIGARO-DKD	628 / 720	640 / 729	44.0	0.99 [0.96,1.03]	
Total	1534 / 1781	1563 / 1798		0.99 [0.97,1.02]	Z=-0.69, p=0.4909
Heterogeneity:	Q=0.03 (df=1)	p=0.8631	I^2=0.0%		
>= 60					
FIDELIO-DKD	181 / 210	178 / 221	8.3	1.07 [0.98,1.16]	
FIGARO-DKD	1939 / 2326	1937 / 2302	91.7	0.99 [0.97,1.02]	
Total	2120 / 2536	2115 / 2523		1.00 [0.97,1.02]	Z=-0.24, p=0.8105
Heterogeneity:	Q=2.94 (df=1)	p=0.0865	I^2=66.0%		
Subgroup Heterogeneity:	Q=0.20 (df=2)	p=0.9068	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.1.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set

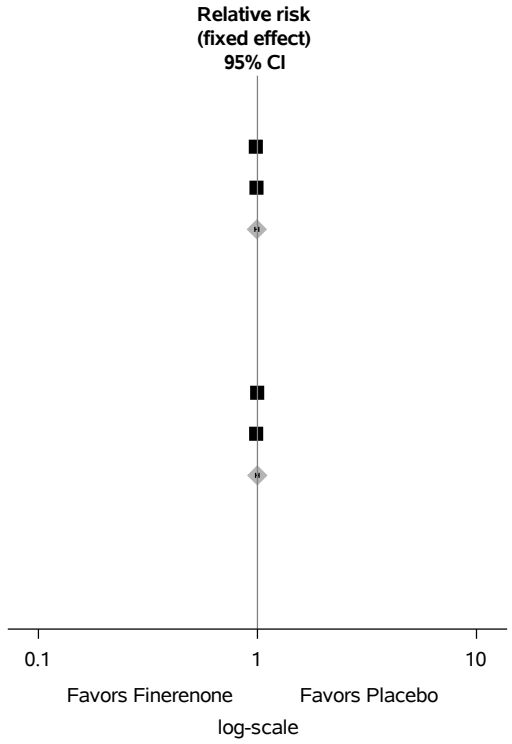
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	188 / 209	194 / 213	13.2	0.99 [0.93,1.05]	
FIGARO-DKD	1522 / 1720	1504 / 1698	86.8	1.00 [0.98,1.02]	
Total	1710 / 1929	1698 / 1911		1.00 [0.98,1.02]	Z=-0.22, p=0.8276
Heterogeneity:	Q=0.12 (df=1)	p=0.7345	I^2=0.0%		
Very High					
FIDELIO-DKD	2280 / 2618	2284 / 2618	65.8	1.00 [0.98,1.02]	
FIGARO-DKD	1612 / 1963	1625 / 1960	34.2	0.99 [0.96,1.02]	
Total	3892 / 4581	3909 / 4578		1.00 [0.98,1.01]	Z=-0.51, p=0.6068
Heterogeneity:	Q=0.19 (df=1)	p=0.6666	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.1.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set

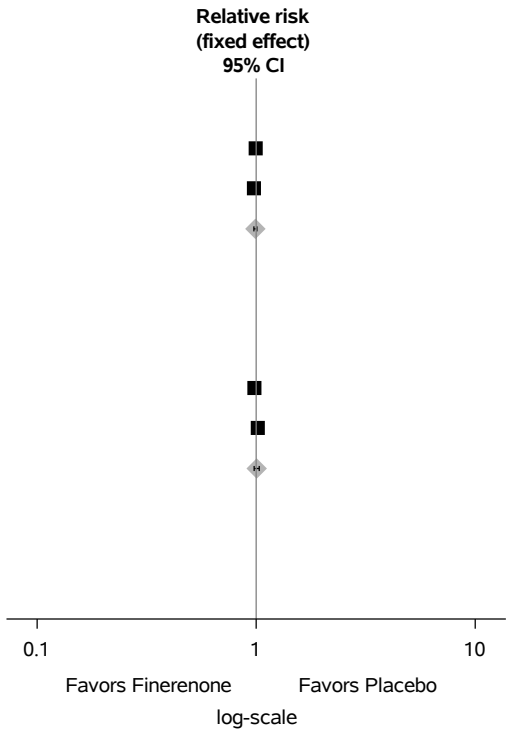
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1123 / 1301	1133 / 1299	47.0	0.99 [0.96,1.02]	
FIGARO-DKD	1424 / 1673	1410 / 1651	53.0	1.00 [0.97,1.03]	
Total	2547 / 2974	2543 / 2950		0.99 [0.97,1.01]	Z=-0.64, p=0.5253
Heterogeneity:	Q=0.11 (df=1)	p=0.7377	I^2=0.0%		
Absent					
FIDELIO-DKD	1345 / 1526	1345 / 1532	48.8	1.00 [0.98,1.03]	
FIGARO-DKD	1710 / 2010	1719 / 2007	51.2	0.99 [0.97,1.02]	
Total	3055 / 3536	3064 / 3539		1.00 [0.98,1.02]	Z=-0.16, p=0.8696
Heterogeneity:	Q=0.33 (df=1)	p=0.5684	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7149	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.1.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

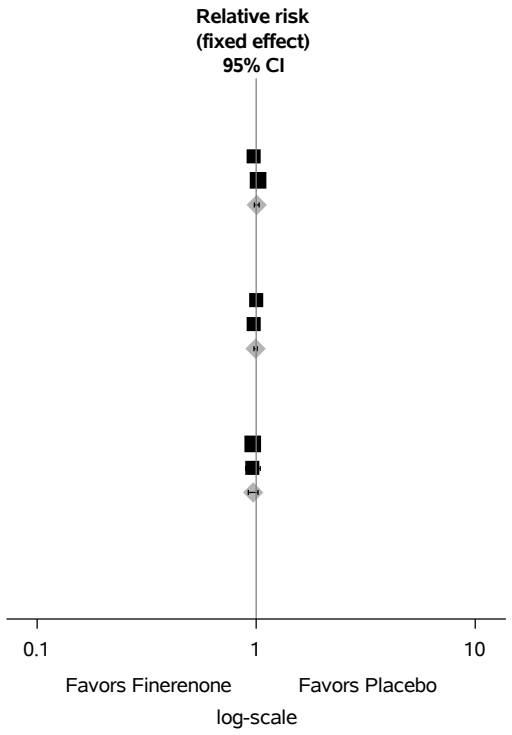
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1665 / 1879	1644 / 1858	47.0	1.00 [0.98,1.02]	
FIGARO-DKD	2257 / 2643	2265 / 2608	53.0	0.98 [0.96,1.00]	
Total	3922 / 4522	3909 / 4466		0.99 [0.98,1.01]	Z=-1.02, p=0.3059
Heterogeneity:	Q=1.29 (df=1)	p=0.2569	I^2=22.2%		
> 4.5					
FIDELIO-DKD	803 / 948	834 / 973	51.4	0.99 [0.95,1.03]	
FIGARO-DKD	877 / 1040	863 / 1048	48.6	1.02 [0.99,1.06]	
Total	1680 / 1988	1697 / 2021		1.01 [0.98,1.03]	Z=0.40, p=0.6901
Heterogeneity:	Q=1.70 (df=1)	p=0.1921	I^2=41.2%		
Subgroup Heterogeneity:	Q=0.75 (df=1)	p=0.3874	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.1.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

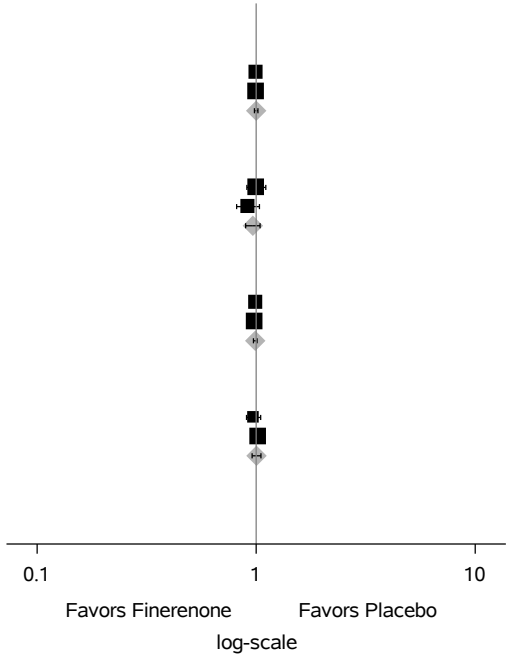
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	682 / 788	686 / 777	44.7	0.98 [0.94,1.02]	
FIGARO-DKD	1022 / 1187	1001 / 1194	55.3	1.03 [0.99,1.06]	
Total	1704 / 1975	1687 / 1971		1.01 [0.98,1.03]	Z=0.46, p=0.6477
Heterogeneity:	Q=3.26 (df=1)	p=0.0712	I^2=69.3%		
130 - < 160					
FIDELIO-DKD	1658 / 1897	1663 / 1916	48.6	1.01 [0.98,1.03]	
FIGARO-DKD	2015 / 2389	2022 / 2351	51.4	0.98 [0.96,1.00]	
Total	3673 / 4286	3685 / 4267		0.99 [0.98,1.01]	Z=-0.77, p=0.4442
Heterogeneity:	Q=2.32 (df=1)	p=0.1281	I^2=56.8%		
>= 160					
FIDELIO-DKD	128 / 141	129 / 138	55.8	0.97 [0.91,1.04]	
FIGARO-DKD	97 / 107	106 / 113	44.2	0.97 [0.89,1.04]	
Total	225 / 248	235 / 251		0.97 [0.92,1.02]	Z=-1.20, p=0.2289
Heterogeneity:	Q=0.01 (df=1)	p=0.9262	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=2)	p=0.4119	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Race
Safety Analysis Set

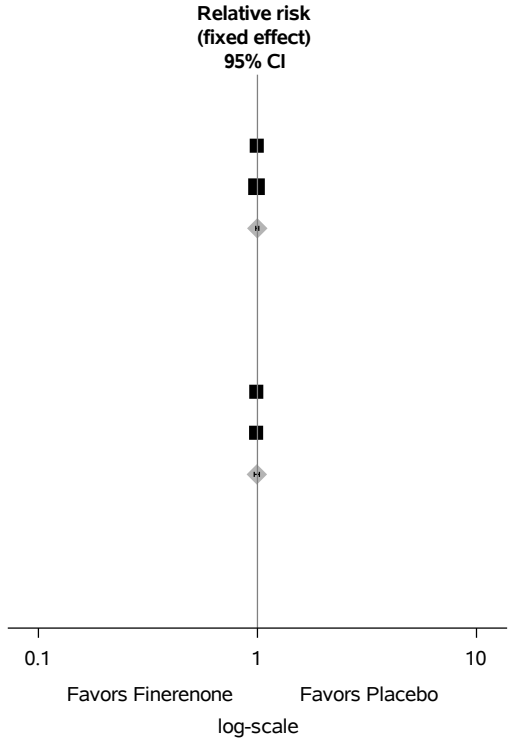
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	1512 / 1773	1543 / 1809	45.5	1.00 [0.97,1.03]	
FIGARO-DKD	2202 / 2668	2146 / 2601	54.5	1.00 [0.98,1.03]	
Total	3714 / 4441	3689 / 4410		1.00 [0.98,1.02]	Z=0.01, p=0.9923
Heterogeneity:	Q=0.00 (df=1)	p=0.9779	I^2=0.0%		
Black					
FIDELIO-DKD	119 / 139	106 / 124	59.2	1.00 [0.91,1.11]	
FIGARO-DKD	88 / 113	123 / 145	40.8	0.92 [0.81,1.04]	
Total	207 / 252	229 / 269		0.97 [0.90,1.04]	Z=-0.90, p=0.3656
Heterogeneity:	Q=1.20 (df=1)	p=0.2739	I^2=16.4%		
Asian					
FIDELIO-DKD	665 / 717	671 / 721	44.1	1.00 [0.97,1.03]	
FIGARO-DKD	670 / 716	699 / 736	55.9	0.99 [0.96,1.01]	
Total	1335 / 1433	1370 / 1457		0.99 [0.97,1.01]	Z=-1.01, p=0.3106
Heterogeneity:	Q=0.34 (df=1)	p=0.5586	I^2=0.0%		
Others					
FIDELIO-DKD	172 / 198	158 / 177	38.4	0.97 [0.90,1.05]	
FIGARO-DKD	174 / 186	161 / 176	61.6	1.02 [0.96,1.08]	
Total	346 / 384	319 / 353		1.00 [0.96,1.05]	Z=0.15, p=0.8786
Heterogeneity:	Q=1.05 (df=1)	p=0.3054	I^2=4.8%		
Subgroup Heterogeneity:	Q=1.28 (df=3)	p=0.7348	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.1.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set

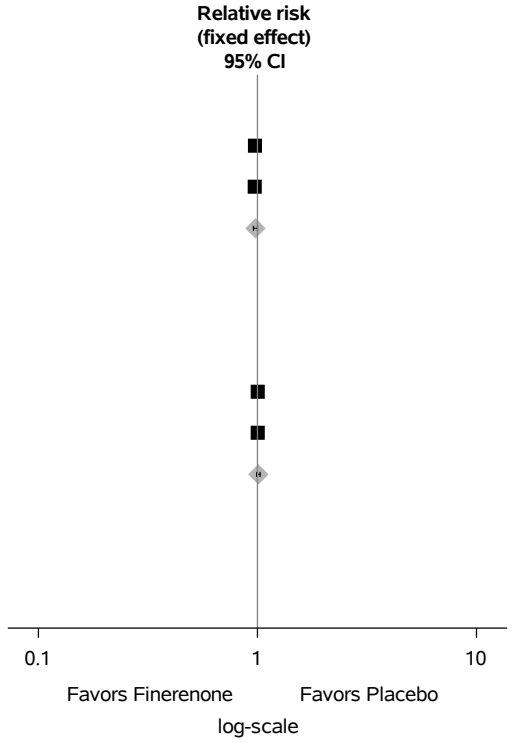
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1713 / 1949	1780 / 2024	46.6	1.00 [0.98,1.02]	
FIGARO-DKD	2186 / 2527	2231 / 2571	53.4	1.00 [0.98,1.02]	
Total	3899 / 4476	4011 / 4595		1.00 [0.98,1.01]	Z=-0.24, p=0.8087
Heterogeneity:	Q=0.02 (df=1)	p=0.8763	I^2=0.0%		
Female					
FIDELIO-DKD	755 / 878	698 / 807	50.3	0.99 [0.96,1.03]	
FIGARO-DKD	948 / 1156	898 / 1087	49.7	0.99 [0.96,1.03]	
Total	1703 / 2034	1596 / 1894		0.99 [0.97,1.02]	Z=-0.48, p=0.6333
Heterogeneity:	Q=0.00 (df=1)	p=0.9557	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7714	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.1.9: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set

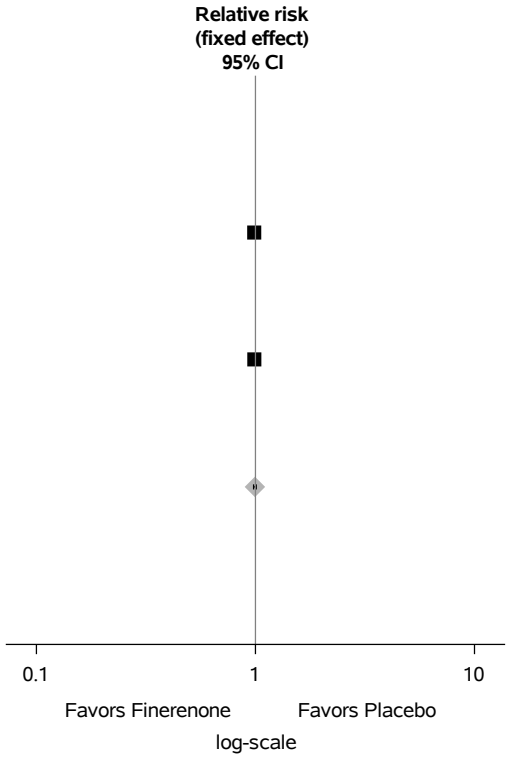
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1039 / 1201	1033 / 1171	47.2	0.98 [0.95,1.01]	
FIGARO-DKD	1455 / 1752	1490 / 1755	52.8	0.98 [0.95,1.01]	
Total	2494 / 2953	2523 / 2926		0.98 [0.96,1.00]	Z=-1.94, p=0.0519
Heterogeneity:	Q=0.01 (df=1)	p=0.9054	I^2=0.0%		
>= 65					
FIDELIO-DKD	1429 / 1626	1445 / 1660	48.2	1.01 [0.98,1.04]	
FIGARO-DKD	1679 / 1931	1639 / 1903	51.8	1.01 [0.98,1.04]	
Total	3108 / 3557	3084 / 3563		1.01 [0.99,1.03]	Z=1.04, p=0.2986
Heterogeneity:	Q=0.00 (df=1)	p=0.9976	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.64 (df=1)	p=0.0313	I^2=78.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set

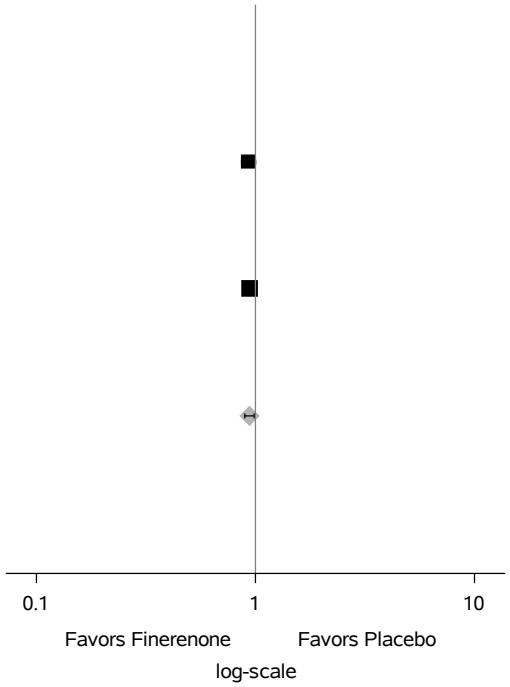
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2439 / 2827	2458 / 2831	47.2	0.99 [0.97,1.01]	
FIGARO-DKD	3112 / 3683	3107 / 3658	52.8	0.99 [0.98,1.01]	
Total	5551 / 6510	5565 / 6489		0.99 [0.98,1.01]	Z=-0.80, p=0.4253
Heterogeneity:	Q=0.01 (df=1)	p=0.9369	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs
Safety Analysis Set

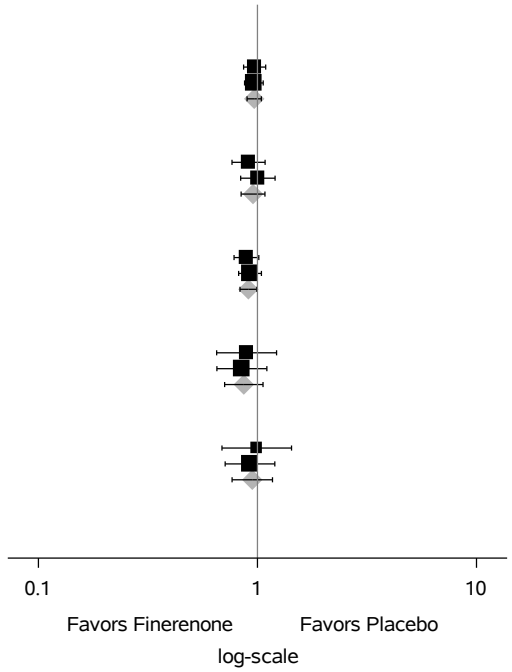
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	902 / 2827	971 / 2831	44.4	0.93 [0.86,1.00]	
FIGARO-DKD	1158 / 3683	1215 / 3658	55.6	0.95 [0.89,1.01]	
Total	2060 / 6510	2186 / 6489		0.94 [0.89,0.99]	Z=-2.48, p=0.0130
Heterogeneity:	Q=0.12 (df=1)	p=0.7310	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.3.1: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Region
Safety Analysis Set

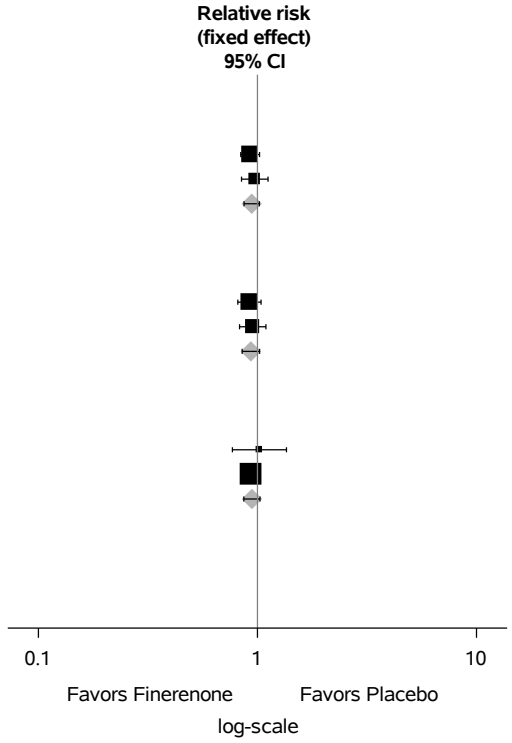
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	379 / 1178	389 / 1174	41.6	0.97 [0.86,1.09]	
FIGARO-DKD	539 / 1752	558 / 1747	58.4	0.96 [0.87,1.06]	
Total	918 / 2930	947 / 2921		0.97 [0.90,1.04]	Z=-0.89, p=0.3717
Heterogeneity:	Q=0.01 (df=1)	p=0.9172	I^2=0.0%		
North America					
FIDELIO-DKD	156 / 466	175 / 476	51.9	0.91 [0.77,1.08]	
FIGARO-DKD	167 / 559	163 / 548	48.1	1.00 [0.84,1.20]	
Total	323 / 1025	338 / 1024		0.95 [0.84,1.08]	Z=-0.73, p=0.4657
Heterogeneity:	Q=0.59 (df=1)	p=0.4436	I^2=0.0%		
Asia					
FIDELIO-DKD	273 / 790	305 / 786	45.9	0.89 [0.78,1.01]	
FIGARO-DKD	310 / 811	336 / 813	54.1	0.92 [0.82,1.04]	
Total	583 / 1601	641 / 1599		0.91 [0.83,0.99]	Z=-2.12, p=0.0337
Heterogeneity:	Q=0.18 (df=1)	p=0.6750	I^2=0.0%		
Latin America					
FIDELIO-DKD	58 / 294	65 / 294	41.0	0.89 [0.65,1.22]	
FIGARO-DKD	82 / 424	95 / 417	59.0	0.85 [0.65,1.10]	
Total	140 / 718	160 / 711		0.87 [0.71,1.06]	Z=-1.39, p=0.1636
Heterogeneity:	Q=0.06 (df=1)	p=0.8117	I^2=0.0%		
Others					
FIDELIO-DKD	36 / 99	37 / 101	33.7	0.99 [0.69,1.43]	
FIGARO-DKD	60 / 137	63 / 133	66.3	0.92 [0.71,1.20]	
Total	96 / 236	100 / 234		0.95 [0.77,1.17]	Z=-0.50, p=0.6151
Heterogeneity:	Q=0.10 (df=1)	p=0.7566	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=4)	p=0.7775	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.3.2: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

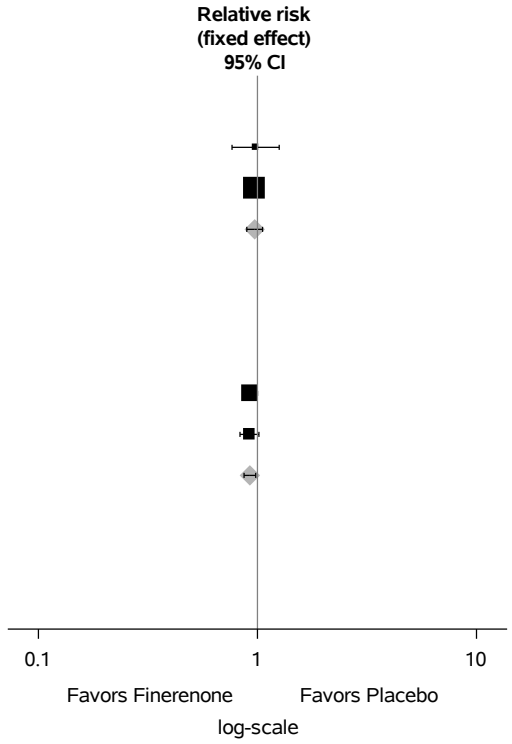
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	505 / 1556	540 / 1541	66.5	0.93 [0.84,1.02]	
FIGARO-DKD	242 / 637	245 / 627	33.5	0.97 [0.85,1.12]	
Total	747 / 2193	785 / 2168		0.94 [0.87,1.02]	Z=-1.47, p=0.1414
Heterogeneity:	Q=0.31 (df=1)	p=0.5773	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	332 / 1061	364 / 1069	56.3	0.92 [0.81,1.04]	
FIGARO-DKD	250 / 720	266 / 729	43.7	0.95 [0.83,1.09]	
Total	582 / 1781	630 / 1798		0.93 [0.85,1.02]	Z=-1.48, p=0.1384
Heterogeneity:	Q=0.14 (df=1)	p=0.7112	I^2=0.0%		
>= 60					
FIDELIO-DKD	65 / 210	67 / 221	8.9	1.02 [0.77,1.36]	
FIGARO-DKD	666 / 2326	704 / 2302	91.1	0.94 [0.86,1.02]	
Total	731 / 2536	771 / 2523		0.94 [0.87,1.03]	Z=-1.34, p=0.1792
Heterogeneity:	Q=0.33 (df=1)	p=0.5686	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=2)	p=0.9835	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.3.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set

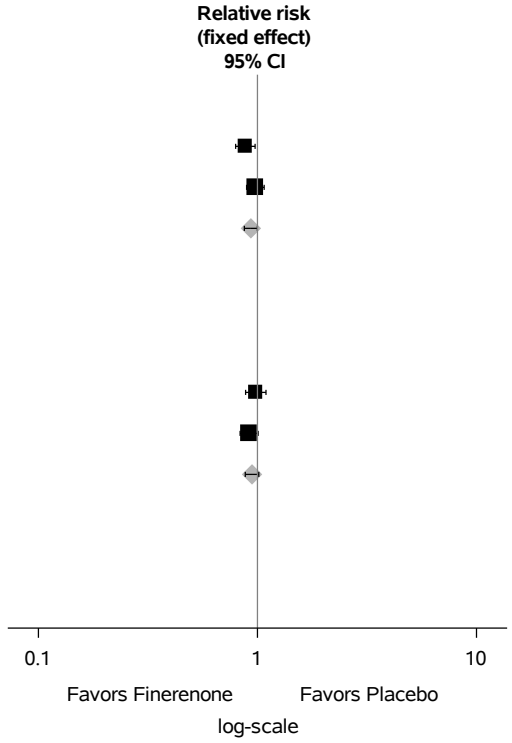
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 209	80 / 213	11.2	0.98 [0.77,1.26]	
FIGARO-DKD	623 / 1720	634 / 1698	88.8	0.97 [0.89,1.06]	
Total	700 / 1929	714 / 1911		0.97 [0.89,1.06]	Z=-0.69, p=0.4907
Heterogeneity:	Q=0.01 (df=1)	p=0.9340	I^2=0.0%		
Very High					
FIDELIO-DKD	825 / 2618	891 / 2618	62.1	0.93 [0.86,1.00]	
FIGARO-DKD	535 / 1963	581 / 1960	37.9	0.92 [0.83,1.02]	
Total	1360 / 4581	1472 / 4578		0.92 [0.87,0.98]	Z=-2.55, p=0.0108
Heterogeneity:	Q=0.01 (df=1)	p=0.9127	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3366	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.3.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set

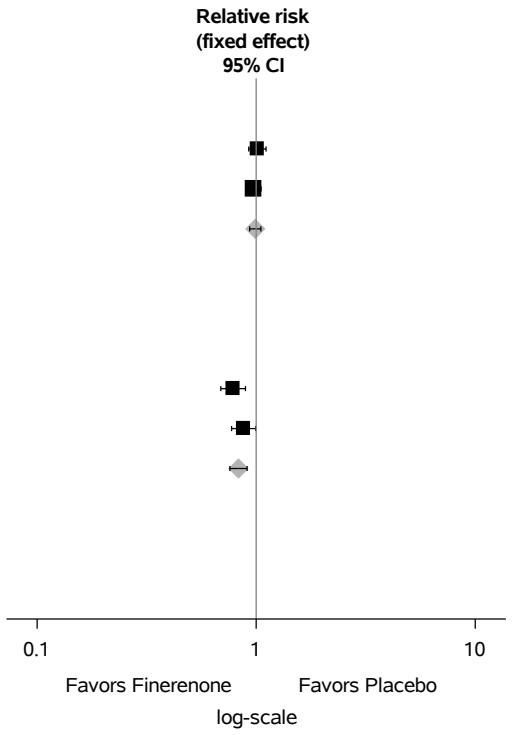
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	441 / 1301	500 / 1299	44.9	0.88 [0.79,0.98]	
FIGARO-DKD	581 / 1673	586 / 1651	55.1	0.98 [0.89,1.07]	
Total	1022 / 2974	1086 / 2950		0.93 [0.87,1.00]	Z=-1.98, p=0.0479
Heterogeneity:	Q=2.24 (df=1)	p=0.1346	I^2=55.3%		
Absent					
FIDELIO-DKD	461 / 1526	471 / 1532	43.8	0.98 [0.88,1.09]	
FIGARO-DKD	577 / 2010	629 / 2007	56.2	0.92 [0.83,1.01]	
Total	1038 / 3536	1100 / 3539		0.94 [0.88,1.01]	Z=-1.58, p=0.1147
Heterogeneity:	Q=0.93 (df=1)	p=0.3351	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8090	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.3.5: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

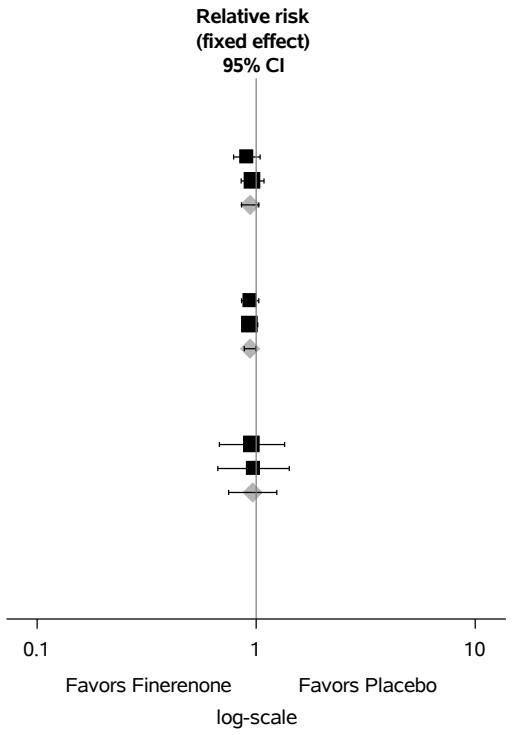
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	629 / 1879	614 / 1858	42.3	1.01 [0.93,1.11]	
FIGARO-DKD	851 / 2643	862 / 2608	57.7	0.97 [0.90,1.05]	
Total	1480 / 4522	1476 / 4466		0.99 [0.93,1.05]	Z=-0.32, p=0.7487
Heterogeneity:	Q=0.41 (df=1)	p=0.5219	I^2=0.0%		
> 4.5					
FIDELIO-DKD	273 / 948	357 / 973	48.8	0.78 [0.69,0.89]	
FIGARO-DKD	307 / 1040	353 / 1048	51.2	0.88 [0.77,0.99]	
Total	580 / 1988	710 / 2021		0.83 [0.76,0.91]	Z=-4.03, p=<.0001
Heterogeneity:	Q=1.42 (df=1)	p=0.2332	I^2=29.6%		
Subgroup Heterogeneity:	Q=10.23 (df=1)	p=0.0014	I^2=90.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.3.6: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

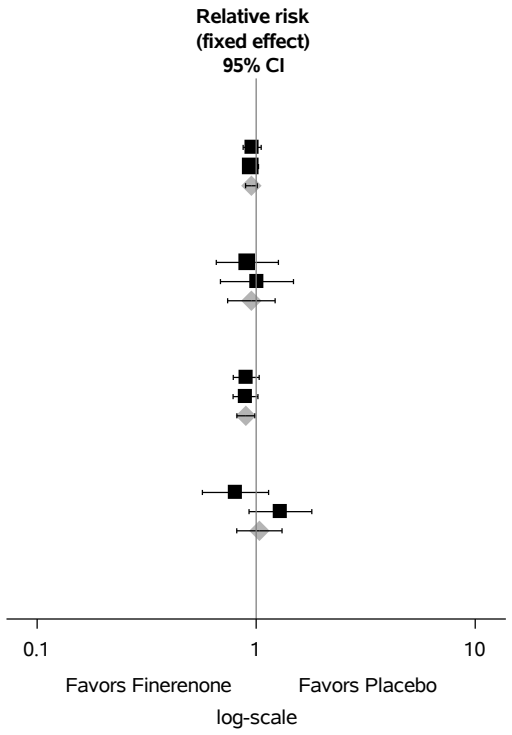
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	252 / 788	274 / 777	42.5	0.91 [0.79,1.04]	
FIGARO-DKD	361 / 1187	377 / 1194	57.5	0.96 [0.85,1.09]	
Total	613 / 1975	651 / 1971		0.94 [0.86,1.03]	Z=-1.36, p=0.1735
Heterogeneity:	Q=0.41 (df=1)	p=0.5207	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	606 / 1897	652 / 1916	44.6	0.94 [0.86,1.03]	
FIGARO-DKD	762 / 2389	800 / 2351	55.4	0.94 [0.86,1.02]	
Total	1368 / 4286	1452 / 4267		0.94 [0.88,1.00]	Z=-2.08, p=0.0380
Heterogeneity:	Q=0.00 (df=1)	p=0.9807	I^2=0.0%		
>= 160					
FIDELIO-DKD	44 / 141	45 / 138	54.5	0.96 [0.68,1.35]	
FIGARO-DKD	35 / 107	38 / 113	45.5	0.97 [0.67,1.42]	
Total	79 / 248	83 / 251		0.96 [0.75,1.24]	Z=-0.28, p=0.7772
Heterogeneity:	Q=0.00 (df=1)	p=0.9499	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=2)	p=0.9788	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.3.7: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Race
Safety Analysis Set

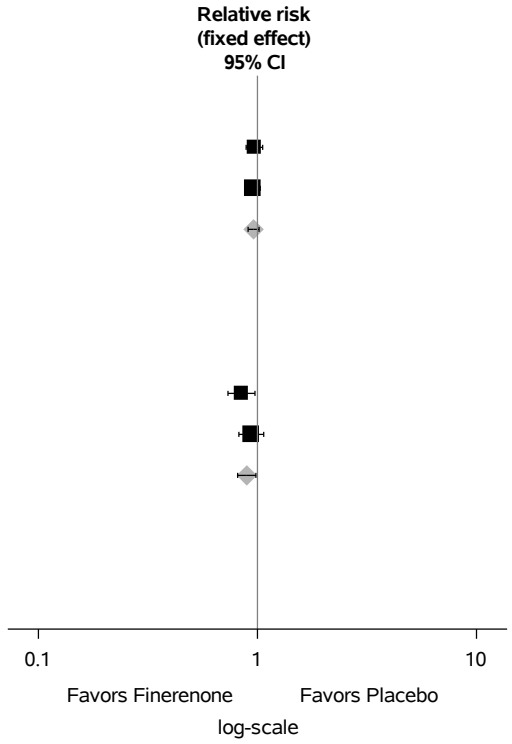
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	561 / 1773	597 / 1809	41.9	0.96 [0.87,1.05]	
FIGARO-DKD	805 / 2668	830 / 2601	58.1	0.95 [0.87,1.02]	
Total	1366 / 4441	1427 / 4410		0.95 [0.89,1.01]	Z=-1.60, p=0.1091
Heterogeneity:	Q=0.05 (df=1)	p=0.8264	I^2=0.0%		
Black					
FIDELIO-DKD	47 / 139	46 / 124	58.0	0.91 [0.66,1.26]	
FIGARO-DKD	33 / 113	42 / 145	42.0	1.01 [0.69,1.48]	
Total	80 / 252	88 / 269		0.95 [0.74,1.22]	Z=-0.40, p=0.6918
Heterogeneity:	Q=0.15 (df=1)	p=0.6949	I^2=0.0%		
Asian					
FIDELIO-DKD	249 / 717	278 / 721	47.9	0.90 [0.79,1.03]	
FIGARO-DKD	260 / 716	299 / 736	52.1	0.89 [0.78,1.02]	
Total	509 / 1433	577 / 1457		0.90 [0.82,0.99]	Z=-2.26, p=0.0240
Heterogeneity:	Q=0.01 (df=1)	p=0.9370	I^2=0.0%		
Others					
FIDELIO-DKD	45 / 198	50 / 177	47.3	0.80 [0.57,1.14]	
FIGARO-DKD	60 / 186	44 / 176	52.7	1.29 [0.93,1.79]	
Total	105 / 384	94 / 353		1.03 [0.82,1.31]	Z=0.28, p=0.7805
Heterogeneity:	Q=3.73 (df=1)	p=0.0535	I^2=73.2%		
Subgroup Heterogeneity:	Q=1.71 (df=3)	p=0.6345	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.3.8: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set

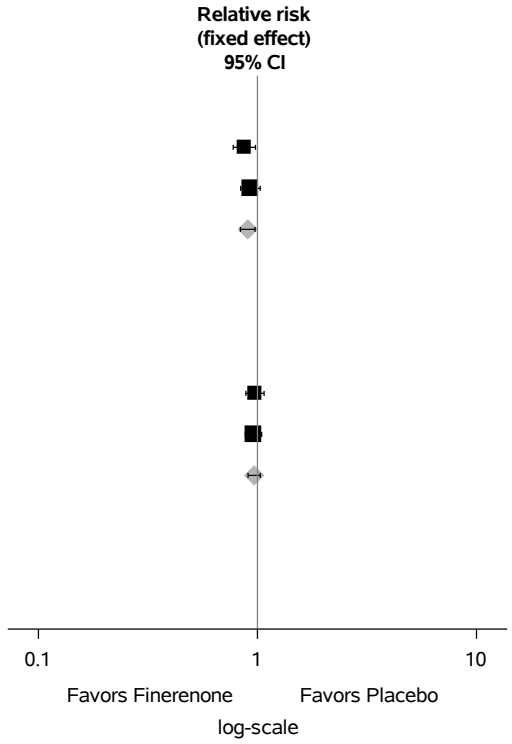
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	650 / 1949	697 / 2024	43.8	0.97 [0.89,1.06]	
FIGARO-DKD	837 / 2527	893 / 2571	56.2	0.95 [0.88,1.03]	
Total	1487 / 4476	1590 / 4595		0.96 [0.91,1.02]	Z=-1.39, p=0.1648
Heterogeneity:	Q=0.07 (df=1)	p=0.7939	I^2=0.0%		
Female					
FIDELIO-DKD	252 / 878	274 / 807	45.8	0.85 [0.73,0.97]	
FIGARO-DKD	321 / 1156	322 / 1087	54.2	0.94 [0.82,1.07]	
Total	573 / 2034	596 / 1894		0.89 [0.81,0.98]	Z=-2.29, p=0.0221
Heterogeneity:	Q=1.10 (df=1)	p=0.2933	I^2=9.4%		
Subgroup Heterogeneity:	Q=1.56 (df=1)	p=0.2114	I^2=36.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.3.9: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set

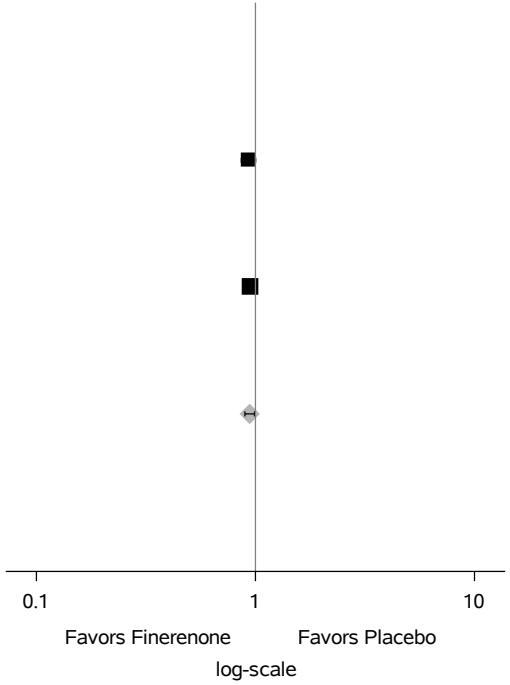
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	361 / 1201	404 / 1171	43.6	0.87 [0.78,0.98]	
FIGARO-DKD	495 / 1752	534 / 1755	56.4	0.93 [0.84,1.03]	
Total	856 / 2953	938 / 2926		0.90 [0.84,0.98]	Z=-2.59, p=0.0096
Heterogeneity:	Q=0.64 (df=1)	p=0.4226	I^2=0.0%		
>= 65					
FIDELIO-DKD	541 / 1626	567 / 1660	44.7	0.97 [0.89,1.07]	
FIGARO-DKD	663 / 1931	681 / 1903	55.3	0.96 [0.88,1.05]	
Total	1204 / 3557	1248 / 3563		0.97 [0.91,1.03]	Z=-1.06, p=0.2897
Heterogeneity:	Q=0.05 (df=1)	p=0.8179	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.73 (df=1)	p=0.1885	I^2=42.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set

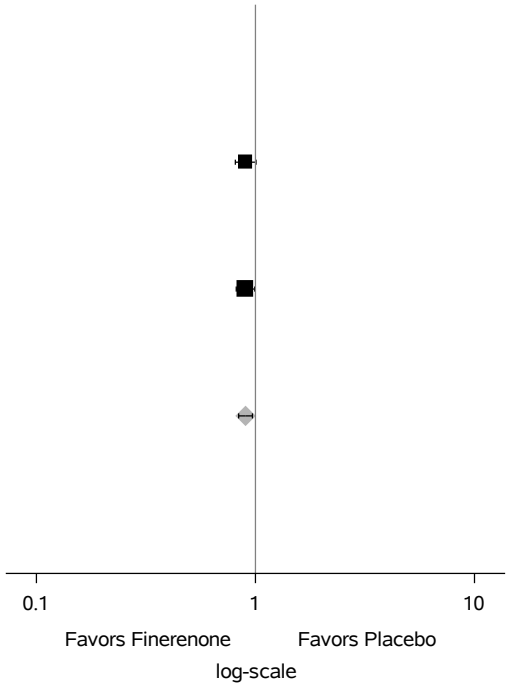
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	878 / 2827	946 / 2831	43.9	0.93 [0.86,1.00]	
FIGARO-DKD	1145 / 3683	1196 / 3658	56.1	0.95 [0.89,1.02]	
Total	2023 / 6510	2142 / 6489		0.94 [0.90,0.99]	Z=-2.36, p=0.0181
Heterogeneity:	Q=0.20 (df=1)	p=0.6582	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs
Safety Analysis Set

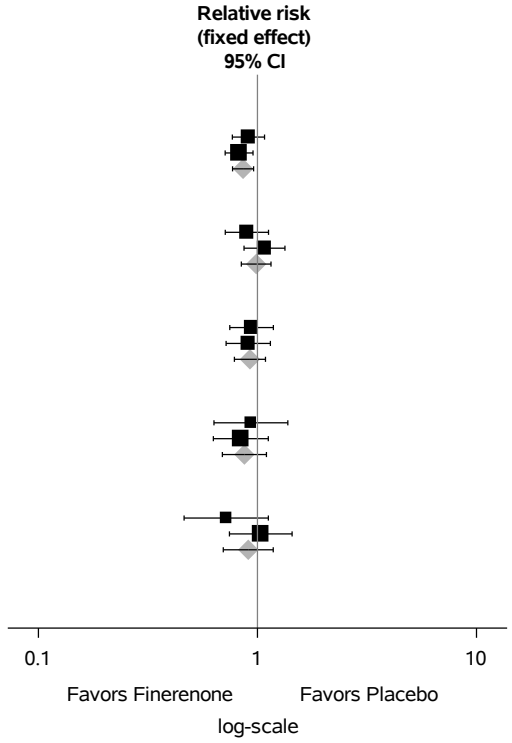
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	501 / 2827	556 / 2831	44.1	0.90 [0.81,1.01]	
FIGARO-DKD	639 / 3683	705 / 3658	55.9	0.90 [0.82,0.99]	
Total	1140 / 6510	1261 / 6489		0.90 [0.84,0.97]	Z=-2.82, p=0.0048
Heterogeneity:	Q=0.00 (df=1)	p=0.9747	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.5.1: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set

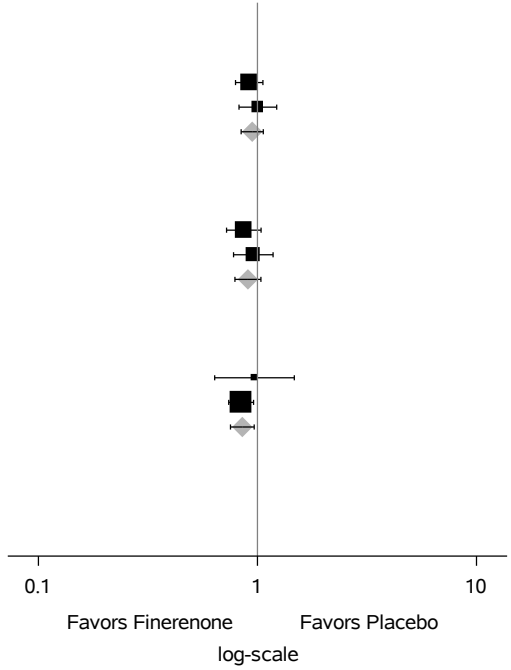
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	209 / 1178	229 / 1174	42.8	0.91 [0.77,1.08]	
FIGARO-DKD	272 / 1752	329 / 1747	57.2	0.82 [0.71,0.95]	
Total	481 / 2930	558 / 2921		0.86 [0.77,0.96]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.74 (df=1)	p=0.3889	I^2=0.0%		
North America					
FIDELIO-DKD	106 / 466	121 / 476	47.2	0.89 [0.71,1.12]	
FIGARO-DKD	134 / 559	122 / 548	52.8	1.08 [0.87,1.34]	
Total	240 / 1025	243 / 1024		0.99 [0.84,1.15]	Z=-0.17, p=0.8646
Heterogeneity:	Q=1.34 (df=1)	p=0.2465	I^2=25.6%		
Asia					
FIDELIO-DKD	120 / 790	127 / 786	50.8	0.94 [0.75,1.18]	
FIGARO-DKD	115 / 811	127 / 813	49.2	0.91 [0.72,1.15]	
Total	235 / 1601	254 / 1599		0.92 [0.78,1.09]	Z=-0.95, p=0.3429
Heterogeneity:	Q=0.04 (df=1)	p=0.8336	I^2=0.0%		
Latin America					
FIDELIO-DKD	42 / 294	45 / 294	35.6	0.93 [0.63,1.38]	
FIGARO-DKD	70 / 424	82 / 417	64.4	0.84 [0.63,1.12]	
Total	112 / 718	127 / 711		0.87 [0.69,1.10]	Z=-1.16, p=0.2456
Heterogeneity:	Q=0.18 (df=1)	p=0.6680	I^2=0.0%		
Others					
FIDELIO-DKD	24 / 99	34 / 101	35.6	0.72 [0.46,1.12]	
FIGARO-DKD	48 / 137	45 / 133	64.4	1.04 [0.74,1.44]	
Total	72 / 236	79 / 234		0.91 [0.70,1.18]	Z=-0.72, p=0.4707
Heterogeneity:	Q=1.66 (df=1)	p=0.1971	I^2=39.9%		
Subgroup Heterogeneity:	Q=2.16 (df=4)	p=0.7062	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.5.2: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

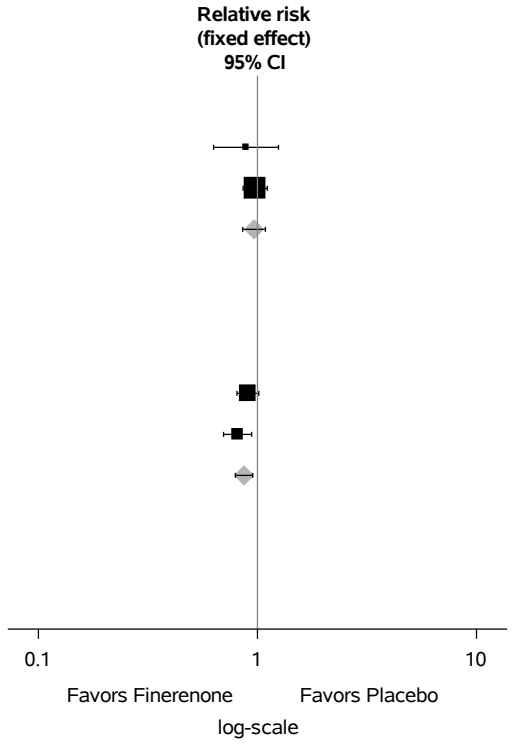
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	288 / 1556	311 / 1541	65.4	0.92 [0.79,1.06]	
FIGARO-DKD	151 / 637	148 / 627	34.6	1.00 [0.82,1.22]	
Total	439 / 2193	459 / 2168		0.95 [0.84,1.06]	Z=-0.93, p=0.3531
Heterogeneity:	Q=0.53 (df=1)	p=0.4676	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	178 / 1061	207 / 1069	56.7	0.87 [0.72,1.04]	
FIGARO-DKD	139 / 720	147 / 729	43.3	0.96 [0.78,1.18]	
Total	317 / 1781	354 / 1798		0.90 [0.79,1.04]	Z=-1.44, p=0.1502
Heterogeneity:	Q=0.50 (df=1)	p=0.4779	I^2=0.0%		
>= 60					
FIDELIO-DKD	35 / 210	38 / 221	8.9	0.97 [0.64,1.47]	
FIGARO-DKD	349 / 2326	410 / 2302	91.1	0.84 [0.74,0.96]	
Total	384 / 2536	448 / 2523		0.85 [0.75,0.97]	Z=-2.50, p=0.0124
Heterogeneity:	Q=0.39 (df=1)	p=0.5306	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=2)	p=0.4899	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.5.3: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set

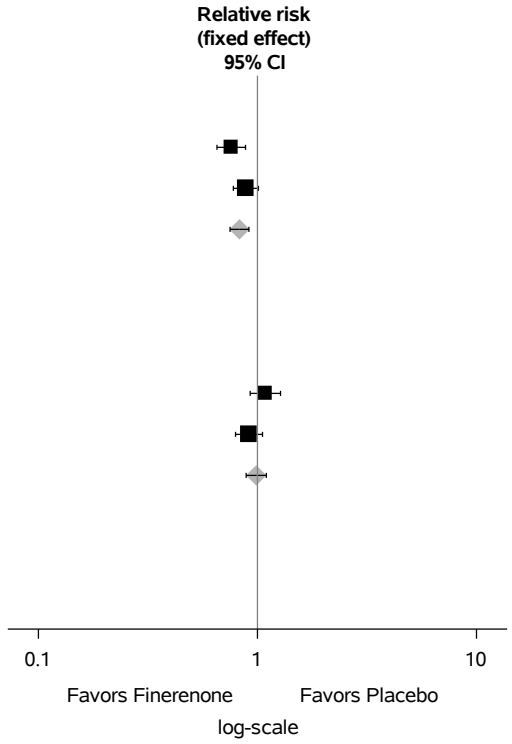
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	54 / 213	12.2	0.89 [0.63,1.25]	
FIGARO-DKD	369 / 1720	373 / 1698	87.8	0.98 [0.86,1.11]	
Total	416 / 1929	427 / 1911		0.97 [0.86,1.09]	Z=-0.58, p=0.5601
Heterogeneity:	Q=0.27 (df=1)	p=0.6046	I^2=0.0%		
Very High					
FIDELIO-DKD	454 / 2618	502 / 2618	62.4	0.90 [0.81,1.01]	
FIGARO-DKD	270 / 1963	332 / 1960	37.6	0.81 [0.70,0.94]	
Total	724 / 4581	834 / 4578		0.87 [0.79,0.95]	Z=-3.05, p=0.0023
Heterogeneity:	Q=1.27 (df=1)	p=0.2594	I^2=21.4%		
Subgroup Heterogeneity:	Q=1.91 (df=1)	p=0.1667	I^2=47.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.5.4: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set

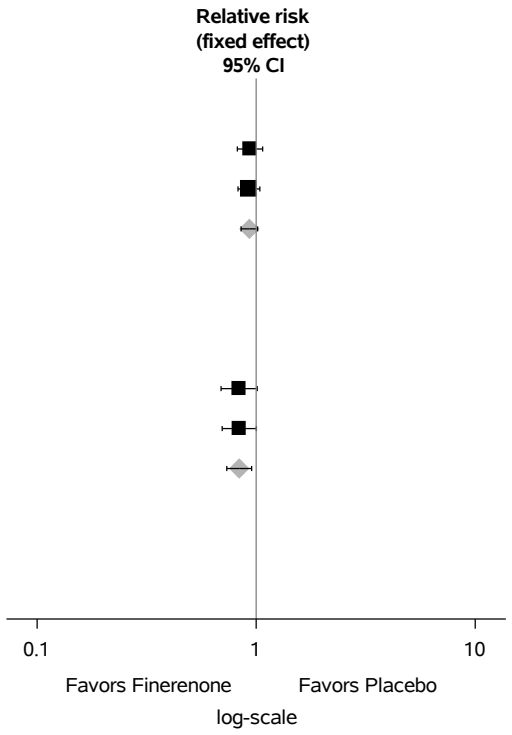
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	238 / 1301	313 / 1299	43.5	0.76 [0.65,0.88]	
FIGARO-DKD	332 / 1673	370 / 1651	56.5	0.89 [0.78,1.01]	
Total	570 / 2974	683 / 2950		0.83 [0.75,0.91]	Z=-3.75, p=0.0002
Heterogeneity:	Q=2.28 (df=1)	p=0.1308	I^2=56.2%		
Absent					
FIDELIO-DKD	263 / 1526	243 / 1532	44.3	1.09 [0.93,1.27]	
FIGARO-DKD	307 / 2010	335 / 2007	55.7	0.92 [0.79,1.05]	
Total	570 / 3536	578 / 3539		0.99 [0.89,1.10]	Z=-0.24, p=0.8133
Heterogeneity:	Q=2.49 (df=1)	p=0.1146	I^2=59.8%		
Subgroup Heterogeneity:	Q=5.69 (df=1)	p=0.0171	I^2=82.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.5.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

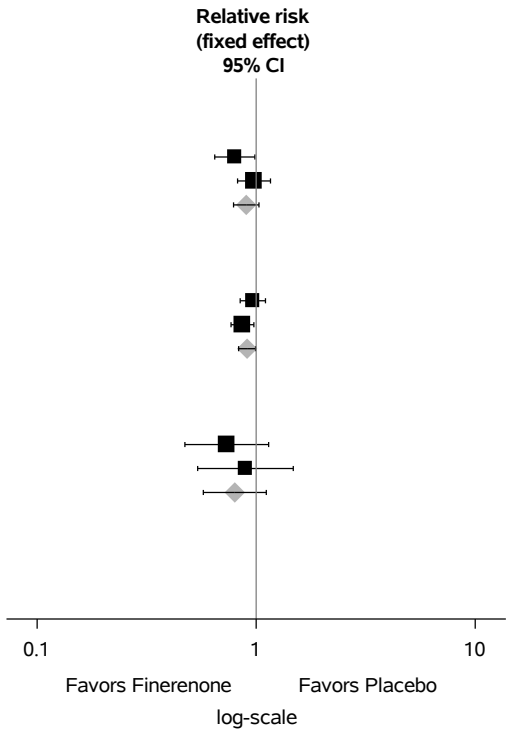
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	343 / 1879	362 / 1858	42.7	0.94 [0.82,1.07]	
FIGARO-DKD	462 / 2643	492 / 2608	57.3	0.93 [0.83,1.04]	
Total	805 / 4522	854 / 4466		0.93 [0.85,1.02]	Z=-1.61, p=0.1070
Heterogeneity:	Q=0.02 (df=1)	p=0.9016	I^2=0.0%		
> 4.5					
FIDELIO-DKD	158 / 948	194 / 973	47.3	0.84 [0.69,1.01]	
FIGARO-DKD	177 / 1040	213 / 1048	52.7	0.84 [0.70,1.00]	
Total	335 / 1988	407 / 2021		0.84 [0.73,0.95]	Z=-2.67, p=0.0075
Heterogeneity:	Q=0.00 (df=1)	p=0.9895	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.78 (df=1)	p=0.1823	I^2=43.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.5.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

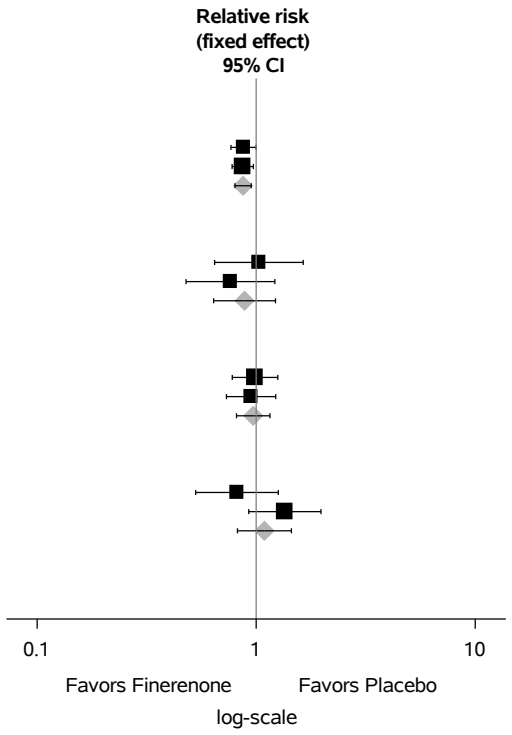
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	128 / 788	158 / 777	40.2	0.80 [0.65,0.99]	
FIGARO-DKD	208 / 1187	214 / 1194	59.8	0.98 [0.82,1.16]	
Total	336 / 1975	372 / 1971		0.90 [0.79,1.03]	Z=-1.53, p=0.1262
Heterogeneity:	Q=2.11 (df=1)	p=0.1467	I^2=52.5%		
130 - < 160					
FIDELIO-DKD	346 / 1897	362 / 1916	44.9	0.97 [0.85,1.10]	
FIGARO-DKD	409 / 2389	465 / 2351	55.1	0.87 [0.77,0.98]	
Total	755 / 4286	827 / 4267		0.91 [0.83,0.99]	Z=-2.10, p=0.0357
Heterogeneity:	Q=1.43 (df=1)	p=0.2326	I^2=29.8%		
>= 160					
FIDELIO-DKD	27 / 141	36 / 138	56.6	0.73 [0.47,1.14]	
FIGARO-DKD	22 / 107	26 / 113	43.4	0.89 [0.54,1.48]	
Total	49 / 248	62 / 251		0.80 [0.57,1.11]	Z=-1.33, p=0.1837
Heterogeneity:	Q=0.33 (df=1)	p=0.5639	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.55 (df=2)	p=0.7614	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.5.7: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set

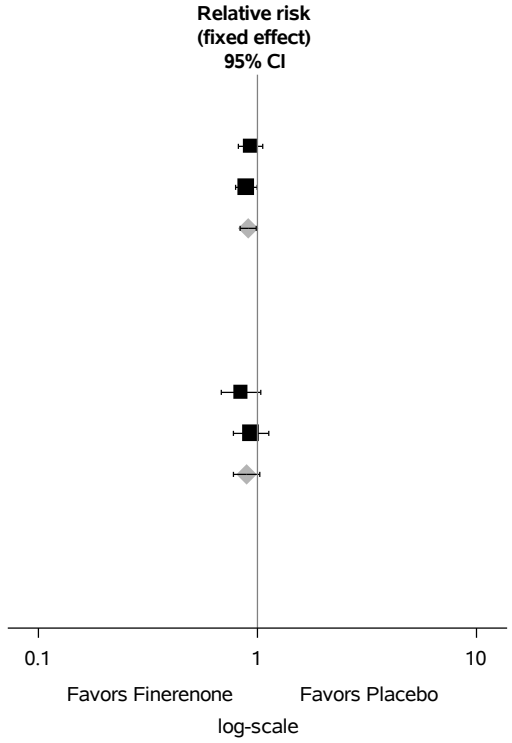
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	327 / 1773	381 / 1809	41.6	0.88 [0.77,1.00]	
FIGARO-DKD	472 / 2668	530 / 2601	58.4	0.87 [0.78,0.97]	
Total	799 / 4441	911 / 4410		0.87 [0.80,0.95]	Z=-3.16, p=0.0016
Heterogeneity:	Q=0.01 (df=1)	p=0.9226	I^2=0.0%		
Black					
FIDELIO-DKD	30 / 139	26 / 124	50.1	1.03 [0.65,1.64]	
FIGARO-DKD	22 / 113	37 / 145	49.9	0.76 [0.48,1.22]	
Total	52 / 252	63 / 269		0.88 [0.64,1.23]	Z=-0.74, p=0.4615
Heterogeneity:	Q=0.79 (df=1)	p=0.3736	I^2=0.0%		
Asian					
FIDELIO-DKD	112 / 717	114 / 721	54.0	0.99 [0.78,1.26]	
FIGARO-DKD	95 / 716	103 / 736	46.0	0.95 [0.73,1.23]	
Total	207 / 1433	217 / 1457		0.97 [0.81,1.16]	Z=-0.35, p=0.7288
Heterogeneity:	Q=0.05 (df=1)	p=0.8191	I^2=0.0%		
Others					
FIDELIO-DKD	32 / 198	35 / 177	43.3	0.82 [0.53,1.26]	
FIGARO-DKD	50 / 186	35 / 176	56.7	1.35 [0.92,1.98]	
Total	82 / 384	70 / 353		1.09 [0.82,1.45]	Z=0.60, p=0.5489
Heterogeneity:	Q=2.92 (df=1)	p=0.0874	I^2=65.8%		
Subgroup Heterogeneity:	Q=3.01 (df=3)	p=0.3901	I^2=0.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.5.8: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set

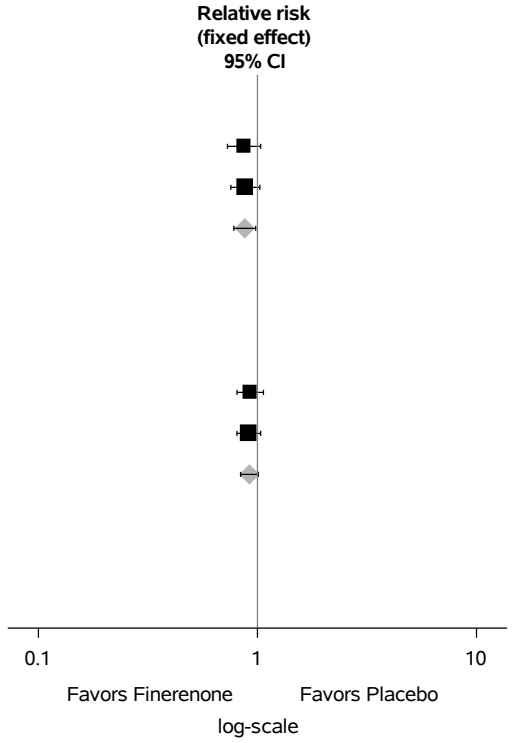
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	360 / 1949	402 / 2024	44.0	0.93 [0.82,1.06]	
FIGARO-DKD	454 / 2527	519 / 2571	56.0	0.89 [0.79,1.00]	
Total	814 / 4476	921 / 4595		0.91 [0.83,0.99]	Z=-2.25, p=0.0247
Heterogeneity:	Q=0.25 (df=1)	p=0.6142	I^2=0.0%		
Female					
FIDELIO-DKD	141 / 878	154 / 807	44.5	0.84 [0.68,1.04]	
FIGARO-DKD	185 / 1156	186 / 1087	55.5	0.94 [0.78,1.13]	
Total	326 / 2034	340 / 1894		0.89 [0.78,1.02]	Z=-1.61, p=0.1065
Heterogeneity:	Q=0.55 (df=1)	p=0.4576	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8396	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.5.9: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set

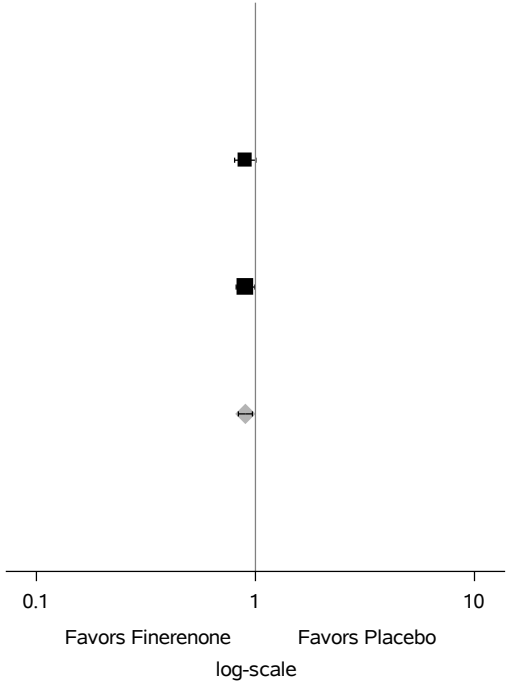
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	196 / 1201	220 / 1171	43.2	0.87 [0.73,1.03]	
FIGARO-DKD	261 / 1752	297 / 1755	56.8	0.88 [0.76,1.03]	
Total	457 / 2953	517 / 2926		0.88 [0.78,0.98]	Z=-2.27, p=0.0231
Heterogeneity:	Q=0.01 (df=1)	p=0.9105	I^2=0.0%		
>= 65					
FIDELIO-DKD	305 / 1626	336 / 1660	44.6	0.93 [0.81,1.07]	
FIGARO-DKD	378 / 1931	408 / 1903	55.4	0.91 [0.81,1.03]	
Total	683 / 3557	744 / 3563		0.92 [0.84,1.01]	Z=-1.78, p=0.0751
Heterogeneity:	Q=0.02 (df=1)	p=0.8760	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5166	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set

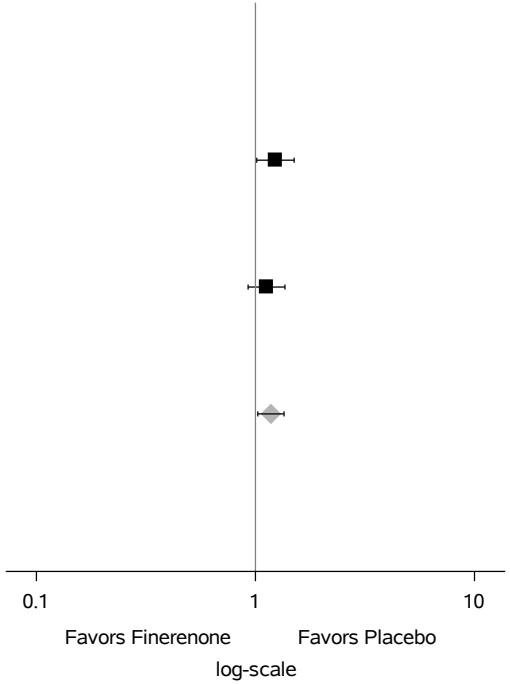
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	479 / 2827	534 / 2831	43.6	0.90 [0.80,1.00]	
FIGARO-DKD	623 / 3683	687 / 3658	56.4	0.90 [0.82,0.99]	
Total	1102 / 6510	1221 / 6489		0.90 [0.84,0.97]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.00 (df=1)	p=0.9718	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set

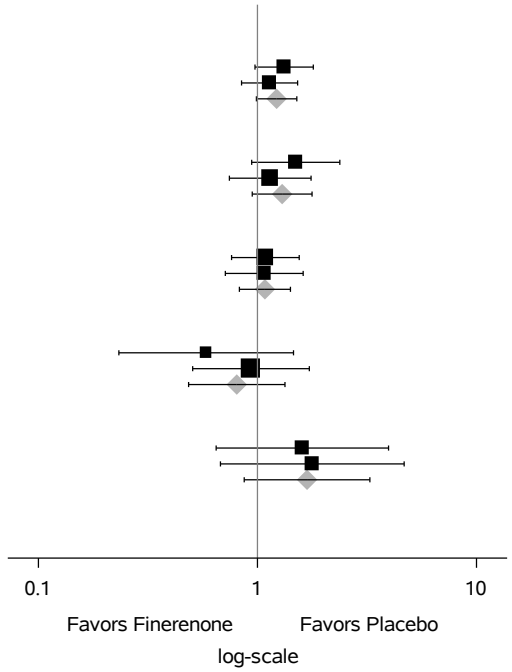
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	207 / 2827	168 / 2831	49.2	1.23 [1.01,1.50]	
FIGARO-DKD	207 / 3683	183 / 3658	50.8	1.12 [0.93,1.36]	
Total	414 / 6510	351 / 6489		1.18 [1.03,1.35]	Z=2.31, p=0.0208
Heterogeneity:	Q=0.44 (df=1)	p=0.5055	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.7.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set

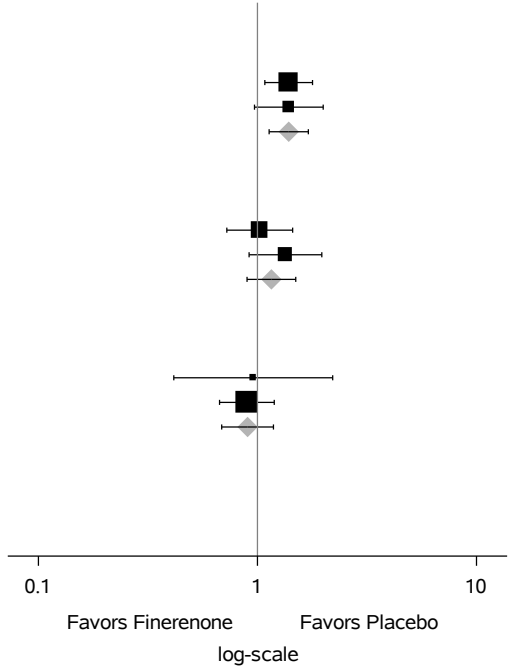
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	89 / 1178	67 / 1174	48.1	1.32 [0.97,1.80]	
FIGARO-DKD	90 / 1752	79 / 1747	51.9	1.14 [0.85,1.53]	
Total	179 / 2930	146 / 2921		1.22 [0.99,1.51]	Z=1.86, p=0.0630
Heterogeneity:	Q=0.50 (df=1)	p=0.4806	I^2=0.0%		
North America					
FIDELIO-DKD	41 / 466	28 / 476	46.2	1.50 [0.94,2.38]	
FIGARO-DKD	42 / 559	36 / 548	53.8	1.14 [0.74,1.76]	
Total	83 / 1025	64 / 1024		1.30 [0.95,1.78]	Z=1.62, p=0.1055
Heterogeneity:	Q=0.69 (df=1)	p=0.4050	I^2=0.0%		
Asia					
FIDELIO-DKD	59 / 790	54 / 786	57.0	1.09 [0.76,1.55]	
FIGARO-DKD	45 / 811	42 / 813	43.0	1.07 [0.71,1.62]	
Total	104 / 1601	96 / 1599		1.08 [0.83,1.41]	Z=0.57, p=0.5675
Heterogeneity:	Q=0.00 (df=1)	p=0.9653	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 294	12 / 294	30.8	0.58 [0.23,1.46]	
FIGARO-DKD	19 / 424	20 / 417	69.2	0.93 [0.51,1.73]	
Total	26 / 718	32 / 711		0.80 [0.48,1.34]	Z=-0.84, p=0.4005
Heterogeneity:	Q=0.70 (df=1)	p=0.4029	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 99	7 / 101	53.2	1.60 [0.65,3.97]	
FIGARO-DKD	11 / 137	6 / 133	46.8	1.78 [0.68,4.67]	
Total	22 / 236	13 / 234		1.68 [0.87,3.26]	Z=1.55, p=0.1219
Heterogeneity:	Q=0.02 (df=1)	p=0.8771	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.17 (df=4)	p=0.3839	I^2=4.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.7.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

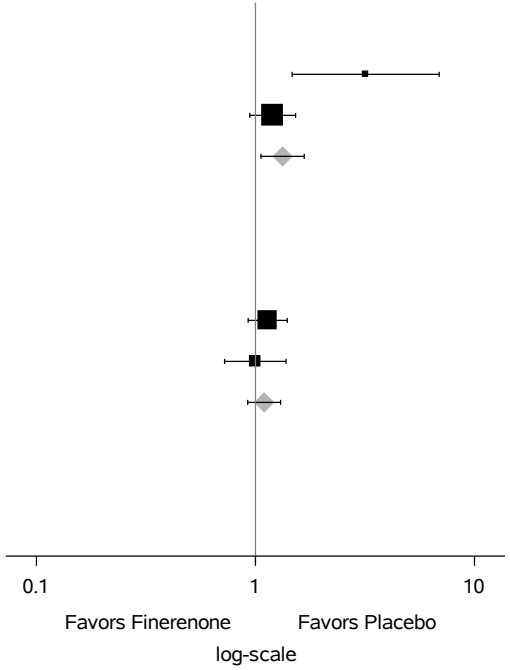
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	136 / 1556	97 / 1541	67.5	1.39 [1.08,1.78]	
FIGARO-DKD	65 / 637	46 / 627	32.5	1.39 [0.97,2.00]	
Total	201 / 2193	143 / 2168		1.39 [1.13,1.71]	Z=3.13, p=0.0018
Heterogeneity:	Q=0.00 (df=1)	p=0.9941	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	61 / 1061	60 / 1069	55.0	1.02 [0.72,1.45]	
FIGARO-DKD	57 / 720	43 / 729	45.0	1.34 [0.92,1.97]	
Total	118 / 1781	103 / 1798		1.16 [0.90,1.50]	Z=1.12, p=0.2618
Heterogeneity:	Q=1.05 (df=1)	p=0.3044	I^2=5.2%		
>= 60					
FIDELIO-DKD	10 / 210	11 / 221	10.6	0.96 [0.41,2.21]	
FIGARO-DKD	85 / 2326	94 / 2302	89.4	0.89 [0.67,1.19]	
Total	95 / 2536	105 / 2523		0.90 [0.69,1.18]	Z=-0.75, p=0.4538
Heterogeneity:	Q=0.02 (df=1)	p=0.8823	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.20 (df=2)	p=0.0449	I^2=67.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.7.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set

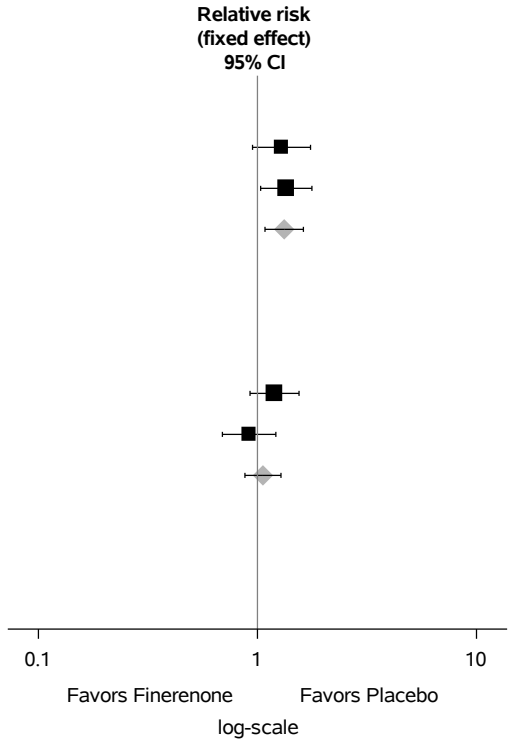
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	25 / 209	8 / 213	8.9	3.18 [1.47,6.90]	
FIGARO-DKD	136 / 1720	112 / 1698	91.1	1.20 [0.94,1.53]	
Total	161 / 1929	120 / 1911		1.33 [1.06,1.67]	Z=2.46, p=0.0141
Heterogeneity:	Q=5.62 (df=1)	p=0.0178	I^2=82.2%		
Very High					
FIDELIO-DKD	182 / 2618	160 / 2618	71.2	1.14 [0.93,1.40]	
FIGARO-DKD	71 / 1963	71 / 1960	28.8	1.00 [0.72,1.38]	
Total	253 / 4581	231 / 4578		1.10 [0.92,1.30]	Z=1.03, p=0.3013
Heterogeneity:	Q=0.45 (df=1)	p=0.5044	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=1)	p=0.1838	I^2=43.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.7.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set

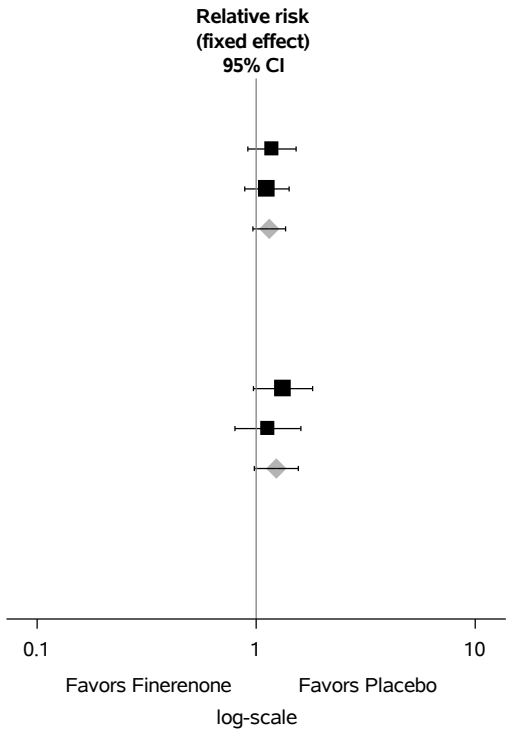
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	89 / 1301	69 / 1299	43.9	1.29 [0.95,1.75]	
FIGARO-DKD	118 / 1673	86 / 1651	56.1	1.35 [1.03,1.77]	
Total	207 / 2974	155 / 2950		1.32 [1.08,1.62]	Z=2.73, p=0.0063
Heterogeneity:	Q=0.06 (df=1)	p=0.8092	I^2=0.0%		
Absent					
FIDELIO-DKD	118 / 1526	99 / 1532	54.3	1.20 [0.92,1.55]	
FIGARO-DKD	89 / 2010	97 / 2007	45.7	0.92 [0.69,1.21]	
Total	207 / 3536	196 / 3539		1.06 [0.88,1.28]	Z=0.60, p=0.5501
Heterogeneity:	Q=1.89 (df=1)	p=0.1697	I^2=47.0%		
Subgroup Heterogeneity:	Q=2.50 (df=1)	p=0.1137	I^2=60.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.7.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

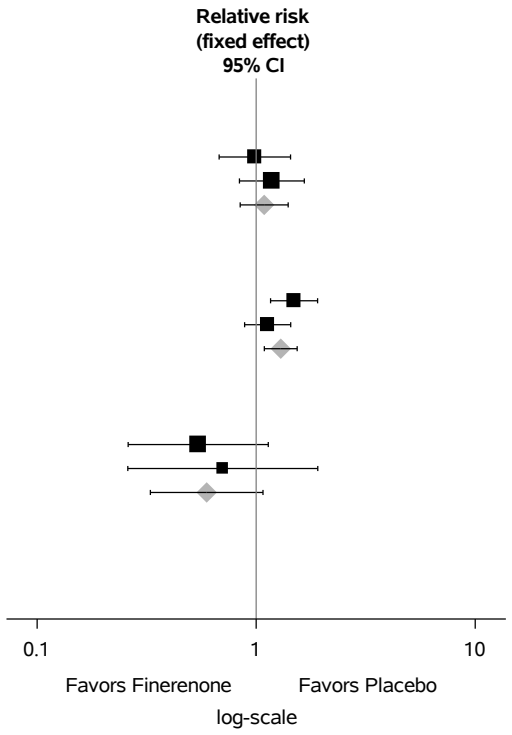
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	123 / 1879	103 / 1858	45.8	1.18 [0.92,1.52]	
FIGARO-DKD	143 / 2643	126 / 2608	54.2	1.12 [0.89,1.41]	
Total	266 / 4522	229 / 4466		1.15 [0.97,1.36]	Z=1.57, p=0.1165
Heterogeneity:	Q=0.09 (df=1)	p=0.7632	I^2=0.0%		
> 4.5					
FIDELIO-DKD	84 / 948	65 / 973	55.4	1.33 [0.97,1.81]	
FIGARO-DKD	64 / 1040	57 / 1048	44.6	1.13 [0.80,1.60]	
Total	148 / 1988	122 / 2021		1.24 [0.98,1.56]	Z=1.79, p=0.0727
Heterogeneity:	Q=0.45 (df=1)	p=0.5035	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6133	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.7.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

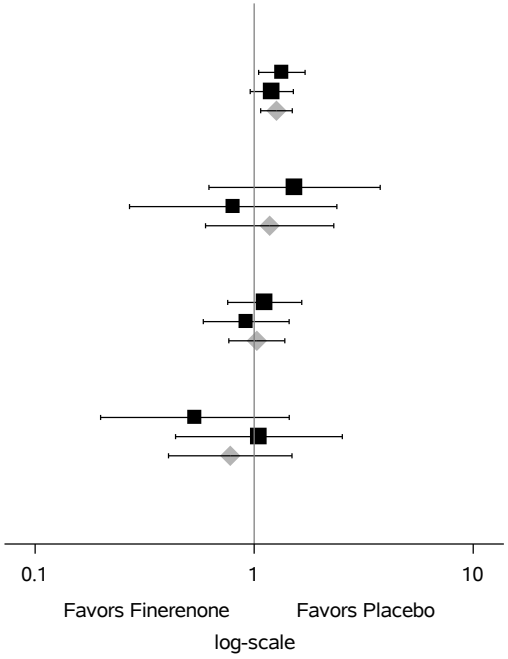
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	51 / 788	51 / 777	45.2	0.99 [0.68,1.44]	
FIGARO-DKD	68 / 1187	58 / 1194	54.8	1.18 [0.84,1.66]	
Total	119 / 1975	109 / 1971		1.09 [0.85,1.40]	Z=0.65, p=0.5130
Heterogeneity:	Q=0.48 (df=1)	p=0.4890	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	146 / 1897	99 / 1916	49.0	1.49 [1.16,1.91]	
FIGARO-DKD	133 / 2389	116 / 2351	51.0	1.13 [0.89,1.44]	
Total	279 / 4286	215 / 4267		1.29 [1.09,1.54]	Z=2.93, p=0.0034
Heterogeneity:	Q=2.47 (df=1)	p=0.1158	I^2=59.6%		
>= 160					
FIDELIO-DKD	10 / 141	18 / 138	64.8	0.54 [0.26,1.14]	
FIGARO-DKD	6 / 107	9 / 113	35.2	0.70 [0.26,1.91]	
Total	16 / 248	27 / 251		0.59 [0.33,1.07]	Z=-1.72, p=0.0849
Heterogeneity:	Q=0.17 (df=1)	p=0.6831	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.66 (df=2)	p=0.0357	I^2=70.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.7.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set

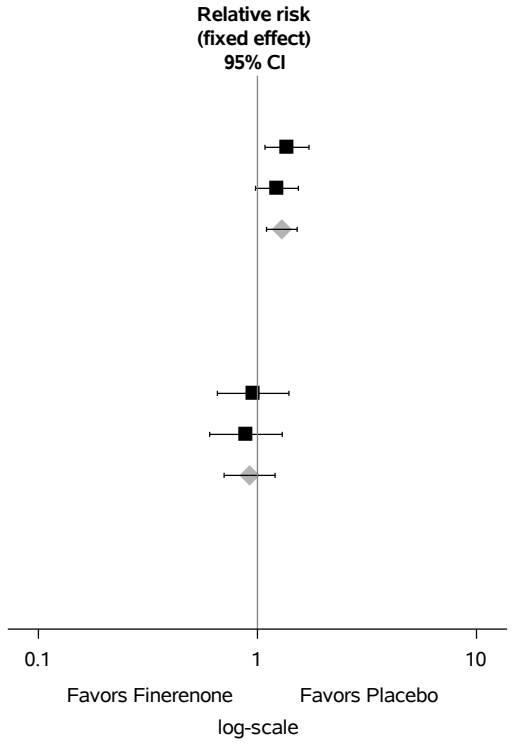
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	139 / 1773	106 / 1809	46.3	1.34 [1.05,1.71]	
FIGARO-DKD	158 / 2668	128 / 2601	53.7	1.20 [0.96,1.51]	
Total	297 / 4441	234 / 4410		1.26 [1.07,1.49]	Z=2.77, p=0.0057
Heterogeneity:	Q=0.39 (df=1)	p=0.5329	I^2=0.0%		
Black					
FIDELIO-DKD	12 / 139	7 / 124	59.5	1.53 [0.62,3.76]	
FIGARO-DKD	5 / 113	8 / 145	40.5	0.80 [0.27,2.39]	
Total	17 / 252	15 / 269		1.18 [0.60,2.31]	Z=0.47, p=0.6361
Heterogeneity:	Q=0.80 (df=1)	p=0.3708	I^2=0.0%		
Asian					
FIDELIO-DKD	50 / 717	45 / 721	57.3	1.12 [0.76,1.65]	
FIGARO-DKD	34 / 716	38 / 736	42.7	0.92 [0.59,1.44]	
Total	84 / 1433	83 / 1457		1.03 [0.77,1.38]	Z=0.19, p=0.8528
Heterogeneity:	Q=0.41 (df=1)	p=0.5221	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 198	10 / 177	43.9	0.54 [0.20,1.45]	
FIGARO-DKD	10 / 186	9 / 176	56.1	1.05 [0.44,2.53]	
Total	16 / 384	19 / 353		0.78 [0.41,1.49]	Z=-0.76, p=0.4476
Heterogeneity:	Q=0.99 (df=1)	p=0.3188	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.09 (df=3)	p=0.3784	I^2=2.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.7.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set

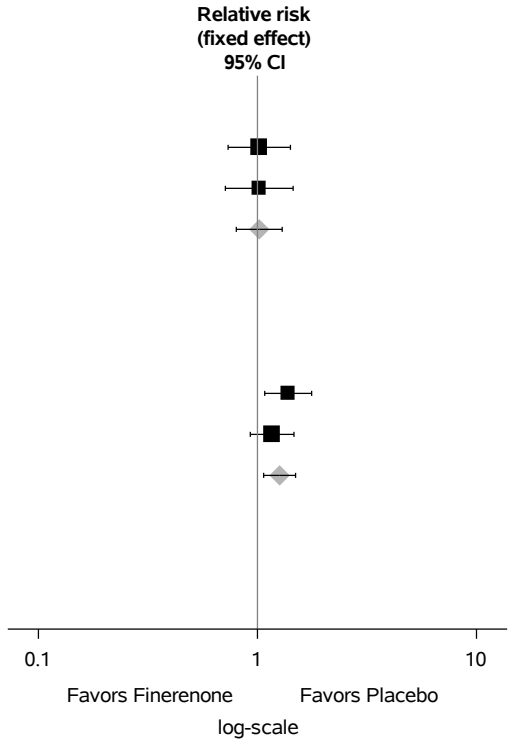
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	155 / 1949	118 / 2024	48.6	1.36 [1.08,1.72]	
FIGARO-DKD	158 / 2527	131 / 2571	51.4	1.23 [0.98,1.54]	
Total	313 / 4476	249 / 4595		1.29 [1.10,1.52]	Z=3.12, p=0.0018
Heterogeneity:	Q=0.41 (df=1)	p=0.5202	I^2=0.0%		
Female					
FIDELIO-DKD	52 / 878	50 / 807	50.7	0.96 [0.66,1.39]	
FIGARO-DKD	49 / 1156	52 / 1087	49.3	0.89 [0.61,1.30]	
Total	101 / 2034	102 / 1894		0.92 [0.70,1.20]	Z=-0.60, p=0.5458
Heterogeneity:	Q=0.08 (df=1)	p=0.7813	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.52 (df=1)	p=0.0336	I^2=77.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.7.9: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set

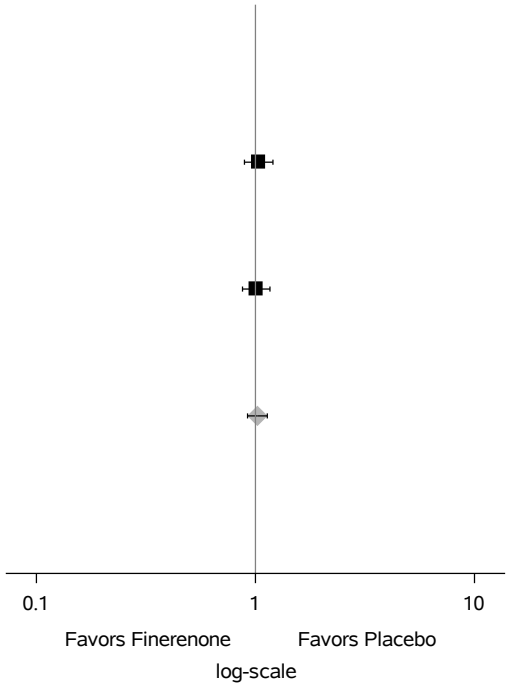
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	69 / 1201	66 / 1171	54.2	1.02 [0.73,1.41]	
FIGARO-DKD	59 / 1752	58 / 1755	45.8	1.02 [0.71,1.46]	
Total	128 / 2953	124 / 2926		1.02 [0.80,1.30]	Z=0.15, p=0.8773
Heterogeneity:	Q=0.00 (df=1)	p=0.9989	I^2=0.0%		
>= 65					
FIDELIO-DKD	138 / 1626	102 / 1660	46.4	1.38 [1.08,1.77]	
FIGARO-DKD	148 / 1931	125 / 1903	53.6	1.17 [0.93,1.47]	
Total	286 / 3557	227 / 3563		1.26 [1.07,1.49]	Z=2.72, p=0.0065
Heterogeneity:	Q=0.96 (df=1)	p=0.3264	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.04 (df=1)	p=0.1534	I^2=50.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

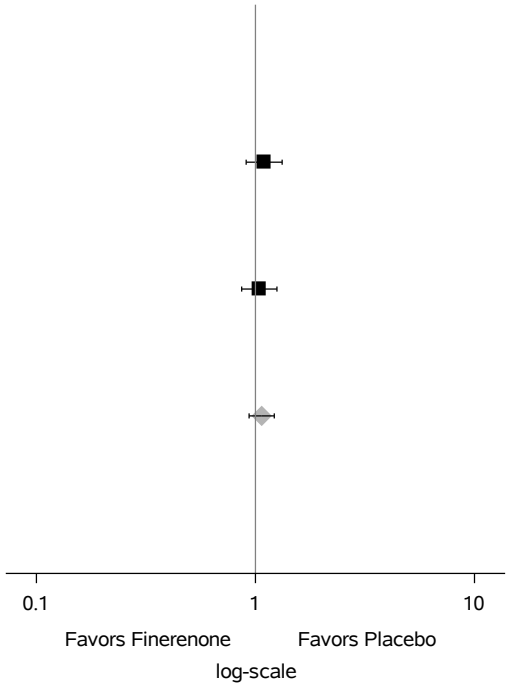
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	311 / 2827	301 / 2831	48.2	1.03 [0.89,1.20]	
FIGARO-DKD	338 / 3683	333 / 3658	51.8	1.01 [0.87,1.16]	
Total	649 / 6510	634 / 6489		1.02 [0.92,1.13]	Z=0.39, p=0.6972
Heterogeneity:	Q=0.06 (df=1)	p=0.8063	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set

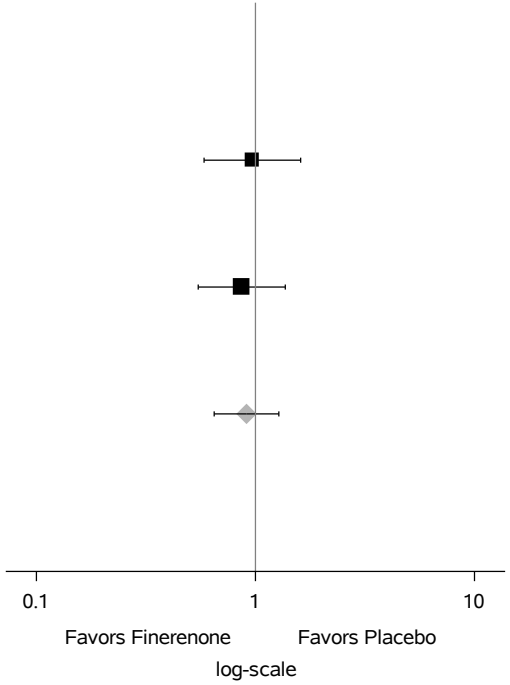
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	209 / 2827	191 / 2831	49.0	1.10 [0.91,1.32]	
FIGARO-DKD	216 / 3683	206 / 3658	51.0	1.04 [0.87,1.25]	
Total	425 / 6510	397 / 6489		1.07 [0.94,1.22]	Z=0.97, p=0.3319
Heterogeneity:	Q=0.14 (df=1)	p=0.7064	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.10: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set

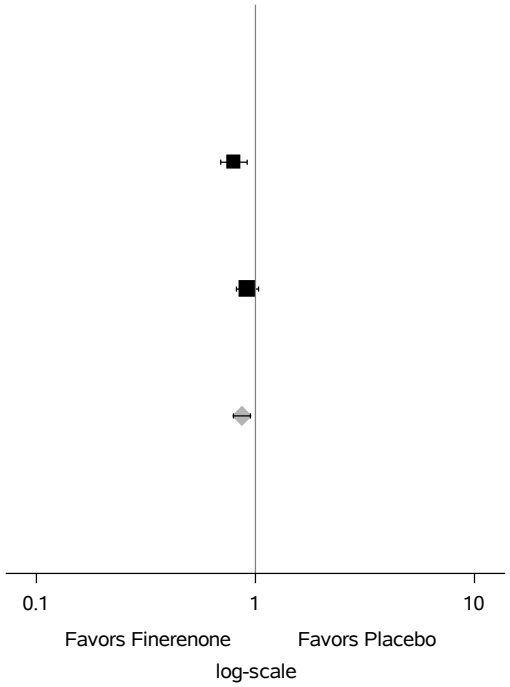
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	44.8	0.97 [0.58,1.61]	
FIGARO-DKD	34 / 3683	39 / 3658	55.2	0.87 [0.55,1.37]	
Total	63 / 6510	69 / 6489		0.91 [0.65,1.28]	Z=-0.54, p=0.5873
Heterogeneity:	Q=0.10 (df=1)	p=0.7491	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.11: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

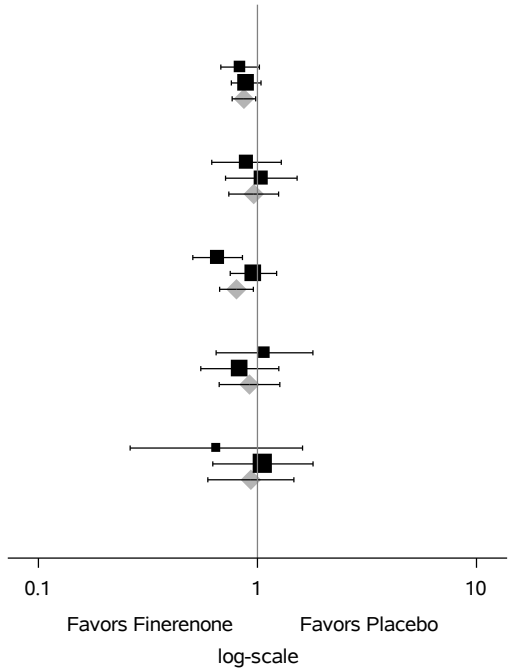
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	313 / 2827	393 / 2831	41.1	0.80 [0.69,0.92]	
FIGARO-DKD	475 / 3683	513 / 3658	58.9	0.92 [0.82,1.03]	
Total	788 / 6510	906 / 6489		0.87 [0.79,0.95]	Z=-3.14, p=0.0017
Heterogeneity:	Q=2.37 (df=1)	p=0.1233	I^2=57.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.11.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

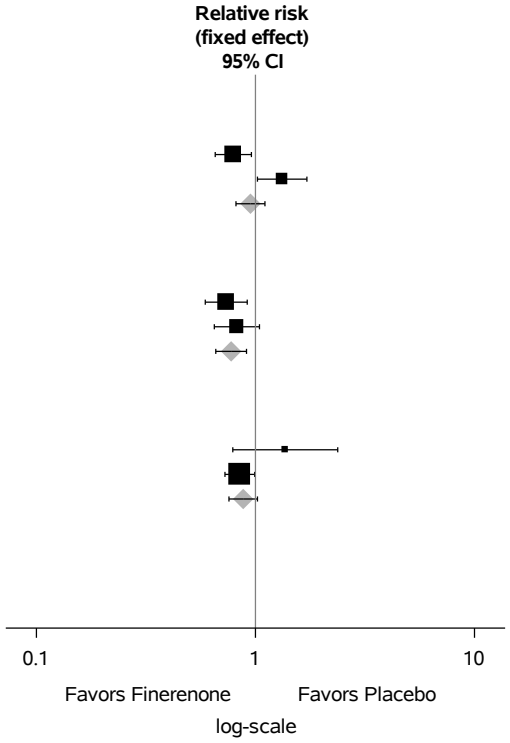
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	148 / 1178	177 / 1174	37.2	0.83 [0.68,1.02]	
FIGARO-DKD	253 / 1752	284 / 1747	62.8	0.89 [0.76,1.04]	
Total	401 / 2930	461 / 2921		0.87 [0.77,0.98]	Z=-2.26, p=0.0241
Heterogeneity:	Q=0.24 (df=1)	p=0.6245	I^2=0.0%		
North America					
FIDELIO-DKD	48 / 466	55 / 476	51.4	0.89 [0.62,1.28]	
FIGARO-DKD	51 / 559	48 / 548	48.6	1.04 [0.72,1.52]	
Total	99 / 1025	103 / 1024		0.96 [0.74,1.25]	Z=-0.29, p=0.7681
Heterogeneity:	Q=0.34 (df=1)	p=0.5608	I^2=0.0%		
Asia					
FIDELIO-DKD	82 / 790	124 / 786	46.6	0.66 [0.51,0.85]	
FIGARO-DKD	109 / 811	114 / 813	53.4	0.96 [0.75,1.22]	
Total	191 / 1601	238 / 1599		0.80 [0.67,0.96]	Z=-2.44, p=0.0148
Heterogeneity:	Q=4.26 (df=1)	p=0.0389	I^2=76.5%		
Latin America					
FIDELIO-DKD	28 / 294	26 / 294	39.4	1.08 [0.65,1.79]	
FIGARO-DKD	38 / 424	45 / 417	60.6	0.83 [0.55,1.25]	
Total	66 / 718	71 / 711		0.92 [0.67,1.27]	Z=-0.51, p=0.6072
Heterogeneity:	Q=0.61 (df=1)	p=0.4358	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 99	11 / 101	25.3	0.65 [0.26,1.61]	
FIGARO-DKD	24 / 137	22 / 133	74.7	1.06 [0.63,1.79]	
Total	31 / 236	33 / 234		0.93 [0.59,1.47]	Z=-0.30, p=0.7637
Heterogeneity:	Q=0.84 (df=1)	p=0.3602	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.57 (df=4)	p=0.8140	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.11.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

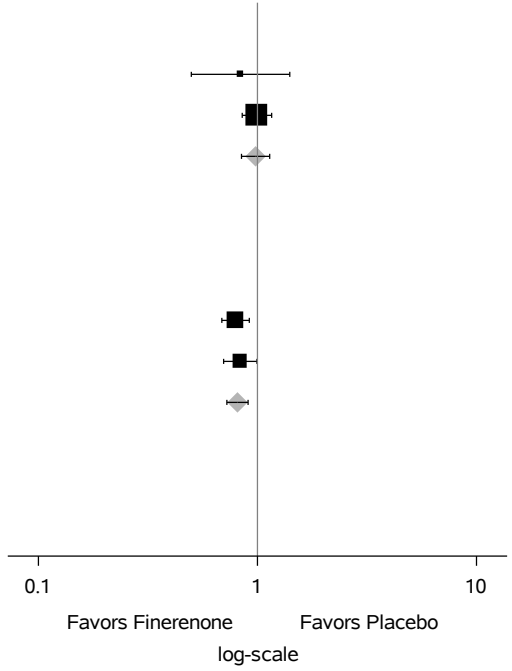
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	168 / 1556	210 / 1541	65.1	0.79 [0.66,0.96]	
FIGARO-DKD	113 / 637	84 / 627	34.9	1.32 [1.02,1.72]	
Total	281 / 2193	294 / 2168		0.95 [0.81,1.10]	Z=-0.68, p=0.4991
Heterogeneity:	Q=9.76 (df=1)	p=0.0018	I^2=89.8%		
45 - < 60					
FIDELIO-DKD	119 / 1061	163 / 1069	53.7	0.74 [0.59,0.92]	
FIGARO-DKD	104 / 720	128 / 729	46.3	0.82 [0.65,1.04]	
Total	223 / 1781	291 / 1798		0.77 [0.66,0.91]	Z=-3.10, p=0.0019
Heterogeneity:	Q=0.46 (df=1)	p=0.4985	I^2=0.0%		
>= 60					
FIDELIO-DKD	26 / 210	20 / 221	7.4	1.37 [0.79,2.37]	
FIGARO-DKD	258 / 2326	301 / 2302	92.6	0.85 [0.73,0.99]	
Total	284 / 2536	321 / 2523		0.88 [0.76,1.02]	Z=-1.68, p=0.0923
Heterogeneity:	Q=2.67 (df=1)	p=0.1022	I^2=62.6%		
Subgroup Heterogeneity:	Q=3.26 (df=2)	p=0.1963	I^2=38.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.11.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

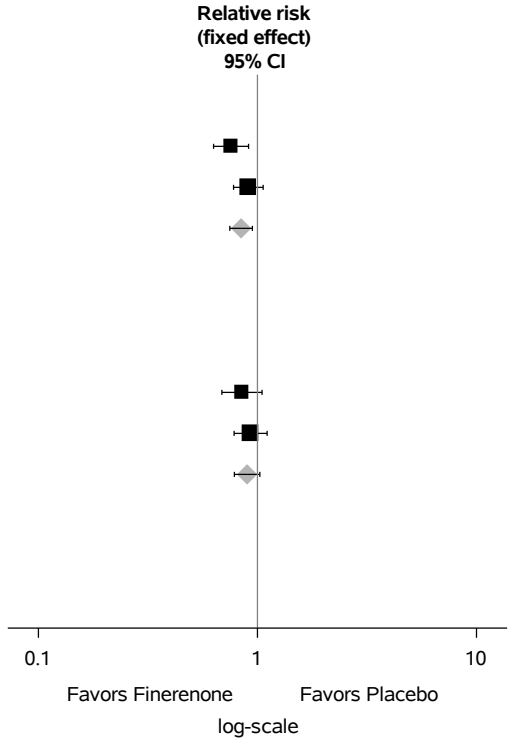
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	23 / 209	28 / 213	8.2	0.84 [0.50,1.40]	
FIGARO-DKD	271 / 1720	269 / 1698	91.8	0.99 [0.85,1.16]	
Total	294 / 1929	297 / 1911		0.98 [0.85,1.14]	Z=-0.26, p=0.7944
Heterogeneity:	Q=0.39 (df=1)	p=0.5319	I^2=0.0%		
Very High					
FIDELIO-DKD	290 / 2618	365 / 2618	59.5	0.79 [0.69,0.92]	
FIGARO-DKD	204 / 1963	244 / 1960	40.5	0.83 [0.70,0.99]	
Total	494 / 4581	609 / 4578		0.81 [0.73,0.91]	Z=-3.70, p=0.0002
Heterogeneity:	Q=0.18 (df=1)	p=0.6694	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.05 (df=1)	p=0.0442	I^2=75.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.11.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

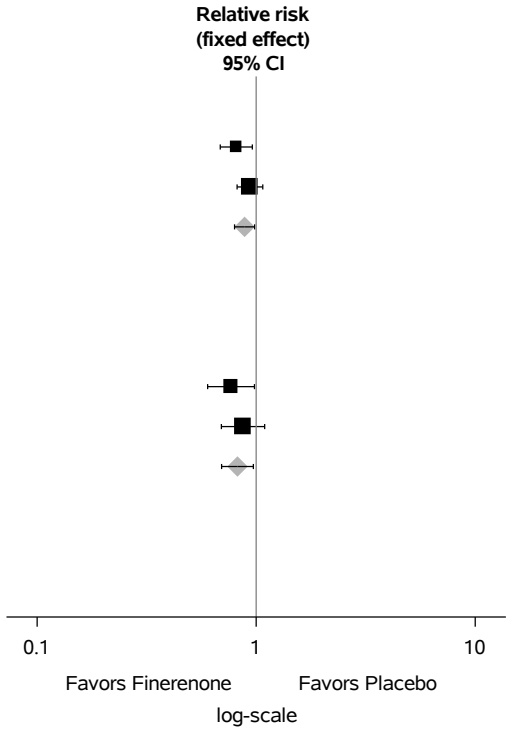
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	170 / 1301	224 / 1299	41.7	0.76 [0.63,0.91]	
FIGARO-DKD	256 / 1673	278 / 1651	58.3	0.91 [0.78,1.06]	
Total	426 / 2974	502 / 2950		0.84 [0.75,0.95]	Z=-2.84, p=0.0045
Heterogeneity:	Q=2.19 (df=1)	p=0.1393	I^2=54.2%		
Absent					
FIDELIO-DKD	143 / 1526	169 / 1532	40.3	0.85 [0.69,1.05]	
FIGARO-DKD	219 / 2010	235 / 2007	59.7	0.93 [0.78,1.11]	
Total	362 / 3536	404 / 3539		0.90 [0.78,1.03]	Z=-1.59, p=0.1114
Heterogeneity:	Q=0.43 (df=1)	p=0.5133	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.48 (df=1)	p=0.4890	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.11.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

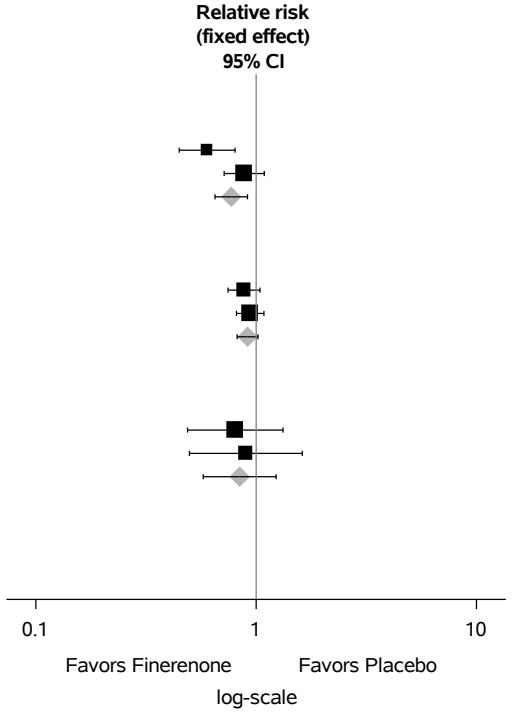
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	215 / 1879	262 / 1858	39.1	0.81 [0.69,0.96]	
FIGARO-DKD	354 / 2643	373 / 2608	60.9	0.94 [0.82,1.07]	
Total	569 / 4522	635 / 4466		0.89 [0.80,0.98]	Z=-2.27, p=0.0234
Heterogeneity:	Q=1.69 (df=1)	p=0.1933	I^2=40.9%		
> 4.5					
FIDELIO-DKD	98 / 948	131 / 973	46.1	0.77 [0.60,0.98]	
FIGARO-DKD	121 / 1040	140 / 1048	53.9	0.87 [0.69,1.09]	
Total	219 / 1988	271 / 2021		0.82 [0.70,0.97]	Z=-2.31, p=0.0210
Heterogeneity:	Q=0.54 (df=1)	p=0.4612	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4579	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.11.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

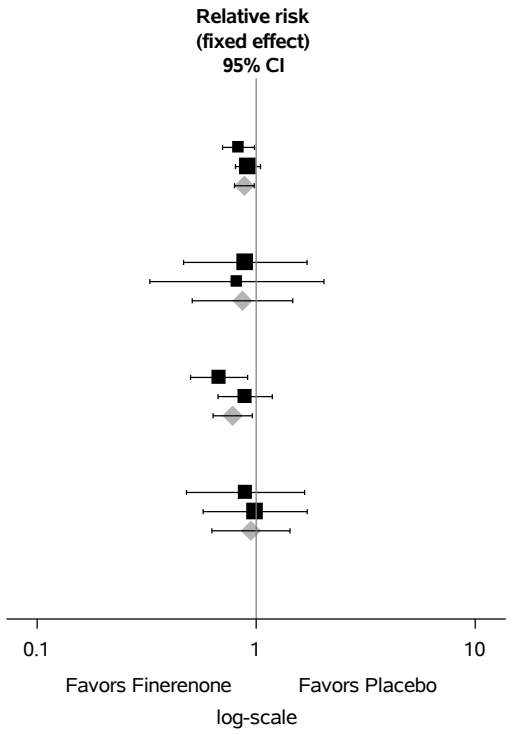
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	65 / 788	107 / 777	34.0	0.60 [0.45,0.80]	
FIGARO-DKD	143 / 1187	163 / 1194	66.0	0.88 [0.72,1.09]	
Total	208 / 1975	270 / 1971		0.77 [0.65,0.91]	Z=-3.01, p=0.0026
Heterogeneity:	Q=4.47 (df=1)	p=0.0346	I^2=77.6%		
130 - < 160					
FIDELIO-DKD	225 / 1897	258 / 1916	42.4	0.88 [0.75,1.04]	
FIGARO-DKD	315 / 2389	330 / 2351	57.6	0.94 [0.81,1.08]	
Total	540 / 4286	588 / 4267		0.91 [0.82,1.02]	Z=-1.62, p=0.1055
Heterogeneity:	Q=0.33 (df=1)	p=0.5670	I^2=0.0%		
>= 160					
FIDELIO-DKD	23 / 141	28 / 138	58.3	0.80 [0.49,1.32]	
FIGARO-DKD	17 / 107	20 / 113	41.7	0.90 [0.50,1.62]	
Total	40 / 248	48 / 251		0.84 [0.57,1.23]	Z=-0.89, p=0.3753
Heterogeneity:	Q=0.08 (df=1)	p=0.7798	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.78 (df=2)	p=0.2496	I^2=28.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.11.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

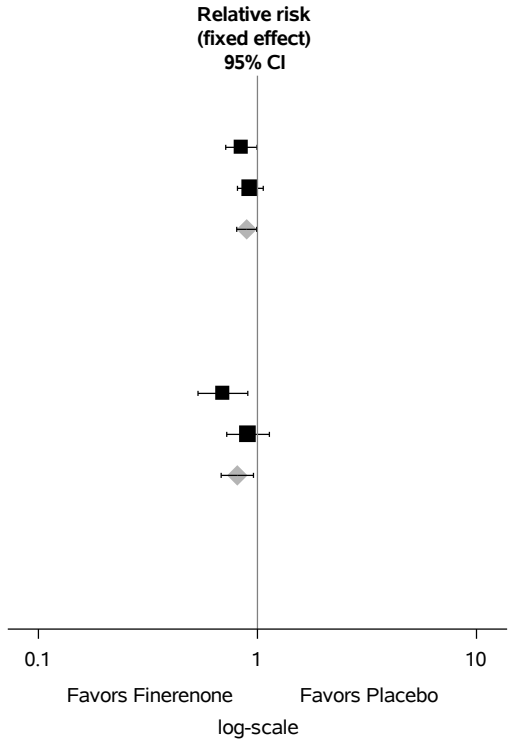
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	215 / 1773	264 / 1809	38.2	0.83 [0.70,0.98]	
FIGARO-DKD	367 / 2668	390 / 2601	61.8	0.92 [0.80,1.05]	
Total	582 / 4441	654 / 4410		0.88 [0.80,0.98]	Z=-2.35, p=0.0188
Heterogeneity:	Q=0.83 (df=1)	p=0.3632	I^2=0.0%		
Black					
FIDELIO-DKD	16 / 139	16 / 124	66.5	0.89 [0.47,1.71]	
FIGARO-DKD	7 / 113	11 / 145	33.5	0.82 [0.33,2.04]	
Total	23 / 252	27 / 269		0.87 [0.51,1.47]	Z=-0.53, p=0.5934
Heterogeneity:	Q=0.02 (df=1)	p=0.8772	I^2=0.0%		
Asian					
FIDELIO-DKD	64 / 717	95 / 721	47.5	0.68 [0.50,0.91]	
FIGARO-DKD	78 / 716	90 / 736	52.5	0.89 [0.67,1.18]	
Total	142 / 1433	185 / 1457		0.78 [0.64,0.96]	Z=-2.35, p=0.0187
Heterogeneity:	Q=1.68 (df=1)	p=0.1944	I^2=40.6%		
Others					
FIDELIO-DKD	18 / 198	18 / 177	43.7	0.89 [0.48,1.66]	
FIGARO-DKD	23 / 186	22 / 176	56.3	0.99 [0.57,1.71]	
Total	41 / 384	40 / 353		0.95 [0.63,1.43]	Z=-0.26, p=0.7927
Heterogeneity:	Q=0.06 (df=1)	p=0.8104	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.29 (df=3)	p=0.7324	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.11.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

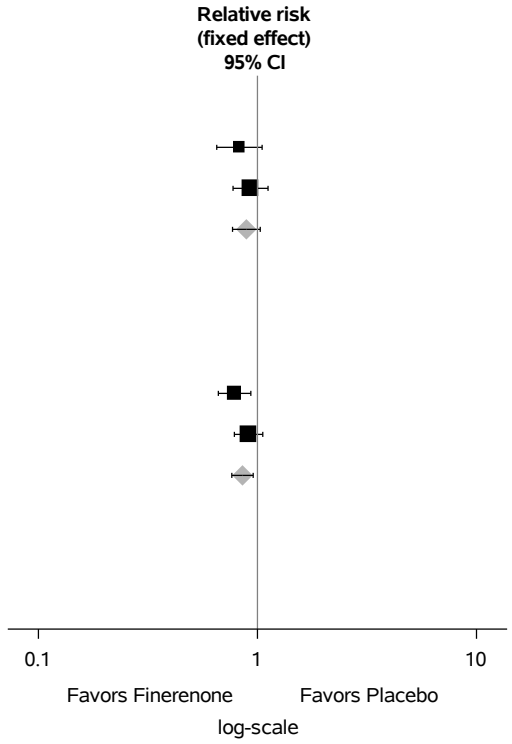
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	226 / 1949	278 / 2024	40.6	0.84 [0.72,0.99]	
FIGARO-DKD	343 / 2527	376 / 2571	59.4	0.93 [0.81,1.06]	
Total	569 / 4476	654 / 4595		0.89 [0.80,0.99]	Z=-2.12, p=0.0339
Heterogeneity:	Q=0.76 (df=1)	p=0.3833	I^2=0.0%		
Female					
FIDELIO-DKD	87 / 878	115 / 807	42.4	0.70 [0.54,0.90]	
FIGARO-DKD	132 / 1156	137 / 1087	57.6	0.91 [0.72,1.13]	
Total	219 / 2034	252 / 1894		0.81 [0.68,0.96]	Z=-2.44, p=0.0146
Heterogeneity:	Q=2.27 (df=1)	p=0.1322	I^2=55.9%		
Subgroup Heterogeneity:	Q=0.94 (df=1)	p=0.3329	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.11.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

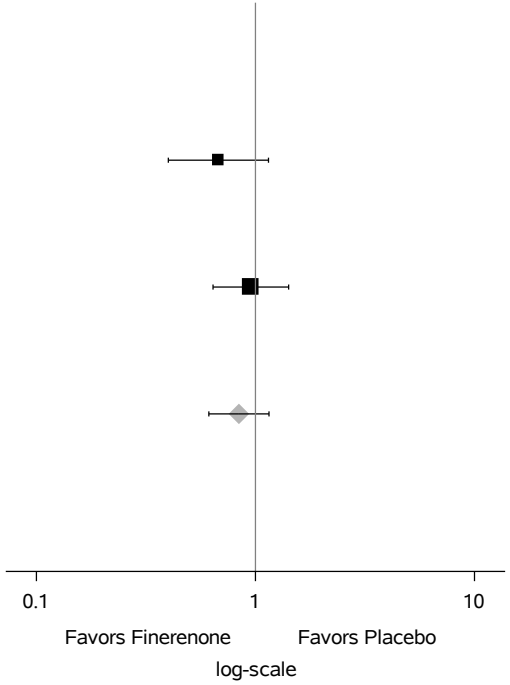
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	112 / 1201	132 / 1171	37.3	0.83 [0.65,1.05]	
FIGARO-DKD	194 / 1752	209 / 1755	62.7	0.93 [0.77,1.12]	
Total	306 / 2953	341 / 2926		0.89 [0.77,1.03]	Z=-1.57, p=0.1171
Heterogeneity:	Q=0.58 (df=1)	p=0.4471	I^2=0.0%		
>= 65					
FIDELIO-DKD	201 / 1626	261 / 1660	43.3	0.79 [0.66,0.93]	
FIGARO-DKD	281 / 1931	304 / 1903	56.7	0.91 [0.78,1.06]	
Total	482 / 3557	565 / 3563		0.85 [0.76,0.96]	Z=-2.75, p=0.0060
Heterogeneity:	Q=1.62 (df=1)	p=0.2033	I^2=38.2%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6621	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.12: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set

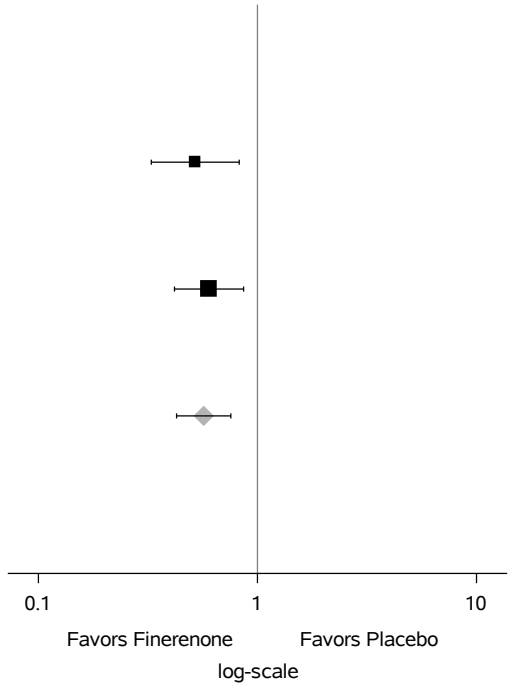
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	34 / 2831	36.3	0.68 [0.40,1.15]	
FIGARO-DKD	47 / 3683	49 / 3658	63.7	0.95 [0.64,1.42]	
Total	70 / 6510	83 / 6489		0.84 [0.61,1.15]	Z=-1.08, p=0.2811
Heterogeneity:	Q=1.03 (df=1)	p=0.3111	I^2=2.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.13: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

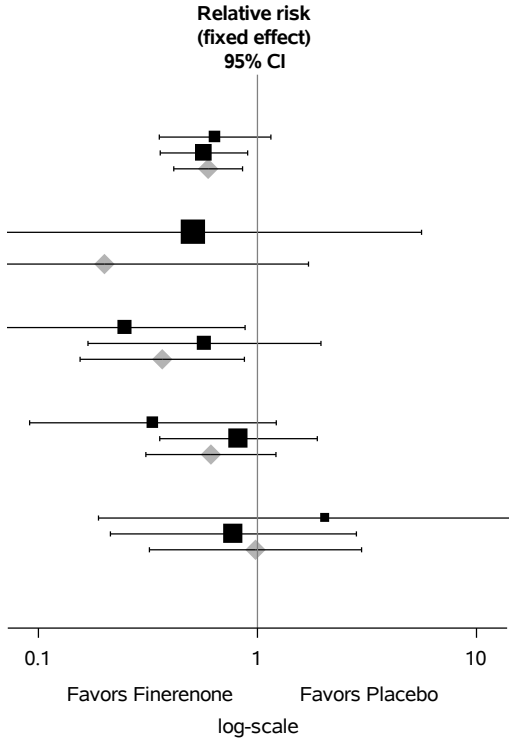
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	52 / 2831	38.2	0.52 [0.33,0.83]	
FIGARO-DKD	46 / 3683	76 / 3658	61.8	0.60 [0.42,0.86]	
Total	73 / 6510	128 / 6489		0.57 [0.43,0.76]	Z=-3.88, p=0.0001
Heterogeneity:	Q=0.23 (df=1)	p=0.6285	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.13.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

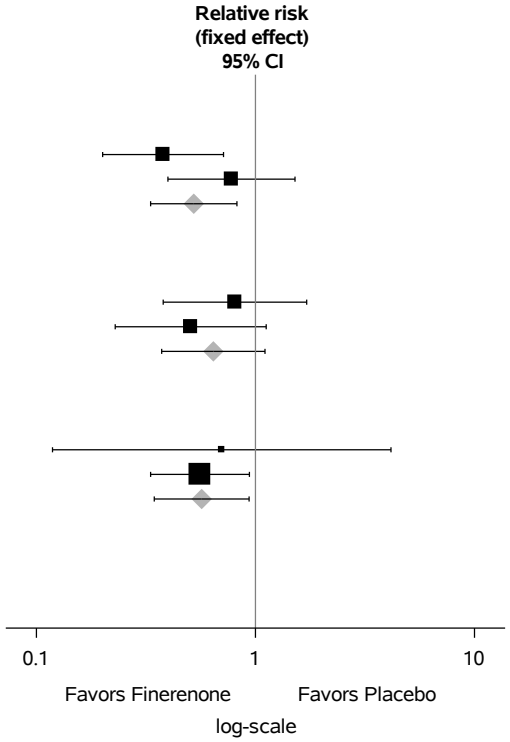
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 1178	28 / 1174	38.0	0.64 [0.36,1.15]	
FIGARO-DKD	28 / 1752	49 / 1747	62.0	0.57 [0.36,0.90]	
Total	46 / 2930	77 / 2921		0.60 [0.41,0.85]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.10 (df=1)	p=0.7578	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 466	2 / 476	100.0	0.51 [0.05,5.61]	
FIGARO-DKD	0 / 559	3 / 548	0.0	0.00 [0.00,23E296]	
Total	1 / 1025	5 / 1024		0.20 [0.02,1.71]	Z=-1.47, p=0.1416
Heterogeneity:	Q=0.59 (df=1)	p=0.4437	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 790	12 / 786	48.5	0.25 [0.07,0.88]	
FIGARO-DKD	4 / 811	7 / 813	51.5	0.57 [0.17,1.95]	
Total	7 / 1601	19 / 1599		0.37 [0.15,0.87]	Z=-2.27, p=0.0231
Heterogeneity:	Q=0.87 (df=1)	p=0.3503	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 294	9 / 294	29.0	0.33 [0.09,1.22]	
FIGARO-DKD	10 / 424	12 / 417	71.0	0.82 [0.36,1.88]	
Total	13 / 718	21 / 711		0.61 [0.31,1.21]	Z=-1.40, p=0.1608
Heterogeneity:	Q=1.32 (df=1)	p=0.2505	I^2=24.3%		
Others					
FIDELIO-DKD	2 / 99	1 / 101	22.7	2.04 [0.19,22.14]	
FIGARO-DKD	4 / 137	5 / 133	77.3	0.78 [0.21,2.83]	
Total	6 / 236	6 / 234		0.98 [0.32,2.99]	Z=-0.04, p=0.9712
Heterogeneity:	Q=0.49 (df=1)	p=0.4850	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.91 (df=4)	p=0.5734	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.13.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

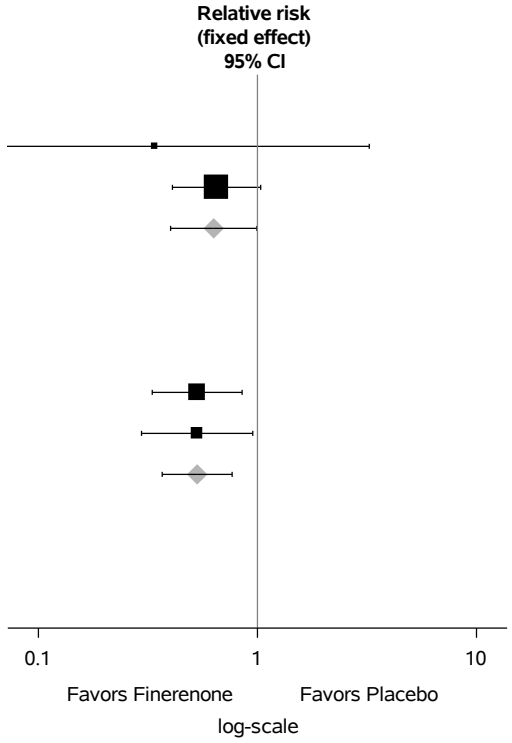
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	34 / 1541	52.5	0.38 [0.20,0.71]	
FIGARO-DKD	15 / 637	19 / 627	47.5	0.78 [0.40,1.52]	
Total	28 / 2193	53 / 2168		0.52 [0.33,0.82]	Z=-2.80, p=0.0051
Heterogeneity:	Q=2.34 (df=1)	p=0.1258	I^2=57.3%		
45 - < 60					
FIDELIO-DKD	12 / 1061	15 / 1069	52.5	0.81 [0.38,1.71]	
FIGARO-DKD	9 / 720	18 / 729	47.5	0.51 [0.23,1.12]	
Total	21 / 1781	33 / 1798		0.64 [0.37,1.11]	Z=-1.60, p=0.1101
Heterogeneity:	Q=0.69 (df=1)	p=0.4049	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	3 / 221	7.9	0.70 [0.12,4.16]	
FIGARO-DKD	22 / 2326	39 / 2302	92.1	0.56 [0.33,0.94]	
Total	24 / 2536	42 / 2523		0.57 [0.35,0.94]	Z=-2.22, p=0.0262
Heterogeneity:	Q=0.06 (df=1)	p=0.8091	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.32 (df=2)	p=0.8501	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.13.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

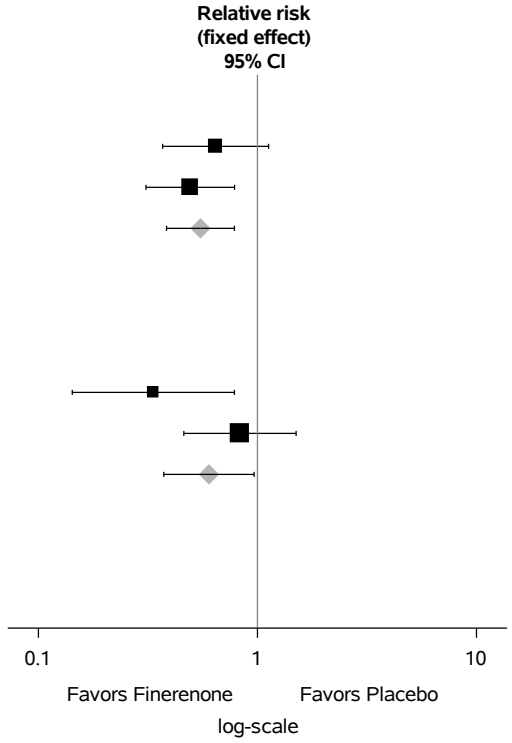
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	3 / 213	4.1	0.34 [0.04,3.24]	
FIGARO-DKD	29 / 1720	44 / 1698	95.9	0.65 [0.41,1.03]	
Total	30 / 1929	47 / 1911		0.63 [0.40,0.99]	Z=-1.99, p=0.0469
Heterogeneity:	Q=0.31 (df=1)	p=0.5799	I^2=0.0%		
Very High					
FIDELIO-DKD	26 / 2618	49 / 2618	60.5	0.53 [0.33,0.85]	
FIGARO-DKD	17 / 1963	32 / 1960	39.5	0.53 [0.30,0.95]	
Total	43 / 4581	81 / 4578		0.53 [0.37,0.77]	Z=-3.38, p=0.0007
Heterogeneity:	Q=0.00 (df=1)	p=0.9993	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5590	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.13.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

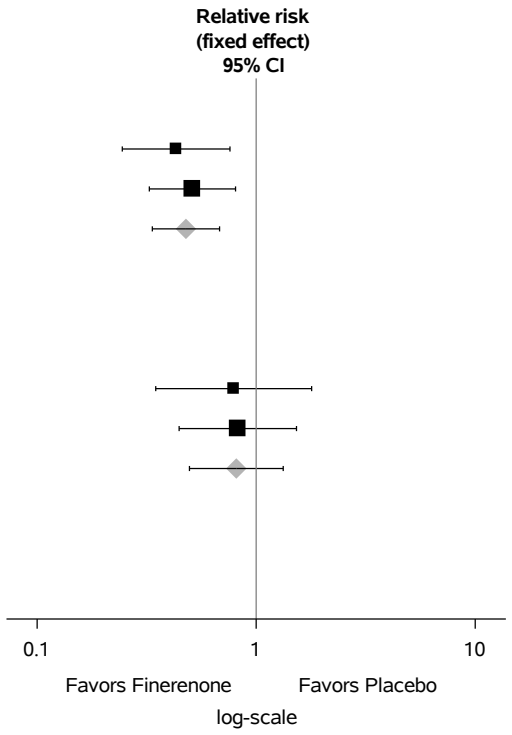
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	31 / 1299	41.2	0.64 [0.37,1.12]	
FIGARO-DKD	26 / 1673	52 / 1651	58.8	0.49 [0.31,0.79]	
Total	46 / 2974	83 / 2950		0.55 [0.38,0.78]	Z=-3.29, p=0.0010
Heterogeneity:	Q=0.52 (df=1)	p=0.4716	I^2=0.0%		
Absent					
FIDELIO-DKD	7 / 1526	21 / 1532	32.4	0.33 [0.14,0.78]	
FIGARO-DKD	20 / 2010	24 / 2007	67.6	0.83 [0.46,1.50]	
Total	27 / 3536	45 / 3539		0.60 [0.37,0.97]	Z=-2.10, p=0.0353
Heterogeneity:	Q=2.98 (df=1)	p=0.0843	I^2=66.4%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7685	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.13.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

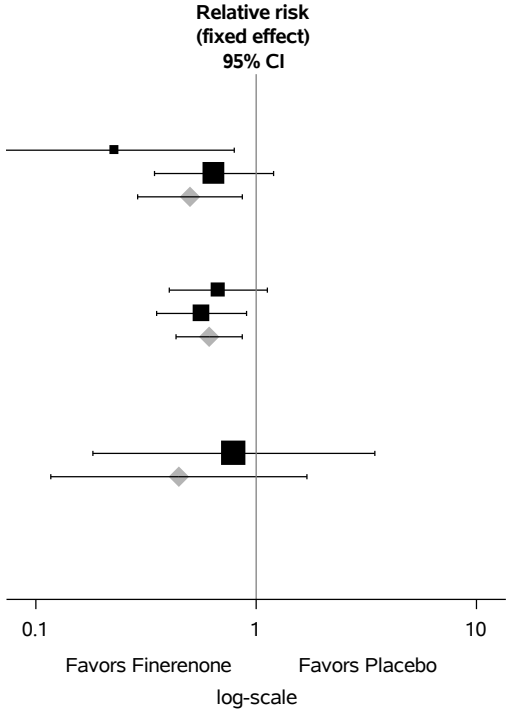
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	17 / 1879	39 / 1858	39.1	0.43 [0.24,0.76]	
FIGARO-DKD	28 / 2643	54 / 2608	60.9	0.51 [0.33,0.81]	
Total	45 / 4522	93 / 4466		0.48 [0.34,0.68]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.21 (df=1)	p=0.6430	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 948	13 / 973	36.2	0.79 [0.35,1.79]	
FIGARO-DKD	18 / 1040	22 / 1048	63.8	0.82 [0.44,1.53]	
Total	28 / 1988	35 / 2021		0.81 [0.50,1.33]	Z=-0.83, p=0.4066
Heterogeneity:	Q=0.01 (df=1)	p=0.9340	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.93 (df=1)	p=0.0870	I^2=65.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.13.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

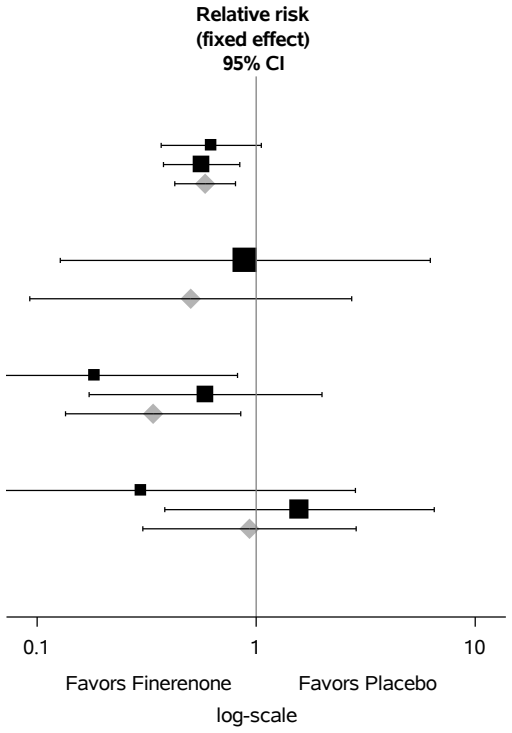
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 788	13 / 777	19.8	0.23 [0.07,0.80]	
FIGARO-DKD	16 / 1187	25 / 1194	80.2	0.64 [0.35,1.20]	
Total	19 / 1975	38 / 1971		0.50 [0.29,0.87]	Z=-2.48, p=0.0132
Heterogeneity:	Q=2.15 (df=1)	p=0.1424	I^2=53.5%		
130 - < 160					
FIDELIO-DKD	24 / 1897	36 / 1916	45.7	0.67 [0.40,1.12]	
FIGARO-DKD	27 / 2389	47 / 2351	54.3	0.57 [0.35,0.90]	
Total	51 / 4286	83 / 4267		0.61 [0.43,0.86]	Z=-2.78, p=0.0054
Heterogeneity:	Q=0.24 (df=1)	p=0.6221	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	3 / 138	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	3 / 107	4 / 113	100.0	0.79 [0.18,3.46]	
Total	3 / 248	7 / 251		0.45 [0.12,1.70]	Z=-1.18, p=0.2367
Heterogeneity:	Q=0.58 (df=1)	p=0.4444	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=2)	p=0.7767	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.13.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

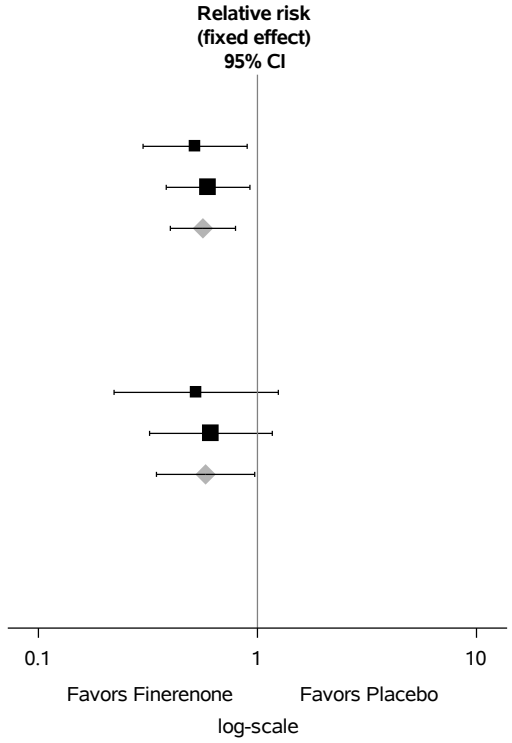
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	36 / 1809	36.7	0.62 [0.37,1.06]	
FIGARO-DKD	37 / 2668	64 / 2601	63.3	0.56 [0.38,0.84]	
Total	59 / 4441	100 / 4410		0.58 [0.43,0.80]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.09 (df=1)	p=0.7648	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	2 / 124	100.0	0.89 [0.13,6.24]	
FIGARO-DKD	0 / 113	2 / 145	0.0	0.00 [0.00,25E296]	
Total	2 / 252	4 / 269		0.50 [0.09,2.73]	Z=-0.80, p=0.4255
Heterogeneity:	Q=0.33 (df=1)	p=0.5631	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 717	11 / 721	39.9	0.18 [0.04,0.82]	
FIGARO-DKD	4 / 716	7 / 736	60.1	0.59 [0.17,2.00]	
Total	6 / 1433	18 / 1457		0.34 [0.13,0.85]	Z=-2.31, p=0.0211
Heterogeneity:	Q=1.42 (df=1)	p=0.2328	I^2=29.8%		
Others					
FIDELIO-DKD	1 / 198	3 / 177	28.3	0.30 [0.03,2.84]	
FIGARO-DKD	5 / 186	3 / 176	71.7	1.58 [0.38,6.50]	
Total	6 / 384	6 / 353		0.93 [0.30,2.86]	Z=-0.12, p=0.9023
Heterogeneity:	Q=1.51 (df=1)	p=0.2187	I^2=33.9%		
Subgroup Heterogeneity:	Q=2.02 (df=3)	p=0.5693	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.13.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

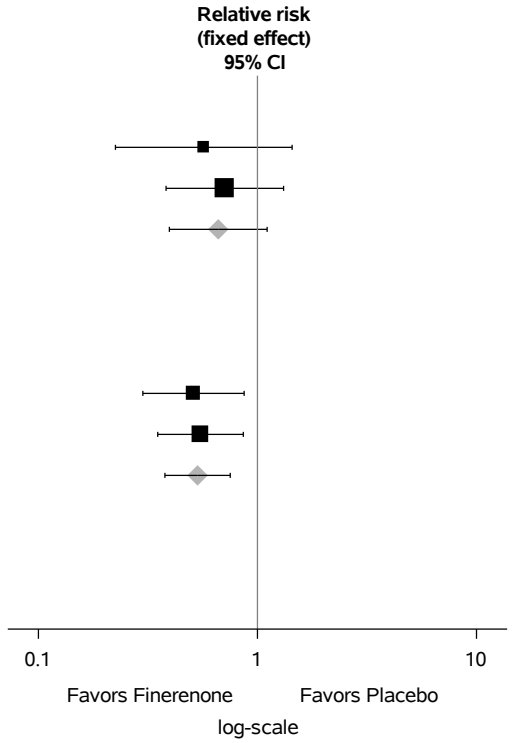
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	19 / 1949	38 / 2024	39.2	0.52 [0.30,0.90]	
FIGARO-DKD	31 / 2527	53 / 2571	60.8	0.60 [0.38,0.92]	
Total	50 / 4476	91 / 4595		0.56 [0.40,0.79]	Z=-3.28, p=0.0010
Heterogeneity:	Q=0.14 (df=1)	p=0.7034	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 878	14 / 807	35.8	0.53 [0.22,1.25]	
FIGARO-DKD	15 / 1156	23 / 1087	64.2	0.61 [0.32,1.17]	
Total	23 / 2034	37 / 1894		0.58 [0.35,0.97]	Z=-2.07, p=0.0386
Heterogeneity:	Q=0.08 (df=1)	p=0.7781	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9294	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.13.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

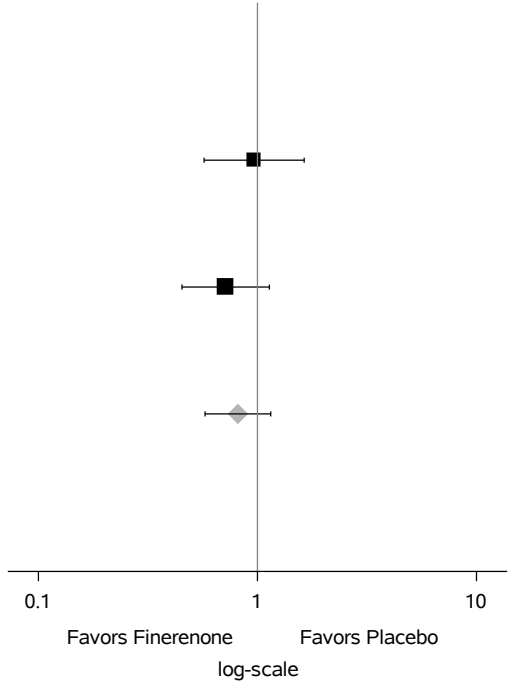
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	7 / 1201	12 / 1171	30.7	0.57 [0.22,1.44]	
FIGARO-DKD	17 / 1752	24 / 1755	69.3	0.71 [0.38,1.32]	
Total	24 / 2953	36 / 2926		0.66 [0.40,1.11]	Z=-1.57, p=0.1160
Heterogeneity:	Q=0.15 (df=1)	p=0.6975	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1626	40 / 1660	41.7	0.51 [0.30,0.87]	
FIGARO-DKD	29 / 1931	52 / 1903	58.3	0.55 [0.35,0.86]	
Total	49 / 3557	92 / 3563		0.53 [0.38,0.75]	Z=-3.59, p=0.0003
Heterogeneity:	Q=0.04 (df=1)	p=0.8354	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.48 (df=1)	p=0.4906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.14: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set

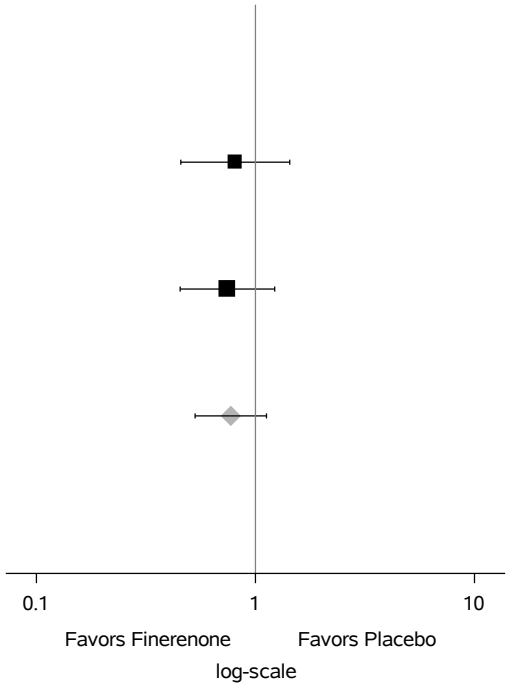
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	28 / 2831	43.3	0.97 [0.57,1.63]	
FIGARO-DKD	31 / 3683	43 / 3658	56.7	0.72 [0.45,1.13]	
Total	58 / 6510	71 / 6489		0.81 [0.58,1.15]	Z=-1.17, p=0.2431
Heterogeneity:	Q=0.70 (df=1)	p=0.4014	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.15: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set

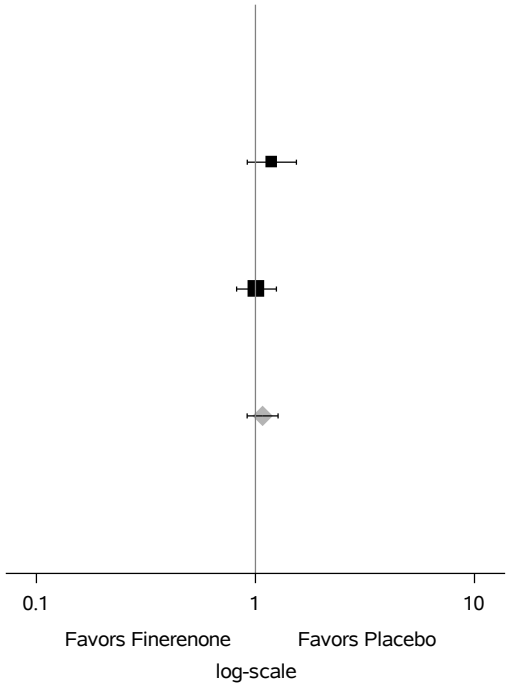
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	26 / 2831	42.9	0.81 [0.46,1.43]	
FIGARO-DKD	27 / 3683	36 / 3658	57.1	0.74 [0.45,1.22]	
Total	48 / 6510	62 / 6489		0.77 [0.53,1.12]	Z=-1.35, p=0.1757
Heterogeneity:	Q=0.05 (df=1)	p=0.8315	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.16: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set

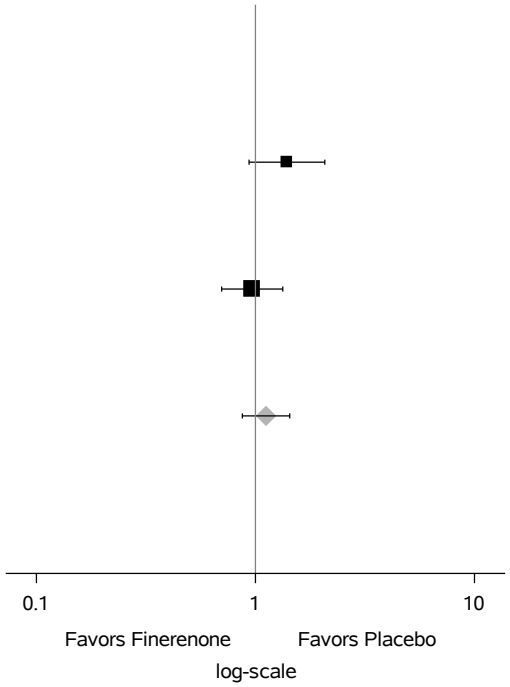
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	121 / 2827	102 / 2831	39.6	1.19 [0.92,1.54]	
FIGARO-DKD	169 / 3683	166 / 3658	60.4	1.01 [0.82,1.25]	
Total	290 / 6510	268 / 6489		1.08 [0.92,1.27]	Z=0.91, p=0.3648
Heterogeneity:	Q=0.90 (df=1)	p=0.3420	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.17: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set

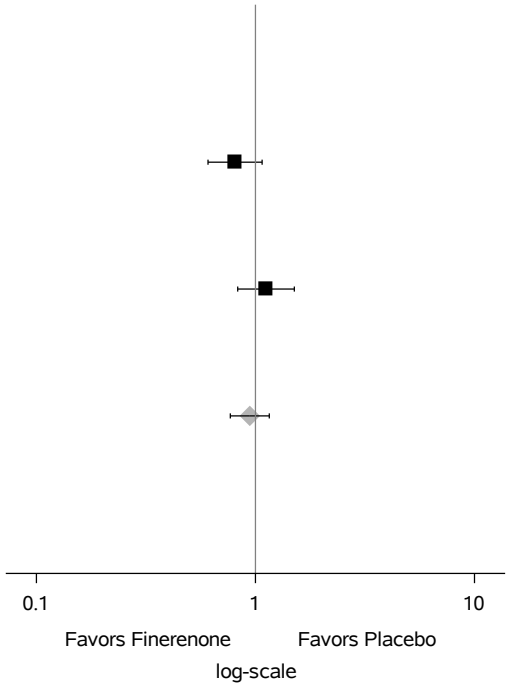
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2827	41 / 2831	39.4	1.39 [0.94,2.07]	
FIGARO-DKD	72 / 3683	74 / 3658	60.6	0.97 [0.70,1.33]	
Total	129 / 6510	115 / 6489		1.12 [0.87,1.43]	Z=0.87, p=0.3816
Heterogeneity:	Q=1.96 (df=1)	p=0.1617	I^2=48.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.18: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set

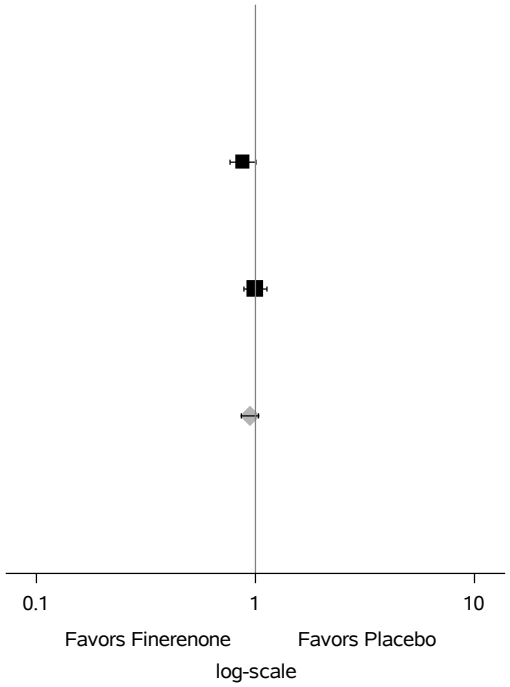
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	83 / 2827	103 / 2831	52.3	0.81 [0.61,1.07]	
FIGARO-DKD	90 / 3683	80 / 3658	47.7	1.12 [0.83,1.50]	
Total	173 / 6510	183 / 6489		0.94 [0.77,1.16]	Z=-0.57, p=0.5691
Heterogeneity:	Q=2.40 (df=1)	p=0.1213	I^2=58.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.19: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set

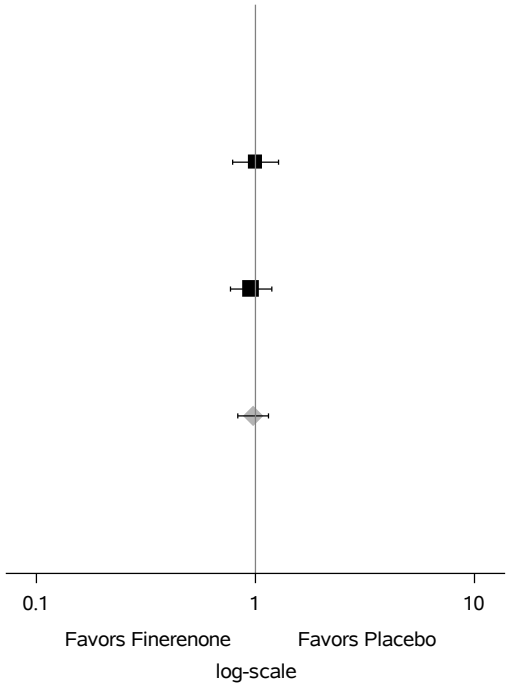
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	339 / 2827	387 / 2831	44.1	0.88 [0.77,1.01]	
FIGARO-DKD	461 / 3683	458 / 3658	55.9	1.00 [0.89,1.13]	
Total	800 / 6510	845 / 6489		0.94 [0.86,1.03]	Z=-1.26, p=0.2082
Heterogeneity:	Q=1.98 (df=1)	p=0.1595	I^2=49.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.20: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set

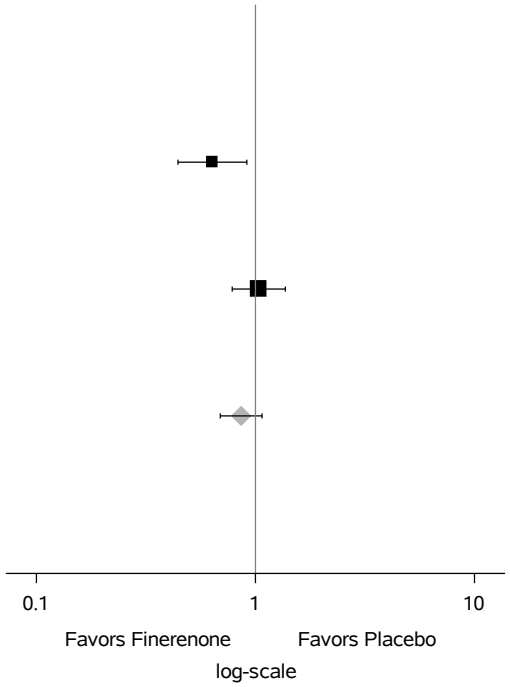
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	126 / 2831	44.7	1.00 [0.79,1.27]	
FIGARO-DKD	153 / 3683	159 / 3658	55.3	0.96 [0.77,1.19]	
Total	279 / 6510	285 / 6489		0.98 [0.83,1.15]	Z=-0.30, p=0.7672
Heterogeneity:	Q=0.08 (df=1)	p=0.7781	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.21: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set

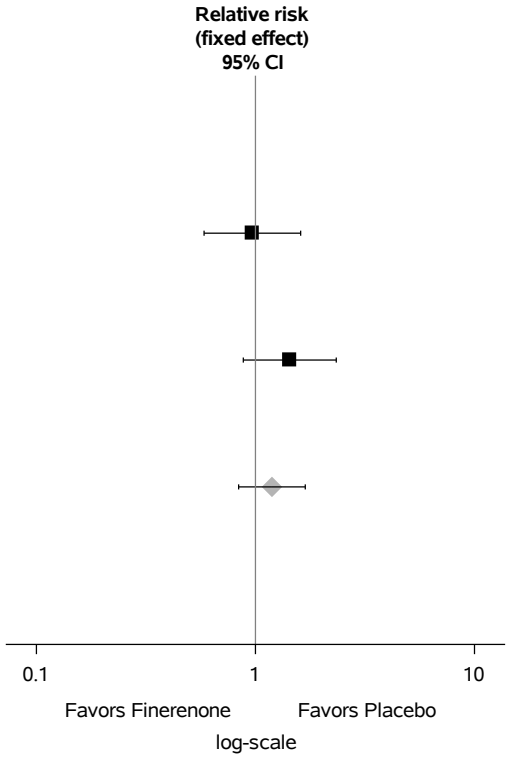
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	74 / 2831	37.3	0.64 [0.44,0.91]	
FIGARO-DKD	98 / 3683	94 / 3658	62.7	1.04 [0.78,1.37]	
Total	145 / 6510	168 / 6489		0.86 [0.69,1.07]	Z=-1.34, p=0.1795
Heterogeneity:	Q=4.37 (df=1)	p=0.0366	I^2=77.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.22: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set

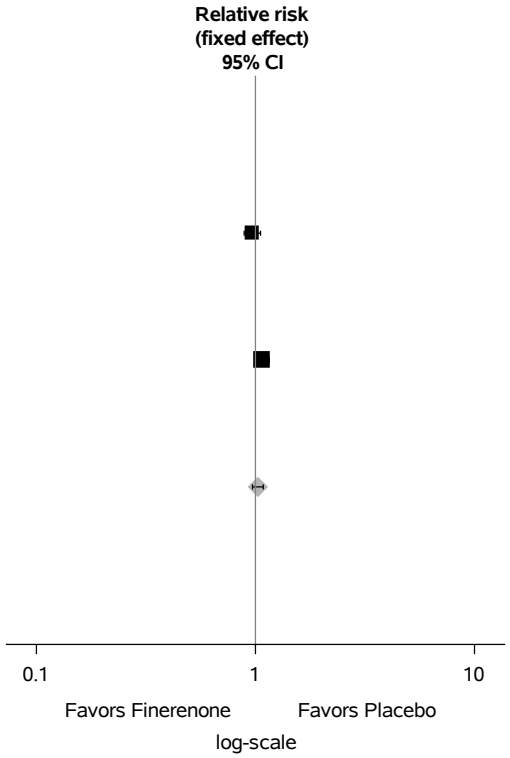
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	48.1	0.97 [0.58,1.61]	
FIGARO-DKD	39 / 3683	27 / 3658	51.9	1.43 [0.88,2.34]	
Total	68 / 6510	57 / 6489		1.19 [0.84,1.69]	Z=0.97, p=0.3320
Heterogeneity:	Q=1.20 (df=1)	p=0.2738	I^2=16.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.23: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

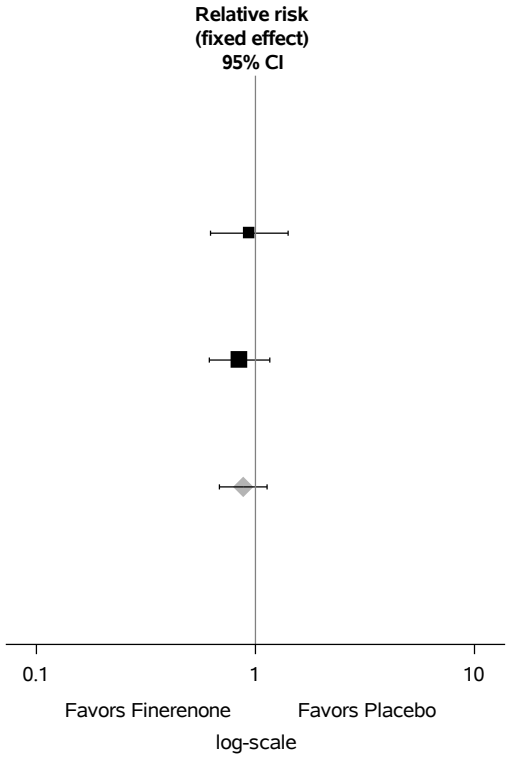
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	747 / 2827	773 / 2831	43.6	0.97 [0.89,1.05]	
FIGARO-DKD	1023 / 3683	947 / 3658	56.4	1.07 [0.99,1.16]	
Total	1770 / 6510	1720 / 6489		1.03 [0.97,1.09]	Z=0.88, p=0.3801
Heterogeneity:	Q=3.12 (df=1)	p=0.0774	I^2=67.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.24: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set

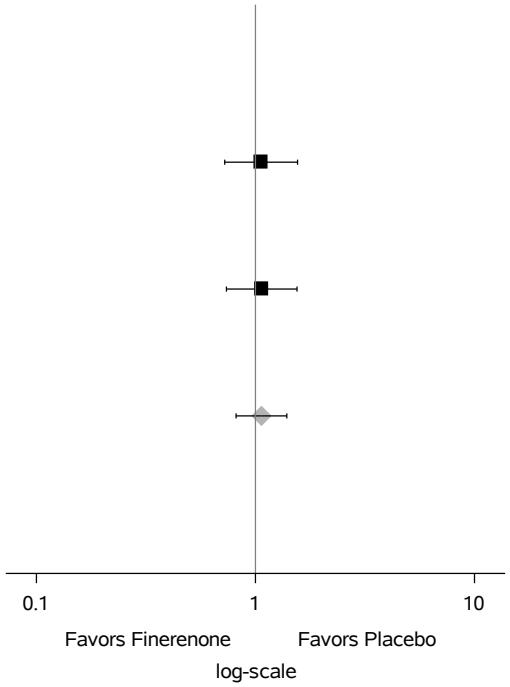
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	47 / 2831	37.8	0.94 [0.62,1.41]	
FIGARO-DKD	69 / 3683	81 / 3658	62.2	0.85 [0.62,1.16]	
Total	113 / 6510	128 / 6489		0.88 [0.68,1.13]	Z=-1.00, p=0.3151
Heterogeneity:	Q=0.15 (df=1)	p=0.6973	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.25: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set

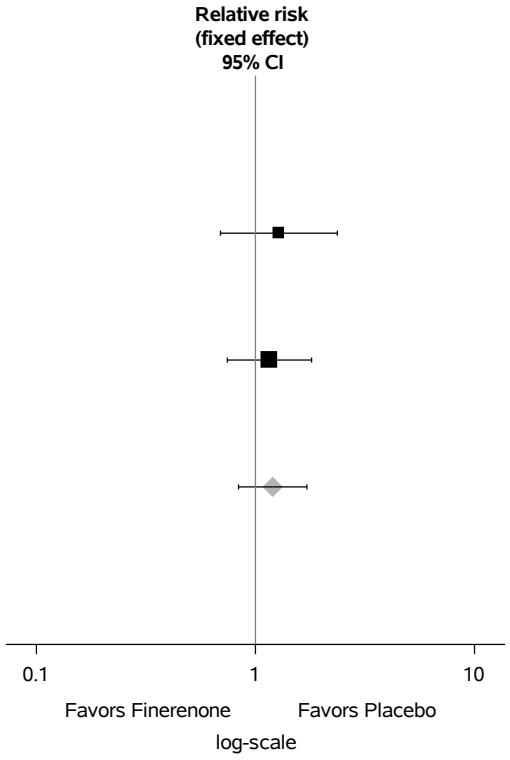
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	50 / 2831	48.5	1.06 [0.72,1.56]	
FIGARO-DKD	57 / 3683	53 / 3658	51.5	1.07 [0.74,1.55]	
Total	110 / 6510	103 / 6489		1.06 [0.82,1.39]	Z=0.46, p=0.6436
Heterogeneity:	Q=0.00 (df=1)	p=0.9816	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.26: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic gastritis (PT with Incidence >=1%)
Safety Analysis Set

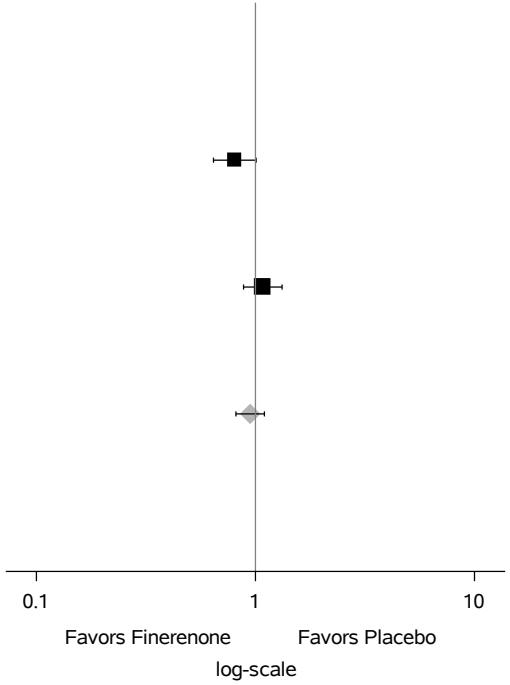
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	18 / 2831	34.2	1.28 [0.69,2.37]	
FIGARO-DKD	42 / 3683	36 / 3658	65.8	1.16 [0.74,1.80]	
Total	65 / 6510	54 / 6489		1.20 [0.84,1.72]	Z=0.99, p=0.3224
Heterogeneity:	Q=0.07 (df=1)	p=0.7974	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.27: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set

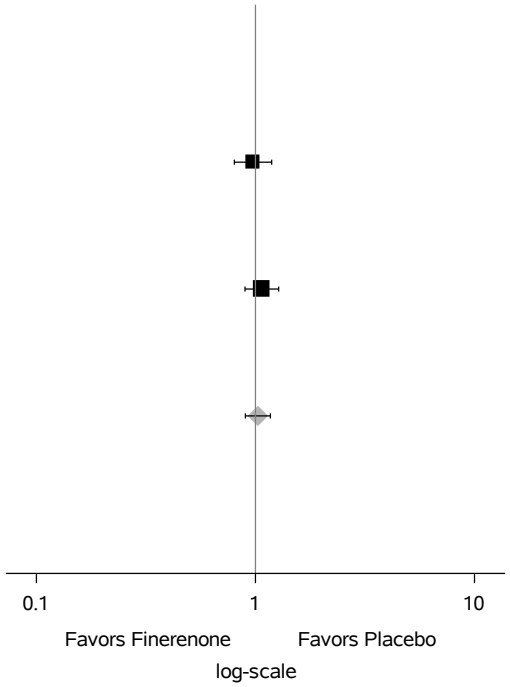
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	131 / 2827	163 / 2831	45.0	0.80 [0.64,1.01]	
FIGARO-DKD	186 / 3683	171 / 3658	55.0	1.08 [0.88,1.32]	
Total	317 / 6510	334 / 6489		0.95 [0.81,1.10]	Z=-0.73, p=0.4670
Heterogeneity:	Q=3.65 (df=1)	p=0.0560	I^2=72.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.28: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set

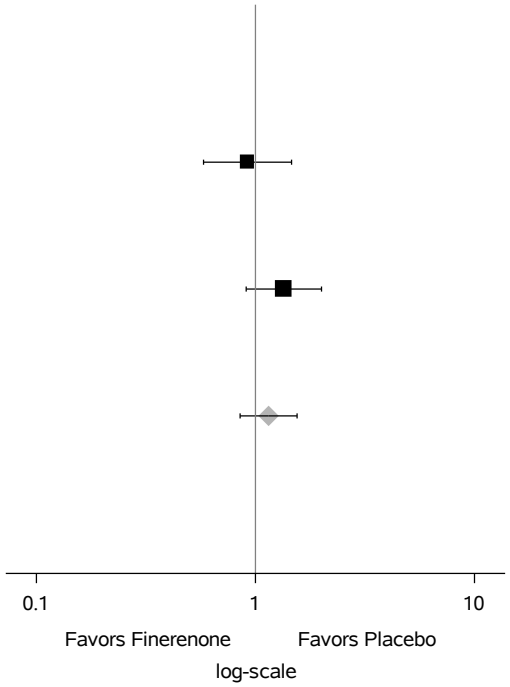
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	184 / 2827	189 / 2831	44.8	0.97 [0.80,1.19]	
FIGARO-DKD	239 / 3683	222 / 3658	55.2	1.07 [0.90,1.28]	
Total	423 / 6510	411 / 6489		1.03 [0.90,1.17]	Z=0.38, p=0.7027
Heterogeneity:	Q=0.47 (df=1)	p=0.4931	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.29: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set

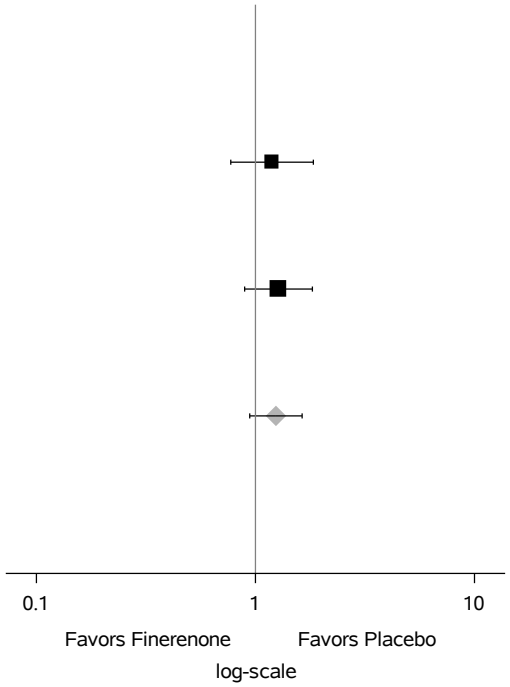
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	37 / 2831	42.3	0.92 [0.58,1.46]	
FIGARO-DKD	57 / 3683	42 / 3658	57.7	1.35 [0.91,2.00]	
Total	91 / 6510	79 / 6489		1.15 [0.85,1.55]	Z=0.90, p=0.3659
Heterogeneity:	Q=1.51 (df=1)	p=0.2192	I^2=33.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.30: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set

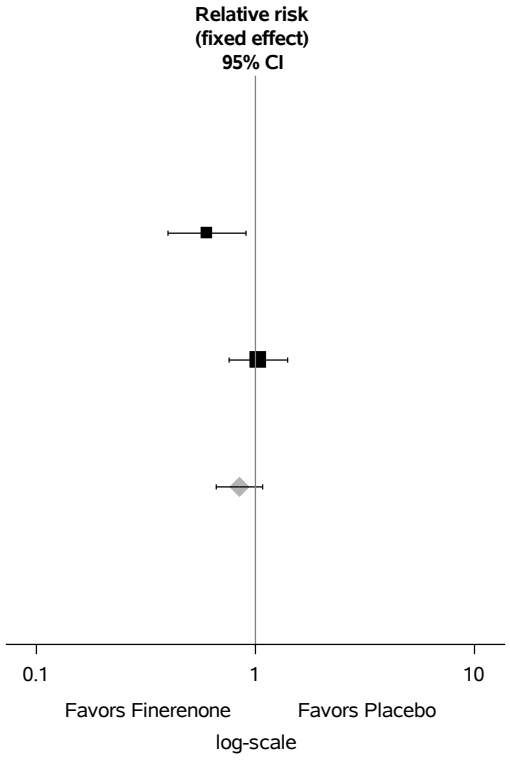
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	37 / 2831	40.2	1.19 [0.77,1.84]	
FIGARO-DKD	68 / 3683	53 / 3658	59.8	1.27 [0.89,1.82]	
Total	112 / 6510	90 / 6489		1.24 [0.94,1.63]	Z=1.53, p=0.1255
Heterogeneity:	Q=0.06 (df=1)	p=0.8131	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.31: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set

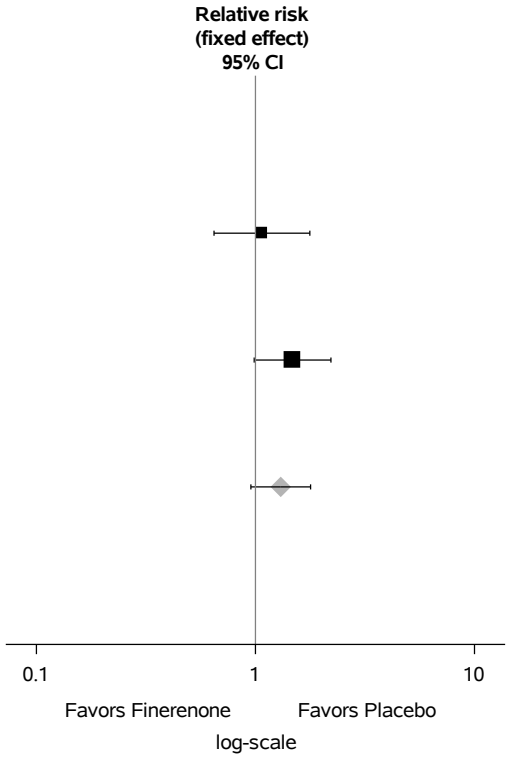
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	60 / 2831	36.0	0.60 [0.40,0.91]	
FIGARO-DKD	81 / 3683	78 / 3658	64.0	1.03 [0.76,1.40]	
Total	117 / 6510	138 / 6489		0.85 [0.66,1.08]	Z=-1.35, p=0.1764
Heterogeneity:	Q=4.27 (df=1)	p=0.0387	I^2=76.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.32: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set

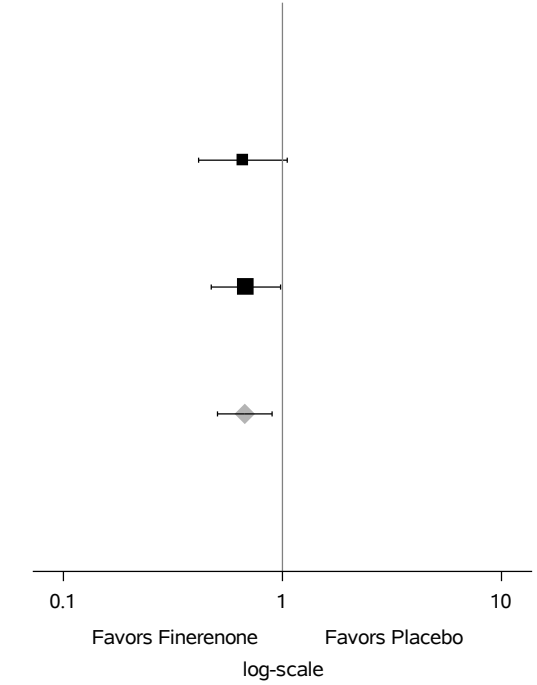
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	29 / 2831	39.1	1.07 [0.65,1.77]	
FIGARO-DKD	58 / 3683	39 / 3658	60.9	1.48 [0.99,2.21]	
Total	89 / 6510	68 / 6489		1.30 [0.95,1.79]	Z=1.66, p=0.0970
Heterogeneity:	Q=0.96 (df=1)	p=0.3280	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.33: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

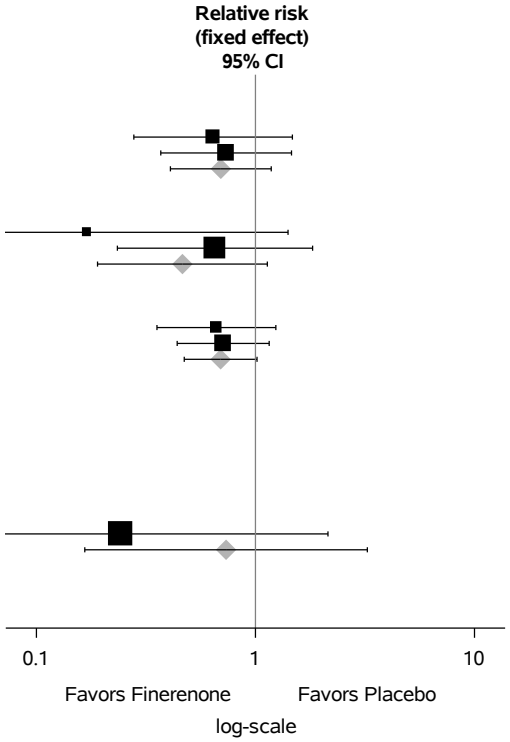
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	44 / 2831	38.0	0.66 [0.41,1.05]	
FIGARO-DKD	48 / 3683	70 / 3658	62.0	0.68 [0.47,0.98]	
Total	77 / 6510	114 / 6489		0.67 [0.51,0.90]	Z=-2.70, p=0.0068
Heterogeneity:	Q=0.01 (df=1)	p=0.9172	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.33.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

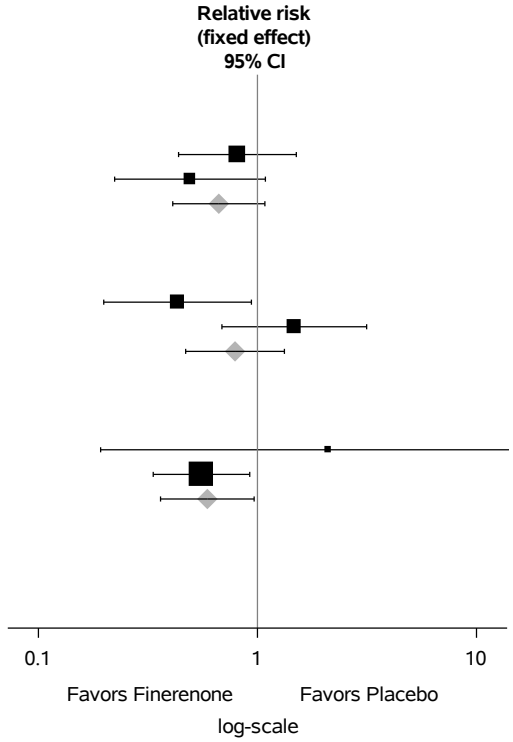
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1178	14 / 1174	40.5	0.64 [0.28,1.47]	
FIGARO-DKD	14 / 1752	19 / 1747	59.5	0.73 [0.37,1.46]	
Total	23 / 2930	33 / 2921		0.69 [0.41,1.18]	Z=-1.35, p=0.1781
Heterogeneity:	Q=0.06 (df=1)	p=0.8037	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 466	6 / 476	19.1	0.17 [0.02,1.41]	
FIGARO-DKD	6 / 559	9 / 548	80.9	0.65 [0.23,1.82]	
Total	7 / 1025	15 / 1024		0.46 [0.19,1.13]	Z=-1.69, p=0.0919
Heterogeneity:	Q=1.29 (df=1)	p=0.2556	I^2=22.6%		
Asia					
FIDELIO-DKD	16 / 790	24 / 786	37.5	0.66 [0.36,1.24]	
FIGARO-DKD	27 / 811	38 / 813	62.5	0.71 [0.44,1.16]	
Total	43 / 1601	62 / 1599		0.69 [0.47,1.02]	Z=-1.88, p=0.0606
Heterogeneity:	Q=0.03 (df=1)	p=0.8597	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	0 / 294	0.0	131E9 [131E9,131E9]	
FIGARO-DKD	0 / 424	0 / 417	0.0	-	
Total	1 / 718	0 / 711		5.48E6 [5.48E6,5.48E6]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	105E9 [105E9,105E9]	
FIGARO-DKD	1 / 137	4 / 133	100.0	0.24 [0.03,2.14]	
Total	3 / 236	4 / 234		0.73 [0.17,3.24]	Z=-0.41, p=0.6835
Heterogeneity:	Q=0.99 (df=1)	p=0.3192	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.71 (df=4)	p=0.9498	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.33.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

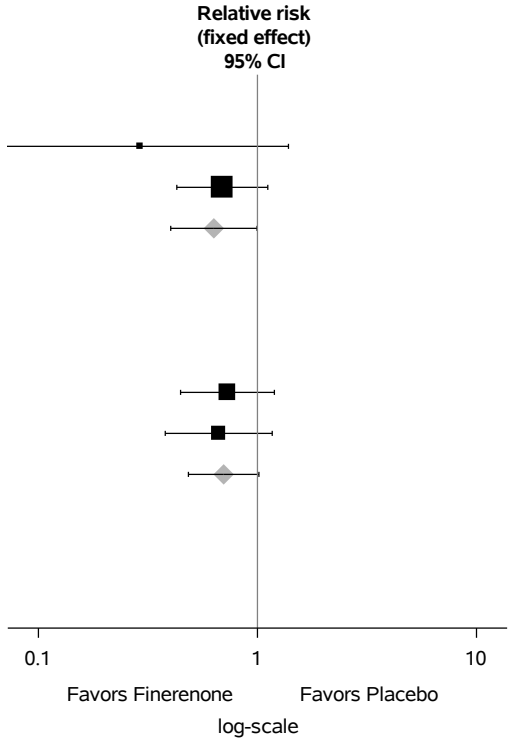
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	18 / 1556	22 / 1541	62.1	0.81 [0.44,1.50]	
FIGARO-DKD	9 / 637	18 / 627	37.9	0.49 [0.22,1.09]	
Total	27 / 2193	40 / 2168		0.67 [0.41,1.08]	Z=-1.64, p=0.1002
Heterogeneity:	Q=0.95 (df=1)	p=0.3309	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	21 / 1069	49.0	0.43 [0.20,0.94]	
FIGARO-DKD	16 / 720	11 / 729	51.0	1.47 [0.69,3.15]	
Total	25 / 1781	32 / 1798		0.79 [0.47,1.33]	Z=-0.89, p=0.3734
Heterogeneity:	Q=4.90 (df=1)	p=0.0268	I^2=79.6%		
>= 60					
FIDELIO-DKD	2 / 210	1 / 221	4.3	2.10 [0.19,23.04]	
FIGARO-DKD	23 / 2326	41 / 2302	95.7	0.56 [0.33,0.92]	
Total	25 / 2536	42 / 2523		0.59 [0.36,0.97]	Z=-2.10, p=0.0358
Heterogeneity:	Q=1.14 (df=1)	p=0.2856	I^2=12.3%		
Subgroup Heterogeneity:	Q=0.64 (df=2)	p=0.7262	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.33.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

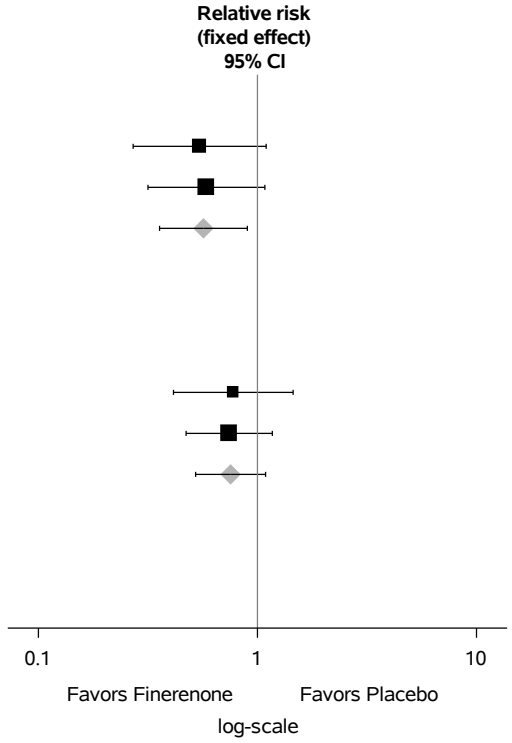
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	7 / 213	8.6	0.29 [0.06,1.39]	
FIGARO-DKD	28 / 1720	40 / 1698	91.4	0.69 [0.43,1.11]	
Total	30 / 1929	47 / 1911		0.63 [0.40,1.00]	Z=-1.98, p=0.0477
Heterogeneity:	Q=1.08 (df=1)	p=0.2983	I^2=7.6%		
Very High					
FIDELIO-DKD	27 / 2618	37 / 2618	56.5	0.73 [0.45,1.19]	
FIGARO-DKD	20 / 1963	30 / 1960	43.5	0.67 [0.38,1.17]	
Total	47 / 4581	67 / 4578		0.70 [0.48,1.02]	Z=-1.88, p=0.0603
Heterogeneity:	Q=0.06 (df=1)	p=0.8097	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7304	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.33.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

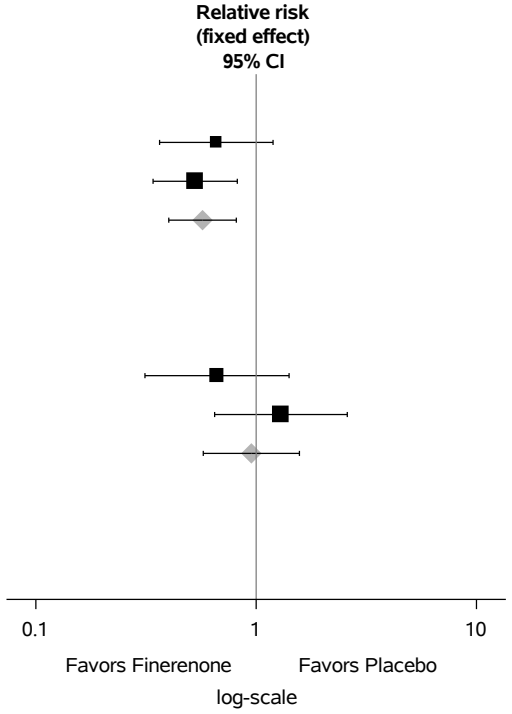
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	12 / 1301	22 / 1299	43.6	0.54 [0.27,1.10]	
FIGARO-DKD	16 / 1673	27 / 1651	56.4	0.58 [0.32,1.08]	
Total	28 / 2974	49 / 2950		0.57 [0.36,0.90]	Z=-2.41, p=0.0159
Heterogeneity:	Q=0.02 (df=1)	p=0.8809	I^2=0.0%		
Absent					
FIDELIO-DKD	17 / 1526	22 / 1532	34.2	0.78 [0.41,1.46]	
FIGARO-DKD	32 / 2010	43 / 2007	65.8	0.74 [0.47,1.17]	
Total	49 / 3536	65 / 3539		0.75 [0.52,1.09]	Z=-1.50, p=0.1325
Heterogeneity:	Q=0.01 (df=1)	p=0.9133	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.90 (df=1)	p=0.3431	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.33.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

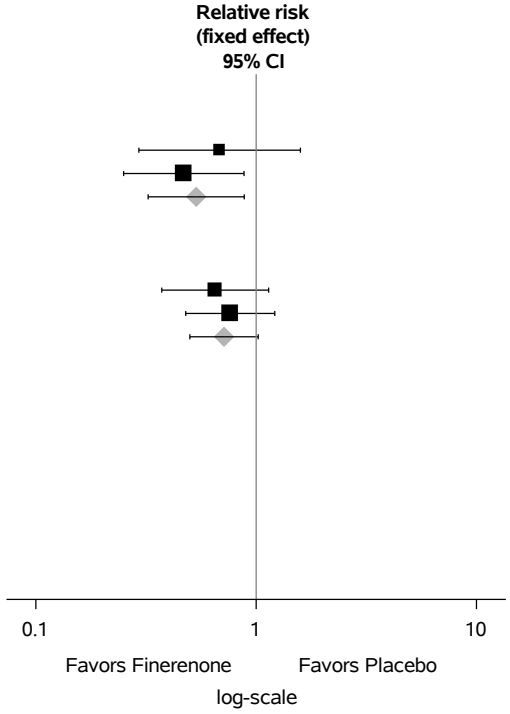
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	18 / 1879	27 / 1858	35.5	0.66 [0.36,1.19]	
FIGARO-DKD	30 / 2643	56 / 2608	64.5	0.53 [0.34,0.82]	
Total	48 / 4522	83 / 4466		0.57 [0.40,0.81]	Z=-3.11, p=0.0019
Heterogeneity:	Q=0.34 (df=1)	p=0.5578	I^2=0.0%		
> 4.5					
FIDELIO-DKD	11 / 948	17 / 973	45.9	0.66 [0.31,1.41]	
FIGARO-DKD	18 / 1040	14 / 1048	54.1	1.30 [0.65,2.59]	
Total	29 / 1988	31 / 2021		0.95 [0.58,1.57]	Z=-0.20, p=0.8444
Heterogeneity:	Q=1.64 (df=1)	p=0.2007	I^2=38.9%		
Subgroup Heterogeneity:	Q=2.65 (df=1)	p=0.1035	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.33.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

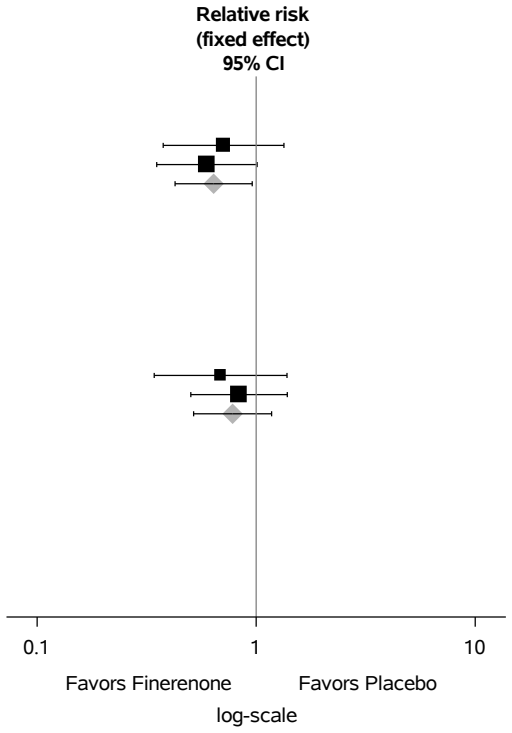
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 788	13 / 777	35.7	0.68 [0.29,1.59]	
FIGARO-DKD	14 / 1187	30 / 1194	64.3	0.47 [0.25,0.88]	
Total	23 / 1975	43 / 1971		0.53 [0.32,0.88]	Z=-2.45, p=0.0145
Heterogeneity:	Q=0.49 (df=1)	p=0.4856	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	20 / 1897	31 / 1916	41.0	0.65 [0.37,1.14]	
FIGARO-DKD	31 / 2389	40 / 2351	59.0	0.76 [0.48,1.21]	
Total	51 / 4286	71 / 4267		0.71 [0.50,1.02]	Z=-1.84, p=0.0653
Heterogeneity:	Q=0.18 (df=1)	p=0.6714	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	0 / 138	0.0	-	
FIGARO-DKD	3 / 107	0 / 113	0.0	146E9 [146E9,146E9]	
Total	3 / 248	0 / 251		1.76E7 [1.76E7,1.76E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.86 (df=2)	p=0.6521	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.33.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

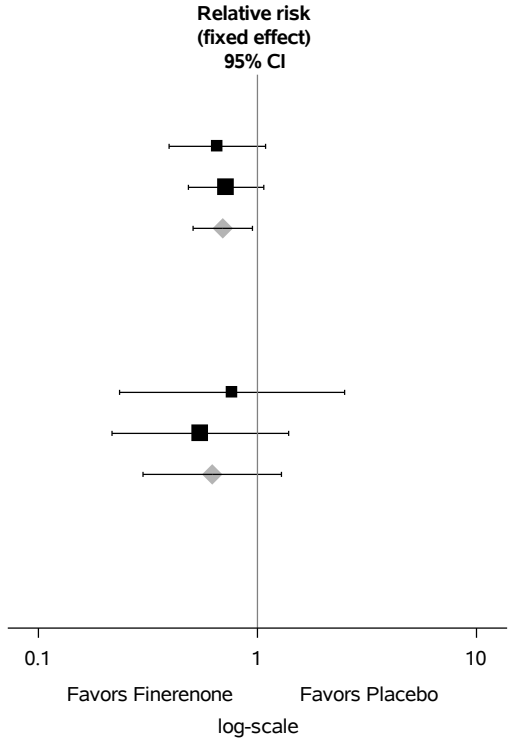
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	16 / 1773	23 / 1809	40.9	0.71 [0.38,1.34]	
FIGARO-DKD	22 / 2668	36 / 2601	59.1	0.60 [0.35,1.01]	
Total	38 / 4441	59 / 4410		0.64 [0.43,0.96]	Z=-2.16, p=0.0307
Heterogeneity:	Q=0.17 (df=1)	p=0.6775	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 139	1 / 124	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	0 / 113	1 / 145	0.0	0.00 [0.00,18E296]	
Total	0 / 252	2 / 269		0.00 [0.00,17E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	13 / 717	19 / 721	34.6	0.69 [0.34,1.38]	
FIGARO-DKD	26 / 716	32 / 736	65.4	0.84 [0.50,1.39]	
Total	39 / 1433	51 / 1457		0.78 [0.52,1.18]	Z=-1.18, p=0.2362
Heterogeneity:	Q=0.19 (df=1)	p=0.6596	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	1 / 177	0.0	0.00 [0.00,83E295]	
FIGARO-DKD	0 / 186	1 / 176	0.0	0.00 [0.00,22E296]	
Total	0 / 384	2 / 353		0.00 [0.00,22E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.46 (df=3)	p=0.9278	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.33.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

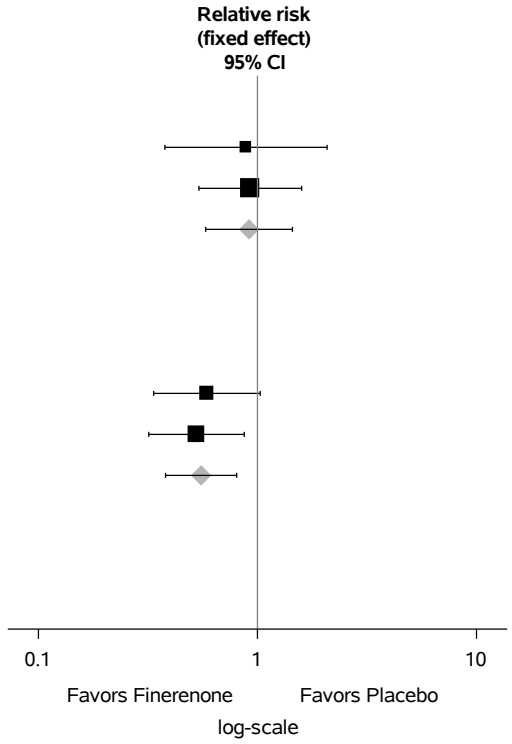
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 1949	38 / 2024	37.9	0.66 [0.39,1.09]	
FIGARO-DKD	41 / 2527	58 / 2571	62.1	0.72 [0.48,1.07]	
Total	65 / 4476	96 / 4595		0.69 [0.51,0.95]	Z=-2.29, p=0.0220
Heterogeneity:	Q=0.08 (df=1)	p=0.7790	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 878	6 / 807	38.1	0.77 [0.23,2.50]	
FIGARO-DKD	7 / 1156	12 / 1087	61.9	0.55 [0.22,1.39]	
Total	12 / 2034	18 / 1894		0.62 [0.30,1.29]	Z=-1.28, p=0.2003
Heterogeneity:	Q=0.19 (df=1)	p=0.6634	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7839	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.33.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

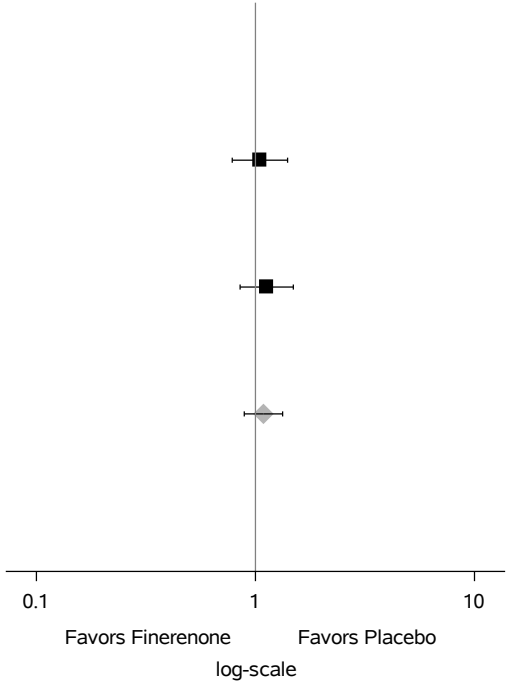
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1201	11 / 1171	28.6	0.89 [0.38,2.08]	
FIGARO-DKD	25 / 1752	27 / 1755	71.4	0.93 [0.54,1.59]	
Total	35 / 2953	38 / 2926		0.92 [0.58,1.44]	Z=-0.38, p=0.7046
Heterogeneity:	Q=0.01 (df=1)	p=0.9298	I^2=0.0%		
>= 65					
FIDELIO-DKD	19 / 1626	33 / 1660	44.6	0.59 [0.34,1.03]	
FIGARO-DKD	23 / 1931	43 / 1903	55.4	0.53 [0.32,0.87]	
Total	42 / 3557	76 / 3563		0.55 [0.38,0.80]	Z=-3.10, p=0.0019
Heterogeneity:	Q=0.08 (df=1)	p=0.7766	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.80 (df=1)	p=0.0940	I^2=64.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.34: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set

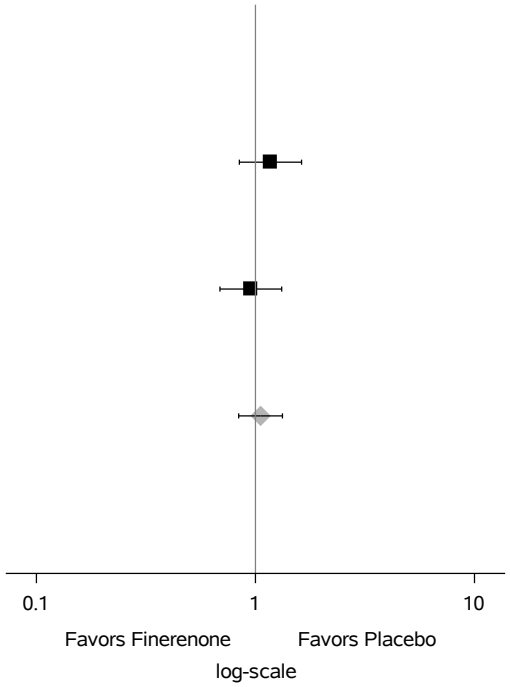
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	90 / 2827	86 / 2831	48.0	1.05 [0.78,1.40]	
FIGARO-DKD	102 / 3683	90 / 3658	52.0	1.13 [0.85,1.49]	
Total	192 / 6510	176 / 6489		1.09 [0.89,1.33]	Z=0.82, p=0.4139
Heterogeneity:	Q=0.12 (df=1)	p=0.7285	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.35: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set

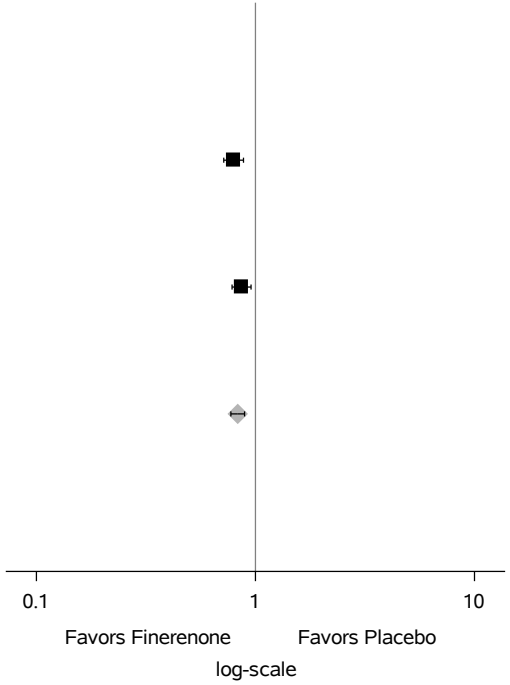
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	76 / 2827	65 / 2831	49.6	1.17 [0.84,1.62]	
FIGARO-DKD	70 / 3683	73 / 3658	50.4	0.95 [0.69,1.32]	
Total	146 / 6510	138 / 6489		1.06 [0.84,1.33]	Z=0.46, p=0.6461
Heterogeneity:	Q=0.77 (df=1)	p=0.3797	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.36: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

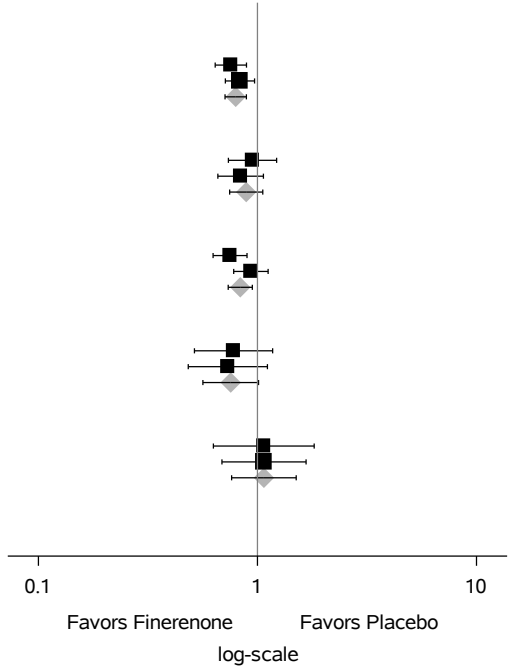
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	512 / 2827	645 / 2831	48.2	0.79 [0.72,0.88]	
FIGARO-DKD	595 / 3683	684 / 3658	51.8	0.86 [0.78,0.95]	
Total	1107 / 6510	1329 / 6489		0.83 [0.77,0.89]	Z=-5.08, p=<.0001
Heterogeneity:	Q=1.29 (df=1)	p=0.2567	I^2=22.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.36.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

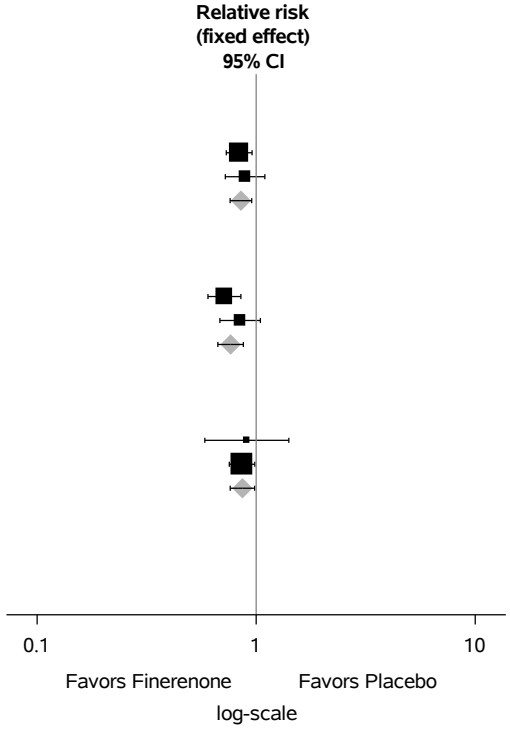
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	201 / 1178	265 / 1174	46.5	0.76 [0.64,0.89]	
FIGARO-DKD	252 / 1752	302 / 1747	53.5	0.83 [0.71,0.97]	
Total	453 / 2930	567 / 2921		0.80 [0.71,0.89]	Z=-4.00, p=<.0001
Heterogeneity:	Q=0.70 (df=1)	p=0.4033	I^2=0.0%		
North America					
FIDELIO-DKD	92 / 466	99 / 476	47.2	0.95 [0.74,1.22]	
FIGARO-DKD	100 / 559	117 / 548	52.8	0.84 [0.66,1.06]	
Total	192 / 1025	216 / 1024		0.89 [0.75,1.06]	Z=-1.33, p=0.1833
Heterogeneity:	Q=0.49 (df=1)	p=0.4831	I^2=0.0%		
Asia					
FIDELIO-DKD	162 / 790	215 / 786	50.7	0.75 [0.63,0.90]	
FIGARO-DKD	176 / 811	189 / 813	49.3	0.93 [0.78,1.12]	
Total	338 / 1601	404 / 1599		0.83 [0.74,0.95]	Z=-2.80, p=0.0052
Heterogeneity:	Q=2.86 (df=1)	p=0.0906	I^2=65.1%		
Latin America					
FIDELIO-DKD	35 / 294	45 / 294	50.6	0.78 [0.52,1.17]	
FIGARO-DKD	35 / 424	47 / 417	49.4	0.73 [0.48,1.11]	
Total	70 / 718	92 / 711		0.75 [0.56,1.01]	Z=-1.88, p=0.0596
Heterogeneity:	Q=0.04 (df=1)	p=0.8403	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 99	21 / 101	41.1	1.07 [0.63,1.82]	
FIGARO-DKD	32 / 137	29 / 133	58.9	1.07 [0.69,1.67]	
Total	54 / 236	50 / 234		1.07 [0.76,1.50]	Z=0.39, p=0.6952
Heterogeneity:	Q=0.00 (df=1)	p=0.9948	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.70 (df=4)	p=0.4483	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.36.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

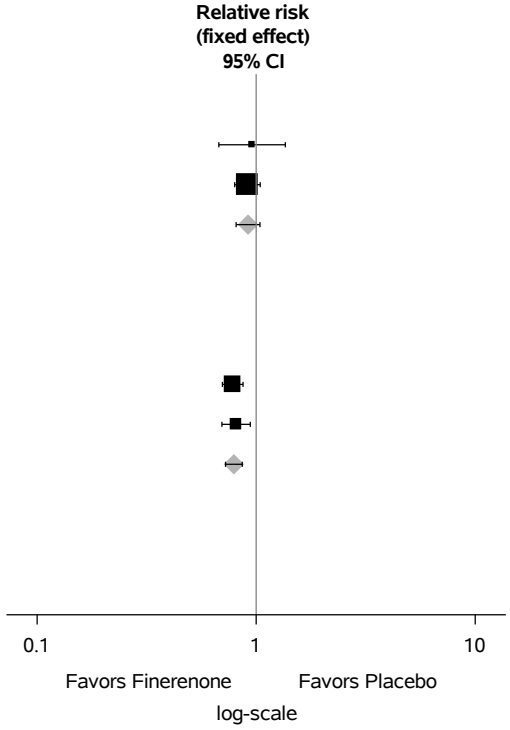
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	304 / 1556	360 / 1541	70.2	0.84 [0.73,0.96]	
FIGARO-DKD	132 / 637	146 / 627	29.8	0.89 [0.72,1.10]	
Total	436 / 2193	506 / 2168		0.85 [0.76,0.95]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.24 (df=1)	p=0.6237	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	177 / 1061	249 / 1069	60.2	0.72 [0.60,0.85]	
FIGARO-DKD	126 / 720	151 / 729	39.8	0.84 [0.68,1.05]	
Total	303 / 1781	400 / 1798		0.76 [0.67,0.87]	Z=-3.93, p=<.0001
Heterogeneity:	Q=1.39 (df=1)	p=0.2378	I^2=28.3%		
>= 60					
FIDELIO-DKD	31 / 210	36 / 221	8.5	0.91 [0.58,1.41]	
FIGARO-DKD	337 / 2326	387 / 2302	91.5	0.86 [0.75,0.99]	
Total	368 / 2536	423 / 2523		0.87 [0.76,0.98]	Z=-2.21, p=0.0274
Heterogeneity:	Q=0.05 (df=1)	p=0.8310	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.06 (df=2)	p=0.3569	I^2=2.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.36.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

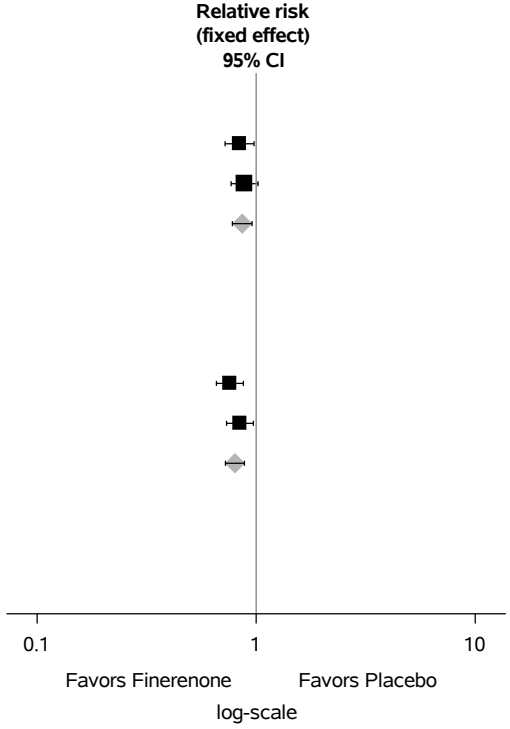
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	50 / 213	12.8	0.96 [0.68,1.36]	
FIGARO-DKD	329 / 1720	356 / 1698	87.2	0.91 [0.80,1.04]	
Total	376 / 1929	406 / 1911		0.92 [0.81,1.04]	Z=-1.34, p=0.1807
Heterogeneity:	Q=0.07 (df=1)	p=0.7982	I^2=0.0%		
Very High					
FIDELIO-DKD	465 / 2618	595 / 2618	65.4	0.78 [0.70,0.87]	
FIGARO-DKD	266 / 1963	328 / 1960	34.6	0.81 [0.70,0.94]	
Total	731 / 4581	923 / 4578		0.79 [0.72,0.86]	Z=-5.23, p=<.0001
Heterogeneity:	Q=0.14 (df=1)	p=0.7062	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.64 (df=1)	p=0.0565	I^2=72.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.36.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

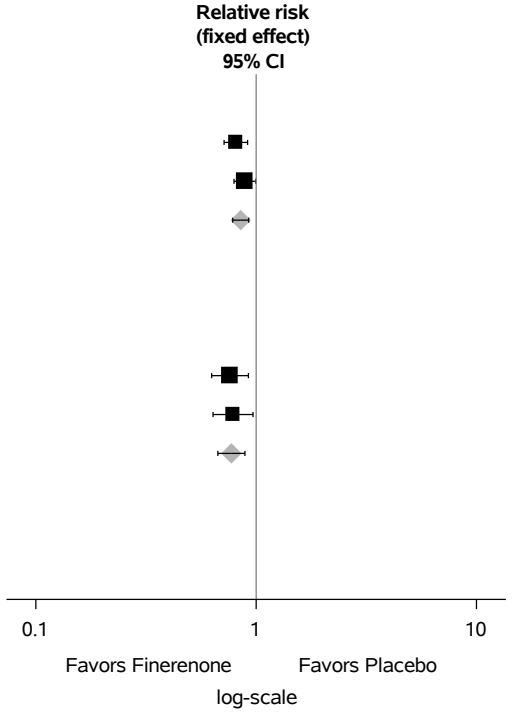
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	243 / 1301	289 / 1299	46.3	0.84 [0.72,0.98]	
FIGARO-DKD	296 / 1673	330 / 1651	53.7	0.89 [0.77,1.02]	
Total	539 / 2974	619 / 2950		0.86 [0.78,0.96]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.25 (df=1)	p=0.6176	I^2=0.0%		
Absent					
FIDELIO-DKD	269 / 1526	356 / 1532	49.8	0.76 [0.66,0.87]	
FIGARO-DKD	299 / 2010	354 / 2007	50.2	0.84 [0.73,0.97]	
Total	568 / 3536	710 / 3539		0.80 [0.72,0.88]	Z=-4.38, p=<.0001
Heterogeneity:	Q=1.08 (df=1)	p=0.2987	I^2=7.4%		
Subgroup Heterogeneity:	Q=1.09 (df=1)	p=0.2954	I^2=8.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.36.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

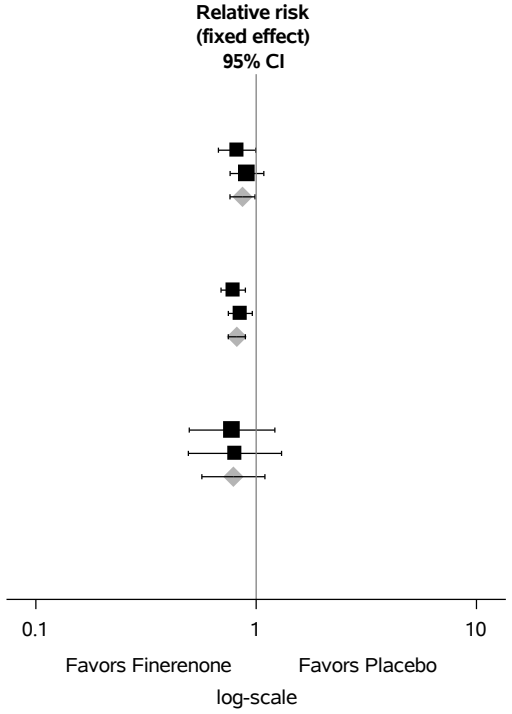
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	363 / 1879	444 / 1858	46.1	0.81 [0.71,0.91]	
FIGARO-DKD	461 / 2643	512 / 2608	53.9	0.89 [0.79,1.00]	
Total	824 / 4522	956 / 4466		0.85 [0.78,0.92]	Z=-3.80, p=0.0001
Heterogeneity:	Q=1.22 (df=1)	p=0.2691	I^2=18.1%		
> 4.5					
FIDELIO-DKD	149 / 948	201 / 973	54.2	0.76 [0.63,0.92]	
FIGARO-DKD	134 / 1040	172 / 1048	45.8	0.79 [0.64,0.97]	
Total	283 / 1988	373 / 2021		0.77 [0.67,0.89]	Z=-3.59, p=0.0003
Heterogeneity:	Q=0.05 (df=1)	p=0.8287	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=1)	p=0.2462	I^2=25.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.36.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

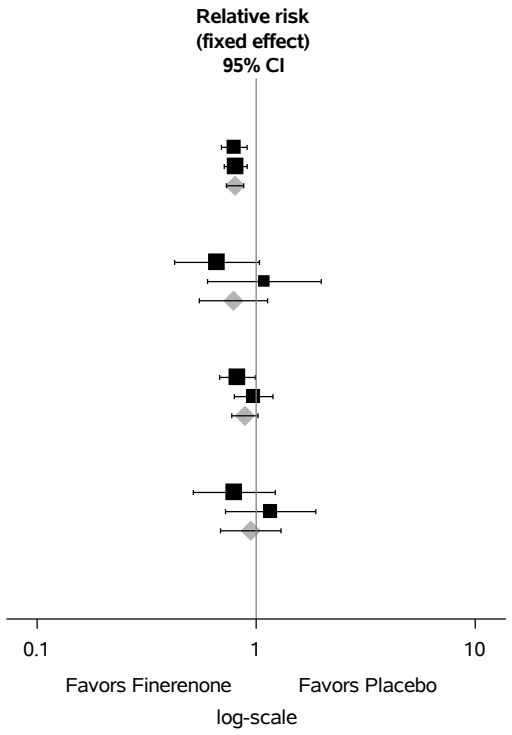
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	147 / 788	177 / 777	44.9	0.82 [0.67,1.00]	
FIGARO-DKD	195 / 1187	216 / 1194	55.1	0.91 [0.76,1.08]	
Total	342 / 1975	393 / 1971		0.87 [0.76,0.99]	Z=-2.14, p=0.0320
Heterogeneity:	Q=0.59 (df=1)	p=0.4407	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	338 / 1897	434 / 1916	49.2	0.79 [0.69,0.89]	
FIGARO-DKD	378 / 2389	439 / 2351	50.8	0.85 [0.75,0.96]	
Total	716 / 4286	873 / 4267		0.82 [0.75,0.89]	Z=-4.45, p=<.0001
Heterogeneity:	Q=0.67 (df=1)	p=0.4140	I^2=0.0%		
>= 160					
FIDELIO-DKD	27 / 141	34 / 138	54.2	0.78 [0.50,1.22]	
FIGARO-DKD	22 / 107	29 / 113	45.8	0.80 [0.49,1.30]	
Total	49 / 248	63 / 251		0.79 [0.57,1.10]	Z=-1.42, p=0.1566
Heterogeneity:	Q=0.01 (df=1)	p=0.9284	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=2)	p=0.7257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.36.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

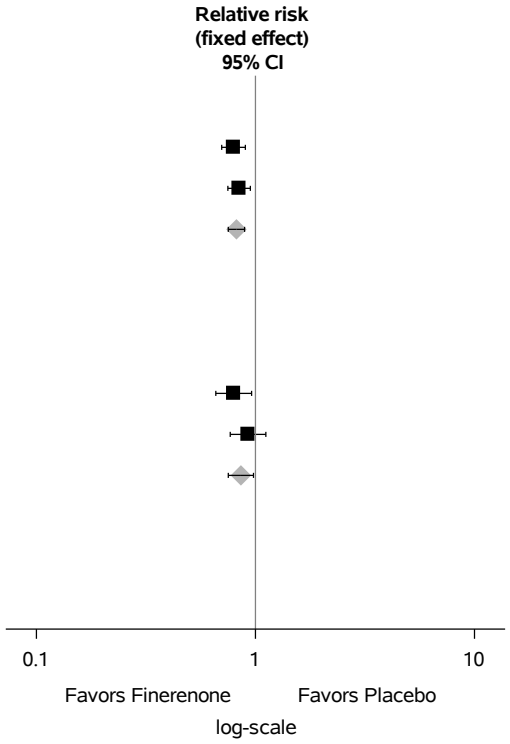
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	302 / 1773	388 / 1809	44.2	0.79 [0.69,0.91]	
FIGARO-DKD	402 / 2668	486 / 2601	55.8	0.81 [0.71,0.91]	
Total	704 / 4441	874 / 4410		0.80 [0.73,0.88]	Z=-4.83, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8687	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 139	35 / 124	64.3	0.66 [0.42,1.04]	
FIGARO-DKD	17 / 113	20 / 145	35.7	1.09 [0.60,1.98]	
Total	43 / 252	55 / 269		0.79 [0.55,1.13]	Z=-1.30, p=0.1923
Heterogeneity:	Q=1.71 (df=1)	p=0.1904	I^2=41.7%		
Asian					
FIDELIO-DKD	152 / 717	186 / 721	54.0	0.82 [0.68,0.99]	
FIGARO-DKD	144 / 716	152 / 736	46.0	0.97 [0.79,1.19]	
Total	296 / 1433	338 / 1457		0.89 [0.77,1.02]	Z=-1.69, p=0.0918
Heterogeneity:	Q=1.45 (df=1)	p=0.2292	I^2=30.8%		
Others					
FIDELIO-DKD	32 / 198	36 / 177	54.8	0.79 [0.52,1.22]	
FIGARO-DKD	32 / 186	26 / 176	45.2	1.16 [0.72,1.87]	
Total	64 / 384	62 / 353		0.94 [0.69,1.30]	Z=-0.35, p=0.7269
Heterogeneity:	Q=1.37 (df=1)	p=0.2425	I^2=26.8%		
Subgroup Heterogeneity:	Q=2.25 (df=3)	p=0.5220	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.36.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

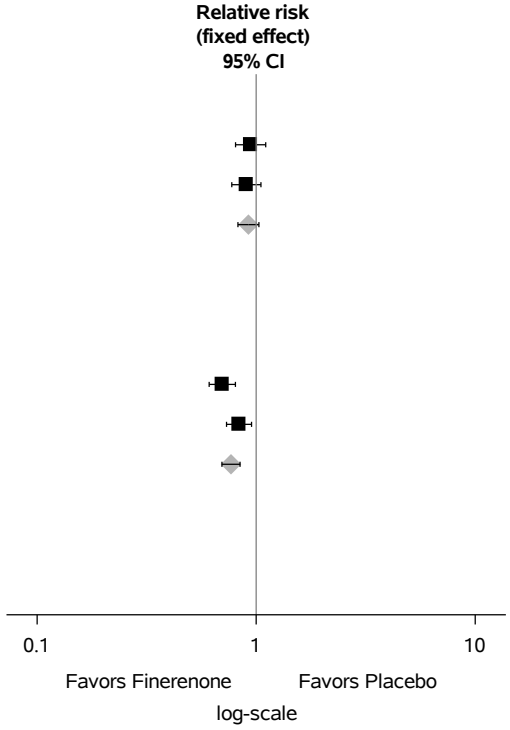
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	351 / 1949	459 / 2024	47.5	0.79 [0.70,0.90]	
FIGARO-DKD	413 / 2527	499 / 2571	52.5	0.84 [0.75,0.95]	
Total	764 / 4476	958 / 4595		0.82 [0.75,0.89]	Z=-4.57, p=<.0001
Heterogeneity:	Q=0.45 (df=1)	p=0.5031	I^2=0.0%		
Female					
FIDELIO-DKD	161 / 878	186 / 807	49.7	0.80 [0.66,0.96]	
FIGARO-DKD	182 / 1156	185 / 1087	50.3	0.93 [0.77,1.12]	
Total	343 / 2034	371 / 1894		0.86 [0.75,0.98]	Z=-2.26, p=0.0236
Heterogeneity:	Q=1.24 (df=1)	p=0.2654	I^2=19.4%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.36.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

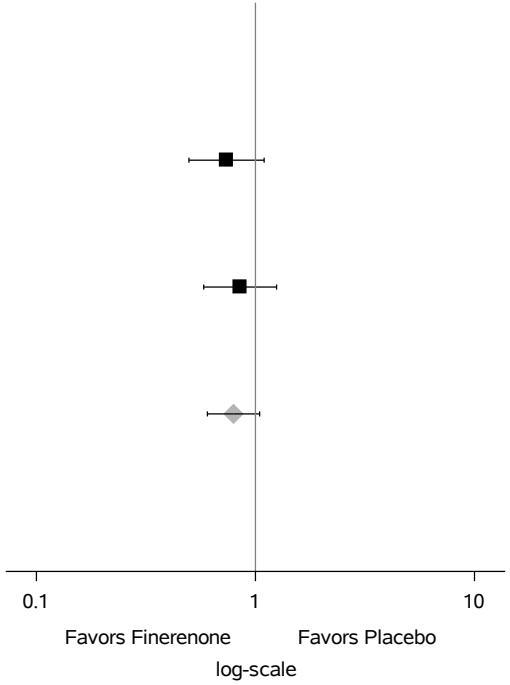
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	239 / 1201	247 / 1171	48.3	0.94 [0.81,1.11]	
FIGARO-DKD	262 / 1752	291 / 1755	51.7	0.90 [0.77,1.05]	
Total	501 / 2953	538 / 2926		0.92 [0.83,1.03]	Z=-1.45, p=0.1470
Heterogeneity:	Q=0.16 (df=1)	p=0.6889	I^2=0.0%		
>= 65					
FIDELIO-DKD	273 / 1626	398 / 1660	47.6	0.70 [0.61,0.80]	
FIGARO-DKD	333 / 1931	393 / 1903	52.4	0.84 [0.73,0.95]	
Total	606 / 3557	791 / 3563		0.77 [0.70,0.84]	Z=-5.46, p=<.0001
Heterogeneity:	Q=3.27 (df=1)	p=0.0704	I^2=69.5%		
Subgroup Heterogeneity:	Q=6.10 (df=1)	p=0.0135	I^2=83.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.37: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set

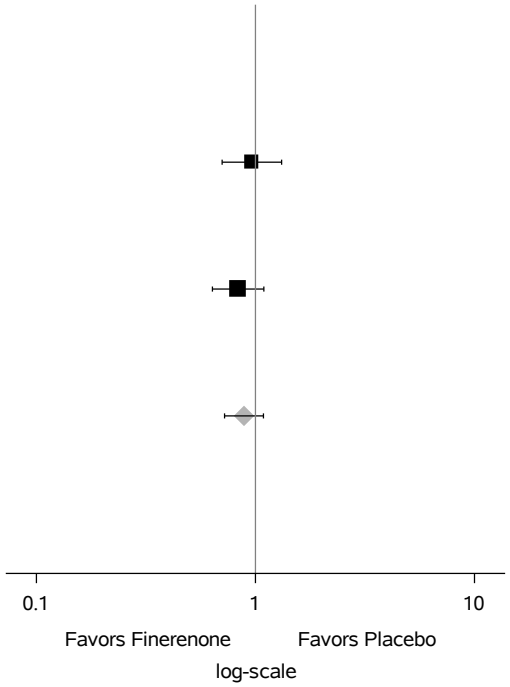
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	57 / 2831	48.4	0.74 [0.50,1.10]	
FIGARO-DKD	48 / 3683	56 / 3658	51.6	0.85 [0.58,1.25]	
Total	90 / 6510	113 / 6489		0.79 [0.60,1.05]	Z=-1.64, p=0.1001
Heterogeneity:	Q=0.26 (df=1)	p=0.6104	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.38: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set

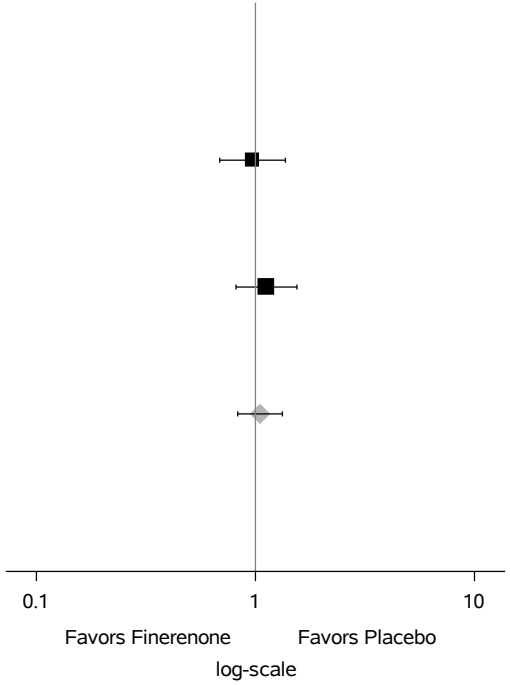
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	78 / 2831	42.8	0.96 [0.70,1.32]	
FIGARO-DKD	94 / 3683	112 / 3658	57.2	0.83 [0.64,1.09]	
Total	169 / 6510	190 / 6489		0.89 [0.72,1.09]	Z=-1.16, p=0.2480
Heterogeneity:	Q=0.47 (df=1)	p=0.4941	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.39: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set

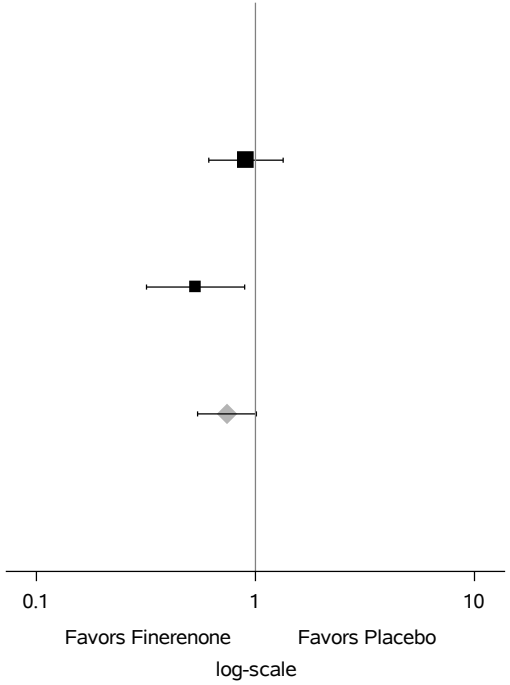
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	64 / 2831	46.3	0.97 [0.69,1.37]	
FIGARO-DKD	78 / 3683	69 / 3658	53.7	1.12 [0.81,1.55]	
Total	140 / 6510	133 / 6489		1.05 [0.83,1.33]	Z=0.40, p=0.6875
Heterogeneity:	Q=0.37 (df=1)	p=0.5434	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.40: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set

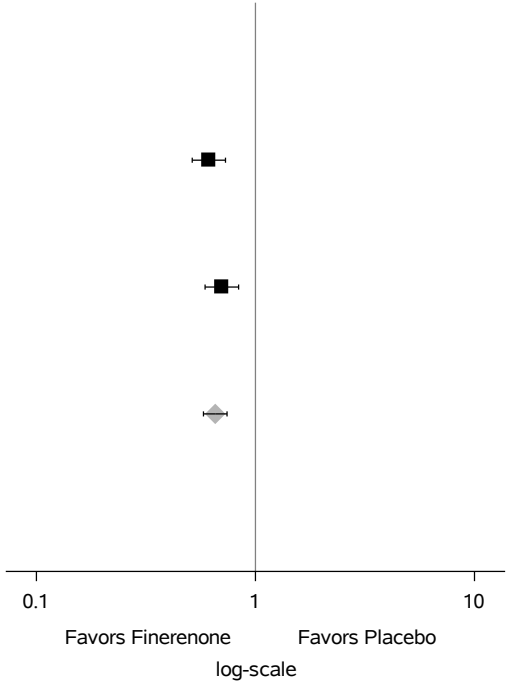
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	52 / 2831	63.5	0.91 [0.61,1.34]	
FIGARO-DKD	22 / 3683	41 / 3658	36.5	0.53 [0.32,0.89]	
Total	69 / 6510	93 / 6489		0.74 [0.54,1.01]	Z=-1.90, p=0.0580
Heterogeneity:	Q=2.57 (df=1)	p=0.1087	I^2=61.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.41: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

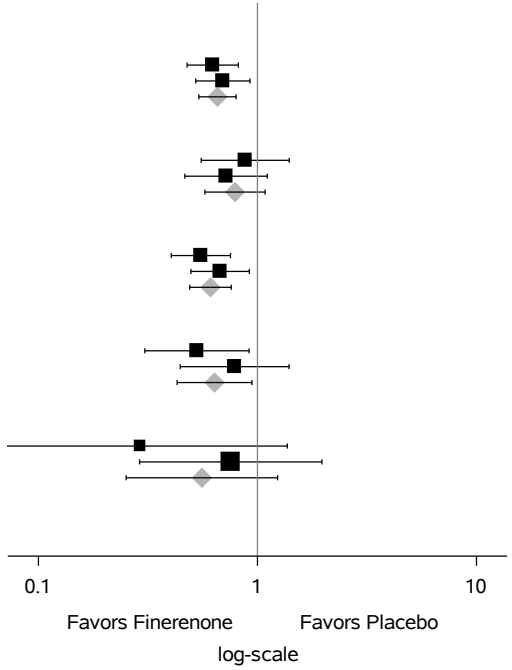
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	186 / 2827	304 / 2831	50.4	0.61 [0.51,0.73]	
FIGARO-DKD	198 / 3683	280 / 3658	49.6	0.70 [0.59,0.84]	
Total	384 / 6510	584 / 6489		0.66 [0.58,0.74]	Z=-6.68, p=<.0001
Heterogeneity:	Q=1.16 (df=1)	p=0.2809	I^2=14.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.41.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

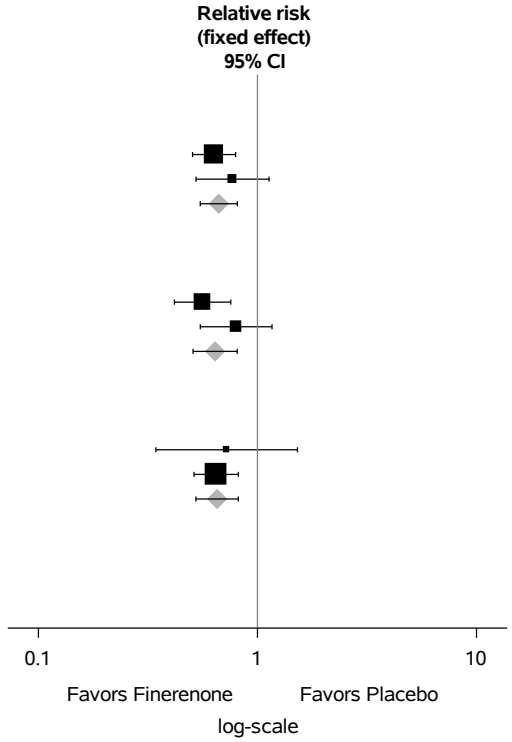
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	79 / 1178	126 / 1174	52.9	0.62 [0.48,0.82]	
FIGARO-DKD	76 / 1752	109 / 1747	47.1	0.70 [0.52,0.92]	
Total	155 / 2930	235 / 2921		0.66 [0.54,0.80]	Z=-4.21, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5938	I^2=0.0%		
North America					
FIDELIO-DKD	31 / 466	36 / 476	46.7	0.88 [0.55,1.40]	
FIGARO-DKD	33 / 559	45 / 548	53.3	0.72 [0.47,1.11]	
Total	64 / 1025	81 / 1024		0.79 [0.58,1.08]	Z=-1.47, p=0.1427
Heterogeneity:	Q=0.39 (df=1)	p=0.5330	I^2=0.0%		
Asia					
FIDELIO-DKD	56 / 790	101 / 786	49.3	0.55 [0.40,0.75]	
FIGARO-DKD	62 / 811	92 / 813	50.7	0.68 [0.50,0.92]	
Total	118 / 1601	193 / 1599		0.61 [0.49,0.76]	Z=-4.43, p=<.0001
Heterogeneity:	Q=0.83 (df=1)	p=0.3636	I^2=0.0%		
Latin America					
FIDELIO-DKD	18 / 294	34 / 294	52.2	0.53 [0.31,0.92]	
FIGARO-DKD	20 / 424	25 / 417	47.8	0.79 [0.44,1.39]	
Total	38 / 718	59 / 711		0.64 [0.43,0.94]	Z=-2.25, p=0.0246
Heterogeneity:	Q=0.96 (df=1)	p=0.3269	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	7 / 101	27.7	0.29 [0.06,1.37]	
FIGARO-DKD	7 / 137	9 / 133	72.3	0.76 [0.29,1.97]	
Total	9 / 236	16 / 234		0.56 [0.25,1.24]	Z=-1.44, p=0.1502
Heterogeneity:	Q=1.06 (df=1)	p=0.3032	I^2=5.7%		
Subgroup Heterogeneity:	Q=1.92 (df=4)	p=0.7509	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.41.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

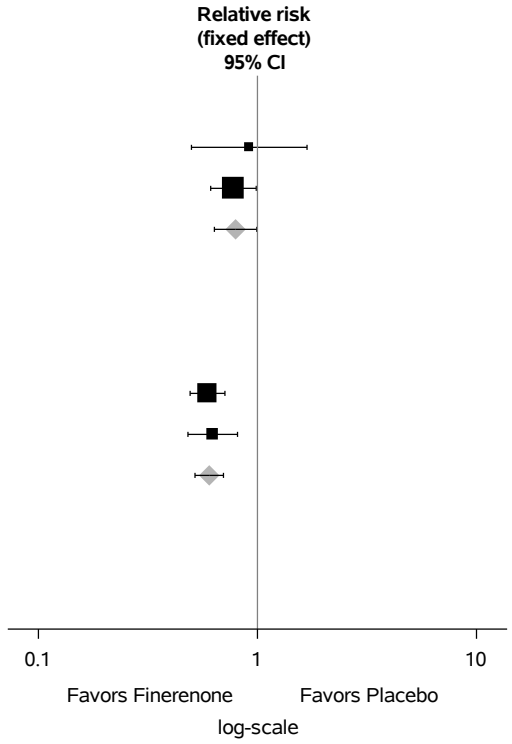
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	112 / 1556	175 / 1541	74.1	0.63 [0.51,0.79]	
FIGARO-DKD	43 / 637	55 / 627	25.9	0.77 [0.52,1.13]	
Total	155 / 2193	230 / 2168		0.67 [0.55,0.81]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.73 (df=1)	p=0.3931	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	63 / 1061	113 / 1069	61.8	0.56 [0.42,0.76]	
FIGARO-DKD	45 / 720	57 / 729	38.2	0.80 [0.55,1.17]	
Total	108 / 1781	170 / 1798		0.64 [0.51,0.81]	Z=-3.76, p=0.0002
Heterogeneity:	Q=2.08 (df=1)	p=0.1492	I^2=51.9%		
>= 60					
FIDELIO-DKD	11 / 210	16 / 221	9.0	0.72 [0.34,1.52]	
FIGARO-DKD	110 / 2326	168 / 2302	91.0	0.65 [0.51,0.82]	
Total	121 / 2536	184 / 2523		0.65 [0.52,0.82]	Z=-3.73, p=0.0002
Heterogeneity:	Q=0.08 (df=1)	p=0.7818	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=2)	p=0.9687	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.41.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

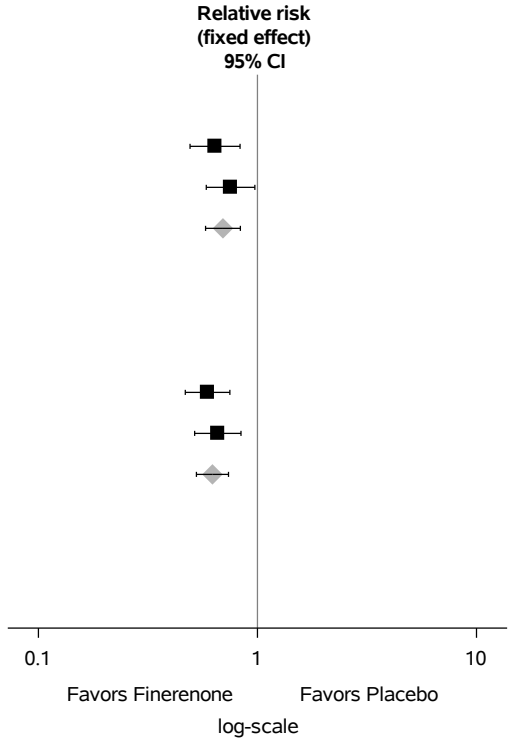
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	18 / 209	20 / 213	13.5	0.92 [0.50,1.68]	
FIGARO-DKD	111 / 1720	141 / 1698	86.5	0.78 [0.61,0.99]	
Total	129 / 1929	161 / 1911		0.79 [0.64,0.99]	Z=-2.02, p=0.0430
Heterogeneity:	Q=0.25 (df=1)	p=0.6190	I^2=0.0%		
Very High					
FIDELIO-DKD	168 / 2618	284 / 2618	67.0	0.59 [0.49,0.71]	
FIGARO-DKD	87 / 1963	139 / 1960	33.0	0.62 [0.48,0.81]	
Total	255 / 4581	423 / 4578		0.60 [0.52,0.70]	Z=-6.64, p=<.0001
Heterogeneity:	Q=0.11 (df=1)	p=0.7353	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.09 (df=1)	p=0.0431	I^2=75.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.41.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

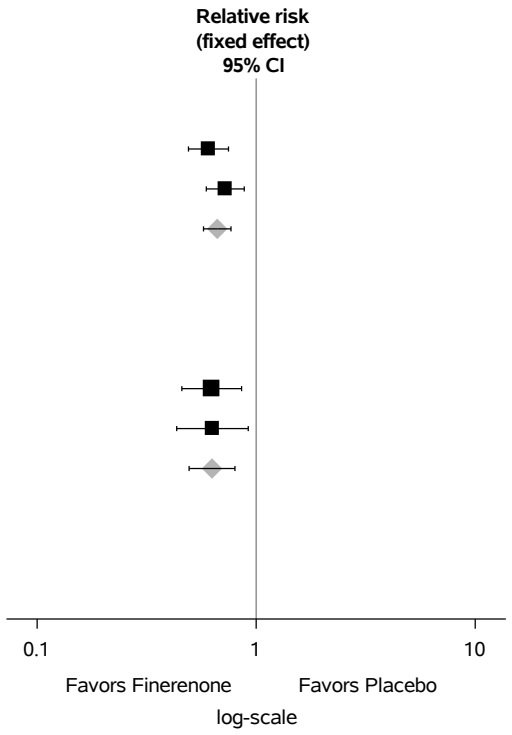
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	84 / 1301	131 / 1299	48.5	0.64 [0.49,0.83]	
FIGARO-DKD	97 / 1673	127 / 1651	51.5	0.75 [0.58,0.97]	
Total	181 / 2974	258 / 2950		0.70 [0.58,0.84]	Z=-3.88, p=0.0001
Heterogeneity:	Q=0.76 (df=1)	p=0.3829	I^2=0.0%		
Absent					
FIDELIO-DKD	102 / 1526	173 / 1532	52.0	0.59 [0.47,0.75]	
FIGARO-DKD	101 / 2010	153 / 2007	48.0	0.66 [0.52,0.84]	
Total	203 / 3536	326 / 3539		0.62 [0.53,0.74]	Z=-5.50, p=<.0001
Heterogeneity:	Q=0.39 (df=1)	p=0.5326	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=1)	p=0.3843	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.41.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	128 / 1879	209 / 1858	47.3	0.61 [0.49,0.75]	
FIGARO-DKD	156 / 2643	213 / 2608	52.7	0.72 [0.59,0.88]	
Total	284 / 4522	422 / 4466		0.66 [0.57,0.77]	Z=-5.55, p=<.0001
Heterogeneity:	Q=1.43 (df=1)	p=0.2319	I^2=30.0%		
> 4.5					
FIDELIO-DKD	58 / 948	95 / 973	58.9	0.63 [0.46,0.86]	
FIGARO-DKD	42 / 1040	67 / 1048	41.1	0.63 [0.43,0.92]	
Total	100 / 1988	162 / 2021		0.63 [0.49,0.80]	Z=-3.77, p=0.0002
Heterogeneity:	Q=0.00 (df=1)	p=0.9743	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7023	I^2=0.0%		

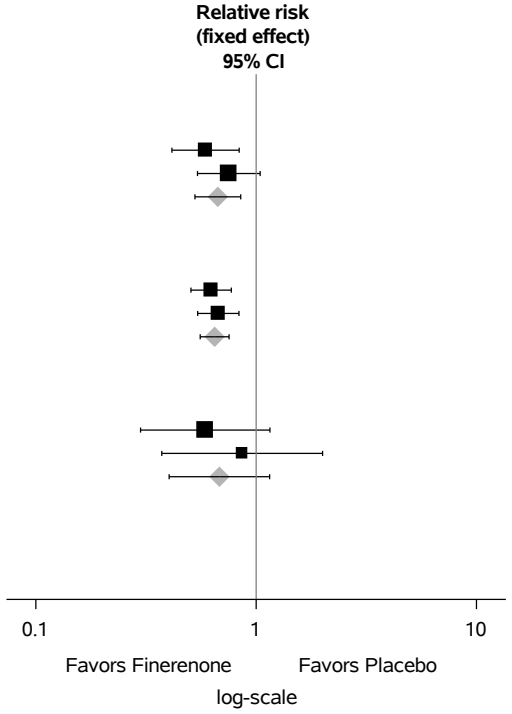


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.41.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set

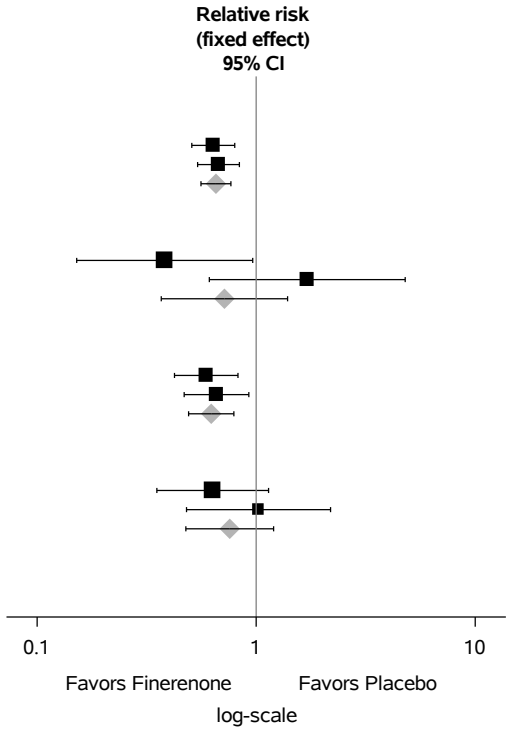
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	46 / 788	77 / 777	46.5	0.59 [0.41,0.84]	
FIGARO-DKD	59 / 1187	79 / 1194	53.5	0.75 [0.54,1.04]	
Total	105 / 1975	156 / 1971		0.67 [0.53,0.85]	Z=-3.28, p=0.0010
Heterogeneity:	Q=0.98 (df=1)	p=0.3211	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	128 / 1897	207 / 1916	51.1	0.62 [0.51,0.77]	
FIGARO-DKD	130 / 2389	190 / 2351	48.9	0.67 [0.54,0.84]	
Total	258 / 4286	397 / 4267		0.65 [0.56,0.75]	Z=-5.64, p=<.0001
Heterogeneity:	Q=0.24 (df=1)	p=0.6253	I^2=0.0%		
>= 160					
FIDELIO-DKD	12 / 141	20 / 138	60.7	0.59 [0.30,1.15]	
FIGARO-DKD	9 / 107	11 / 113	39.3	0.86 [0.37,2.00]	
Total	21 / 248	31 / 251		0.68 [0.40,1.15]	Z=-1.43, p=0.1514
Heterogeneity:	Q=0.49 (df=1)	p=0.4827	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=2)	p=0.9632	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.41.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

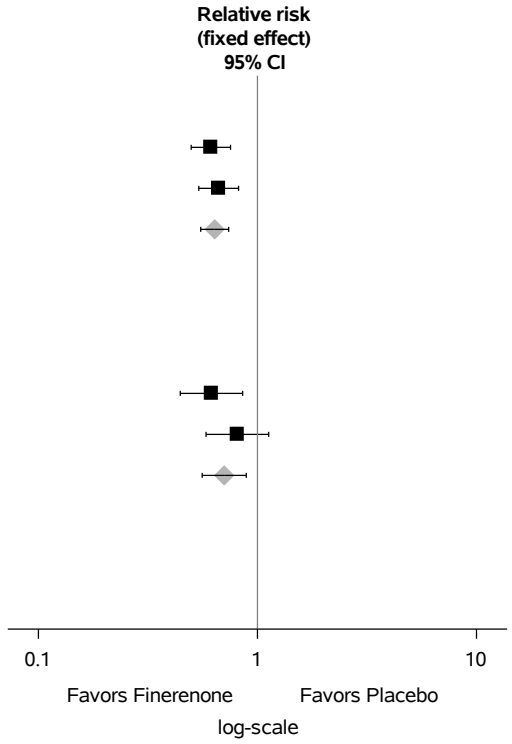
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	113 / 1773	181 / 1809	48.6	0.64 [0.51,0.80]	
FIGARO-DKD	127 / 2668	184 / 2601	51.4	0.67 [0.54,0.84]	
Total	240 / 4441	365 / 4410		0.66 [0.56,0.77]	Z=-5.27, p=<.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7329	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	14 / 124	55.3	0.38 [0.15,0.96]	
FIGARO-DKD	8 / 113	6 / 145	44.7	1.71 [0.61,4.79]	
Total	14 / 252	20 / 269		0.72 [0.37,1.39]	Z=-0.99, p=0.3244
Heterogeneity:	Q=4.52 (df=1)	p=0.0336	I^2=77.9%		
Asian					
FIDELIO-DKD	50 / 717	85 / 721	50.9	0.59 [0.42,0.83]	
FIGARO-DKD	50 / 716	78 / 736	49.1	0.66 [0.47,0.93]	
Total	100 / 1433	163 / 1457		0.62 [0.49,0.79]	Z=-3.89, p=0.0001
Heterogeneity:	Q=0.20 (df=1)	p=0.6569	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 198	24 / 177	62.4	0.63 [0.35,1.14]	
FIGARO-DKD	13 / 186	12 / 176	37.6	1.03 [0.48,2.19]	
Total	30 / 384	36 / 353		0.76 [0.48,1.20]	Z=-1.18, p=0.2375
Heterogeneity:	Q=0.97 (df=1)	p=0.3244	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=3)	p=0.8930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.41.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

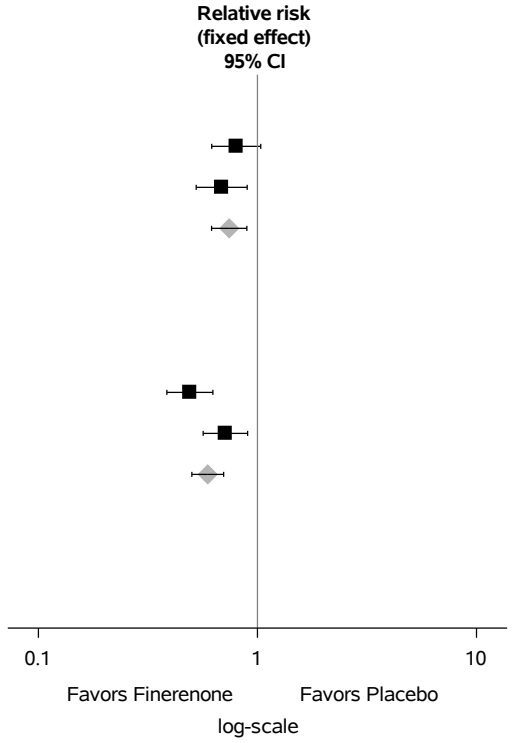
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	131 / 1949	222 / 2024	50.5	0.61 [0.50,0.75]	
FIGARO-DKD	136 / 2527	208 / 2571	49.5	0.67 [0.54,0.82]	
Total	267 / 4476	430 / 4595		0.64 [0.55,0.74]	Z=-5.99, p=<.0001
Heterogeneity:	Q=0.30 (df=1)	p=0.5842	I^2=0.0%		
Female					
FIDELIO-DKD	55 / 878	82 / 807	50.2	0.62 [0.44,0.86]	
FIGARO-DKD	62 / 1156	72 / 1087	49.8	0.81 [0.58,1.13]	
Total	117 / 2034	154 / 1894		0.71 [0.56,0.89]	Z=-2.95, p=0.0031
Heterogeneity:	Q=1.32 (df=1)	p=0.2502	I^2=24.4%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4756	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.41.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

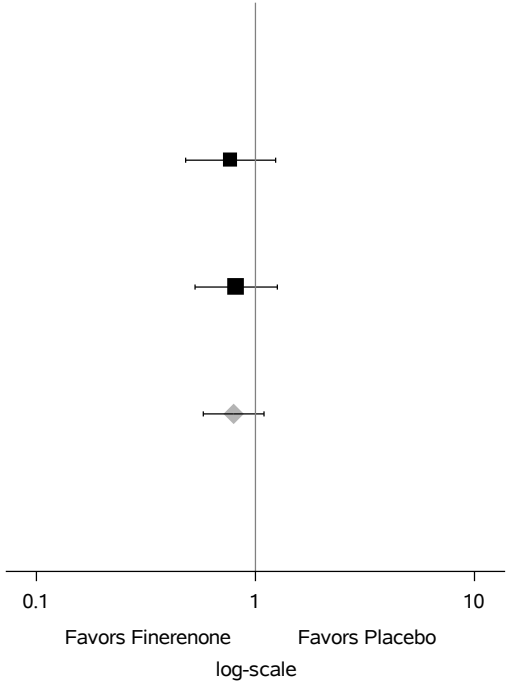
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	96 / 1201	117 / 1171	52.0	0.80 [0.62,1.04]	
FIGARO-DKD	85 / 1752	124 / 1755	48.0	0.69 [0.53,0.90]	
Total	181 / 2953	241 / 2926		0.74 [0.62,0.89]	Z=-3.14, p=0.0017
Heterogeneity:	Q=0.65 (df=1)	p=0.4204	I^2=0.0%		
>= 65					
FIDELIO-DKD	90 / 1626	187 / 1660	48.3	0.49 [0.39,0.63]	
FIGARO-DKD	113 / 1931	156 / 1903	51.7	0.71 [0.57,0.90]	
Total	203 / 3557	343 / 3563		0.59 [0.50,0.70]	Z=-6.13, p=<.0001
Heterogeneity:	Q=4.74 (df=1)	p=0.0295	I^2=78.9%		
Subgroup Heterogeneity:	Q=3.13 (df=1)	p=0.0767	I^2=68.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.42: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set

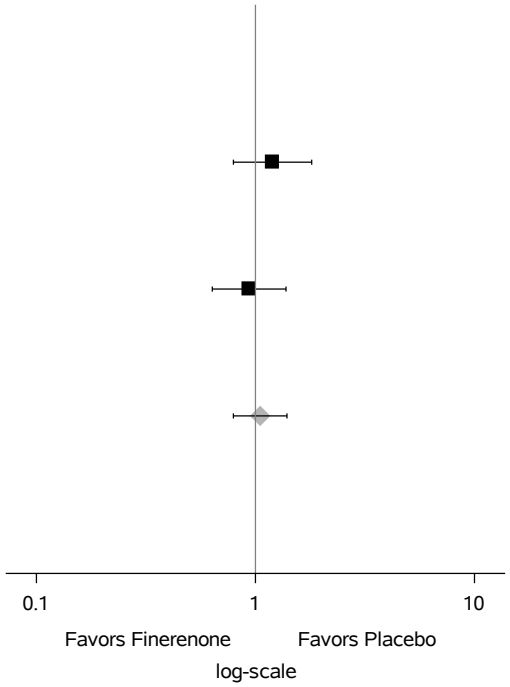
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2827	39 / 2831	45.5	0.77 [0.48,1.24]	
FIGARO-DKD	37 / 3683	45 / 3658	54.5	0.82 [0.53,1.26]	
Total	67 / 6510	84 / 6489		0.80 [0.58,1.09]	Z=-1.41, p=0.1593
Heterogeneity:	Q=0.03 (df=1)	p=0.8583	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.43: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set

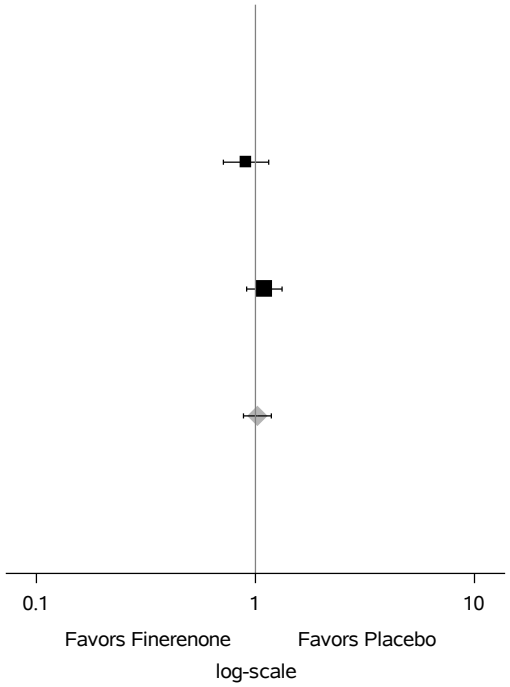
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2827	41 / 2831	47.0	1.20 [0.79,1.81]	
FIGARO-DKD	49 / 3683	52 / 3658	53.0	0.94 [0.64,1.38]	
Total	98 / 6510	93 / 6489		1.05 [0.79,1.39]	Z=0.34, p=0.7301
Heterogeneity:	Q=0.73 (df=1)	p=0.3939	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.44: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

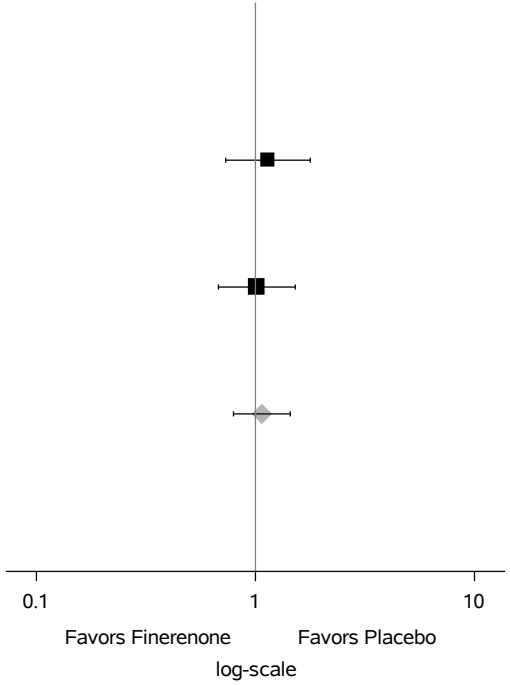
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	123 / 2827	136 / 2831	37.9	0.91 [0.71,1.15]	
FIGARO-DKD	220 / 3683	199 / 3658	62.1	1.10 [0.91,1.32]	
Total	343 / 6510	335 / 6489		1.02 [0.88,1.18]	Z=0.27, p=0.7842
Heterogeneity:	Q=1.56 (df=1)	p=0.2120	I^2=35.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.45: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set

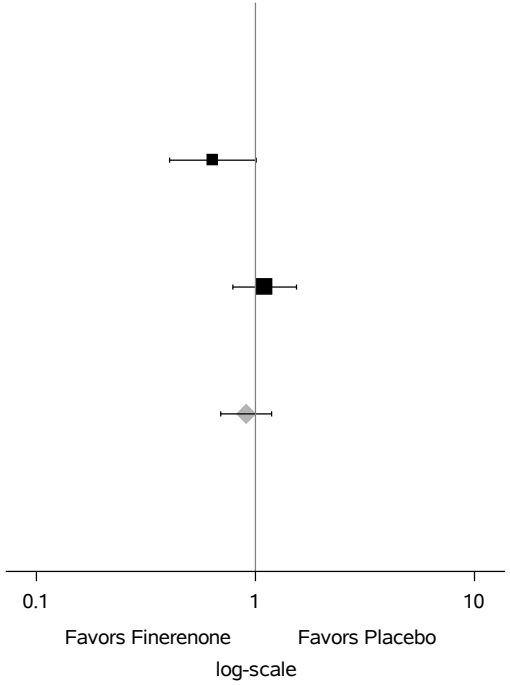
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2827	36 / 2831	45.2	1.14 [0.73,1.78]	
FIGARO-DKD	47 / 3683	46 / 3658	54.8	1.01 [0.68,1.52]	
Total	88 / 6510	82 / 6489		1.07 [0.79,1.44]	Z=0.44, p=0.6577
Heterogeneity:	Q=0.15 (df=1)	p=0.7032	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.46: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set

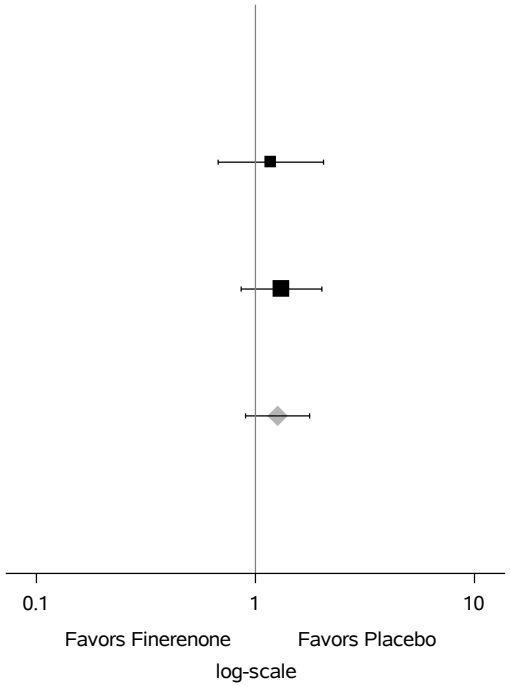
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2827	47 / 2831	35.1	0.64 [0.41,1.01]	
FIGARO-DKD	71 / 3683	64 / 3658	64.9	1.10 [0.79,1.54]	
Total	101 / 6510	111 / 6489		0.91 [0.69,1.18]	Z=-0.72, p=0.4740
Heterogeneity:	Q=3.57 (df=1)	p=0.0588	I^2=72.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.47: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

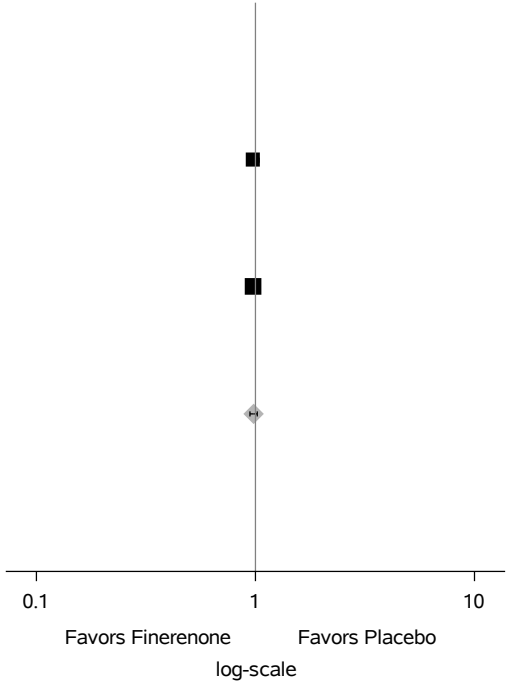
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	23 / 2831	37.0	1.18 [0.68,2.05]	
FIGARO-DKD	49 / 3683	37 / 3658	63.0	1.32 [0.86,2.01]	
Total	76 / 6510	60 / 6489		1.26 [0.90,1.77]	Z=1.35, p=0.1756
Heterogeneity:	Q=0.10 (df=1)	p=0.7523	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.48: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

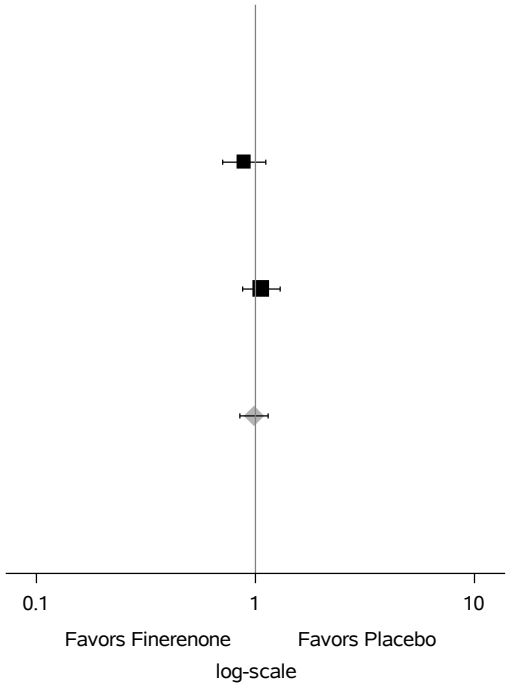
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1227 / 2827	1255 / 2831	42.5	0.98 [0.92,1.04]	
FIGARO-DKD	1637 / 3683	1656 / 3658	57.5	0.98 [0.93,1.03]	
Total	2864 / 6510	2911 / 6489		0.98 [0.94,1.02]	Z=-1.00, p=0.3192
Heterogeneity:	Q=0.00 (df=1)	p=0.9438	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.49: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set

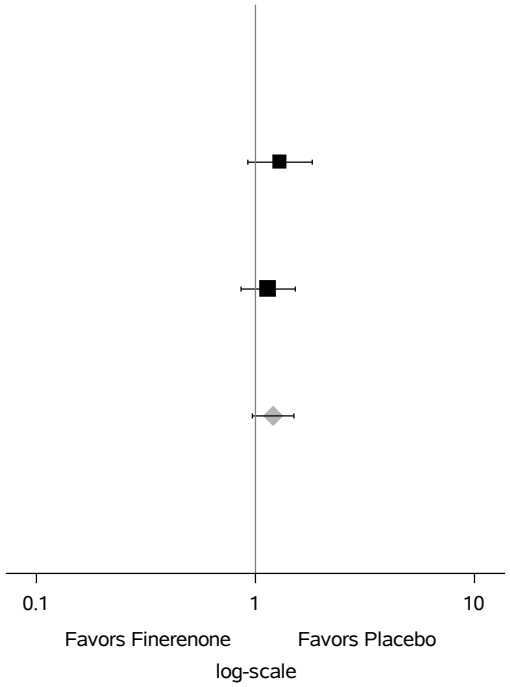
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	134 / 2827	151 / 2831	43.1	0.89 [0.71,1.11]	
FIGARO-DKD	194 / 3683	181 / 3658	56.9	1.06 [0.87,1.30]	
Total	328 / 6510	332 / 6489		0.98 [0.85,1.14]	Z=-0.20, p=0.8396
Heterogeneity:	Q=1.39 (df=1)	p=0.2389	I^2=27.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.50: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set

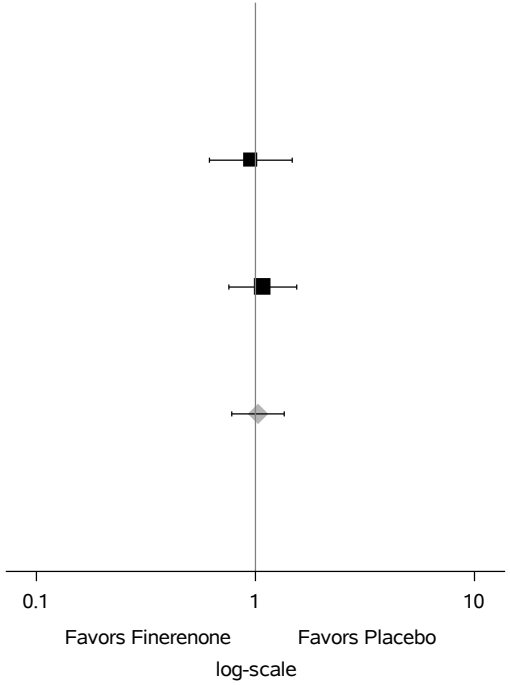
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	58 / 2831	41.5	1.29 [0.92,1.82]	
FIGARO-DKD	99 / 3683	86 / 3658	58.5	1.14 [0.86,1.52]	
Total	174 / 6510	144 / 6489		1.20 [0.97,1.50]	Z=1.67, p=0.0950
Heterogeneity:	Q=0.30 (df=1)	p=0.5816	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.51: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set

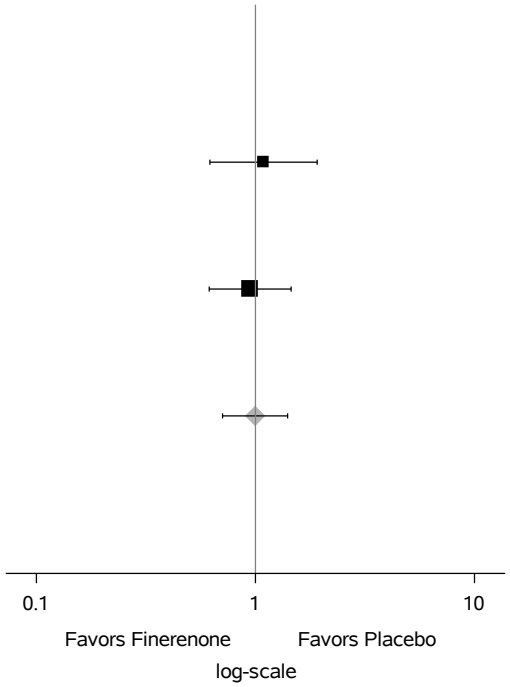
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	41 / 2831	40.2	0.95 [0.62,1.47]	
FIGARO-DKD	62 / 3683	57 / 3658	59.8	1.08 [0.76,1.54]	
Total	101 / 6510	98 / 6489		1.03 [0.78,1.35]	Z=0.19, p=0.8494
Heterogeneity:	Q=0.19 (df=1)	p=0.6611	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.52: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cystitis (PT with Incidence >=1%)
Safety Analysis Set

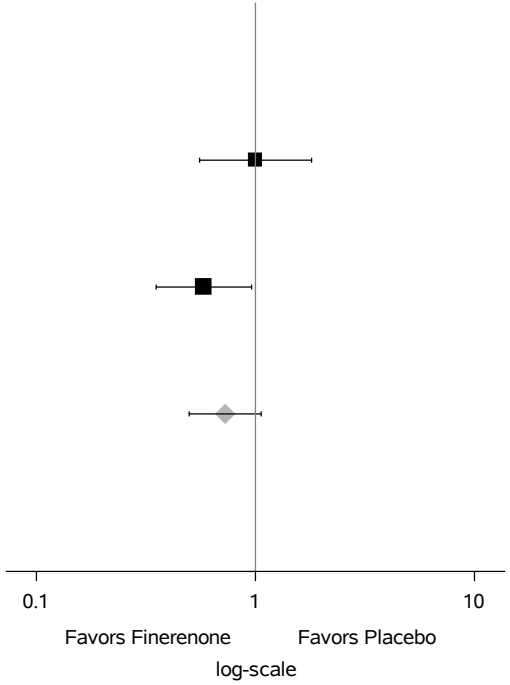
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2827	23 / 2831	36.8	1.09 [0.62,1.91]	
FIGARO-DKD	40 / 3683	42 / 3658	63.2	0.95 [0.61,1.45]	
Total	65 / 6510	65 / 6489		1.00 [0.71,1.40]	Z=-0.02, p=0.9823
Heterogeneity:	Q=0.15 (df=1)	p=0.6981	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.53: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set

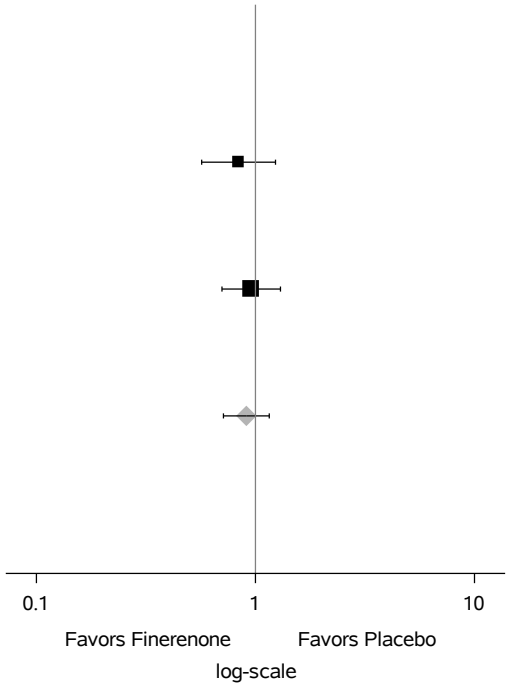
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	22 / 2827	22 / 2831	42.1	1.00 [0.56,1.80]	
FIGARO-DKD	24 / 3683	41 / 3658	57.9	0.58 [0.35,0.96]	
Total	46 / 6510	63 / 6489		0.73 [0.50,1.06]	Z=-1.65, p=0.0995
Heterogeneity:	Q=1.90 (df=1)	p=0.1682	I^2=47.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.54: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set

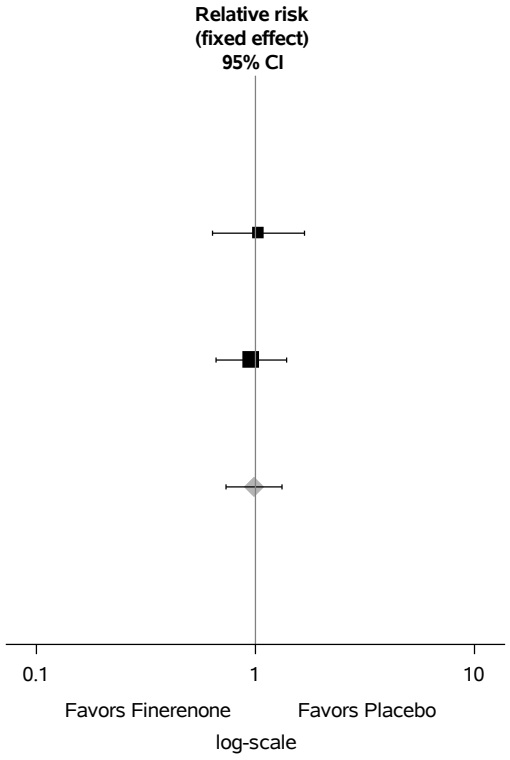
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2827	55 / 2831	38.6	0.84 [0.57,1.23]	
FIGARO-DKD	78 / 3683	81 / 3658	61.4	0.96 [0.70,1.30]	
Total	124 / 6510	136 / 6489		0.91 [0.71,1.16]	Z=-0.78, p=0.4354
Heterogeneity:	Q=0.28 (df=1)	p=0.5994	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.55: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set

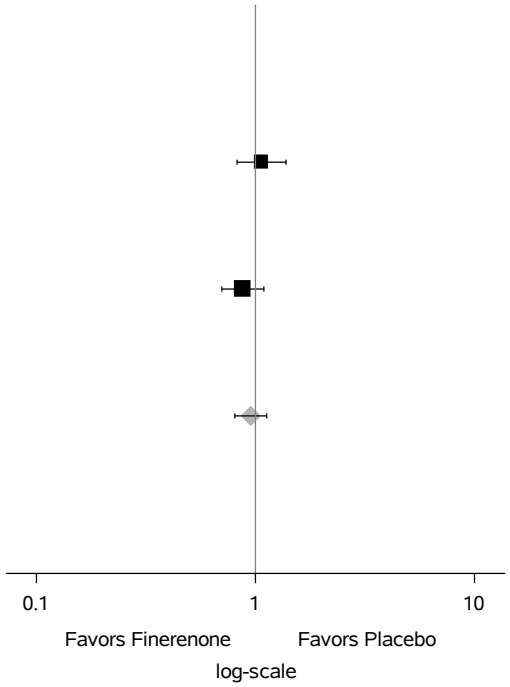
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	32 / 2831	37.1	1.03 [0.64,1.67]	
FIGARO-DKD	54 / 3683	56 / 3658	62.9	0.96 [0.66,1.39]	
Total	87 / 6510	88 / 6489		0.98 [0.73,1.32]	Z=-0.10, p=0.9191
Heterogeneity:	Q=0.06 (df=1)	p=0.8085	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.56: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set

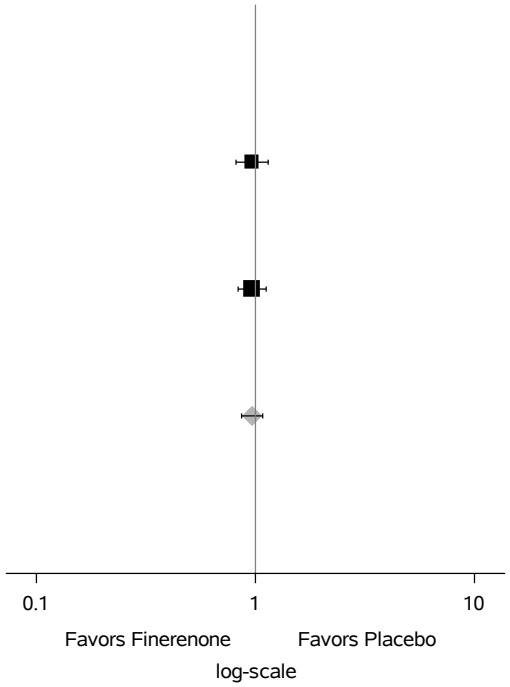
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	115 / 2827	108 / 2831	42.4	1.07 [0.82,1.38]	
FIGARO-DKD	142 / 3683	161 / 3658	57.6	0.88 [0.70,1.09]	
Total	257 / 6510	269 / 6489		0.95 [0.81,1.13]	Z=-0.57, p=0.5659
Heterogeneity:	Q=1.29 (df=1)	p=0.2560	I^2=22.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.57: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set

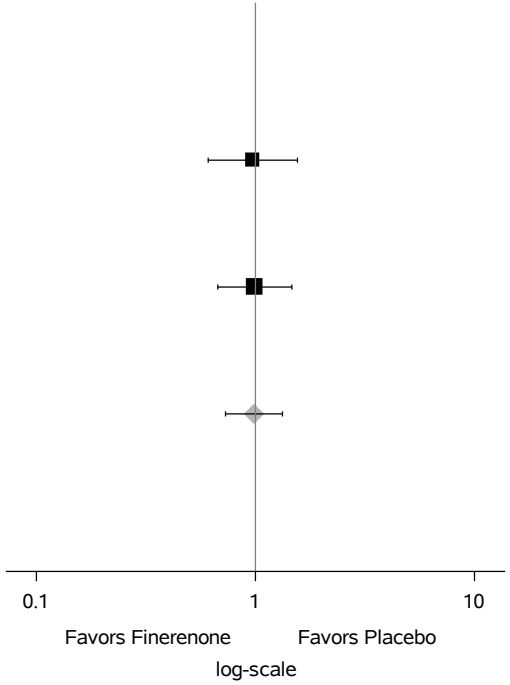
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	241 / 2827	250 / 2831	43.2	0.97 [0.82,1.14]	
FIGARO-DKD	318 / 3683	327 / 3658	56.8	0.97 [0.83,1.12]	
Total	559 / 6510	577 / 6489		0.97 [0.86,1.08]	Z=-0.62, p=0.5376
Heterogeneity:	Q=0.00 (df=1)	p=0.9963	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.58: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set

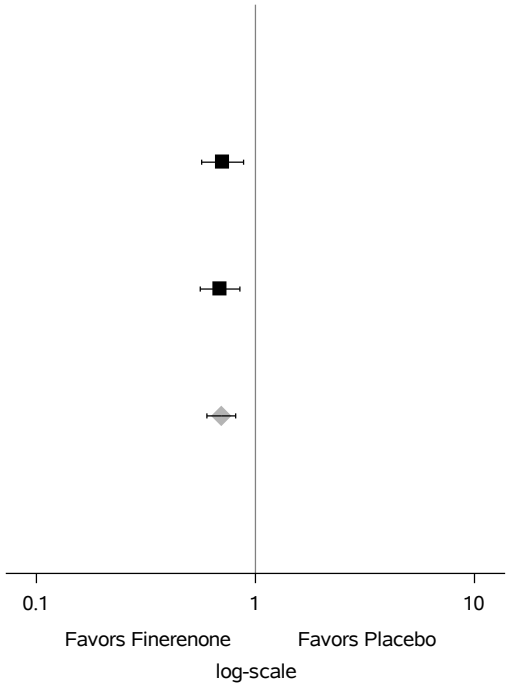
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	35 / 2831	40.8	0.97 [0.61,1.56]	
FIGARO-DKD	50 / 3683	50 / 3658	59.2	0.99 [0.67,1.47]	
Total	84 / 6510	85 / 6489		0.98 [0.73,1.33]	Z=-0.10, p=0.9204
Heterogeneity:	Q=0.00 (df=1)	p=0.9468	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.59: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

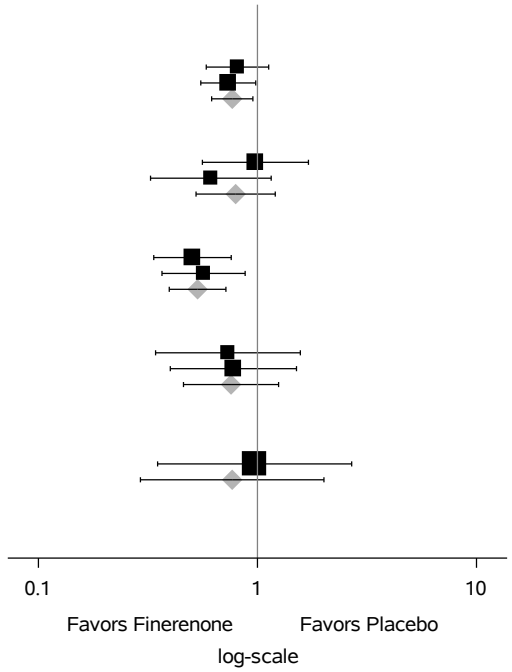
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	128 / 2827	181 / 2831	47.2	0.71 [0.57,0.88]	
FIGARO-DKD	143 / 3683	206 / 3658	52.8	0.69 [0.56,0.85]	
Total	271 / 6510	387 / 6489		0.70 [0.60,0.81]	Z=-4.65, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8625	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.59.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

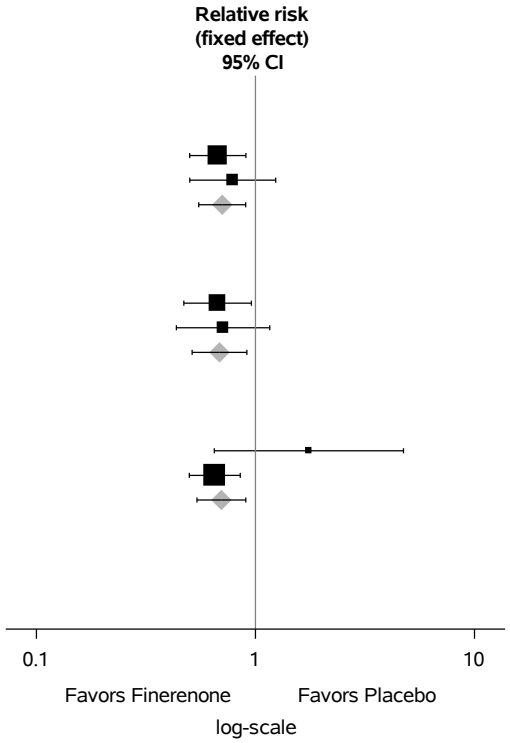
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	61 / 1178	75 / 1174	43.7	0.81 [0.58,1.13]	
FIGARO-DKD	76 / 1752	103 / 1747	56.3	0.74 [0.55,0.98]	
Total	137 / 2930	178 / 2921		0.77 [0.62,0.95]	Z=-2.39, p=0.0167
Heterogeneity:	Q=0.19 (df=1)	p=0.6642	I^2=0.0%		
North America					
FIDELIO-DKD	23 / 466	24 / 476	56.4	0.98 [0.56,1.71]	
FIGARO-DKD	15 / 559	24 / 548	43.6	0.61 [0.32,1.16]	
Total	38 / 1025	48 / 1024		0.80 [0.52,1.21]	Z=-1.08, p=0.2804
Heterogeneity:	Q=1.18 (df=1)	p=0.2767	I^2=15.5%		
Asia					
FIDELIO-DKD	33 / 790	65 / 786	53.5	0.51 [0.34,0.76]	
FIGARO-DKD	30 / 811	53 / 813	46.5	0.57 [0.37,0.88]	
Total	63 / 1601	118 / 1599		0.53 [0.40,0.72]	Z=-4.14, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.7027	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 294	15 / 294	43.2	0.73 [0.34,1.57]	
FIGARO-DKD	15 / 424	19 / 417	56.8	0.78 [0.40,1.51]	
Total	26 / 718	34 / 711		0.76 [0.46,1.25]	Z=-1.09, p=0.2762
Heterogeneity:	Q=0.01 (df=1)	p=0.9117	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	2 / 101	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	7 / 137	7 / 133	100.0	0.97 [0.35,2.69]	
Total	7 / 236	9 / 234		0.77 [0.29,2.01]	Z=-0.54, p=0.5894
Heterogeneity:	Q=0.21 (df=1)	p=0.6502	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.40 (df=4)	p=0.3541	I^2=9.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.59.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

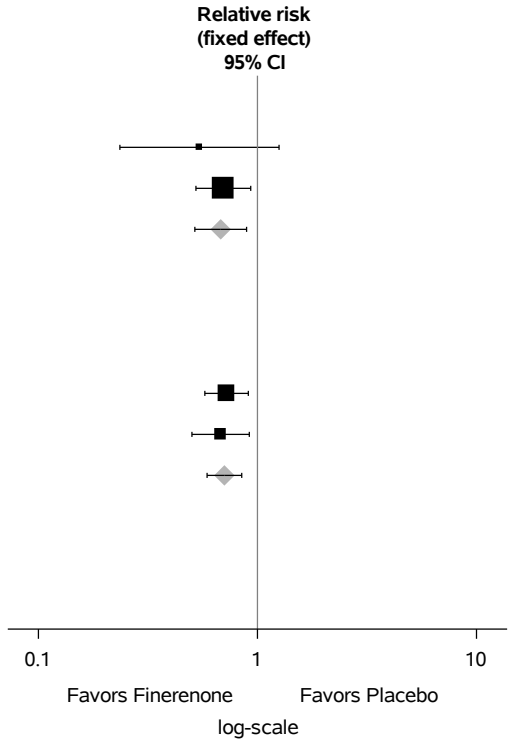
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	70 / 1556	103 / 1541	70.0	0.67 [0.50,0.90]	
FIGARO-DKD	32 / 637	40 / 627	30.0	0.79 [0.50,1.24]	
Total	102 / 2193	143 / 2168		0.71 [0.55,0.90]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.33 (df=1)	p=0.5686	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	48 / 1061	72 / 1069	65.6	0.67 [0.47,0.96]	
FIGARO-DKD	26 / 720	37 / 729	34.4	0.71 [0.44,1.16]	
Total	74 / 1781	109 / 1798		0.69 [0.51,0.91]	Z=-2.58, p=0.0100
Heterogeneity:	Q=0.03 (df=1)	p=0.8523	I^2=0.0%		
>= 60					
FIDELIO-DKD	10 / 210	6 / 221	6.8	1.75 [0.65,4.74]	
FIGARO-DKD	85 / 2326	129 / 2302	93.2	0.65 [0.50,0.85]	
Total	95 / 2536	135 / 2523		0.70 [0.54,0.90]	Z=-2.74, p=0.0062
Heterogeneity:	Q=3.55 (df=1)	p=0.0597	I^2=71.8%		
Subgroup Heterogeneity:	Q=0.02 (df=2)	p=0.9887	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.59.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

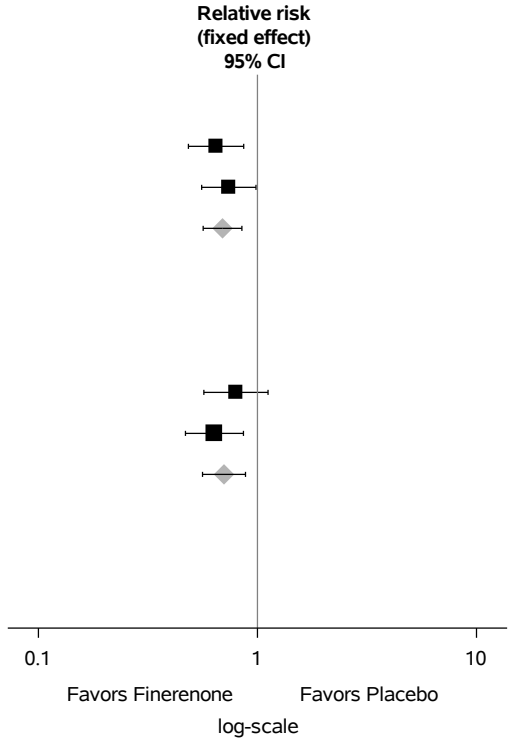
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	15 / 213	10.6	0.54 [0.24,1.25]	
FIGARO-DKD	75 / 1720	106 / 1698	89.4	0.70 [0.52,0.93]	
Total	83 / 1929	121 / 1911		0.68 [0.52,0.89]	Z=-2.78, p=0.0054
Heterogeneity:	Q=0.31 (df=1)	p=0.5784	I^2=0.0%		
Very High					
FIDELIO-DKD	120 / 2618	166 / 2618	63.5	0.72 [0.58,0.91]	
FIGARO-DKD	68 / 1963	100 / 1960	36.5	0.68 [0.50,0.92]	
Total	188 / 4581	266 / 4578		0.71 [0.59,0.85]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.11 (df=1)	p=0.7454	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8162	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.59.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

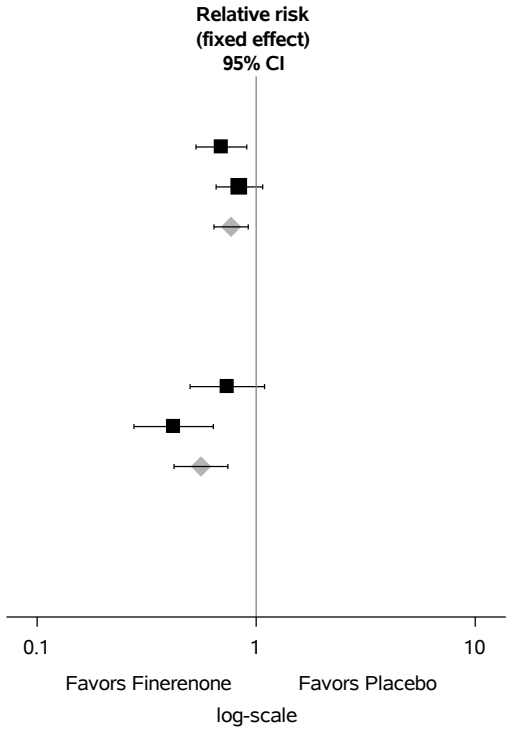
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	70 / 1301	108 / 1299	49.1	0.65 [0.48,0.87]	
FIGARO-DKD	78 / 1673	104 / 1651	50.9	0.74 [0.56,0.98]	
Total	148 / 2974	212 / 2950		0.69 [0.57,0.85]	Z=-3.54, p=0.0004
Heterogeneity:	Q=0.42 (df=1)	p=0.5185	I^2=0.0%		
Absent					
FIDELIO-DKD	58 / 1526	73 / 1532	44.9	0.80 [0.57,1.12]	
FIGARO-DKD	65 / 2010	102 / 2007	55.1	0.64 [0.47,0.86]	
Total	123 / 3536	175 / 3539		0.70 [0.56,0.88]	Z=-3.05, p=0.0023
Heterogeneity:	Q=0.95 (df=1)	p=0.3300	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9196	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.59.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

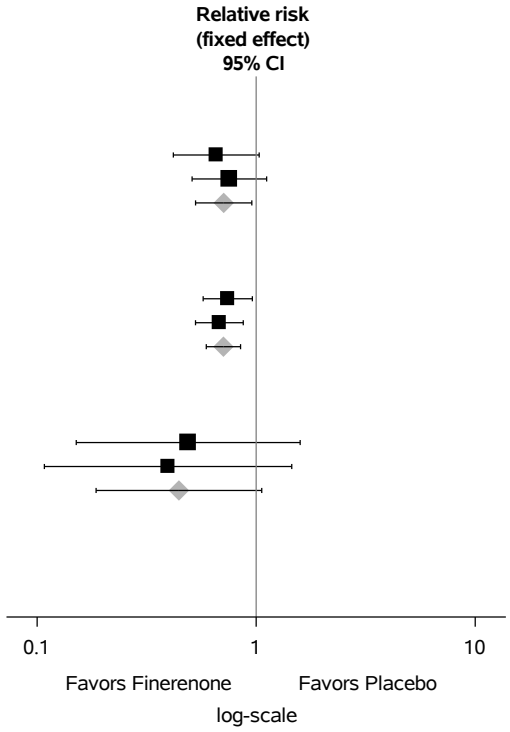
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	87 / 1879	124 / 1858	45.8	0.69 [0.53,0.91]	
FIGARO-DKD	113 / 2643	133 / 2608	54.2	0.84 [0.66,1.07]	
Total	200 / 4522	257 / 4466		0.77 [0.64,0.92]	Z=-2.87, p=0.0041
Heterogeneity:	Q=1.05 (df=1)	p=0.3052	I^2=4.9%		
> 4.5					
FIDELIO-DKD	41 / 948	57 / 973	53.2	0.74 [0.50,1.09]	
FIGARO-DKD	30 / 1040	72 / 1048	46.8	0.42 [0.28,0.64]	
Total	71 / 1988	129 / 2021		0.56 [0.42,0.74]	Z=-4.02, p=<.0001
Heterogeneity:	Q=3.75 (df=1)	p=0.0529	I^2=73.3%		
Subgroup Heterogeneity:	Q=3.42 (df=1)	p=0.0642	I^2=70.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.59.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

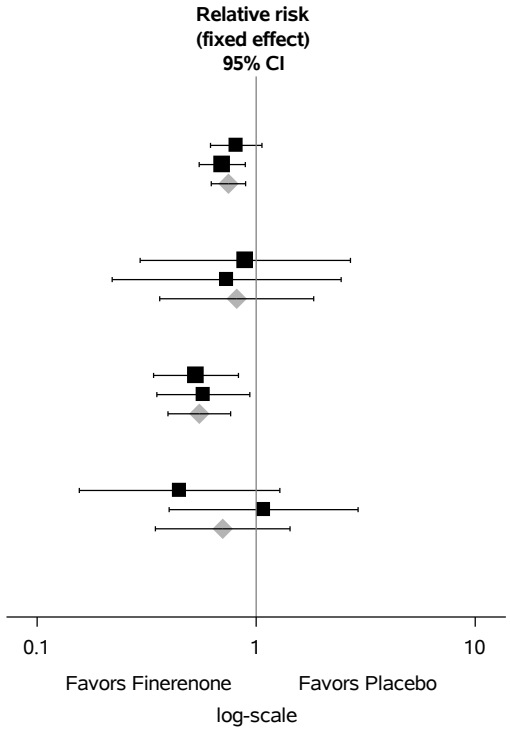
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	30 / 788	45 / 777	43.0	0.66 [0.42,1.03]	
FIGARO-DKD	42 / 1187	56 / 1194	57.0	0.75 [0.51,1.12]	
Total	72 / 1975	101 / 1971		0.71 [0.53,0.96]	Z=-2.26, p=0.0236
Heterogeneity:	Q=0.20 (df=1)	p=0.6515	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	94 / 1897	128 / 1916	48.5	0.74 [0.57,0.96]	
FIGARO-DKD	98 / 2389	142 / 2351	51.5	0.68 [0.53,0.87]	
Total	192 / 4286	270 / 4267		0.71 [0.59,0.85]	Z=-3.75, p=0.0002
Heterogeneity:	Q=0.23 (df=1)	p=0.6317	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	8 / 138	55.0	0.49 [0.15,1.59]	
FIGARO-DKD	3 / 107	8 / 113	45.0	0.40 [0.11,1.45]	
Total	7 / 248	16 / 251		0.44 [0.19,1.06]	Z=-1.83, p=0.0675
Heterogeneity:	Q=0.06 (df=1)	p=0.8130	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=2)	p=0.5827	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.59.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

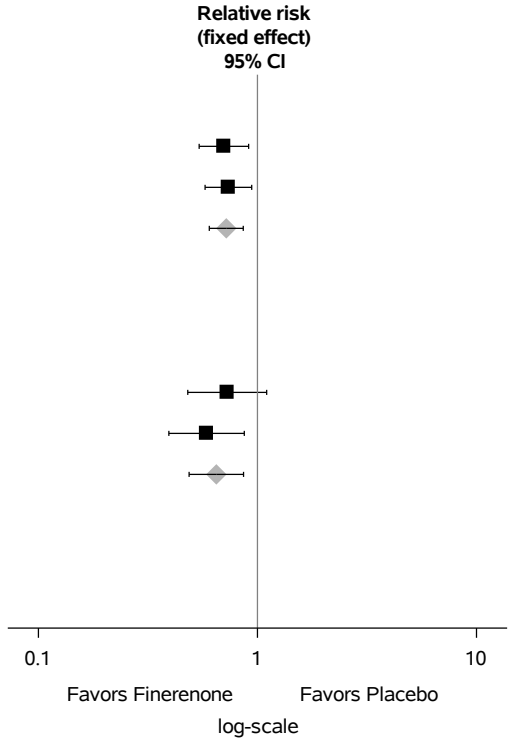
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	89 / 1773	112 / 1809	44.5	0.81 [0.62,1.06]	
FIGARO-DKD	107 / 2668	149 / 2601	55.5	0.70 [0.55,0.89]	
Total	196 / 4441	261 / 4410		0.75 [0.62,0.89]	Z=-3.17, p=0.0015
Heterogeneity:	Q=0.63 (df=1)	p=0.4283	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	6 / 124	54.2	0.89 [0.30,2.69]	
FIGARO-DKD	4 / 113	7 / 145	45.8	0.73 [0.22,2.44]	
Total	10 / 252	13 / 269		0.81 [0.36,1.83]	Z=-0.50, p=0.6202
Heterogeneity:	Q=0.06 (df=1)	p=0.8141	I^2=0.0%		
Asian					
FIDELIO-DKD	28 / 717	53 / 721	54.5	0.53 [0.34,0.83]	
FIGARO-DKD	24 / 716	43 / 736	45.5	0.57 [0.35,0.94]	
Total	52 / 1433	96 / 1457		0.55 [0.40,0.76]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.05 (df=1)	p=0.8197	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 198	10 / 177	47.0	0.45 [0.16,1.28]	
FIGARO-DKD	8 / 186	7 / 176	53.0	1.08 [0.40,2.92]	
Total	13 / 384	17 / 353		0.70 [0.35,1.43]	Z=-0.97, p=0.3299
Heterogeneity:	Q=1.43 (df=1)	p=0.2316	I^2=30.1%		
Subgroup Heterogeneity:	Q=2.69 (df=3)	p=0.4413	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.59.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

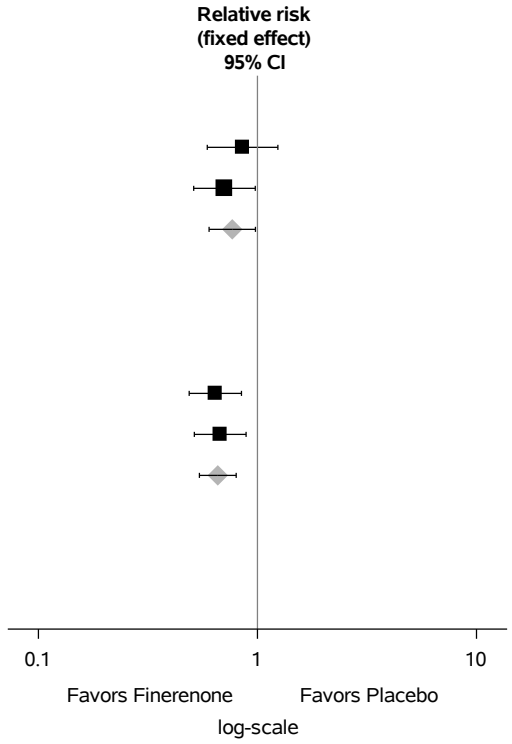
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	90 / 1949	133 / 2024	47.0	0.70 [0.54,0.91]	
FIGARO-DKD	105 / 2527	145 / 2571	53.0	0.74 [0.58,0.94]	
Total	195 / 4476	278 / 4595		0.72 [0.60,0.86]	Z=-3.60, p=0.0003
Heterogeneity:	Q=0.07 (df=1)	p=0.7955	I^2=0.0%		
Female					
FIDELIO-DKD	38 / 878	48 / 807	47.8	0.73 [0.48,1.10]	
FIGARO-DKD	38 / 1156	61 / 1087	52.2	0.59 [0.39,0.87]	
Total	76 / 2034	109 / 1894		0.65 [0.49,0.86]	Z=-2.96, p=0.0031
Heterogeneity:	Q=0.55 (df=1)	p=0.4587	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.59.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

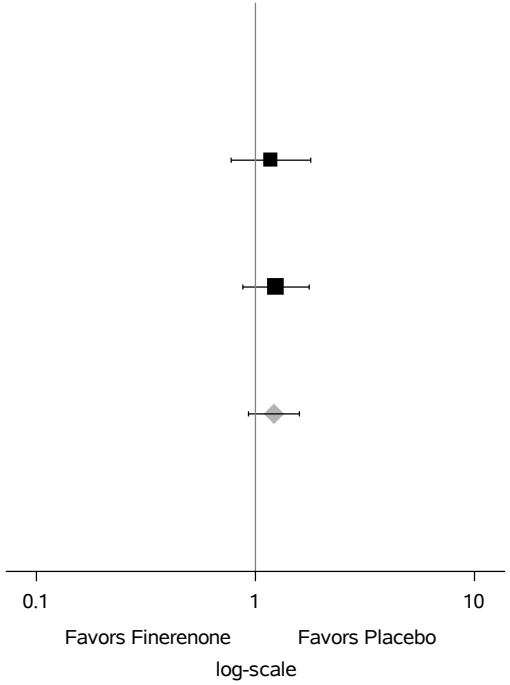
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	50 / 1201	57 / 1171	43.2	0.86 [0.59,1.24]	
FIGARO-DKD	60 / 1752	85 / 1755	56.8	0.71 [0.51,0.98]	
Total	110 / 2953	142 / 2926		0.77 [0.60,0.98]	Z=-2.13, p=0.0331
Heterogeneity:	Q=0.57 (df=1)	p=0.4489	I^2=0.0%		
>= 65					
FIDELIO-DKD	78 / 1626	124 / 1660	49.5	0.64 [0.49,0.85]	
FIGARO-DKD	83 / 1931	121 / 1903	50.5	0.68 [0.51,0.89]	
Total	161 / 3557	245 / 3563		0.66 [0.54,0.80]	Z=-4.23, p=<.0001
Heterogeneity:	Q=0.07 (df=1)	p=0.7948	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3378	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.60: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set

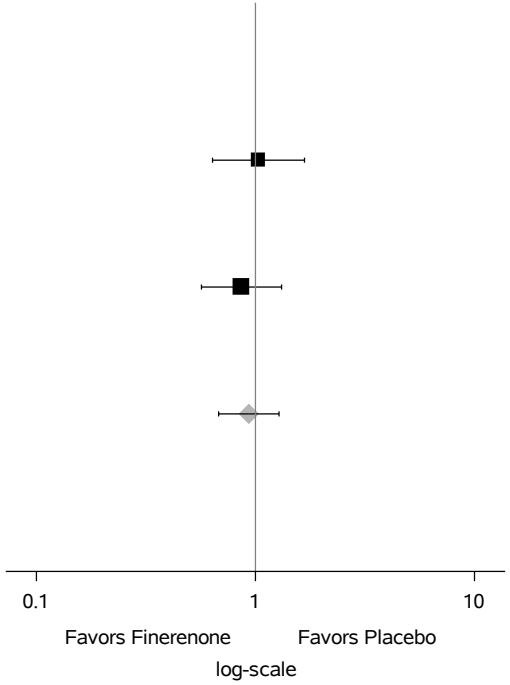
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	40 / 2831	40.9	1.18 [0.77,1.79]	
FIGARO-DKD	70 / 3683	56 / 3658	59.1	1.24 [0.88,1.76]	
Total	117 / 6510	96 / 6489		1.21 [0.93,1.59]	Z=1.42, p=0.1547
Heterogeneity:	Q=0.04 (df=1)	p=0.8469	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.61: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set

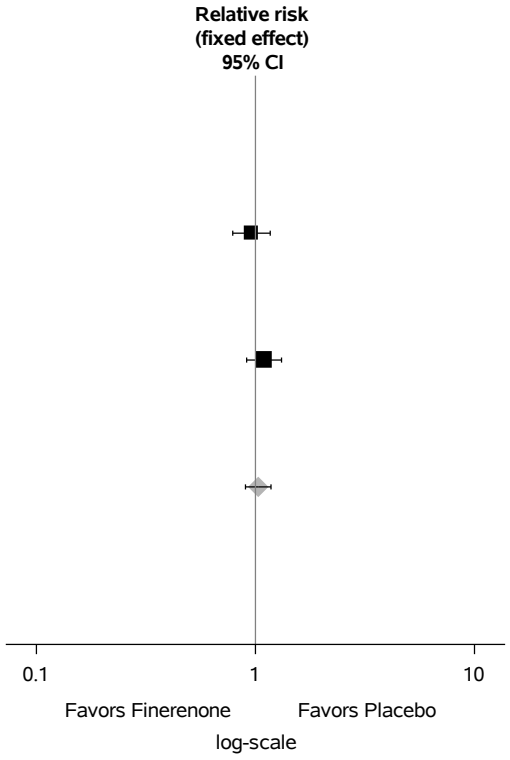
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	32 / 2831	43.2	1.03 [0.64,1.67]	
FIGARO-DKD	40 / 3683	46 / 3658	56.8	0.86 [0.57,1.32]	
Total	73 / 6510	78 / 6489		0.93 [0.68,1.28]	Z=-0.43, p=0.6676
Heterogeneity:	Q=0.30 (df=1)	p=0.5848	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.62: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set

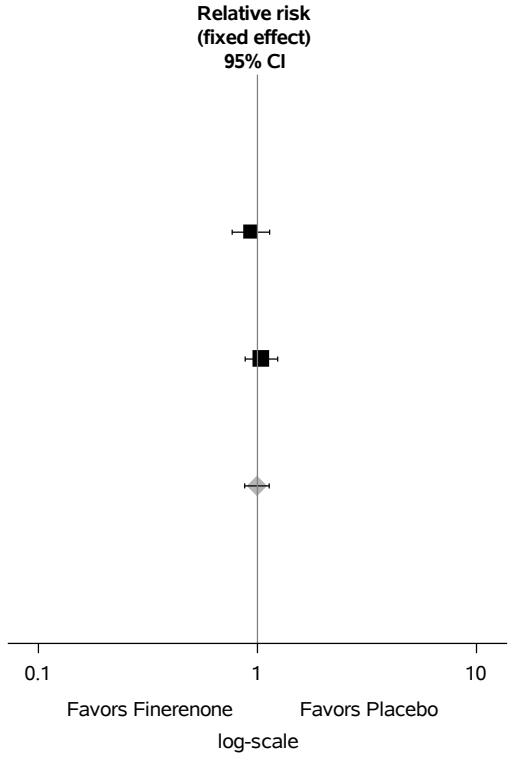
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 2827	189 / 2831	46.4	0.96 [0.79,1.17]	
FIGARO-DKD	226 / 3683	205 / 3658	53.6	1.09 [0.91,1.32]	
Total	407 / 6510	394 / 6489		1.03 [0.90,1.18]	Z=0.43, p=0.6695
Heterogeneity:	Q=0.93 (df=1)	p=0.3345	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.63: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set

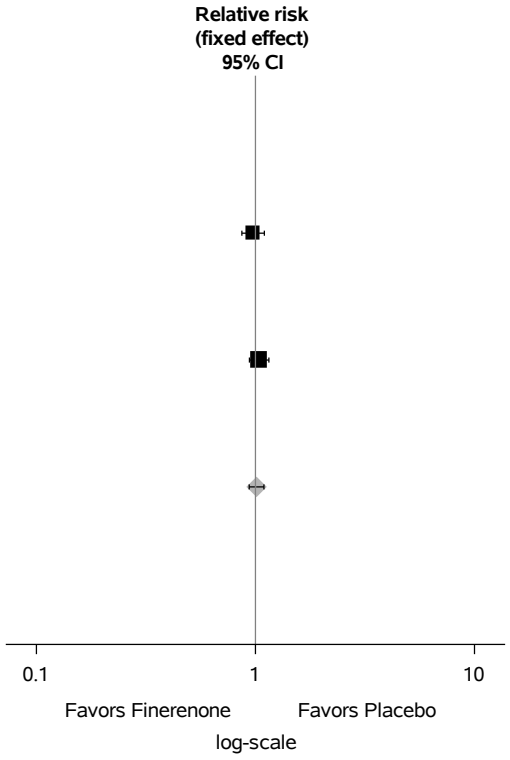
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	179 / 2827	192 / 2831	42.9	0.93 [0.77,1.14]	
FIGARO-DKD	252 / 3683	240 / 3658	57.1	1.04 [0.88,1.24]	
Total	431 / 6510	432 / 6489		0.99 [0.87,1.13]	Z=-0.08, p=0.9328
Heterogeneity:	Q=0.69 (df=1)	p=0.4052	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.64: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

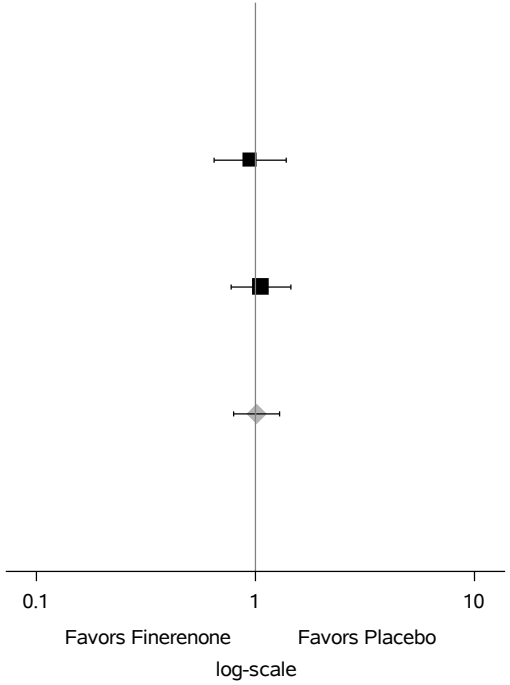
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	455 / 2827	467 / 2831	42.9	0.98 [0.87,1.10]	
FIGARO-DKD	626 / 3683	598 / 3658	57.1	1.04 [0.94,1.15]	
Total	1081 / 6510	1065 / 6489		1.01 [0.94,1.09]	Z=0.30, p=0.7667
Heterogeneity:	Q=0.64 (df=1)	p=0.4253	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.65: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set

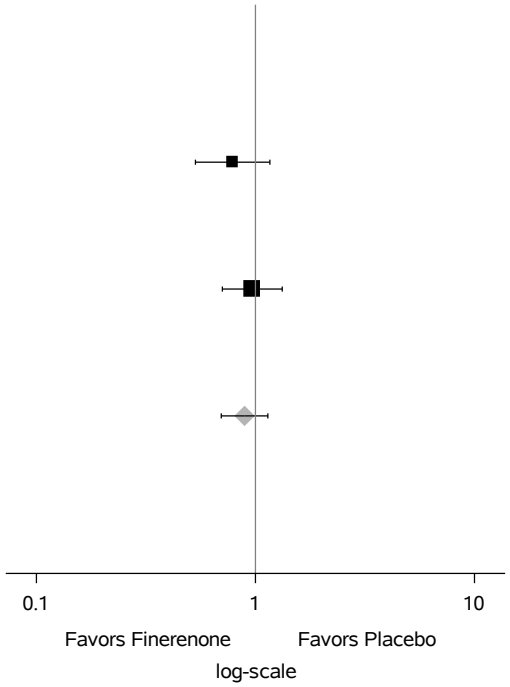
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2827	54 / 2831	40.6	0.95 [0.65,1.38]	
FIGARO-DKD	79 / 3683	74 / 3658	59.4	1.06 [0.77,1.45]	
Total	130 / 6510	128 / 6489		1.01 [0.79,1.29]	Z=0.10, p=0.9218
Heterogeneity:	Q=0.21 (df=1)	p=0.6489	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.66: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set

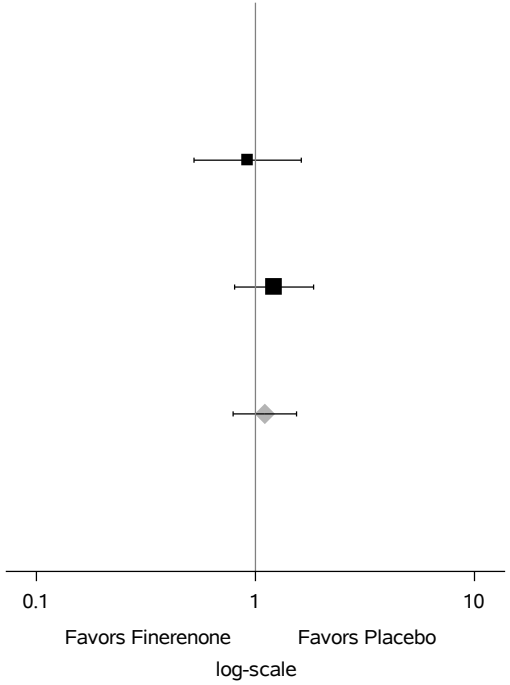
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	56 / 2831	39.3	0.79 [0.53,1.16]	
FIGARO-DKD	75 / 3683	77 / 3658	60.7	0.97 [0.71,1.33]	
Total	119 / 6510	133 / 6489		0.89 [0.70,1.14]	Z=-0.92, p=0.3590
Heterogeneity:	Q=0.65 (df=1)	p=0.4200	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.67: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set

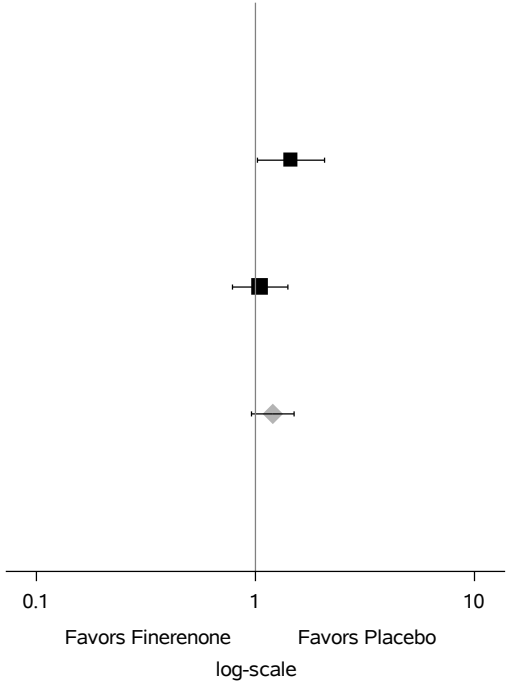
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	25 / 2831	35.1	0.92 [0.52,1.62]	
FIGARO-DKD	49 / 3683	40 / 3658	64.9	1.22 [0.80,1.84]	
Total	72 / 6510	65 / 6489		1.10 [0.79,1.54]	Z=0.58, p=0.5624
Heterogeneity:	Q=0.61 (df=1)	p=0.4363	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.68: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set

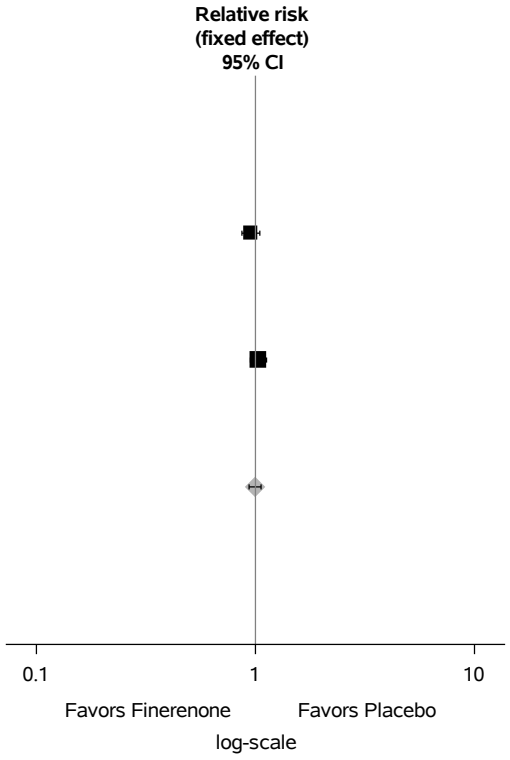
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	74 / 2827	51 / 2831	40.5	1.45 [1.02,2.07]	
FIGARO-DKD	91 / 3683	86 / 3658	59.5	1.05 [0.79,1.41]	
Total	165 / 6510	137 / 6489		1.20 [0.96,1.50]	Z=1.60, p=0.1104
Heterogeneity:	Q=1.93 (df=1)	p=0.1652	I^2=48.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.69: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

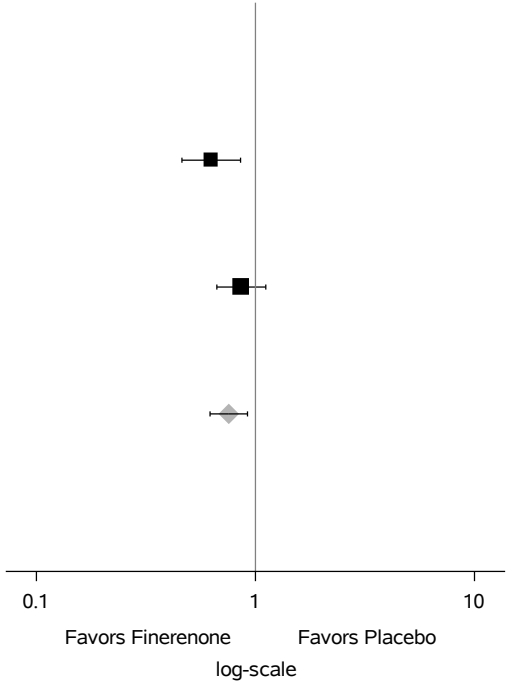
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	649 / 2827	682 / 2831	44.8	0.95 [0.87,1.05]	
FIGARO-DKD	845 / 3683	813 / 3658	55.2	1.03 [0.95,1.12]	
Total	1494 / 6510	1495 / 6489		1.00 [0.94,1.06]	Z=-0.13, p=0.8994
Heterogeneity:	Q=1.53 (df=1)	p=0.2155	I^2=34.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.70: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

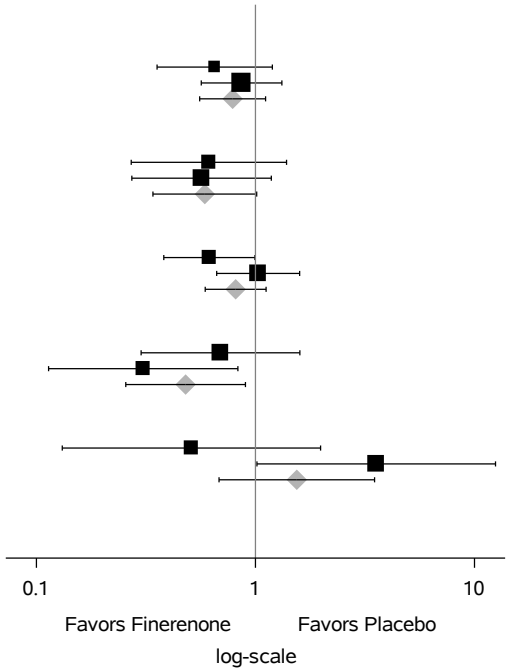
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	102 / 2831	41.1	0.63 [0.46,0.86]	
FIGARO-DKD	105 / 3683	121 / 3658	58.9	0.86 [0.67,1.11]	
Total	169 / 6510	223 / 6489		0.76 [0.62,0.92]	Z=-2.79, p=0.0052
Heterogeneity:	Q=2.38 (df=1)	p=0.1229	I^2=58.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.70.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

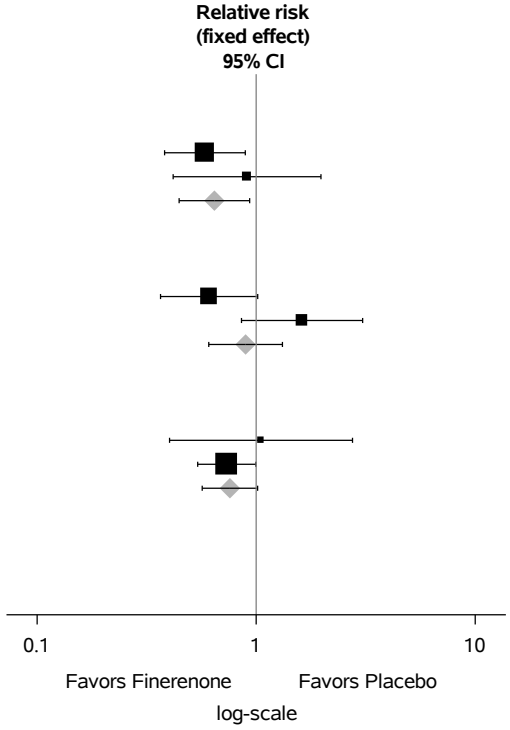
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	17 / 1178	26 / 1174	32.8	0.65 [0.36,1.19]	
FIGARO-DKD	39 / 1752	45 / 1747	67.2	0.86 [0.57,1.32]	
Total	56 / 2930	71 / 2921		0.79 [0.56,1.11]	Z=-1.36, p=0.1745
Heterogeneity:	Q=0.56 (df=1)	p=0.4542	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 466	15 / 476	44.6	0.61 [0.27,1.39]	
FIGARO-DKD	11 / 559	19 / 548	55.4	0.57 [0.27,1.18]	
Total	20 / 1025	34 / 1024		0.59 [0.34,1.01]	Z=-1.91, p=0.0558
Heterogeneity:	Q=0.02 (df=1)	p=0.8909	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 790	42 / 786	45.3	0.62 [0.38,0.99]	
FIGARO-DKD	39 / 811	38 / 813	54.7	1.03 [0.67,1.59]	
Total	65 / 1601	80 / 1599		0.81 [0.59,1.12]	Z=-1.28, p=0.2021
Heterogeneity:	Q=2.41 (df=1)	p=0.1205	I^2=58.5%		
Latin America					
FIDELIO-DKD	9 / 294	13 / 294	58.7	0.69 [0.30,1.59]	
FIGARO-DKD	5 / 424	16 / 417	41.3	0.31 [0.11,0.83]	
Total	14 / 718	29 / 711		0.48 [0.26,0.90]	Z=-2.29, p=0.0222
Heterogeneity:	Q=1.51 (df=1)	p=0.2189	I^2=33.8%		
Others					
FIDELIO-DKD	3 / 99	6 / 101	46.0	0.51 [0.13,1.98]	
FIGARO-DKD	11 / 137	3 / 133	54.0	3.56 [1.02,12.48]	
Total	14 / 236	9 / 234		1.54 [0.68,3.50]	Z=1.04, p=0.2974
Heterogeneity:	Q=4.26 (df=1)	p=0.0390	I^2=76.5%		
Subgroup Heterogeneity:	Q=6.00 (df=4)	p=0.1989	I^2=33.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.70.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

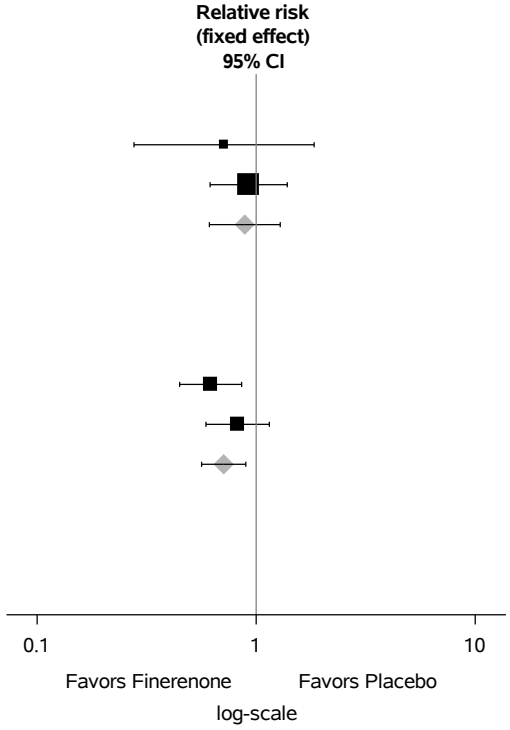
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	33 / 1556	56 / 1541	77.0	0.58 [0.38,0.89]	
FIGARO-DKD	12 / 637	13 / 627	23.0	0.91 [0.42,1.98]	
Total	45 / 2193	69 / 2168		0.64 [0.44,0.93]	Z=-2.32, p=0.0202
Heterogeneity:	Q=0.96 (df=1)	p=0.3270	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	23 / 1061	38 / 1069	60.9	0.61 [0.37,1.02]	
FIGARO-DKD	24 / 720	15 / 729	39.1	1.62 [0.86,3.06]	
Total	47 / 1781	53 / 1798		0.89 [0.61,1.32]	Z=-0.56, p=0.5738
Heterogeneity:	Q=5.50 (df=1)	p=0.0190	I^2=81.8%		
>= 60					
FIDELIO-DKD	8 / 210	8 / 221	9.2	1.05 [0.40,2.75]	
FIGARO-DKD	69 / 2326	93 / 2302	90.8	0.73 [0.54,1.00]	
Total	77 / 2536	101 / 2523		0.76 [0.57,1.02]	Z=-1.86, p=0.0632
Heterogeneity:	Q=0.49 (df=1)	p=0.4845	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.44 (df=2)	p=0.4869	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.70.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

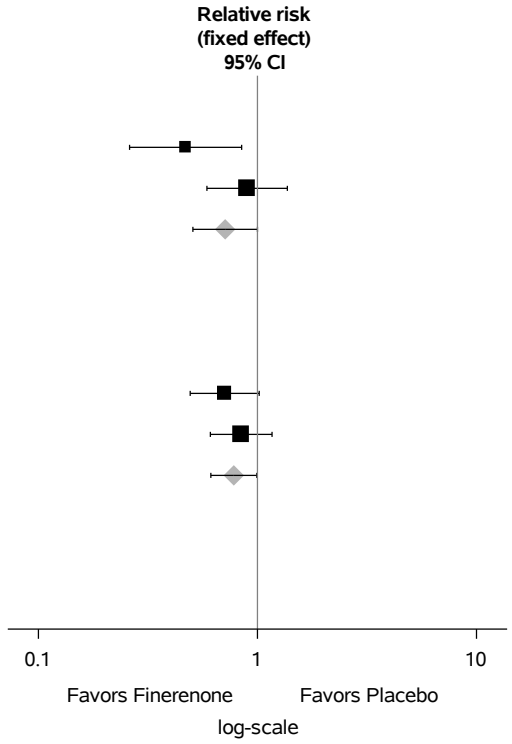
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	10 / 213	15.5	0.71 [0.28,1.84]	
FIGARO-DKD	44 / 1720	47 / 1698	84.5	0.92 [0.62,1.39]	
Total	51 / 1929	57 / 1911		0.89 [0.61,1.29]	Z=-0.63, p=0.5291
Heterogeneity:	Q=0.24 (df=1)	p=0.6223	I^2=0.0%		
Very High					
FIDELIO-DKD	57 / 2618	92 / 2618	51.1	0.62 [0.45,0.86]	
FIGARO-DKD	61 / 1963	74 / 1960	48.9	0.82 [0.59,1.15]	
Total	118 / 4581	166 / 4578		0.71 [0.56,0.90]	Z=-2.88, p=0.0040
Heterogeneity:	Q=1.43 (df=1)	p=0.2323	I^2=29.9%		
Subgroup Heterogeneity:	Q=0.98 (df=1)	p=0.3214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.70.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

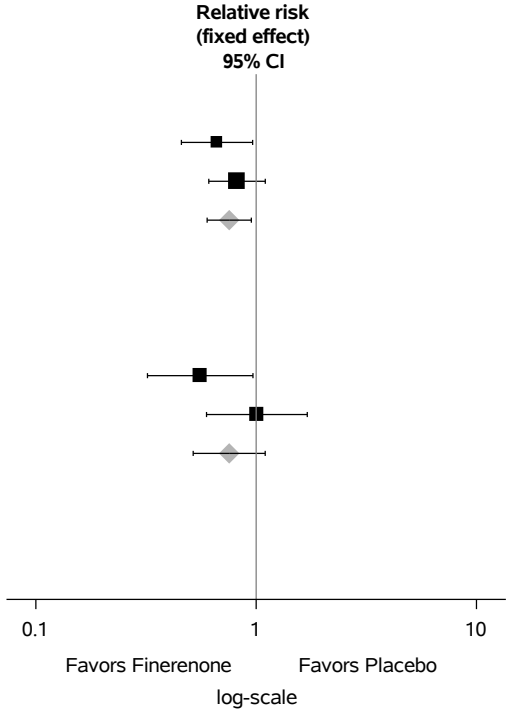
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	16 / 1301	34 / 1299	34.0	0.47 [0.26,0.85]	
FIGARO-DKD	40 / 1673	44 / 1651	66.0	0.90 [0.59,1.37]	
Total	56 / 2974	78 / 2950		0.71 [0.51,1.00]	Z=-1.96, p=0.0501
Heterogeneity:	Q=3.06 (df=1)	p=0.0803	I^2=67.3%		
Absent					
FIDELIO-DKD	48 / 1526	68 / 1532	44.4	0.71 [0.49,1.02]	
FIGARO-DKD	65 / 2010	77 / 2007	55.6	0.84 [0.61,1.17]	
Total	113 / 3536	145 / 3539		0.78 [0.61,0.99]	Z=-2.02, p=0.0437
Heterogeneity:	Q=0.49 (df=1)	p=0.4846	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6691	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.70.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

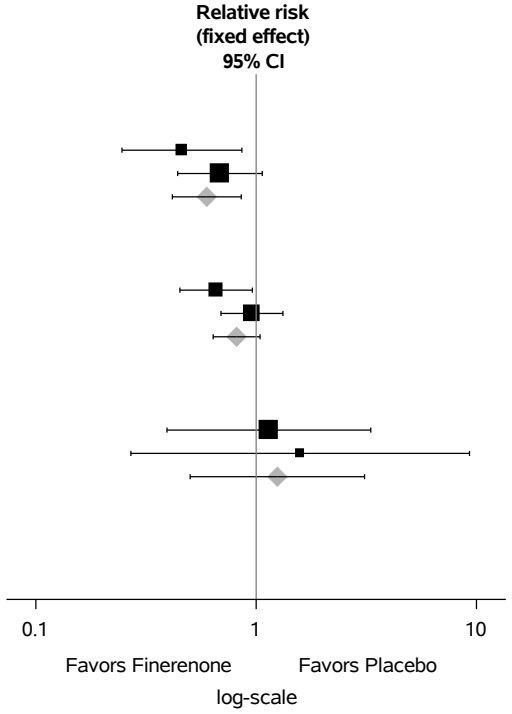
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	45 / 1879	67 / 1858	38.6	0.66 [0.46,0.96]	
FIGARO-DKD	78 / 2643	94 / 2608	61.4	0.82 [0.61,1.10]	
Total	123 / 4522	161 / 4466		0.75 [0.60,0.95]	Z=-2.39, p=0.0169
Heterogeneity:	Q=0.75 (df=1)	p=0.3878	I^2=0.0%		
> 4.5					
FIDELIO-DKD	19 / 948	35 / 973	47.7	0.56 [0.32,0.97]	
FIGARO-DKD	27 / 1040	27 / 1048	52.3	1.01 [0.60,1.71]	
Total	46 / 1988	62 / 2021		0.75 [0.52,1.10]	Z=-1.47, p=0.1420
Heterogeneity:	Q=2.32 (df=1)	p=0.1275	I^2=56.9%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9986	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.70.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

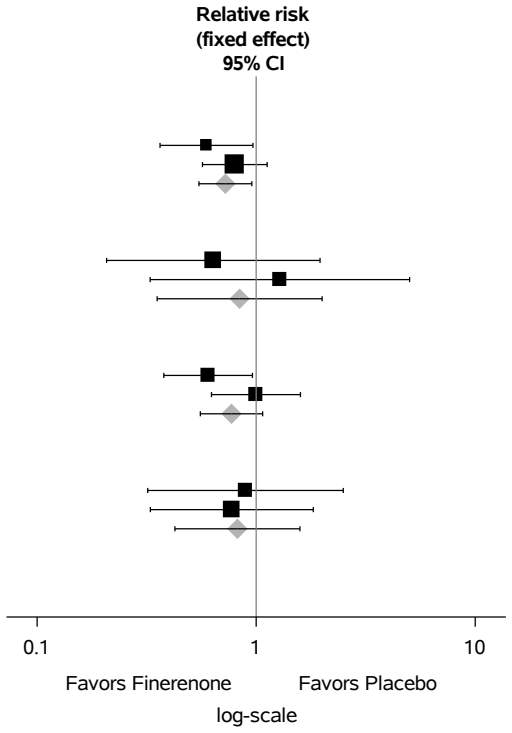
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 788	30 / 777	33.2	0.46 [0.25,0.86]	
FIGARO-DKD	32 / 1187	47 / 1194	66.8	0.68 [0.44,1.07]	
Total	46 / 1975	77 / 1971		0.60 [0.42,0.86]	Z=-2.81, p=0.0049
Heterogeneity:	Q=1.03 (df=1)	p=0.3092	I^2=3.3%		
130 - < 160					
FIDELIO-DKD	43 / 1897	66 / 1916	42.2	0.66 [0.45,0.96]	
FIGARO-DKD	70 / 2389	72 / 2351	57.8	0.96 [0.69,1.32]	
Total	113 / 4286	138 / 4267		0.82 [0.64,1.04]	Z=-1.64, p=0.1019
Heterogeneity:	Q=2.17 (df=1)	p=0.1411	I^2=53.8%		
>= 160					
FIDELIO-DKD	7 / 141	6 / 138	73.4	1.14 [0.39,3.31]	
FIGARO-DKD	3 / 107	2 / 113	26.6	1.58 [0.27,9.30]	
Total	10 / 248	8 / 251		1.25 [0.50,3.10]	Z=0.48, p=0.6342
Heterogeneity:	Q=0.10 (df=1)	p=0.7560	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.18 (df=2)	p=0.2040	I^2=37.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.70.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

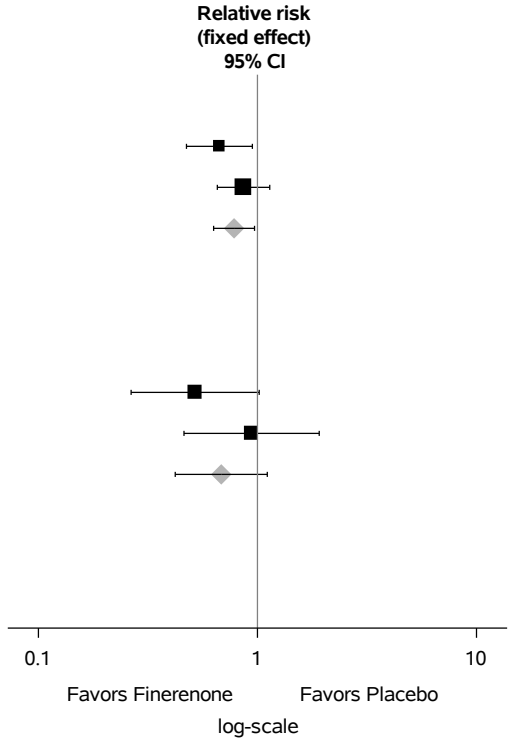
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	25 / 1773	43 / 1809	32.6	0.59 [0.36,0.97]	
FIGARO-DKD	59 / 2668	72 / 2601	67.4	0.80 [0.57,1.12]	
Total	84 / 4441	115 / 4410		0.72 [0.55,0.96]	Z=-2.28, p=0.0226
Heterogeneity:	Q=0.96 (df=1)	p=0.3269	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	7 / 124	59.6	0.64 [0.21,1.96]	
FIGARO-DKD	4 / 113	4 / 145	40.4	1.28 [0.33,5.02]	
Total	9 / 252	11 / 269		0.84 [0.35,2.00]	Z=-0.39, p=0.6942
Heterogeneity:	Q=0.60 (df=1)	p=0.4372	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 717	45 / 721	50.2	0.60 [0.38,0.96]	
FIGARO-DKD	33 / 716	34 / 736	49.8	1.00 [0.62,1.59]	
Total	60 / 1433	79 / 1457		0.77 [0.56,1.07]	Z=-1.55, p=0.1206
Heterogeneity:	Q=2.23 (df=1)	p=0.1353	I^2=55.2%		
Others					
FIDELIO-DKD	7 / 198	7 / 177	41.0	0.89 [0.32,2.50]	
FIGARO-DKD	9 / 186	11 / 176	59.0	0.77 [0.33,1.82]	
Total	16 / 384	18 / 353		0.82 [0.43,1.58]	Z=-0.59, p=0.5566
Heterogeneity:	Q=0.04 (df=1)	p=0.8331	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=3)	p=0.9730	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.70.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

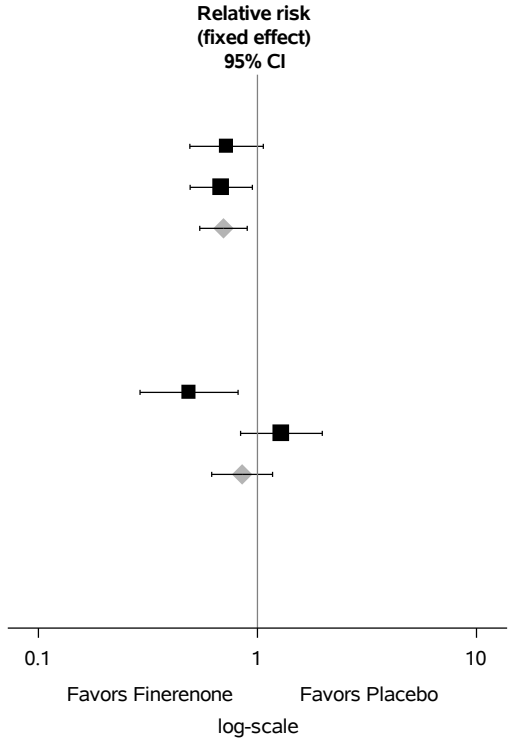
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 1949	79 / 2024	38.7	0.67 [0.47,0.95]	
FIGARO-DKD	90 / 2527	106 / 2571	61.3	0.86 [0.66,1.14]	
Total	141 / 4476	185 / 4595		0.78 [0.63,0.97]	Z=-2.24, p=0.0252
Heterogeneity:	Q=1.26 (df=1)	p=0.2617	I^2=20.6%		
Female					
FIDELIO-DKD	13 / 878	23 / 807	52.7	0.52 [0.26,1.02]	
FIGARO-DKD	15 / 1156	15 / 1087	47.3	0.94 [0.46,1.91]	
Total	28 / 2034	38 / 1894		0.68 [0.42,1.11]	Z=-1.54, p=0.1232
Heterogeneity:	Q=1.41 (df=1)	p=0.2349	I^2=29.1%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6180	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.70.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

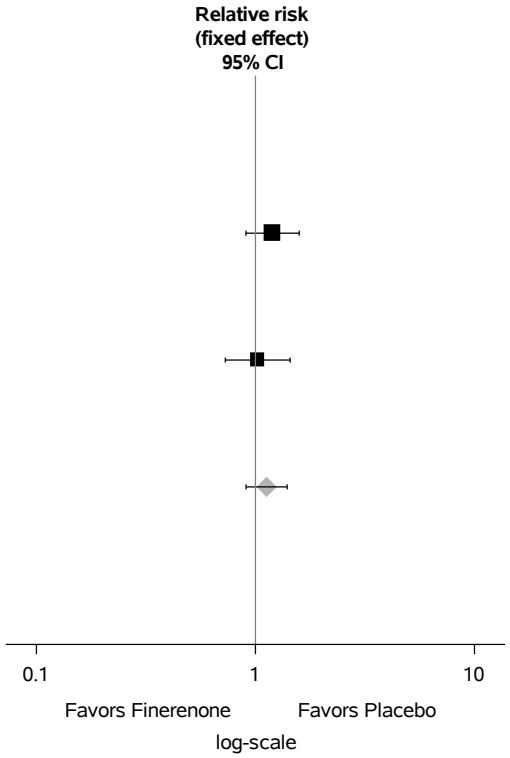
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	43 / 1201	58 / 1171	41.8	0.72 [0.49,1.06]	
FIGARO-DKD	58 / 1752	85 / 1755	58.2	0.68 [0.49,0.95]	
Total	101 / 2953	143 / 2926		0.70 [0.55,0.90]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.05 (df=1)	p=0.8284	I^2=0.0%		
>= 65					
FIDELIO-DKD	21 / 1626	44 / 1660	41.0	0.49 [0.29,0.82]	
FIGARO-DKD	47 / 1931	36 / 1903	59.0	1.29 [0.84,1.98]	
Total	68 / 3557	80 / 3563		0.85 [0.62,1.17]	Z=-0.99, p=0.3234
Heterogeneity:	Q=8.06 (df=1)	p=0.0045	I^2=87.6%		
Subgroup Heterogeneity:	Q=0.90 (df=1)	p=0.3438	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.71: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set

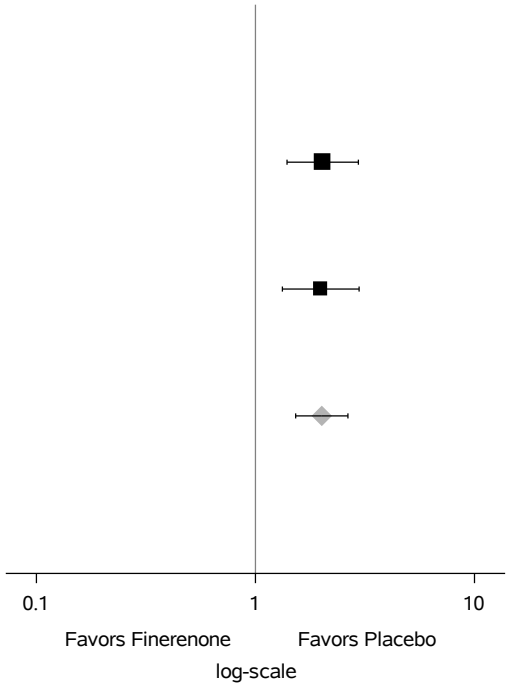
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	87 / 2831	59.7	1.20 [0.90,1.58]	
FIGARO-DKD	66 / 3683	64 / 3658	40.3	1.02 [0.73,1.44]	
Total	170 / 6510	151 / 6489		1.12 [0.91,1.40]	Z=1.06, p=0.2879
Heterogeneity:	Q=0.48 (df=1)	p=0.4883	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.72: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

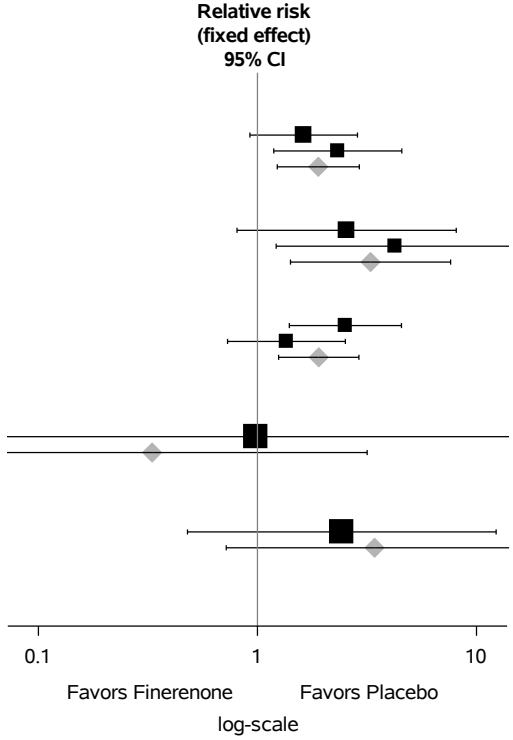
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	81 / 2827	40 / 2831	53.6	2.03 [1.39,2.95]	
FIGARO-DKD	70 / 3683	35 / 3658	46.4	1.99 [1.33,2.97]	
Total	151 / 6510	75 / 6489		2.01 [1.53,2.64]	Z=4.98, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9414	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.72.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	31 / 1178	19 / 1174	58.6	1.63 [0.92,2.86]	
FIGARO-DKD	28 / 1752	12 / 1747	41.4	2.33 [1.19,4.56]	
Total	59 / 2930	31 / 2921		1.90 [1.23,2.92]	Z=2.91, p=0.0037
Heterogeneity:	Q=0.64 (df=1)	p=0.4241	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	4 / 476	54.0	2.55 [0.81,8.08]	
FIGARO-DKD	13 / 559	3 / 548	46.0	4.25 [1.22,14.82]	
Total	23 / 1025	7 / 1024		3.28 [1.42,7.62]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.35 (df=1)	p=0.5564	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	15 / 786	52.5	2.52 [1.40,4.54]	
FIGARO-DKD	23 / 811	17 / 813	47.5	1.36 [0.73,2.52]	
Total	61 / 1601	32 / 1599		1.91 [1.25,2.91]	Z=2.99, p=0.0028
Heterogeneity:	Q=2.02 (df=1)	p=0.1549	I^2=50.6%		
Latin America					
FIDELIO-DKD	0 / 294	2 / 294	0.0	0.00 [0.00,19E296]	
FIGARO-DKD	1 / 424	1 / 417	100.0	0.98 [0.06,15.67]	
Total	1 / 718	3 / 711		0.33 [0.03,3.17]	Z=-0.96, p=0.3370
Heterogeneity:	Q=0.60 (df=1)	p=0.4400	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	105E9 [105E9,105E9]	
FIGARO-DKD	5 / 137	2 / 133	100.0	2.43 [0.48,12.29]	
Total	7 / 236	2 / 234		3.42 [0.72,16.29]	Z=1.55, p=0.1218
Heterogeneity:	Q=0.17 (df=1)	p=0.6773	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.34 (df=4)	p=0.3623	I^2=7.8%		

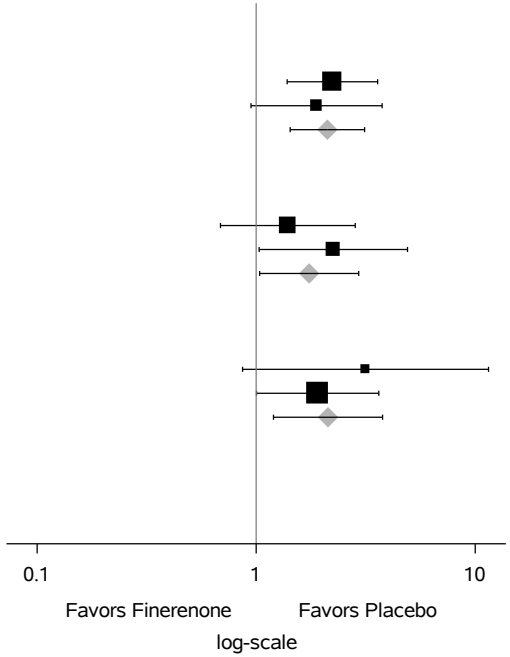


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.72.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood potassium increased (PT with Incidence >=1%)

Safety Analysis Set

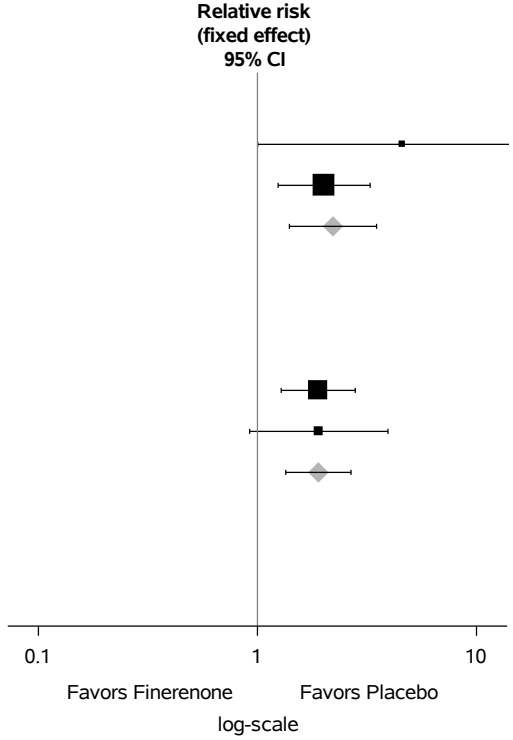
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	54 / 1556	24 / 1541	67.7	2.23 [1.38,3.59]	
FIGARO-DKD	23 / 637	12 / 627	32.3	1.89 [0.95,3.76]	
Total	77 / 2193	36 / 2168		2.11 [1.43,3.13]	Z=3.75, p=0.0002
Heterogeneity:	Q=0.15 (df=1)	p=0.6968	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	18 / 1061	13 / 1069	54.8	1.40 [0.69,2.83]	
FIGARO-DKD	20 / 720	9 / 729	45.2	2.25 [1.03,4.91]	
Total	38 / 1781	22 / 1798		1.75 [1.04,2.94]	Z=2.10, p=0.0361
Heterogeneity:	Q=0.79 (df=1)	p=0.3736	I^2=0.0%		
>= 60					
FIDELIO-DKD	9 / 210	3 / 221	19.8	3.16 [0.87,11.50]	
FIGARO-DKD	27 / 2326	14 / 2302	80.2	1.91 [1.00,3.63]	
Total	36 / 2536	17 / 2523		2.13 [1.20,3.78]	Z=2.58, p=0.0098
Heterogeneity:	Q=0.47 (df=1)	p=0.4941	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.38 (df=2)	p=0.8253	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.72.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

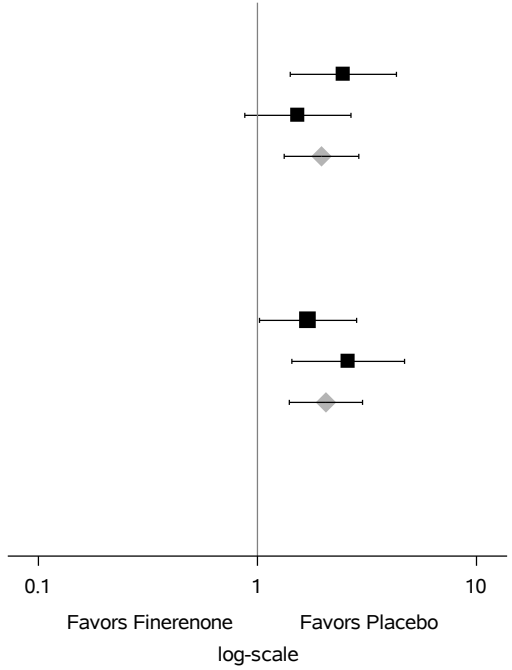
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	9 / 209	2 / 213	9.2	4.59 [1.00,20.97]	
FIGARO-DKD	49 / 1720	24 / 1698	90.8	2.02 [1.24,3.27]	
Total	58 / 1929	26 / 1911		2.21 [1.40,3.50]	Z=3.40, p=0.0007
Heterogeneity:	Q=1.03 (df=1)	p=0.3112	I^2=2.5%		
Very High					
FIDELIO-DKD	72 / 2618	38 / 2618	77.7	1.89 [1.28,2.80]	
FIGARO-DKD	21 / 1963	11 / 1960	22.3	1.91 [0.92,3.94]	
Total	93 / 4581	49 / 4578		1.90 [1.35,2.67]	Z=3.66, p=0.0003
Heterogeneity:	Q=0.00 (df=1)	p=0.9886	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5990	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.72.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

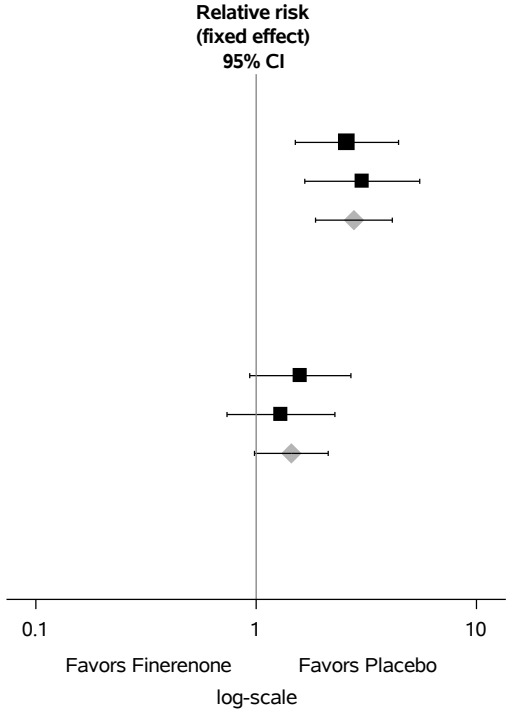
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	42 / 1301	17 / 1299	50.0	2.47 [1.41,4.31]	
FIGARO-DKD	31 / 1673	20 / 1651	50.0	1.53 [0.88,2.67]	
Total	73 / 2974	37 / 2950		1.96 [1.32,2.90]	Z=3.37, p=0.0008
Heterogeneity:	Q=1.41 (df=1)	p=0.2349	I^2=29.1%		
Absent					
FIDELIO-DKD	39 / 1526	23 / 1532	57.4	1.70 [1.02,2.84]	
FIGARO-DKD	39 / 2010	15 / 2007	42.6	2.60 [1.44,4.69]	
Total	78 / 3536	38 / 3539		2.05 [1.40,3.02]	Z=3.67, p=0.0002
Heterogeneity:	Q=1.12 (df=1)	p=0.2897	I^2=10.8%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8682	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.72.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

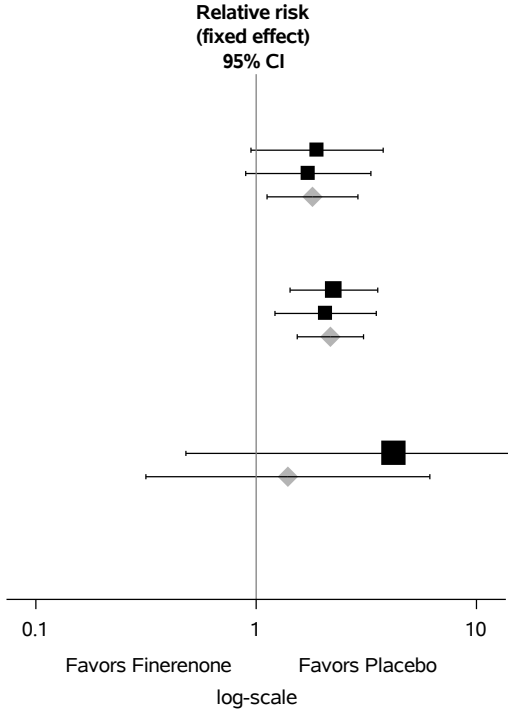
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	47 / 1879	18 / 1858	55.4	2.58 [1.51,4.43]	
FIGARO-DKD	43 / 2643	14 / 2608	44.6	3.03 [1.66,5.53]	
Total	90 / 4522	32 / 4466		2.78 [1.86,4.15]	Z=4.99, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.6972	I^2=0.0%		
> 4.5					
FIDELIO-DKD	34 / 948	22 / 973	53.2	1.59 [0.93,2.69]	
FIGARO-DKD	27 / 1040	21 / 1048	46.8	1.30 [0.74,2.28]	
Total	61 / 1988	43 / 2021		1.44 [0.98,2.12]	Z=1.87, p=0.0615
Heterogeneity:	Q=0.26 (df=1)	p=0.6078	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.31 (df=1)	p=0.0212	I^2=81.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.72.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

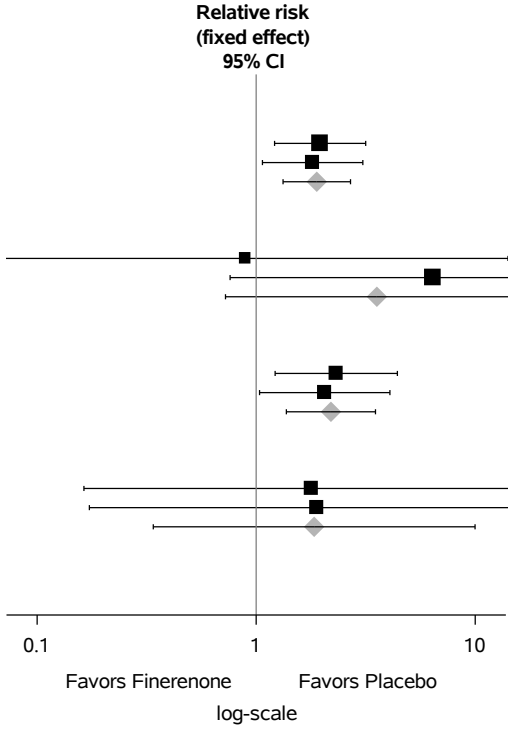
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	23 / 788	12 / 777	47.3	1.89 [0.95,3.77]	
FIGARO-DKD	24 / 1187	14 / 1194	52.7	1.72 [0.90,3.32]	
Total	47 / 1975	26 / 1971		1.80 [1.12,2.90]	Z=2.43, p=0.0151
Heterogeneity:	Q=0.04 (df=1)	p=0.8502	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	58 / 1897	26 / 1916	57.2	2.25 [1.42,3.56]	
FIGARO-DKD	42 / 2389	20 / 2351	42.8	2.07 [1.22,3.51]	
Total	100 / 4286	46 / 4267		2.17 [1.54,3.07]	Z=4.39, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.8089	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	2 / 138	0.0	0.00 [0.00,88E295]	
FIGARO-DKD	4 / 107	1 / 113	100.0	4.22 [0.48,37.19]	
Total	4 / 248	3 / 251		1.39 [0.32,6.14]	Z=0.44, p=0.6617
Heterogeneity:	Q=1.00 (df=1)	p=0.3174	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=2)	p=0.7291	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.72.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

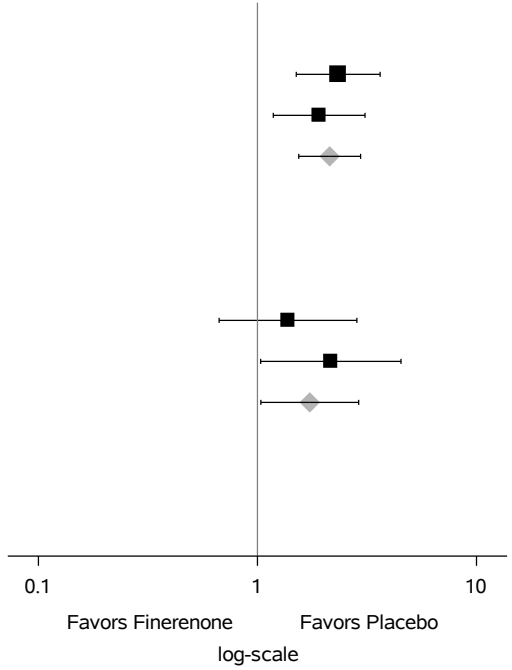
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	48 / 1773	25 / 1809	54.8	1.96 [1.21,3.16]	
FIGARO-DKD	39 / 2668	21 / 2601	45.2	1.81 [1.07,3.07]	
Total	87 / 4441	46 / 4410		1.89 [1.33,2.70]	Z=3.52, p=0.0004
Heterogeneity:	Q=0.05 (df=1)	p=0.8284	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	1 / 124	37.4	0.89 [0.06,14.11]	
FIGARO-DKD	5 / 113	1 / 145	62.6	6.42 [0.76,54.15]	
Total	6 / 252	2 / 269		3.56 [0.72,17.47]	Z=1.56, p=0.1181
Heterogeneity:	Q=1.26 (df=1)	p=0.2621	I^2=20.5%		
Asian					
FIDELIO-DKD	30 / 717	13 / 721	53.2	2.32 [1.22,4.41]	
FIGARO-DKD	24 / 716	12 / 736	46.8	2.06 [1.04,4.08]	
Total	54 / 1433	25 / 1457		2.19 [1.37,3.51]	Z=3.29, p=0.0010
Heterogeneity:	Q=0.06 (df=1)	p=0.8005	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	1 / 177	50.0	1.79 [0.16,19.55]	
FIGARO-DKD	2 / 186	1 / 176	50.0	1.89 [0.17,20.69]	
Total	4 / 384	2 / 353		1.84 [0.34,9.98]	Z=0.71, p=0.4799
Heterogeneity:	Q=0.00 (df=1)	p=0.9737	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.75 (df=3)	p=0.8615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.72.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

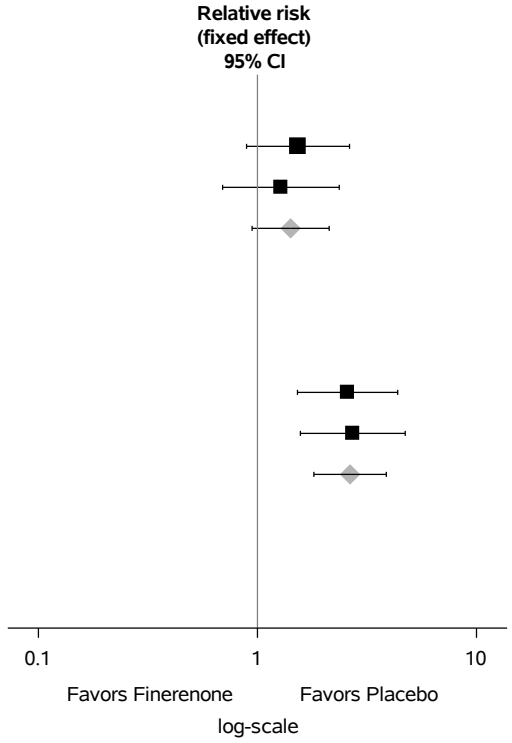
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	63 / 1949	28 / 2024	54.5	2.34 [1.50,3.63]	
FIGARO-DKD	47 / 2527	25 / 2571	45.5	1.91 [1.18,3.10]	
Total	110 / 4476	53 / 4595		2.14 [1.54,2.96]	Z=4.58, p=<.0001
Heterogeneity:	Q=0.36 (df=1)	p=0.5481	I^2=0.0%		
Female					
FIDELIO-DKD	18 / 878	12 / 807	50.9	1.38 [0.67,2.84]	
FIGARO-DKD	23 / 1156	10 / 1087	49.1	2.16 [1.03,4.52]	
Total	41 / 2034	22 / 1894		1.73 [1.04,2.90]	Z=2.10, p=0.0361
Heterogeneity:	Q=0.73 (df=1)	p=0.3931	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4997	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.72.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

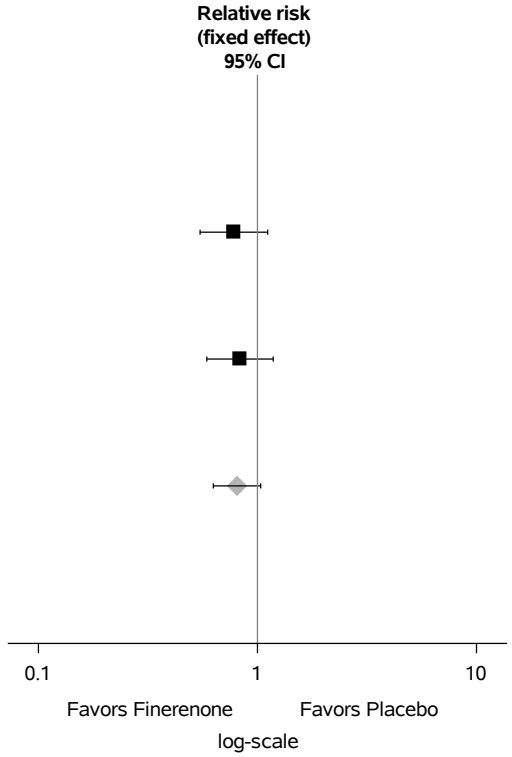
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 1201	21 / 1171	56.2	1.53 [0.89,2.63]	
FIGARO-DKD	23 / 1752	18 / 1755	43.8	1.28 [0.69,2.36]	
Total	56 / 2953	39 / 2926		1.42 [0.95,2.13]	Z=1.69, p=0.0917
Heterogeneity:	Q=0.19 (df=1)	p=0.6665	I^2=0.0%		
>= 65					
FIDELIO-DKD	48 / 1626	19 / 1660	52.3	2.58 [1.52,4.37]	
FIGARO-DKD	47 / 1931	17 / 1903	47.7	2.72 [1.57,4.73]	
Total	95 / 3557	36 / 3563		2.65 [1.81,3.88]	Z=5.01, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8878	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.86 (df=1)	p=0.0275	I^2=79.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.73: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set

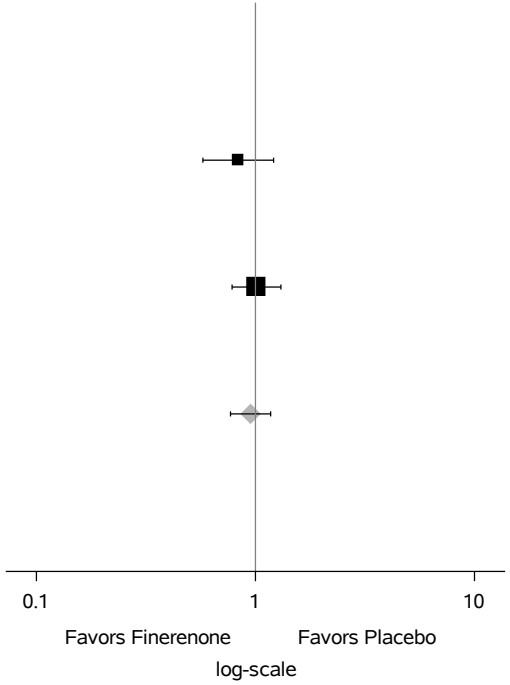
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	68 / 2831	49.1	0.78 [0.55,1.11]	
FIGARO-DKD	57 / 3683	68 / 3658	50.9	0.83 [0.59,1.18]	
Total	110 / 6510	136 / 6489		0.81 [0.63,1.03]	Z=-1.69, p=0.0905
Heterogeneity:	Q=0.06 (df=1)	p=0.7995	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.74: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set

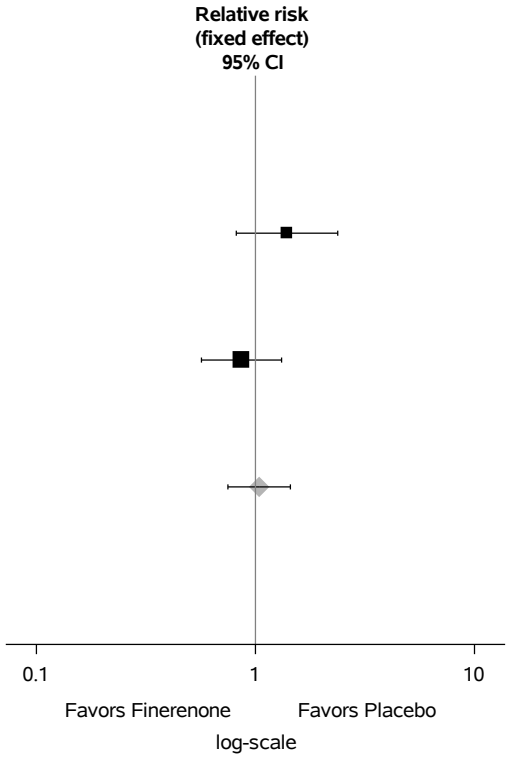
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	50 / 2827	60 / 2831	32.3	0.83 [0.58,1.21]	
FIGARO-DKD	114 / 3683	112 / 3658	67.7	1.01 [0.78,1.31]	
Total	164 / 6510	172 / 6489		0.95 [0.77,1.17]	Z=-0.48, p=0.6340
Heterogeneity:	Q=0.69 (df=1)	p=0.4053	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.75: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set

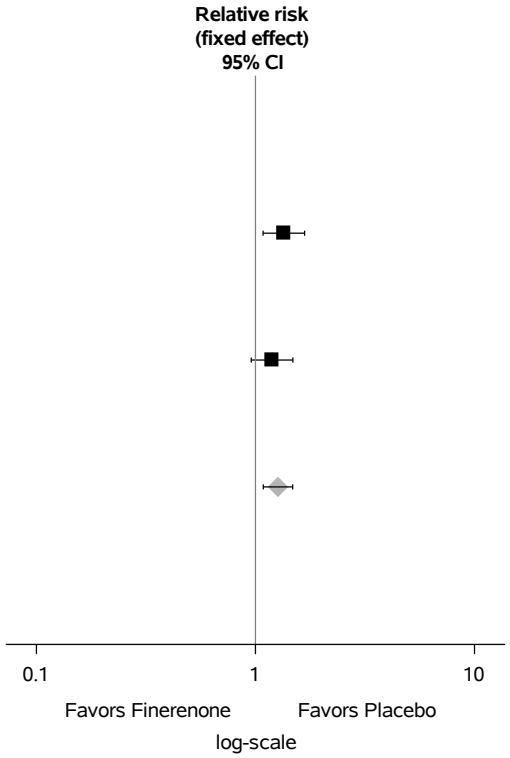
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	23 / 2831	38.4	1.39 [0.82,2.37]	
FIGARO-DKD	40 / 3683	46 / 3658	61.6	0.86 [0.57,1.32]	
Total	72 / 6510	69 / 6489		1.04 [0.75,1.44]	Z=0.23, p=0.8172
Heterogeneity:	Q=1.90 (df=1)	p=0.1678	I^2=47.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.76: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

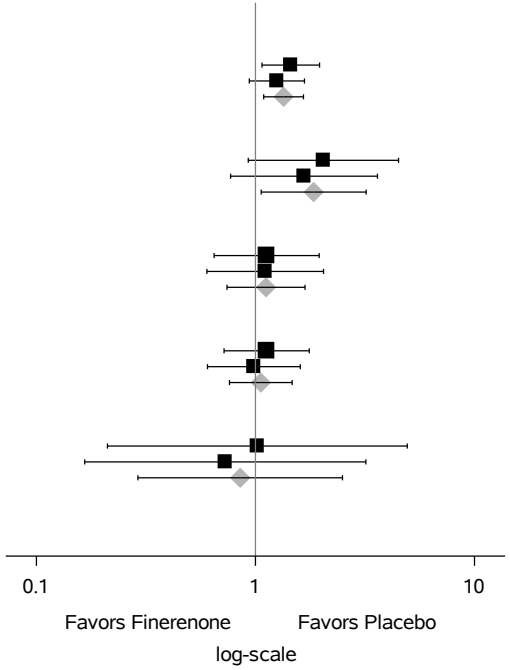
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	179 / 2827	133 / 2831	50.1	1.35 [1.08,1.68]	
FIGARO-DKD	169 / 3683	141 / 3658	49.9	1.19 [0.96,1.48]	
Total	348 / 6510	274 / 6489		1.27 [1.09,1.48]	Z=3.01, p=0.0027
Heterogeneity:	Q=0.62 (df=1)	p=0.4312	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.76.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

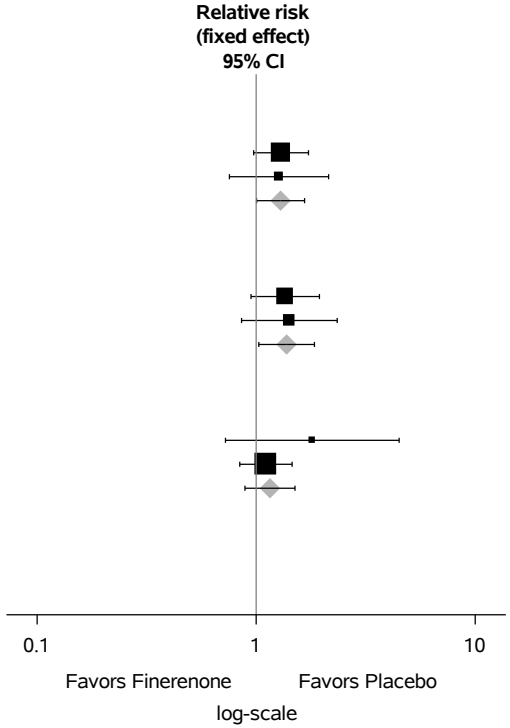
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	96 / 1178	66 / 1174	47.8	1.45 [1.07,1.96]	
FIGARO-DKD	98 / 1752	78 / 1747	52.2	1.25 [0.94,1.67]	
Total	194 / 2930	144 / 2921		1.34 [1.09,1.66]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.47 (df=1)	p=0.4952	I^2=0.0%		
North America					
FIDELIO-DKD	18 / 466	9 / 476	48.9	2.04 [0.93,4.50]	
FIGARO-DKD	17 / 559	10 / 548	51.1	1.67 [0.77,3.61]	
Total	35 / 1025	19 / 1024		1.84 [1.06,3.20]	Z=2.17, p=0.0297
Heterogeneity:	Q=0.13 (df=1)	p=0.7178	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 790	23 / 786	55.2	1.12 [0.65,1.95]	
FIGARO-DKD	21 / 811	19 / 813	44.8	1.11 [0.60,2.05]	
Total	47 / 1601	42 / 1599		1.12 [0.74,1.68]	Z=0.53, p=0.5965
Heterogeneity:	Q=0.00 (df=1)	p=0.9716	I^2=0.0%		
Latin America					
FIDELIO-DKD	36 / 294	32 / 294	54.2	1.12 [0.72,1.76]	
FIGARO-DKD	30 / 424	30 / 417	45.8	0.98 [0.60,1.60]	
Total	66 / 718	62 / 711		1.06 [0.76,1.47]	Z=0.33, p=0.7376
Heterogeneity:	Q=0.16 (df=1)	p=0.6907	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 99	3 / 101	46.8	1.02 [0.21,4.93]	
FIGARO-DKD	3 / 137	4 / 133	53.2	0.73 [0.17,3.19]	
Total	6 / 236	7 / 234		0.85 [0.29,2.50]	Z=-0.29, p=0.7698
Heterogeneity:	Q=0.09 (df=1)	p=0.7596	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.11 (df=4)	p=0.3909	I^2=2.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.76.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

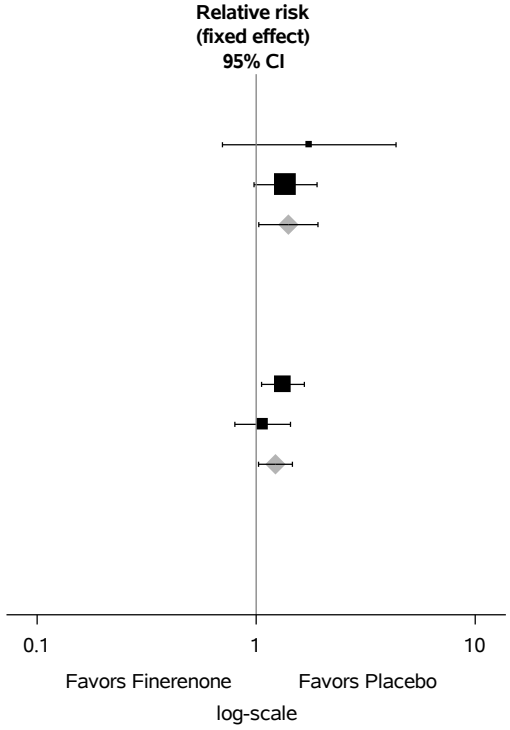
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	101 / 1556	77 / 1541	76.6	1.30 [0.97,1.73]	
FIGARO-DKD	31 / 637	24 / 627	23.4	1.27 [0.75,2.14]	
Total	132 / 2193	101 / 2168		1.29 [1.00,1.66]	Z=1.99, p=0.0461
Heterogeneity:	Q=0.01 (df=1)	p=0.9436	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	66 / 1061	49 / 1069	66.1	1.36 [0.95,1.94]	
FIGARO-DKD	35 / 720	25 / 729	33.9	1.42 [0.86,2.34]	
Total	101 / 1781	74 / 1798		1.38 [1.03,1.85]	Z=2.14, p=0.0320
Heterogeneity:	Q=0.02 (df=1)	p=0.8902	I^2=0.0%		
>= 60					
FIDELIO-DKD	12 / 210	7 / 221	8.3	1.80 [0.72,4.49]	
FIGARO-DKD	103 / 2326	92 / 2302	91.7	1.11 [0.84,1.46]	
Total	115 / 2536	99 / 2523		1.16 [0.89,1.50]	Z=1.08, p=0.2799
Heterogeneity:	Q=1.00 (df=1)	p=0.3162	I^2=0.4%		
Subgroup Heterogeneity:	Q=0.80 (df=2)	p=0.6692	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.76.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

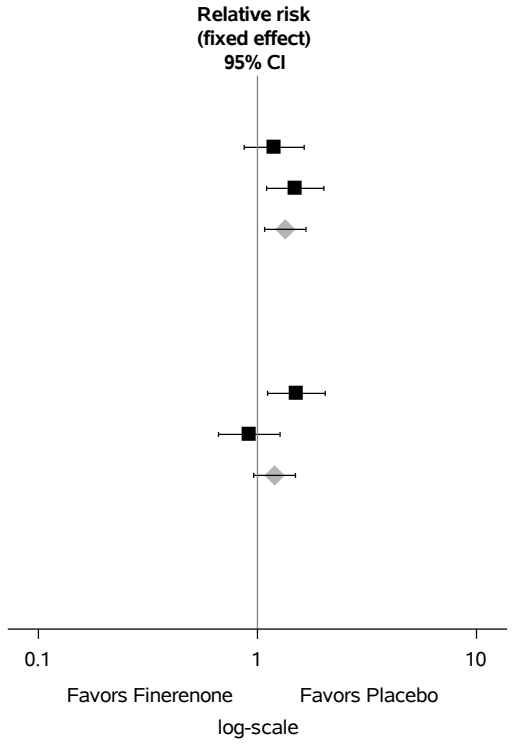
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	12 / 209	7 / 213	11.6	1.75 [0.70,4.35]	
FIGARO-DKD	80 / 1720	58 / 1698	88.4	1.36 [0.98,1.90]	
Total	92 / 1929	65 / 1911		1.40 [1.03,1.92]	Z=2.13, p=0.0330
Heterogeneity:	Q=0.25 (df=1)	p=0.6148	I^2=0.0%		
Very High					
FIDELIO-DKD	167 / 2618	126 / 2618	62.8	1.33 [1.06,1.66]	
FIGARO-DKD	89 / 1963	83 / 1960	37.2	1.07 [0.80,1.43]	
Total	256 / 4581	209 / 4578		1.22 [1.03,1.46]	Z=2.23, p=0.0255
Heterogeneity:	Q=1.29 (df=1)	p=0.2568	I^2=22.2%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4585	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.76.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

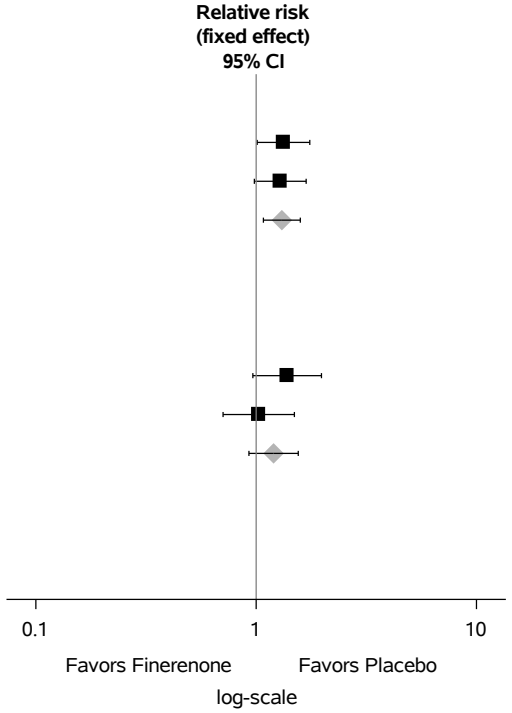
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	80 / 1301	67 / 1299	47.7	1.19 [0.87,1.63]	
FIGARO-DKD	101 / 1673	67 / 1651	52.3	1.49 [1.10,2.01]	
Total	181 / 2974	134 / 2950		1.34 [1.08,1.67]	Z=2.64, p=0.0084
Heterogeneity:	Q=0.99 (df=1)	p=0.3197	I^2=0.0%		
Absent					
FIDELIO-DKD	99 / 1526	66 / 1532	53.2	1.51 [1.11,2.04]	
FIGARO-DKD	68 / 2010	74 / 2007	46.8	0.92 [0.66,1.27]	
Total	167 / 3536	140 / 3539		1.20 [0.96,1.49]	Z=1.61, p=0.1077
Heterogeneity:	Q=4.80 (df=1)	p=0.0285	I^2=79.2%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4759	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.76.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

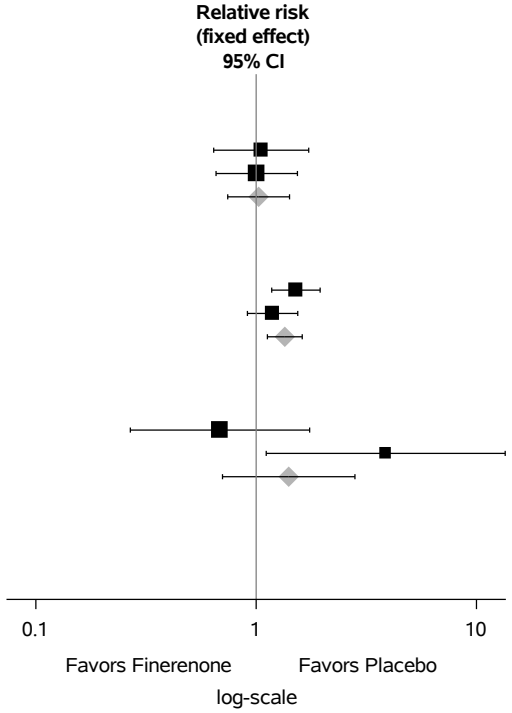
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	113 / 1879	84 / 1858	49.2	1.33 [1.01,1.75]	
FIGARO-DKD	116 / 2643	89 / 2608	50.8	1.29 [0.98,1.69]	
Total	229 / 4522	173 / 4466		1.31 [1.08,1.59]	Z=2.72, p=0.0064
Heterogeneity:	Q=0.03 (df=1)	p=0.8641	I^2=0.0%		
> 4.5					
FIDELIO-DKD	66 / 948	49 / 973	51.9	1.38 [0.97,1.98]	
FIGARO-DKD	53 / 1040	52 / 1048	48.1	1.03 [0.71,1.49]	
Total	119 / 1988	101 / 2021		1.20 [0.93,1.55]	Z=1.38, p=0.1664
Heterogeneity:	Q=1.27 (df=1)	p=0.2602	I^2=21.1%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5997	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.76.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

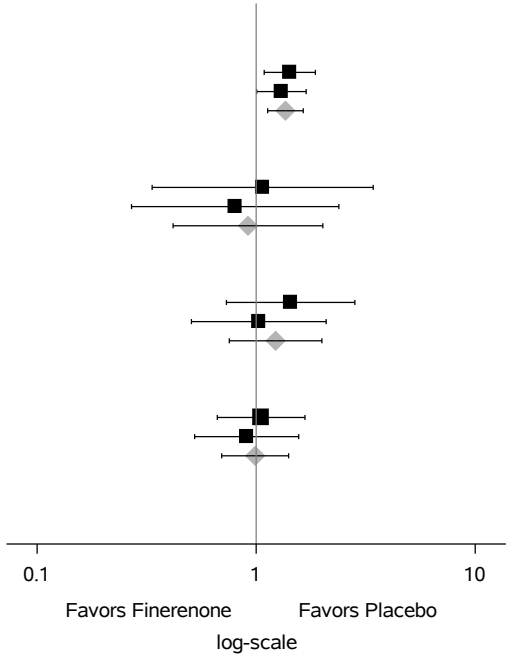
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	31 / 788	29 / 777	42.3	1.05 [0.64,1.73]	
FIGARO-DKD	41 / 1187	41 / 1194	57.7	1.01 [0.66,1.54]	
Total	72 / 1975	70 / 1971		1.03 [0.74,1.42]	Z=0.16, p=0.8762
Heterogeneity:	Q=0.02 (df=1)	p=0.8885	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	141 / 1897	94 / 1916	51.9	1.52 [1.18,1.95]	
FIGARO-DKD	117 / 2389	97 / 2351	48.1	1.19 [0.91,1.54]	
Total	258 / 4286	191 / 4267		1.35 [1.12,1.62]	Z=3.22, p=0.0013
Heterogeneity:	Q=1.72 (df=1)	p=0.1902	I^2=41.7%		
>= 160					
FIDELIO-DKD	7 / 141	10 / 138	64.0	0.69 [0.27,1.75]	
FIGARO-DKD	11 / 107	3 / 113	36.0	3.87 [1.11,13.50]	
Total	18 / 248	13 / 251		1.41 [0.70,2.81]	Z=0.96, p=0.3355
Heterogeneity:	Q=4.79 (df=1)	p=0.0286	I^2=79.1%		
Subgroup Heterogeneity:	Q=2.18 (df=2)	p=0.3364	I^2=8.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.76.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

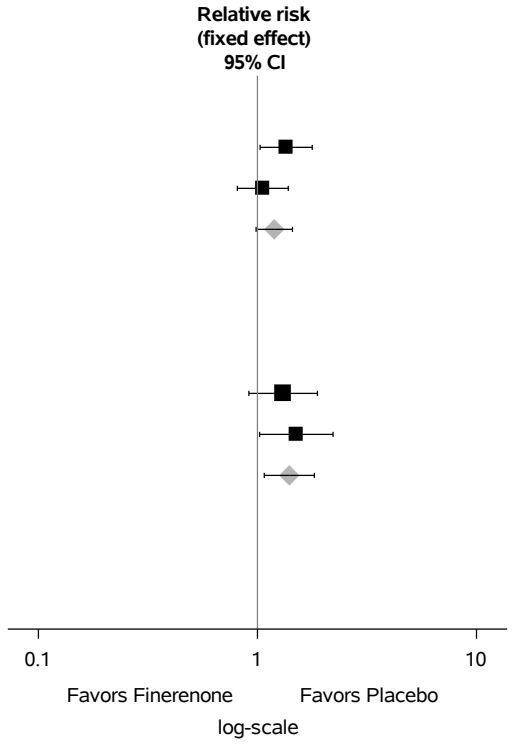
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	120 / 1773	86 / 1809	48.4	1.42 [1.09,1.86]	
FIGARO-DKD	127 / 2668	95 / 2601	51.6	1.30 [1.00,1.69]	
Total	247 / 4441	181 / 4410		1.36 [1.13,1.64]	Z=3.22, p=0.0013
Heterogeneity:	Q=0.21 (df=1)	p=0.6436	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	5 / 124	46.8	1.07 [0.33,3.42]	
FIGARO-DKD	5 / 113	8 / 145	53.2	0.80 [0.27,2.39]	
Total	11 / 252	13 / 269		0.92 [0.42,2.02]	Z=-0.21, p=0.8300
Heterogeneity:	Q=0.13 (df=1)	p=0.7224	I^2=0.0%		
Asian					
FIDELIO-DKD	20 / 717	14 / 721	52.4	1.44 [0.73,2.82]	
FIGARO-DKD	15 / 716	15 / 736	47.6	1.03 [0.51,2.09]	
Total	35 / 1433	29 / 1457		1.23 [0.75,2.00]	Z=0.82, p=0.4110
Heterogeneity:	Q=0.45 (df=1)	p=0.5026	I^2=0.0%		
Others					
FIDELIO-DKD	33 / 198	28 / 177	58.5	1.05 [0.66,1.67]	
FIGARO-DKD	22 / 186	23 / 176	41.5	0.91 [0.52,1.56]	
Total	55 / 384	51 / 353		0.99 [0.70,1.41]	Z=-0.06, p=0.9520
Heterogeneity:	Q=0.17 (df=1)	p=0.6773	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.08 (df=3)	p=0.3791	I^2=2.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.76.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

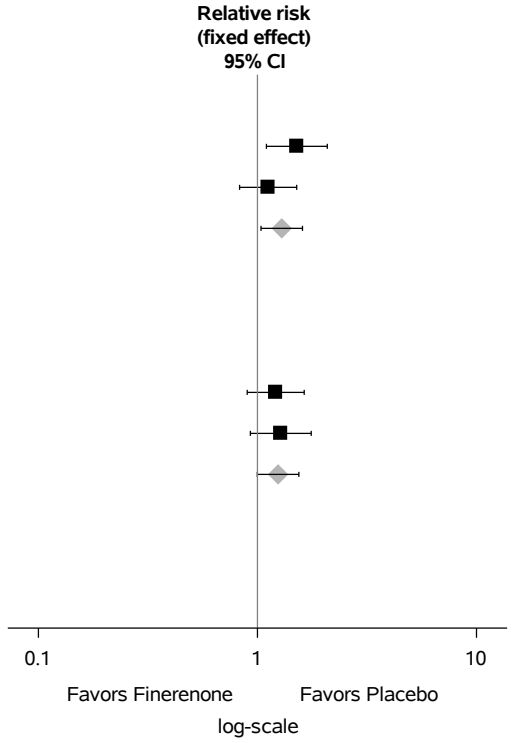
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	112 / 1949	86 / 2024	48.8	1.35 [1.03,1.78]	
FIGARO-DKD	105 / 2527	101 / 2571	51.2	1.06 [0.81,1.38]	
Total	217 / 4476	187 / 4595		1.19 [0.99,1.44]	Z=1.81, p=0.0700
Heterogeneity:	Q=1.58 (df=1)	p=0.2084	I^2=36.8%		
Female					
FIDELIO-DKD	67 / 878	47 / 807	53.5	1.31 [0.91,1.88]	
FIGARO-DKD	64 / 1156	40 / 1087	46.5	1.50 [1.02,2.21]	
Total	131 / 2034	87 / 1894		1.40 [1.07,1.82]	Z=2.49, p=0.0127
Heterogeneity:	Q=0.26 (df=1)	p=0.6081	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.91 (df=1)	p=0.3402	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.76.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

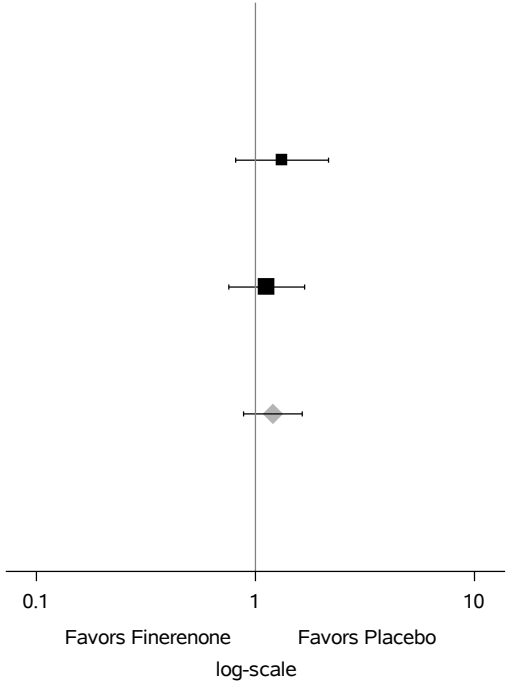
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	90 / 1201	58 / 1171	46.8	1.51 [1.10,2.08]	
FIGARO-DKD	86 / 1752	77 / 1755	53.2	1.12 [0.83,1.51]	
Total	176 / 2953	135 / 2926		1.29 [1.04,1.61]	Z=2.29, p=0.0218
Heterogeneity:	Q=1.82 (df=1)	p=0.1777	I^2=45.0%		
>= 65					
FIDELIO-DKD	89 / 1626	75 / 1660	53.3	1.21 [0.90,1.63]	
FIGARO-DKD	83 / 1931	64 / 1903	46.7	1.28 [0.93,1.76]	
Total	172 / 3557	139 / 3563		1.24 [1.00,1.55]	Z=1.94, p=0.0518
Heterogeneity:	Q=0.06 (df=1)	p=0.8108	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8073	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.77: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set

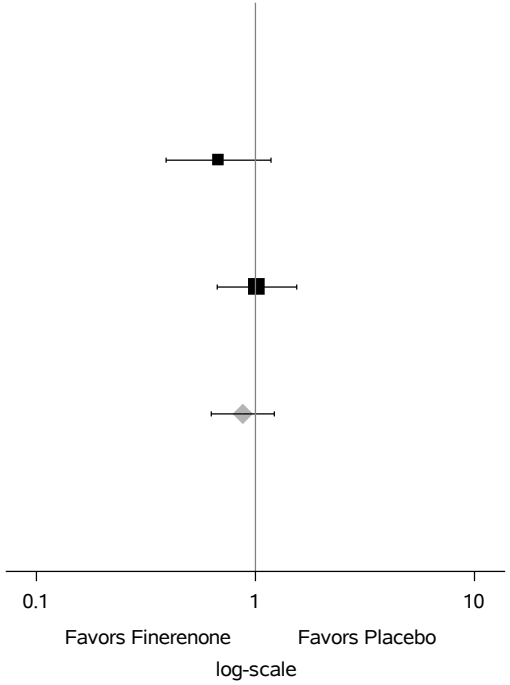
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2827	28 / 2831	40.0	1.32 [0.81,2.16]	
FIGARO-DKD	51 / 3683	45 / 3658	60.0	1.13 [0.76,1.68]	
Total	88 / 6510	73 / 6489		1.20 [0.88,1.64]	Z=1.17, p=0.2439
Heterogeneity:	Q=0.25 (df=1)	p=0.6148	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.78: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set

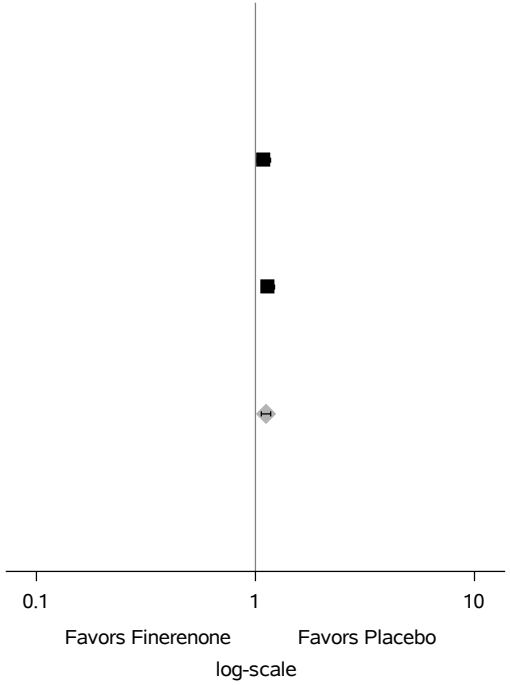
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	31 / 2831	36.5	0.68 [0.39,1.18]	
FIGARO-DKD	44 / 3683	43 / 3658	63.5	1.02 [0.67,1.54]	
Total	65 / 6510	74 / 6489		0.88 [0.63,1.22]	Z=-0.79, p=0.4309
Heterogeneity:	Q=1.31 (df=1)	p=0.2521	I^2=23.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.79: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

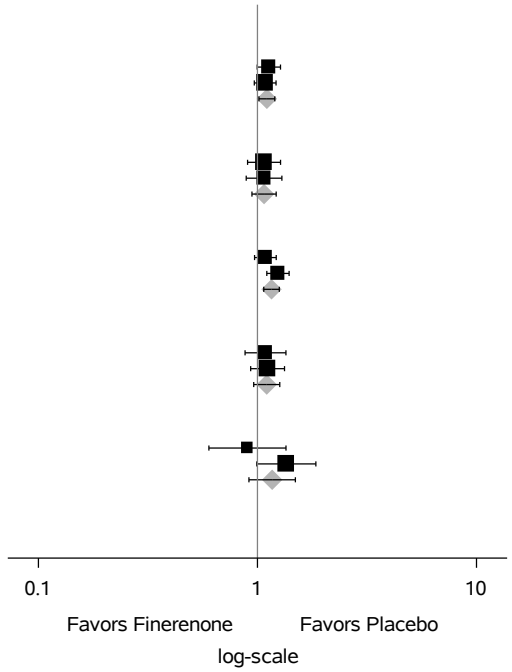
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1045 / 2827	958 / 2831	48.5	1.09 [1.02,1.17]	
FIGARO-DKD	1218 / 3683	1060 / 3658	51.5	1.14 [1.07,1.22]	
Total	2263 / 6510	2018 / 6489		1.12 [1.06,1.17]	Z=4.43, p=<.0001
Heterogeneity:	Q=0.76 (df=1)	p=0.3824	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.79.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

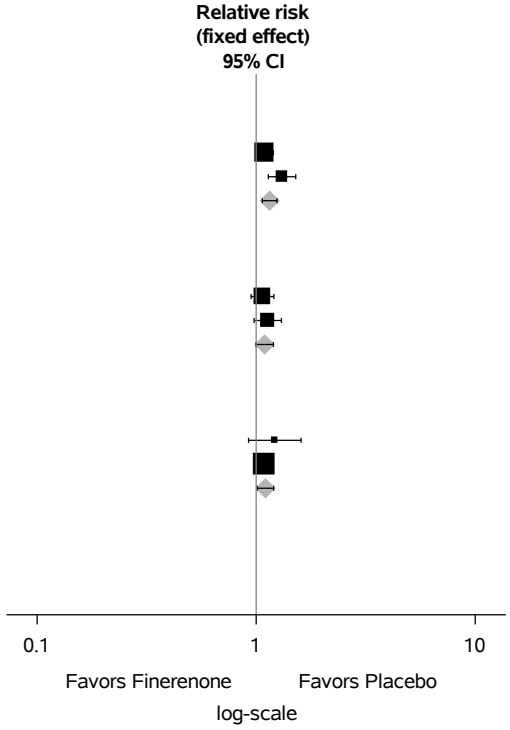
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	380 / 1178	336 / 1174	46.5	1.13 [1.00,1.27]	
FIGARO-DKD	460 / 1752	423 / 1747	53.5	1.08 [0.97,1.22]	
Total	840 / 2930	759 / 2921		1.10 [1.02,1.20]	Z=2.32, p=0.0202
Heterogeneity:	Q=0.20 (df=1)	p=0.6509	I^2=0.0%		
North America					
FIDELIO-DKD	170 / 466	162 / 476	54.0	1.07 [0.90,1.27]	
FIGARO-DKD	164 / 559	150 / 548	46.0	1.07 [0.89,1.29]	
Total	334 / 1025	312 / 1024		1.07 [0.94,1.22]	Z=1.07, p=0.2850
Heterogeneity:	Q=0.00 (df=1)	p=0.9995	I^2=0.0%		
Asia					
FIDELIO-DKD	354 / 790	324 / 786	51.5	1.09 [0.97,1.22]	
FIGARO-DKD	370 / 811	299 / 813	48.5	1.24 [1.10,1.39]	
Total	724 / 1601	623 / 1599		1.16 [1.07,1.26]	Z=3.55, p=0.0004
Heterogeneity:	Q=2.51 (df=1)	p=0.1134	I^2=60.1%		
Latin America					
FIDELIO-DKD	111 / 294	102 / 294	40.7	1.09 [0.88,1.35]	
FIGARO-DKD	164 / 424	145 / 417	59.3	1.11 [0.93,1.33]	
Total	275 / 718	247 / 711		1.10 [0.96,1.26]	Z=1.40, p=0.1627
Heterogeneity:	Q=0.02 (df=1)	p=0.8775	I^2=0.0%		
Others					
FIDELIO-DKD	30 / 99	34 / 101	37.0	0.90 [0.60,1.35]	
FIGARO-DKD	60 / 137	43 / 133	63.0	1.35 [0.99,1.85]	
Total	90 / 236	77 / 234		1.17 [0.91,1.49]	Z=1.24, p=0.2144
Heterogeneity:	Q=2.46 (df=1)	p=0.1166	I^2=59.4%		
Subgroup Heterogeneity:	Q=1.42 (df=4)	p=0.8403	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.79.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

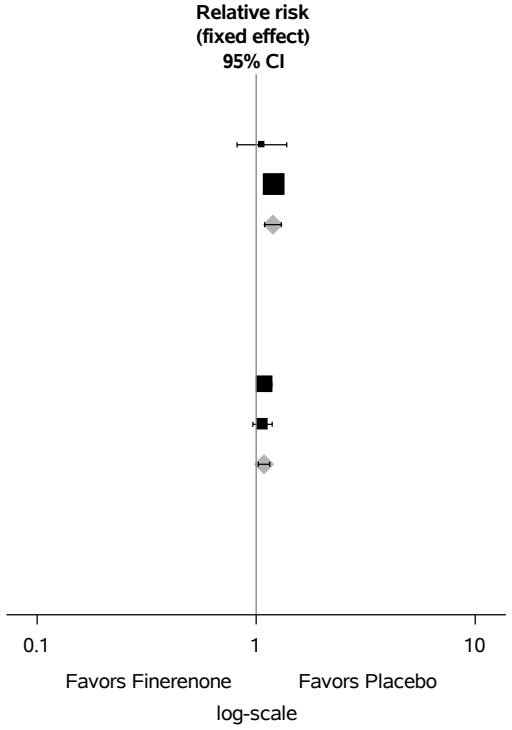
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	603 / 1556	547 / 1541	71.2	1.09 [1.00,1.20]	
FIGARO-DKD	272 / 637	204 / 627	28.8	1.31 [1.14,1.52]	
Total	875 / 2193	751 / 2168		1.15 [1.07,1.24]	Z=3.59, p=0.0003
Heterogeneity:	Q=4.45 (df=1)	p=0.0348	I^2=77.5%		
45 - < 60					
FIDELIO-DKD	368 / 1061	347 / 1069	59.1	1.07 [0.95,1.20]	
FIGARO-DKD	260 / 720	233 / 729	40.9	1.13 [0.98,1.30]	
Total	628 / 1781	580 / 1798		1.09 [1.00,1.20]	Z=1.90, p=0.0573
Heterogeneity:	Q=0.34 (df=1)	p=0.5586	I^2=0.0%		
>= 60					
FIDELIO-DKD	74 / 210	64 / 221	10.0	1.22 [0.92,1.60]	
FIGARO-DKD	686 / 2326	623 / 2302	90.0	1.09 [0.99,1.19]	
Total	760 / 2536	687 / 2523		1.10 [1.01,1.20]	Z=2.18, p=0.0292
Heterogeneity:	Q=0.55 (df=1)	p=0.4577	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=2)	p=0.6319	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.79.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

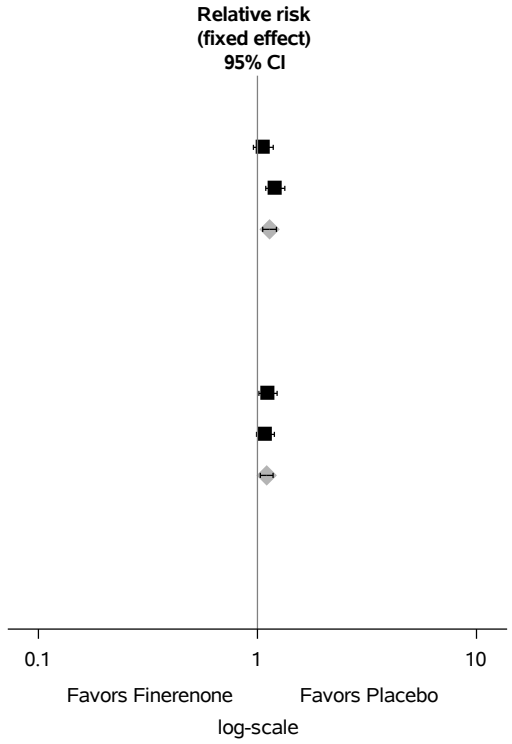
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	75 / 209	72 / 213	11.1	1.06 [0.82,1.38]	
FIGARO-DKD	657 / 1720	536 / 1698	88.9	1.21 [1.10,1.33]	
Total	732 / 1929	608 / 1911		1.19 [1.09,1.30]	Z=3.97, p=<.0001
Heterogeneity:	Q=0.86 (df=1)	p=0.3542	I^2=0.0%		
Very High					
FIDELIO-DKD	970 / 2618	886 / 2618	65.7	1.09 [1.02,1.18]	
FIGARO-DKD	561 / 1963	524 / 1960	34.3	1.07 [0.97,1.18]	
Total	1531 / 4581	1410 / 4578		1.09 [1.02,1.15]	Z=2.72, p=0.0065
Heterogeneity:	Q=0.14 (df=1)	p=0.7081	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.05 (df=1)	p=0.0806	I^2=67.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.79.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

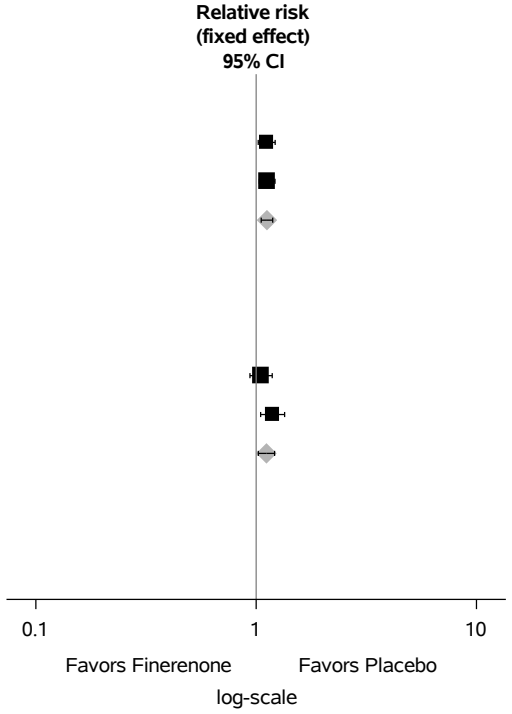
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	473 / 1301	444 / 1299	48.0	1.06 [0.96,1.18]	
FIGARO-DKD	583 / 1673	477 / 1651	52.0	1.21 [1.09,1.33]	
Total	1056 / 2974	921 / 2950		1.14 [1.06,1.22]	Z=3.46, p=0.0005
Heterogeneity:	Q=2.91 (df=1)	p=0.0882	I^2=65.6%		
Absent					
FIDELIO-DKD	572 / 1526	514 / 1532	49.0	1.12 [1.02,1.23]	
FIGARO-DKD	635 / 2010	583 / 2007	51.0	1.09 [0.99,1.19]	
Total	1207 / 3536	1097 / 3539		1.10 [1.03,1.18]	Z=2.84, p=0.0045
Heterogeneity:	Q=0.15 (df=1)	p=0.6942	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5469	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.79.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

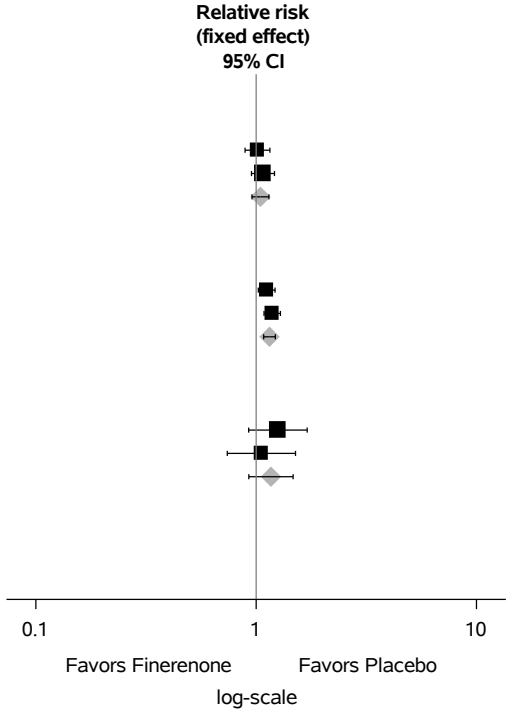
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	684 / 1879	606 / 1858	46.0	1.12 [1.02,1.22]	
FIGARO-DKD	855 / 2643	752 / 2608	54.0	1.12 [1.03,1.22]	
Total	1539 / 4522	1358 / 4466		1.12 [1.05,1.19]	Z=3.68, p=0.0002
Heterogeneity:	Q=0.01 (df=1)	p=0.9327	I^2=0.0%		
> 4.5					
FIDELIO-DKD	361 / 948	352 / 973	53.7	1.05 [0.94,1.18]	
FIGARO-DKD	363 / 1040	308 / 1048	46.3	1.19 [1.05,1.35]	
Total	724 / 1988	660 / 2021		1.11 [1.02,1.21]	Z=2.47, p=0.0135
Heterogeneity:	Q=1.91 (df=1)	p=0.1666	I^2=47.7%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9215	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.79.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

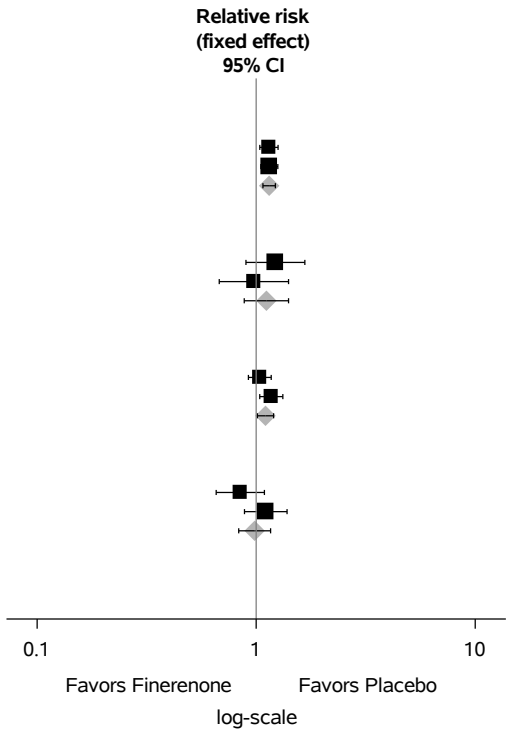
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	292 / 788	284 / 777	46.1	1.01 [0.89,1.15]	
FIGARO-DKD	380 / 1187	356 / 1194	53.9	1.07 [0.95,1.21]	
Total	672 / 1975	640 / 1971		1.05 [0.96,1.14]	Z=0.99, p=0.3211
Heterogeneity:	Q=0.40 (df=1)	p=0.5249	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	694 / 1897	628 / 1916	49.1	1.12 [1.02,1.22]	
FIGARO-DKD	799 / 2389	665 / 2351	50.9	1.18 [1.09,1.29]	
Total	1493 / 4286	1293 / 4267		1.15 [1.08,1.22]	Z=4.47, p=<.0001
Heterogeneity:	Q=0.85 (df=1)	p=0.3557	I^2=0.0%		
>= 160					
FIDELIO-DKD	59 / 141	46 / 138	57.6	1.26 [0.92,1.70]	
FIGARO-DKD	39 / 107	39 / 113	42.4	1.06 [0.74,1.51]	
Total	98 / 248	85 / 251		1.17 [0.93,1.47]	Z=1.31, p=0.1902
Heterogeneity:	Q=0.52 (df=1)	p=0.4708	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.13 (df=2)	p=0.2087	I^2=36.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.79.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

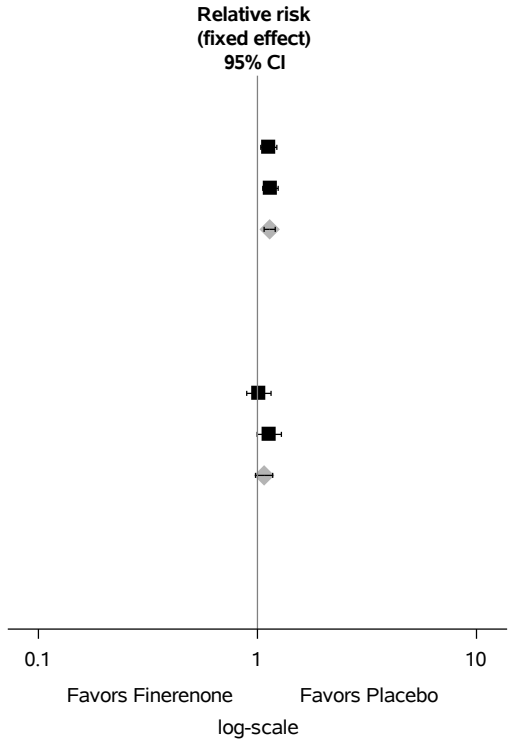
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	603 / 1773	538 / 1809	46.4	1.14 [1.04,1.26]	
FIGARO-DKD	768 / 2668	652 / 2601	53.6	1.15 [1.05,1.26]	
Total	1371 / 4441	1190 / 4410		1.15 [1.07,1.22]	Z=4.09, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9505	I^2=0.0%		
Black					
FIDELIO-DKD	59 / 139	43 / 124	58.1	1.22 [0.90,1.67]	
FIGARO-DKD	35 / 113	46 / 145	41.9	0.98 [0.68,1.41]	
Total	94 / 252	89 / 269		1.11 [0.88,1.41]	Z=0.90, p=0.3657
Heterogeneity:	Q=0.86 (df=1)	p=0.3540	I^2=0.0%		
Asian					
FIDELIO-DKD	312 / 717	302 / 721	50.6	1.04 [0.92,1.17]	
FIGARO-DKD	325 / 716	285 / 736	49.4	1.17 [1.04,1.32]	
Total	637 / 1433	587 / 1457		1.10 [1.01,1.20]	Z=2.25, p=0.0242
Heterogeneity:	Q=1.93 (df=1)	p=0.1651	I^2=48.1%		
Others					
FIDELIO-DKD	71 / 198	75 / 177	43.8	0.85 [0.66,1.09]	
FIGARO-DKD	90 / 186	77 / 176	56.2	1.11 [0.88,1.38]	
Total	161 / 384	152 / 353		0.98 [0.83,1.16]	Z=-0.19, p=0.8517
Heterogeneity:	Q=2.41 (df=1)	p=0.1207	I^2=58.5%		
Subgroup Heterogeneity:	Q=2.87 (df=3)	p=0.4118	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.79.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

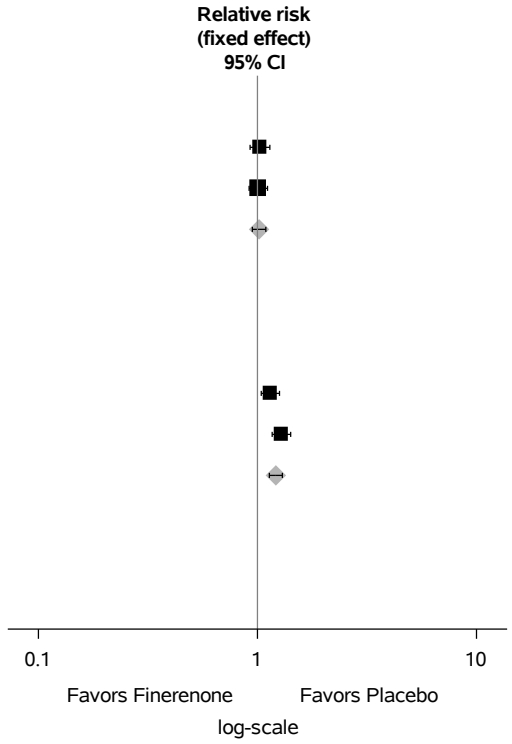
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	728 / 1949	671 / 2024	48.0	1.13 [1.04,1.23]	
FIGARO-DKD	852 / 2527	756 / 2571	52.0	1.15 [1.06,1.24]	
Total	1580 / 4476	1427 / 4595		1.14 [1.07,1.21]	Z=4.30, p=<.0001
Heterogeneity:	Q=0.09 (df=1)	p=0.7694	I^2=0.0%		
Female					
FIDELIO-DKD	317 / 878	287 / 807	49.9	1.02 [0.89,1.15]	
FIGARO-DKD	366 / 1156	304 / 1087	50.1	1.13 [1.00,1.29]	
Total	683 / 2034	591 / 1894		1.07 [0.98,1.17]	Z=1.52, p=0.1291
Heterogeneity:	Q=1.40 (df=1)	p=0.2372	I^2=28.4%		
Subgroup Heterogeneity:	Q=1.13 (df=1)	p=0.2871	I^2=11.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.79.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

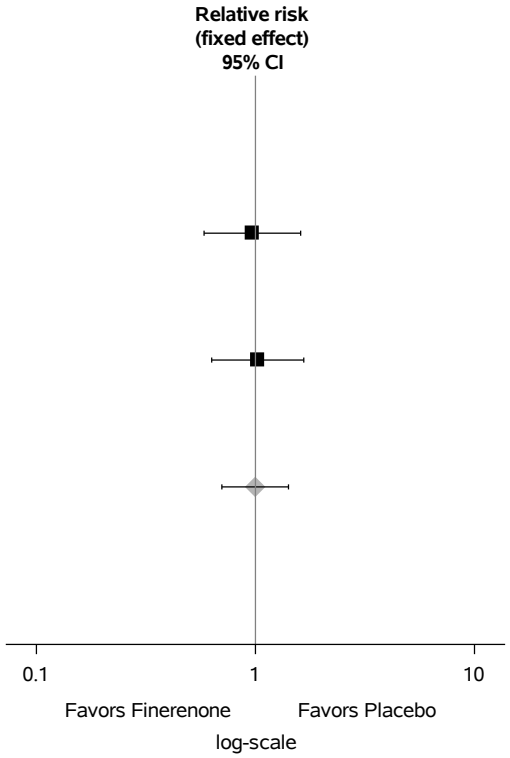
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	457 / 1201	434 / 1171	46.6	1.03 [0.93,1.14]	
FIGARO-DKD	560 / 1752	556 / 1755	53.4	1.01 [0.92,1.11]	
Total	1017 / 2953	990 / 2926		1.02 [0.95,1.09]	Z=0.47, p=0.6378
Heterogeneity:	Q=0.06 (df=1)	p=0.8095	I^2=0.0%		
>= 65					
FIDELIO-DKD	588 / 1626	524 / 1660	50.7	1.15 [1.04,1.26]	
FIGARO-DKD	658 / 1931	504 / 1903	49.3	1.29 [1.17,1.42]	
Total	1246 / 3557	1028 / 3563		1.21 [1.13,1.30]	Z=5.56, p=<.0001
Heterogeneity:	Q=2.78 (df=1)	p=0.0956	I^2=64.0%		
Subgroup Heterogeneity:	Q=12.37 (df=1)	p=0.0004	I^2=91.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.80: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set

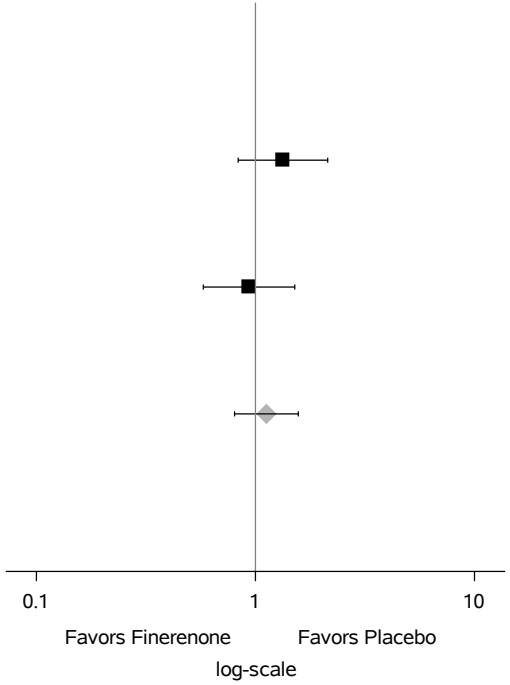
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	47.6	0.97 [0.58,1.61]	
FIGARO-DKD	33 / 3683	32 / 3658	52.4	1.02 [0.63,1.66]	
Total	62 / 6510	62 / 6489		1.00 [0.70,1.42]	Z=-0.02, p=0.9870
Heterogeneity:	Q=0.02 (df=1)	p=0.8747	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.81: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set

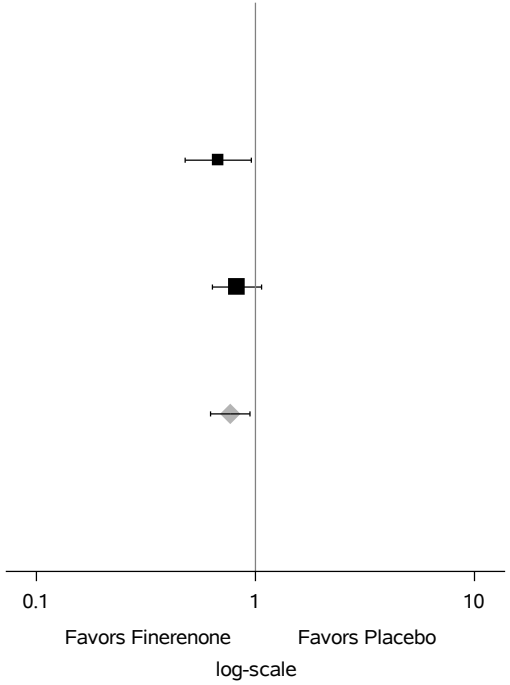
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	30 / 2831	51.1	1.34 [0.83,2.14]	
FIGARO-DKD	32 / 3683	34 / 3658	48.9	0.93 [0.58,1.51]	
Total	72 / 6510	64 / 6489		1.12 [0.80,1.57]	Z=0.68, p=0.4991
Heterogeneity:	Q=1.08 (df=1)	p=0.2988	I^2=7.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.82: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

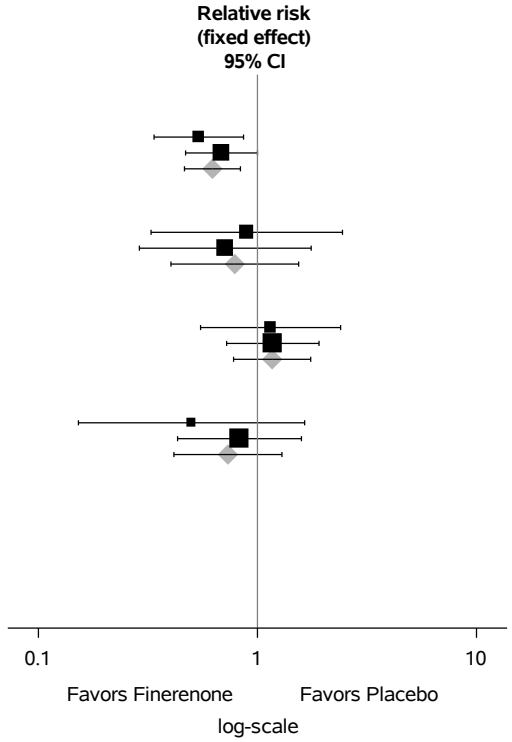
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 2827	77 / 2831	35.6	0.68 [0.48,0.96]	
FIGARO-DKD	102 / 3683	123 / 3658	64.4	0.82 [0.64,1.07]	
Total	154 / 6510	200 / 6489		0.77 [0.62,0.94]	Z=-2.50, p=0.0123
Heterogeneity:	Q=0.79 (df=1)	p=0.3727	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.82.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

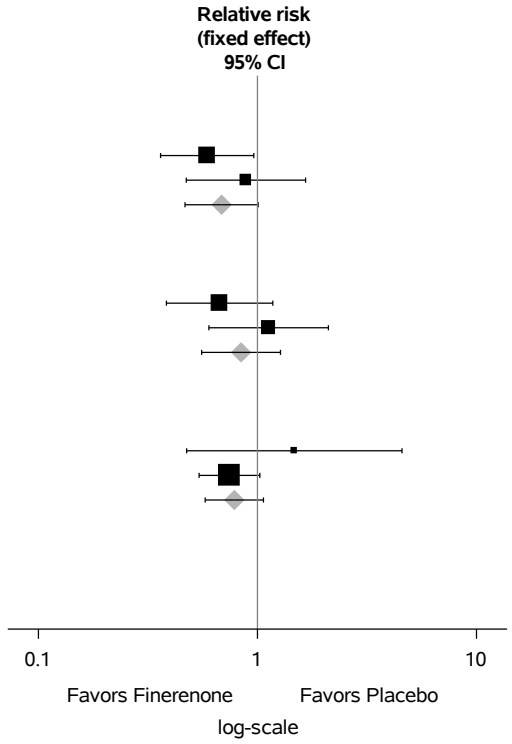
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 1178	48 / 1174	39.2	0.54 [0.34,0.86]	
FIGARO-DKD	44 / 1752	64 / 1747	60.8	0.69 [0.47,1.00]	
Total	70 / 2930	112 / 2921		0.62 [0.46,0.84]	Z=-3.15, p=0.0016
Heterogeneity:	Q=0.60 (df=1)	p=0.4377	I^2=0.0%		
North America					
FIDELIO-DKD	7 / 466	8 / 476	44.6	0.89 [0.33,2.44]	
FIGARO-DKD	8 / 559	11 / 548	55.4	0.71 [0.29,1.76]	
Total	15 / 1025	19 / 1024		0.79 [0.40,1.54]	Z=-0.70, p=0.4868
Heterogeneity:	Q=0.11 (df=1)	p=0.7432	I^2=0.0%		
Asia					
FIDELIO-DKD	15 / 790	13 / 786	30.3	1.15 [0.55,2.40]	
FIGARO-DKD	34 / 811	29 / 813	69.7	1.18 [0.72,1.91]	
Total	49 / 1601	42 / 1599		1.17 [0.78,1.75]	Z=0.75, p=0.4554
Heterogeneity:	Q=0.00 (df=1)	p=0.9583	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 294	8 / 294	23.1	0.50 [0.15,1.64]	
FIGARO-DKD	16 / 424	19 / 417	76.9	0.83 [0.43,1.59]	
Total	20 / 718	27 / 711		0.73 [0.42,1.29]	Z=-1.07, p=0.2838
Heterogeneity:	Q=0.53 (df=1)	p=0.4655	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	0 / 137	0 / 133	0.0	-	
Total	0 / 236	0 / 234		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=6.06 (df=4)	p=0.1945	I^2=34.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.82.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

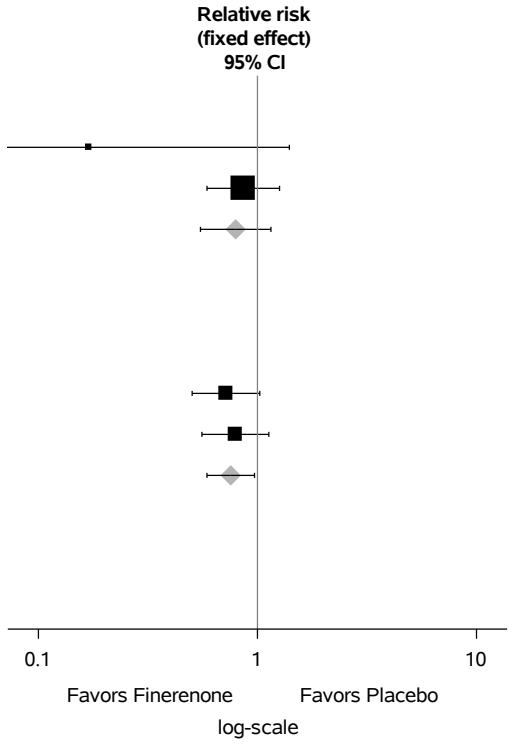
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	25 / 1556	42 / 1541	62.1	0.59 [0.36,0.96]	
FIGARO-DKD	18 / 637	20 / 627	37.9	0.89 [0.47,1.66]	
Total	43 / 2193	62 / 2168		0.69 [0.47,1.01]	Z=-1.92, p=0.0545
Heterogeneity:	Q=1.01 (df=1)	p=0.3158	I^2=0.6%		
45 - < 60					
FIDELIO-DKD	20 / 1061	30 / 1069	55.8	0.67 [0.38,1.18]	
FIGARO-DKD	20 / 720	18 / 729	44.2	1.12 [0.60,2.11]	
Total	40 / 1781	48 / 1798		0.84 [0.56,1.27]	Z=-0.82, p=0.4151
Heterogeneity:	Q=1.44 (df=1)	p=0.2295	I^2=30.7%		
>= 60					
FIDELIO-DKD	7 / 210	5 / 221	7.4	1.47 [0.47,4.57]	
FIGARO-DKD	64 / 2326	85 / 2302	92.6	0.75 [0.54,1.03]	
Total	71 / 2536	90 / 2523		0.78 [0.58,1.07]	Z=-1.56, p=0.1196
Heterogeneity:	Q=1.29 (df=1)	p=0.2560	I^2=22.5%		
Subgroup Heterogeneity:	Q=0.54 (df=2)	p=0.7641	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.82.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

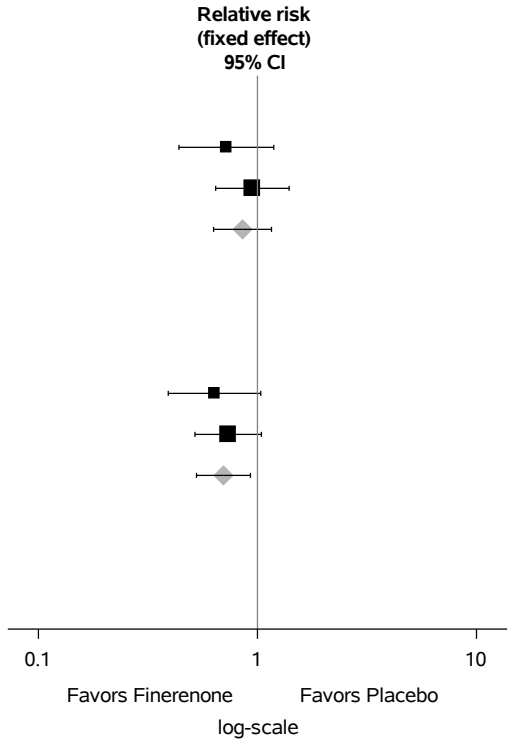
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	6 / 213	3.2	0.17 [0.02,1.40]	
FIGARO-DKD	48 / 1720	55 / 1698	96.8	0.86 [0.59,1.26]	
Total	49 / 1929	61 / 1911		0.80 [0.55,1.15]	Z=-1.21, p=0.2260
Heterogeneity:	Q=2.23 (df=1)	p=0.1355	I^2=55.1%		
Very High					
FIDELIO-DKD	51 / 2618	71 / 2618	49.4	0.72 [0.50,1.03]	
FIGARO-DKD	54 / 1963	68 / 1960	50.6	0.79 [0.56,1.13]	
Total	105 / 4581	139 / 4578		0.75 [0.59,0.97]	Z=-2.20, p=0.0276
Heterogeneity:	Q=0.15 (df=1)	p=0.6987	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8189	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.82.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

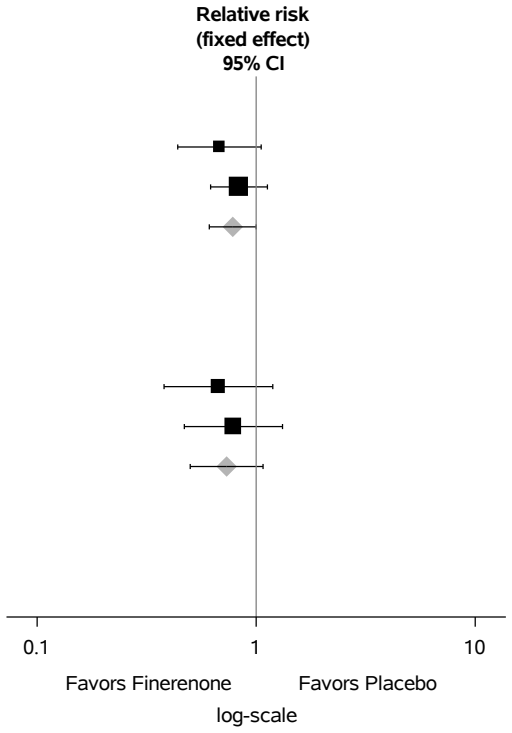
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 1301	36 / 1299	37.5	0.72 [0.44,1.19]	
FIGARO-DKD	49 / 1673	51 / 1651	62.5	0.95 [0.64,1.39]	
Total	75 / 2974	87 / 2950		0.85 [0.63,1.16]	Z=-1.01, p=0.3130
Heterogeneity:	Q=0.72 (df=1)	p=0.3949	I^2=0.0%		
Absent					
FIDELIO-DKD	26 / 1526	41 / 1532	34.0	0.64 [0.39,1.04]	
FIGARO-DKD	53 / 2010	72 / 2007	66.0	0.74 [0.52,1.04]	
Total	79 / 3536	113 / 3539		0.70 [0.53,0.93]	Z=-2.47, p=0.0135
Heterogeneity:	Q=0.22 (df=1)	p=0.6381	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3450	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.82.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	33 / 1879	48 / 1858	31.7	0.68 [0.44,1.05]	
FIGARO-DKD	77 / 2643	91 / 2608	68.3	0.83 [0.62,1.13]	
Total	110 / 4522	139 / 4466		0.78 [0.61,1.00]	Z=-1.96, p=0.0504
Heterogeneity:	Q=0.58 (df=1)	p=0.4477	I^2=0.0%		
> 4.5					
FIDELIO-DKD	19 / 948	29 / 973	44.9	0.67 [0.38,1.19]	
FIGARO-DKD	25 / 1040	32 / 1048	55.1	0.79 [0.47,1.32]	
Total	44 / 1988	61 / 2021		0.73 [0.50,1.07]	Z=-1.59, p=0.1117
Heterogeneity:	Q=0.16 (df=1)	p=0.6883	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7817	I^2=0.0%		

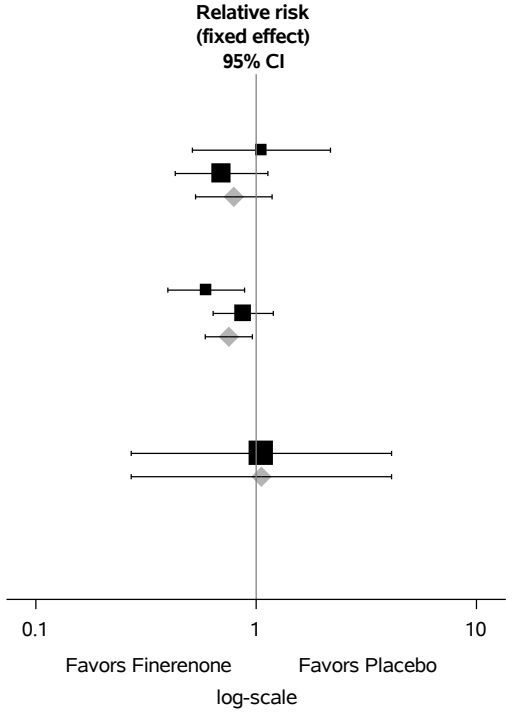


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.82.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)

Safety Analysis Set

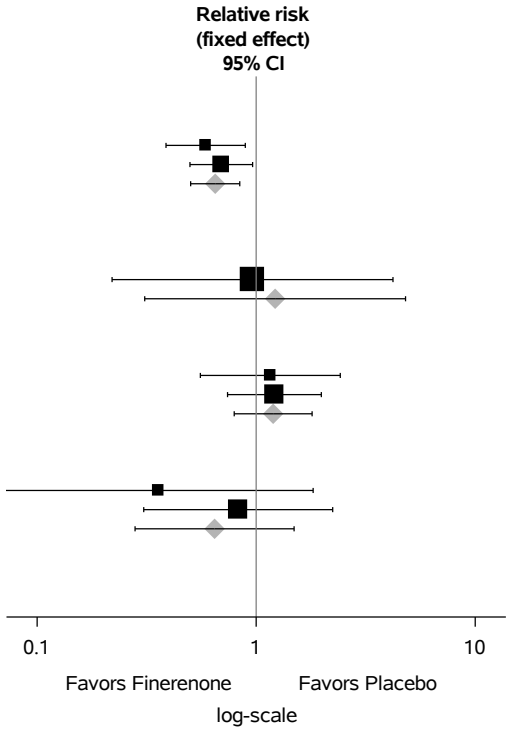
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	14 / 777	31.0	1.06 [0.51,2.17]	
FIGARO-DKD	27 / 1187	39 / 1194	69.0	0.70 [0.43,1.13]	
Total	42 / 1975	53 / 1971		0.79 [0.53,1.18]	Z=-1.15, p=0.2521
Heterogeneity:	Q=0.88 (df=1)	p=0.3471	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	37 / 1897	63 / 1916	38.1	0.59 [0.40,0.89]	
FIGARO-DKD	71 / 2389	80 / 2351	61.9	0.87 [0.64,1.20]	
Total	108 / 4286	143 / 4267		0.75 [0.59,0.96]	Z=-2.28, p=0.0229
Heterogeneity:	Q=2.21 (df=1)	p=0.1367	I^2=54.9%		
>= 160					
FIDELIO-DKD	0 / 141	0 / 138	0.0	-	
FIGARO-DKD	4 / 107	4 / 113	100.0	1.06 [0.27,4.12]	
Total	4 / 248	4 / 251		1.06 [0.27,4.12]	Z=0.08, p=0.9373
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=2)	p=0.8768	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.82.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

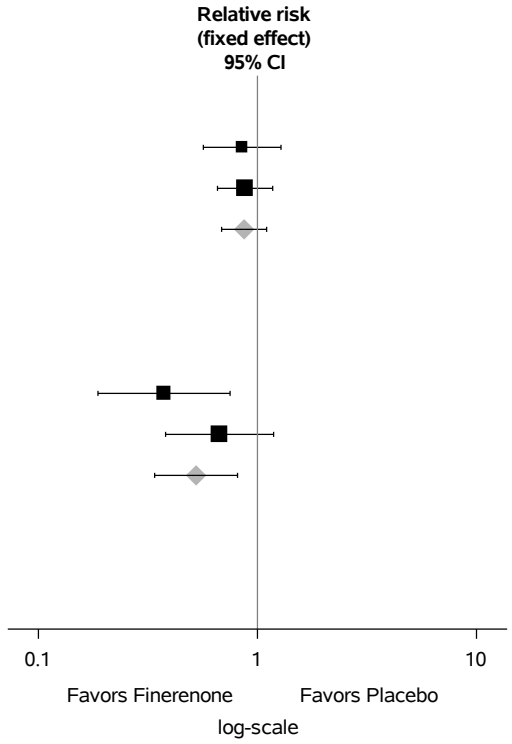
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	34 / 1773	59 / 1809	38.4	0.59 [0.39,0.89]	
FIGARO-DKD	59 / 2668	83 / 2601	61.6	0.69 [0.50,0.96]	
Total	93 / 4441	142 / 4410		0.65 [0.50,0.84]	Z=-3.27, p=0.0011
Heterogeneity:	Q=0.37 (df=1)	p=0.5443	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	0 / 124	0.0	102E9 [102E9,102E9]	
FIGARO-DKD	3 / 113	4 / 145	100.0	0.96 [0.22,4.21]	
Total	4 / 252	4 / 269		1.22 [0.31,4.81]	Z=0.28, p=0.7759
Heterogeneity:	Q=0.10 (df=1)	p=0.7526	I^2=0.0%		
Asian					
FIDELIO-DKD	15 / 717	13 / 721	31.0	1.16 [0.56,2.42]	
FIGARO-DKD	33 / 716	28 / 736	69.0	1.21 [0.74,1.98]	
Total	48 / 1433	41 / 1457		1.20 [0.79,1.80]	Z=0.85, p=0.3929
Heterogeneity:	Q=0.01 (df=1)	p=0.9238	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	5 / 177	27.1	0.36 [0.07,1.82]	
FIGARO-DKD	7 / 186	8 / 176	72.9	0.83 [0.31,2.24]	
Total	9 / 384	13 / 353		0.65 [0.28,1.49]	Z=-1.03, p=0.3052
Heterogeneity:	Q=0.75 (df=1)	p=0.3873	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.69 (df=3)	p=0.0826	I^2=55.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.82.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

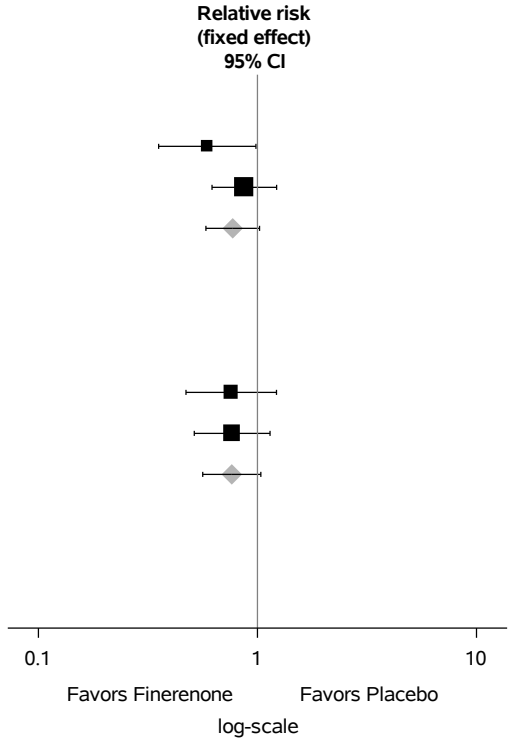
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	41 / 1949	50 / 2024	33.6	0.85 [0.57,1.28]	
FIGARO-DKD	82 / 2527	95 / 2571	66.4	0.88 [0.66,1.17]	
Total	123 / 4476	145 / 4595		0.87 [0.69,1.10]	Z=-1.16, p=0.2452
Heterogeneity:	Q=0.01 (df=1)	p=0.9041	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 878	27 / 807	40.1	0.37 [0.19,0.75]	
FIGARO-DKD	20 / 1156	28 / 1087	59.9	0.67 [0.38,1.19]	
Total	31 / 2034	55 / 1894		0.52 [0.34,0.81]	Z=-2.90, p=0.0037
Heterogeneity:	Q=1.63 (df=1)	p=0.2013	I^2=38.8%		
Subgroup Heterogeneity:	Q=3.98 (df=1)	p=0.0459	I^2=74.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.82.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

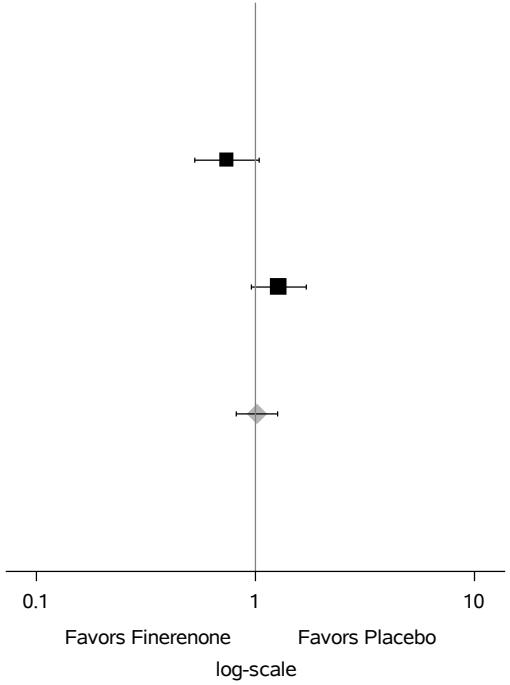
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	23 / 1201	38 / 1171	30.6	0.59 [0.35,0.98]	
FIGARO-DKD	60 / 1752	69 / 1755	69.4	0.87 [0.62,1.22]	
Total	83 / 2953	107 / 2926		0.77 [0.58,1.02]	Z=-1.81, p=0.0707
Heterogeneity:	Q=1.55 (df=1)	p=0.2138	I^2=35.3%		
>= 65					
FIDELIO-DKD	29 / 1626	39 / 1660	41.2	0.76 [0.47,1.22]	
FIGARO-DKD	42 / 1931	54 / 1903	58.8	0.77 [0.51,1.14]	
Total	71 / 3557	93 / 3563		0.76 [0.56,1.04]	Z=-1.73, p=0.0832
Heterogeneity:	Q=0.00 (df=1)	p=0.9757	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9629	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.83: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set

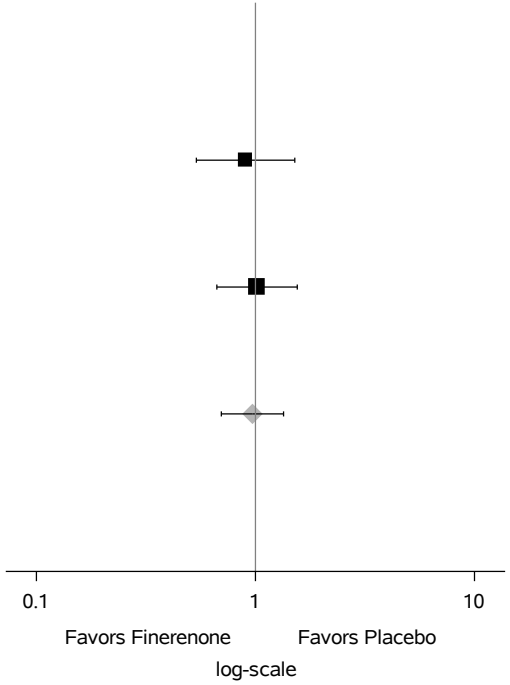
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2827	77 / 2831	42.1	0.74 [0.53,1.04]	
FIGARO-DKD	103 / 3683	80 / 3658	57.9	1.28 [0.96,1.71]	
Total	160 / 6510	157 / 6489		1.02 [0.82,1.26]	Z=0.14, p=0.8870
Heterogeneity:	Q=5.77 (df=1)	p=0.0163	I^2=82.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.84: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set

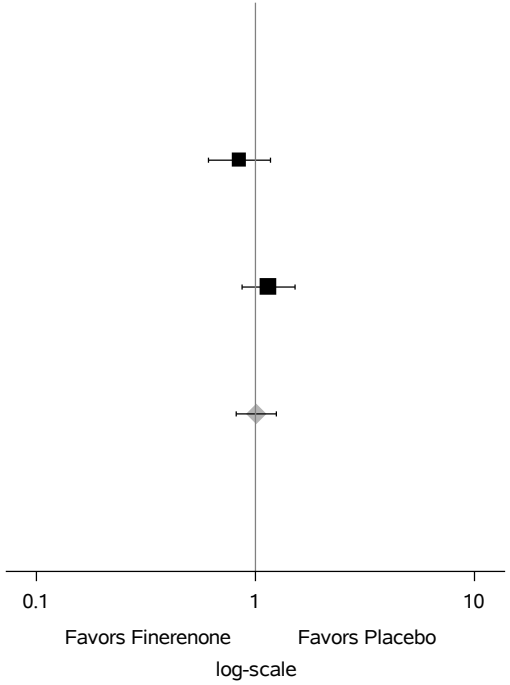
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	30 / 2831	40.0	0.90 [0.54,1.51]	
FIGARO-DKD	43 / 3683	42 / 3658	60.0	1.02 [0.67,1.55]	
Total	70 / 6510	72 / 6489		0.97 [0.70,1.34]	Z=-0.19, p=0.8497
Heterogeneity:	Q=0.13 (df=1)	p=0.7233	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.85: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set

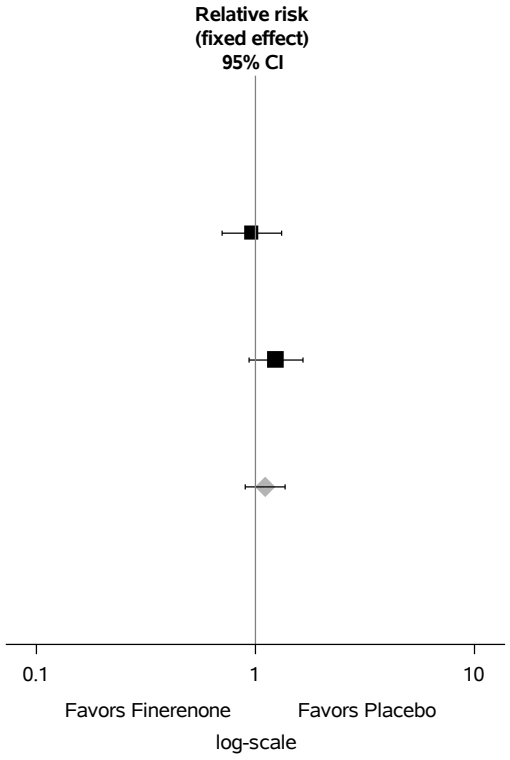
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 2827	77 / 2831	42.2	0.85 [0.61,1.17]	
FIGARO-DKD	104 / 3683	90 / 3658	57.8	1.15 [0.87,1.52]	
Total	169 / 6510	167 / 6489		1.01 [0.82,1.25]	Z=0.08, p=0.9358
Heterogeneity:	Q=1.95 (df=1)	p=0.1621	I^2=48.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.86: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set

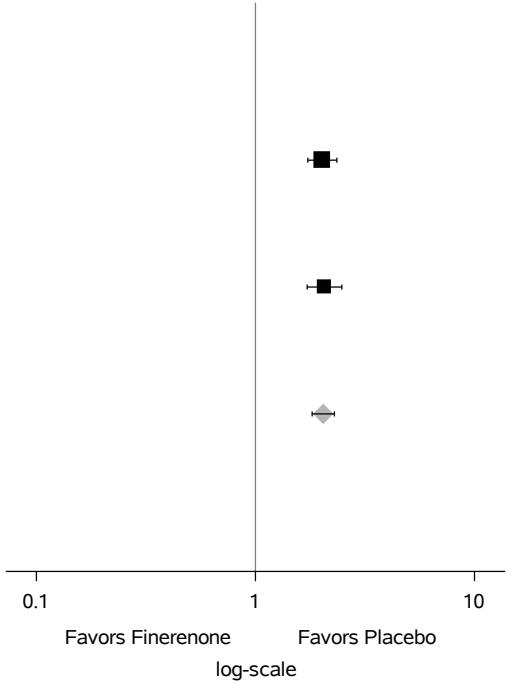
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	78 / 2831	45.1	0.96 [0.70,1.32]	
FIGARO-DKD	105 / 3683	84 / 3658	54.9	1.24 [0.94,1.65]	
Total	180 / 6510	162 / 6489		1.11 [0.90,1.37]	Z=0.96, p=0.3392
Heterogeneity:	Q=1.39 (df=1)	p=0.2377	I^2=28.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.87: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

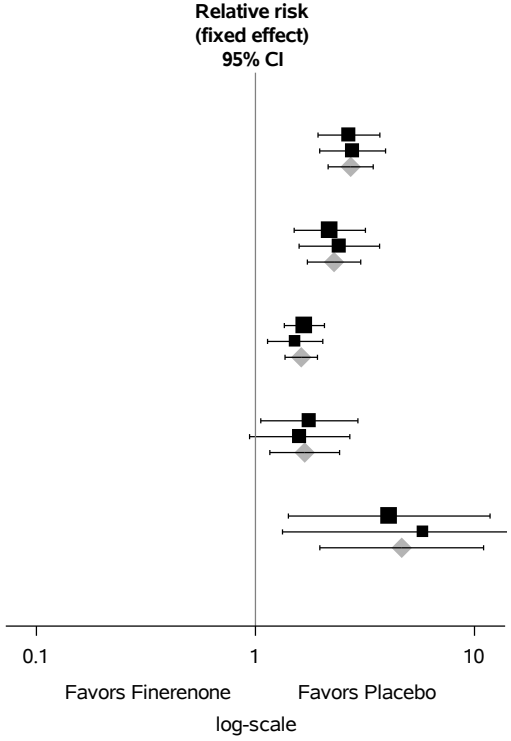
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	446 / 2827	221 / 2831	58.8	2.02 [1.73,2.35]	
FIGARO-DKD	335 / 3683	161 / 3658	41.2	2.07 [1.72,2.48]	
Total	781 / 6510	382 / 6489		2.04 [1.81,2.29]	Z=11.94, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8538	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.87.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

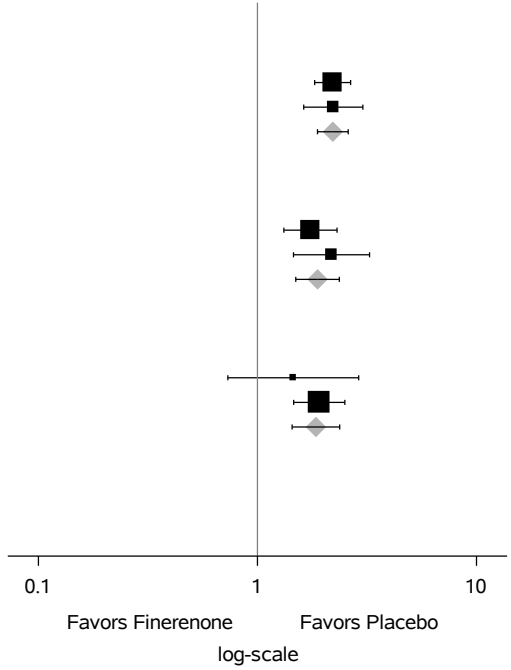
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	126 / 1178	47 / 1174	53.2	2.67 [1.93,3.70]	
FIGARO-DKD	117 / 1752	42 / 1747	46.8	2.78 [1.96,3.93]	
Total	243 / 2930	89 / 2921		2.72 [2.15,3.45]	Z=8.28, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8724	I^2=0.0%		
North America					
FIDELIO-DKD	77 / 466	36 / 476	56.1	2.18 [1.50,3.18]	
FIGARO-DKD	69 / 559	28 / 548	43.9	2.42 [1.58,3.69]	
Total	146 / 1025	64 / 1024		2.28 [1.73,3.02]	Z=5.78, p=<.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7273	I^2=0.0%		
Asia					
FIDELIO-DKD	190 / 790	113 / 786	65.5	1.67 [1.35,2.07]	
FIGARO-DKD	103 / 811	68 / 813	34.5	1.52 [1.14,2.03]	
Total	293 / 1601	181 / 1599		1.62 [1.36,1.92]	Z=5.54, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5967	I^2=0.0%		
Latin America					
FIDELIO-DKD	37 / 294	21 / 294	51.6	1.76 [1.06,2.94]	
FIGARO-DKD	34 / 424	21 / 417	48.4	1.59 [0.94,2.70]	
Total	71 / 718	42 / 711		1.68 [1.16,2.42]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.07 (df=1)	p=0.7869	I^2=0.0%		
Others					
FIDELIO-DKD	16 / 99	4 / 101	66.0	4.08 [1.41,11.78]	
FIGARO-DKD	12 / 137	2 / 133	34.0	5.82 [1.33,25.53]	
Total	28 / 236	6 / 234		4.65 [1.97,11.01]	Z=3.50, p=0.0005
Heterogeneity:	Q=0.15 (df=1)	p=0.7008	I^2=0.0%		
Subgroup Heterogeneity:	Q=17.85 (df=4)	p=0.0013	I^2=77.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.87.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

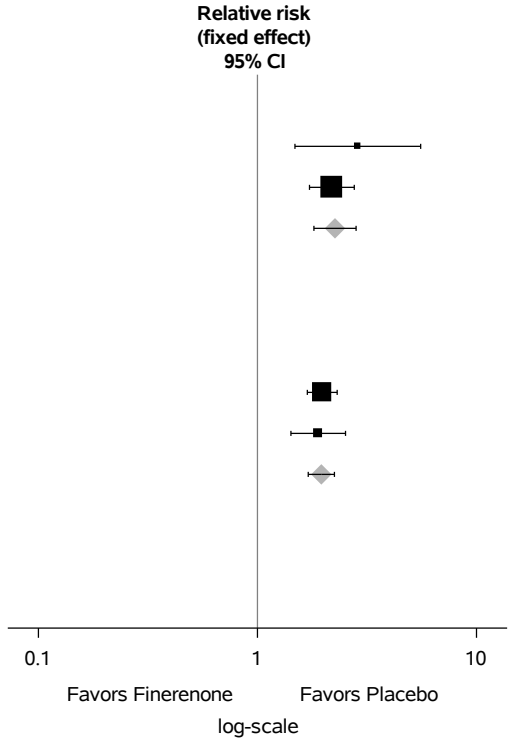
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	305 / 1556	137 / 1541	73.0	2.20 [1.83,2.66]	
FIGARO-DKD	115 / 637	51 / 627	27.0	2.22 [1.63,3.03]	
Total	420 / 2193	188 / 2168		2.21 [1.88,2.60]	Z=9.62, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9715	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	123 / 1061	71 / 1069	67.2	1.75 [1.32,2.31]	
FIGARO-DKD	71 / 720	33 / 729	32.8	2.18 [1.46,3.25]	
Total	194 / 1781	104 / 1798		1.88 [1.50,2.36]	Z=5.41, p=<.0001
Heterogeneity:	Q=0.79 (df=1)	p=0.3733	I^2=0.0%		
>= 60					
FIDELIO-DKD	18 / 210	13 / 221	13.3	1.46 [0.73,2.90]	
FIGARO-DKD	149 / 2326	77 / 2302	86.7	1.92 [1.46,2.51]	
Total	167 / 2536	90 / 2523		1.85 [1.44,2.37]	Z=4.81, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4683	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.01 (df=2)	p=0.3663	I^2=0.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.87.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

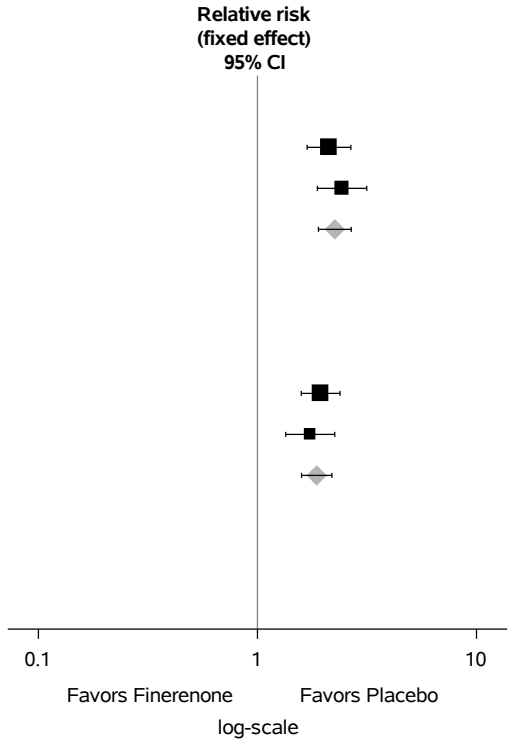
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	31 / 209	11 / 213	11.3	2.87 [1.48,5.56]	
FIGARO-DKD	206 / 1720	93 / 1698	88.7	2.19 [1.73,2.77]	
Total	237 / 1929	104 / 1911		2.26 [1.81,2.82]	Z=7.21, p=<.0001
Heterogeneity:	Q=0.58 (df=1)	p=0.4461	I^2=0.0%		
Very High					
FIDELIO-DKD	415 / 2618	210 / 2618	77.0	1.98 [1.69,2.31]	
FIGARO-DKD	129 / 1963	68 / 1960	23.0	1.89 [1.42,2.52]	
Total	544 / 4581	278 / 4578		1.96 [1.71,2.25]	Z=9.56, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.7994	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.16 (df=1)	p=0.2806	I^2=14.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.87.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

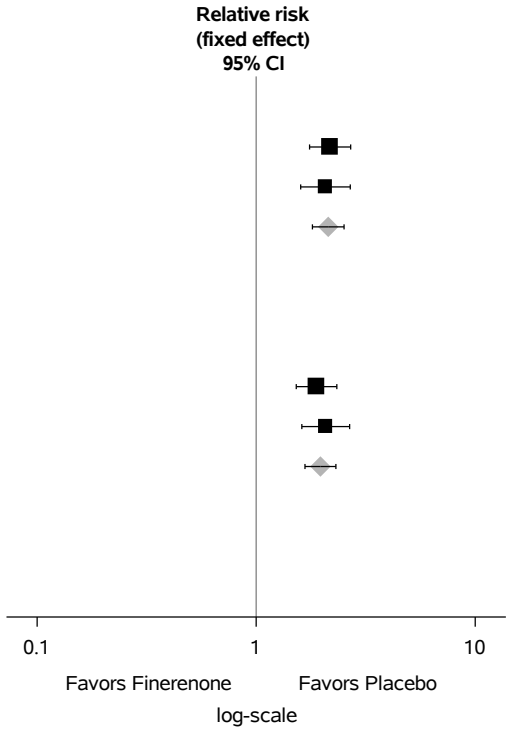
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	204 / 1301	96 / 1299	56.0	2.12 [1.69,2.67]	
FIGARO-DKD	185 / 1673	75 / 1651	44.0	2.43 [1.88,3.16]	
Total	389 / 2974	171 / 2950		2.26 [1.90,2.68]	Z=9.26, p=<.0001
Heterogeneity:	Q=0.60 (df=1)	p=0.4374	I^2=0.0%		
Absent					
FIDELIO-DKD	242 / 1526	125 / 1532	61.5	1.94 [1.59,2.38]	
FIGARO-DKD	150 / 2010	86 / 2007	38.5	1.74 [1.35,2.25]	
Total	392 / 3536	211 / 3539		1.86 [1.59,2.19]	Z=7.64, p=<.0001
Heterogeneity:	Q=0.43 (df=1)	p=0.5128	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.54 (df=1)	p=0.1110	I^2=60.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.87.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

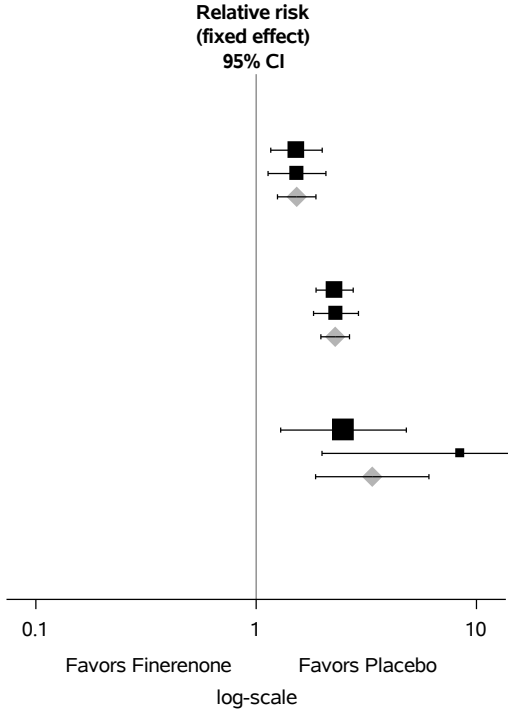
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	242 / 1879	110 / 1858	59.3	2.18 [1.75,2.70]	
FIGARO-DKD	168 / 2643	80 / 2608	40.7	2.07 [1.60,2.69]	
Total	410 / 4522	190 / 4466		2.13 [1.81,2.52]	Z=8.93, p=<.0001
Heterogeneity:	Q=0.08 (df=1)	p=0.7784	I^2=0.0%		
> 4.5					
FIDELIO-DKD	204 / 948	111 / 973	58.1	1.89 [1.52,2.33]	
FIGARO-DKD	167 / 1040	81 / 1048	41.9	2.08 [1.62,2.67]	
Total	371 / 1988	192 / 2021		1.97 [1.67,2.31]	Z=8.15, p=<.0001
Heterogeneity:	Q=0.33 (df=1)	p=0.5655	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.48 (df=1)	p=0.4895	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.87.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

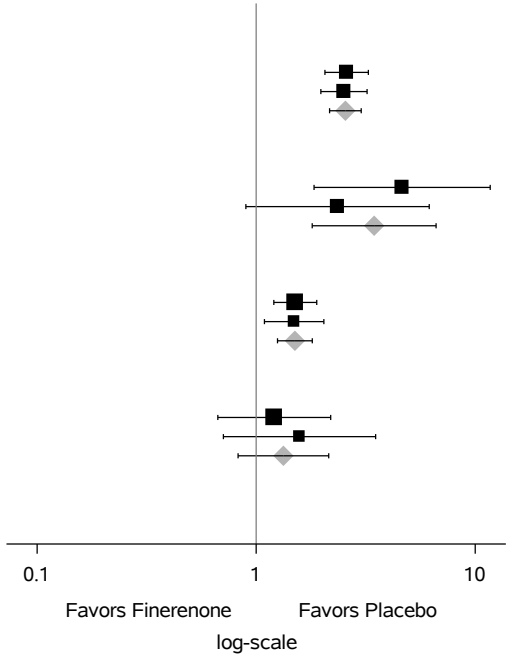
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	119 / 788	77 / 777	55.8	1.52 [1.16,1.99]	
FIGARO-DKD	99 / 1187	65 / 1194	44.2	1.53 [1.13,2.07]	
Total	218 / 1975	142 / 1971		1.53 [1.25,1.87]	Z=4.13, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9793	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	299 / 1897	133 / 1916	59.4	2.27 [1.87,2.76]	
FIGARO-DKD	220 / 2389	94 / 2351	40.6	2.30 [1.82,2.91]	
Total	519 / 4286	227 / 4267		2.28 [1.97,2.65]	Z=10.82, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9270	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 141	11 / 138	82.9	2.49 [1.29,4.80]	
FIGARO-DKD	16 / 107	2 / 113	17.1	8.45 [1.99,35.87]	
Total	44 / 248	13 / 251		3.36 [1.86,6.08]	Z=4.01, p=<.0001
Heterogeneity:	Q=2.36 (df=1)	p=0.1244	I^2=57.7%		
Subgroup Heterogeneity:	Q=12.86 (df=2)	p=0.0016	I^2=84.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.87.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

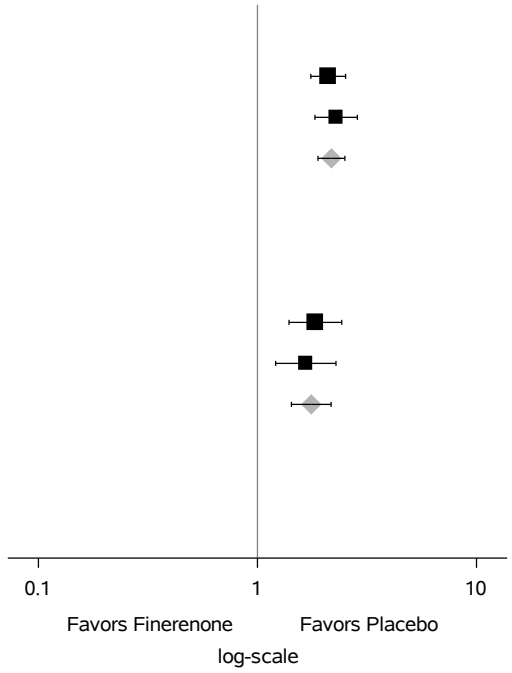
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	241 / 1773	95 / 1809	53.1	2.59 [2.06,3.25]	
FIGARO-DKD	222 / 2668	86 / 2601	46.9	2.52 [1.97,3.21]	
Total	463 / 4441	181 / 4410		2.55 [2.16,3.02]	Z=11.05, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8687	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 139	5 / 124	52.0	4.64 [1.84,11.71]	
FIGARO-DKD	11 / 113	6 / 145	48.0	2.35 [0.90,6.17]	
Total	37 / 252	11 / 269		3.46 [1.80,6.63]	Z=3.73, p=0.0002
Heterogeneity:	Q=1.00 (df=1)	p=0.3173	I^2=0.0%		
Asian					
FIDELIO-DKD	156 / 717	104 / 721	65.7	1.51 [1.20,1.89]	
FIGARO-DKD	87 / 716	60 / 736	34.3	1.49 [1.09,2.04]	
Total	243 / 1433	164 / 1457		1.50 [1.25,1.80]	Z=4.36, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9517	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 198	17 / 177	64.5	1.21 [0.67,2.19]	
FIGARO-DKD	15 / 186	9 / 176	35.5	1.58 [0.71,3.51]	
Total	38 / 384	26 / 353		1.33 [0.83,2.14]	Z=1.18, p=0.2389
Heterogeneity:	Q=0.27 (df=1)	p=0.6015	I^2=0.0%		
Subgroup Heterogeneity:	Q=23.24 (df=3)	p=<.0001	I^2=87.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.87.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

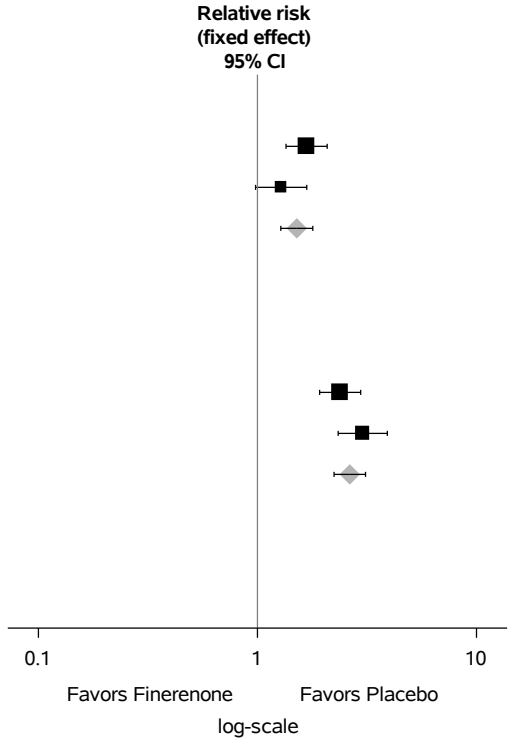
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	312 / 1949	154 / 2024	59.9	2.10 [1.75,2.53]	
FIGARO-DKD	236 / 2527	105 / 2571	40.1	2.29 [1.83,2.86]	
Total	548 / 4476	259 / 4595		2.18 [1.89,2.51]	Z=10.78, p=<.0001
Heterogeneity:	Q=0.32 (df=1)	p=0.5713	I^2=0.0%		
Female					
FIDELIO-DKD	134 / 878	67 / 807	56.7	1.84 [1.39,2.43]	
FIGARO-DKD	99 / 1156	56 / 1087	43.3	1.66 [1.21,2.28]	
Total	233 / 2034	123 / 1894		1.76 [1.43,2.17]	Z=5.32, p=<.0001
Heterogeneity:	Q=0.22 (df=1)	p=0.6397	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.72 (df=1)	p=0.0993	I^2=63.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.87.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

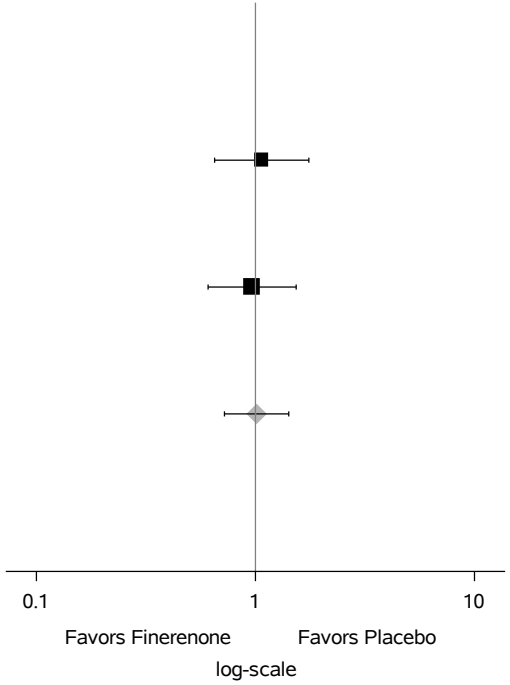
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	196 / 1201	114 / 1171	60.8	1.68 [1.35,2.08]	
FIGARO-DKD	114 / 1752	89 / 1755	39.2	1.28 [0.98,1.68]	
Total	310 / 2953	203 / 2926		1.51 [1.28,1.79]	Z=4.83, p=<.0001
Heterogeneity:	Q=2.30 (df=1)	p=0.1292	I^2=56.6%		
>= 65					
FIDELIO-DKD	250 / 1626	107 / 1660	58.9	2.39 [1.92,2.96]	
FIGARO-DKD	221 / 1931	72 / 1903	41.1	3.02 [2.34,3.92]	
Total	471 / 3557	179 / 3563		2.64 [2.24,3.11]	Z=11.50, p=<.0001
Heterogeneity:	Q=1.92 (df=1)	p=0.1664	I^2=47.8%		
Subgroup Heterogeneity:	Q=21.43 (df=1)	p=<.0001	I^2=95.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.88: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set

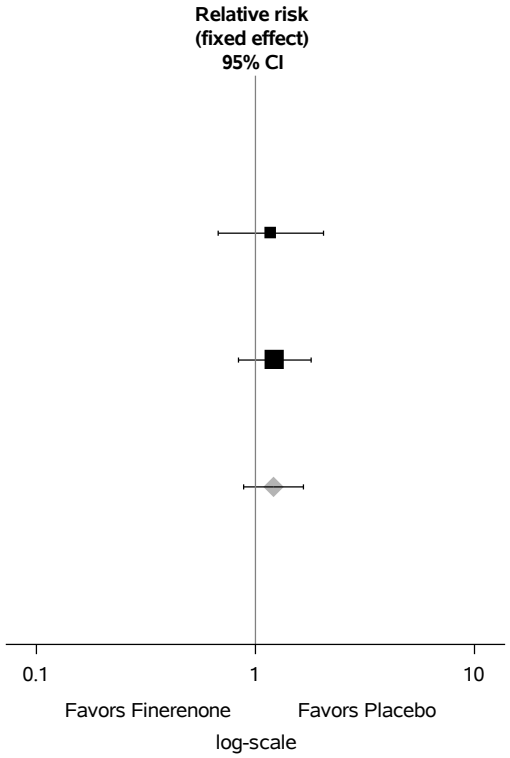
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	30 / 2831	46.6	1.07 [0.65,1.75]	
FIGARO-DKD	35 / 3683	36 / 3658	53.4	0.97 [0.61,1.53]	
Total	67 / 6510	66 / 6489		1.01 [0.72,1.42]	Z=0.07, p=0.9441
Heterogeneity:	Q=0.09 (df=1)	p=0.7705	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.89: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set

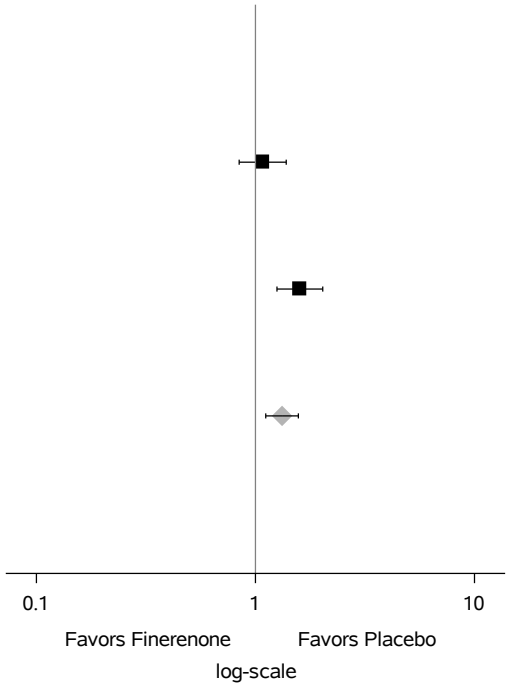
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	23 / 2831	32.2	1.18 [0.68,2.05]	
FIGARO-DKD	58 / 3683	47 / 3658	67.8	1.23 [0.84,1.80]	
Total	85 / 6510	70 / 6489		1.21 [0.88,1.66]	Z=1.18, p=0.2361
Heterogeneity:	Q=0.01 (df=1)	p=0.9032	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.90: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

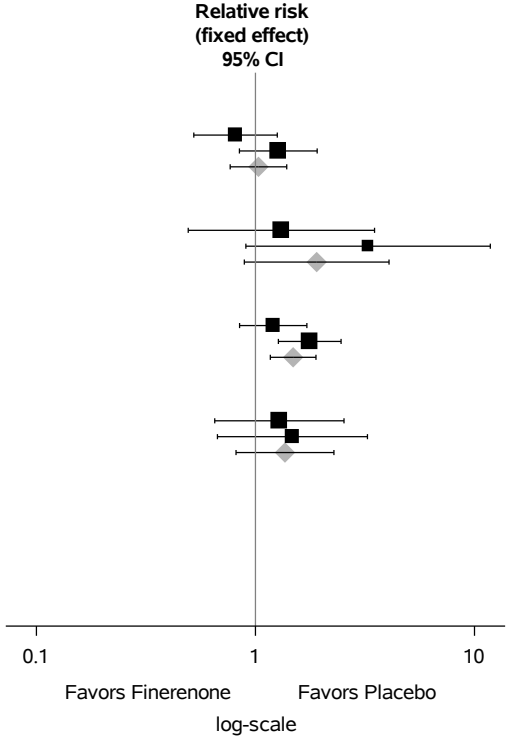
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	125 / 2827	116 / 2831	48.6	1.08 [0.84,1.38]	
FIGARO-DKD	167 / 3683	104 / 3658	51.4	1.59 [1.25,2.03]	
Total	292 / 6510	220 / 6489		1.32 [1.11,1.57]	Z=3.19, p=0.0014
Heterogeneity:	Q=4.93 (df=1)	p=0.0264	I^2=79.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.90.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

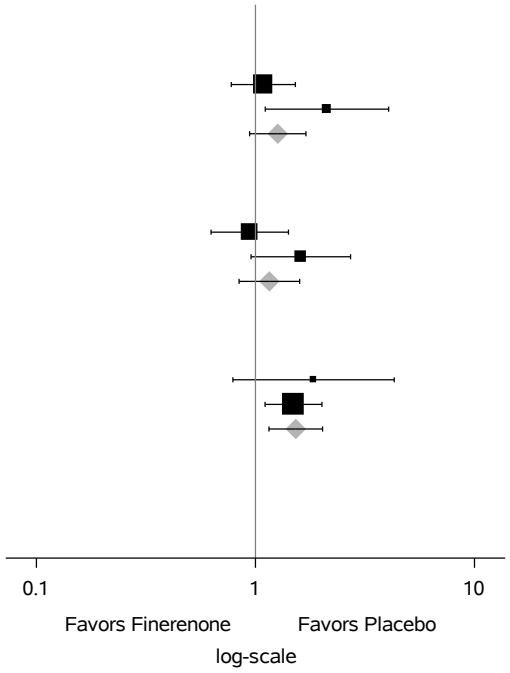
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	35 / 1178	43 / 1174	46.4	0.81 [0.52,1.26]	
FIGARO-DKD	51 / 1752	40 / 1747	53.6	1.27 [0.84,1.91]	
Total	86 / 2930	83 / 2921		1.03 [0.77,1.39]	Z=0.21, p=0.8350
Heterogeneity:	Q=2.16 (df=1)	p=0.1419	I^2=53.6%		
North America					
FIDELIO-DKD	9 / 466	7 / 476	63.2	1.31 [0.49,3.50]	
FIGARO-DKD	10 / 559	3 / 548	36.8	3.27 [0.90,11.81]	
Total	19 / 1025	10 / 1024		1.90 [0.89,4.07]	Z=1.66, p=0.0972
Heterogeneity:	Q=1.23 (df=1)	p=0.2672	I^2=18.8%		
Asia					
FIDELIO-DKD	63 / 790	52 / 786	46.5	1.21 [0.85,1.72]	
FIGARO-DKD	90 / 811	51 / 813	53.5	1.77 [1.27,2.46]	
Total	153 / 1601	103 / 1599		1.49 [1.17,1.89]	Z=3.24, p=0.0012
Heterogeneity:	Q=2.42 (df=1)	p=0.1197	I^2=58.7%		
Latin America					
FIDELIO-DKD	18 / 294	14 / 294	57.4	1.29 [0.65,2.54]	
FIGARO-DKD	15 / 424	10 / 417	42.6	1.48 [0.67,3.25]	
Total	33 / 718	24 / 711		1.36 [0.82,2.28]	Z=1.18, p=0.2371
Heterogeneity:	Q=0.07 (df=1)	p=0.7957	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	1 / 137	0 / 133	0.0	103E9 [103E9,103E9]	
Total	1 / 236	0 / 234		1.72E7 [1.72E7,1.72E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.48 (df=4)	p=0.3453	I^2=10.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.90.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

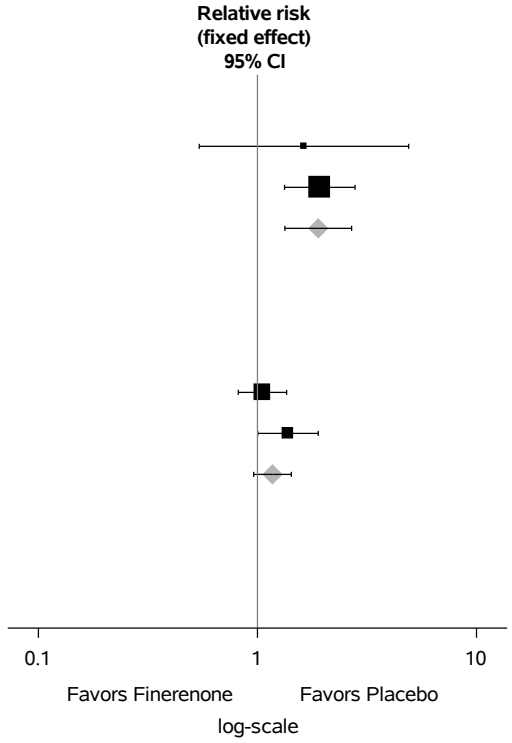
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	68 / 1556	62 / 1541	78.7	1.09 [0.78,1.52]	
FIGARO-DKD	28 / 637	13 / 627	21.3	2.12 [1.11,4.05]	
Total	96 / 2193	75 / 2168		1.26 [0.94,1.70]	Z=1.55, p=0.1205
Heterogeneity:	Q=3.22 (df=1)	p=0.0727	I^2=69.0%		
45 - < 60					
FIDELIO-DKD	43 / 1061	46 / 1069	62.3	0.94 [0.63,1.41]	
FIGARO-DKD	35 / 720	22 / 729	37.7	1.61 [0.95,2.72]	
Total	78 / 1781	68 / 1798		1.16 [0.84,1.59]	Z=0.90, p=0.3679
Heterogeneity:	Q=2.52 (df=1)	p=0.1125	I^2=60.3%		
>= 60					
FIDELIO-DKD	14 / 210	8 / 221	11.0	1.84 [0.79,4.30]	
FIGARO-DKD	104 / 2326	69 / 2302	89.0	1.49 [1.11,2.01]	
Total	118 / 2536	77 / 2523		1.53 [1.15,2.02]	Z=2.95, p=0.0032
Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=2)	p=0.4132	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.90.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

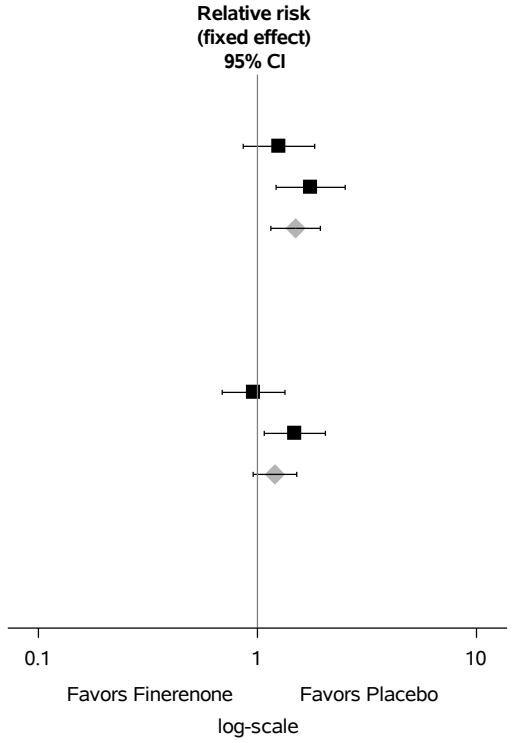
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	5 / 213	10.2	1.63 [0.54,4.90]	
FIGARO-DKD	80 / 1720	41 / 1698	89.8	1.93 [1.33,2.79]	
Total	88 / 1929	46 / 1911		1.89 [1.33,2.69]	Z=3.57, p=0.0004
Heterogeneity:	Q=0.08 (df=1)	p=0.7786	I^2=0.0%		
Very High					
FIDELIO-DKD	117 / 2618	111 / 2618	61.1	1.05 [0.82,1.36]	
FIGARO-DKD	87 / 1963	63 / 1960	38.9	1.38 [1.00,1.90]	
Total	204 / 4581	174 / 4578		1.17 [0.96,1.43]	Z=1.56, p=0.1177
Heterogeneity:	Q=1.67 (df=1)	p=0.1959	I^2=40.2%		
Subgroup Heterogeneity:	Q=5.47 (df=1)	p=0.0193	I^2=81.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.90.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

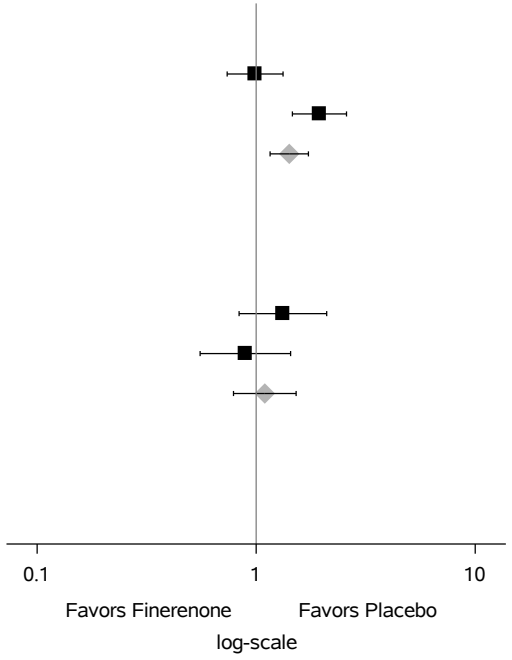
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	59 / 1301	47 / 1299	48.4	1.25 [0.86,1.82]	
FIGARO-DKD	78 / 1673	44 / 1651	51.6	1.75 [1.22,2.52]	
Total	137 / 2974	91 / 2950		1.49 [1.15,1.94]	Z=3.02, p=0.0025
Heterogeneity:	Q=1.57 (df=1)	p=0.2108	I^2=36.1%		
Absent					
FIDELIO-DKD	66 / 1526	69 / 1532	48.7	0.96 [0.69,1.34]	
FIGARO-DKD	89 / 2010	60 / 2007	51.3	1.48 [1.07,2.04]	
Total	155 / 3536	129 / 3539		1.20 [0.96,1.51]	Z=1.58, p=0.1152
Heterogeneity:	Q=3.40 (df=1)	p=0.0652	I^2=70.6%		
Subgroup Heterogeneity:	Q=1.51 (df=1)	p=0.2194	I^2=33.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.90.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	85 / 1879	85 / 1858	48.4	0.99 [0.74,1.33]	
FIGARO-DKD	136 / 2643	69 / 2608	51.6	1.94 [1.46,2.59]	
Total	221 / 4522	154 / 4466		1.42 [1.16,1.73]	Z=3.38, p=0.0007
Heterogeneity:	Q=10.52 (df=1)	p=0.0012	I^2=90.5%		
> 4.5					
FIDELIO-DKD	40 / 948	31 / 973	51.6	1.32 [0.84,2.10]	
FIGARO-DKD	31 / 1040	35 / 1048	48.4	0.89 [0.55,1.44]	
Total	71 / 1988	66 / 2021		1.10 [0.79,1.52]	Z=0.54, p=0.5891
Heterogeneity:	Q=1.36 (df=1)	p=0.2427	I^2=26.7%		
Subgroup Heterogeneity:	Q=1.70 (df=1)	p=0.1920	I^2=41.2%		

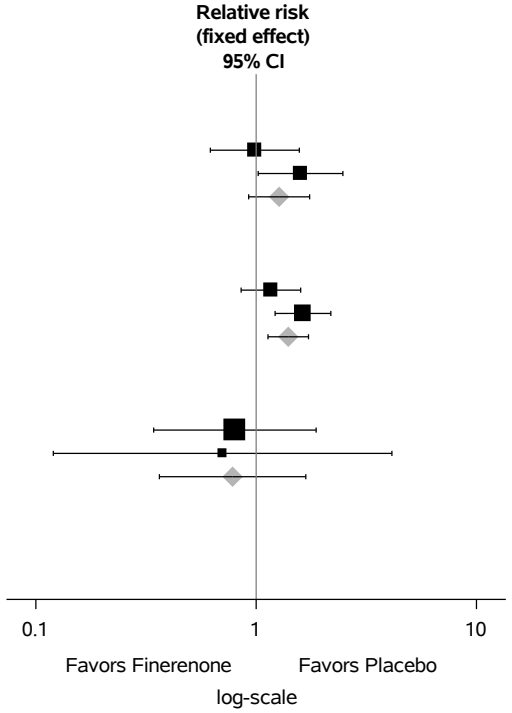


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.90.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)

Safety Analysis Set

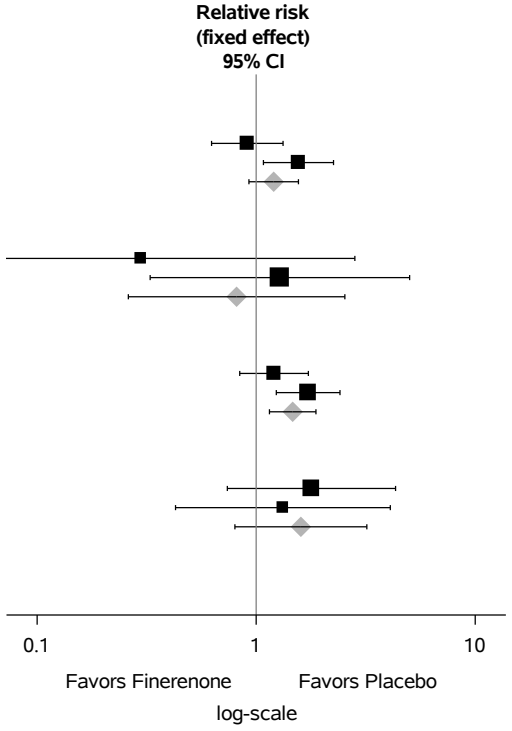
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	34 / 788	34 / 777	47.5	0.99 [0.62,1.57]	
FIGARO-DKD	49 / 1187	31 / 1194	52.5	1.59 [1.02,2.48]	
Total	83 / 1975	65 / 1971		1.27 [0.92,1.75]	Z=1.48, p=0.1397
Heterogeneity:	Q=2.13 (df=1)	p=0.1446	I^2=53.0%		
130 - < 160					
FIDELIO-DKD	82 / 1897	71 / 1916	46.7	1.17 [0.85,1.59]	
FIGARO-DKD	116 / 2389	70 / 2351	53.3	1.63 [1.22,2.18]	
Total	198 / 4286	141 / 4267		1.40 [1.13,1.73]	Z=3.10, p=0.0019
Heterogeneity:	Q=2.37 (df=1)	p=0.1234	I^2=57.9%		
>= 160					
FIDELIO-DKD	9 / 141	11 / 138	81.3	0.80 [0.34,1.87]	
FIGARO-DKD	2 / 107	3 / 113	18.7	0.70 [0.12,4.13]	
Total	11 / 248	14 / 251		0.78 [0.36,1.68]	Z=-0.63, p=0.5277
Heterogeneity:	Q=0.02 (df=1)	p=0.8977	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.14 (df=2)	p=0.3431	I^2=6.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.90.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

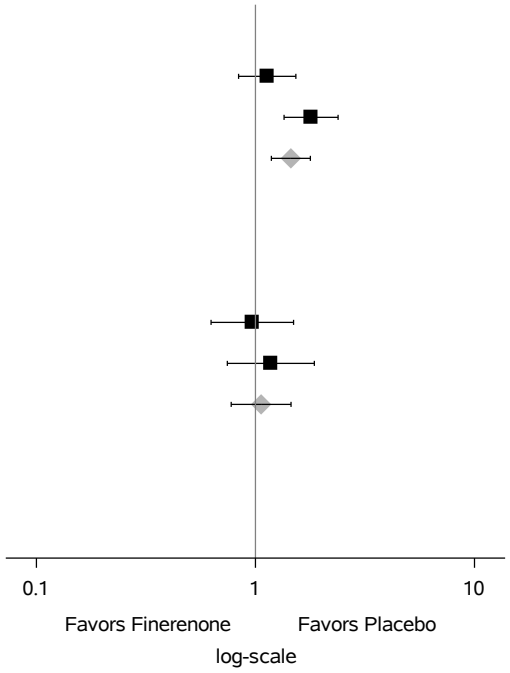
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	50 / 1773	56 / 1809	49.0	0.91 [0.63,1.33]	
FIGARO-DKD	72 / 2668	45 / 2601	51.0	1.56 [1.08,2.25]	
Total	122 / 4441	101 / 4410		1.20 [0.93,1.56]	Z=1.39, p=0.1656
Heterogeneity:	Q=4.01 (df=1)	p=0.0452	I^2=75.1%		
Black					
FIDELIO-DKD	1 / 139	3 / 124	26.9	0.30 [0.03,2.82]	
FIGARO-DKD	4 / 113	4 / 145	73.1	1.28 [0.33,5.02]	
Total	5 / 252	7 / 269		0.81 [0.26,2.54]	Z=-0.35, p=0.7230
Heterogeneity:	Q=1.20 (df=1)	p=0.2739	I^2=16.5%		
Asian					
FIDELIO-DKD	60 / 717	50 / 721	46.2	1.21 [0.84,1.73]	
FIGARO-DKD	84 / 716	50 / 736	53.8	1.73 [1.24,2.41]	
Total	144 / 1433	100 / 1457		1.47 [1.15,1.87]	Z=3.08, p=0.0021
Heterogeneity:	Q=2.04 (df=1)	p=0.1533	I^2=51.0%		
Others					
FIDELIO-DKD	14 / 198	7 / 177	62.0	1.79 [0.74,4.33]	
FIGARO-DKD	7 / 186	5 / 176	38.0	1.32 [0.43,4.10]	
Total	21 / 384	12 / 353		1.60 [0.80,3.20]	Z=1.33, p=0.1842
Heterogeneity:	Q=0.17 (df=1)	p=0.6819	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.19 (df=3)	p=0.5341	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.90.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

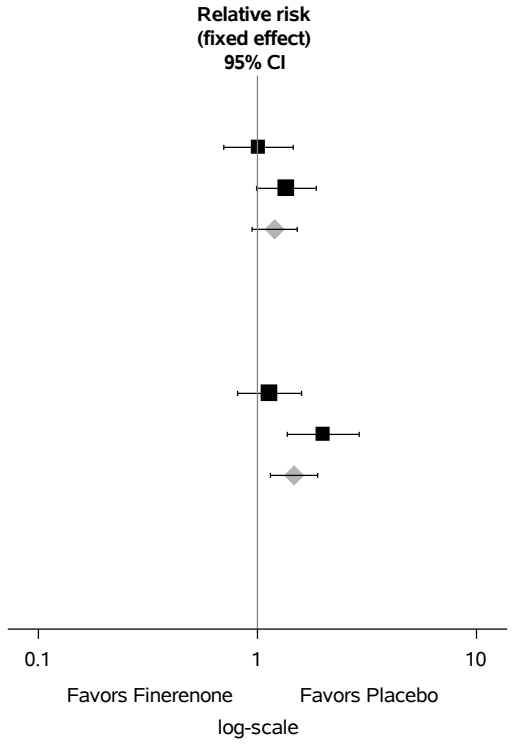
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	85 / 1949	78 / 2024	47.1	1.13 [0.84,1.53]	
FIGARO-DKD	127 / 2527	72 / 2571	52.9	1.79 [1.35,2.38]	
Total	212 / 4476	150 / 4595		1.45 [1.18,1.78]	Z=3.56, p=0.0004
Heterogeneity:	Q=4.77 (df=1)	p=0.0289	I^2=79.0%		
Female					
FIDELIO-DKD	40 / 878	38 / 807	52.7	0.97 [0.63,1.49]	
FIGARO-DKD	40 / 1156	32 / 1087	47.3	1.18 [0.74,1.86]	
Total	80 / 2034	70 / 1894		1.06 [0.77,1.45]	Z=0.37, p=0.7110
Heterogeneity:	Q=0.37 (df=1)	p=0.5450	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.67 (df=1)	p=0.1024	I^2=62.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.90.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

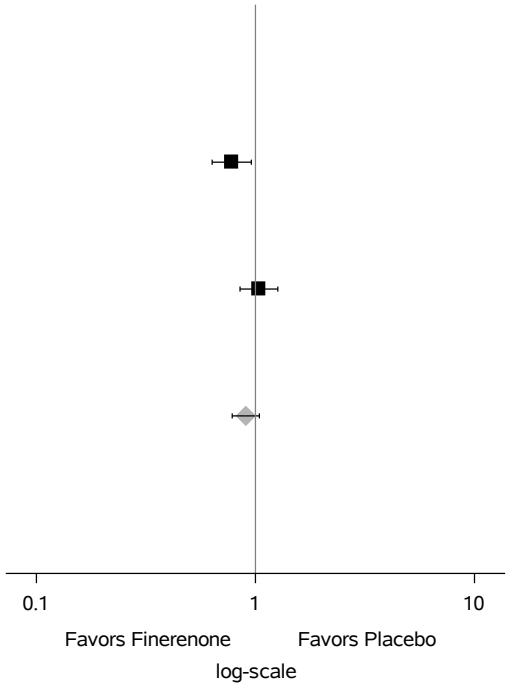
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	56 / 1201	54 / 1171	42.5	1.01 [0.70,1.46]	
FIGARO-DKD	88 / 1752	65 / 1755	57.5	1.36 [0.99,1.86]	
Total	144 / 2953	119 / 2926		1.20 [0.95,1.52]	Z=1.49, p=0.1352
Heterogeneity:	Q=1.43 (df=1)	p=0.2318	I^2=30.0%		
>= 65					
FIDELIO-DKD	69 / 1626	62 / 1660	55.9	1.14 [0.81,1.59]	
FIGARO-DKD	79 / 1931	39 / 1903	44.1	2.00 [1.37,2.91]	
Total	148 / 3557	101 / 3563		1.47 [1.15,1.88]	Z=3.03, p=0.0024
Heterogeneity:	Q=4.77 (df=1)	p=0.0290	I^2=79.0%		
Subgroup Heterogeneity:	Q=1.35 (df=1)	p=0.2450	I^2=26.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.91: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set

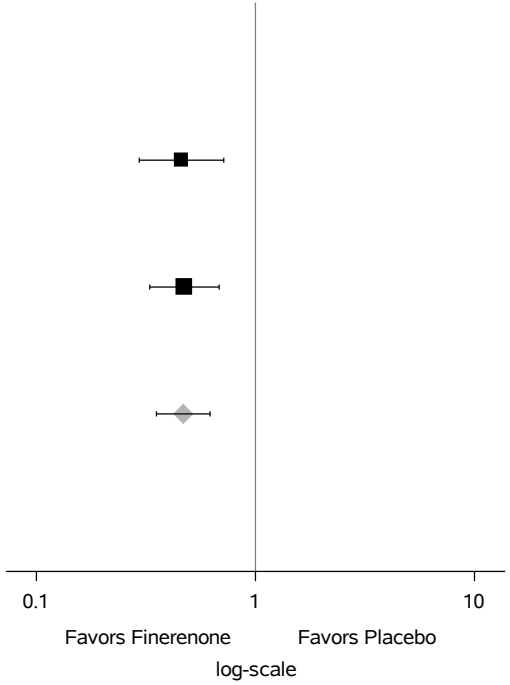
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	151 / 2827	194 / 2831	48.1	0.78 [0.63,0.96]	
FIGARO-DKD	189 / 3683	181 / 3658	51.9	1.04 [0.85,1.27]	
Total	340 / 6510	375 / 6489		0.90 [0.78,1.04]	Z=-1.40, p=0.1627
Heterogeneity:	Q=3.82 (df=1)	p=0.0506	I^2=73.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.92: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

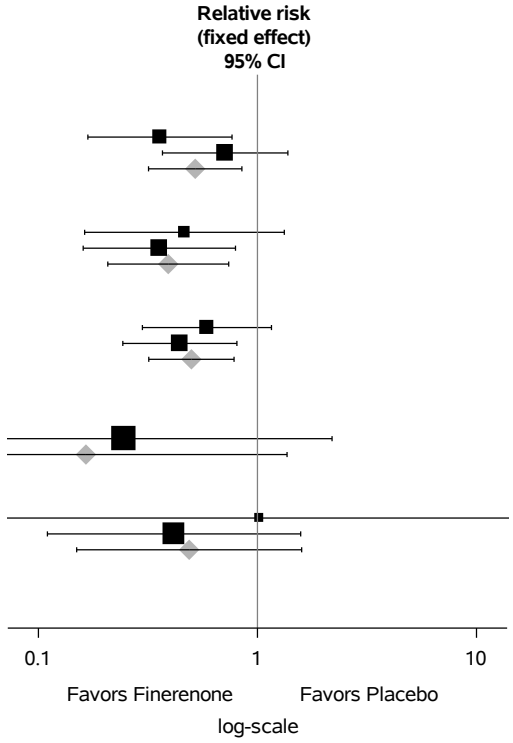
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2827	61 / 2831	40.3	0.46 [0.29,0.72]	
FIGARO-DKD	42 / 3683	88 / 3658	59.7	0.47 [0.33,0.68]	
Total	70 / 6510	149 / 6489		0.47 [0.35,0.62]	Z=-5.28, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9164	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.92.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

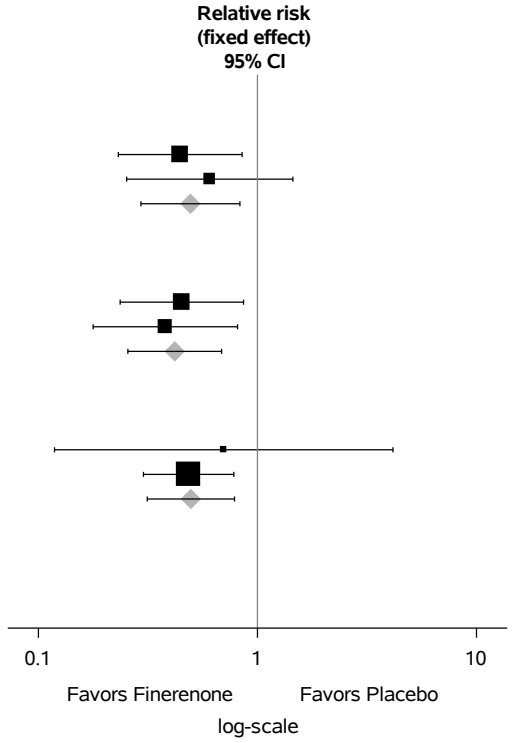
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1178	25 / 1174	43.1	0.36 [0.17,0.77]	
FIGARO-DKD	15 / 1752	21 / 1747	56.9	0.71 [0.37,1.38]	
Total	24 / 2930	46 / 2921		0.52 [0.32,0.85]	Z=-2.61, p=0.0090
Heterogeneity:	Q=1.80 (df=1)	p=0.1801	I^2=44.3%		
North America					
FIDELIO-DKD	5 / 466	11 / 476	36.8	0.46 [0.16,1.33]	
FIGARO-DKD	8 / 559	22 / 548	63.2	0.36 [0.16,0.79]	
Total	13 / 1025	33 / 1024		0.39 [0.21,0.74]	Z=-2.89, p=0.0038
Heterogeneity:	Q=0.15 (df=1)	p=0.6947	I^2=0.0%		
Asia					
FIDELIO-DKD	13 / 790	22 / 786	43.9	0.59 [0.30,1.16]	
FIGARO-DKD	15 / 811	34 / 813	56.1	0.44 [0.24,0.81]	
Total	28 / 1601	56 / 1599		0.50 [0.32,0.78]	Z=-3.04, p=0.0024
Heterogeneity:	Q=0.38 (df=1)	p=0.5377	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 294	2 / 294	0.0	0.00 [0.00,19E296]	
FIGARO-DKD	1 / 424	4 / 417	100.0	0.25 [0.03,2.19]	
Total	1 / 718	6 / 711		0.16 [0.02,1.36]	Z=-1.67, p=0.0946
Heterogeneity:	Q=0.13 (df=1)	p=0.7198	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 99	1 / 101	18.9	1.02 [0.06,16.09]	
FIGARO-DKD	3 / 137	7 / 133	81.1	0.42 [0.11,1.58]	
Total	4 / 236	8 / 234		0.49 [0.15,1.59]	Z=-1.19, p=0.2342
Heterogeneity:	Q=0.33 (df=1)	p=0.5658	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.50 (df=4)	p=0.8273	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.92.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

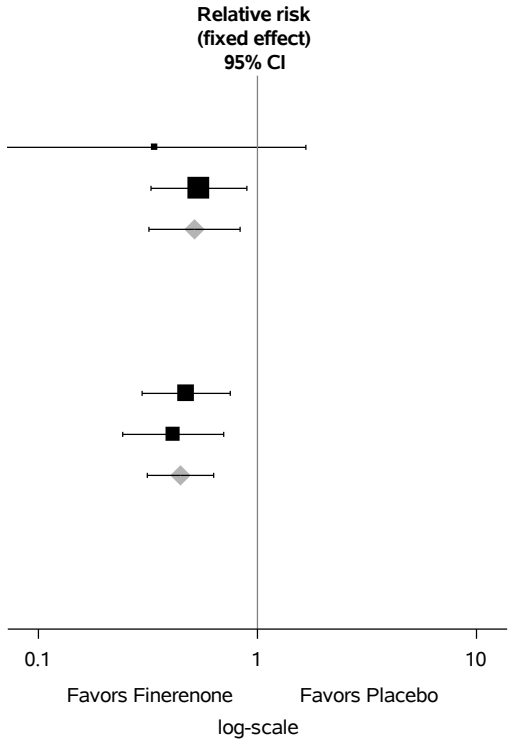
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	29 / 1541	64.3	0.44 [0.23,0.85]	
FIGARO-DKD	8 / 637	13 / 627	35.7	0.61 [0.25,1.45]	
Total	21 / 2193	42 / 2168		0.49 [0.29,0.83]	Z=-2.65, p=0.0080
Heterogeneity:	Q=0.31 (df=1)	p=0.5760	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	13 / 1061	29 / 1069	57.8	0.45 [0.24,0.86]	
FIGARO-DKD	9 / 720	24 / 729	42.2	0.38 [0.18,0.81]	
Total	22 / 1781	53 / 1798		0.42 [0.26,0.69]	Z=-3.46, p=0.0005
Heterogeneity:	Q=0.12 (df=1)	p=0.7333	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	3 / 221	6.7	0.70 [0.12,4.16]	
FIGARO-DKD	25 / 2326	51 / 2302	93.3	0.49 [0.30,0.78]	
Total	27 / 2536	54 / 2523		0.50 [0.31,0.79]	Z=-2.99, p=0.0028
Heterogeneity:	Q=0.15 (df=1)	p=0.6946	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=2)	p=0.8610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.92.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

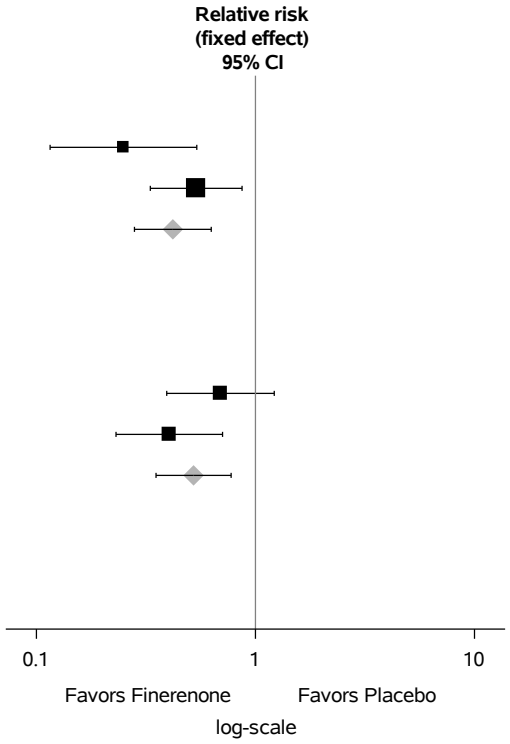
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	6 / 213	9.1	0.34 [0.07,1.66]	
FIGARO-DKD	23 / 1720	42 / 1698	90.9	0.54 [0.33,0.89]	
Total	25 / 1929	48 / 1911		0.52 [0.32,0.83]	Z=-2.71, p=0.0068
Heterogeneity:	Q=0.30 (df=1)	p=0.5847	I^2=0.0%		
Very High					
FIDELIO-DKD	26 / 2618	55 / 2618	56.8	0.47 [0.30,0.75]	
FIGARO-DKD	19 / 1963	46 / 1960	43.2	0.41 [0.24,0.70]	
Total	45 / 4581	101 / 4578		0.45 [0.31,0.63]	Z=-4.55, p=<.0001
Heterogeneity:	Q=0.14 (df=1)	p=0.7041	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6259	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.92.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

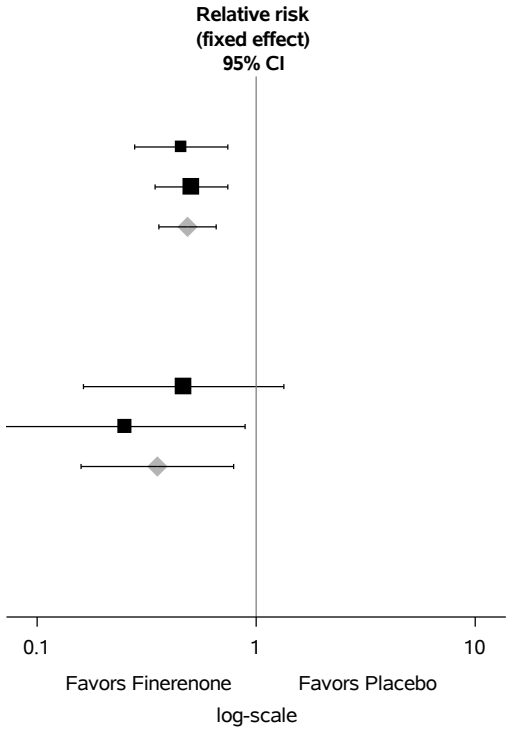
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	8 / 1301	32 / 1299	28.1	0.25 [0.12,0.54]	
FIGARO-DKD	25 / 1673	46 / 1651	71.9	0.54 [0.33,0.87]	
Total	33 / 2974	78 / 2950		0.42 [0.28,0.63]	Z=-4.22, p=<.0001
Heterogeneity:	Q=2.74 (df=1)	p=0.0979	I^2=63.5%		
Absent					
FIDELIO-DKD	20 / 1526	29 / 1532	49.5	0.69 [0.39,1.22]	
FIGARO-DKD	17 / 2010	42 / 2007	50.5	0.40 [0.23,0.71]	
Total	37 / 3536	71 / 3539		0.52 [0.35,0.77]	Z=-3.23, p=0.0012
Heterogeneity:	Q=1.76 (df=1)	p=0.1845	I^2=43.2%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4497	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.92.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

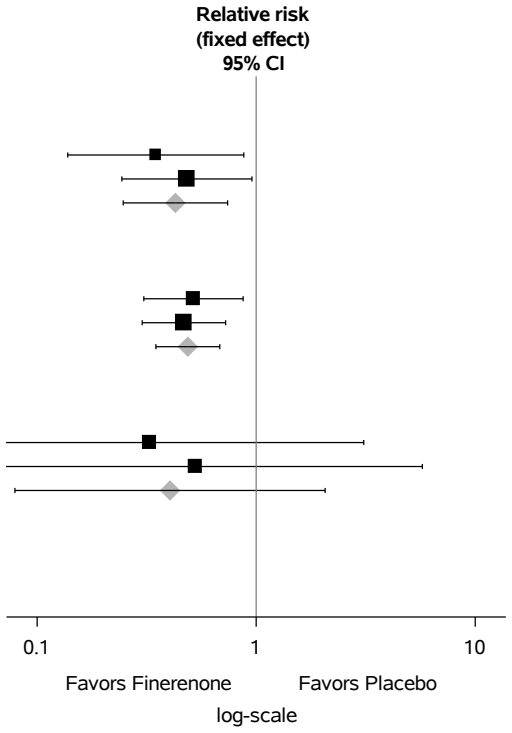
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	50 / 1858	37.9	0.45 [0.28,0.74]	
FIGARO-DKD	39 / 2643	76 / 2608	62.1	0.51 [0.35,0.74]	
Total	62 / 4522	126 / 4466		0.49 [0.36,0.66]	Z=-4.70, p=<.0001
Heterogeneity:	Q=0.11 (df=1)	p=0.7350	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 948	11 / 973	58.9	0.47 [0.16,1.34]	
FIGARO-DKD	3 / 1040	12 / 1048	41.1	0.25 [0.07,0.89]	
Total	8 / 1988	23 / 2021		0.35 [0.16,0.79]	Z=-2.54, p=0.0111
Heterogeneity:	Q=0.54 (df=1)	p=0.4612	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4681	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.92.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

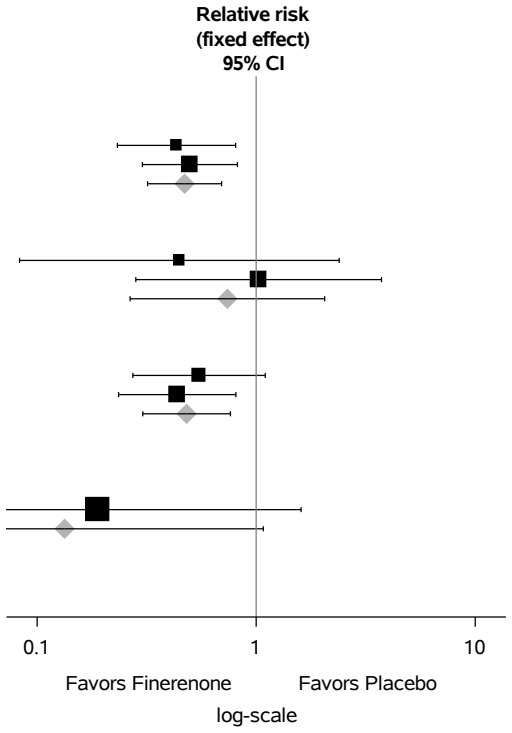
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 788	17 / 777	35.3	0.35 [0.14,0.88]	
FIGARO-DKD	12 / 1187	25 / 1194	64.7	0.48 [0.24,0.96]	
Total	18 / 1975	42 / 1971		0.43 [0.25,0.74]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.31 (df=1)	p=0.5768	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	21 / 1897	41 / 1916	41.4	0.52 [0.31,0.87]	
FIGARO-DKD	29 / 2389	61 / 2351	58.6	0.47 [0.30,0.73]	
Total	50 / 4286	102 / 4267		0.49 [0.35,0.68]	Z=-4.19, p=<.0001
Heterogeneity:	Q=0.08 (df=1)	p=0.7726	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 141	3 / 138	52.9	0.33 [0.03,3.10]	
FIGARO-DKD	1 / 107	2 / 113	47.1	0.53 [0.05,5.74]	
Total	2 / 248	5 / 251		0.40 [0.08,2.06]	Z=-1.09, p=0.2764
Heterogeneity:	Q=0.08 (df=1)	p=0.7733	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=2)	p=0.9091	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.92.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

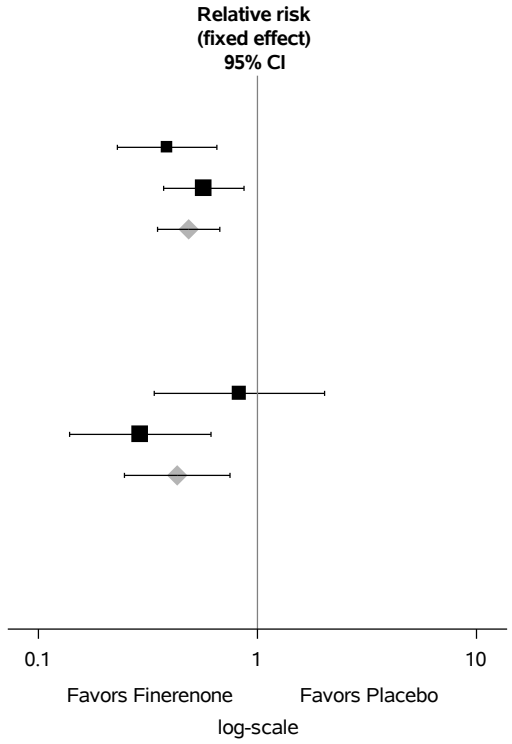
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1773	33 / 1809	39.2	0.43 [0.23,0.81]	
FIGARO-DKD	23 / 2668	45 / 2601	60.8	0.50 [0.30,0.82]	
Total	37 / 4441	78 / 4410		0.47 [0.32,0.70]	Z=-3.79, p=0.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7294	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	4 / 124	37.1	0.45 [0.08,2.39]	
FIGARO-DKD	4 / 113	5 / 145	62.9	1.03 [0.28,3.74]	
Total	6 / 252	9 / 269		0.74 [0.27,2.05]	Z=-0.58, p=0.5621
Heterogeneity:	Q=0.60 (df=1)	p=0.4402	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 717	22 / 721	44.0	0.55 [0.27,1.10]	
FIGARO-DKD	14 / 716	33 / 736	56.0	0.44 [0.24,0.81]	
Total	26 / 1433	55 / 1457		0.48 [0.30,0.76]	Z=-3.11, p=0.0019
Heterogeneity:	Q=0.23 (df=1)	p=0.6287	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	2 / 177	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	1 / 186	5 / 176	100.0	0.19 [0.02,1.60]	
Total	1 / 384	7 / 353		0.13 [0.02,1.08]	Z=-1.89, p=0.0588
Heterogeneity:	Q=0.10 (df=1)	p=0.7486	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.14 (df=3)	p=0.5447	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.92.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

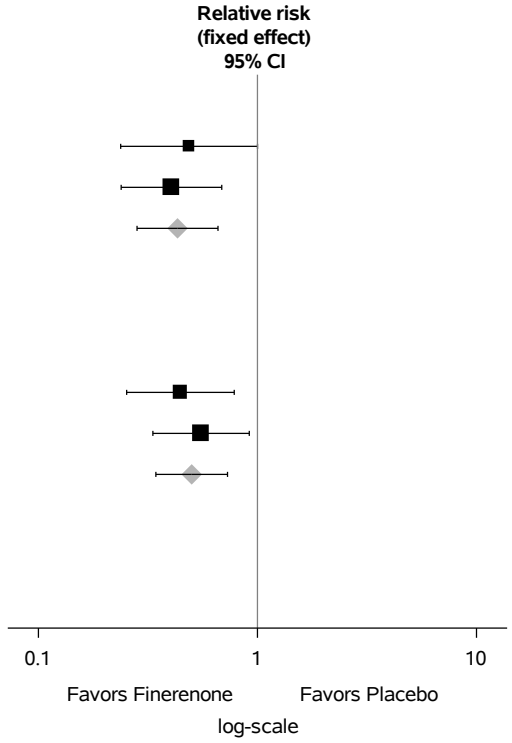
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	19 / 1949	51 / 2024	39.5	0.39 [0.23,0.65]	
FIGARO-DKD	33 / 2527	59 / 2571	60.5	0.57 [0.37,0.87]	
Total	52 / 4476	110 / 4595		0.49 [0.35,0.67]	Z=-4.33, p=<.0001
Heterogeneity:	Q=1.27 (df=1)	p=0.2604	I^2=21.1%		
Female					
FIDELIO-DKD	9 / 878	10 / 807	40.8	0.83 [0.34,2.03]	
FIGARO-DKD	9 / 1156	29 / 1087	59.2	0.29 [0.14,0.61]	
Total	18 / 2034	39 / 1894		0.43 [0.25,0.75]	Z=-2.98, p=0.0029
Heterogeneity:	Q=3.10 (df=1)	p=0.0785	I^2=67.7%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7141	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.92.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

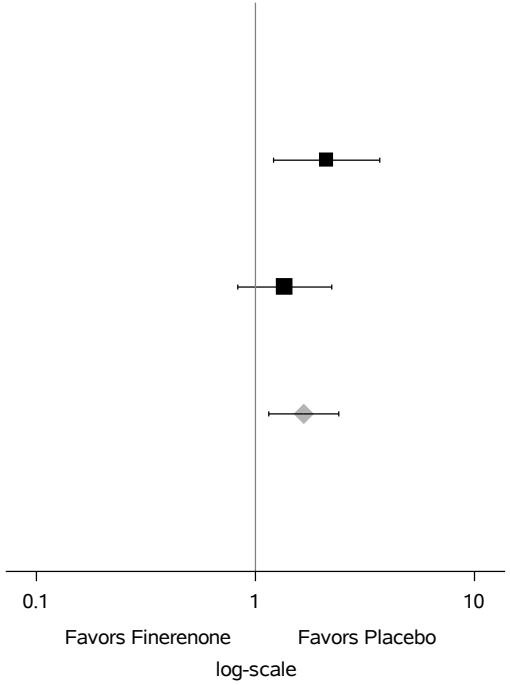
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1201	22 / 1171	35.1	0.49 [0.24,1.00]	
FIGARO-DKD	19 / 1752	47 / 1755	64.9	0.40 [0.24,0.69]	
Total	30 / 2953	69 / 2926		0.43 [0.28,0.66]	Z=-3.87, p=0.0001
Heterogeneity:	Q=0.17 (df=1)	p=0.6837	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 1626	39 / 1660	44.5	0.45 [0.25,0.78]	
FIGARO-DKD	23 / 1931	41 / 1903	55.5	0.55 [0.33,0.92]	
Total	40 / 3557	80 / 3563		0.50 [0.34,0.73]	Z=-3.60, p=0.0003
Heterogeneity:	Q=0.31 (df=1)	p=0.5754	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6072	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

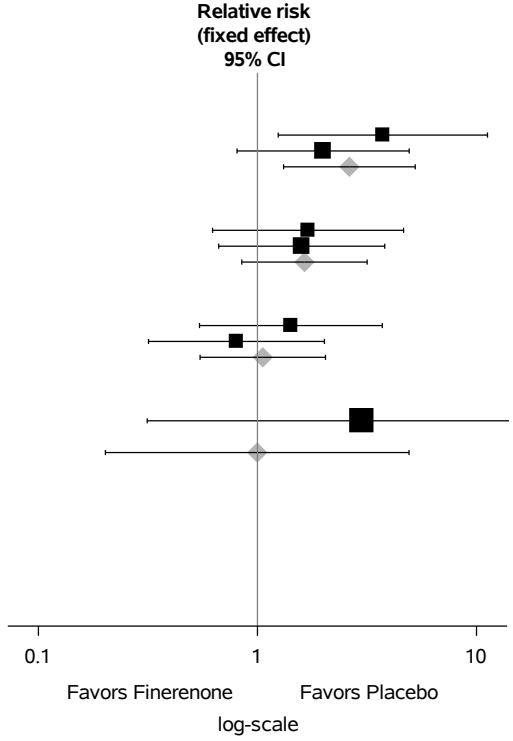
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2827	18 / 2831	43.9	2.11 [1.21,3.70]	
FIGARO-DKD	37 / 3683	27 / 3658	56.1	1.36 [0.83,2.23]	
Total	75 / 6510	45 / 6489		1.66 [1.15,2.40]	Z=2.71, p=0.0068
Heterogeneity:	Q=1.34 (df=1)	p=0.2468	I^2=25.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.93.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

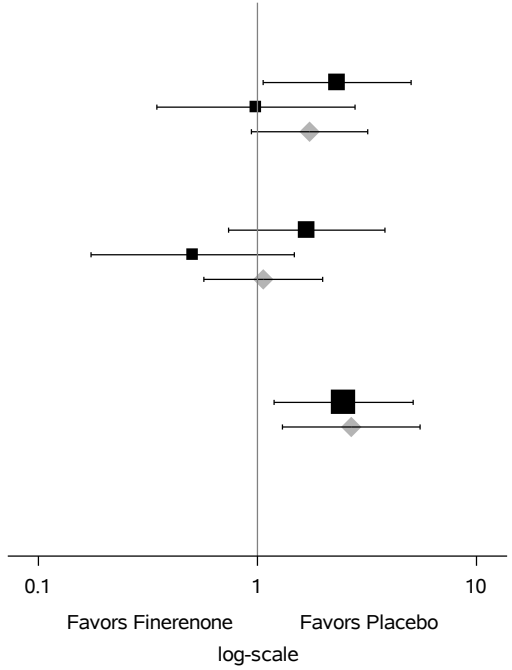
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1178	4 / 1174	40.4	3.74 [1.24,11.23]	
FIGARO-DKD	14 / 1752	7 / 1747	59.6	1.99 [0.81,4.93]	
Total	29 / 2930	11 / 2921		2.63 [1.32,5.25]	Z=2.74, p=0.0062
Heterogeneity:	Q=0.75 (df=1)	p=0.3862	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	6 / 476	43.0	1.70 [0.62,4.65]	
FIGARO-DKD	13 / 559	8 / 548	57.0	1.59 [0.67,3.81]	
Total	23 / 1025	14 / 1024		1.64 [0.85,3.17]	Z=1.47, p=0.1413
Heterogeneity:	Q=0.01 (df=1)	p=0.9220	I^2=0.0%		
Asia					
FIDELIO-DKD	10 / 790	7 / 786	48.1	1.42 [0.54,3.72]	
FIGARO-DKD	8 / 811	10 / 813	51.9	0.80 [0.32,2.02]	
Total	18 / 1601	17 / 1599		1.06 [0.55,2.04]	Z=0.17, p=0.8680
Heterogeneity:	Q=0.71 (df=1)	p=0.4002	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 294	1 / 294	100.0	3.00 [0.31,28.67]	
FIGARO-DKD	0 / 424	2 / 417	0.0	0.00 [0.00,97E295]	
Total	3 / 718	3 / 711		1.00 [0.20,4.92]	Z=-0.00, p=0.9975
Heterogeneity:	Q=0.91 (df=1)	p=0.3390	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	2 / 137	0 / 133	0.0	207E9 [207E9,207E9]	
Total	2 / 236	0 / 234		3.39E7 [3.39E7,3.39E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.83 (df=4)	p=0.4290	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

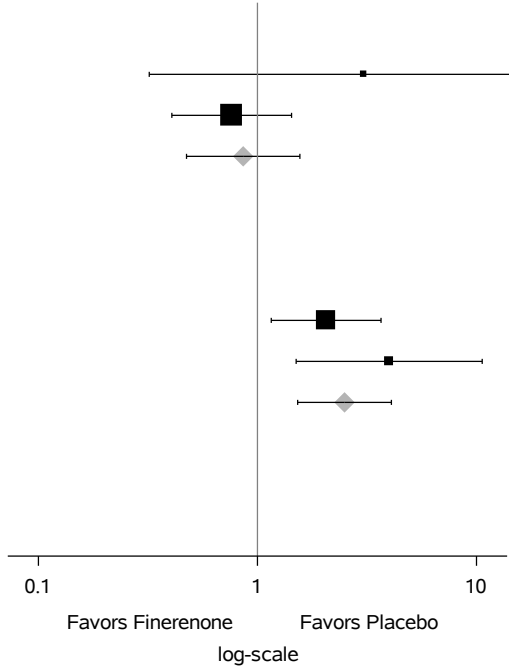
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	21 / 1556	9 / 1541	64.2	2.31 [1.06,5.03]	
FIGARO-DKD	7 / 637	7 / 627	35.8	0.98 [0.35,2.79]	
Total	28 / 2193	16 / 2168		1.73 [0.94,3.19]	Z=1.76, p=0.0791
Heterogeneity:	Q=1.66 (df=1)	p=0.1979	I^2=39.7%		
45 - < 60					
FIDELIO-DKD	15 / 1061	9 / 1069	62.8	1.68 [0.74,3.82]	
FIGARO-DKD	5 / 720	10 / 729	37.2	0.51 [0.17,1.47]	
Total	20 / 1781	19 / 1798		1.06 [0.57,1.98]	Z=0.19, p=0.8483
Heterogeneity:	Q=3.04 (df=1)	p=0.0812	I^2=67.1%		
>= 60					
FIDELIO-DKD	2 / 210	0 / 221	0.0	135E9 [135E9,135E9]	
FIGARO-DKD	25 / 2326	10 / 2302	100.0	2.47 [1.19,5.14]	
Total	27 / 2536	10 / 2523		2.68 [1.30,5.53]	Z=2.67, p=0.0076
Heterogeneity:	Q=0.05 (df=1)	p=0.8299	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.65 (df=2)	p=0.1609	I^2=45.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

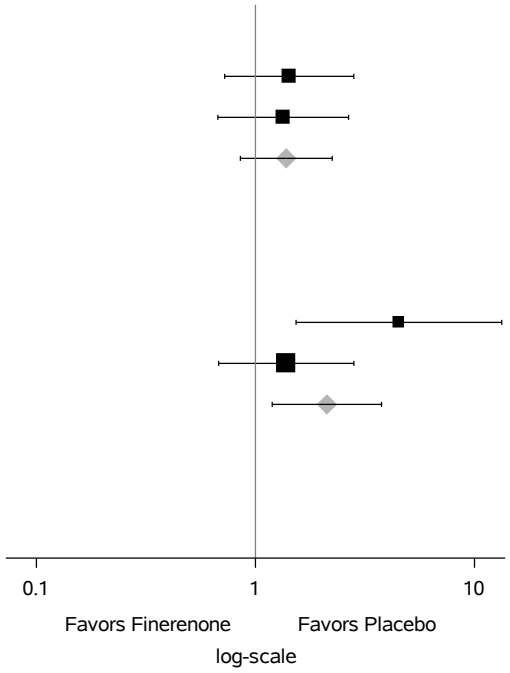
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	1 / 213	7.2	3.06 [0.32,29.16]	
FIGARO-DKD	17 / 1720	22 / 1698	92.8	0.76 [0.41,1.43]	
Total	20 / 1929	23 / 1911		0.86 [0.47,1.56]	Z=-0.49, p=0.6220
Heterogeneity:	Q=1.36 (df=1)	p=0.2444	I^2=26.2%		
Very High					
FIDELIO-DKD	35 / 2618	17 / 2618	74.2	2.06 [1.16,3.67]	
FIGARO-DKD	20 / 1963	5 / 1960	25.8	3.99 [1.50,10.62]	
Total	55 / 4581	22 / 4578		2.50 [1.53,4.09]	Z=3.64, p=0.0003
Heterogeneity:	Q=1.32 (df=1)	p=0.2513	I^2=24.0%		
Subgroup Heterogeneity:	Q=7.29 (df=1)	p=0.0069	I^2=86.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

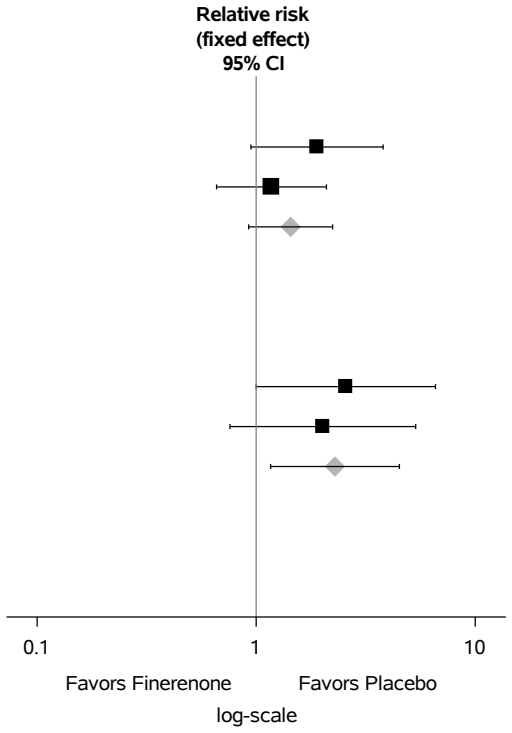
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	14 / 1299	50.6	1.43 [0.72,2.81]	
FIGARO-DKD	19 / 1673	14 / 1651	49.4	1.34 [0.67,2.66]	
Total	39 / 2974	28 / 2950		1.38 [0.85,2.24]	Z=1.32, p=0.1882
Heterogeneity:	Q=0.02 (df=1)	p=0.8983	I^2=0.0%		
Absent					
FIDELIO-DKD	18 / 1526	4 / 1532	30.2	4.52 [1.53,13.32]	
FIGARO-DKD	18 / 2010	13 / 2007	69.8	1.38 [0.68,2.81]	
Total	36 / 3536	17 / 3539		2.12 [1.19,3.77]	Z=2.56, p=0.0105
Heterogeneity:	Q=3.27 (df=1)	p=0.0705	I^2=69.4%		
Subgroup Heterogeneity:	Q=1.24 (df=1)	p=0.2651	I^2=19.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

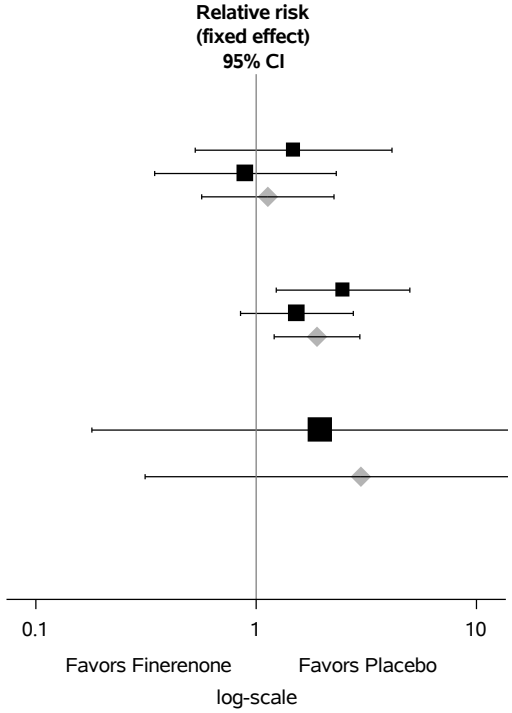
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	12 / 1858	40.9	1.90 [0.95,3.80]	
FIGARO-DKD	25 / 2643	21 / 2608	59.1	1.17 [0.66,2.09]	
Total	48 / 4522	33 / 4466		1.44 [0.92,2.23]	Z=1.61, p=0.1075
Heterogeneity:	Q=1.08 (df=1)	p=0.2994	I^2=7.1%		
> 4.5					
FIDELIO-DKD	15 / 948	6 / 973	51.8	2.57 [1.00,6.59]	
FIGARO-DKD	12 / 1040	6 / 1048	48.2	2.02 [0.76,5.35]	
Total	27 / 1988	12 / 2021		2.29 [1.16,4.51]	Z=2.40, p=0.0165
Heterogeneity:	Q=0.12 (df=1)	p=0.7271	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=1)	p=0.2582	I^2=21.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.93.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

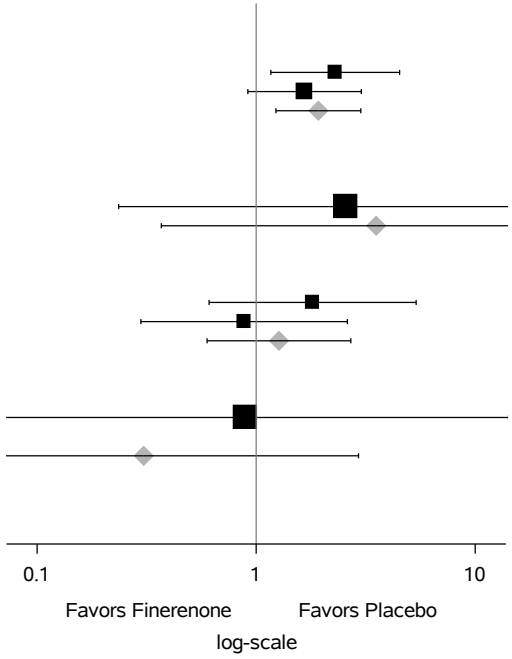
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 788	6 / 777	46.0	1.48 [0.53,4.14]	
FIGARO-DKD	8 / 1187	9 / 1194	54.0	0.89 [0.35,2.31]	
Total	17 / 1975	15 / 1971		1.13 [0.57,2.26]	Z=0.35, p=0.7295
Heterogeneity:	Q=0.50 (df=1)	p=0.4808	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	27 / 1897	11 / 1916	41.6	2.48 [1.23,4.98]	
FIGARO-DKD	28 / 2389	18 / 2351	58.4	1.53 [0.85,2.76]	
Total	55 / 4286	29 / 4267		1.89 [1.21,2.96]	Z=2.78, p=0.0054
Heterogeneity:	Q=1.07 (df=1)	p=0.3007	I^2=6.6%		
>= 160					
FIDELIO-DKD	2 / 141	1 / 138	100.0	1.96 [0.18,21.34]	
FIGARO-DKD	1 / 107	0 / 113	0.0	132E9 [132E9,132E9]	
Total	3 / 248	1 / 251		2.99 [0.31,28.52]	Z=0.95, p=0.3415
Heterogeneity:	Q=0.12 (df=1)	p=0.7284	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=2)	p=0.4130	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.93.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

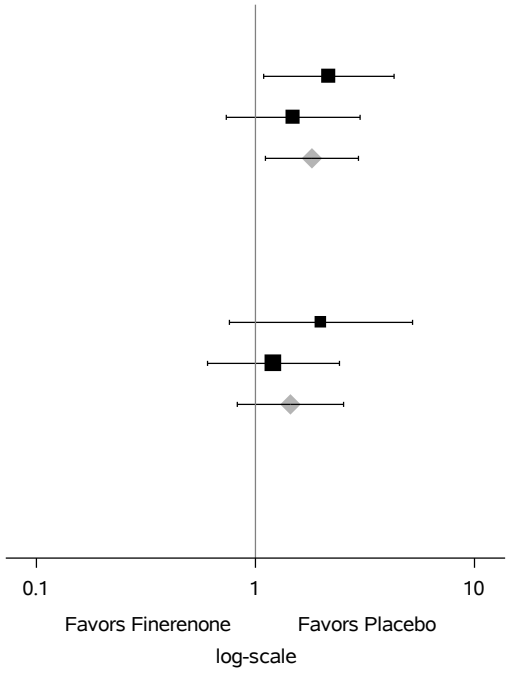
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	27 / 1773	12 / 1809	43.7	2.30 [1.17,4.52]	
FIGARO-DKD	29 / 2668	17 / 2601	56.3	1.66 [0.92,3.02]	
Total	56 / 4441	29 / 4410		1.92 [1.23,3.00]	Z=2.87, p=0.0041
Heterogeneity:	Q=0.49 (df=1)	p=0.4835	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	0 / 124	0.0	102E9 [102E9,102E9]	
FIGARO-DKD	2 / 113	1 / 145	100.0	2.57 [0.24,27.95]	
Total	3 / 252	1 / 269		3.53 [0.37,33.80]	Z=1.09, p=0.2737
Heterogeneity:	Q=0.07 (df=1)	p=0.7934	I^2=0.0%		
Asian					
FIDELIO-DKD	9 / 717	5 / 721	49.9	1.81 [0.61,5.37]	
FIGARO-DKD	6 / 716	7 / 736	50.1	0.88 [0.30,2.61]	
Total	15 / 1433	12 / 1457		1.27 [0.60,2.70]	Z=0.62, p=0.5345
Heterogeneity:	Q=0.84 (df=1)	p=0.3585	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 198	1 / 177	100.0	0.89 [0.06,14.19]	
FIGARO-DKD	0 / 186	2 / 176	0.0	0.00 [0.00,11E296]	
Total	1 / 384	3 / 353		0.31 [0.03,2.93]	Z=-1.03, p=0.3048
Heterogeneity:	Q=0.58 (df=1)	p=0.4479	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.47 (df=3)	p=0.3245	I^2=13.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.93.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

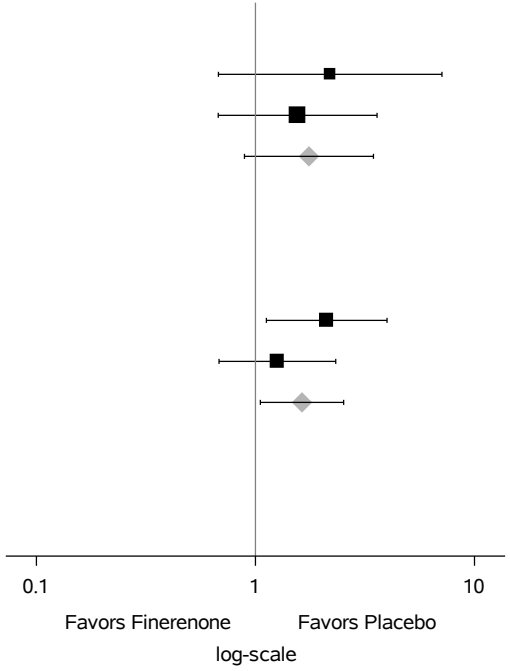
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1949	12 / 2024	51.3	2.16 [1.09,4.29]	
FIGARO-DKD	19 / 2527	13 / 2571	48.7	1.49 [0.74,3.00]	
Total	44 / 4476	25 / 4595		1.81 [1.11,2.95]	Z=2.38, p=0.0173
Heterogeneity:	Q=0.56 (df=1)	p=0.4541	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 878	6 / 807	34.2	1.99 [0.76,5.21]	
FIGARO-DKD	18 / 1156	14 / 1087	65.8	1.21 [0.60,2.42]	
Total	31 / 2034	20 / 1894		1.44 [0.83,2.53]	Z=1.29, p=0.1967
Heterogeneity:	Q=0.68 (df=1)	p=0.4094	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5509	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.93.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

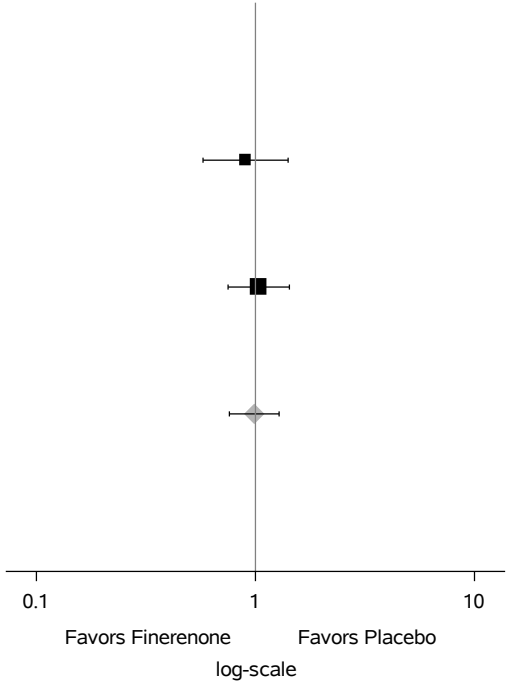
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1201	4 / 1171	33.5	2.19 [0.68,7.10]	
FIGARO-DKD	14 / 1752	9 / 1755	66.5	1.56 [0.68,3.59]	
Total	23 / 2953	13 / 2926		1.75 [0.89,3.46]	Z=1.63, p=0.1040
Heterogeneity:	Q=0.22 (df=1)	p=0.6417	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 1626	14 / 1660	48.3	2.11 [1.12,3.99]	
FIGARO-DKD	23 / 1931	18 / 1903	51.7	1.26 [0.68,2.33]	
Total	52 / 3557	32 / 3563		1.63 [1.05,2.53]	Z=2.19, p=0.0285
Heterogeneity:	Q=1.33 (df=1)	p=0.2493	I^2=24.7%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8591	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.94: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

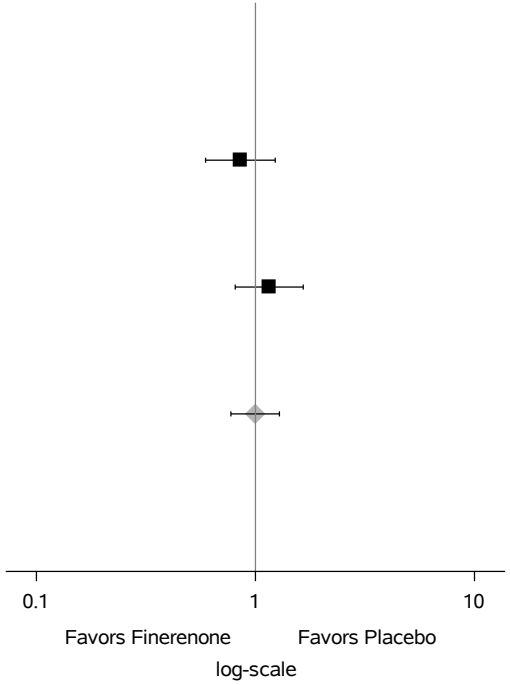
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	40 / 2831	34.2	0.90 [0.58,1.41]	
FIGARO-DKD	74 / 3683	71 / 3658	65.8	1.04 [0.75,1.43]	
Total	110 / 6510	111 / 6489		0.99 [0.76,1.28]	Z=-0.10, p=0.9233
Heterogeneity:	Q=0.24 (df=1)	p=0.6224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.95: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set

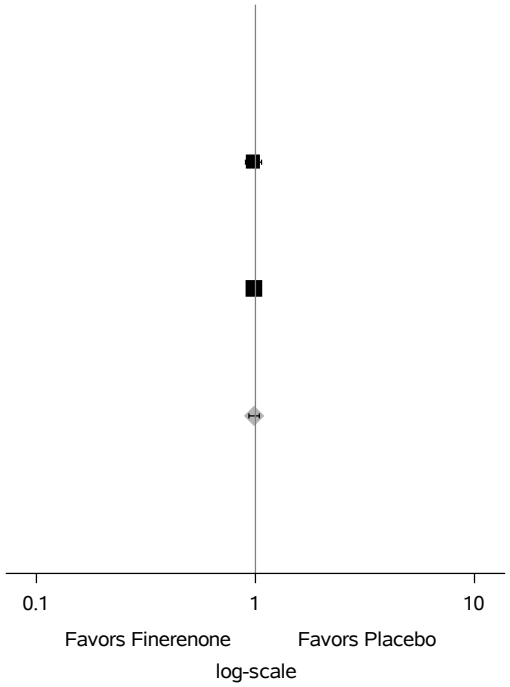
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 2827	61 / 2831	48.8	0.85 [0.59,1.23]	
FIGARO-DKD	64 / 3683	55 / 3658	51.2	1.16 [0.81,1.65]	
Total	116 / 6510	116 / 6489		1.00 [0.77,1.29]	Z=-0.02, p=0.9810
Heterogeneity:	Q=1.35 (df=1)	p=0.2459	I^2=25.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.96: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

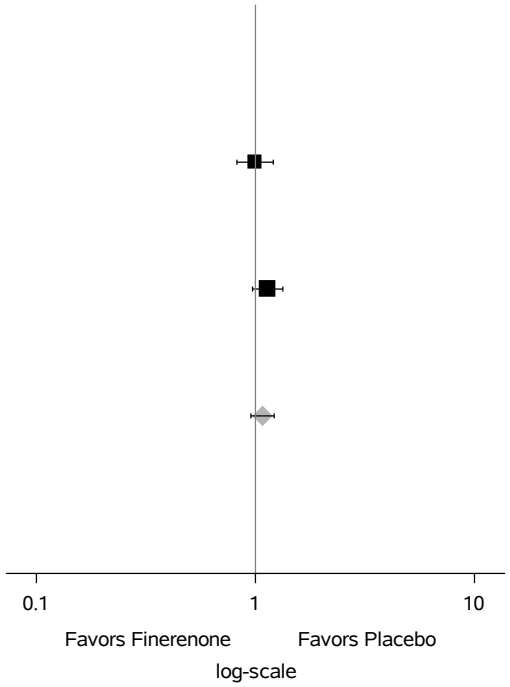
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	773 / 2827	790 / 2831	41.8	0.98 [0.90,1.07]	
FIGARO-DKD	1065 / 3683	1068 / 3658	58.2	0.99 [0.92,1.06]	
Total	1838 / 6510	1858 / 6489		0.99 [0.93,1.04]	Z=-0.51, p=0.6123
Heterogeneity:	Q=0.04 (df=1)	p=0.8494	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.97: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set

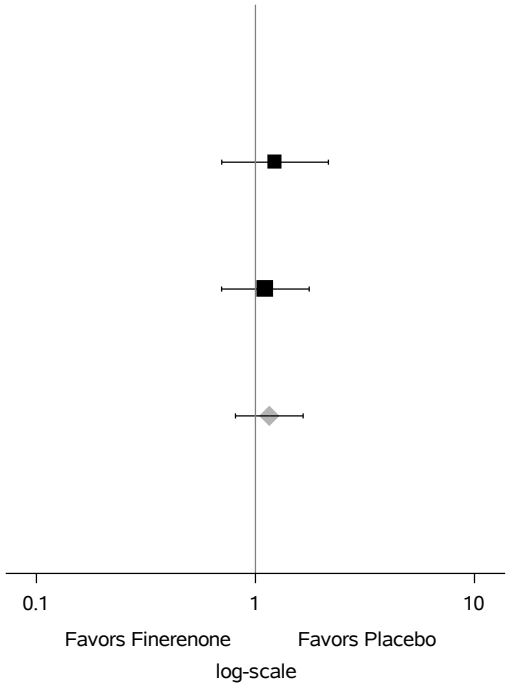
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	196 / 2827	197 / 2831	41.1	1.00 [0.82,1.21]	
FIGARO-DKD	300 / 3683	262 / 3658	58.9	1.14 [0.97,1.33]	
Total	496 / 6510	459 / 6489		1.08 [0.95,1.22]	Z=1.19, p=0.2330
Heterogeneity:	Q=1.09 (df=1)	p=0.2967	I^2=8.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.98: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set

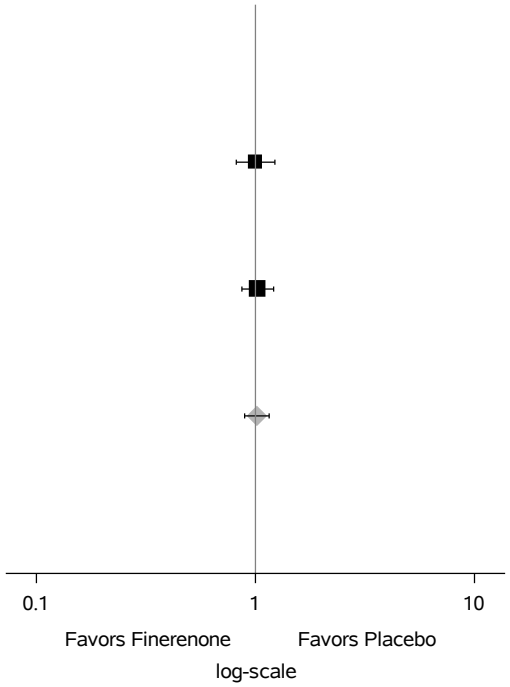
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	22 / 2831	40.3	1.23 [0.70,2.15]	
FIGARO-DKD	38 / 3683	34 / 3658	59.7	1.11 [0.70,1.76]	
Total	65 / 6510	56 / 6489		1.16 [0.81,1.65]	Z=0.80, p=0.4226
Heterogeneity:	Q=0.08 (df=1)	p=0.7833	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.99: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set

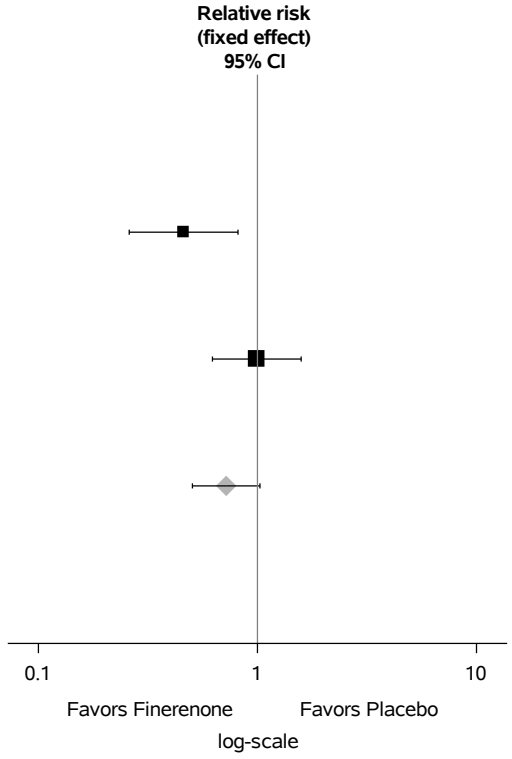
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	175 / 2827	175 / 2831	40.3	1.00 [0.82,1.23]	
FIGARO-DKD	261 / 3683	253 / 3658	59.7	1.02 [0.87,1.21]	
Total	436 / 6510	428 / 6489		1.02 [0.89,1.15]	Z=0.23, p=0.8185
Heterogeneity:	Q=0.03 (df=1)	p=0.8643	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.100: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set

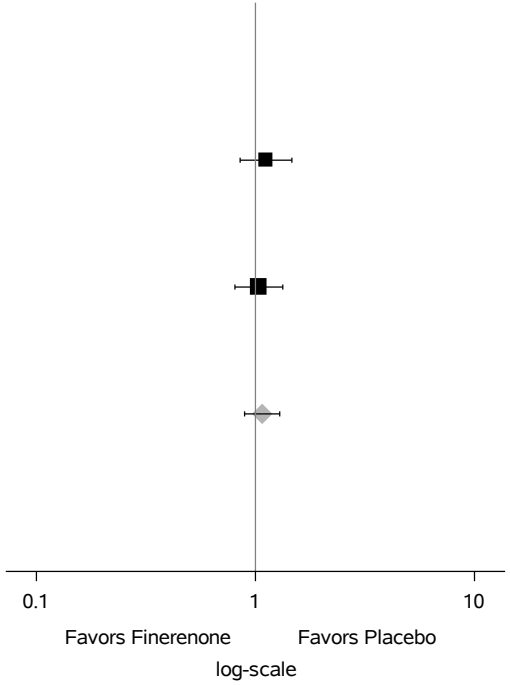
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 2827	37 / 2831	39.9	0.46 [0.26,0.82]	
FIGARO-DKD	35 / 3683	35 / 3658	60.1	0.99 [0.62,1.58]	
Total	52 / 6510	72 / 6489		0.72 [0.50,1.03]	Z=-1.81, p=0.0696
Heterogeneity:	Q=4.18 (df=1)	p=0.0408	I^2=76.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.101: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set

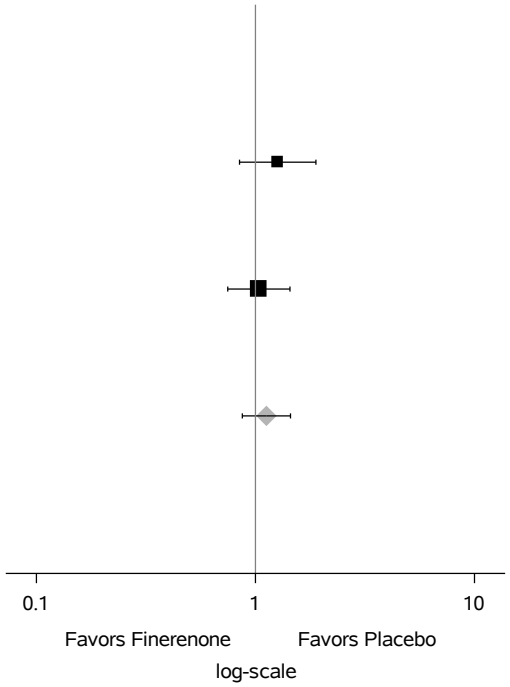
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	106 / 2827	95 / 2831	46.1	1.12 [0.85,1.47]	
FIGARO-DKD	120 / 3683	115 / 3658	53.9	1.04 [0.81,1.33]	
Total	226 / 6510	210 / 6489		1.07 [0.89,1.29]	Z=0.75, p=0.4545
Heterogeneity:	Q=0.16 (df=1)	p=0.6907	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.102: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set

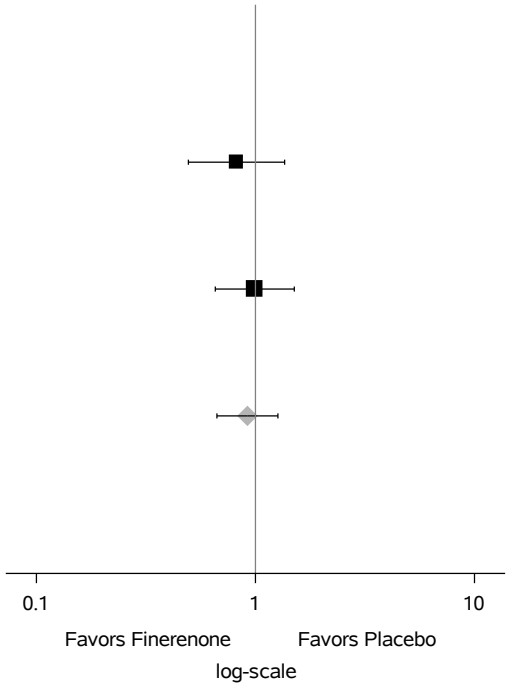
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	42 / 2831	39.9	1.26 [0.85,1.89]	
FIGARO-DKD	72 / 3683	69 / 3658	60.1	1.04 [0.75,1.44]	
Total	125 / 6510	111 / 6489		1.12 [0.87,1.45]	Z=0.89, p=0.3728
Heterogeneity:	Q=0.56 (df=1)	p=0.4530	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.103: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set

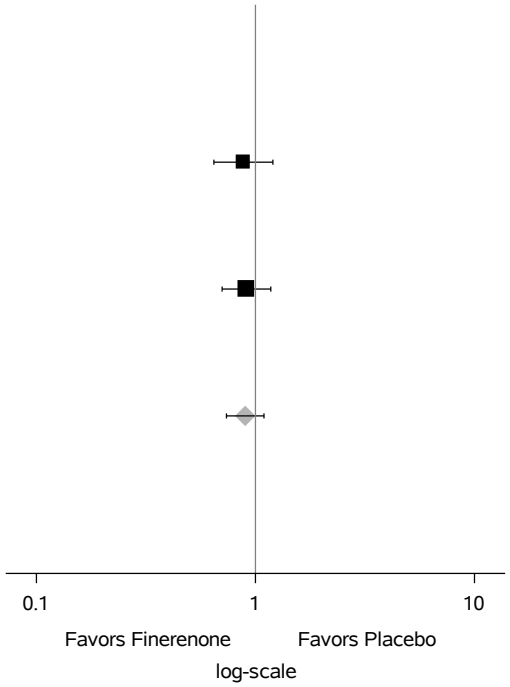
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	33 / 2831	40.3	0.82 [0.49,1.36]	
FIGARO-DKD	44 / 3683	44 / 3658	59.7	0.99 [0.66,1.50]	
Total	71 / 6510	77 / 6489		0.92 [0.67,1.27]	Z=-0.52, p=0.6053
Heterogeneity:	Q=0.33 (df=1)	p=0.5645	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.104: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set

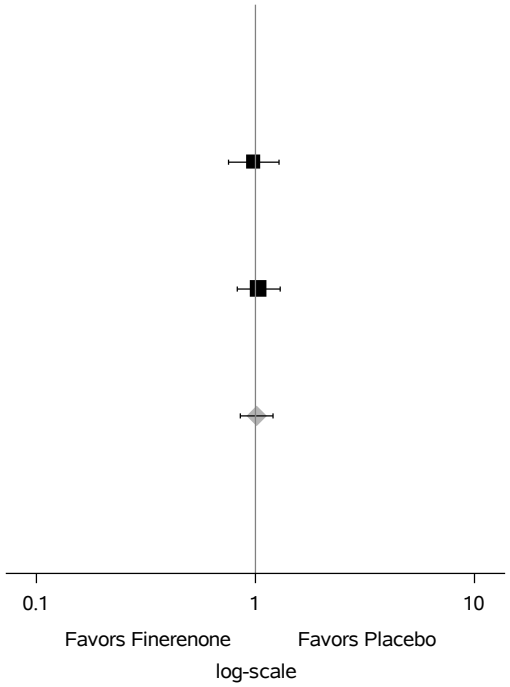
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	73 / 2827	83 / 2831	40.5	0.88 [0.65,1.20]	
FIGARO-DKD	109 / 3683	119 / 3658	59.5	0.91 [0.70,1.17]	
Total	182 / 6510	202 / 6489		0.90 [0.74,1.09]	Z=-1.07, p=0.2847
Heterogeneity:	Q=0.02 (df=1)	p=0.8746	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.105: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set

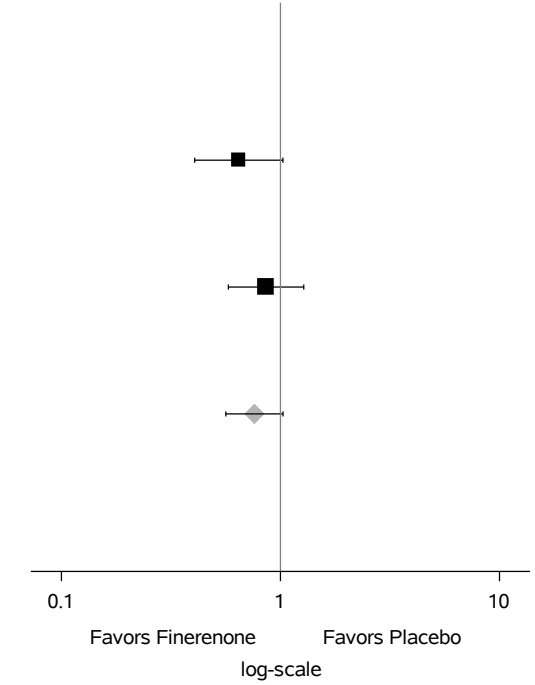
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	106 / 2831	41.9	0.98 [0.75,1.28]	
FIGARO-DKD	148 / 3683	142 / 3658	58.1	1.04 [0.83,1.30]	
Total	252 / 6510	248 / 6489		1.01 [0.85,1.20]	Z=0.14, p=0.8851
Heterogeneity:	Q=0.09 (df=1)	p=0.7690	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.106: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set

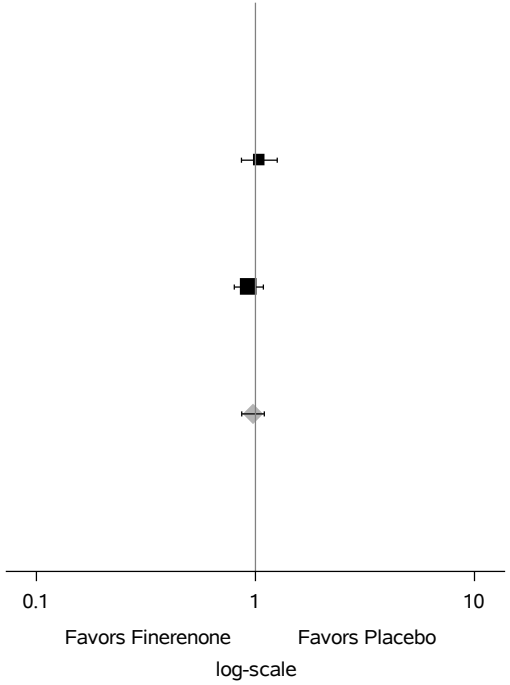
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	45 / 2831	42.2	0.65 [0.41,1.03]	
FIGARO-DKD	45 / 3683	52 / 3658	57.8	0.86 [0.58,1.28]	
Total	74 / 6510	97 / 6489		0.76 [0.56,1.03]	Z=-1.79, p=0.0741
Heterogeneity:	Q=0.85 (df=1)	p=0.3573	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.107: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

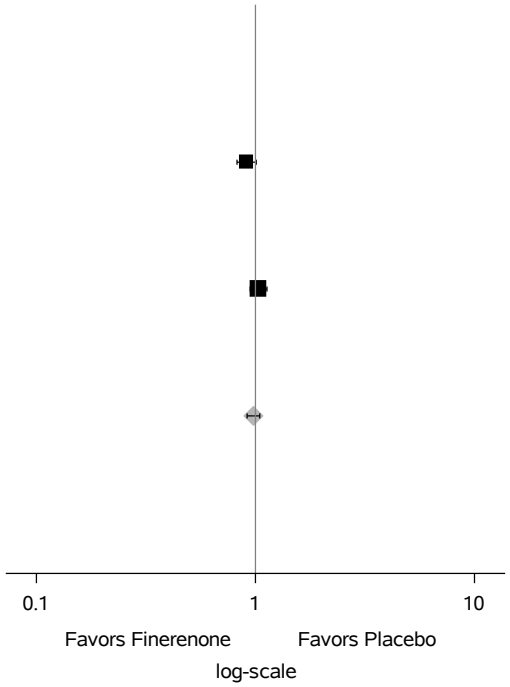
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	206 / 2827	198 / 2831	39.8	1.04 [0.86,1.26]	
FIGARO-DKD	293 / 3683	312 / 3658	60.2	0.93 [0.80,1.09]	
Total	499 / 6510	510 / 6489		0.97 [0.87,1.10]	Z=-0.42, p=0.6715
Heterogeneity:	Q=0.80 (df=1)	p=0.3705	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.108: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

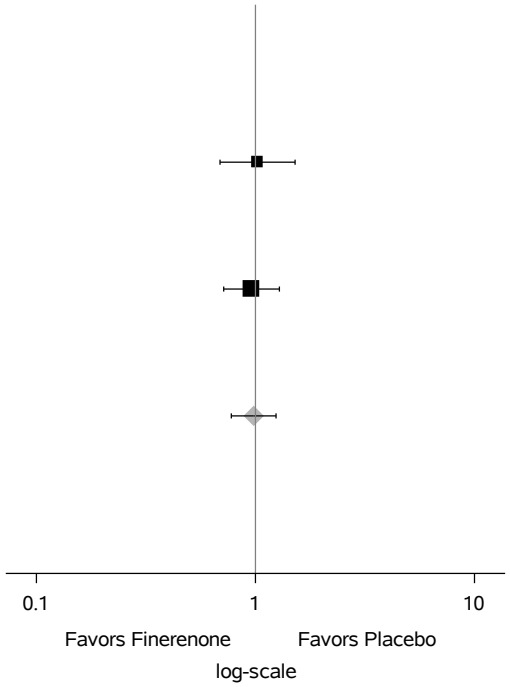
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	567 / 2827	623 / 2831	43.2	0.91 [0.82,1.01]	
FIGARO-DKD	795 / 3683	764 / 3658	56.8	1.03 [0.95,1.13]	
Total	1362 / 6510	1387 / 6489		0.98 [0.92,1.05]	Z=-0.63, p=0.5283
Heterogeneity:	Q=3.38 (df=1)	p=0.0662	I^2=70.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.109: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set

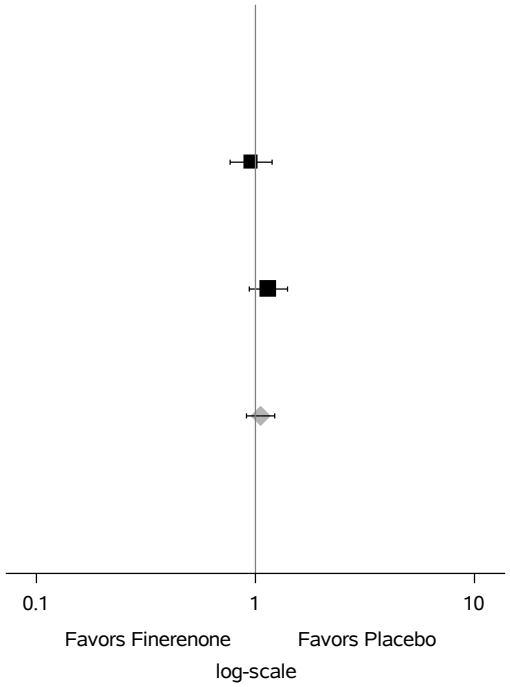
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2827	48 / 2831	35.5	1.02 [0.69,1.52]	
FIGARO-DKD	86 / 3683	89 / 3658	64.5	0.96 [0.72,1.29]	
Total	135 / 6510	137 / 6489		0.98 [0.78,1.24]	Z=-0.16, p=0.8762
Heterogeneity:	Q=0.06 (df=1)	p=0.8012	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.110: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set

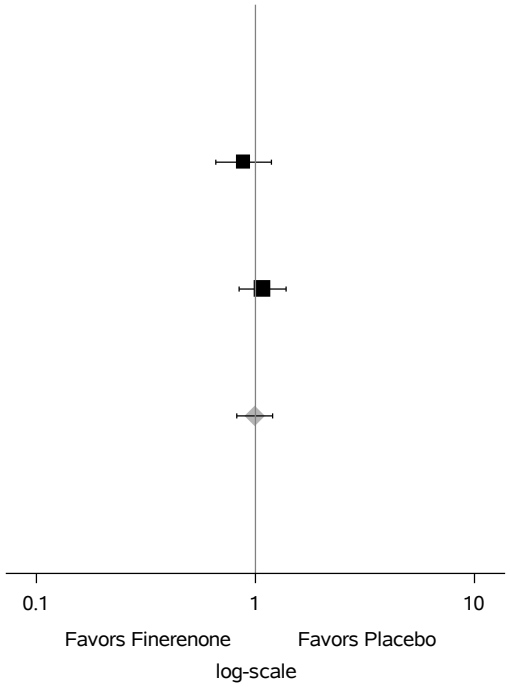
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	146 / 2827	153 / 2831	45.3	0.96 [0.77,1.19]	
FIGARO-DKD	195 / 3683	169 / 3658	54.7	1.15 [0.94,1.40]	
Total	341 / 6510	322 / 6489		1.06 [0.91,1.22]	Z=0.71, p=0.4750
Heterogeneity:	Q=1.42 (df=1)	p=0.2327	I^2=29.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.111: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set

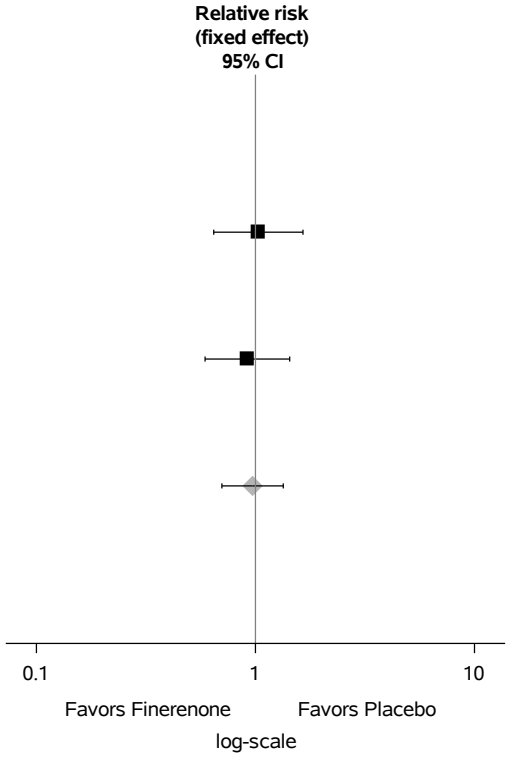
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	82 / 2827	93 / 2831	41.7	0.88 [0.66,1.18]	
FIGARO-DKD	127 / 3683	117 / 3658	58.3	1.08 [0.84,1.38]	
Total	209 / 6510	210 / 6489		0.99 [0.82,1.20]	Z=-0.08, p=0.9334
Heterogeneity:	Q=1.05 (df=1)	p=0.3064	I^2=4.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.112: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set

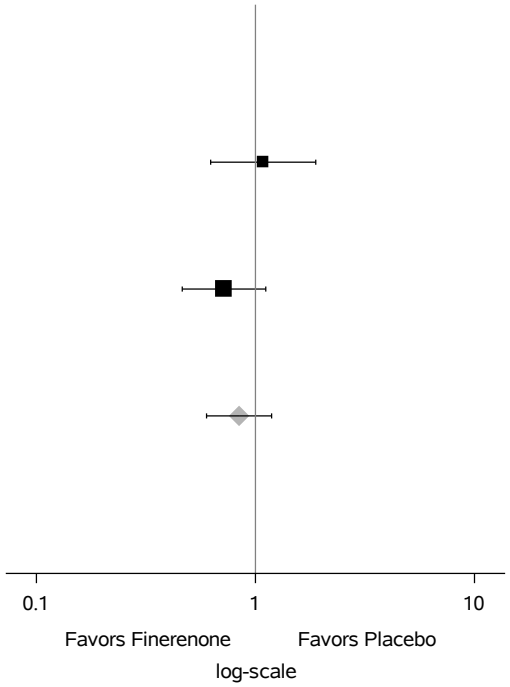
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2827	34 / 2831	47.3	1.03 [0.64,1.65]	
FIGARO-DKD	37 / 3683	40 / 3658	52.7	0.92 [0.59,1.43]	
Total	72 / 6510	74 / 6489		0.97 [0.70,1.34]	Z=-0.18, p=0.8541
Heterogeneity:	Q=0.12 (df=1)	p=0.7269	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.113: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set

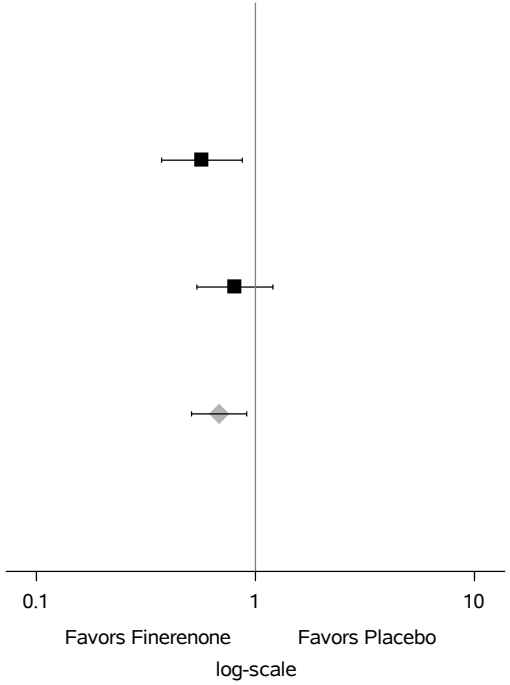
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2827	24 / 2831	38.7	1.08 [0.62,1.88]	
FIGARO-DKD	34 / 3683	47 / 3658	61.3	0.72 [0.46,1.11]	
Total	60 / 6510	71 / 6489		0.84 [0.60,1.18]	Z=-0.99, p=0.3236
Heterogeneity:	Q=1.31 (df=1)	p=0.2523	I^2=23.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.114: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set

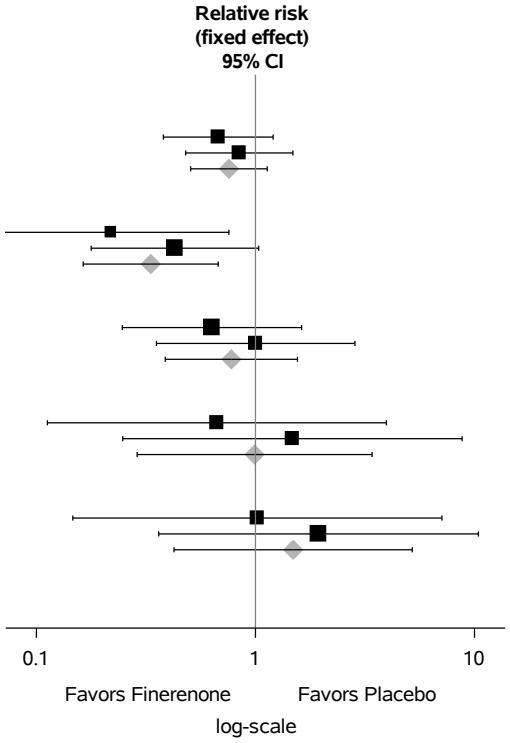
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	58 / 2831	47.0	0.57 [0.37,0.87]	
FIGARO-DKD	43 / 3683	53 / 3658	53.0	0.81 [0.54,1.20]	
Total	76 / 6510	111 / 6489		0.68 [0.51,0.91]	Z=-2.58, p=0.0098
Heterogeneity:	Q=1.36 (df=1)	p=0.2437	I^2=26.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.114.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Syncope (PT with Incidence >=1%)
Safety Analysis Set

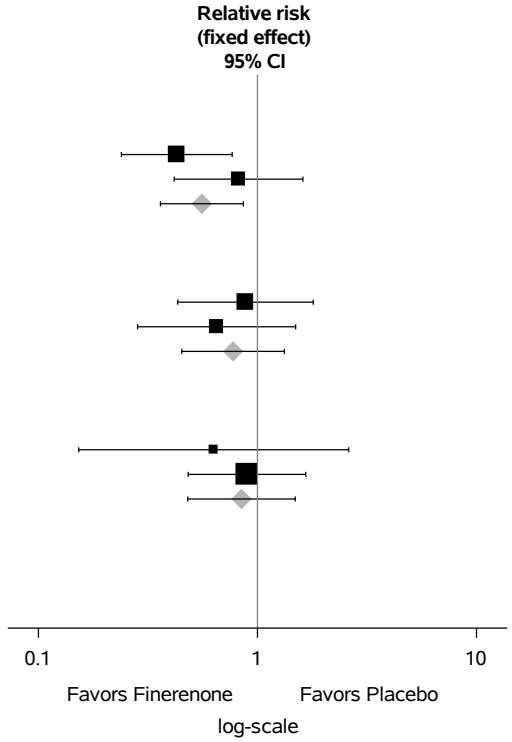
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	19 / 1178	28 / 1174	48.9	0.68 [0.38,1.20]	
FIGARO-DKD	22 / 1752	26 / 1747	51.1	0.84 [0.48,1.48]	
Total	41 / 2930	54 / 2921		0.76 [0.51,1.13]	Z=-1.36, p=0.1746
Heterogeneity:	Q=0.29 (df=1)	p=0.5909	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 466	14 / 476	33.5	0.22 [0.06,0.76]	
FIGARO-DKD	7 / 559	16 / 548	66.5	0.43 [0.18,1.03]	
Total	10 / 1025	30 / 1024		0.33 [0.16,0.68]	Z=-3.04, p=0.0024
Heterogeneity:	Q=0.76 (df=1)	p=0.3841	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 790	11 / 786	55.1	0.63 [0.25,1.62]	
FIGARO-DKD	7 / 811	7 / 813	44.9	1.00 [0.35,2.85]	
Total	14 / 1601	18 / 1599		0.78 [0.39,1.56]	Z=-0.71, p=0.4748
Heterogeneity:	Q=0.41 (df=1)	p=0.5217	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	3 / 294	50.1	0.67 [0.11,3.96]	
FIGARO-DKD	3 / 424	2 / 417	49.9	1.48 [0.25,8.78]	
Total	5 / 718	5 / 711		0.99 [0.29,3.41]	Z=-0.01, p=0.9888
Heterogeneity:	Q=0.38 (df=1)	p=0.5370	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	2 / 101	42.9	1.02 [0.15,7.10]	
FIGARO-DKD	4 / 137	2 / 133	57.1	1.94 [0.36,10.42]	
Total	6 / 236	4 / 234		1.49 [0.42,5.20]	Z=0.62, p=0.5353
Heterogeneity:	Q=0.24 (df=1)	p=0.6230	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.13 (df=4)	p=0.1894	I^2=34.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.114.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set

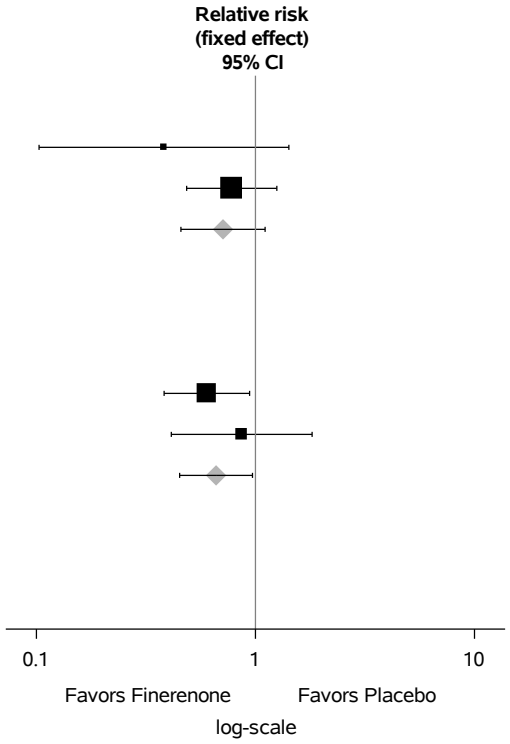
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	16 / 1556	37 / 1541	57.4	0.43 [0.24,0.77]	
FIGARO-DKD	15 / 637	18 / 627	42.6	0.82 [0.42,1.61]	
Total	31 / 2193	55 / 2168		0.56 [0.36,0.86]	Z=-2.63, p=0.0086
Heterogeneity:	Q=2.04 (df=1)	p=0.1532	I^2=51.0%		
45 - < 60					
FIDELIO-DKD	14 / 1061	16 / 1069	57.7	0.88 [0.43,1.80]	
FIGARO-DKD	9 / 720	14 / 729	42.3	0.65 [0.28,1.49]	
Total	23 / 1781	30 / 1798		0.77 [0.45,1.33]	Z=-0.93, p=0.3517
Heterogeneity:	Q=0.30 (df=1)	p=0.5869	I^2=0.0%		
>= 60					
FIDELIO-DKD	3 / 210	5 / 221	15.9	0.63 [0.15,2.61]	
FIGARO-DKD	19 / 2326	21 / 2302	84.1	0.90 [0.48,1.66]	
Total	22 / 2536	26 / 2523		0.85 [0.48,1.49]	Z=-0.58, p=0.5607
Heterogeneity:	Q=0.20 (df=1)	p=0.6582	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.59 (df=2)	p=0.4523	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.114.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set

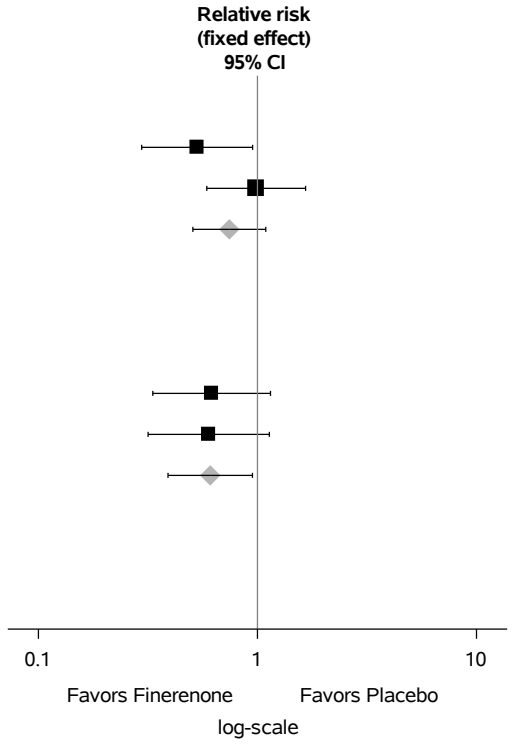
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	8 / 213	11.5	0.38 [0.10,1.42]	
FIGARO-DKD	30 / 1720	38 / 1698	88.5	0.78 [0.49,1.25]	
Total	33 / 1929	46 / 1911		0.71 [0.46,1.11]	Z=-1.51, p=0.1309
Heterogeneity:	Q=1.00 (df=1)	p=0.3166	I^2=0.3%		
Very High					
FIDELIO-DKD	30 / 2618	50 / 2618	73.1	0.60 [0.38,0.94]	
FIGARO-DKD	13 / 1963	15 / 1960	26.9	0.87 [0.41,1.81]	
Total	43 / 4581	65 / 4578		0.66 [0.45,0.97]	Z=-2.12, p=0.0340
Heterogeneity:	Q=0.69 (df=1)	p=0.4071	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8066	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.114.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Syncope (PT with Incidence >=1%)
Safety Analysis Set

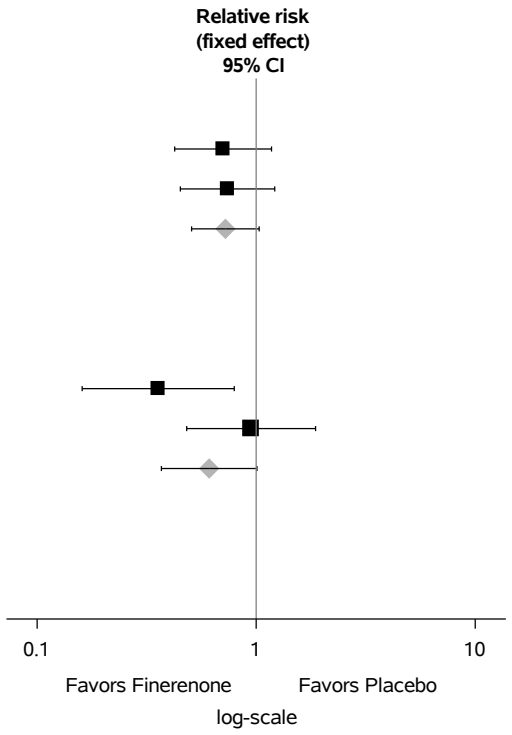
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 1301	32 / 1299	44.2	0.53 [0.30,0.95]	
FIGARO-DKD	28 / 1673	28 / 1651	55.8	0.99 [0.59,1.66]	
Total	45 / 2974	60 / 2950		0.74 [0.51,1.09]	Z=-1.51, p=0.1303
Heterogeneity:	Q=2.43 (df=1)	p=0.1191	I^2=58.8%		
Absent					
FIDELIO-DKD	16 / 1526	26 / 1532	51.5	0.62 [0.33,1.15]	
FIGARO-DKD	15 / 2010	25 / 2007	48.5	0.60 [0.32,1.13]	
Total	31 / 3536	51 / 3539		0.61 [0.39,0.95]	Z=-2.19, p=0.0283
Heterogeneity:	Q=0.00 (df=1)	p=0.9459	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.45 (df=1)	p=0.5022	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.114.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set

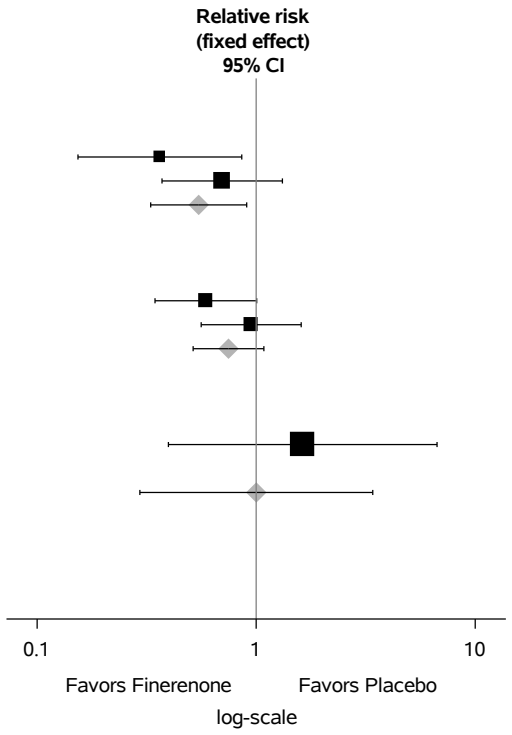
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1879	35 / 1858	48.7	0.71 [0.42,1.18]	
FIGARO-DKD	27 / 2643	36 / 2608	51.3	0.74 [0.45,1.22]	
Total	52 / 4522	71 / 4466		0.72 [0.51,1.03]	Z=-1.79, p=0.0741
Heterogeneity:	Q=0.02 (df=1)	p=0.8976	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 948	23 / 973	41.8	0.36 [0.16,0.79]	
FIGARO-DKD	16 / 1040	17 / 1048	58.2	0.95 [0.48,1.87]	
Total	24 / 1988	40 / 2021		0.61 [0.37,1.01]	Z=-1.93, p=0.0537
Heterogeneity:	Q=3.36 (df=1)	p=0.0670	I^2=70.2%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5869	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.114.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set

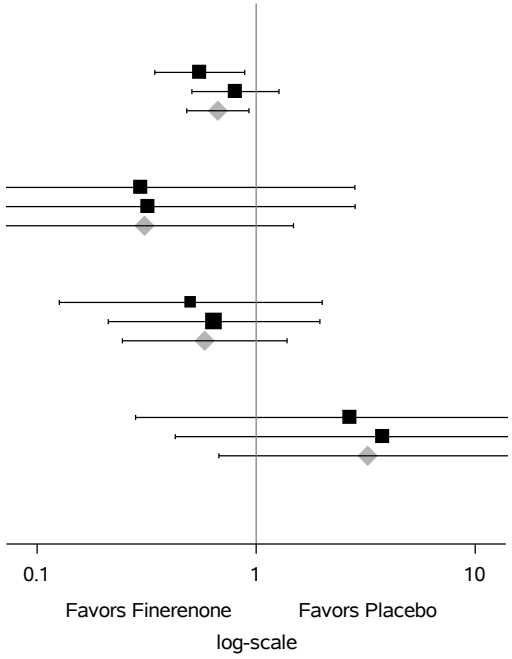
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 788	19 / 777	35.1	0.36 [0.15,0.86]	
FIGARO-DKD	16 / 1187	23 / 1194	64.9	0.70 [0.37,1.32]	
Total	23 / 1975	42 / 1971		0.55 [0.33,0.91]	Z=-2.35, p=0.0189
Heterogeneity:	Q=1.45 (df=1)	p=0.2285	I^2=31.0%		
130 - < 160					
FIDELIO-DKD	21 / 1897	36 / 1916	49.2	0.59 [0.35,1.01]	
FIGARO-DKD	27 / 2389	28 / 2351	50.8	0.95 [0.56,1.61]	
Total	48 / 4286	64 / 4267		0.75 [0.52,1.08]	Z=-1.53, p=0.1252
Heterogeneity:	Q=1.55 (df=1)	p=0.2126	I^2=35.6%		
>= 160					
FIDELIO-DKD	5 / 141	3 / 138	100.0	1.63 [0.40,6.69]	
FIGARO-DKD	0 / 107	2 / 113	0.0	0.00 [0.00,2E297]	
Total	5 / 248	5 / 251		1.00 [0.29,3.41]	Z=0.00, p=0.9982
Heterogeneity:	Q=0.46 (df=1)	p=0.4982	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.35 (df=2)	p=0.5084	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.114.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Syncope (PT with Incidence >=1%)
Safety Analysis Set

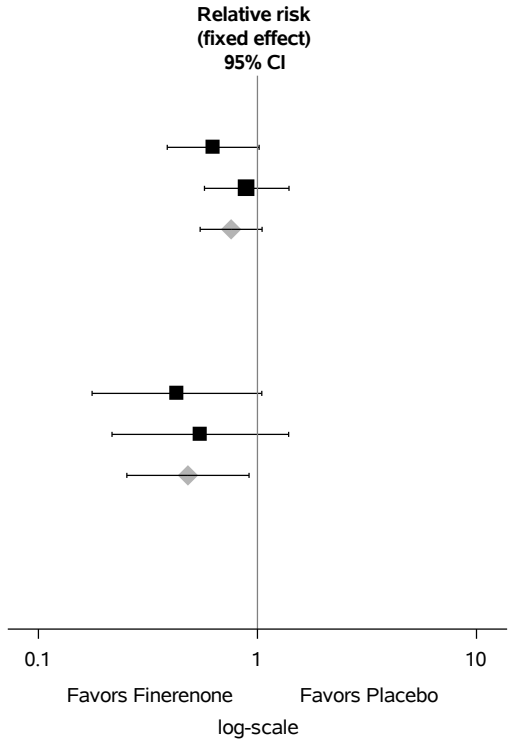
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	26 / 1773	48 / 1809	48.4	0.55 [0.34,0.89]	
FIGARO-DKD	33 / 2668	40 / 2601	51.6	0.80 [0.51,1.27]	
Total	59 / 4441	88 / 4410		0.67 [0.48,0.93]	Z=-2.41, p=0.0157
Heterogeneity:	Q=1.25 (df=1)	p=0.2637	I^2=20.0%		
Black					
FIDELIO-DKD	1 / 139	3 / 124	48.4	0.30 [0.03,2.82]	
FIGARO-DKD	1 / 113	4 / 145	51.6	0.32 [0.04,2.83]	
Total	2 / 252	7 / 269		0.31 [0.06,1.48]	Z=-1.47, p=0.1419
Heterogeneity:	Q=0.00 (df=1)	p=0.9621	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 717	6 / 721	39.3	0.50 [0.13,2.00]	
FIGARO-DKD	5 / 716	8 / 736	60.7	0.64 [0.21,1.95]	
Total	8 / 1433	14 / 1457		0.58 [0.25,1.38]	Z=-1.22, p=0.2206
Heterogeneity:	Q=0.07 (df=1)	p=0.7865	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	48.4	2.68 [0.28,25.55]	
FIGARO-DKD	4 / 186	1 / 176	51.6	3.78 [0.43,33.54]	
Total	7 / 384	2 / 353		3.23 [0.68,15.45]	Z=1.47, p=0.1419
Heterogeneity:	Q=0.05 (df=1)	p=0.8294	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.92 (df=3)	p=0.1780	I^2=39.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.114.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Syncope (PT with Incidence >=1%)
Safety Analysis Set

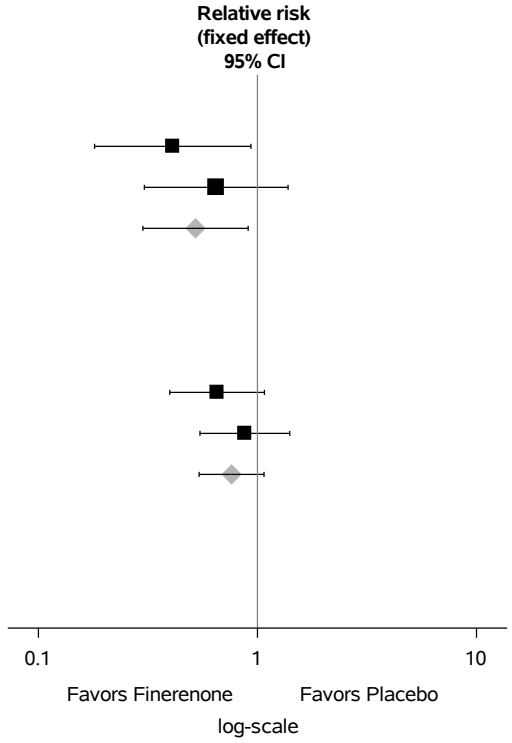
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 1949	43 / 2024	45.8	0.63 [0.39,1.02]	
FIGARO-DKD	36 / 2527	41 / 2571	54.2	0.89 [0.57,1.39]	
Total	62 / 4476	84 / 4595		0.76 [0.55,1.05]	Z=-1.67, p=0.0955
Heterogeneity:	Q=1.11 (df=1)	p=0.2923	I^2=9.8%		
Female					
FIDELIO-DKD	7 / 878	15 / 807	52.0	0.43 [0.18,1.05]	
FIGARO-DKD	7 / 1156	12 / 1087	48.0	0.55 [0.22,1.39]	
Total	14 / 2034	27 / 1894		0.48 [0.25,0.92]	Z=-2.23, p=0.0257
Heterogeneity:	Q=0.14 (df=1)	p=0.7081	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.53 (df=1)	p=0.2167	I^2=34.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.114.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Syncope (PT with Incidence >=1%)
Safety Analysis Set

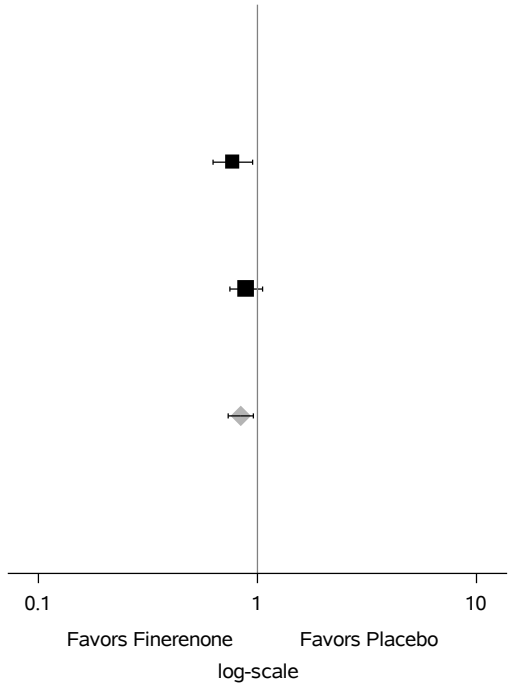
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 1201	19 / 1171	45.8	0.41 [0.18,0.93]	
FIGARO-DKD	11 / 1752	17 / 1755	54.2	0.65 [0.30,1.38]	
Total	19 / 2953	36 / 2926		0.52 [0.30,0.91]	Z=-2.31, p=0.0211
Heterogeneity:	Q=0.64 (df=1)	p=0.4224	I^2=0.0%		
>= 65					
FIDELIO-DKD	25 / 1626	39 / 1660	47.4	0.65 [0.40,1.08]	
FIGARO-DKD	32 / 1931	36 / 1903	52.6	0.88 [0.55,1.40]	
Total	57 / 3557	75 / 3563		0.76 [0.54,1.07]	Z=-1.56, p=0.1181
Heterogeneity:	Q=0.69 (df=1)	p=0.4046	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.31 (df=1)	p=0.2533	I^2=23.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

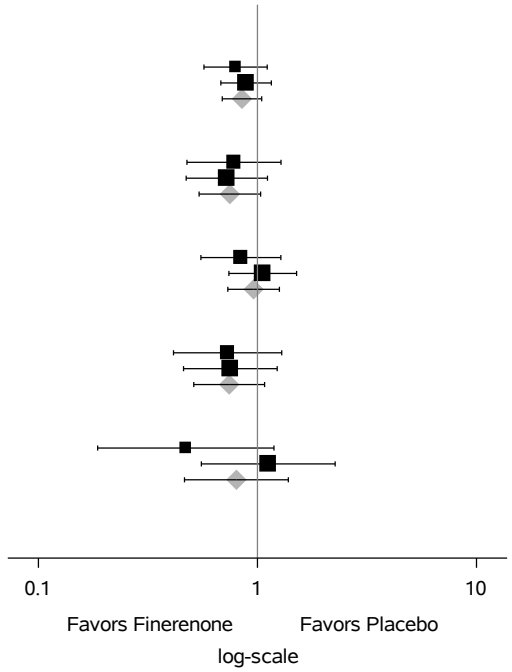
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	148 / 2827	192 / 2831	40.6	0.77 [0.63,0.95]	
FIGARO-DKD	230 / 3683	257 / 3658	59.4	0.89 [0.75,1.06]	
Total	378 / 6510	449 / 6489		0.84 [0.74,0.96]	Z=-2.60, p=0.0095
Heterogeneity:	Q=1.05 (df=1)	p=0.3055	I^2=4.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.115.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	59 / 1178	74 / 1174	38.9	0.79 [0.57,1.11]	
FIGARO-DKD	97 / 1752	109 / 1747	61.1	0.89 [0.68,1.16]	
Total	156 / 2930	183 / 2921		0.85 [0.69,1.05]	Z=-1.54, p=0.1242
Heterogeneity:	Q=0.26 (df=1)	p=0.6109	I^2=0.0%		
North America					
FIDELIO-DKD	26 / 466	34 / 476	42.8	0.78 [0.48,1.28]	
FIGARO-DKD	34 / 559	46 / 548	57.2	0.72 [0.47,1.11]	
Total	60 / 1025	80 / 1024		0.75 [0.54,1.03]	Z=-1.76, p=0.0786
Heterogeneity:	Q=0.05 (df=1)	p=0.8217	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	45 / 786	41.7	0.84 [0.55,1.28]	
FIGARO-DKD	58 / 811	55 / 813	58.3	1.06 [0.74,1.51]	
Total	96 / 1601	100 / 1599		0.96 [0.73,1.26]	Z=-0.29, p=0.7695
Heterogeneity:	Q=0.67 (df=1)	p=0.4136	I^2=0.0%		
Latin America					
FIDELIO-DKD	19 / 294	26 / 294	42.8	0.73 [0.41,1.29]	
FIGARO-DKD	26 / 424	34 / 417	57.2	0.75 [0.46,1.23]	
Total	45 / 718	60 / 711		0.74 [0.51,1.08]	Z=-1.56, p=0.1177
Heterogeneity:	Q=0.01 (df=1)	p=0.9403	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 99	13 / 101	36.5	0.47 [0.19,1.19]	
FIGARO-DKD	15 / 137	13 / 133	63.5	1.12 [0.55,2.26]	
Total	21 / 236	26 / 234		0.80 [0.46,1.38]	Z=-0.79, p=0.4270
Heterogeneity:	Q=2.14 (df=1)	p=0.1439	I^2=53.2%		
Subgroup Heterogeneity:	Q=1.89 (df=4)	p=0.7565	I^2=0.0%		

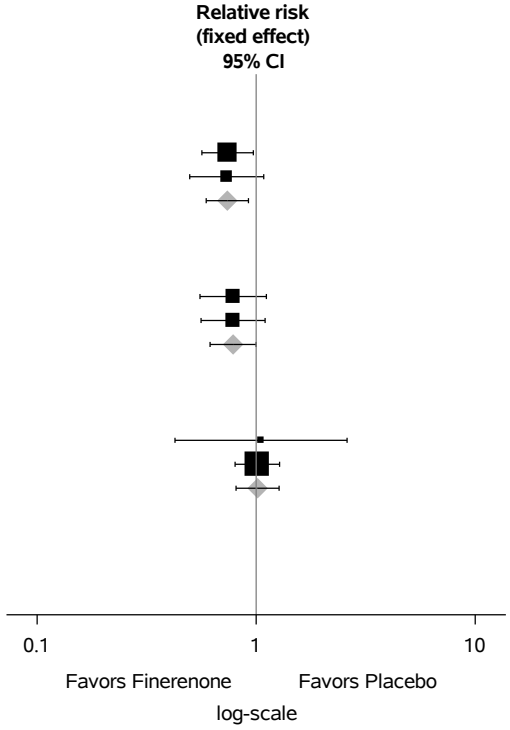


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Psychiatric Disorders (SOC with Incidence >=1%)

Safety Analysis Set

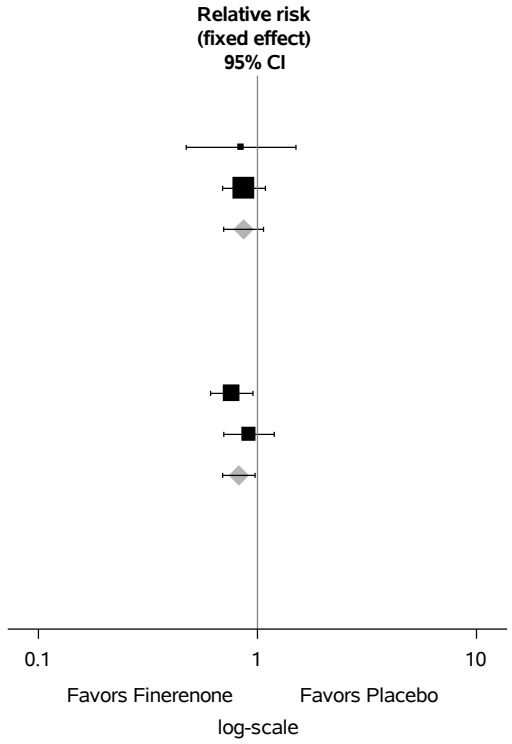
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	86 / 1556	115 / 1541	67.4	0.74 [0.57,0.97]	
FIGARO-DKD	41 / 637	55 / 627	32.6	0.73 [0.50,1.08]	
Total	127 / 2193	170 / 2168		0.74 [0.59,0.92]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.00 (df=1)	p=0.9693	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	53 / 1061	68 / 1069	48.2	0.79 [0.55,1.11]	
FIGARO-DKD	55 / 720	71 / 729	51.8	0.78 [0.56,1.10]	
Total	108 / 1781	139 / 1798		0.78 [0.62,1.00]	Z=-1.96, p=0.0499
Heterogeneity:	Q=0.00 (df=1)	p=0.9961	I^2=0.0%		
>= 60					
FIDELIO-DKD	9 / 210	9 / 221	6.3	1.05 [0.43,2.60]	
FIGARO-DKD	134 / 2326	131 / 2302	93.7	1.01 [0.80,1.28]	
Total	143 / 2536	140 / 2523		1.01 [0.81,1.27]	Z=0.13, p=0.8987
Heterogeneity:	Q=0.01 (df=1)	p=0.9351	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.28 (df=2)	p=0.1178	I^2=53.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

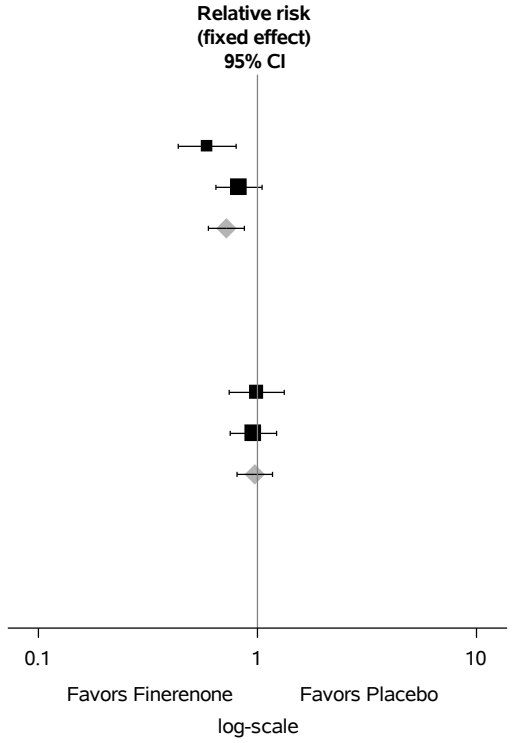
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	19 / 209	23 / 213	13.2	0.84 [0.47,1.50]	
FIGARO-DKD	131 / 1720	149 / 1698	86.8	0.87 [0.69,1.09]	
Total	150 / 1929	172 / 1911		0.86 [0.70,1.07]	Z=-1.36, p=0.1732
Heterogeneity:	Q=0.01 (df=1)	p=0.9232	I^2=0.0%		
Very High					
FIDELIO-DKD	129 / 2618	169 / 2618	58.7	0.76 [0.61,0.95]	
FIGARO-DKD	99 / 1963	108 / 1960	41.3	0.92 [0.70,1.19]	
Total	228 / 4581	277 / 4578		0.82 [0.69,0.98]	Z=-2.25, p=0.0245
Heterogeneity:	Q=1.05 (df=1)	p=0.3044	I^2=5.2%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7176	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	62 / 1301	105 / 1299	38.9	0.59 [0.43,0.80]	
FIGARO-DKD	111 / 1673	133 / 1651	61.1	0.82 [0.65,1.05]	
Total	173 / 2974	238 / 2950		0.72 [0.60,0.87]	Z=-3.39, p=0.0007
Heterogeneity:	Q=2.83 (df=1)	p=0.0923	I^2=64.7%		
Absent					
FIDELIO-DKD	86 / 1526	87 / 1532	41.5	0.99 [0.74,1.33]	
FIGARO-DKD	119 / 2010	124 / 2007	58.5	0.96 [0.75,1.22]	
Total	205 / 3536	211 / 3539		0.97 [0.81,1.17]	Z=-0.30, p=0.7675
Heterogeneity:	Q=0.03 (df=1)	p=0.8561	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.86 (df=1)	p=0.0275	I^2=79.4%		

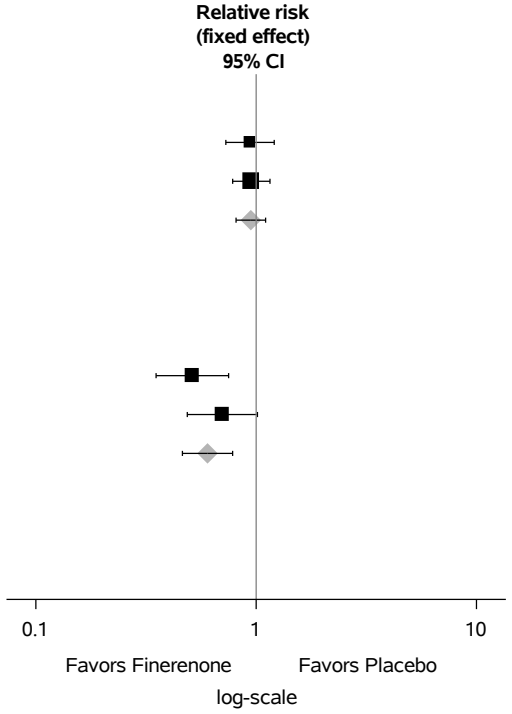


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)

Safety Analysis Set

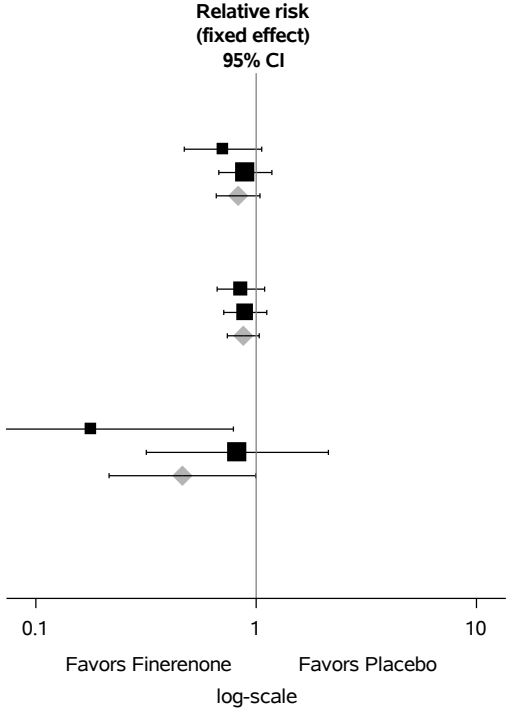
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	110 / 1879	116 / 1858	37.3	0.94 [0.73,1.21]	
FIGARO-DKD	184 / 2643	191 / 2608	62.7	0.95 [0.78,1.16]	
Total	294 / 4522	307 / 4466		0.95 [0.81,1.10]	Z=-0.71, p=0.4791
Heterogeneity:	Q=0.01 (df=1)	p=0.9331	I^2=0.0%		
> 4.5					
FIDELIO-DKD	38 / 948	76 / 973	48.3	0.51 [0.35,0.75]	
FIGARO-DKD	46 / 1040	66 / 1048	51.7	0.70 [0.49,1.01]	
Total	84 / 1988	142 / 2021		0.60 [0.46,0.78]	Z=-3.80, p=0.0001
Heterogeneity:	Q=1.36 (df=1)	p=0.2433	I^2=26.5%		
Subgroup Heterogeneity:	Q=8.49 (df=1)	p=0.0036	I^2=88.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.115.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

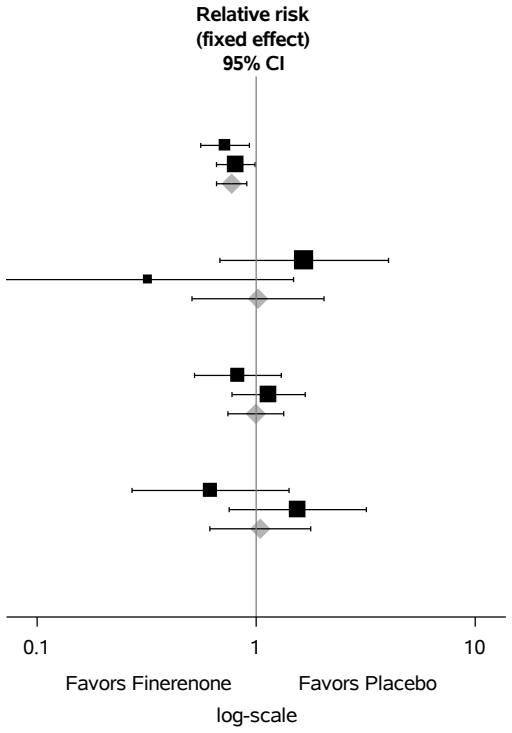
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	38 / 788	53 / 777	32.0	0.71 [0.47,1.06]	
FIGARO-DKD	87 / 1187	98 / 1194	68.0	0.89 [0.68,1.18]	
Total	125 / 1975	151 / 1971		0.83 [0.66,1.04]	Z=-1.62, p=0.1057
Heterogeneity:	Q=0.87 (df=1)	p=0.3507	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	108 / 1897	128 / 1916	45.1	0.85 [0.66,1.09]	
FIGARO-DKD	136 / 2389	150 / 2351	54.9	0.89 [0.71,1.12]	
Total	244 / 4286	278 / 4267		0.87 [0.74,1.03]	Z=-1.59, p=0.1130
Heterogeneity:	Q=0.07 (df=1)	p=0.7881	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 141	11 / 138	29.0	0.18 [0.04,0.79]	
FIGARO-DKD	7 / 107	9 / 113	71.0	0.82 [0.32,2.13]	
Total	9 / 248	20 / 251		0.46 [0.21,1.00]	Z=-1.97, p=0.0487
Heterogeneity:	Q=2.98 (df=1)	p=0.0842	I^2=66.5%		
Subgroup Heterogeneity:	Q=2.56 (df=2)	p=0.2784	I^2=21.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.115.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

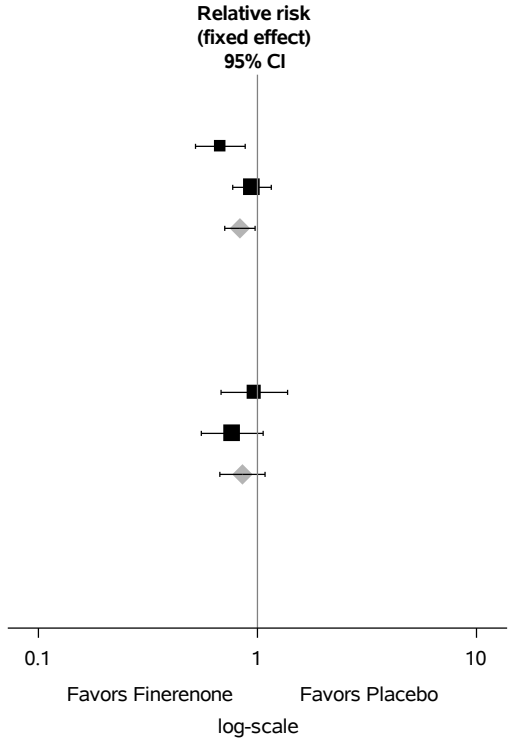
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	94 / 1773	133 / 1809	38.7	0.72 [0.56,0.93]	
FIGARO-DKD	159 / 2668	192 / 2601	61.3	0.81 [0.66,0.99]	
Total	253 / 4441	325 / 4410		0.77 [0.66,0.91]	Z=-3.18, p=0.0015
Heterogeneity:	Q=0.46 (df=1)	p=0.4980	I^2=0.0%		
Black					
FIDELIO-DKD	13 / 139	7 / 124	74.9	1.66 [0.68,4.02]	
FIGARO-DKD	2 / 113	8 / 145	25.1	0.32 [0.07,1.48]	
Total	15 / 252	15 / 269		1.02 [0.51,2.04]	Z=0.05, p=0.9566
Heterogeneity:	Q=3.35 (df=1)	p=0.0673	I^2=70.1%		
Asian					
FIDELIO-DKD	32 / 717	39 / 721	41.6	0.83 [0.52,1.30]	
FIGARO-DKD	51 / 716	46 / 736	58.4	1.14 [0.78,1.67]	
Total	83 / 1433	85 / 1457		1.00 [0.74,1.34]	Z=-0.03, p=0.9781
Heterogeneity:	Q=1.13 (df=1)	p=0.2888	I^2=11.1%		
Others					
FIDELIO-DKD	9 / 198	13 / 177	43.3	0.62 [0.27,1.41]	
FIGARO-DKD	18 / 186	11 / 176	56.7	1.55 [0.75,3.18]	
Total	27 / 384	24 / 353		1.04 [0.61,1.77]	Z=0.16, p=0.8733
Heterogeneity:	Q=2.69 (df=1)	p=0.1010	I^2=62.8%		
Subgroup Heterogeneity:	Q=3.30 (df=3)	p=0.3477	I^2=9.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.115.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

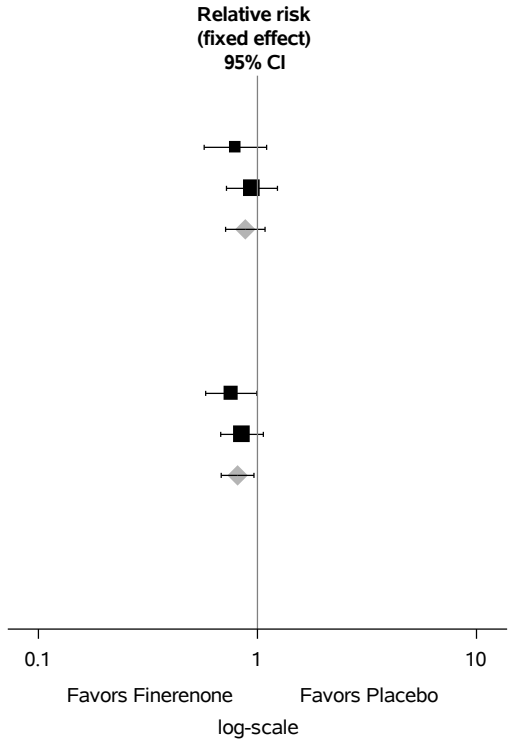
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	88 / 1949	135 / 2024	37.6	0.68 [0.52,0.88]	
FIGARO-DKD	168 / 2527	181 / 2571	62.4	0.94 [0.77,1.16]	
Total	256 / 4476	316 / 4595		0.83 [0.71,0.98]	Z=-2.26, p=0.0236
Heterogeneity:	Q=3.90 (df=1)	p=0.0484	I^2=74.3%		
Female					
FIDELIO-DKD	60 / 878	57 / 807	46.4	0.97 [0.68,1.37]	
FIGARO-DKD	62 / 1156	76 / 1087	53.6	0.77 [0.55,1.06]	
Total	122 / 2034	133 / 1894		0.85 [0.67,1.08]	Z=-1.30, p=0.1929
Heterogeneity:	Q=0.91 (df=1)	p=0.3406	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8562	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.115.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

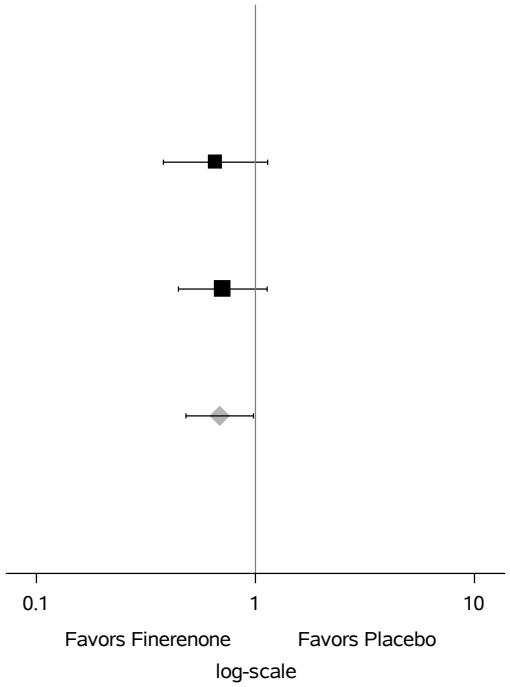
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	61 / 1201	75 / 1171	40.0	0.79 [0.57,1.10]	
FIGARO-DKD	98 / 1752	104 / 1755	60.0	0.94 [0.72,1.23]	
Total	159 / 2953	179 / 2926		0.88 [0.72,1.08]	Z=-1.21, p=0.2277
Heterogeneity:	Q=0.65 (df=1)	p=0.4203	I^2=0.0%		
>= 65					
FIDELIO-DKD	87 / 1626	117 / 1660	41.0	0.76 [0.58,0.99]	
FIGARO-DKD	132 / 1931	153 / 1903	59.0	0.85 [0.68,1.06]	
Total	219 / 3557	270 / 3563		0.81 [0.68,0.96]	Z=-2.38, p=0.0173
Heterogeneity:	Q=0.40 (df=1)	p=0.5257	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5545	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

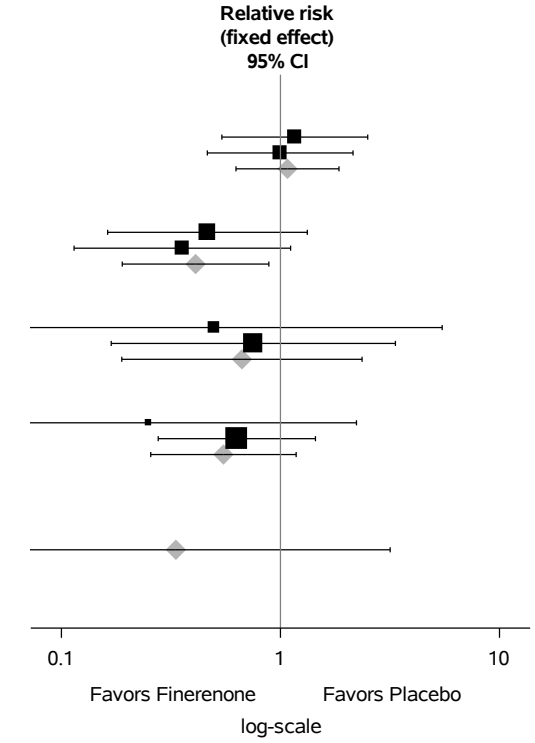
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	32 / 2831	42.0	0.66 [0.38,1.14]	
FIGARO-DKD	30 / 3683	42 / 3658	58.0	0.71 [0.45,1.13]	
Total	51 / 6510	74 / 6489		0.69 [0.48,0.98]	Z=-2.07, p=0.0382
Heterogeneity:	Q=0.04 (df=1)	p=0.8349	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.116.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

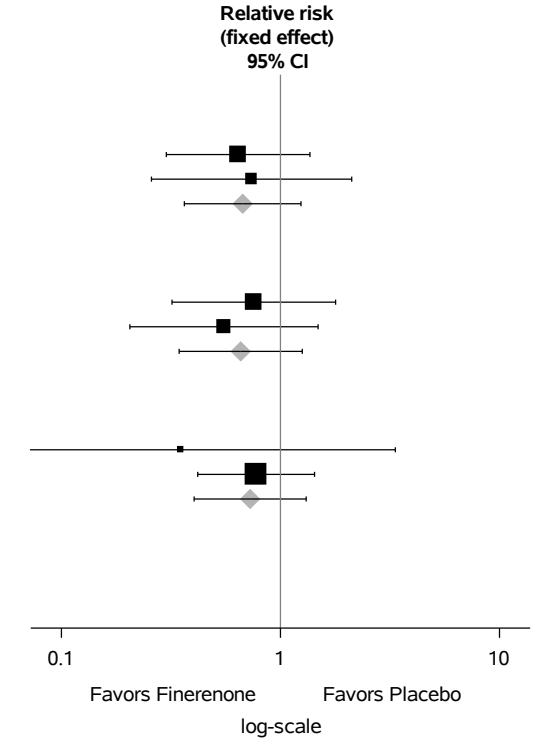
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	14 / 1178	12 / 1174	49.9	1.16 [0.54,2.50]	
FIGARO-DKD	13 / 1752	13 / 1747	50.1	1.00 [0.46,2.14]	
Total	27 / 2930	25 / 2921		1.08 [0.63,1.85]	Z=0.27, p=0.7889
Heterogeneity:	Q=0.08 (df=1)	p=0.7812	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 466	11 / 476	54.1	0.46 [0.16,1.33]	
FIGARO-DKD	4 / 559	11 / 548	45.9	0.36 [0.11,1.11]	
Total	9 / 1025	22 / 1024		0.41 [0.19,0.89]	Z=-2.27, p=0.0232
Heterogeneity:	Q=0.11 (df=1)	p=0.7379	I^2=0.0%		
Asia					
FIDELIO-DKD	1 / 790	2 / 786	27.9	0.50 [0.05,5.48]	
FIGARO-DKD	3 / 811	4 / 813	72.1	0.75 [0.17,3.35]	
Total	4 / 1601	6 / 1599		0.67 [0.19,2.36]	Z=-0.63, p=0.5296
Heterogeneity:	Q=0.08 (df=1)	p=0.7744	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	4 / 294	12.5	0.25 [0.03,2.22]	
FIGARO-DKD	9 / 424	14 / 417	87.5	0.63 [0.28,1.44]	
Total	10 / 718	18 / 711		0.55 [0.26,1.18]	Z=-1.54, p=0.1244
Heterogeneity:	Q=0.61 (df=1)	p=0.4349	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	3 / 101	0.0	0.00 [0.00,1E296]	
FIGARO-DKD	1 / 137	0 / 133	0.0	103E9 [103E9,103E9]	
Total	1 / 236	3 / 234		0.33 [0.04,3.17]	Z=-0.96, p=0.3388
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=5.10 (df=4)	p=0.2776	I^2=21.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

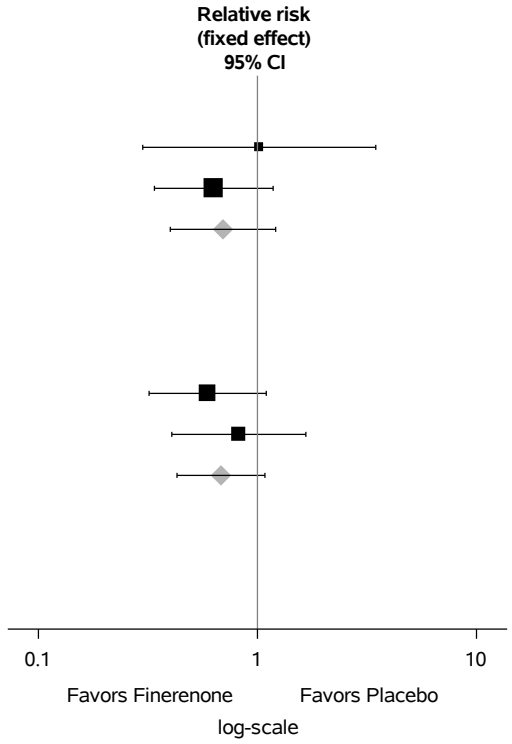
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	11 / 1556	17 / 1541	66.0	0.64 [0.30,1.36]	
FIGARO-DKD	6 / 637	8 / 627	34.0	0.74 [0.26,2.12]	
Total	17 / 2193	25 / 2168		0.67 [0.36,1.24]	Z=-1.27, p=0.2041
Heterogeneity:	Q=0.05 (df=1)	p=0.8305	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	12 / 1069	57.0	0.76 [0.32,1.79]	
FIGARO-DKD	6 / 720	11 / 729	43.0	0.55 [0.21,1.49]	
Total	15 / 1781	23 / 1798		0.66 [0.34,1.26]	Z=-1.27, p=0.2057
Heterogeneity:	Q=0.22 (df=1)	p=0.6392	I^2=0.0%		
>= 60					
FIDELIO-DKD	1 / 210	3 / 221	6.9	0.35 [0.04,3.35]	
FIGARO-DKD	18 / 2326	23 / 2302	93.1	0.77 [0.42,1.43]	
Total	19 / 2536	26 / 2523		0.73 [0.40,1.31]	Z=-1.06, p=0.2890
Heterogeneity:	Q=0.44 (df=1)	p=0.5062	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=2)	p=0.9718	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

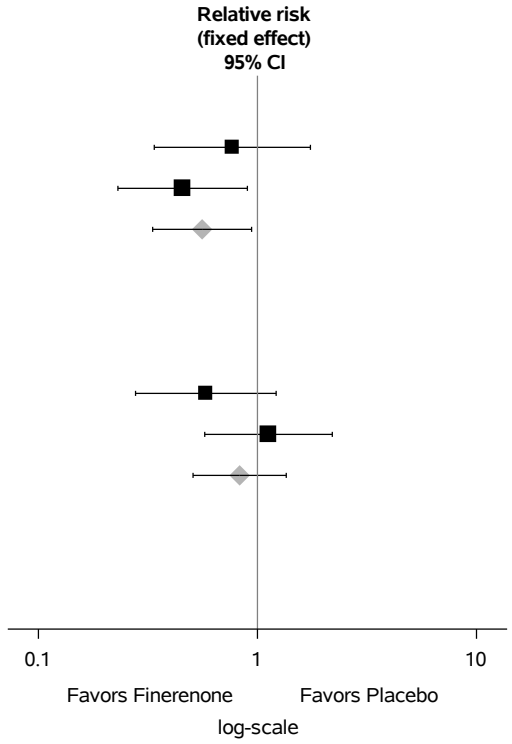
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	5 / 209	5 / 213	20.6	1.02 [0.30,3.47]	
FIGARO-DKD	16 / 1720	25 / 1698	79.4	0.63 [0.34,1.18]	
Total	21 / 1929	30 / 1911		0.70 [0.40,1.21]	Z=-1.28, p=0.1996
Heterogeneity:	Q=0.46 (df=1)	p=0.4954	I^2=0.0%		
Very High					
FIDELIO-DKD	16 / 2618	27 / 2618	56.7	0.59 [0.32,1.10]	
FIGARO-DKD	14 / 1963	17 / 1960	43.3	0.82 [0.41,1.66]	
Total	30 / 4581	44 / 4578		0.68 [0.43,1.08]	Z=-1.63, p=0.1038
Heterogeneity:	Q=0.47 (df=1)	p=0.4927	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9540	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

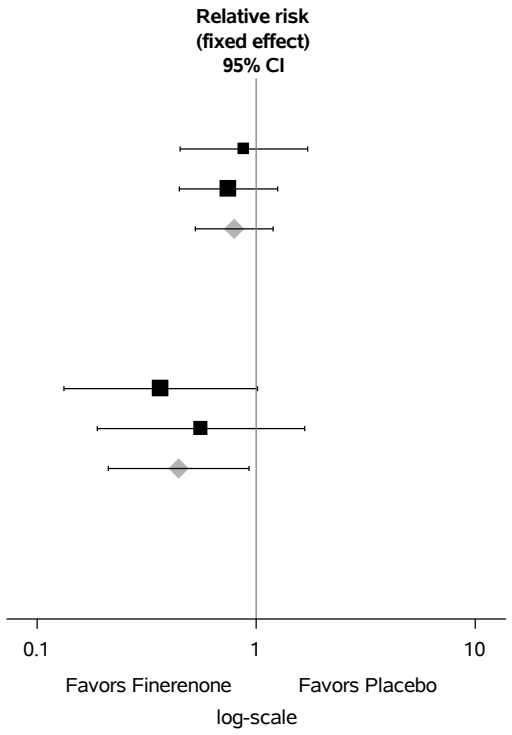
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	10 / 1301	13 / 1299	40.7	0.77 [0.34,1.75]	
FIGARO-DKD	12 / 1673	26 / 1651	59.3	0.46 [0.23,0.90]	
Total	22 / 2974	39 / 2950		0.56 [0.33,0.94]	Z=-2.19, p=0.0284
Heterogeneity:	Q=0.92 (df=1)	p=0.3366	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	19 / 1532	45.1	0.58 [0.28,1.22]	
FIGARO-DKD	18 / 2010	16 / 2007	54.9	1.12 [0.57,2.20]	
Total	29 / 3536	35 / 3539		0.83 [0.51,1.35]	Z=-0.75, p=0.4539
Heterogeneity:	Q=1.67 (df=1)	p=0.1956	I^2=40.3%		
Subgroup Heterogeneity:	Q=1.17 (df=1)	p=0.2793	I^2=14.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

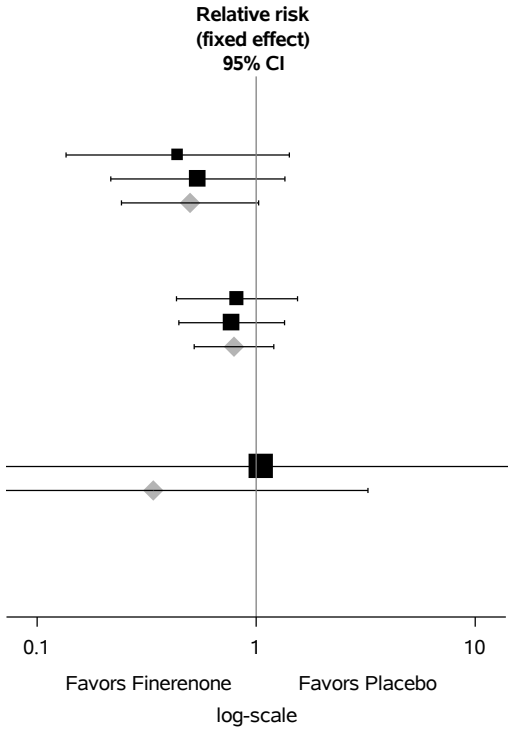
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1879	18 / 1858	37.3	0.88 [0.45,1.72]	
FIGARO-DKD	25 / 2643	33 / 2608	62.7	0.75 [0.45,1.25]	
Total	41 / 4522	51 / 4466		0.79 [0.53,1.19]	Z=-1.11, p=0.2686
Heterogeneity:	Q=0.14 (df=1)	p=0.7077	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 948	14 / 973	53.4	0.37 [0.13,1.01]	
FIGARO-DKD	5 / 1040	9 / 1048	46.6	0.56 [0.19,1.66]	
Total	10 / 1988	23 / 2021		0.44 [0.21,0.93]	Z=-2.16, p=0.0308
Heterogeneity:	Q=0.31 (df=1)	p=0.5774	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1756	I^2=45.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.116.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

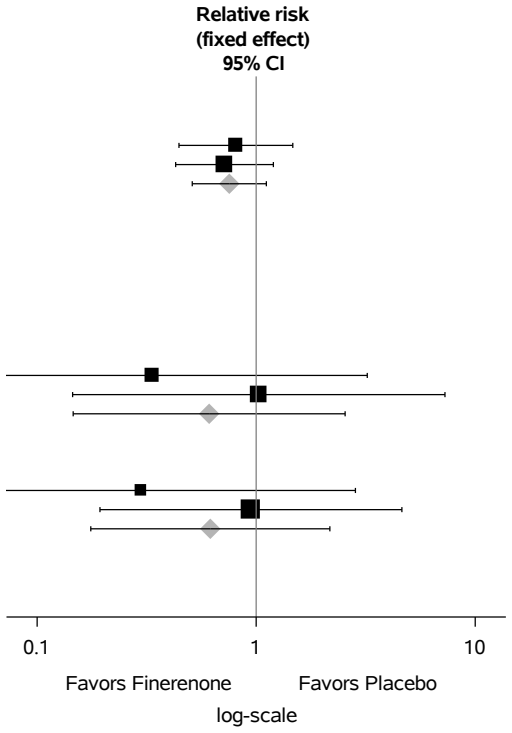
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 788	9 / 777	37.8	0.44 [0.14,1.42]	
FIGARO-DKD	7 / 1187	13 / 1194	62.2	0.54 [0.22,1.35]	
Total	11 / 1975	22 / 1971		0.50 [0.24,1.03]	Z=-1.89, p=0.0588
Heterogeneity:	Q=0.08 (df=1)	p=0.7802	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	17 / 1897	21 / 1916	43.3	0.82 [0.43,1.54]	
FIGARO-DKD	22 / 2389	28 / 2351	56.7	0.77 [0.44,1.35]	
Total	39 / 4286	49 / 4267		0.79 [0.52,1.20]	Z=-1.09, p=0.2750
Heterogeneity:	Q=0.02 (df=1)	p=0.8969	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	2 / 138	0.0	0.00 [0.00,88E295]	
FIGARO-DKD	1 / 107	1 / 113	100.0	1.06 [0.07,16.67]	
Total	1 / 248	3 / 251		0.34 [0.04,3.24]	Z=-0.94, p=0.3475
Heterogeneity:	Q=0.65 (df=1)	p=0.4196	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.57 (df=2)	p=0.4552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.116.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

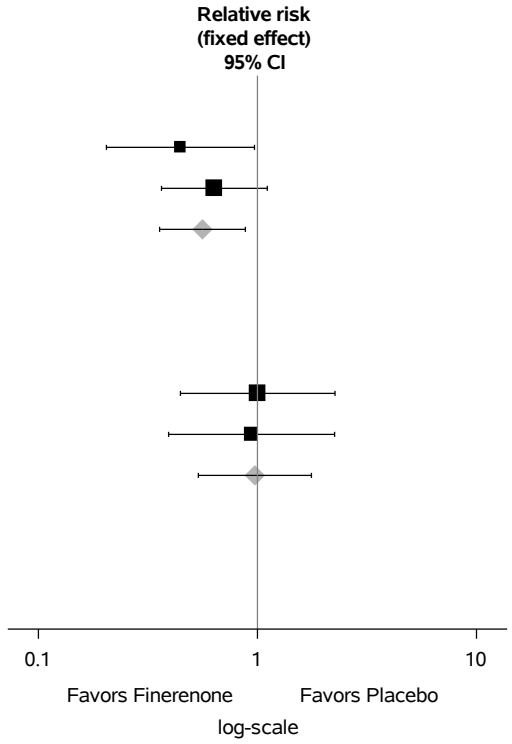
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	19 / 1773	24 / 1809	42.4	0.81 [0.44,1.47]	
FIGARO-DKD	25 / 2668	34 / 2601	57.6	0.72 [0.43,1.20]	
Total	44 / 4441	58 / 4410		0.75 [0.51,1.11]	Z=-1.42, p=0.1553
Heterogeneity:	Q=0.09 (df=1)	p=0.7666	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 139	2 / 124	0.0	0.00 [0.00,79E295]	
FIGARO-DKD	0 / 113	3 / 145	0.0	0.00 [0.00,17E296]	
Total	0 / 252	5 / 269		0.00 [0.00,19E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	1 / 717	3 / 721	42.8	0.34 [0.03,3.21]	
FIGARO-DKD	2 / 716	2 / 736	57.2	1.03 [0.15,7.28]	
Total	3 / 1433	5 / 1457		0.61 [0.15,2.55]	Z=-0.68, p=0.4980
Heterogeneity:	Q=0.54 (df=1)	p=0.4614	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 198	3 / 177	33.1	0.30 [0.03,2.84]	
FIGARO-DKD	3 / 186	3 / 176	66.9	0.95 [0.19,4.63]	
Total	4 / 384	6 / 353		0.62 [0.18,2.17]	Z=-0.75, p=0.4521
Heterogeneity:	Q=0.68 (df=1)	p=0.4098	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=3)	p=0.9845	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.116.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

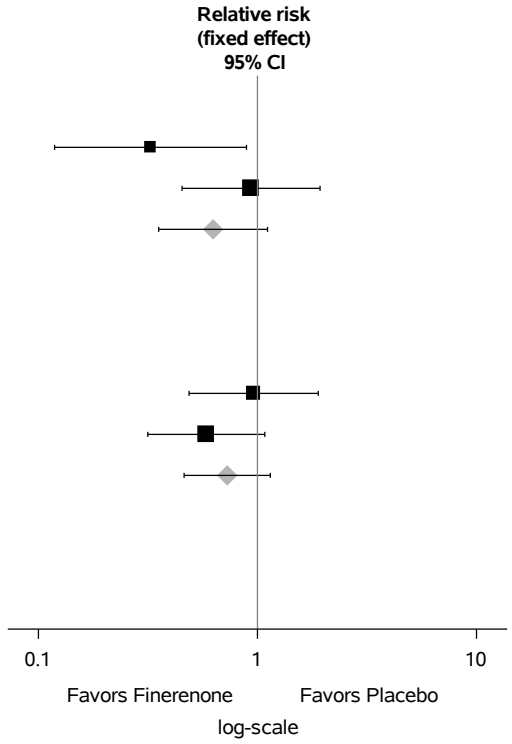
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 1949	21 / 2024	33.8	0.45 [0.20,0.97]	
FIGARO-DKD	20 / 2527	32 / 2571	66.2	0.64 [0.36,1.11]	
Total	29 / 4476	53 / 4595		0.56 [0.36,0.88]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.53 (df=1)	p=0.4646	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 878	11 / 807	53.6	1.00 [0.44,2.26]	
FIGARO-DKD	10 / 1156	10 / 1087	46.4	0.94 [0.39,2.25]	
Total	22 / 2034	21 / 1894		0.97 [0.54,1.76]	Z=-0.09, p=0.9287
Heterogeneity:	Q=0.01 (df=1)	p=0.9159	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1478	I^2=52.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.116.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

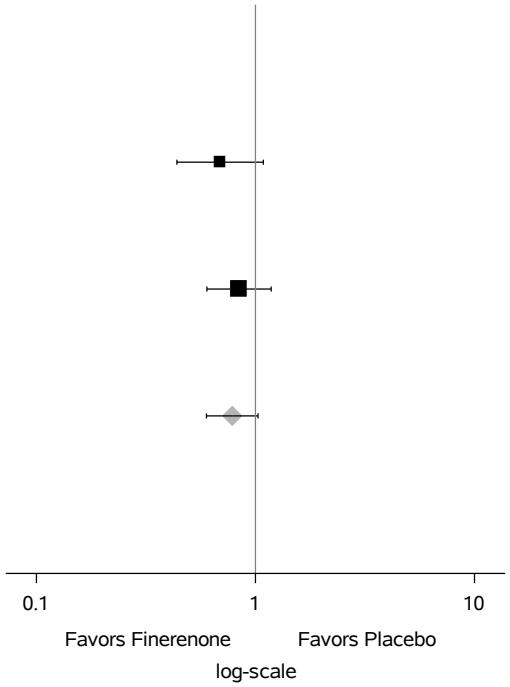
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	5 / 1201	15 / 1171	34.1	0.33 [0.12,0.89]	
FIGARO-DKD	14 / 1752	15 / 1755	65.9	0.93 [0.45,1.93]	
Total	19 / 2953	30 / 2926		0.63 [0.35,1.11]	Z=-1.60, p=0.1105
Heterogeneity:	Q=2.79 (df=1)	p=0.0946	I^2=64.2%		
>= 65					
FIDELIO-DKD	16 / 1626	17 / 1660	45.1	0.96 [0.49,1.90]	
FIGARO-DKD	16 / 1931	27 / 1903	54.9	0.58 [0.32,1.08]	
Total	32 / 3557	44 / 3563		0.73 [0.46,1.14]	Z=-1.38, p=0.1690
Heterogeneity:	Q=1.13 (df=1)	p=0.2868	I^2=11.9%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.117: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set

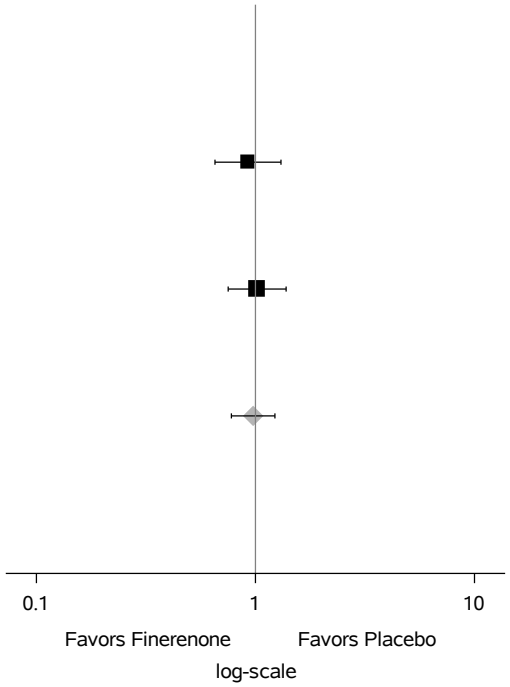
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	45 / 2831	35.6	0.69 [0.44,1.09]	
FIGARO-DKD	61 / 3683	72 / 3658	64.4	0.84 [0.60,1.18]	
Total	92 / 6510	117 / 6489		0.78 [0.60,1.03]	Z=-1.77, p=0.0775
Heterogeneity:	Q=0.47 (df=1)	p=0.4918	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.118: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set

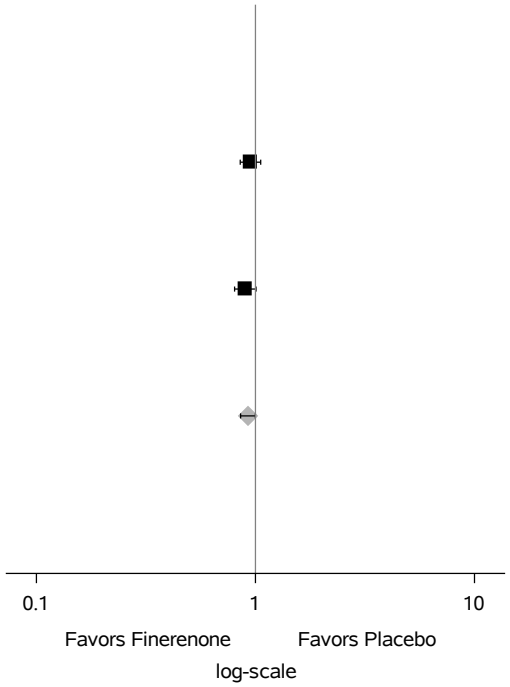
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	60 / 2827	65 / 2831	43.5	0.92 [0.65,1.31]	
FIGARO-DKD	82 / 3683	80 / 3658	56.5	1.02 [0.75,1.38]	
Total	142 / 6510	145 / 6489		0.98 [0.78,1.23]	Z=-0.21, p=0.8362
Heterogeneity:	Q=0.17 (df=1)	p=0.6820	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.119: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

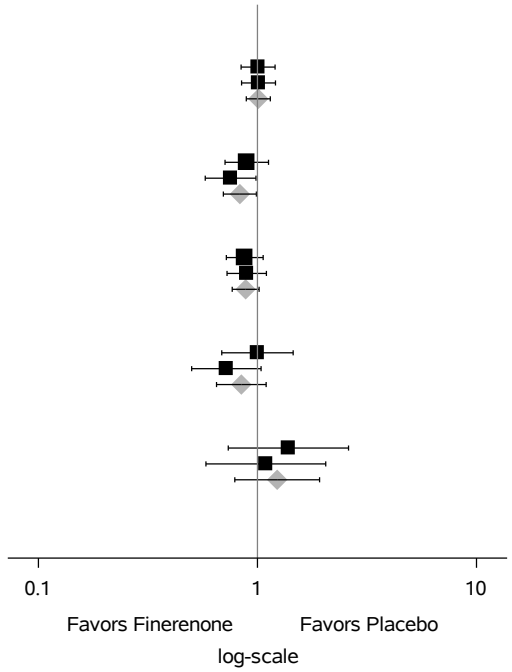
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	524 / 2827	553 / 2831	52.3	0.95 [0.85,1.06]	
FIGARO-DKD	495 / 3683	547 / 3658	47.7	0.90 [0.80,1.01]	
Total	1019 / 6510	1100 / 6489		0.92 [0.86,1.00]	Z=-1.97, p=0.0484
Heterogeneity:	Q=0.47 (df=1)	p=0.4948	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.119.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

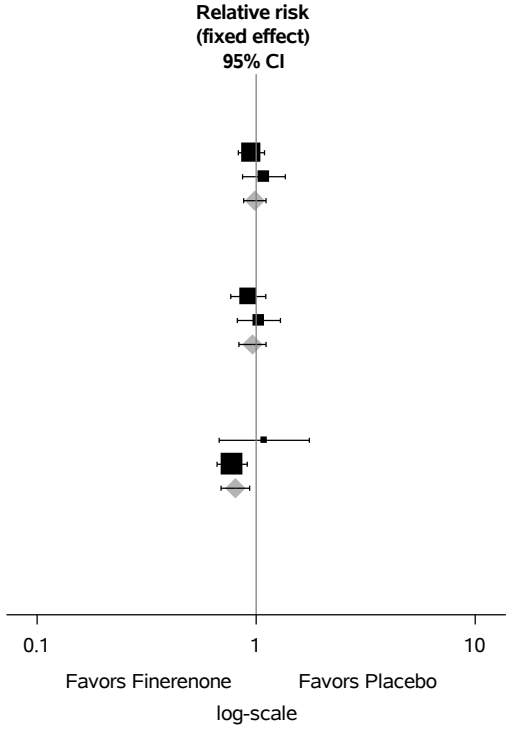
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	201 / 1178	199 / 1174	49.9	1.01 [0.84,1.20]	
FIGARO-DKD	214 / 1752	211 / 1747	50.1	1.01 [0.85,1.21]	
Total	415 / 2930	410 / 2921		1.01 [0.89,1.14]	Z=0.14, p=0.8896
Heterogeneity:	Q=0.00 (df=1)	p=0.9711	I^2=0.0%		
North America					
FIDELIO-DKD	105 / 466	120 / 476	57.6	0.89 [0.71,1.12]	
FIGARO-DKD	80 / 559	104 / 548	42.4	0.75 [0.58,0.98]	
Total	185 / 1025	224 / 1024		0.83 [0.70,0.99]	Z=-2.09, p=0.0369
Heterogeneity:	Q=0.90 (df=1)	p=0.3430	I^2=0.0%		
Asia					
FIDELIO-DKD	153 / 790	174 / 786	53.3	0.87 [0.72,1.06]	
FIGARO-DKD	139 / 811	156 / 813	46.7	0.89 [0.73,1.10]	
Total	292 / 1601	330 / 1599		0.88 [0.77,1.02]	Z=-1.72, p=0.0854
Heterogeneity:	Q=0.02 (df=1)	p=0.8857	I^2=0.0%		
Latin America					
FIDELIO-DKD	46 / 294	46 / 294	48.6	1.00 [0.69,1.46]	
FIGARO-DKD	44 / 424	60 / 417	51.4	0.72 [0.50,1.04]	
Total	90 / 718	106 / 711		0.84 [0.65,1.10]	Z=-1.27, p=0.2029
Heterogeneity:	Q=1.50 (df=1)	p=0.2210	I^2=33.2%		
Others					
FIDELIO-DKD	19 / 99	14 / 101	49.8	1.38 [0.74,2.61]	
FIGARO-DKD	18 / 137	16 / 133	50.2	1.09 [0.58,2.05]	
Total	37 / 236	30 / 234		1.23 [0.79,1.92]	Z=0.91, p=0.3618
Heterogeneity:	Q=0.27 (df=1)	p=0.6023	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.73 (df=4)	p=0.2200	I^2=30.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.119.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

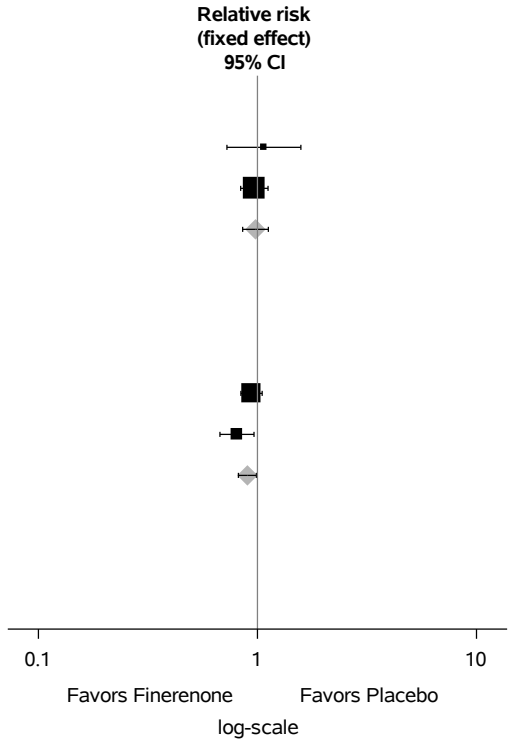
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	315 / 1556	328 / 1541	72.7	0.95 [0.83,1.09]	
FIGARO-DKD	129 / 637	117 / 627	27.3	1.09 [0.87,1.36]	
Total	444 / 2193	445 / 2168		0.99 [0.88,1.11]	Z=-0.23, p=0.8142
Heterogeneity:	Q=0.96 (df=1)	p=0.3263	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	179 / 1061	196 / 1069	60.3	0.92 [0.77,1.11]	
FIGARO-DKD	125 / 720	123 / 729	39.7	1.03 [0.82,1.29]	
Total	304 / 1781	319 / 1798		0.96 [0.83,1.11]	Z=-0.53, p=0.5937
Heterogeneity:	Q=0.56 (df=1)	p=0.4530	I^2=0.0%		
>= 60					
FIDELIO-DKD	30 / 210	29 / 221	10.1	1.09 [0.68,1.75]	
FIGARO-DKD	241 / 2326	307 / 2302	89.9	0.78 [0.66,0.91]	
Total	271 / 2536	336 / 2523		0.80 [0.69,0.93]	Z=-2.85, p=0.0043
Heterogeneity:	Q=1.75 (df=1)	p=0.1860	I^2=42.8%		
Subgroup Heterogeneity:	Q=4.80 (df=2)	p=0.0906	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.119.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

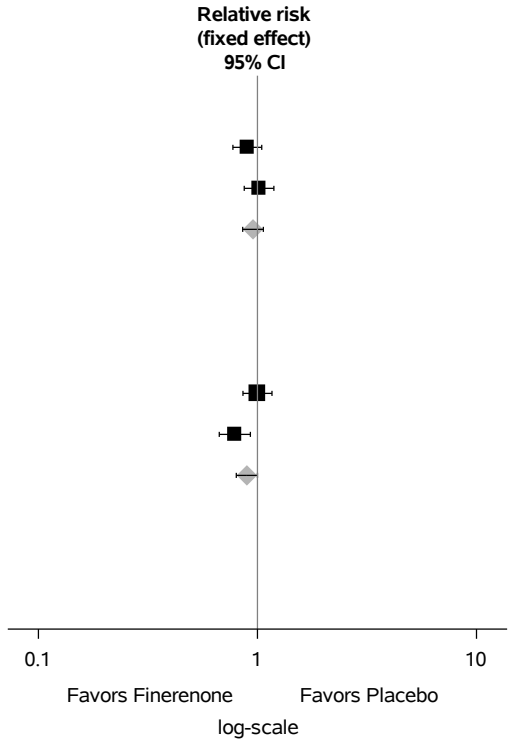
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 209	40 / 213	12.0	1.07 [0.73,1.58]	
FIGARO-DKD	302 / 1720	308 / 1698	88.0	0.97 [0.84,1.12]	
Total	344 / 1929	348 / 1911		0.98 [0.86,1.12]	Z=-0.30, p=0.7663
Heterogeneity:	Q=0.22 (df=1)	p=0.6353	I^2=0.0%		
Very High					
FIDELIO-DKD	482 / 2618	513 / 2618	71.9	0.94 [0.84,1.05]	
FIGARO-DKD	193 / 1963	239 / 1960	28.1	0.81 [0.67,0.96]	
Total	675 / 4581	752 / 4578		0.90 [0.82,0.99]	Z=-2.18, p=0.0292
Heterogeneity:	Q=2.02 (df=1)	p=0.1556	I^2=50.4%		
Subgroup Heterogeneity:	Q=1.02 (df=1)	p=0.3120	I^2=2.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.119.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

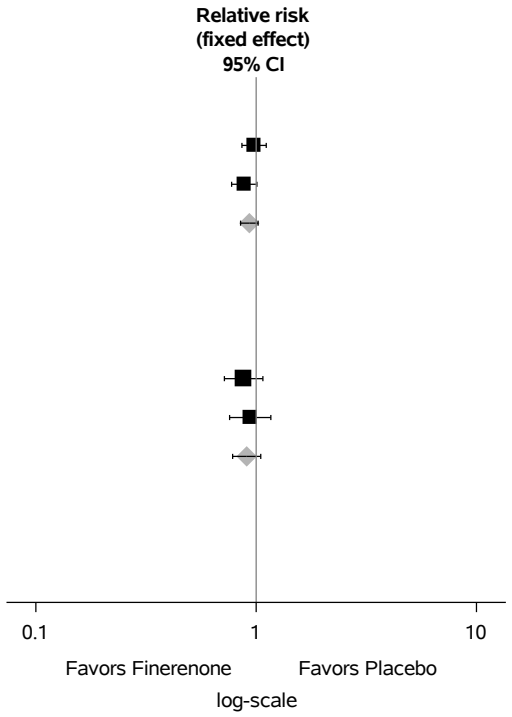
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	253 / 1301	281 / 1299	51.4	0.90 [0.77,1.05]	
FIGARO-DKD	270 / 1673	262 / 1651	48.6	1.02 [0.87,1.19]	
Total	523 / 2974	543 / 2950		0.95 [0.86,1.06]	Z=-0.84, p=0.3998
Heterogeneity:	Q=1.24 (df=1)	p=0.2659	I^2=19.2%		
Absent					
FIDELIO-DKD	271 / 1526	272 / 1532	53.5	1.00 [0.86,1.17]	
FIGARO-DKD	225 / 2010	285 / 2007	46.5	0.79 [0.67,0.93]	
Total	496 / 3536	557 / 3539		0.89 [0.80,1.00]	Z=-1.96, p=0.0504
Heterogeneity:	Q=4.36 (df=1)	p=0.0369	I^2=77.0%		
Subgroup Heterogeneity:	Q=0.66 (df=1)	p=0.4157	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.119.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

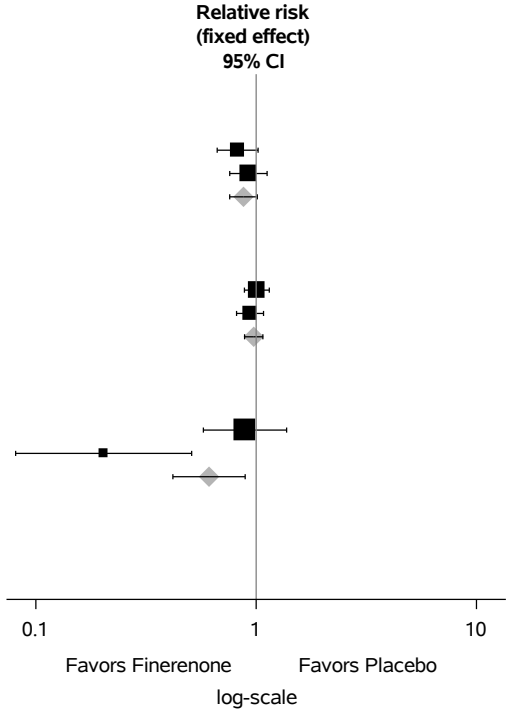
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	377 / 1879	381 / 1858	51.9	0.98 [0.86,1.11]	
FIGARO-DKD	357 / 2643	399 / 2608	48.1	0.88 [0.77,1.01]	
Total	734 / 4522	780 / 4466		0.93 [0.85,1.02]	Z=-1.52, p=0.1274
Heterogeneity:	Q=1.21 (df=1)	p=0.2720	I^2=17.1%		
> 4.5					
FIDELIO-DKD	147 / 948	172 / 973	53.4	0.88 [0.72,1.07]	
FIGARO-DKD	138 / 1040	148 / 1048	46.6	0.94 [0.76,1.17]	
Total	285 / 1988	320 / 2021		0.91 [0.78,1.05]	Z=-1.32, p=0.1865
Heterogeneity:	Q=0.21 (df=1)	p=0.6477	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7528	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.119.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

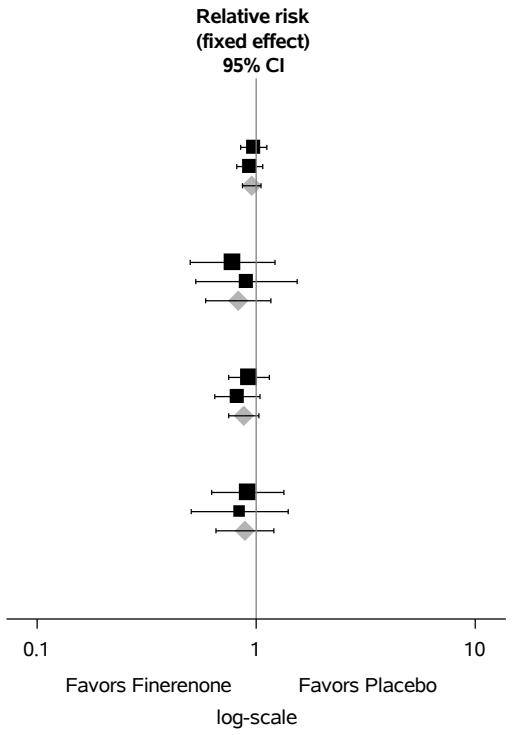
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	127 / 788	152 / 777	45.5	0.82 [0.67,1.02]	
FIGARO-DKD	165 / 1187	180 / 1194	54.5	0.92 [0.76,1.12]	
Total	292 / 1975	332 / 1971		0.88 [0.76,1.01]	Z=-1.80, p=0.0716
Heterogeneity:	Q=0.58 (df=1)	p=0.4459	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	367 / 1897	368 / 1916	54.0	1.01 [0.88,1.15]	
FIGARO-DKD	325 / 2389	341 / 2351	46.0	0.94 [0.81,1.08]	
Total	692 / 4286	709 / 4267		0.97 [0.89,1.07]	Z=-0.52, p=0.6000
Heterogeneity:	Q=0.53 (df=1)	p=0.4656	I^2=0.0%		
>= 160					
FIDELIO-DKD	30 / 141	33 / 138	81.7	0.89 [0.58,1.37]	
FIGARO-DKD	5 / 107	26 / 113	18.3	0.20 [0.08,0.51]	
Total	35 / 248	59 / 251		0.61 [0.42,0.89]	Z=-2.56, p=0.0106
Heterogeneity:	Q=8.37 (df=1)	p=0.0038	I^2=88.1%		
Subgroup Heterogeneity:	Q=6.34 (df=2)	p=0.0420	I^2=68.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.119.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

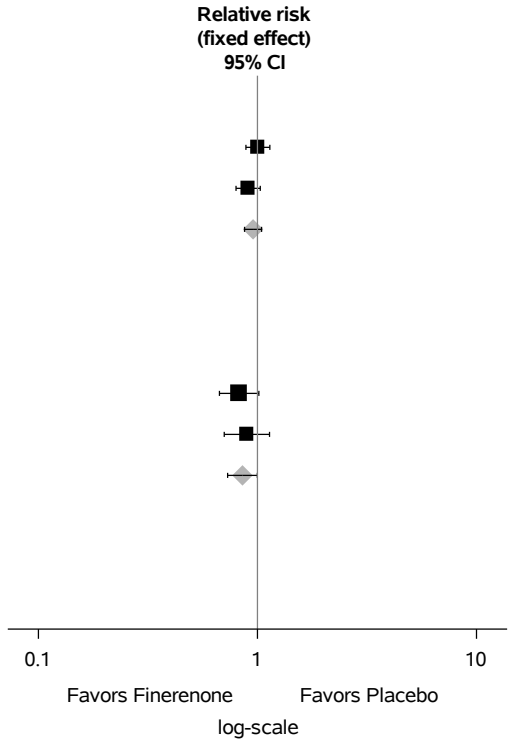
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	323 / 1773	338 / 1809	49.6	0.98 [0.85,1.12]	
FIGARO-DKD	349 / 2668	364 / 2601	50.4	0.93 [0.82,1.07]	
Total	672 / 4441	702 / 4410		0.95 [0.87,1.05]	Z=-0.94, p=0.3464
Heterogeneity:	Q=0.18 (df=1)	p=0.6696	I^2=0.0%		
Black					
FIDELIO-DKD	28 / 139	32 / 124	58.8	0.78 [0.50,1.22]	
FIGARO-DKD	19 / 113	27 / 145	41.2	0.90 [0.53,1.54]	
Total	47 / 252	59 / 269		0.83 [0.59,1.17]	Z=-1.08, p=0.2821
Heterogeneity:	Q=0.17 (df=1)	p=0.6811	I^2=0.0%		
Asian					
FIDELIO-DKD	131 / 717	142 / 721	55.3	0.93 [0.75,1.15]	
FIGARO-DKD	103 / 716	129 / 736	44.7	0.82 [0.65,1.04]	
Total	234 / 1433	271 / 1457		0.88 [0.75,1.03]	Z=-1.60, p=0.1086
Heterogeneity:	Q=0.56 (df=1)	p=0.4527	I^2=0.0%		
Others					
FIDELIO-DKD	42 / 198	41 / 177	64.3	0.92 [0.63,1.34]	
FIGARO-DKD	24 / 186	27 / 176	35.7	0.84 [0.51,1.40]	
Total	66 / 384	68 / 353		0.89 [0.66,1.20]	Z=-0.76, p=0.4457
Heterogeneity:	Q=0.07 (df=1)	p=0.7932	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=3)	p=0.7340	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.119.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

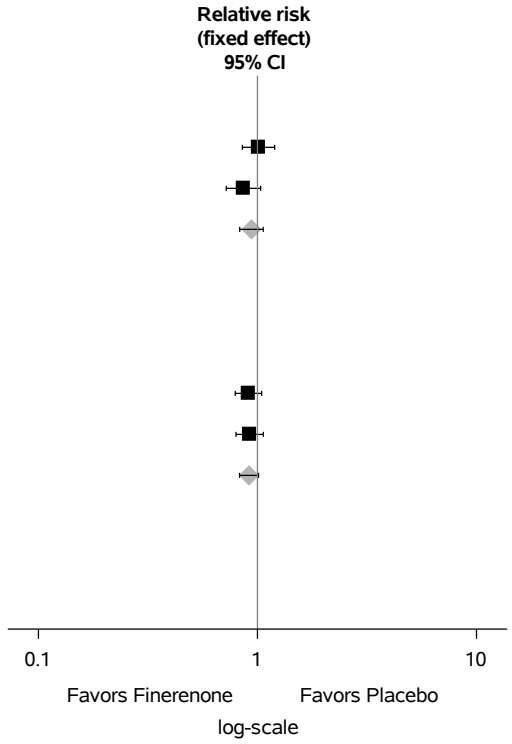
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	384 / 1949	397 / 2024	50.7	1.00 [0.89,1.14]	
FIGARO-DKD	377 / 2527	423 / 2571	49.3	0.91 [0.80,1.03]	
Total	761 / 4476	820 / 4595		0.95 [0.87,1.04]	Z=-1.01, p=0.3132
Heterogeneity:	Q=1.25 (df=1)	p=0.2627	I^2=20.3%		
Female					
FIDELIO-DKD	140 / 878	156 / 807	56.9	0.82 [0.67,1.01]	
FIGARO-DKD	118 / 1156	124 / 1087	43.1	0.89 [0.71,1.14]	
Total	258 / 2034	280 / 1894		0.85 [0.73,1.00]	Z=-1.98, p=0.0482
Heterogeneity:	Q=0.26 (df=1)	p=0.6132	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.47 (df=1)	p=0.2252	I^2=32.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.119.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

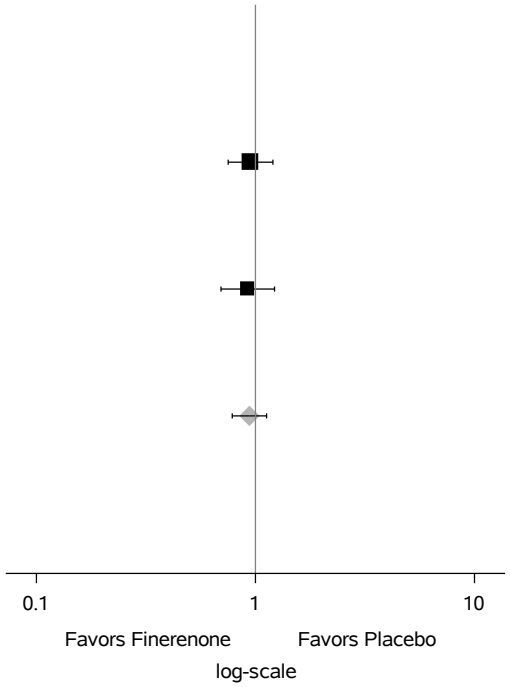
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	222 / 1201	214 / 1171	53.2	1.01 [0.85,1.20]	
FIGARO-DKD	193 / 1752	224 / 1755	46.8	0.86 [0.72,1.03]	
Total	415 / 2953	438 / 2926		0.94 [0.83,1.06]	Z=-1.00, p=0.3175
Heterogeneity:	Q=1.57 (df=1)	p=0.2097	I^2=36.4%		
>= 65					
FIDELIO-DKD	302 / 1626	339 / 1660	51.5	0.91 [0.79,1.05]	
FIGARO-DKD	302 / 1931	323 / 1903	48.5	0.92 [0.80,1.06]	
Total	604 / 3557	662 / 3563		0.92 [0.83,1.01]	Z=-1.74, p=0.0824
Heterogeneity:	Q=0.02 (df=1)	p=0.8982	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7527	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.120: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

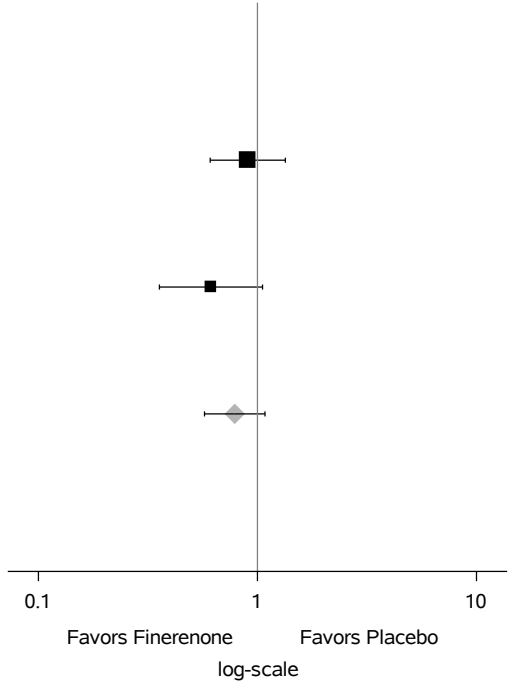
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2827	136 / 2831	58.9	0.95 [0.75,1.20]	
FIGARO-DKD	91 / 3683	98 / 3658	41.1	0.92 [0.70,1.22]	
Total	220 / 6510	234 / 6489		0.94 [0.78,1.12]	Z=-0.69, p=0.4902
Heterogeneity:	Q=0.02 (df=1)	p=0.8748	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.121: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set

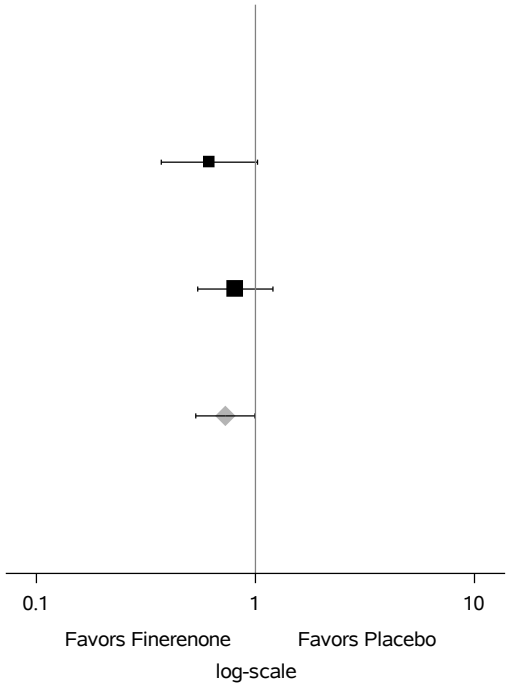
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2827	51 / 2831	65.3	0.90 [0.61,1.34]	
FIGARO-DKD	21 / 3683	34 / 3658	34.7	0.61 [0.36,1.05]	
Total	67 / 6510	85 / 6489		0.79 [0.57,1.08]	Z=-1.47, p=0.1413
Heterogeneity:	Q=1.28 (df=1)	p=0.2582	I^2=21.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.122: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

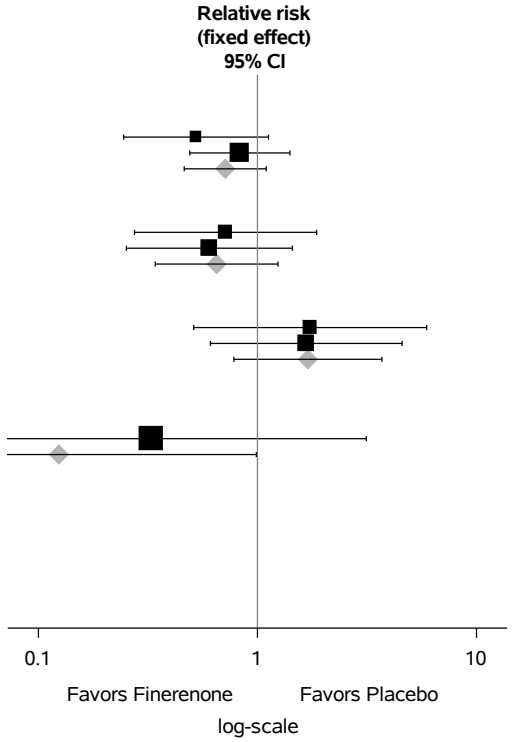
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2827	39 / 2831	37.9	0.62 [0.37,1.02]	
FIGARO-DKD	44 / 3683	54 / 3658	62.1	0.81 [0.54,1.20]	
Total	68 / 6510	93 / 6489		0.73 [0.53,0.99]	Z=-2.00, p=0.0459
Heterogeneity:	Q=0.69 (df=1)	p=0.4055	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.122.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

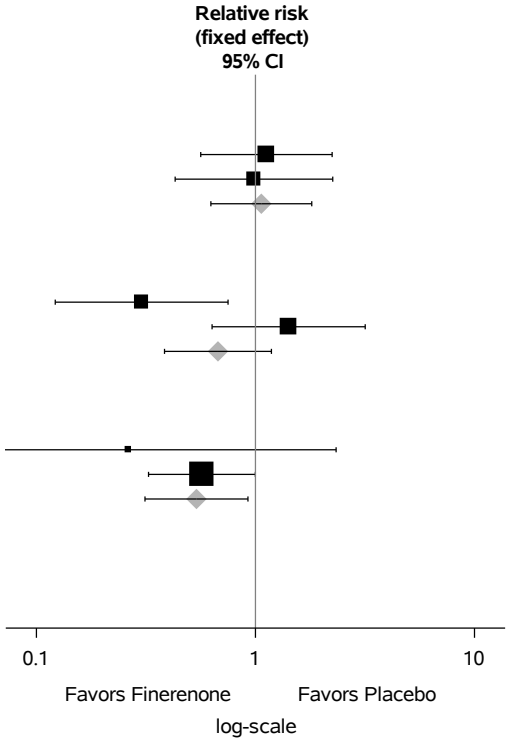
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 1178	19 / 1174	32.4	0.52 [0.24,1.12]	
FIGARO-DKD	25 / 1752	30 / 1747	67.6	0.83 [0.49,1.41]	
Total	35 / 2930	49 / 2921		0.71 [0.46,1.10]	Z=-1.54, p=0.1227
Heterogeneity:	Q=0.95 (df=1)	p=0.3299	I^2=0.0%		
North America					
FIDELIO-DKD	7 / 466	10 / 476	45.4	0.72 [0.27,1.86]	
FIGARO-DKD	8 / 559	13 / 548	54.6	0.60 [0.25,1.44]	
Total	15 / 1025	23 / 1024		0.65 [0.34,1.24]	Z=-1.30, p=0.1922
Heterogeneity:	Q=0.07 (df=1)	p=0.7971	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 790	4 / 786	40.4	1.74 [0.51,5.92]	
FIGARO-DKD	10 / 811	6 / 813	59.6	1.67 [0.61,4.58]	
Total	17 / 1601	10 / 1599		1.70 [0.78,3.70]	Z=1.34, p=0.1818
Heterogeneity:	Q=0.00 (df=1)	p=0.9593	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 294	5 / 294	0.0	0.00 [0.00,75E295]	
FIGARO-DKD	1 / 424	3 / 417	100.0	0.33 [0.03,3.14]	
Total	1 / 718	8 / 711		0.12 [0.02,0.99]	Z=-1.97, p=0.0487
Heterogeneity:	Q=0.71 (df=1)	p=0.3988	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	0 / 137	2 / 133	0.0	0.00 [0.00,84E295]	
Total	0 / 236	3 / 234		0.00 [0.00,99E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=7.33 (df=4)	p=0.1193	I^2=45.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.122.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

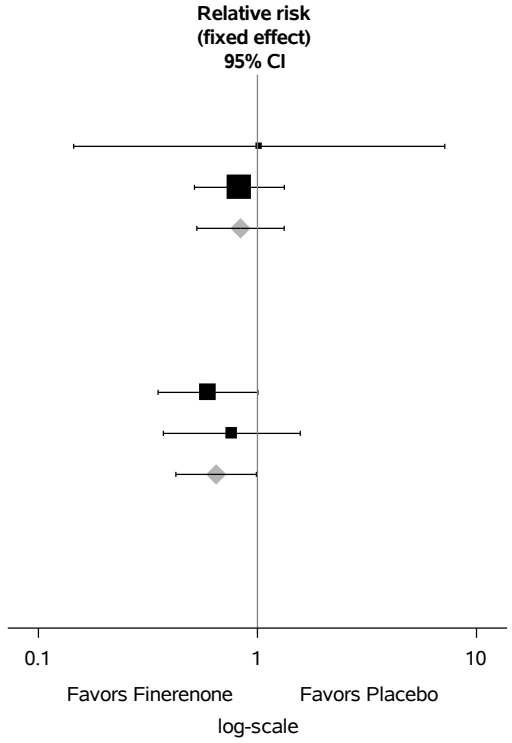
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	17 / 1556	15 / 1541	59.0	1.12 [0.56,2.24]	
FIGARO-DKD	11 / 637	11 / 627	41.0	0.98 [0.43,2.25]	
Total	28 / 2193	26 / 2168		1.06 [0.63,1.81]	Z=0.23, p=0.8196
Heterogeneity:	Q=0.06 (df=1)	p=0.8114	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	6 / 1061	20 / 1069	44.0	0.30 [0.12,0.75]	
FIGARO-DKD	14 / 720	10 / 729	56.0	1.42 [0.63,3.17]	
Total	20 / 1781	30 / 1798		0.67 [0.38,1.18]	Z=-1.37, p=0.1693
Heterogeneity:	Q=6.27 (df=1)	p=0.0123	I^2=84.1%		
>= 60					
FIDELIO-DKD	1 / 210	4 / 221	6.2	0.26 [0.03,2.33]	
FIGARO-DKD	19 / 2326	33 / 2302	93.8	0.57 [0.33,1.00]	
Total	20 / 2536	37 / 2523		0.54 [0.31,0.92]	Z=-2.25, p=0.0247
Heterogeneity:	Q=0.45 (df=1)	p=0.5010	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.24 (df=2)	p=0.1983	I^2=38.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.122.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

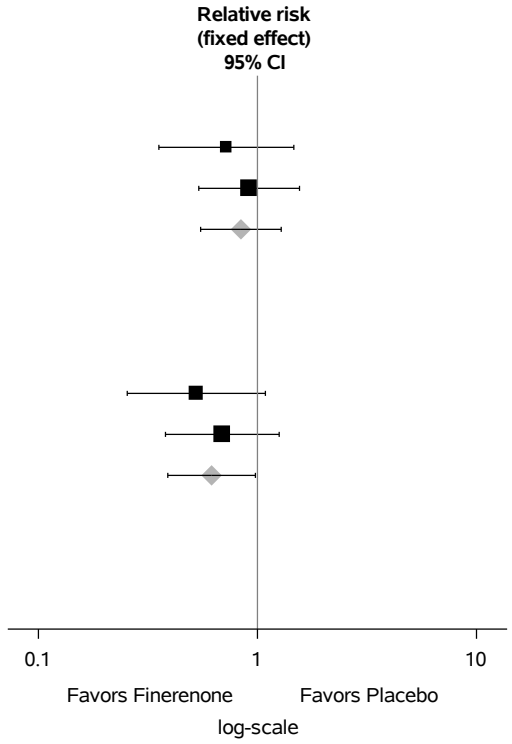
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	2 / 213	5.5	1.02 [0.14,7.17]	
FIGARO-DKD	31 / 1720	37 / 1698	94.5	0.83 [0.52,1.33]	
Total	33 / 1929	39 / 1911		0.84 [0.53,1.32]	Z=-0.76, p=0.4466
Heterogeneity:	Q=0.04 (df=1)	p=0.8385	I^2=0.0%		
Very High					
FIDELIO-DKD	22 / 2618	37 / 2618	65.3	0.59 [0.35,1.01]	
FIGARO-DKD	13 / 1963	17 / 1960	34.7	0.76 [0.37,1.57]	
Total	35 / 4581	54 / 4578		0.65 [0.42,0.99]	Z=-2.01, p=0.0443
Heterogeneity:	Q=0.30 (df=1)	p=0.5820	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4216	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.122.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

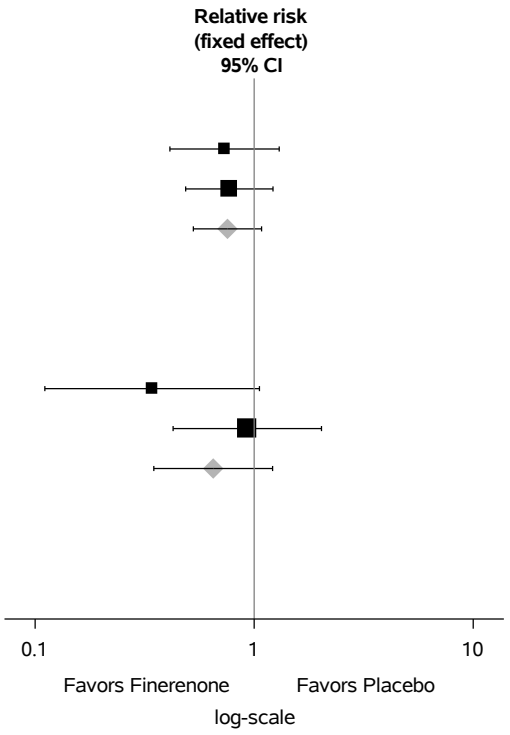
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1301	18 / 1299	35.8	0.72 [0.35,1.47]	
FIGARO-DKD	26 / 1673	28 / 1651	64.2	0.92 [0.54,1.56]	
Total	39 / 2974	46 / 2950		0.84 [0.55,1.28]	Z=-0.80, p=0.4212
Heterogeneity:	Q=0.28 (df=1)	p=0.5957	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	21 / 1532	40.4	0.53 [0.25,1.09]	
FIGARO-DKD	18 / 2010	26 / 2007	59.6	0.69 [0.38,1.26]	
Total	29 / 3536	47 / 3539		0.62 [0.39,0.98]	Z=-2.05, p=0.0402
Heterogeneity:	Q=0.32 (df=1)	p=0.5686	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=1)	p=0.3342	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.122.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

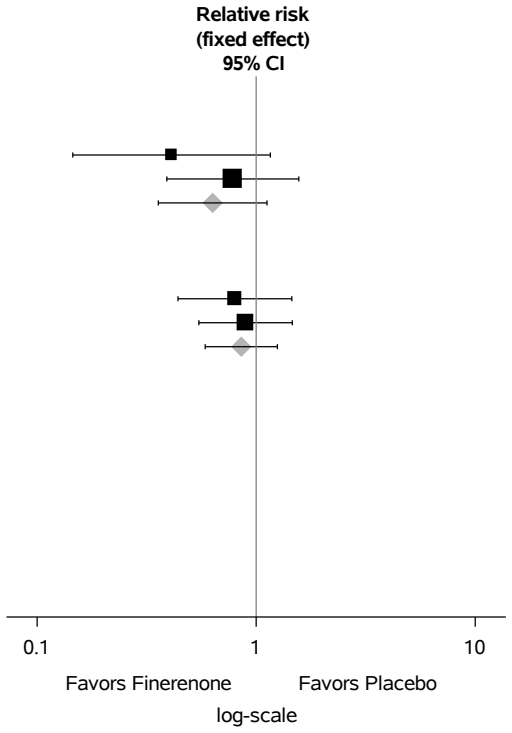
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	20 / 1879	27 / 1858	39.0	0.73 [0.41,1.30]	
FIGARO-DKD	32 / 2643	41 / 2608	61.0	0.77 [0.49,1.22]	
Total	52 / 4522	68 / 4466		0.76 [0.53,1.08]	Z=-1.53, p=0.1250
Heterogeneity:	Q=0.02 (df=1)	p=0.8936	I^2=0.0%		
> 4.5					
FIDELIO-DKD	4 / 948	12 / 973	32.3	0.34 [0.11,1.06]	
FIGARO-DKD	12 / 1040	13 / 1048	67.7	0.93 [0.43,2.03]	
Total	16 / 1988	25 / 2021		0.65 [0.35,1.21]	Z=-1.35, p=0.1764
Heterogeneity:	Q=2.05 (df=1)	p=0.1517	I^2=51.3%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6832	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.122.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

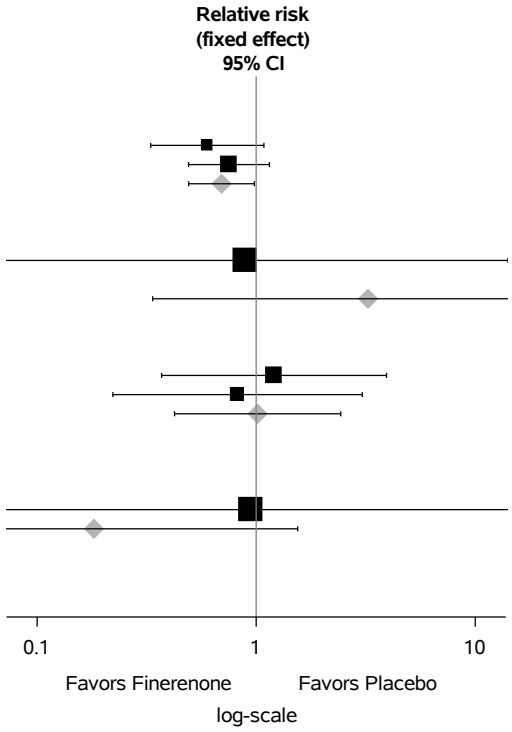
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 788	12 / 777	30.9	0.41 [0.15,1.16]	
FIGARO-DKD	14 / 1187	18 / 1194	69.1	0.78 [0.39,1.57]	
Total	19 / 1975	30 / 1971		0.63 [0.36,1.12]	Z=-1.57, p=0.1165
Heterogeneity:	Q=1.02 (df=1)	p=0.3117	I^2=2.3%		
130 - < 160					
FIDELIO-DKD	19 / 1897	24 / 1916	40.2	0.80 [0.44,1.45]	
FIGARO-DKD	30 / 2389	33 / 2351	59.8	0.89 [0.55,1.46]	
Total	49 / 4286	57 / 4267		0.85 [0.59,1.25]	Z=-0.81, p=0.4184
Heterogeneity:	Q=0.08 (df=1)	p=0.7762	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	3 / 138	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	0 / 107	3 / 113	0.0	0.00 [0.00,13E296]	
Total	0 / 248	6 / 251		0.00 [0.00,15E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.74 (df=2)	p=0.6911	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.122.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

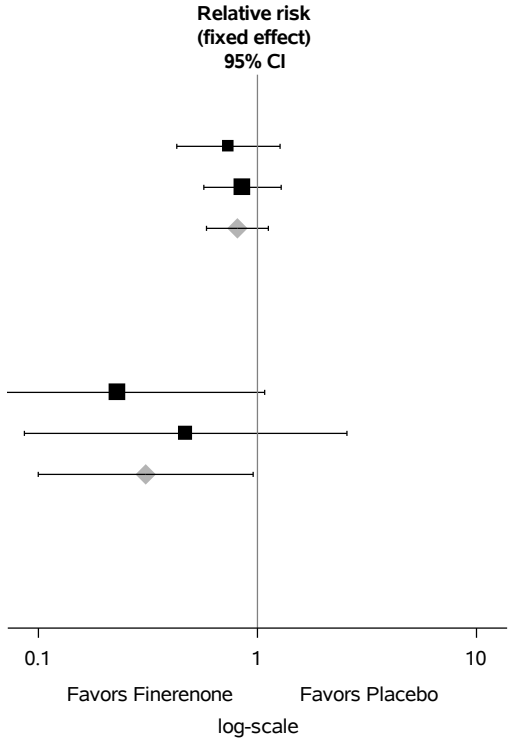
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 1773	29 / 1809	33.8	0.60 [0.33,1.08]	
FIGARO-DKD	37 / 2668	48 / 2601	66.2	0.75 [0.49,1.15]	
Total	54 / 4441	77 / 4410		0.69 [0.49,0.98]	Z=-2.07, p=0.0388
Heterogeneity:	Q=0.37 (df=1)	p=0.5408	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	1 / 124	100.0	0.89 [0.06,14.11]	
FIGARO-DKD	2 / 113	0 / 145	0.0	251E9 [251E9,251E9]	
Total	3 / 252	1 / 269		3.24 [0.34,31.17]	Z=1.02, p=0.3089
Heterogeneity:	Q=0.84 (df=1)	p=0.3600	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 717	5 / 721	55.1	1.21 [0.37,3.94]	
FIGARO-DKD	4 / 716	5 / 736	44.9	0.82 [0.22,3.05]	
Total	10 / 1433	10 / 1457		1.02 [0.42,2.43]	Z=0.03, p=0.9721
Heterogeneity:	Q=0.18 (df=1)	p=0.6703	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	4 / 177	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	1 / 186	1 / 176	100.0	0.95 [0.06,15.01]	
Total	1 / 384	5 / 353		0.18 [0.02,1.55]	Z=-1.56, p=0.1186
Heterogeneity:	Q=1.37 (df=1)	p=0.2420	I^2=27.0%		
Subgroup Heterogeneity:	Q=3.91 (df=3)	p=0.2712	I^2=23.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.122.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

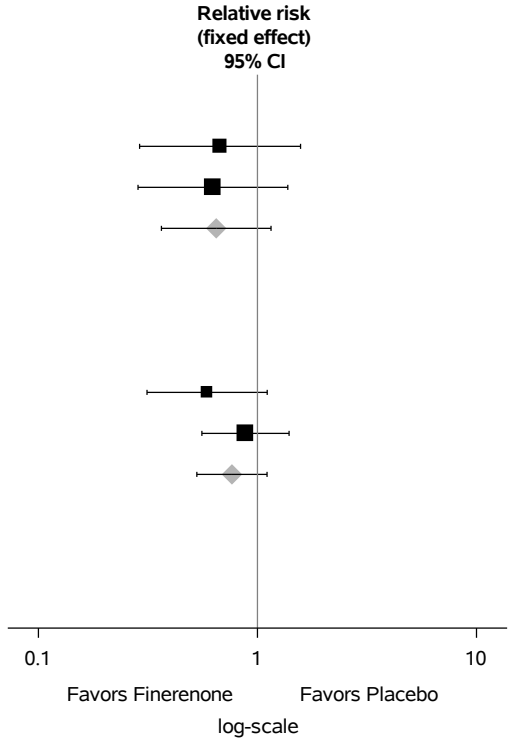
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	22 / 1949	31 / 2024	35.9	0.74 [0.43,1.27]	
FIGARO-DKD	42 / 2527	50 / 2571	64.1	0.85 [0.57,1.28]	
Total	64 / 4476	81 / 4595		0.81 [0.59,1.12]	Z=-1.27, p=0.2041
Heterogeneity:	Q=0.18 (df=1)	p=0.6687	I^2=0.0%		
Female					
FIDELIO-DKD	2 / 878	8 / 807	54.6	0.23 [0.05,1.08]	
FIGARO-DKD	2 / 1156	4 / 1087	45.4	0.47 [0.09,2.56]	
Total	4 / 2034	12 / 1894		0.31 [0.10,0.96]	Z=-2.04, p=0.0415
Heterogeneity:	Q=0.38 (df=1)	p=0.5395	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.58 (df=1)	p=0.1079	I^2=61.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.122.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

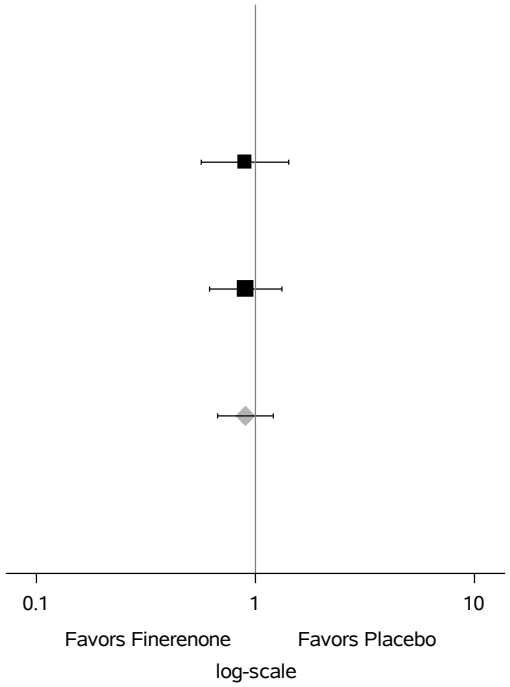
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1201	13 / 1171	46.4	0.68 [0.29,1.57]	
FIGARO-DKD	10 / 1752	16 / 1755	53.6	0.63 [0.28,1.38]	
Total	19 / 2953	29 / 2926		0.65 [0.36,1.15]	Z=-1.47, p=0.1403
Heterogeneity:	Q=0.02 (df=1)	p=0.8984	I^2=0.0%		
>= 65					
FIDELIO-DKD	15 / 1626	26 / 1660	34.5	0.59 [0.31,1.11]	
FIGARO-DKD	34 / 1931	38 / 1903	65.5	0.88 [0.56,1.39]	
Total	49 / 3557	64 / 3563		0.76 [0.53,1.11]	Z=-1.42, p=0.1542
Heterogeneity:	Q=1.03 (df=1)	p=0.3109	I^2=2.6%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6360	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.123: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set

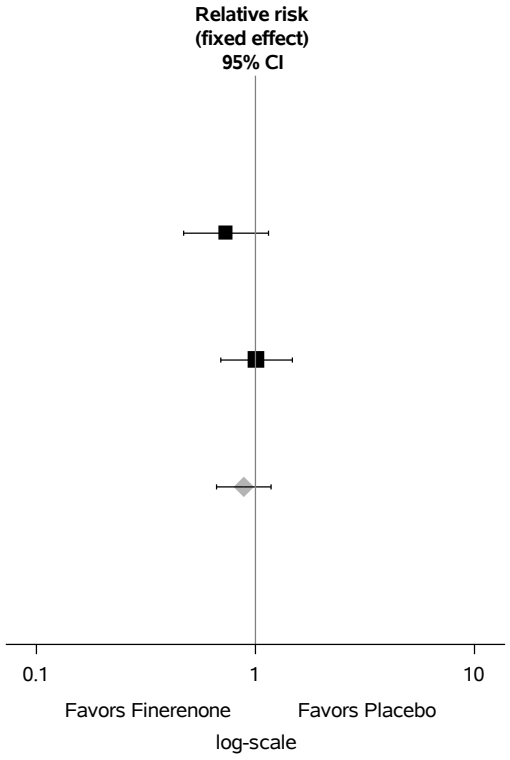
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	38 / 2831	40.6	0.90 [0.57,1.42]	
FIGARO-DKD	50 / 3683	55 / 3658	59.4	0.90 [0.62,1.32]	
Total	84 / 6510	93 / 6489		0.90 [0.67,1.21]	Z=-0.70, p=0.4814
Heterogeneity:	Q=0.00 (df=1)	p=0.9798	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.124: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set

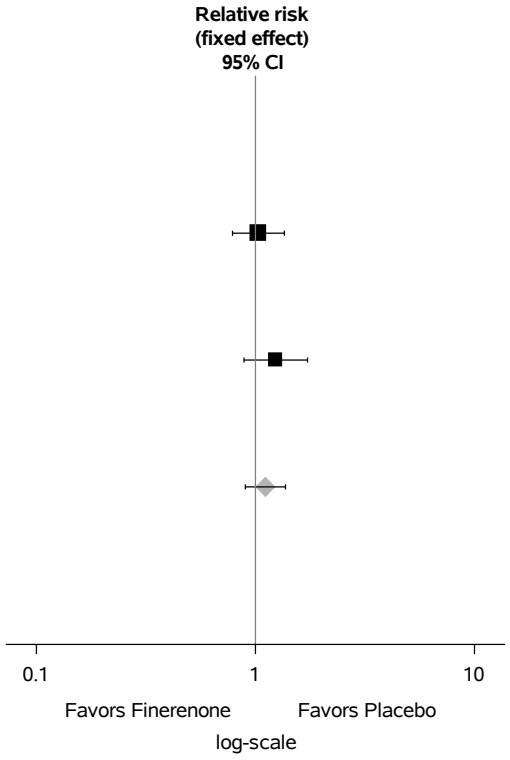
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	45 / 2831	41.6	0.73 [0.47,1.15]	
FIGARO-DKD	54 / 3683	53 / 3658	58.4	1.01 [0.69,1.47]	
Total	87 / 6510	98 / 6489		0.88 [0.66,1.18]	Z=-0.84, p=0.4029
Heterogeneity:	Q=1.16 (df=1)	p=0.2816	I^2=13.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.125: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set

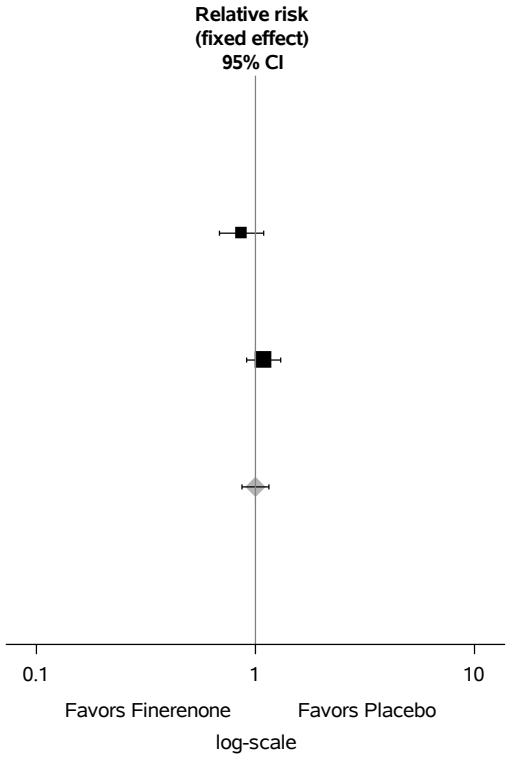
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	101 / 2827	98 / 2831	59.9	1.03 [0.79,1.36]	
FIGARO-DKD	76 / 3683	61 / 3658	40.1	1.24 [0.89,1.73]	
Total	177 / 6510	159 / 6489		1.11 [0.90,1.37]	Z=0.97, p=0.3316
Heterogeneity:	Q=0.68 (df=1)	p=0.4094	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.126: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set

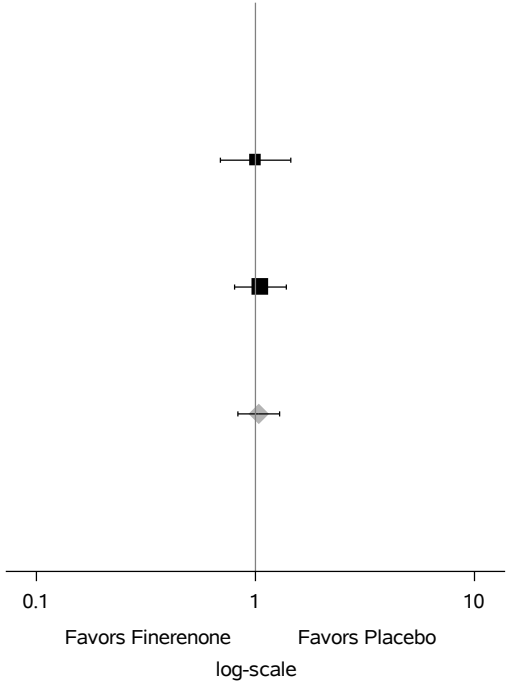
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	146 / 2831	37.2	0.86 [0.68,1.09]	
FIGARO-DKD	236 / 3683	215 / 3658	62.8	1.09 [0.91,1.30]	
Total	362 / 6510	361 / 6489		1.00 [0.87,1.15]	Z=-0.00, p=0.9980
Heterogeneity:	Q=2.41 (df=1)	p=0.1208	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.127: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set

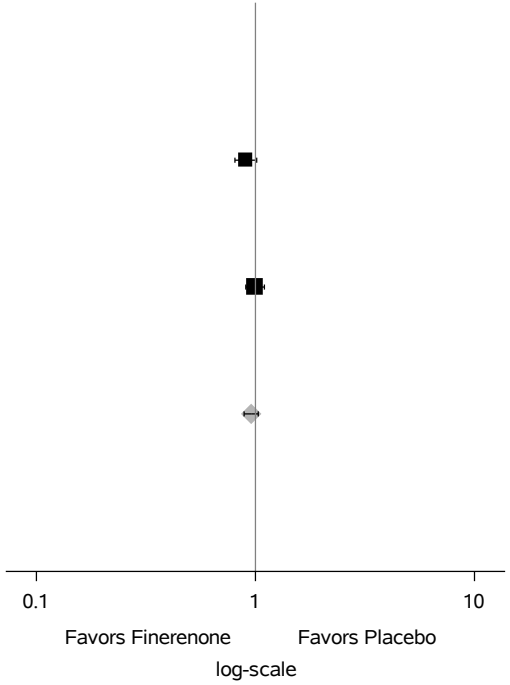
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	55 / 2827	55 / 2831	35.1	1.00 [0.69,1.45]	
FIGARO-DKD	104 / 3683	98 / 3658	64.9	1.05 [0.80,1.38]	
Total	159 / 6510	153 / 6489		1.04 [0.83,1.29]	Z=0.31, p=0.7567
Heterogeneity:	Q=0.05 (df=1)	p=0.8271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.128: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

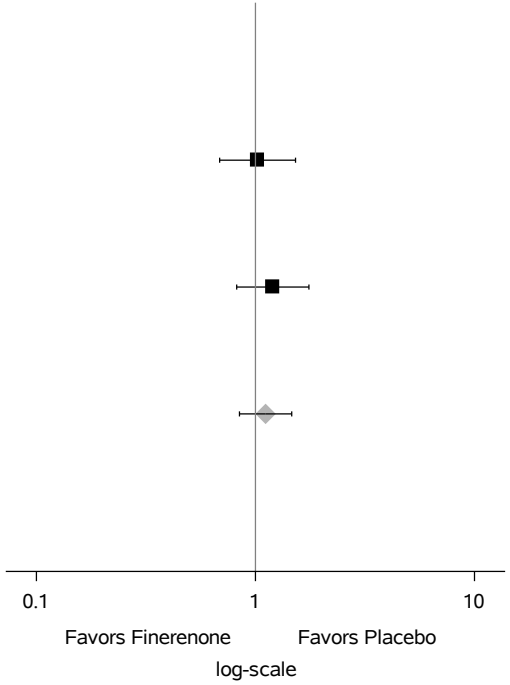
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	462 / 2827	512 / 2831	42.2	0.90 [0.81,1.01]	
FIGARO-DKD	660 / 3683	658 / 3658	57.8	1.00 [0.90,1.10]	
Total	1122 / 6510	1170 / 6489		0.96 [0.89,1.03]	Z=-1.19, p=0.2354
Heterogeneity:	Q=1.61 (df=1)	p=0.2040	I^2=38.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.129: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set

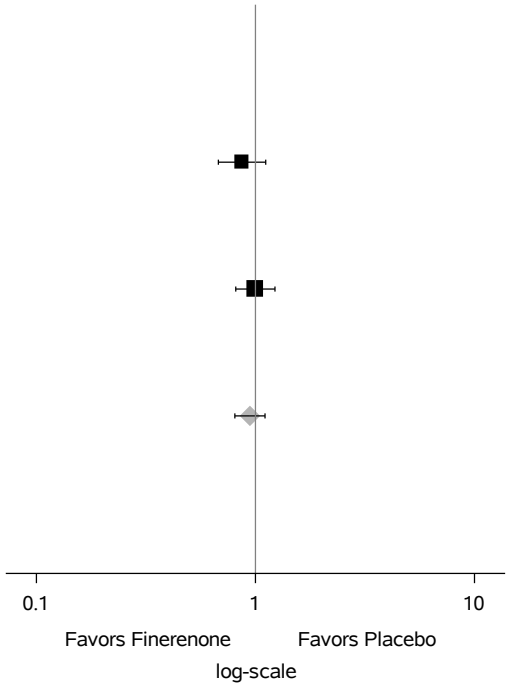
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 2827	47 / 2831	47.5	1.02 [0.69,1.52]	
FIGARO-DKD	58 / 3683	48 / 3658	52.5	1.20 [0.82,1.75]	
Total	106 / 6510	95 / 6489		1.11 [0.85,1.46]	Z=0.76, p=0.4472
Heterogeneity:	Q=0.32 (df=1)	p=0.5691	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.130: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set

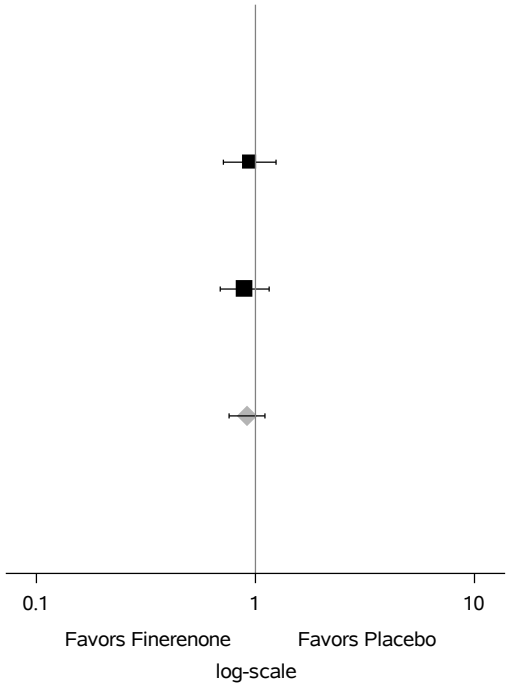
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2827	128 / 2831	40.7	0.87 [0.68,1.11]	
FIGARO-DKD	173 / 3683	172 / 3658	59.3	1.00 [0.81,1.23]	
Total	284 / 6510	300 / 6489		0.94 [0.81,1.11]	Z=-0.72, p=0.4728
Heterogeneity:	Q=0.72 (df=1)	p=0.3954	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.131: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set

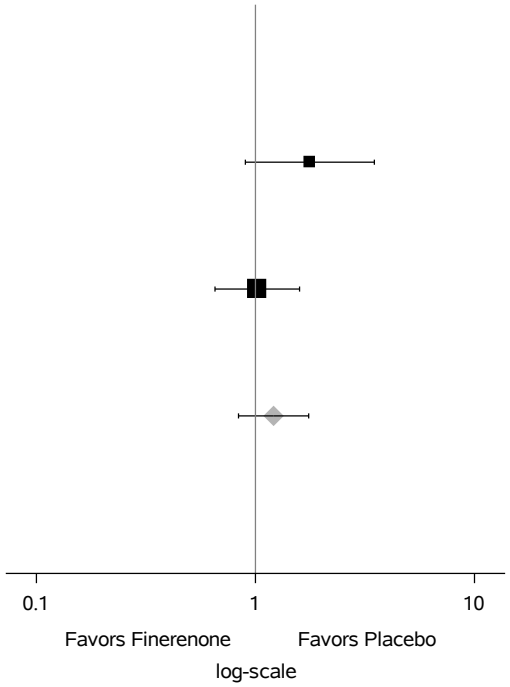
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2827	100 / 2831	46.3	0.94 [0.71,1.24]	
FIGARO-DKD	107 / 3683	119 / 3658	53.7	0.89 [0.69,1.15]	
Total	201 / 6510	219 / 6489		0.92 [0.76,1.10]	Z=-0.92, p=0.3558
Heterogeneity:	Q=0.07 (df=1)	p=0.7847	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.132: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oropharyngeal pain (PT with Incidence >=1%)
Safety Analysis Set

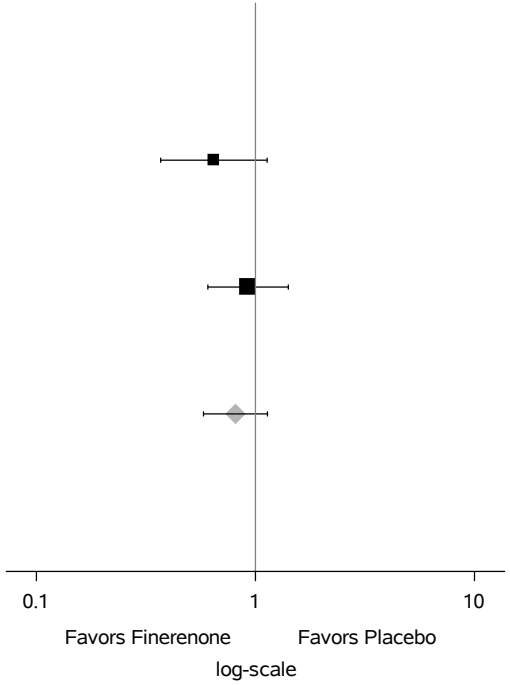
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	13 / 2831	30.0	1.77 [0.90,3.49]	
FIGARO-DKD	39 / 3683	38 / 3658	70.0	1.02 [0.65,1.59]	
Total	62 / 6510	51 / 6489		1.21 [0.84,1.75]	Z=1.01, p=0.3110
Heterogeneity:	Q=1.79 (df=1)	p=0.1813	I^2=44.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.133: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set

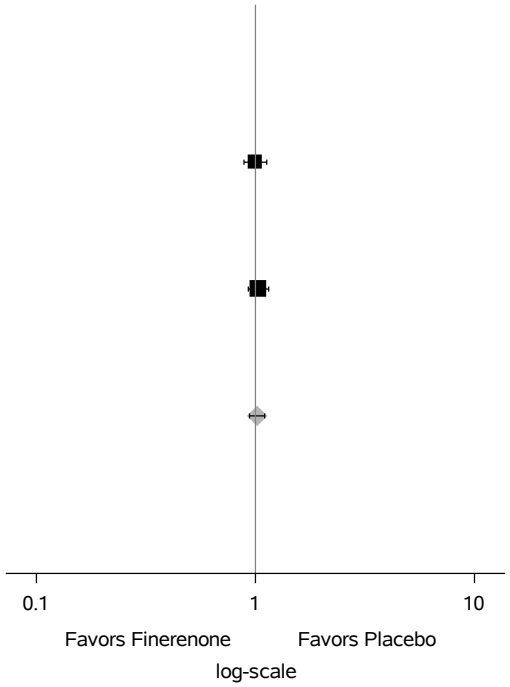
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2827	31 / 2831	36.3	0.65 [0.37,1.13]	
FIGARO-DKD	41 / 3683	44 / 3658	63.7	0.93 [0.61,1.41]	
Total	61 / 6510	75 / 6489		0.81 [0.58,1.13]	Z=-1.23, p=0.2205
Heterogeneity:	Q=1.01 (df=1)	p=0.3153	I^2=0.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.134: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

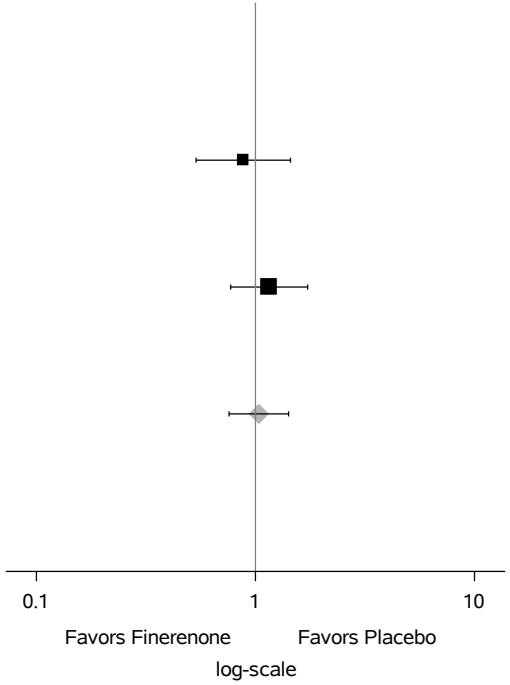
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	450 / 2827	451 / 2831	44.4	1.00 [0.89,1.13]	
FIGARO-DKD	578 / 3683	556 / 3658	55.6	1.03 [0.93,1.15]	
Total	1028 / 6510	1007 / 6489		1.02 [0.94,1.10]	Z=0.43, p=0.6687
Heterogeneity:	Q=0.16 (df=1)	p=0.6890	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.135: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set

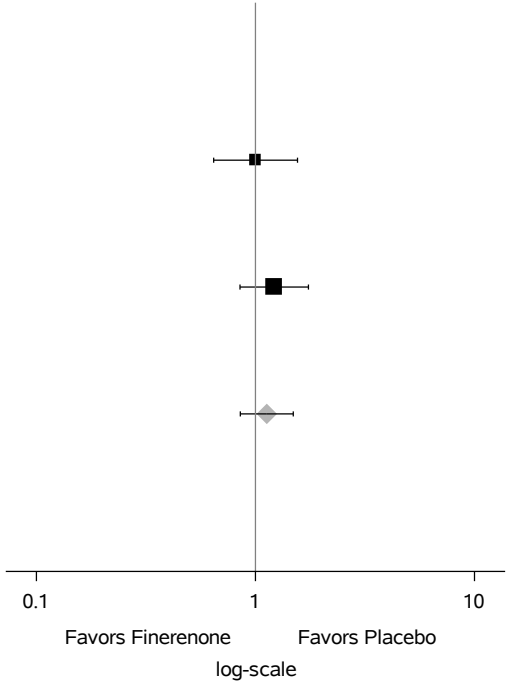
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	33 / 2831	40.0	0.88 [0.54,1.45]	
FIGARO-DKD	50 / 3683	43 / 3658	60.0	1.15 [0.77,1.73]	
Total	79 / 6510	76 / 6489		1.04 [0.76,1.42]	Z=0.22, p=0.8250
Heterogeneity:	Q=0.69 (df=1)	p=0.4055	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.136: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set

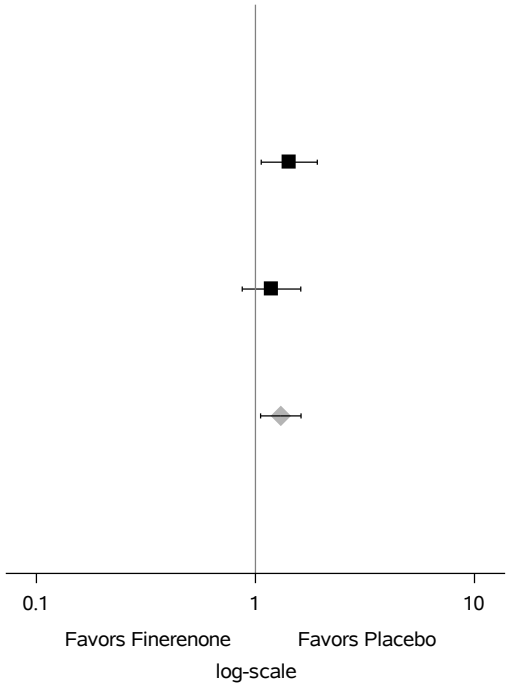
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	39 / 2831	40.0	1.00 [0.64,1.56]	
FIGARO-DKD	65 / 3683	53 / 3658	60.0	1.22 [0.85,1.75]	
Total	104 / 6510	92 / 6489		1.13 [0.85,1.49]	Z=0.84, p=0.4015
Heterogeneity:	Q=0.46 (df=1)	p=0.4999	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.137: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

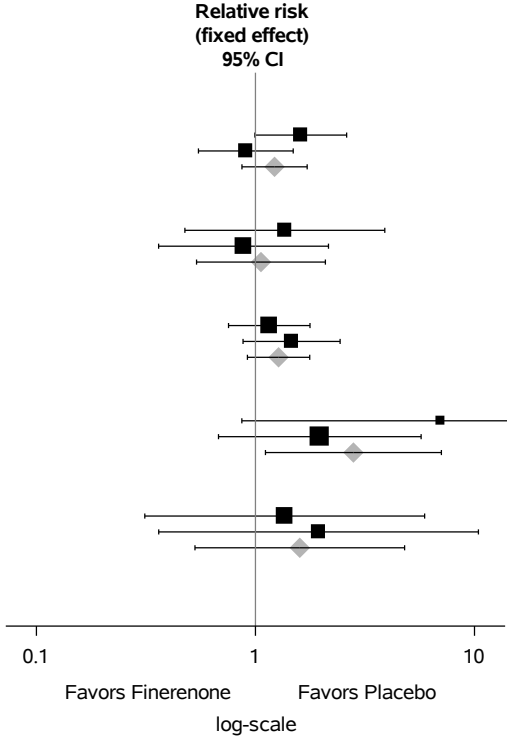
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	73 / 2831	52.2	1.43 [1.06,1.92]	
FIGARO-DKD	87 / 3683	73 / 3658	47.8	1.18 [0.87,1.61]	
Total	191 / 6510	146 / 6489		1.31 [1.06,1.61]	Z=2.46, p=0.0140
Heterogeneity:	Q=0.74 (df=1)	p=0.3904	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.137.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

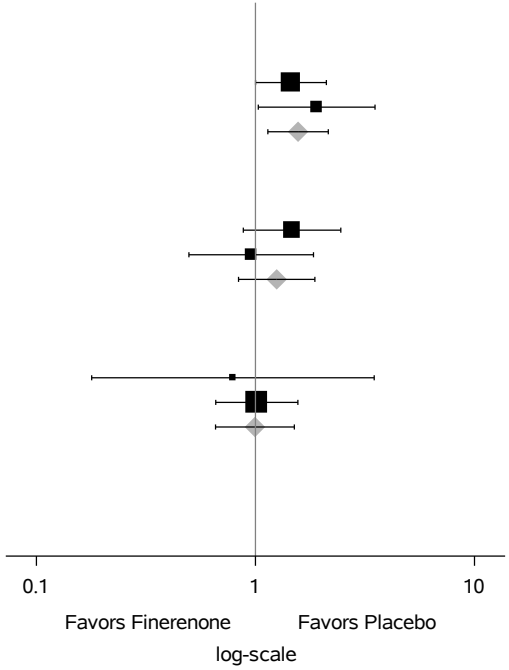
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	42 / 1178	26 / 1174	51.6	1.61 [0.99,2.61]	
FIGARO-DKD	29 / 1752	32 / 1747	48.4	0.90 [0.55,1.49]	
Total	71 / 2930	58 / 2921		1.22 [0.87,1.72]	Z=1.15, p=0.2511
Heterogeneity:	Q=2.66 (df=1)	p=0.1026	I^2=62.5%		
North America					
FIDELIO-DKD	8 / 466	6 / 476	41.9	1.36 [0.48,3.89]	
FIGARO-DKD	9 / 559	10 / 548	58.1	0.88 [0.36,2.15]	
Total	17 / 1025	16 / 1024		1.06 [0.54,2.09]	Z=0.17, p=0.8668
Heterogeneity:	Q=0.38 (df=1)	p=0.5371	I^2=0.0%		
Asia					
FIDELIO-DKD	43 / 790	37 / 786	58.7	1.16 [0.75,1.77]	
FIGARO-DKD	35 / 811	24 / 813	41.3	1.46 [0.88,2.44]	
Total	78 / 1601	61 / 1599		1.28 [0.92,1.77]	Z=1.45, p=0.1457
Heterogeneity:	Q=0.48 (df=1)	p=0.4901	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 294	1 / 294	20.6	7.00 [0.87,56.54]	
FIGARO-DKD	10 / 424	5 / 417	79.4	1.97 [0.68,5.71]	
Total	17 / 718	6 / 711		2.80 [1.11,7.06]	Z=2.18, p=0.0291
Heterogeneity:	Q=1.16 (df=1)	p=0.2811	I^2=13.9%		
Others					
FIDELIO-DKD	4 / 99	3 / 101	56.6	1.36 [0.31,5.92]	
FIGARO-DKD	4 / 137	2 / 133	43.4	1.94 [0.36,10.42]	
Total	8 / 236	5 / 234		1.59 [0.53,4.80]	Z=0.83, p=0.4071
Heterogeneity:	Q=0.10 (df=1)	p=0.7548	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.26 (df=4)	p=0.5149	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.137.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

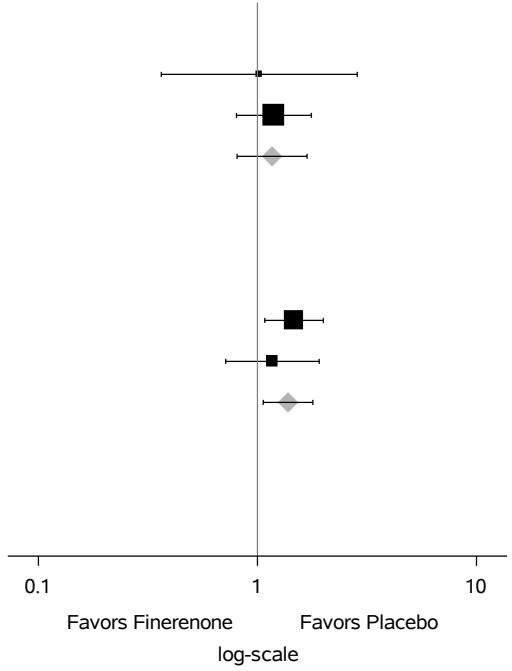
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	66 / 1556	45 / 1541	73.1	1.45 [1.00,2.11]	
FIGARO-DKD	29 / 637	15 / 627	26.9	1.90 [1.03,3.51]	
Total	95 / 2193	60 / 2168		1.57 [1.14,2.15]	Z=2.76, p=0.0057
Heterogeneity:	Q=0.54 (df=1)	p=0.4606	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	24 / 1069	62.0	1.47 [0.88,2.45]	
FIGARO-DKD	17 / 720	18 / 729	38.0	0.96 [0.50,1.84]	
Total	52 / 1781	42 / 1798		1.25 [0.84,1.87]	Z=1.09, p=0.2755
Heterogeneity:	Q=1.03 (df=1)	p=0.3113	I^2=2.5%		
>= 60					
FIDELIO-DKD	3 / 210	4 / 221	7.8	0.79 [0.18,3.48]	
FIGARO-DKD	41 / 2326	40 / 2302	92.2	1.01 [0.66,1.56]	
Total	44 / 2536	44 / 2523		0.99 [0.66,1.50]	Z=-0.03, p=0.9794
Heterogeneity:	Q=0.10 (df=1)	p=0.7504	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.95 (df=2)	p=0.2283	I^2=32.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.137.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

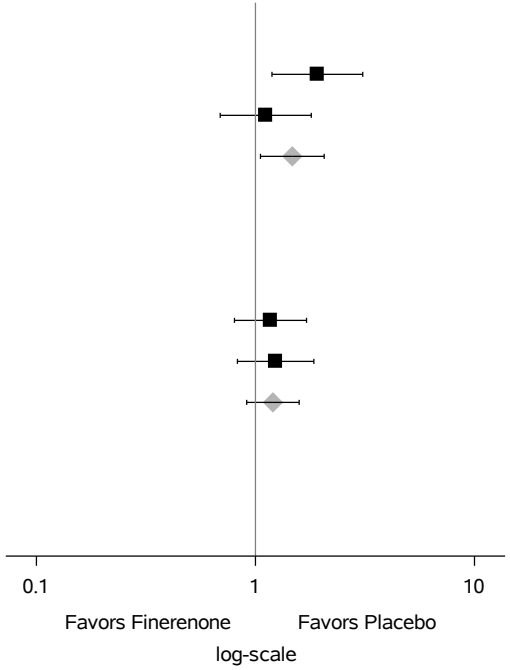
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	7 / 213	12.8	1.02 [0.36,2.86]	
FIGARO-DKD	53 / 1720	44 / 1698	87.2	1.19 [0.80,1.76]	
Total	60 / 1929	51 / 1911		1.17 [0.81,1.68]	Z=0.82, p=0.4132
Heterogeneity:	Q=0.08 (df=1)	p=0.7840	I^2=0.0%		
Very High					
FIDELIO-DKD	97 / 2618	66 / 2618	71.8	1.47 [1.08,2.00]	
FIGARO-DKD	34 / 1963	29 / 1960	28.2	1.17 [0.72,1.91]	
Total	131 / 4581	95 / 4578		1.38 [1.06,1.79]	Z=2.42, p=0.0156
Heterogeneity:	Q=0.59 (df=1)	p=0.4420	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4652	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.137.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

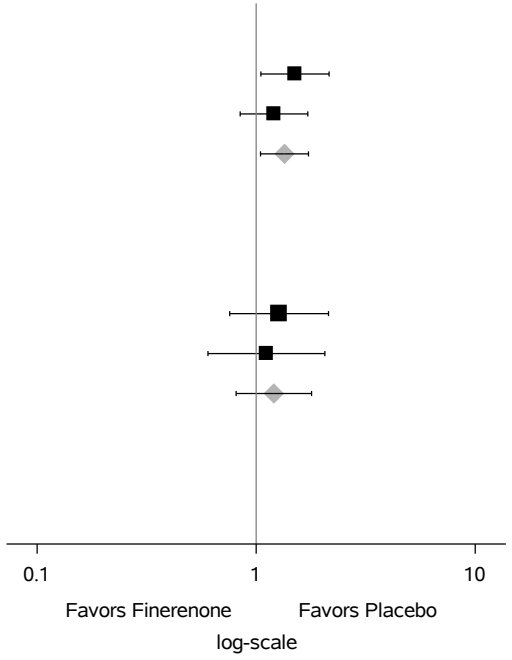
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	48 / 1301	25 / 1299	50.1	1.92 [1.19,3.09]	
FIGARO-DKD	35 / 1673	31 / 1651	49.9	1.11 [0.69,1.80]	
Total	83 / 2974	56 / 2950		1.47 [1.05,2.06]	Z=2.27, p=0.0234
Heterogeneity:	Q=2.48 (df=1)	p=0.1154	I^2=59.6%		
Absent					
FIDELIO-DKD	56 / 1526	48 / 1532	52.9	1.17 [0.80,1.71]	
FIGARO-DKD	52 / 2010	42 / 2007	47.1	1.24 [0.83,1.85]	
Total	108 / 3536	90 / 3539		1.20 [0.91,1.58]	Z=1.30, p=0.1920
Heterogeneity:	Q=0.04 (df=1)	p=0.8480	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.85 (df=1)	p=0.3568	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.137.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

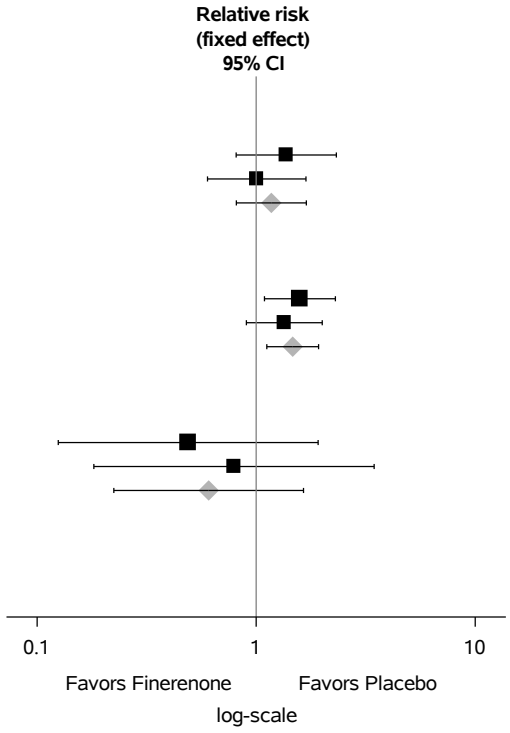
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	73 / 1879	48 / 1858	49.6	1.50 [1.05,2.15]	
FIGARO-DKD	66 / 2643	54 / 2608	50.4	1.21 [0.85,1.72]	
Total	139 / 4522	102 / 4466		1.35 [1.05,1.73]	Z=2.32, p=0.0206
Heterogeneity:	Q=0.73 (df=1)	p=0.3916	I^2=0.0%		
> 4.5					
FIDELIO-DKD	31 / 948	25 / 973	58.4	1.27 [0.76,2.14]	
FIGARO-DKD	21 / 1040	19 / 1048	41.6	1.11 [0.60,2.06]	
Total	52 / 1988	44 / 2021		1.20 [0.81,1.79]	Z=0.92, p=0.3584
Heterogeneity:	Q=0.11 (df=1)	p=0.7452	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6404	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.137.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

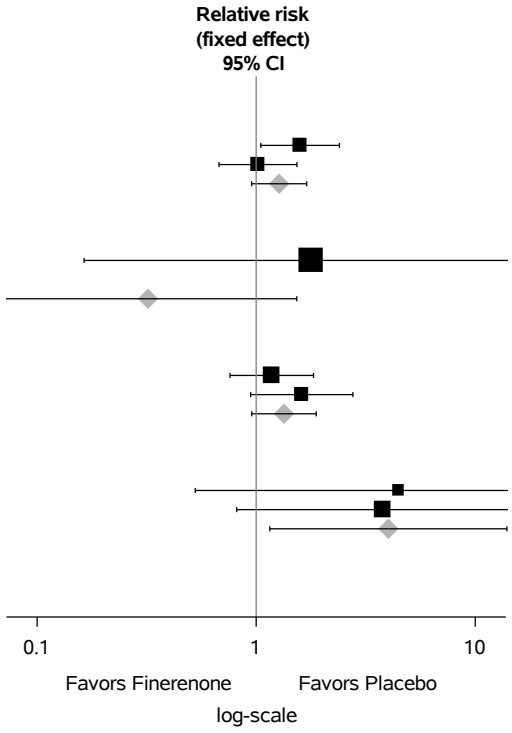
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	32 / 788	23 / 777	49.1	1.37 [0.81,2.32]	
FIGARO-DKD	28 / 1187	28 / 1194	50.9	1.01 [0.60,1.69]	
Total	60 / 1975	51 / 1971		1.17 [0.81,1.69]	Z=0.85, p=0.3955
Heterogeneity:	Q=0.68 (df=1)	p=0.4101	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	69 / 1897	44 / 1916	53.4	1.58 [1.09,2.30]	
FIGARO-DKD	56 / 2389	41 / 2351	46.6	1.34 [0.90,2.00]	
Total	125 / 4286	85 / 4267		1.47 [1.12,1.93]	Z=2.77, p=0.0057
Heterogeneity:	Q=0.35 (df=1)	p=0.5556	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 141	6 / 138	53.8	0.49 [0.12,1.92]	
FIGARO-DKD	3 / 107	4 / 113	46.2	0.79 [0.18,3.46]	
Total	6 / 248	10 / 251		0.61 [0.22,1.64]	Z=-0.98, p=0.3263
Heterogeneity:	Q=0.22 (df=1)	p=0.6384	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.31 (df=2)	p=0.1913	I^2=39.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.137.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

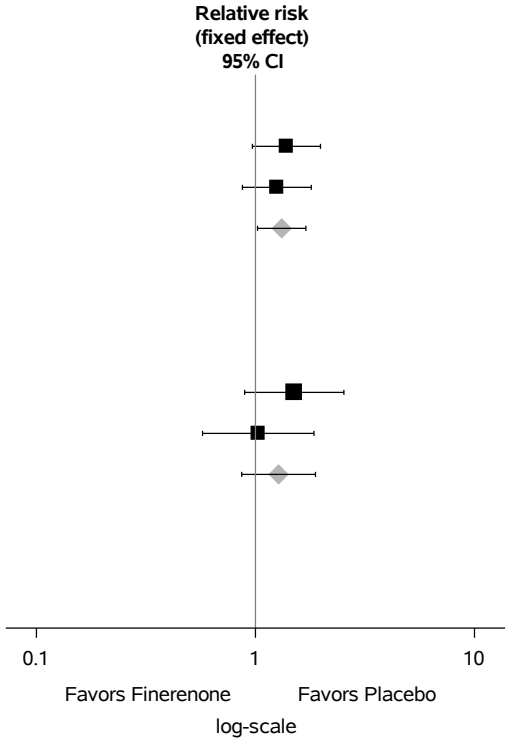
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	56 / 1773	36 / 1809	49.5	1.59 [1.05,2.40]	
FIGARO-DKD	46 / 2668	44 / 2601	50.5	1.02 [0.68,1.54]	
Total	102 / 4441	80 / 4410		1.27 [0.95,1.70]	Z=1.63, p=0.1022
Heterogeneity:	Q=2.22 (df=1)	p=0.1359	I^2=55.0%		
Black					
FIDELIO-DKD	2 / 139	1 / 124	100.0	1.78 [0.16,19.44]	
FIGARO-DKD	0 / 113	6 / 145	0.0	0.00 [0.00,83E295]	
Total	2 / 252	7 / 269		0.32 [0.07,1.53]	Z=-1.43, p=0.1541
Heterogeneity:	Q=1.98 (df=1)	p=0.1589	I^2=49.6%		
Asian					
FIDELIO-DKD	41 / 717	35 / 721	60.0	1.18 [0.76,1.83]	
FIGARO-DKD	33 / 716	21 / 736	40.0	1.62 [0.94,2.76]	
Total	74 / 1433	56 / 1457		1.34 [0.95,1.88]	Z=1.69, p=0.0913
Heterogeneity:	Q=0.80 (df=1)	p=0.3724	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 198	1 / 177	34.0	4.47 [0.53,37.89]	
FIGARO-DKD	8 / 186	2 / 176	66.0	3.78 [0.81,17.58]	
Total	13 / 384	3 / 353		4.01 [1.15,13.96]	Z=2.19, p=0.0289
Heterogeneity:	Q=0.02 (df=1)	p=0.9014	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.26 (df=3)	p=0.0995	I^2=52.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.137.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

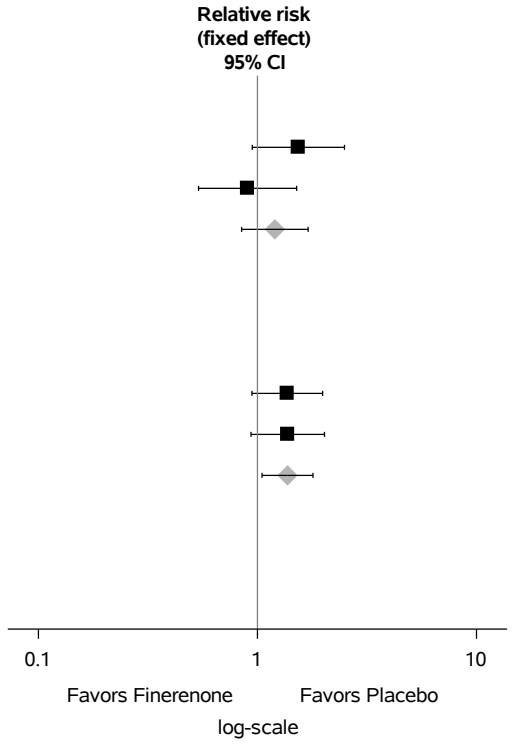
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	68 / 1949	51 / 2024	50.6	1.38 [0.97,1.98]	
FIGARO-DKD	64 / 2527	52 / 2571	49.4	1.25 [0.87,1.80]	
Total	132 / 4476	103 / 4595		1.32 [1.02,1.70]	Z=2.13, p=0.0335
Heterogeneity:	Q=0.15 (df=1)	p=0.6985	I^2=0.0%		
Female					
FIDELIO-DKD	36 / 878	22 / 807	55.8	1.50 [0.89,2.53]	
FIGARO-DKD	23 / 1156	21 / 1087	44.2	1.03 [0.57,1.85]	
Total	59 / 2034	43 / 1894		1.28 [0.87,1.88]	Z=1.23, p=0.2187
Heterogeneity:	Q=0.90 (df=1)	p=0.3439	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8901	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.137.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

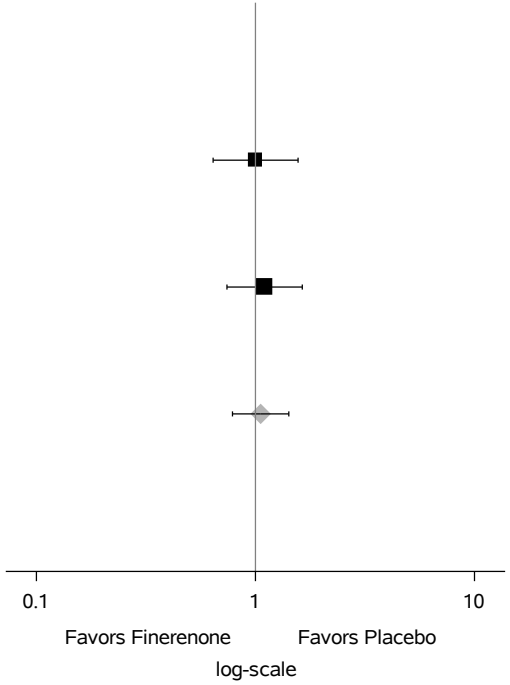
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	41 / 1201	26 / 1171	53.1	1.54 [0.95,2.50]	
FIGARO-DKD	27 / 1752	30 / 1755	46.9	0.90 [0.54,1.51]	
Total	68 / 2953	56 / 2926		1.20 [0.85,1.70]	Z=1.03, p=0.3053
Heterogeneity:	Q=2.19 (df=1)	p=0.1393	I^2=54.2%		
>= 65					
FIDELIO-DKD	63 / 1626	47 / 1660	52.0	1.37 [0.94,1.98]	
FIGARO-DKD	60 / 1931	43 / 1903	48.0	1.38 [0.93,2.02]	
Total	123 / 3557	90 / 3563		1.37 [1.05,1.79]	Z=2.31, p=0.0207
Heterogeneity:	Q=0.00 (df=1)	p=0.9858	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5536	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.138: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set

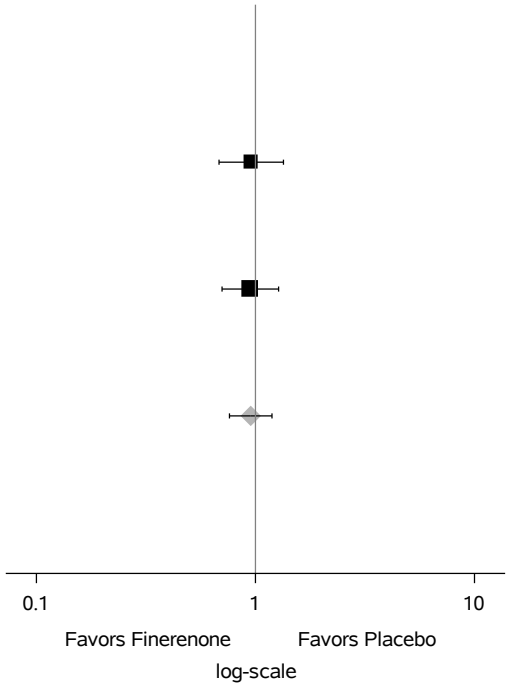
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2827	38 / 2831	44.0	1.00 [0.64,1.57]	
FIGARO-DKD	51 / 3683	46 / 3658	56.0	1.10 [0.74,1.64]	
Total	89 / 6510	84 / 6489		1.06 [0.79,1.42]	Z=0.36, p=0.7178
Heterogeneity:	Q=0.10 (df=1)	p=0.7552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.139: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set

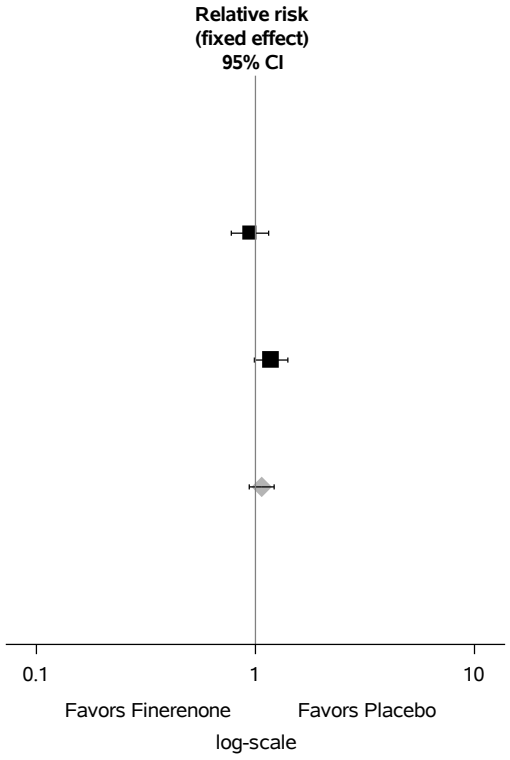
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	67 / 2831	43.5	0.96 [0.68,1.34]	
FIGARO-DKD	83 / 3683	87 / 3658	56.5	0.95 [0.70,1.28]	
Total	147 / 6510	154 / 6489		0.95 [0.76,1.19]	Z=-0.44, p=0.6624
Heterogeneity:	Q=0.00 (df=1)	p=0.9671	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.140: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set

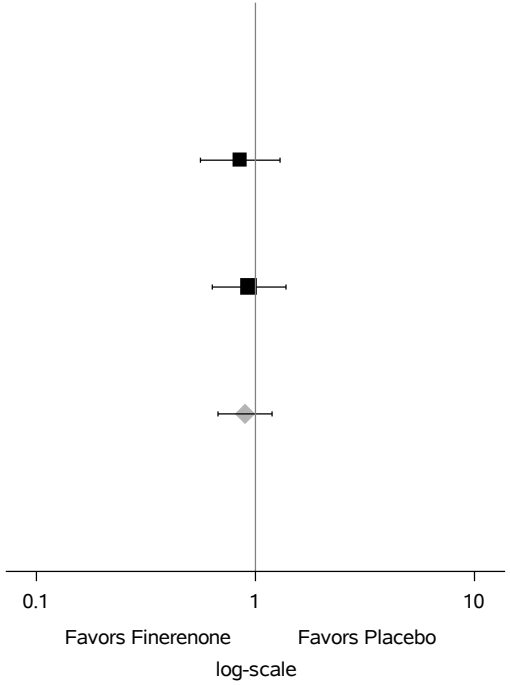
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 2827	192 / 2831	44.6	0.94 [0.78,1.15]	
FIGARO-DKD	254 / 3683	214 / 3658	55.4	1.18 [0.99,1.41]	
Total	435 / 6510	406 / 6489		1.07 [0.94,1.22]	Z=0.98, p=0.3249
Heterogeneity:	Q=2.73 (df=1)	p=0.0986	I^2=63.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.141: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set

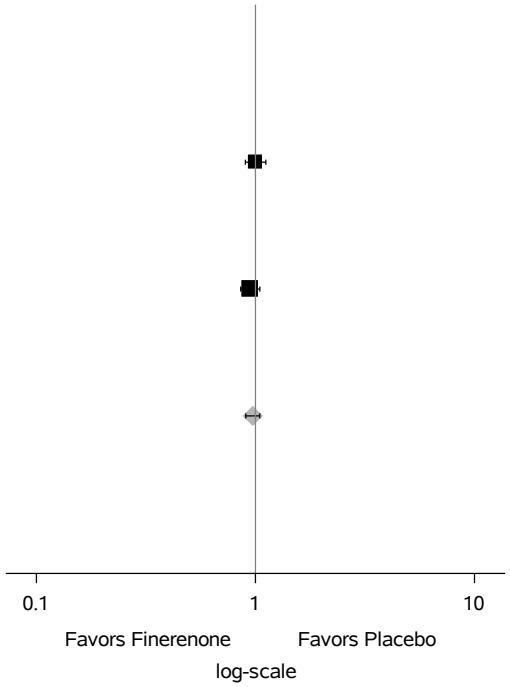
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	47 / 2831	46.2	0.85 [0.56,1.30]	
FIGARO-DKD	49 / 3683	52 / 3658	53.8	0.94 [0.64,1.38]	
Total	89 / 6510	99 / 6489		0.90 [0.67,1.19]	Z=-0.76, p=0.4501
Heterogeneity:	Q=0.10 (df=1)	p=0.7476	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.142: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

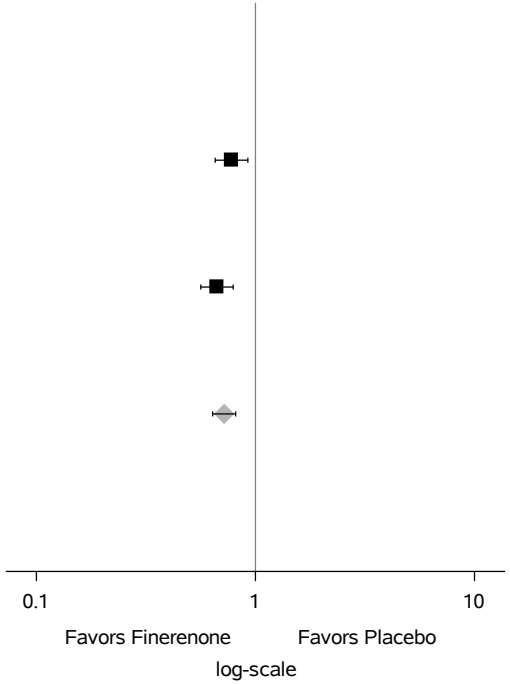
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	537 / 2827	537 / 2831	46.5	1.00 [0.90,1.12]	
FIGARO-DKD	616 / 3683	646 / 3658	53.5	0.95 [0.86,1.05]	
Total	1153 / 6510	1183 / 6489		0.97 [0.90,1.05]	Z=-0.76, p=0.4483
Heterogeneity:	Q=0.55 (df=1)	p=0.4578	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.143: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

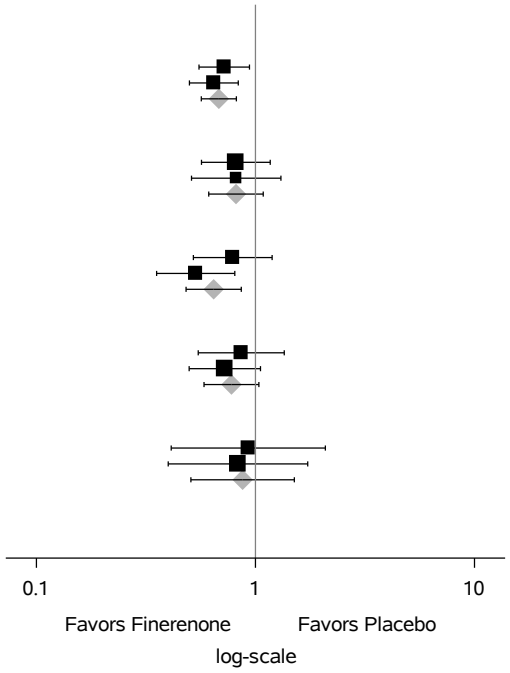
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	212 / 2827	273 / 2831	49.5	0.78 [0.65,0.92]	
FIGARO-DKD	207 / 3683	308 / 3658	50.5	0.67 [0.56,0.79]	
Total	419 / 6510	581 / 6489		0.72 [0.64,0.81]	Z=-5.34, p=<.0001
Heterogeneity:	Q=1.53 (df=1)	p=0.2155	I^2=34.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.143.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

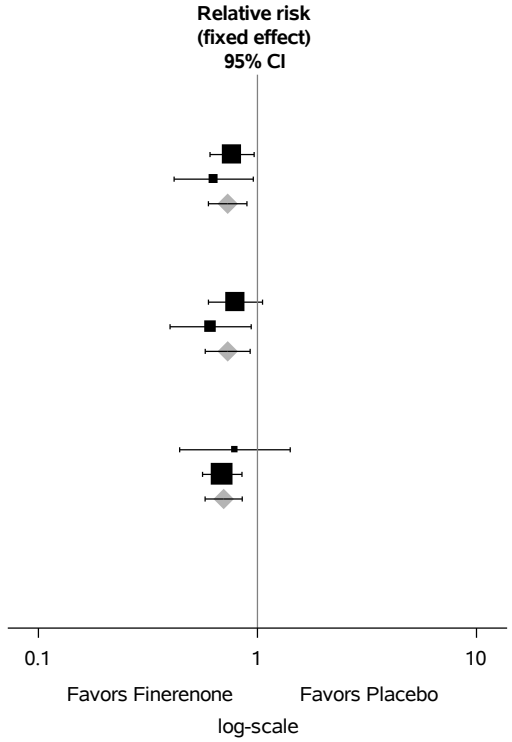
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	86 / 1178	119 / 1174	48.4	0.72 [0.55,0.94]	
FIGARO-DKD	90 / 1752	139 / 1747	51.6	0.65 [0.50,0.83]	
Total	176 / 2930	258 / 2921		0.68 [0.57,0.82]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.34 (df=1)	p=0.5616	I^2=0.0%		
North America					
FIDELIO-DKD	47 / 466	59 / 476	62.9	0.81 [0.57,1.17]	
FIGARO-DKD	30 / 559	36 / 548	37.1	0.82 [0.51,1.31]	
Total	77 / 1025	95 / 1024		0.81 [0.61,1.09]	Z=-1.40, p=0.1613
Heterogeneity:	Q=0.00 (df=1)	p=0.9895	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	48 / 786	49.6	0.79 [0.52,1.19]	
FIGARO-DKD	33 / 811	62 / 813	50.4	0.53 [0.35,0.80]	
Total	71 / 1601	110 / 1599		0.64 [0.48,0.86]	Z=-2.97, p=0.0030
Heterogeneity:	Q=1.71 (df=1)	p=0.1906	I^2=41.6%		
Latin America					
FIDELIO-DKD	31 / 294	36 / 294	40.7	0.86 [0.55,1.35]	
FIGARO-DKD	42 / 424	57 / 417	59.3	0.72 [0.50,1.05]	
Total	73 / 718	93 / 711		0.78 [0.58,1.04]	Z=-1.71, p=0.0865
Heterogeneity:	Q=0.33 (df=1)	p=0.5649	I^2=0.0%		
Others					
FIDELIO-DKD	10 / 99	11 / 101	45.0	0.93 [0.41,2.09]	
FIGARO-DKD	12 / 137	14 / 133	55.0	0.83 [0.40,1.73]	
Total	22 / 236	25 / 234		0.87 [0.51,1.50]	Z=-0.49, p=0.6263
Heterogeneity:	Q=0.04 (df=1)	p=0.8457	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.39 (df=4)	p=0.6641	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.143.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

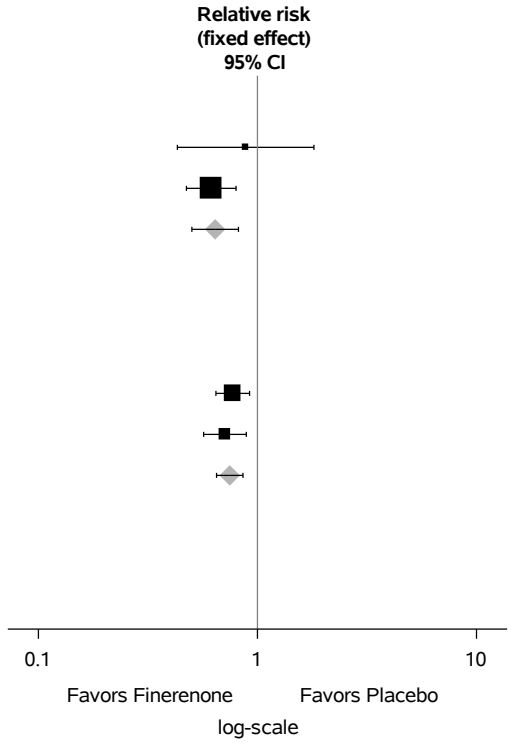
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	116 / 1556	150 / 1541	76.3	0.77 [0.61,0.97]	
FIGARO-DKD	34 / 637	53 / 627	23.7	0.63 [0.42,0.96]	
Total	150 / 2193	203 / 2168		0.73 [0.60,0.90]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.63 (df=1)	p=0.4272	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	78 / 1061	99 / 1069	69.2	0.79 [0.60,1.05]	
FIGARO-DKD	32 / 720	53 / 729	30.8	0.61 [0.40,0.94]	
Total	110 / 1781	152 / 1798		0.73 [0.58,0.93]	Z=-2.60, p=0.0094
Heterogeneity:	Q=1.00 (df=1)	p=0.3178	I^2=0.0%		
>= 60					
FIDELIO-DKD	18 / 210	24 / 221	11.3	0.79 [0.44,1.41]	
FIGARO-DKD	141 / 2326	202 / 2302	88.7	0.69 [0.56,0.85]	
Total	159 / 2536	226 / 2523		0.70 [0.58,0.85]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.18 (df=1)	p=0.6721	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=2)	p=0.9466	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.143.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

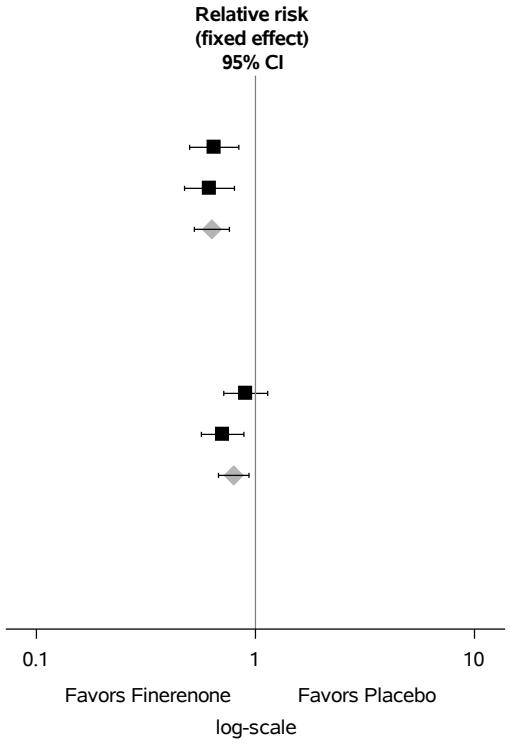
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	13 / 209	15 / 213	11.7	0.88 [0.43,1.81]	
FIGARO-DKD	86 / 1720	138 / 1698	88.3	0.62 [0.47,0.80]	
Total	99 / 1929	153 / 1911		0.64 [0.50,0.82]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.86 (df=1)	p=0.3533	I^2=0.0%		
Very High					
FIDELIO-DKD	199 / 2618	258 / 2618	61.7	0.77 [0.65,0.92]	
FIGARO-DKD	121 / 1963	170 / 1960	38.3	0.71 [0.57,0.89]	
Total	320 / 4581	428 / 4578		0.75 [0.65,0.86]	Z=-4.11, p=<.0001
Heterogeneity:	Q=0.32 (df=1)	p=0.5744	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.14 (df=1)	p=0.2850	I^2=12.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.143.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

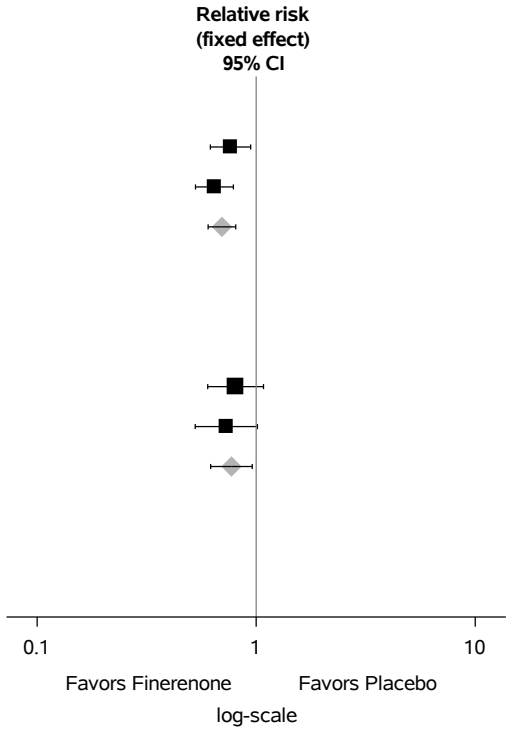
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	87 / 1301	134 / 1299	50.7	0.65 [0.50,0.84]	
FIGARO-DKD	85 / 1673	136 / 1651	49.3	0.62 [0.47,0.80]	
Total	172 / 2974	270 / 2950		0.63 [0.53,0.76]	Z=-4.87, p=<.0001
Heterogeneity:	Q=0.07 (df=1)	p=0.7912	I^2=0.0%		
Absent					
FIDELIO-DKD	125 / 1526	139 / 1532	48.4	0.90 [0.72,1.14]	
FIGARO-DKD	122 / 2010	172 / 2007	51.6	0.71 [0.57,0.89]	
Total	247 / 3536	311 / 3539		0.80 [0.68,0.93]	Z=-2.79, p=0.0052
Heterogeneity:	Q=2.19 (df=1)	p=0.1389	I^2=54.3%		
Subgroup Heterogeneity:	Q=3.39 (df=1)	p=0.0654	I^2=70.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.143.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	139 / 1879	180 / 1858	46.9	0.76 [0.62,0.94]	
FIGARO-DKD	149 / 2643	228 / 2608	53.1	0.64 [0.53,0.79]	
Total	288 / 4522	408 / 4466		0.70 [0.60,0.81]	Z=-4.87, p=<.0001
Heterogeneity:	Q=1.30 (df=1)	p=0.2547	I^2=22.9%		
> 4.5					
FIDELIO-DKD	73 / 948	93 / 973	55.4	0.81 [0.60,1.08]	
FIGARO-DKD	58 / 1040	80 / 1048	44.6	0.73 [0.53,1.01]	
Total	131 / 1988	173 / 2021		0.77 [0.62,0.96]	Z=-2.33, p=0.0196
Heterogeneity:	Q=0.19 (df=1)	p=0.6624	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4536	I^2=0.0%		

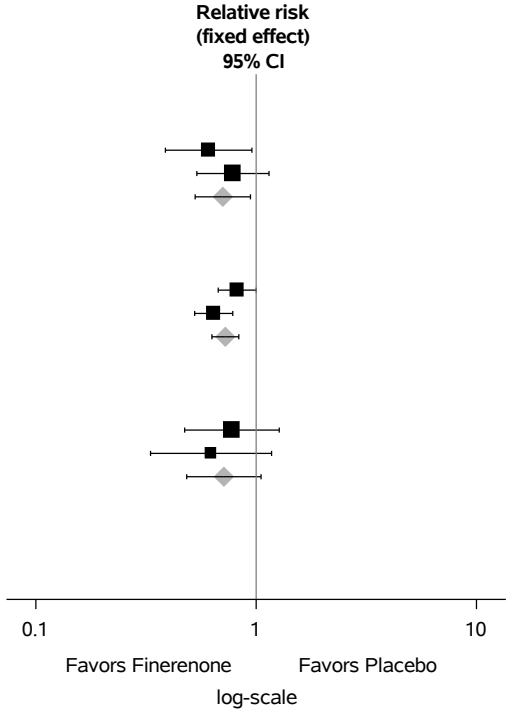


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.143.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)

Safety Analysis Set

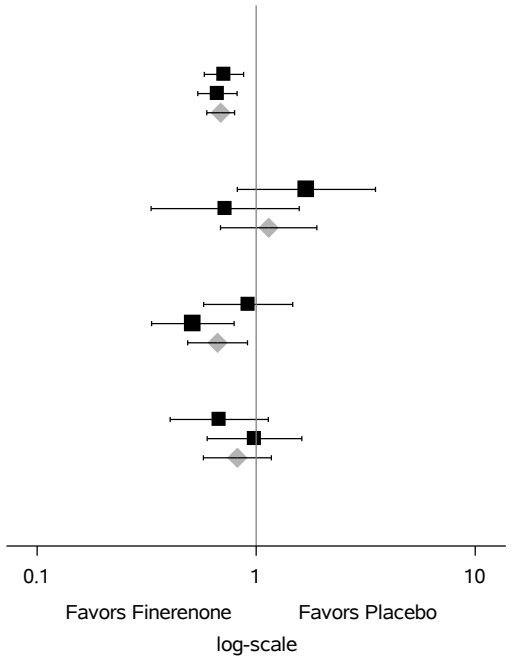
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	29 / 788	47 / 777	41.0	0.61 [0.39,0.96]	
FIGARO-DKD	46 / 1187	59 / 1194	59.0	0.78 [0.54,1.14]	
Total	75 / 1975	106 / 1971		0.71 [0.53,0.94]	Z=-2.36, p=0.0181
Heterogeneity:	Q=0.71 (df=1)	p=0.3979	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	160 / 1897	197 / 1916	50.1	0.82 [0.67,1.00]	
FIGARO-DKD	148 / 2389	227 / 2351	49.9	0.64 [0.53,0.78]	
Total	308 / 4286	424 / 4267		0.72 [0.63,0.83]	Z=-4.49, p=<.0001
Heterogeneity:	Q=2.93 (df=1)	p=0.0869	I^2=65.9%		
>= 160					
FIDELIO-DKD	23 / 141	29 / 138	62.1	0.78 [0.47,1.27]	
FIGARO-DKD	13 / 107	22 / 113	37.9	0.62 [0.33,1.17]	
Total	36 / 248	51 / 251		0.71 [0.48,1.05]	Z=-1.70, p=0.0886
Heterogeneity:	Q=0.28 (df=1)	p=0.5942	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=2)	p=0.9856	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.143.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

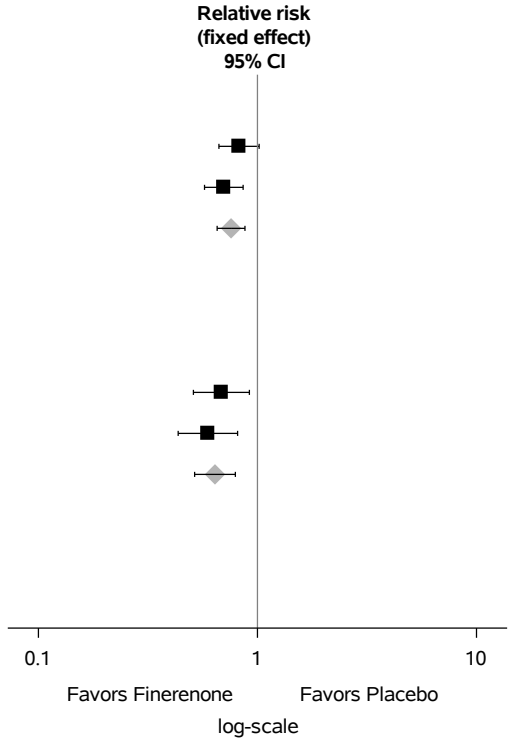
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	139 / 1773	199 / 1809	50.0	0.71 [0.58,0.88]	
FIGARO-DKD	142 / 2668	208 / 2601	50.0	0.67 [0.54,0.82]	
Total	281 / 4441	407 / 4410		0.69 [0.60,0.80]	Z=-5.01, p=<.0001
Heterogeneity:	Q=0.21 (df=1)	p=0.6461	I^2=0.0%		
Black					
FIDELIO-DKD	19 / 139	10 / 124	53.5	1.69 [0.82,3.50]	
FIGARO-DKD	9 / 113	16 / 145	46.5	0.72 [0.33,1.57]	
Total	28 / 252	26 / 269		1.14 [0.69,1.89]	Z=0.51, p=0.6113
Heterogeneity:	Q=2.47 (df=1)	p=0.1162	I^2=59.5%		
Asian					
FIDELIO-DKD	32 / 717	35 / 721	46.2	0.92 [0.58,1.47]	
FIGARO-DKD	29 / 716	58 / 736	53.8	0.51 [0.33,0.79]	
Total	61 / 1433	93 / 1457		0.67 [0.49,0.91]	Z=-2.53, p=0.0115
Heterogeneity:	Q=3.19 (df=1)	p=0.0739	I^2=68.7%		
Others					
FIDELIO-DKD	22 / 198	29 / 177	48.2	0.68 [0.40,1.14]	
FIGARO-DKD	27 / 186	26 / 176	51.8	0.98 [0.60,1.62]	
Total	49 / 384	55 / 353		0.82 [0.57,1.17]	Z=-1.09, p=0.2778
Heterogeneity:	Q=1.03 (df=1)	p=0.3104	I^2=2.8%		
Subgroup Heterogeneity:	Q=4.27 (df=3)	p=0.2335	I^2=29.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.143.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

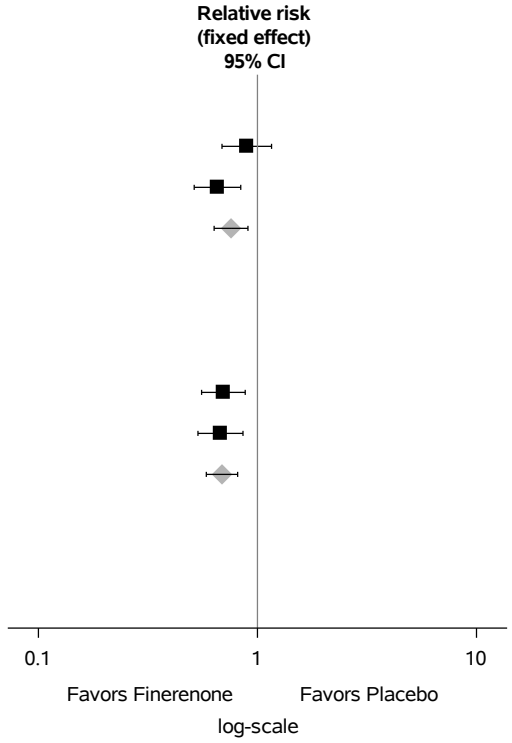
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	142 / 1949	179 / 2024	48.0	0.82 [0.67,1.02]	
FIGARO-DKD	147 / 2527	213 / 2571	52.0	0.70 [0.57,0.86]	
Total	289 / 4476	392 / 4595		0.76 [0.65,0.88]	Z=-3.72, p=0.0002
Heterogeneity:	Q=1.14 (df=1)	p=0.2849	I^2=12.5%		
Female					
FIDELIO-DKD	70 / 878	94 / 807	53.0	0.68 [0.51,0.92]	
FIGARO-DKD	60 / 1156	95 / 1087	47.0	0.59 [0.43,0.81]	
Total	130 / 2034	189 / 1894		0.64 [0.52,0.79]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.42 (df=1)	p=0.5168	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.63 (df=1)	p=0.2016	I^2=38.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.143.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

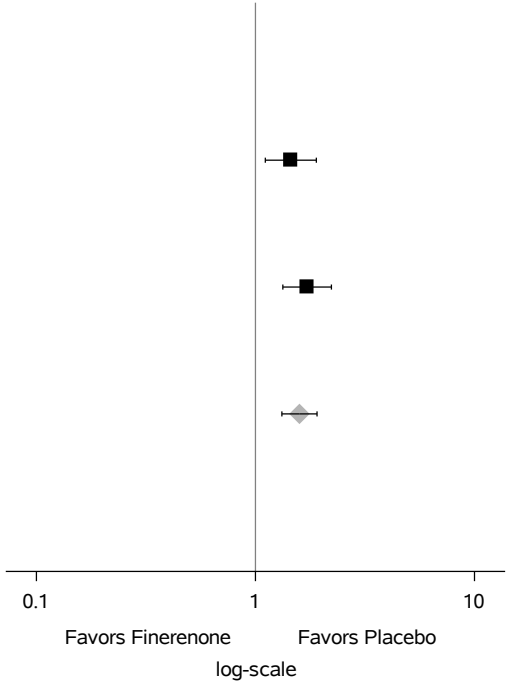
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	99 / 1201	108 / 1171	46.9	0.89 [0.69,1.16]	
FIGARO-DKD	99 / 1752	151 / 1755	53.1	0.66 [0.51,0.84]	
Total	198 / 2953	259 / 2926		0.76 [0.63,0.90]	Z=-3.06, p=0.0022
Heterogeneity:	Q=2.86 (df=1)	p=0.0911	I^2=65.0%		
>= 65					
FIDELIO-DKD	113 / 1626	165 / 1660	51.6	0.70 [0.56,0.88]	
FIGARO-DKD	108 / 1931	157 / 1903	48.4	0.68 [0.54,0.86]	
Total	221 / 3557	322 / 3563		0.69 [0.58,0.81]	Z=-4.44, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8544	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=1)	p=0.4420	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

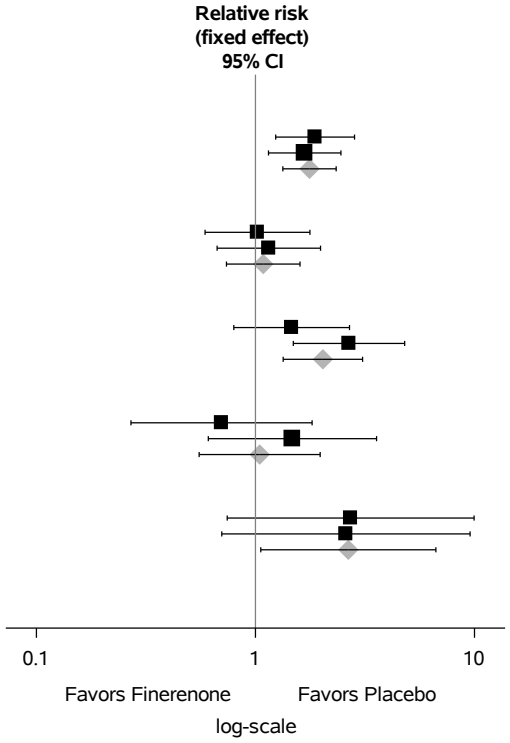
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	87 / 2831	47.6	1.45 [1.11,1.90]	
FIGARO-DKD	156 / 3683	90 / 3658	52.4	1.72 [1.33,2.22]	
Total	282 / 6510	177 / 6489		1.59 [1.32,1.91]	Z=4.91, p=<.0001
Heterogeneity:	Q=0.82 (df=1)	p=0.3642	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.144.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

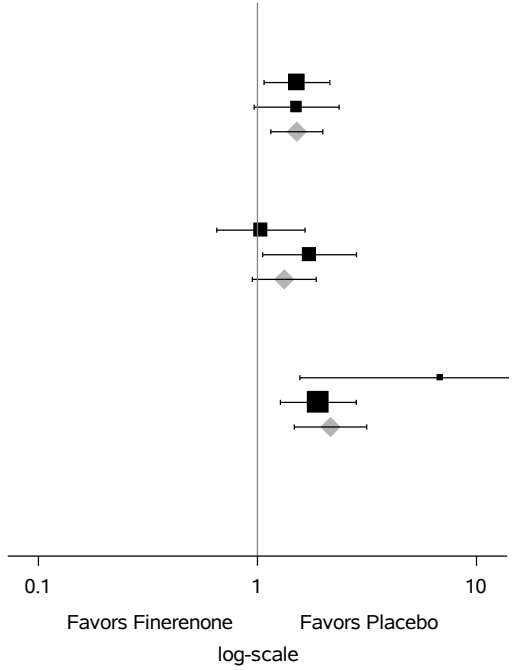
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	62 / 1178	33 / 1174	45.8	1.87 [1.24,2.83]	
FIGARO-DKD	69 / 1752	41 / 1747	54.2	1.68 [1.15,2.46]	
Total	131 / 2930	74 / 2921		1.77 [1.33,2.34]	Z=3.97, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.7028	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 466	24 / 476	49.3	1.02 [0.59,1.77]	
FIGARO-DKD	27 / 559	23 / 548	50.7	1.15 [0.67,1.98]	
Total	51 / 1025	47 / 1024		1.09 [0.74,1.60]	Z=0.41, p=0.6786
Heterogeneity:	Q=0.09 (df=1)	p=0.7627	I^2=0.0%		
Asia					
FIDELIO-DKD	25 / 790	17 / 786	48.1	1.46 [0.80,2.69]	
FIGARO-DKD	40 / 811	15 / 813	51.9	2.67 [1.49,4.80]	
Total	65 / 1601	32 / 1599		2.03 [1.34,3.08]	Z=3.33, p=0.0009
Heterogeneity:	Q=1.96 (df=1)	p=0.1611	I^2=49.1%		
Latin America					
FIDELIO-DKD	7 / 294	10 / 294	46.3	0.70 [0.27,1.81]	
FIGARO-DKD	12 / 424	8 / 417	53.7	1.48 [0.61,3.57]	
Total	19 / 718	18 / 711		1.05 [0.55,1.97]	Z=0.14, p=0.8919
Heterogeneity:	Q=1.26 (df=1)	p=0.2609	I^2=20.9%		
Others					
FIDELIO-DKD	8 / 99	3 / 101	50.3	2.72 [0.74,9.96]	
FIGARO-DKD	8 / 137	3 / 133	49.7	2.59 [0.70,9.55]	
Total	16 / 236	6 / 234		2.65 [1.06,6.66]	Z=2.08, p=0.0376
Heterogeneity:	Q=0.00 (df=1)	p=0.9579	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.46 (df=4)	p=0.0761	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

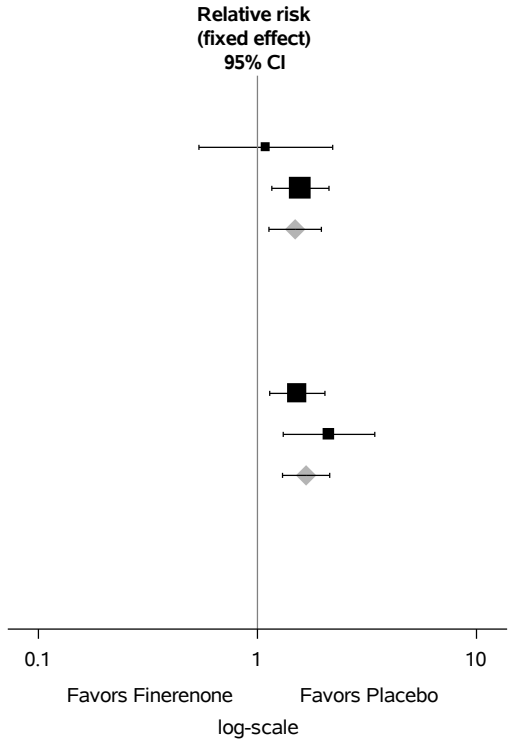
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	78 / 1556	51 / 1541	62.5	1.51 [1.07,2.14]	
FIGARO-DKD	46 / 637	30 / 627	37.5	1.51 [0.97,2.36]	
Total	124 / 2193	81 / 2168		1.51 [1.15,1.99]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.00 (df=1)	p=0.9901	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	34 / 1069	53.0	1.04 [0.65,1.65]	
FIGARO-DKD	41 / 720	24 / 729	47.0	1.73 [1.06,2.83]	
Total	76 / 1781	58 / 1798		1.33 [0.95,1.85]	Z=1.65, p=0.0994
Heterogeneity:	Q=2.19 (df=1)	p=0.1388	I^2=54.4%		
>= 60					
FIDELIO-DKD	13 / 210	2 / 221	6.8	6.84 [1.56,29.95]	
FIGARO-DKD	69 / 2326	36 / 2302	93.2	1.90 [1.27,2.83]	
Total	82 / 2536	38 / 2523		2.16 [1.47,3.15]	Z=3.95, p=<.0001
Heterogeneity:	Q=2.74 (df=1)	p=0.0976	I^2=63.6%		
Subgroup Heterogeneity:	Q=3.71 (df=2)	p=0.1567	I^2=46.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

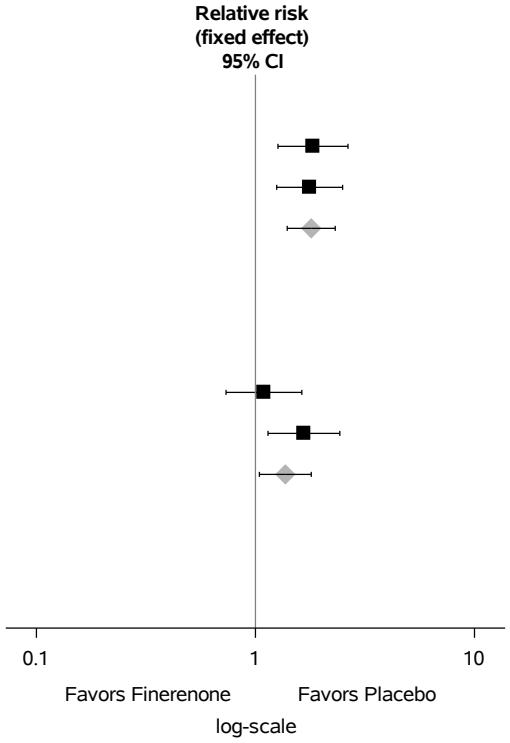
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	15 / 209	14 / 213	15.5	1.09 [0.54,2.21]	
FIGARO-DKD	105 / 1720	66 / 1698	84.5	1.57 [1.16,2.12]	
Total	120 / 1929	80 / 1911		1.49 [1.13,1.96]	Z=2.82, p=0.0048
Heterogeneity:	Q=0.87 (df=1)	p=0.3514	I^2=0.0%		
Very High					
FIDELIO-DKD	111 / 2618	73 / 2618	73.3	1.52 [1.14,2.03]	
FIGARO-DKD	51 / 1963	24 / 1960	26.7	2.12 [1.31,3.43]	
Total	162 / 4581	97 / 4578		1.67 [1.30,2.14]	Z=4.04, p=<.0001
Heterogeneity:	Q=1.35 (df=1)	p=0.2451	I^2=26.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5429	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

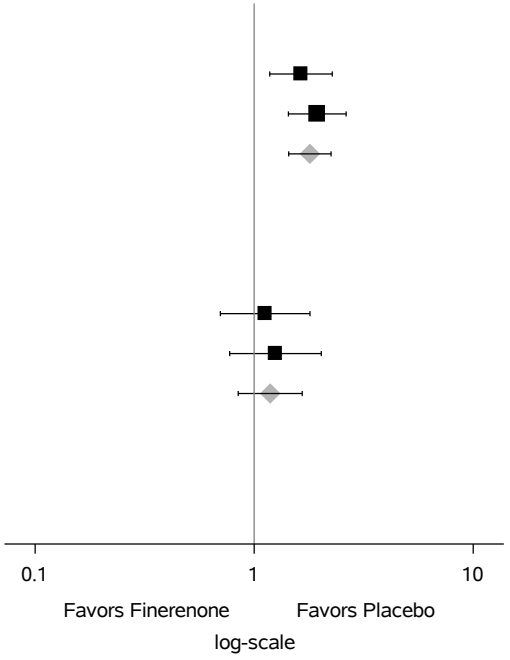
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	77 / 1301	42 / 1299	47.0	1.83 [1.27,2.64]	
FIGARO-DKD	86 / 1673	48 / 1651	53.0	1.77 [1.25,2.50]	
Total	163 / 2974	90 / 2950		1.80 [1.40,2.31]	Z=4.55, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		
Absent					
FIDELIO-DKD	49 / 1526	45 / 1532	47.3	1.09 [0.73,1.63]	
FIGARO-DKD	70 / 2010	42 / 2007	52.7	1.66 [1.14,2.43]	
Total	119 / 3536	87 / 3539		1.37 [1.04,1.80]	Z=2.26, p=0.0240
Heterogeneity:	Q=2.25 (df=1)	p=0.1334	I^2=55.6%		
Subgroup Heterogeneity:	Q=2.07 (df=1)	p=0.1506	I^2=51.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

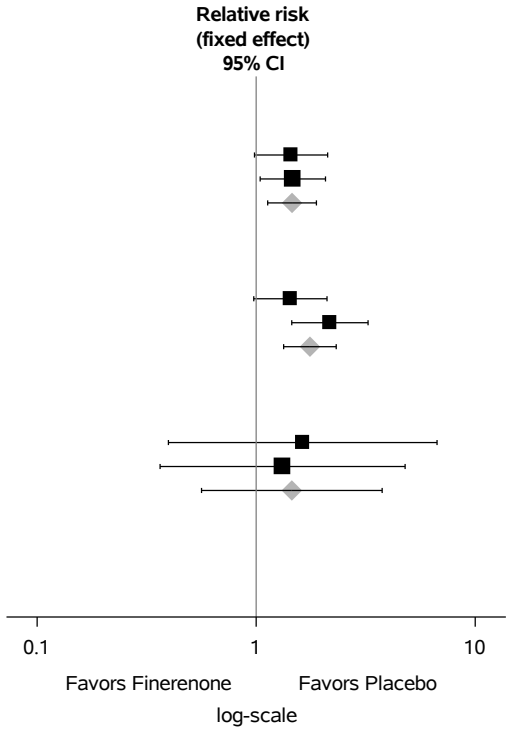
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	91 / 1879	55 / 1858	46.0	1.64 [1.18,2.27]	
FIGARO-DKD	120 / 2643	61 / 2608	54.0	1.94 [1.43,2.63]	
Total	211 / 4522	116 / 4466		1.80 [1.44,2.24]	Z=5.15, p=<.0001
Heterogeneity:	Q=0.56 (df=1)	p=0.4536	I^2=0.0%		
> 4.5					
FIDELIO-DKD	35 / 948	32 / 973	51.1	1.12 [0.70,1.80]	
FIGARO-DKD	36 / 1040	29 / 1048	48.9	1.25 [0.77,2.02]	
Total	71 / 1988	61 / 2021		1.18 [0.85,1.66]	Z=0.98, p=0.3258
Heterogeneity:	Q=0.10 (df=1)	p=0.7528	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.10 (df=1)	p=0.0428	I^2=75.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.144.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

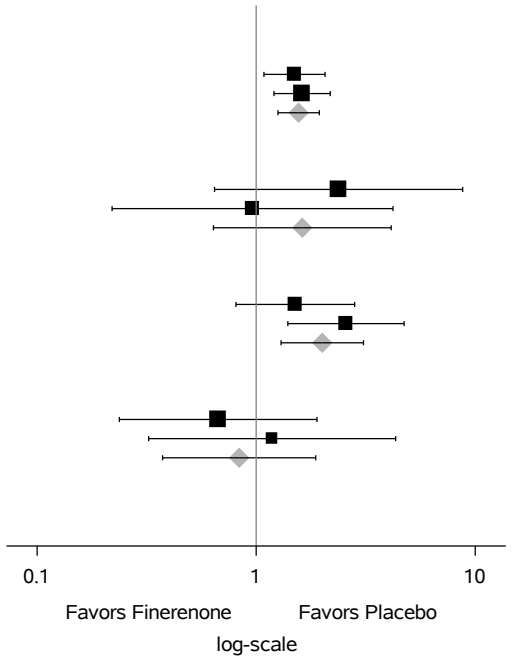
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	60 / 788	41 / 777	44.4	1.44 [0.98,2.12]	
FIGARO-DKD	76 / 1187	52 / 1194	55.6	1.47 [1.04,2.07]	
Total	136 / 1975	93 / 1971		1.46 [1.13,1.88]	Z=2.89, p=0.0039
Heterogeneity:	Q=0.01 (df=1)	p=0.9435	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	61 / 1897	43 / 1916	52.1	1.43 [0.97,2.11]	
FIGARO-DKD	75 / 2389	34 / 2351	47.9	2.17 [1.45,3.24]	
Total	136 / 4286	77 / 4267		1.76 [1.33,2.32]	Z=4.01, p=<.0001
Heterogeneity:	Q=2.15 (df=1)	p=0.1429	I^2=53.4%		
>= 160					
FIDELIO-DKD	5 / 141	3 / 138	45.4	1.63 [0.40,6.69]	
FIGARO-DKD	5 / 107	4 / 113	54.6	1.32 [0.36,4.79]	
Total	10 / 248	7 / 251		1.45 [0.56,3.76]	Z=0.77, p=0.4389
Heterogeneity:	Q=0.05 (df=1)	p=0.8282	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.99 (df=2)	p=0.6099	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.144.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

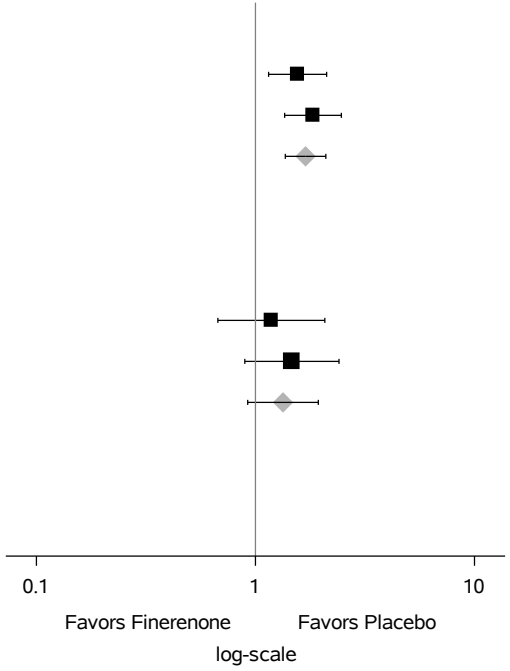
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	88 / 1773	60 / 1809	45.9	1.50 [1.08,2.06]	
FIGARO-DKD	113 / 2668	68 / 2601	54.1	1.62 [1.21,2.18]	
Total	201 / 4441	128 / 4410		1.56 [1.26,1.94]	Z=4.02, p=<.0001
Heterogeneity:	Q=0.13 (df=1)	p=0.7219	I^2=0.0%		
Black					
FIDELIO-DKD	8 / 139	3 / 124	56.2	2.38 [0.65,8.77]	
FIGARO-DKD	3 / 113	4 / 145	43.8	0.96 [0.22,4.21]	
Total	11 / 252	7 / 269		1.62 [0.64,4.13]	Z=1.02, p=0.3090
Heterogeneity:	Q=0.81 (df=1)	p=0.3678	I^2=0.0%		
Asian					
FIDELIO-DKD	24 / 717	16 / 721	49.0	1.51 [0.81,2.82]	
FIGARO-DKD	35 / 716	14 / 736	51.0	2.57 [1.39,4.74]	
Total	59 / 1433	30 / 1457		2.00 [1.30,3.09]	Z=3.14, p=0.0017
Heterogeneity:	Q=1.43 (df=1)	p=0.2314	I^2=30.2%		
Others					
FIDELIO-DKD	6 / 198	8 / 177	61.0	0.67 [0.24,1.89]	
FIGARO-DKD	5 / 186	4 / 176	39.0	1.18 [0.32,4.33]	
Total	11 / 384	12 / 353		0.84 [0.37,1.87]	Z=-0.44, p=0.6635
Heterogeneity:	Q=0.45 (df=1)	p=0.5035	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.56 (df=3)	p=0.3125	I^2=15.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.144.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

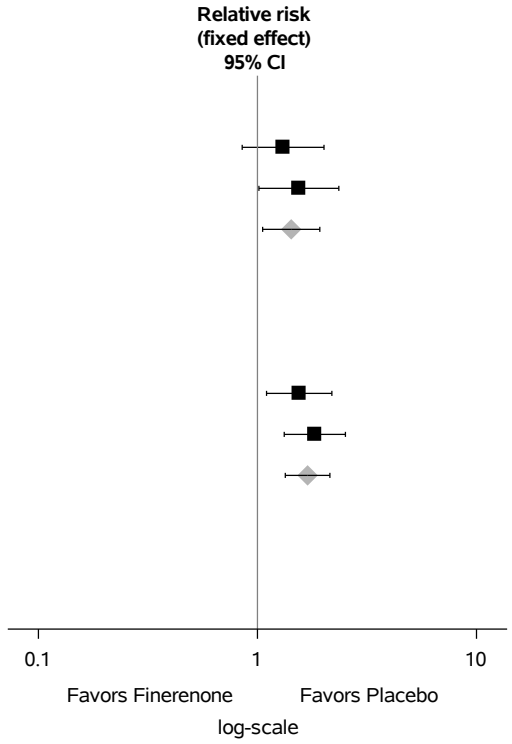
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	99 / 1949	66 / 2024	48.8	1.56 [1.15,2.11]	
FIGARO-DKD	117 / 2527	65 / 2571	51.2	1.83 [1.36,2.47]	
Total	216 / 4476	131 / 4595		1.69 [1.37,2.10]	Z=4.85, p=<.0001
Heterogeneity:	Q=0.55 (df=1)	p=0.4572	I^2=0.0%		
Female					
FIDELIO-DKD	27 / 878	21 / 807	43.7	1.18 [0.67,2.07]	
FIGARO-DKD	39 / 1156	25 / 1087	56.3	1.47 [0.89,2.41]	
Total	66 / 2034	46 / 1894		1.34 [0.92,1.94]	Z=1.53, p=0.1261
Heterogeneity:	Q=0.32 (df=1)	p=0.5718	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.18 (df=1)	p=0.2775	I^2=15.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.144.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

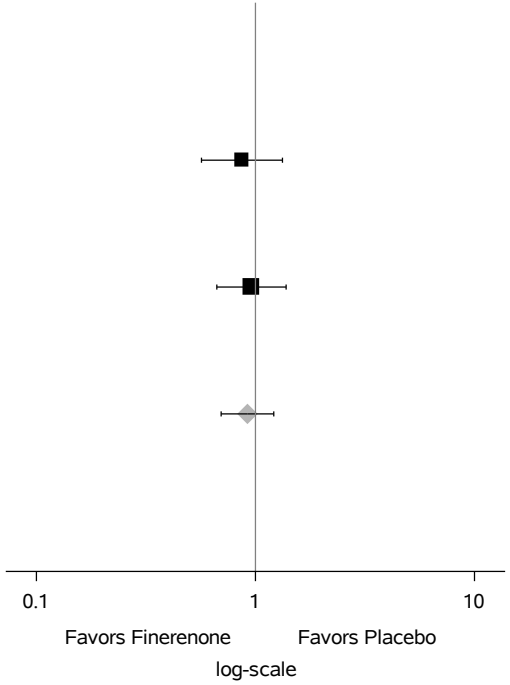
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	47 / 1201	35 / 1171	48.8	1.31 [0.85,2.01]	
FIGARO-DKD	54 / 1752	35 / 1755	51.2	1.55 [1.02,2.35]	
Total	101 / 2953	70 / 2926		1.43 [1.06,1.93]	Z=2.32, p=0.0205
Heterogeneity:	Q=0.29 (df=1)	p=0.5888	I^2=0.0%		
>= 65					
FIDELIO-DKD	79 / 1626	52 / 1660	46.8	1.55 [1.10,2.19]	
FIGARO-DKD	102 / 1931	55 / 1903	53.2	1.83 [1.32,2.52]	
Total	181 / 3557	107 / 3563		1.69 [1.34,2.14]	Z=4.41, p=<.0001
Heterogeneity:	Q=0.47 (df=1)	p=0.4941	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.78 (df=1)	p=0.3759	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.145: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set

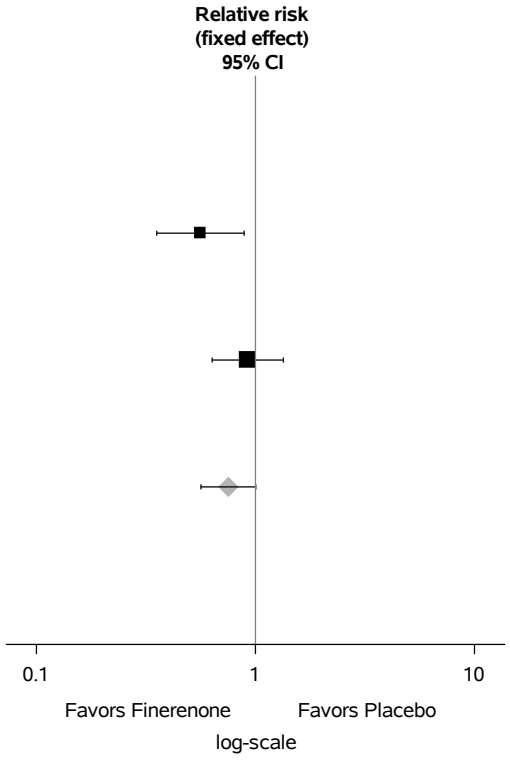
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	45 / 2831	42.3	0.87 [0.57,1.33]	
FIGARO-DKD	56 / 3683	58 / 3658	57.7	0.96 [0.67,1.38]	
Total	95 / 6510	103 / 6489		0.92 [0.70,1.21]	Z=-0.60, p=0.5511
Heterogeneity:	Q=0.12 (df=1)	p=0.7270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.146: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

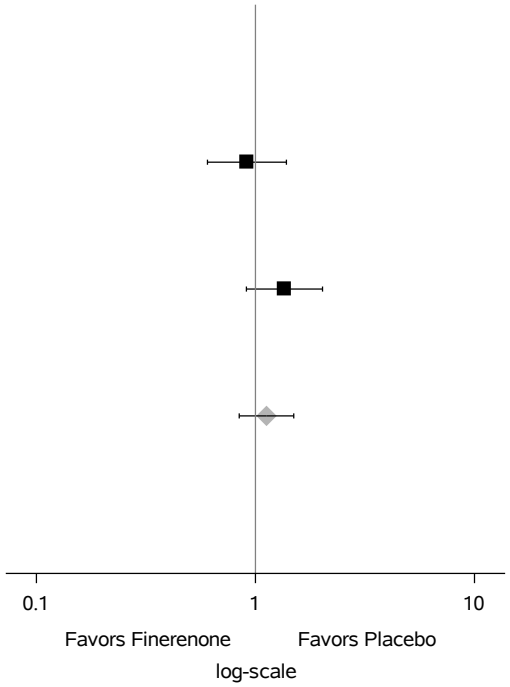
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2827	50 / 2831	39.9	0.56 [0.35,0.89]	
FIGARO-DKD	52 / 3683	56 / 3658	60.1	0.92 [0.63,1.34]	
Total	80 / 6510	106 / 6489		0.75 [0.56,1.00]	Z=-1.94, p=0.0529
Heterogeneity:	Q=2.70 (df=1)	p=0.1001	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.147: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set

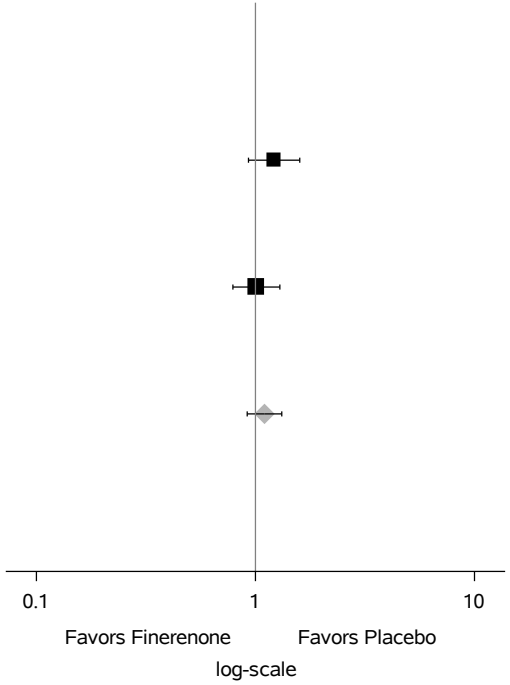
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	46 / 2831	48.2	0.91 [0.60,1.38]	
FIGARO-DKD	56 / 3683	41 / 3658	51.8	1.36 [0.91,2.02]	
Total	98 / 6510	87 / 6489		1.12 [0.84,1.50]	Z=0.79, p=0.4280
Heterogeneity:	Q=1.80 (df=1)	p=0.1799	I^2=44.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.148: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

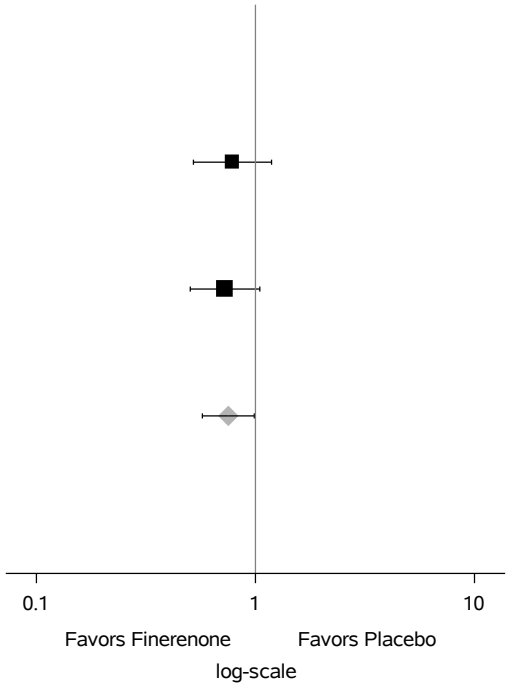
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2827	93 / 2831	45.6	1.22 [0.93,1.59]	
FIGARO-DKD	123 / 3683	121 / 3658	54.4	1.01 [0.79,1.29]	
Total	236 / 6510	214 / 6489		1.10 [0.92,1.32]	Z=1.02, p=0.3059
Heterogeneity:	Q=1.00 (df=1)	p=0.3167	I^2=0.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.149: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

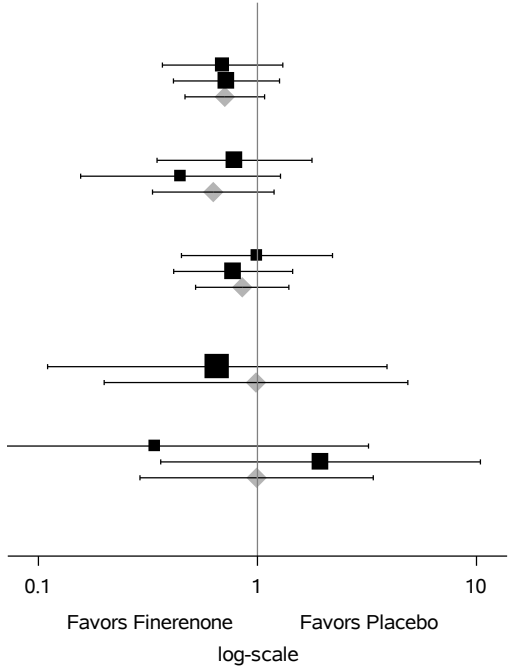
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	51 / 2831	44.2	0.79 [0.52,1.18]	
FIGARO-DKD	49 / 3683	67 / 3658	55.8	0.73 [0.50,1.05]	
Total	89 / 6510	118 / 6489		0.75 [0.57,0.99]	Z=-2.05, p=0.0406
Heterogeneity:	Q=0.08 (df=1)	p=0.7806	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.149.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

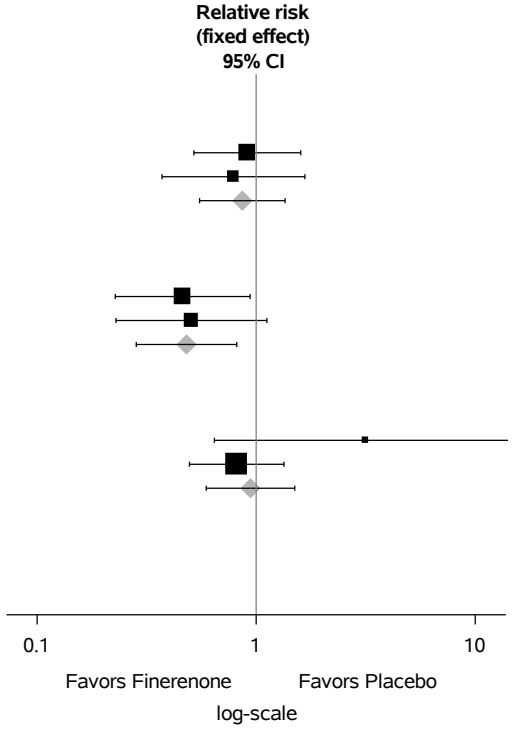
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1178	23 / 1174	43.7	0.69 [0.37,1.31]	
FIGARO-DKD	21 / 1752	29 / 1747	56.3	0.72 [0.41,1.26]	
Total	37 / 2930	52 / 2921		0.71 [0.47,1.08]	Z=-1.61, p=0.1076
Heterogeneity:	Q=0.01 (df=1)	p=0.9247	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	13 / 476	62.5	0.79 [0.35,1.77]	
FIGARO-DKD	5 / 559	11 / 548	37.5	0.45 [0.16,1.27]	
Total	15 / 1025	24 / 1024		0.63 [0.33,1.19]	Z=-1.42, p=0.1543
Heterogeneity:	Q=0.70 (df=1)	p=0.4026	I^2=0.0%		
Asia					
FIDELIO-DKD	12 / 790	12 / 786	38.3	0.99 [0.45,2.20]	
FIGARO-DKD	17 / 811	22 / 813	61.7	0.77 [0.41,1.45]	
Total	29 / 1601	34 / 1599		0.85 [0.52,1.39]	Z=-0.64, p=0.5224
Heterogeneity:	Q=0.24 (df=1)	p=0.6274	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	0 / 294	0.0	131E9 [131E9,131E9]	
FIGARO-DKD	2 / 424	3 / 417	100.0	0.66 [0.11,3.90]	
Total	3 / 718	3 / 711		0.98 [0.20,4.86]	Z=-0.02, p=0.9850
Heterogeneity:	Q=0.20 (df=1)	p=0.6549	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 99	3 / 101	35.9	0.34 [0.04,3.21]	
FIGARO-DKD	4 / 137	2 / 133	64.1	1.94 [0.36,10.42]	
Total	5 / 236	5 / 234		0.99 [0.29,3.38]	Z=-0.01, p=0.9887
Heterogeneity:	Q=1.49 (df=1)	p=0.2228	I^2=32.7%		
Subgroup Heterogeneity:	Q=0.93 (df=4)	p=0.9200	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.149.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

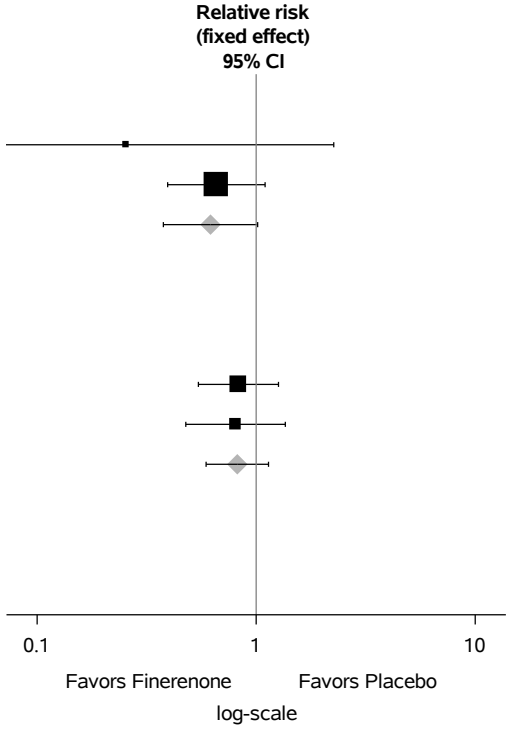
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	23 / 1556	25 / 1541	64.1	0.91 [0.52,1.60]	
FIGARO-DKD	12 / 637	15 / 627	35.9	0.79 [0.37,1.67]	
Total	35 / 2193	40 / 2168		0.86 [0.55,1.36]	Z=-0.63, p=0.5256
Heterogeneity:	Q=0.09 (df=1)	p=0.7605	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	24 / 1069	55.6	0.46 [0.23,0.94]	
FIGARO-DKD	9 / 720	18 / 729	44.4	0.51 [0.23,1.12]	
Total	20 / 1781	42 / 1798		0.48 [0.28,0.82]	Z=-2.72, p=0.0066
Heterogeneity:	Q=0.03 (df=1)	p=0.8655	I^2=0.0%		
>= 60					
FIDELIO-DKD	6 / 210	2 / 221	8.9	3.16 [0.64,15.47]	
FIGARO-DKD	28 / 2326	34 / 2302	91.1	0.82 [0.50,1.34]	
Total	34 / 2536	36 / 2523		0.94 [0.59,1.50]	Z=-0.25, p=0.8010
Heterogeneity:	Q=2.55 (df=1)	p=0.1102	I^2=60.8%		
Subgroup Heterogeneity:	Q=4.02 (df=2)	p=0.1343	I^2=50.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.149.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

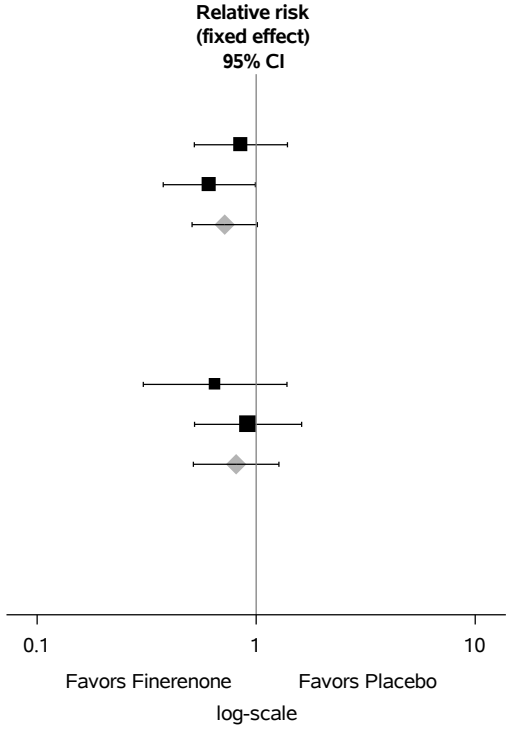
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	4 / 213	5.2	0.25 [0.03,2.26]	
FIGARO-DKD	24 / 1720	36 / 1698	94.8	0.66 [0.39,1.10]	
Total	25 / 1929	40 / 1911		0.62 [0.38,1.02]	Z=-1.90, p=0.0576
Heterogeneity:	Q=0.69 (df=1)	p=0.4060	I^2=0.0%		
Very High					
FIDELIO-DKD	39 / 2618	47 / 2618	60.7	0.83 [0.54,1.26]	
FIGARO-DKD	25 / 1963	31 / 1960	39.3	0.81 [0.48,1.36]	
Total	64 / 4581	78 / 4578		0.82 [0.59,1.14]	Z=-1.19, p=0.2358
Heterogeneity:	Q=0.01 (df=1)	p=0.9301	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.86 (df=1)	p=0.3529	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.149.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

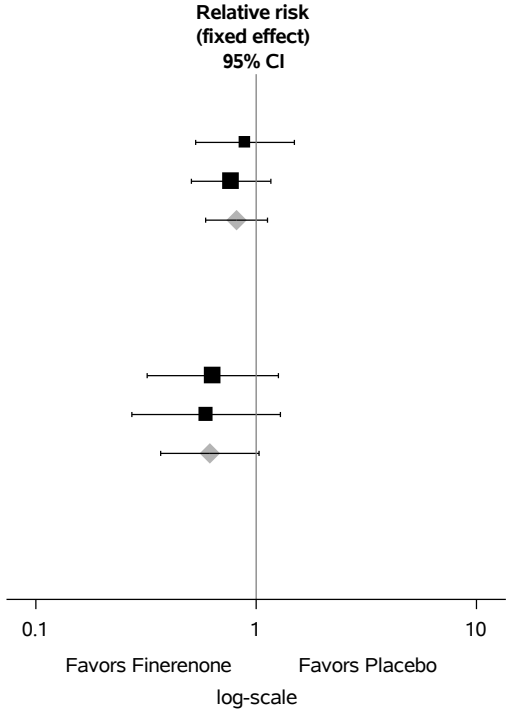
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	29 / 1301	34 / 1299	49.5	0.85 [0.52,1.39]	
FIGARO-DKD	26 / 1673	42 / 1651	50.5	0.61 [0.38,0.99]	
Total	55 / 2974	76 / 2950		0.72 [0.51,1.01]	Z=-1.89, p=0.0589
Heterogeneity:	Q=0.89 (df=1)	p=0.3443	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	17 / 1532	35.7	0.65 [0.31,1.38]	
FIGARO-DKD	23 / 2010	25 / 2007	64.3	0.92 [0.52,1.61]	
Total	34 / 3536	42 / 3539		0.81 [0.52,1.27]	Z=-0.92, p=0.3587
Heterogeneity:	Q=0.52 (df=1)	p=0.4708	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6773	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.149.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

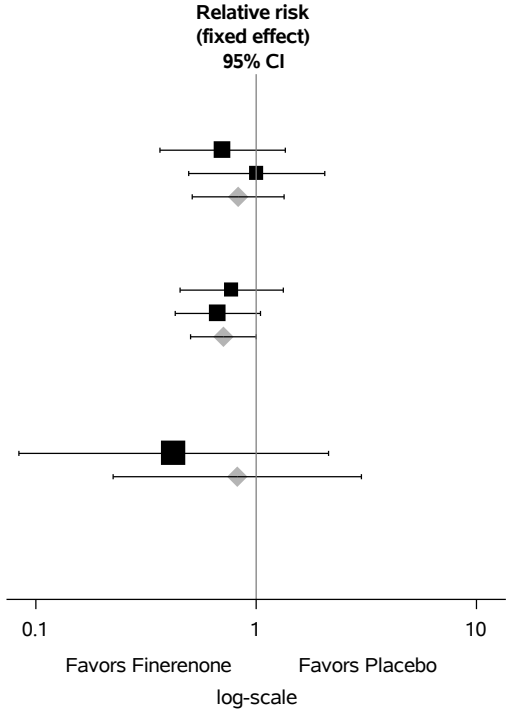
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	27 / 1879	30 / 1858	39.3	0.89 [0.53,1.49]	
FIGARO-DKD	39 / 2643	50 / 2608	60.7	0.77 [0.51,1.17]	
Total	66 / 4522	80 / 4466		0.81 [0.59,1.13]	Z=-1.24, p=0.2140
Heterogeneity:	Q=0.18 (df=1)	p=0.6674	I^2=0.0%		
> 4.5					
FIDELIO-DKD	13 / 948	21 / 973	56.2	0.64 [0.32,1.26]	
FIGARO-DKD	10 / 1040	17 / 1048	43.8	0.59 [0.27,1.29]	
Total	23 / 1988	38 / 2021		0.62 [0.37,1.03]	Z=-1.85, p=0.0649
Heterogeneity:	Q=0.02 (df=1)	p=0.8955	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=1)	p=0.3675	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.149.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

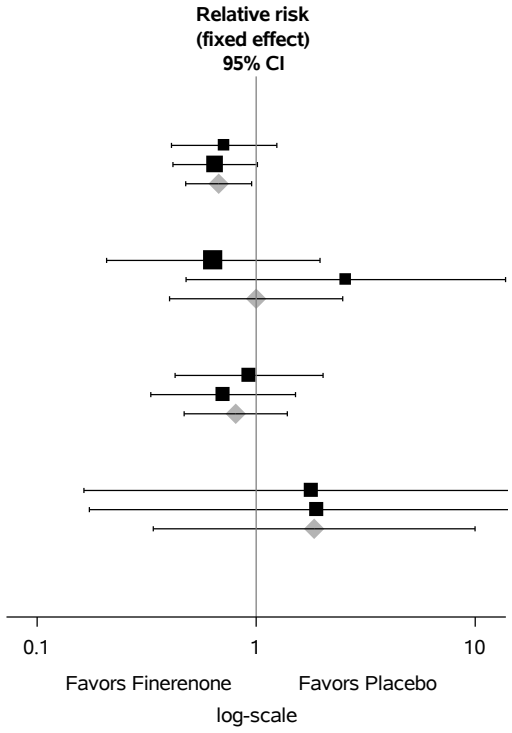
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	21 / 777	54.1	0.70 [0.37,1.36]	
FIGARO-DKD	15 / 1187	15 / 1194	45.9	1.01 [0.49,2.05]	
Total	30 / 1975	36 / 1971		0.83 [0.51,1.34]	Z=-0.77, p=0.4422
Heterogeneity:	Q=0.52 (df=1)	p=0.4700	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 1897	30 / 1916	40.6	0.77 [0.45,1.33]	
FIGARO-DKD	32 / 2389	47 / 2351	59.4	0.67 [0.43,1.05]	
Total	55 / 4286	77 / 4267		0.71 [0.50,1.00]	Z=-1.95, p=0.0508
Heterogeneity:	Q=0.16 (df=1)	p=0.6852	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 141	0 / 138	0.0	201E9 [201E9,201E9]	
FIGARO-DKD	2 / 107	5 / 113	100.0	0.42 [0.08,2.13]	
Total	4 / 248	5 / 251		0.82 [0.22,3.00]	Z=-0.30, p=0.7654
Heterogeneity:	Q=0.65 (df=1)	p=0.4212	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=2)	p=0.8694	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.149.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

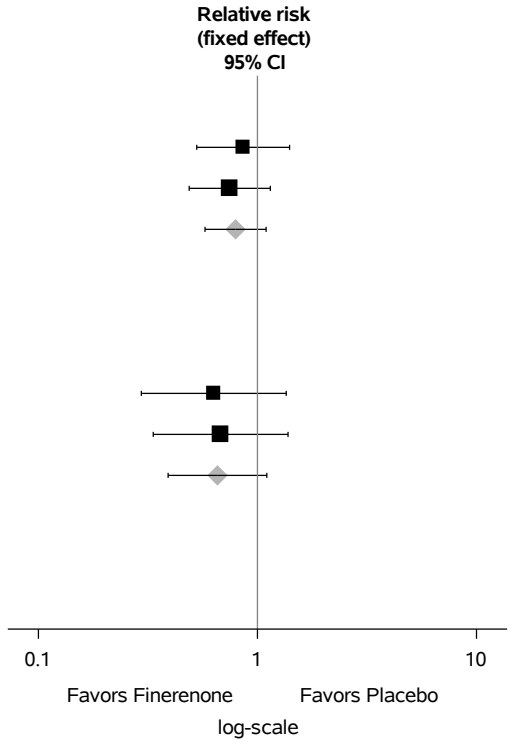
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1773	30 / 1809	39.1	0.71 [0.41,1.24]	
FIGARO-DKD	32 / 2668	48 / 2601	60.9	0.65 [0.42,1.01]	
Total	53 / 4441	78 / 4410		0.67 [0.48,0.95]	Z=-2.23, p=0.0257
Heterogeneity:	Q=0.07 (df=1)	p=0.7945	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	7 / 124	69.1	0.64 [0.21,1.96]	
FIGARO-DKD	4 / 113	2 / 145	30.9	2.57 [0.48,13.76]	
Total	9 / 252	9 / 269		1.00 [0.40,2.48]	Z=-0.00, p=0.9994
Heterogeneity:	Q=1.83 (df=1)	p=0.1762	I^2=45.3%		
Asian					
FIDELIO-DKD	12 / 717	13 / 721	48.9	0.93 [0.43,2.02]	
FIGARO-DKD	11 / 716	16 / 736	51.1	0.71 [0.33,1.51]	
Total	23 / 1433	29 / 1457		0.81 [0.47,1.39]	Z=-0.78, p=0.4374
Heterogeneity:	Q=0.24 (df=1)	p=0.6233	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	1 / 177	50.0	1.79 [0.16,19.55]	
FIGARO-DKD	2 / 186	1 / 176	50.0	1.89 [0.17,20.69]	
Total	4 / 384	2 / 353		1.84 [0.34,9.98]	Z=0.71, p=0.4799
Heterogeneity:	Q=0.00 (df=1)	p=0.9737	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.90 (df=3)	p=0.5942	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.149.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

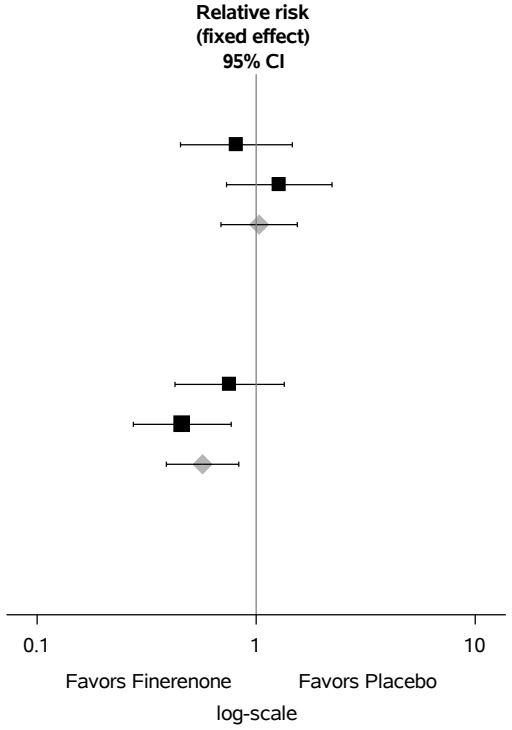
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 1949	35 / 2024	43.3	0.86 [0.53,1.40]	
FIGARO-DKD	36 / 2527	49 / 2571	56.7	0.75 [0.49,1.15]	
Total	65 / 4476	84 / 4595		0.79 [0.58,1.10]	Z=-1.41, p=0.1597
Heterogeneity:	Q=0.18 (df=1)	p=0.6705	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 878	16 / 807	46.4	0.63 [0.30,1.35]	
FIGARO-DKD	13 / 1156	18 / 1087	53.6	0.68 [0.33,1.38]	
Total	24 / 2034	34 / 1894		0.66 [0.39,1.10]	Z=-1.59, p=0.1121
Heterogeneity:	Q=0.02 (df=1)	p=0.8920	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5414	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.149.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

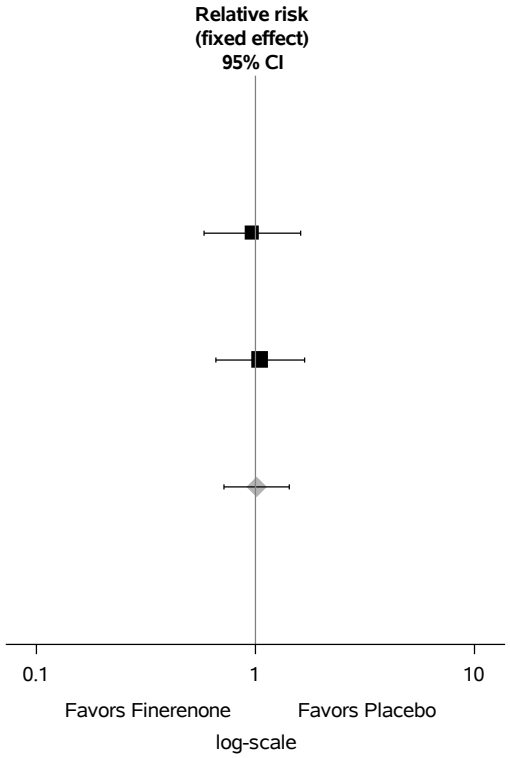
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	20 / 1201	24 / 1171	47.1	0.81 [0.45,1.46]	
FIGARO-DKD	28 / 1752	22 / 1755	52.9	1.27 [0.73,2.22]	
Total	48 / 2953	46 / 2926		1.03 [0.69,1.54]	Z=0.15, p=0.8790
Heterogeneity:	Q=1.19 (df=1)	p=0.2746	I^2=16.2%		
>= 65					
FIDELIO-DKD	20 / 1626	27 / 1660	44.5	0.76 [0.43,1.34]	
FIGARO-DKD	21 / 1931	45 / 1903	55.5	0.46 [0.28,0.77]	
Total	41 / 3557	72 / 3563		0.57 [0.39,0.83]	Z=-2.90, p=0.0037
Heterogeneity:	Q=1.60 (df=1)	p=0.2057	I^2=37.6%		
Subgroup Heterogeneity:	Q=4.44 (df=1)	p=0.0351	I^2=77.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.150: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

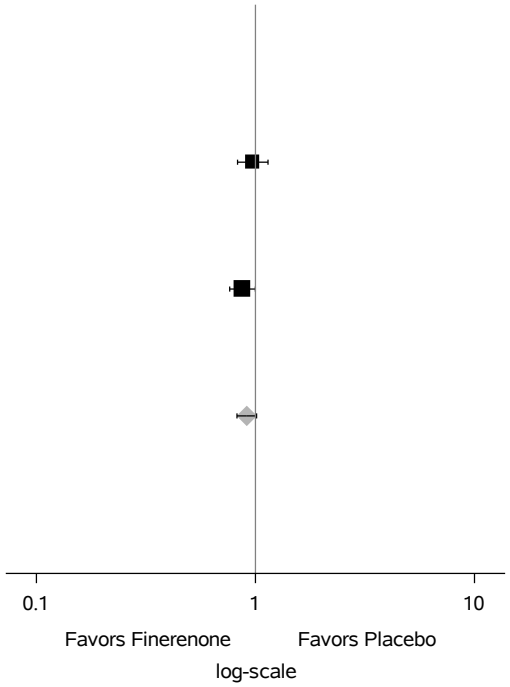
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	45.8	0.97 [0.58,1.61]	
FIGARO-DKD	36 / 3683	34 / 3658	54.2	1.05 [0.66,1.68]	
Total	65 / 6510	64 / 6489		1.01 [0.72,1.43]	Z=0.07, p=0.9434
Heterogeneity:	Q=0.06 (df=1)	p=0.8138	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.151: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

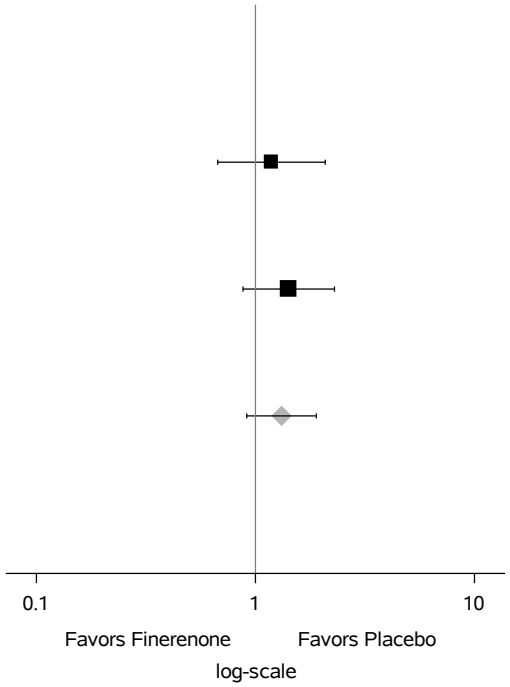
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	267 / 2827	275 / 2831	41.5	0.97 [0.83,1.14]	
FIGARO-DKD	356 / 3683	405 / 3658	58.5	0.87 [0.76,1.00]	
Total	623 / 6510	680 / 6489		0.91 [0.82,1.01]	Z=-1.73, p=0.0831
Heterogeneity:	Q=1.02 (df=1)	p=0.3135	I^2=1.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.152: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set

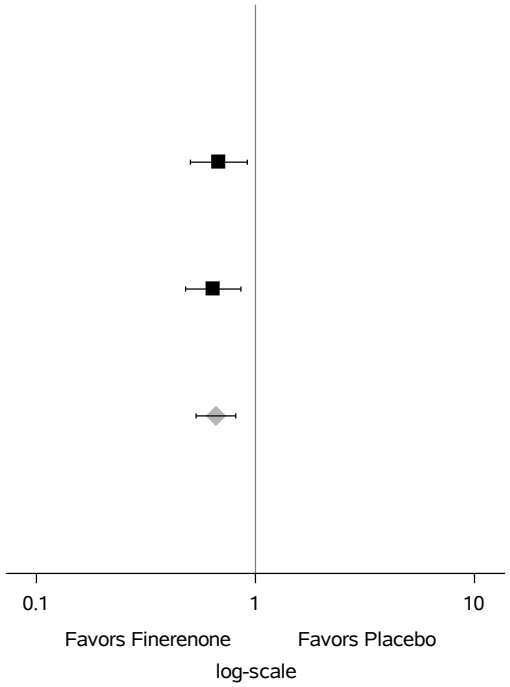
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2827	22 / 2831	42.0	1.18 [0.67,2.08]	
FIGARO-DKD	40 / 3683	28 / 3658	58.0	1.42 [0.88,2.29]	
Total	66 / 6510	50 / 6489		1.32 [0.91,1.90]	Z=1.47, p=0.1418
Heterogeneity:	Q=0.23 (df=1)	p=0.6319	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.153: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

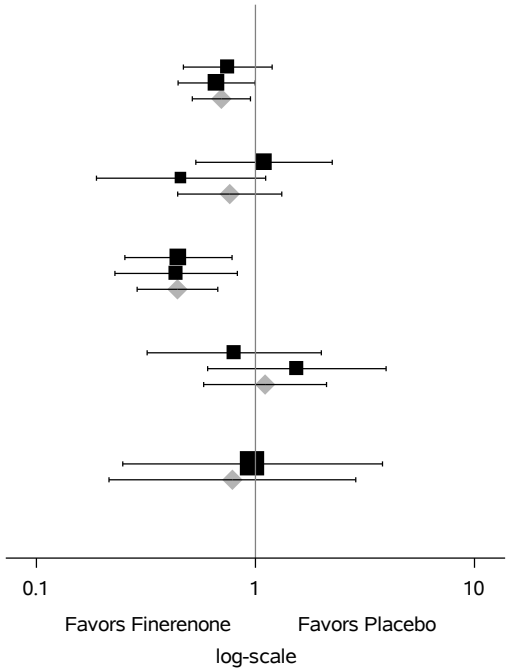
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2827	103 / 2831	48.6	0.68 [0.50,0.92]	
FIGARO-DKD	73 / 3683	113 / 3658	51.4	0.64 [0.48,0.86]	
Total	143 / 6510	216 / 6489		0.66 [0.54,0.81]	Z=-3.90, p=<.0001
Heterogeneity:	Q=0.08 (df=1)	p=0.7819	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.153.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

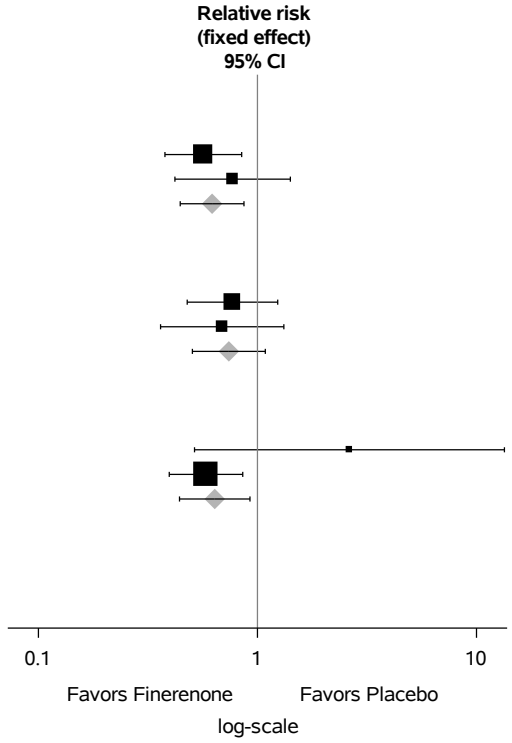
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	30 / 1178	40 / 1174	43.0	0.75 [0.47,1.19]	
FIGARO-DKD	38 / 1752	57 / 1747	57.0	0.66 [0.44,1.00]	
Total	68 / 2930	97 / 2921		0.70 [0.51,0.95]	Z=-2.30, p=0.0216
Heterogeneity:	Q=0.14 (df=1)	p=0.7099	I^2=0.0%		
North America					
FIDELIO-DKD	15 / 466	14 / 476	60.6	1.09 [0.53,2.24]	
FIGARO-DKD	7 / 559	15 / 548	39.4	0.46 [0.19,1.11]	
Total	22 / 1025	29 / 1024		0.76 [0.44,1.32]	Z=-0.97, p=0.3325
Heterogeneity:	Q=2.24 (df=1)	p=0.1342	I^2=55.4%		
Asia					
FIDELIO-DKD	17 / 790	38 / 786	56.6	0.45 [0.25,0.78]	
FIGARO-DKD	13 / 811	30 / 813	43.4	0.43 [0.23,0.83]	
Total	30 / 1601	68 / 1599		0.44 [0.29,0.67]	Z=-3.79, p=0.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9555	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 294	10 / 294	51.2	0.80 [0.32,2.00]	
FIGARO-DKD	11 / 424	7 / 417	48.8	1.55 [0.60,3.95]	
Total	19 / 718	17 / 711		1.11 [0.58,2.11]	Z=0.31, p=0.7584
Heterogeneity:	Q=0.97 (df=1)	p=0.3248	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	4 / 137	4 / 133	100.0	0.97 [0.25,3.80]	
Total	4 / 236	5 / 234		0.78 [0.21,2.87]	Z=-0.37, p=0.7141
Heterogeneity:	Q=0.09 (df=1)	p=0.7599	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.43 (df=4)	p=0.1694	I^2=37.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.153.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

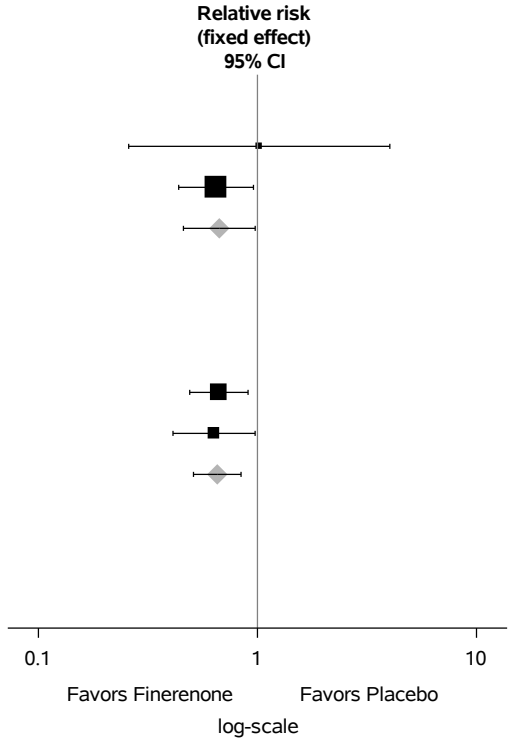
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	36 / 1556	63 / 1541	69.4	0.57 [0.38,0.85]	
FIGARO-DKD	18 / 637	23 / 627	30.6	0.77 [0.42,1.41]	
Total	54 / 2193	86 / 2168		0.62 [0.44,0.87]	Z=-2.79, p=0.0053
Heterogeneity:	Q=0.69 (df=1)	p=0.4068	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	38 / 1069	65.0	0.77 [0.48,1.24]	
FIGARO-DKD	15 / 720	22 / 729	35.0	0.69 [0.36,1.32]	
Total	44 / 1781	60 / 1798		0.74 [0.50,1.09]	Z=-1.54, p=0.1242
Heterogeneity:	Q=0.07 (df=1)	p=0.7927	I^2=0.0%		
>= 60					
FIDELIO-DKD	5 / 210	2 / 221	5.3	2.63 [0.52,13.41]	
FIGARO-DKD	40 / 2326	68 / 2302	94.7	0.58 [0.40,0.86]	
Total	45 / 2536	70 / 2523		0.64 [0.44,0.92]	Z=-2.38, p=0.0175
Heterogeneity:	Q=3.12 (df=1)	p=0.0772	I^2=68.0%		
Subgroup Heterogeneity:	Q=0.50 (df=2)	p=0.7771	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.153.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

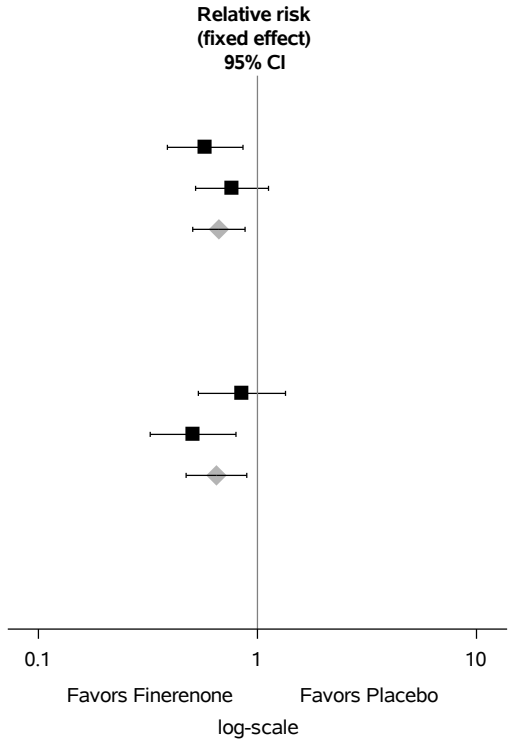
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	4 / 213	7.6	1.02 [0.26,4.02]	
FIGARO-DKD	40 / 1720	61 / 1698	92.4	0.65 [0.44,0.96]	
Total	44 / 1929	65 / 1911		0.67 [0.46,0.98]	Z=-2.08, p=0.0372
Heterogeneity:	Q=0.39 (df=1)	p=0.5333	I^2=0.0%		
Very High					
FIDELIO-DKD	66 / 2618	99 / 2618	66.5	0.67 [0.49,0.91]	
FIGARO-DKD	33 / 1963	52 / 1960	33.5	0.63 [0.41,0.98]	
Total	99 / 4581	151 / 4578		0.66 [0.51,0.84]	Z=-3.31, p=0.0009
Heterogeneity:	Q=0.04 (df=1)	p=0.8509	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9258	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.153.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

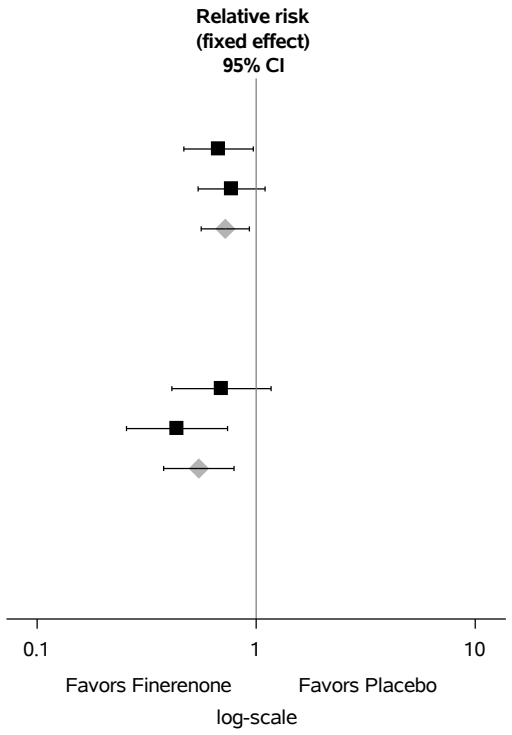
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	37 / 1301	64 / 1299	48.2	0.58 [0.39,0.86]	
FIGARO-DKD	45 / 1673	58 / 1651	51.8	0.77 [0.52,1.12]	
Total	82 / 2974	122 / 2950		0.67 [0.51,0.88]	Z=-2.89, p=0.0039
Heterogeneity:	Q=1.01 (df=1)	p=0.3160	I^2=0.6%		
Absent					
FIDELIO-DKD	33 / 1526	39 / 1532	49.2	0.85 [0.54,1.34]	
FIGARO-DKD	28 / 2010	55 / 2007	50.8	0.51 [0.32,0.80]	
Total	61 / 3536	94 / 3539		0.65 [0.47,0.89]	Z=-2.65, p=0.0081
Heterogeneity:	Q=2.45 (df=1)	p=0.1172	I^2=59.2%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9046	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.153.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

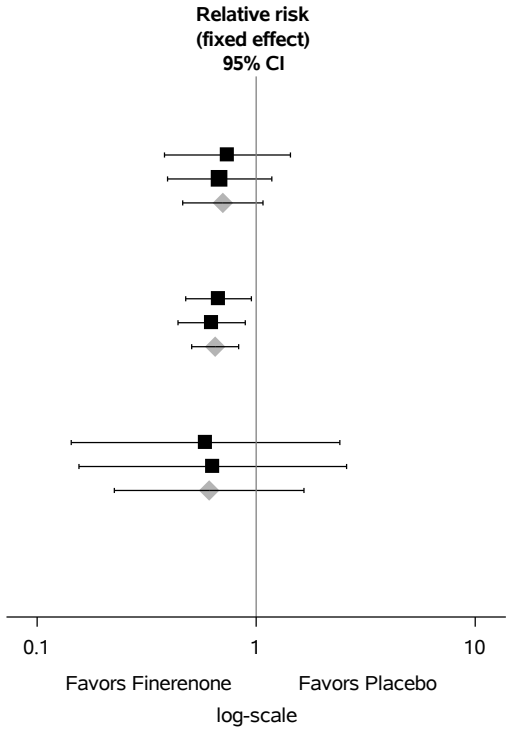
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	47 / 1879	69 / 1858	48.2	0.67 [0.47,0.97]	
FIGARO-DKD	54 / 2643	69 / 2608	51.8	0.77 [0.54,1.10]	
Total	101 / 4522	138 / 4466		0.72 [0.56,0.93]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.28 (df=1)	p=0.5972	I^2=0.0%		
> 4.5					
FIDELIO-DKD	23 / 948	34 / 973	50.9	0.69 [0.41,1.17]	
FIGARO-DKD	19 / 1040	44 / 1048	49.1	0.44 [0.26,0.74]	
Total	42 / 1988	78 / 2021		0.55 [0.38,0.79]	Z=-3.19, p=0.0014
Heterogeneity:	Q=1.52 (df=1)	p=0.2183	I^2=34.0%		
Subgroup Heterogeneity:	Q=1.48 (df=1)	p=0.2242	I^2=32.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.153.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

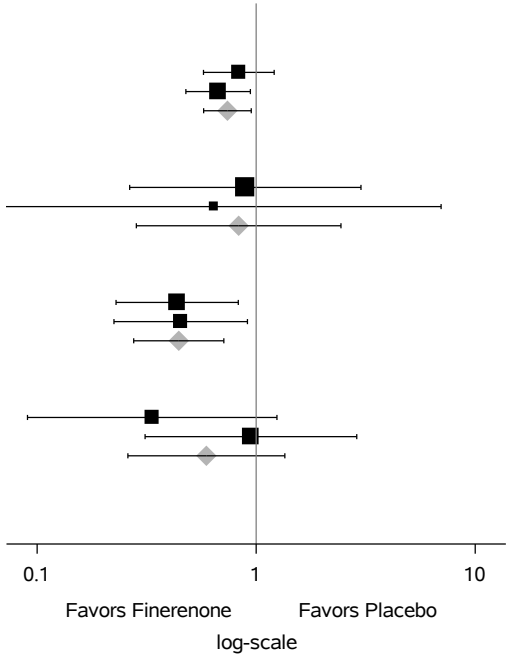
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	20 / 777	40.7	0.74 [0.38,1.43]	
FIGARO-DKD	21 / 1187	31 / 1194	59.3	0.68 [0.39,1.18]	
Total	36 / 1975	51 / 1971		0.70 [0.46,1.07]	Z=-1.63, p=0.1037
Heterogeneity:	Q=0.03 (df=1)	p=0.8519	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	52 / 1897	78 / 1916	51.2	0.67 [0.48,0.95]	
FIGARO-DKD	49 / 2389	77 / 2351	48.8	0.63 [0.44,0.89]	
Total	101 / 4286	155 / 4267		0.65 [0.51,0.83]	Z=-3.42, p=0.0006
Heterogeneity:	Q=0.08 (df=1)	p=0.7736	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 141	5 / 138	49.8	0.59 [0.14,2.41]	
FIGARO-DKD	3 / 107	5 / 113	50.2	0.63 [0.16,2.59]	
Total	6 / 248	10 / 251		0.61 [0.23,1.65]	Z=-0.97, p=0.3310
Heterogeneity:	Q=0.01 (df=1)	p=0.9404	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=2)	p=0.9369	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.153.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

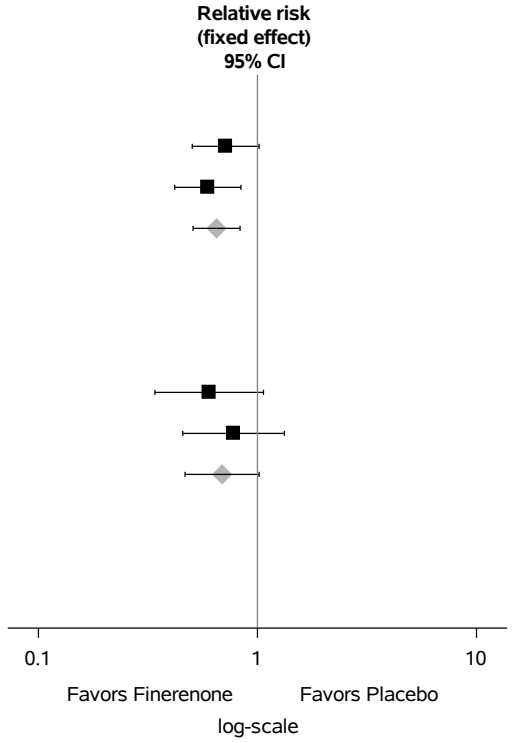
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	49 / 1773	60 / 1809	45.4	0.83 [0.57,1.21]	
FIGARO-DKD	55 / 2668	80 / 2601	54.6	0.67 [0.48,0.94]	
Total	104 / 4441	140 / 4410		0.74 [0.58,0.95]	Z=-2.37, p=0.0180
Heterogeneity:	Q=0.72 (df=1)	p=0.3963	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	5 / 124	79.4	0.89 [0.26,3.01]	
FIGARO-DKD	1 / 113	2 / 145	20.6	0.64 [0.06,6.99]	
Total	6 / 252	7 / 269		0.83 [0.28,2.44]	Z=-0.34, p=0.7371
Heterogeneity:	Q=0.06 (df=1)	p=0.8095	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 717	30 / 721	54.4	0.44 [0.23,0.83]	
FIGARO-DKD	11 / 716	25 / 736	45.6	0.45 [0.22,0.91]	
Total	24 / 1433	55 / 1457		0.44 [0.28,0.71]	Z=-3.37, p=0.0008
Heterogeneity:	Q=0.01 (df=1)	p=0.9388	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	8 / 177	41.9	0.34 [0.09,1.24]	
FIGARO-DKD	6 / 186	6 / 176	58.1	0.95 [0.31,2.88]	
Total	9 / 384	14 / 353		0.59 [0.26,1.35]	Z=-1.24, p=0.2135
Heterogeneity:	Q=1.40 (df=1)	p=0.2359	I^2=28.8%		
Subgroup Heterogeneity:	Q=3.74 (df=3)	p=0.2904	I^2=19.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.153.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

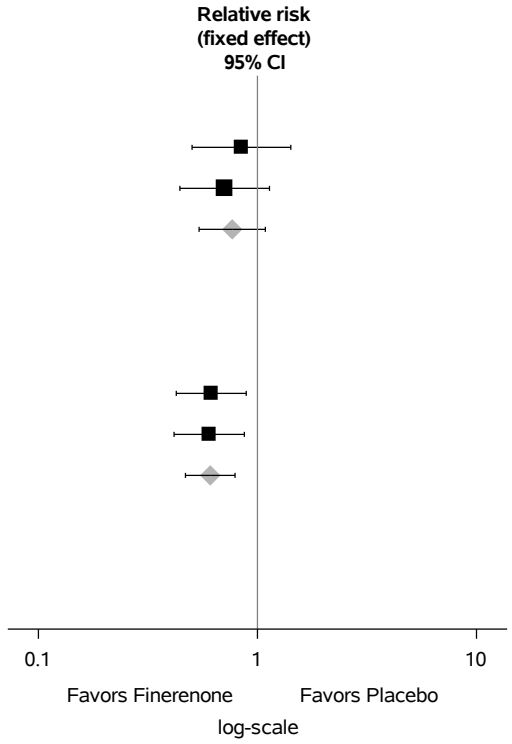
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 1949	74 / 2024	49.5	0.72 [0.50,1.02]	
FIGARO-DKD	49 / 2527	84 / 2571	50.5	0.59 [0.42,0.84]	
Total	100 / 4476	158 / 4595		0.65 [0.51,0.83]	Z=-3.41, p=0.0006
Heterogeneity:	Q=0.55 (df=1)	p=0.4579	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 878	29 / 807	46.7	0.60 [0.34,1.07]	
FIGARO-DKD	24 / 1156	29 / 1087	53.3	0.78 [0.46,1.33]	
Total	43 / 2034	58 / 1894		0.69 [0.47,1.02]	Z=-1.87, p=0.0612
Heterogeneity:	Q=0.41 (df=1)	p=0.5203	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8051	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.153.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

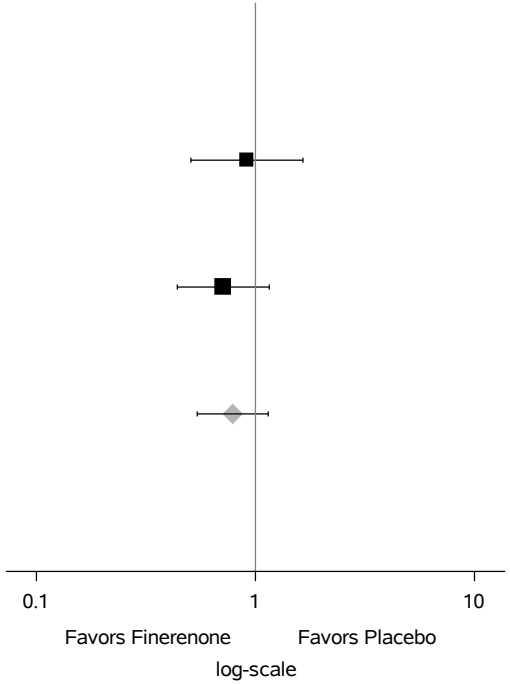
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	26 / 1201	30 / 1171	45.2	0.85 [0.50,1.42]	
FIGARO-DKD	29 / 1752	41 / 1755	54.8	0.71 [0.44,1.13]	
Total	55 / 2953	71 / 2926		0.77 [0.54,1.09]	Z=-1.49, p=0.1352
Heterogeneity:	Q=0.24 (df=1)	p=0.6222	I^2=0.0%		
>= 65					
FIDELIO-DKD	44 / 1626	73 / 1660	50.3	0.62 [0.43,0.89]	
FIGARO-DKD	44 / 1931	72 / 1903	49.7	0.60 [0.42,0.87]	
Total	88 / 3557	145 / 3563		0.61 [0.47,0.79]	Z=-3.73, p=0.0002
Heterogeneity:	Q=0.01 (df=1)	p=0.9356	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=1)	p=0.2985	I^2=7.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.154: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set

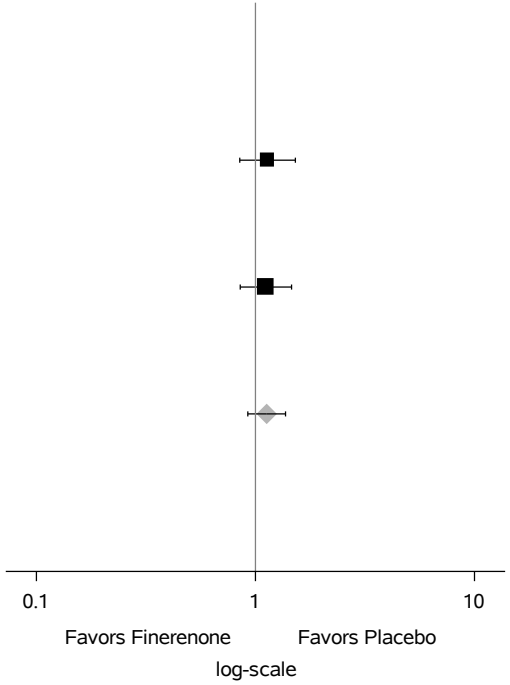
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	23 / 2831	40.2	0.91 [0.51,1.65]	
FIGARO-DKD	28 / 3683	39 / 3658	59.8	0.71 [0.44,1.16]	
Total	49 / 6510	62 / 6489		0.79 [0.54,1.14]	Z=-1.26, p=0.2093
Heterogeneity:	Q=0.41 (df=1)	p=0.5226	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.155: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

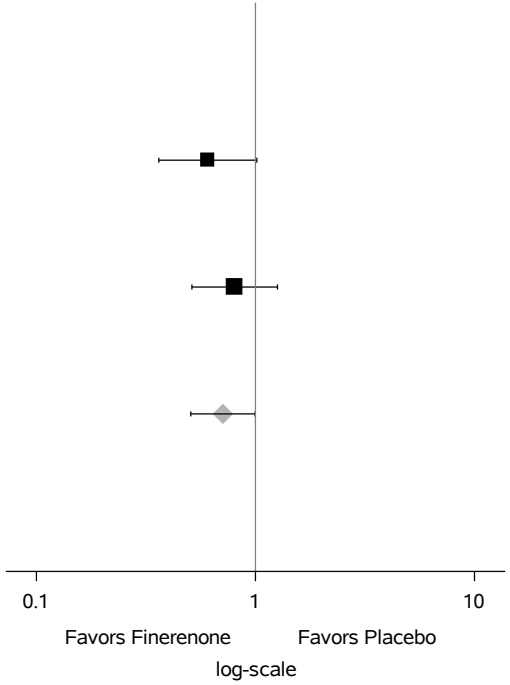
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	93 / 2827	82 / 2831	46.0	1.14 [0.85,1.52]	
FIGARO-DKD	109 / 3683	97 / 3658	54.0	1.12 [0.85,1.46]	
Total	202 / 6510	179 / 6489		1.13 [0.92,1.37]	Z=1.17, p=0.2439
Heterogeneity:	Q=0.01 (df=1)	p=0.9314	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.156: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

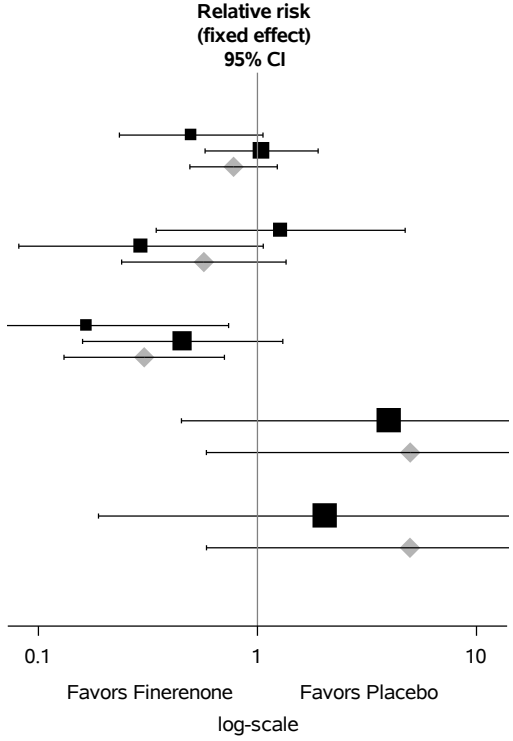
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	38 / 2831	43.3	0.61 [0.36,1.01]	
FIGARO-DKD	34 / 3683	42 / 3658	56.7	0.80 [0.51,1.26]	
Total	57 / 6510	80 / 6489		0.71 [0.51,1.00]	Z=-1.98, p=0.0472
Heterogeneity:	Q=0.66 (df=1)	p=0.4180	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.156.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

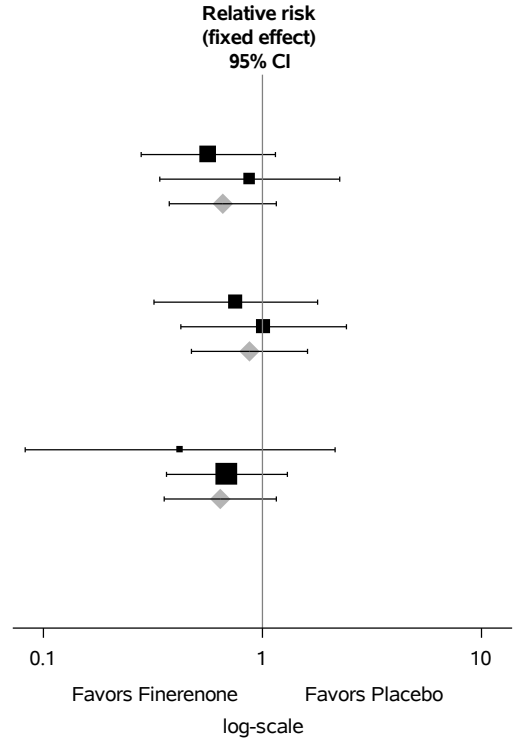
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 1178	20 / 1174	38.3	0.50 [0.23,1.06]	
FIGARO-DKD	22 / 1752	21 / 1747	61.7	1.04 [0.58,1.89]	
Total	32 / 2930	41 / 2921		0.78 [0.49,1.23]	Z=-1.07, p=0.2843
Heterogeneity:	Q=2.28 (df=1)	p=0.1308	I^2=56.2%		
North America					
FIDELIO-DKD	5 / 466	4 / 476	49.1	1.28 [0.35,4.73]	
FIGARO-DKD	3 / 559	10 / 548	50.9	0.29 [0.08,1.06]	
Total	8 / 1025	14 / 1024		0.57 [0.24,1.35]	Z=-1.28, p=0.2013
Heterogeneity:	Q=2.48 (df=1)	p=0.1154	I^2=59.7%		
Asia					
FIDELIO-DKD	2 / 790	12 / 786	33.2	0.17 [0.04,0.74]	
FIGARO-DKD	5 / 811	11 / 813	66.8	0.46 [0.16,1.31]	
Total	7 / 1601	23 / 1599		0.30 [0.13,0.71]	Z=-2.77, p=0.0057
Heterogeneity:	Q=1.20 (df=1)	p=0.2733	I^2=16.7%		
Latin America					
FIDELIO-DKD	4 / 294	1 / 294	100.0	4.00 [0.45,35.57]	
FIGARO-DKD	1 / 424	0 / 417	0.0	908E8 [908E8,908E8]	
Total	5 / 718	1 / 711		4.98 [0.58,42.46]	Z=1.47, p=0.1419
Heterogeneity:	Q=0.04 (df=1)	p=0.8439	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	1 / 101	100.0	2.04 [0.19,22.14]	
FIGARO-DKD	3 / 137	0 / 133	0.0	114E9 [114E9,114E9]	
Total	5 / 236	1 / 234		4.97 [0.59,42.21]	Z=1.47, p=0.1418
Heterogeneity:	Q=0.54 (df=1)	p=0.4643	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.62 (df=4)	p=0.0311	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.156.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

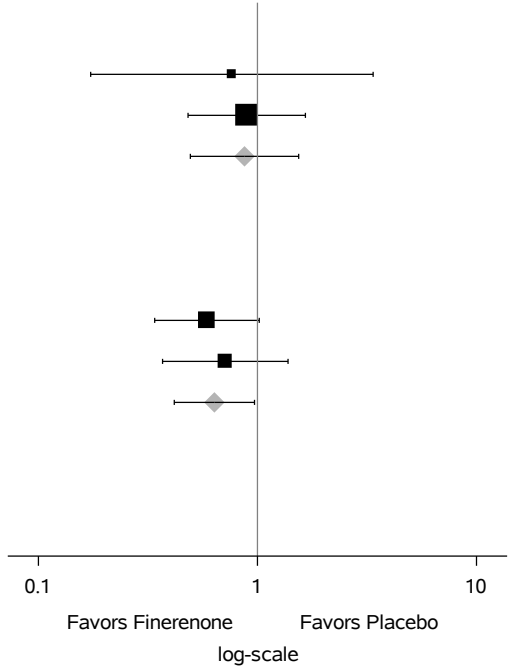
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	12 / 1556	21 / 1541	64.2	0.57 [0.28,1.15]	
FIGARO-DKD	8 / 637	9 / 627	35.8	0.87 [0.34,2.25]	
Total	20 / 2193	30 / 2168		0.66 [0.38,1.16]	Z=-1.45, p=0.1464
Heterogeneity:	Q=0.52 (df=1)	p=0.4693	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	12 / 1069	50.6	0.76 [0.32,1.79]	
FIGARO-DKD	10 / 720	10 / 729	49.4	1.01 [0.42,2.42]	
Total	19 / 1781	22 / 1798		0.87 [0.47,1.61]	Z=-0.44, p=0.6613
Heterogeneity:	Q=0.22 (df=1)	p=0.6393	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	5 / 221	13.2	0.42 [0.08,2.15]	
FIGARO-DKD	16 / 2326	23 / 2302	86.8	0.69 [0.36,1.30]	
Total	18 / 2536	28 / 2523		0.64 [0.36,1.16]	Z=-1.47, p=0.1404
Heterogeneity:	Q=0.30 (df=1)	p=0.5811	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.62 (df=2)	p=0.7343	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.156.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

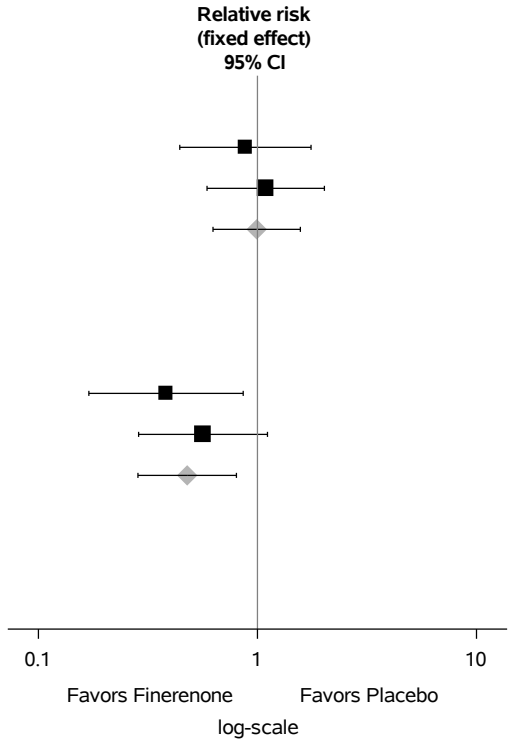
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	4 / 213	14.7	0.76 [0.17,3.37]	
FIGARO-DKD	19 / 1720	21 / 1698	85.3	0.89 [0.48,1.66]	
Total	22 / 1929	25 / 1911		0.87 [0.49,1.54]	Z=-0.47, p=0.6395
Heterogeneity:	Q=0.04 (df=1)	p=0.8494	I^2=0.0%		
Very High					
FIDELIO-DKD	20 / 2618	34 / 2618	59.0	0.59 [0.34,1.02]	
FIGARO-DKD	15 / 1963	21 / 1960	41.0	0.71 [0.37,1.38]	
Total	35 / 4581	55 / 4578		0.64 [0.42,0.97]	Z=-2.10, p=0.0354
Heterogeneity:	Q=0.19 (df=1)	p=0.6601	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3812	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.156.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

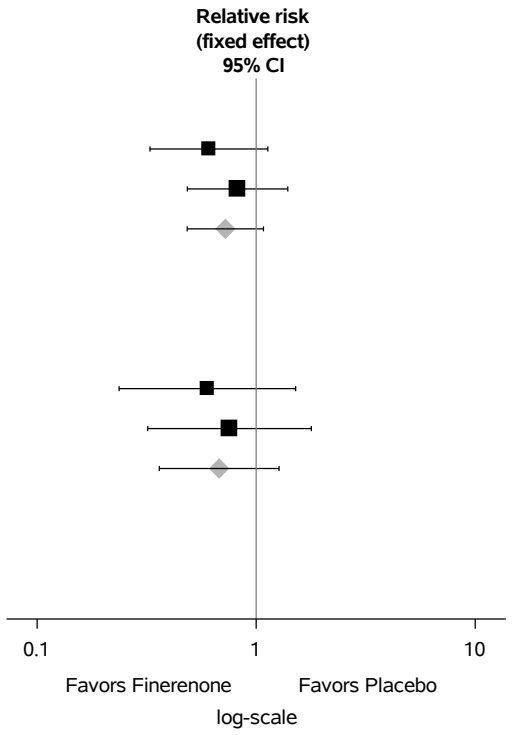
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 1301	17 / 1299	44.4	0.88 [0.44,1.76]	
FIGARO-DKD	21 / 1673	19 / 1651	55.6	1.09 [0.59,2.02]	
Total	36 / 2974	36 / 2950		0.99 [0.63,1.57]	Z=-0.03, p=0.9726
Heterogeneity:	Q=0.20 (df=1)	p=0.6511	I^2=0.0%		
Absent					
FIDELIO-DKD	8 / 1526	21 / 1532	41.1	0.38 [0.17,0.86]	
FIGARO-DKD	13 / 2010	23 / 2007	58.9	0.56 [0.29,1.11]	
Total	21 / 3536	44 / 3539		0.48 [0.28,0.80]	Z=-2.80, p=0.0052
Heterogeneity:	Q=0.52 (df=1)	p=0.4702	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.28 (df=1)	p=0.0385	I^2=76.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.156.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1879	26 / 1858	42.1	0.61 [0.33,1.13]	
FIGARO-DKD	25 / 2643	30 / 2608	57.9	0.82 [0.48,1.39]	
Total	41 / 4522	56 / 4466		0.72 [0.48,1.08]	Z=-1.59, p=0.1127
Heterogeneity:	Q=0.53 (df=1)	p=0.4684	I^2=0.0%		
> 4.5					
FIDELIO-DKD	7 / 948	12 / 973	46.2	0.60 [0.24,1.51]	
FIGARO-DKD	9 / 1040	12 / 1048	53.8	0.76 [0.32,1.79]	
Total	16 / 1988	24 / 2021		0.68 [0.36,1.27]	Z=-1.21, p=0.2258
Heterogeneity:	Q=0.13 (df=1)	p=0.7182	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8648	I^2=0.0%		

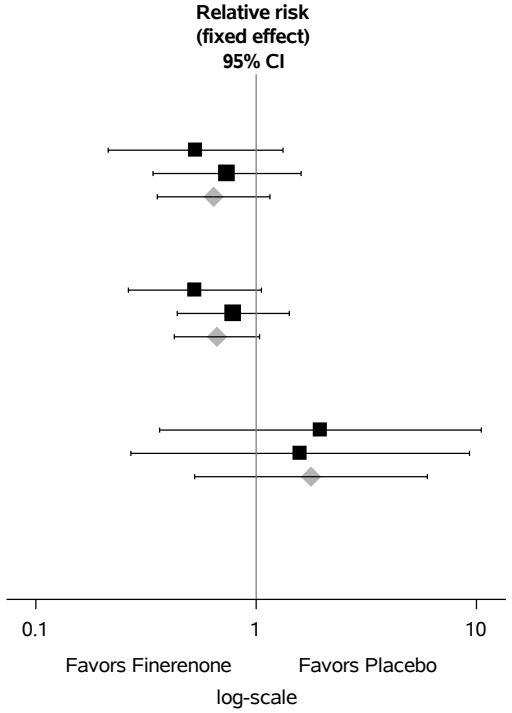


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.156.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Investigations (SOC with Incidence >=1%)

Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 788	13 / 777	41.8	0.53 [0.21,1.32]	
FIGARO-DKD	11 / 1187	15 / 1194	58.2	0.74 [0.34,1.60]	
Total	18 / 1975	28 / 1971		0.64 [0.36,1.15]	Z=-1.48, p=0.1387
Heterogeneity:	Q=0.29 (df=1)	p=0.5903	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 1897	23 / 1916	41.5	0.53 [0.26,1.06]	
FIGARO-DKD	20 / 2389	25 / 2351	58.5	0.79 [0.44,1.41]	
Total	32 / 4286	48 / 4267		0.66 [0.43,1.04]	Z=-1.81, p=0.0711
Heterogeneity:	Q=0.75 (df=1)	p=0.3864	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	2 / 138	52.6	1.96 [0.36,10.51]	
FIGARO-DKD	3 / 107	2 / 113	47.4	1.58 [0.27,9.30]	
Total	7 / 248	4 / 251		1.77 [0.53,5.98]	Z=0.92, p=0.3559
Heterogeneity:	Q=0.03 (df=1)	p=0.8651	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.38 (df=2)	p=0.3041	I^2=16.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.

Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.

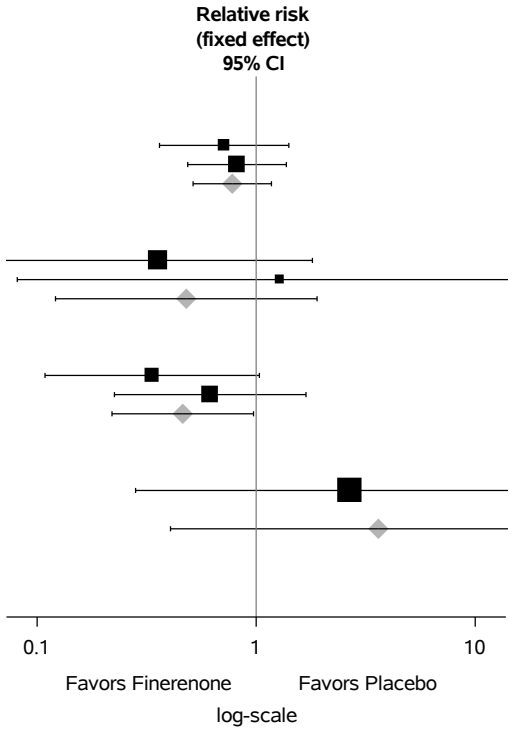
For 'Total' the same model as for single studies including study as additional factor was applied.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure 2.1.156.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

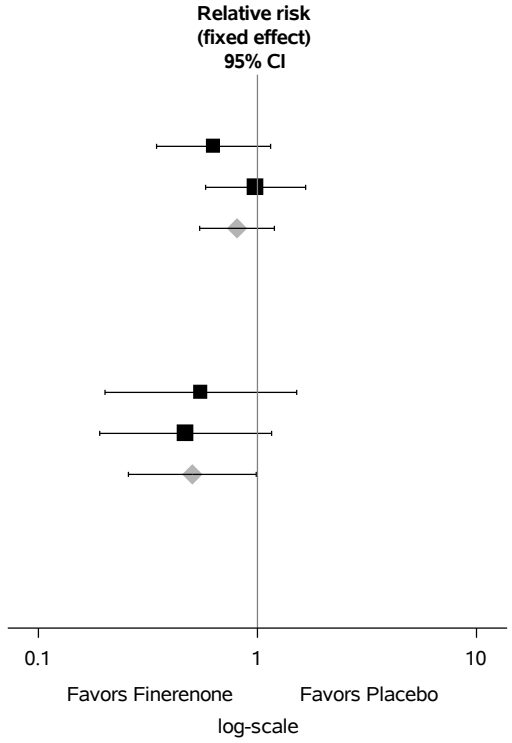
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1773	20 / 1809	36.8	0.71 [0.36,1.41]	
FIGARO-DKD	26 / 2668	31 / 2601	63.2	0.82 [0.49,1.37]	
Total	40 / 4441	51 / 4410		0.78 [0.52,1.17]	Z=-1.20, p=0.2316
Heterogeneity:	Q=0.10 (df=1)	p=0.7565	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	5 / 124	74.3	0.36 [0.07,1.81]	
FIGARO-DKD	1 / 113	1 / 145	25.7	1.28 [0.08,20.29]	
Total	3 / 252	6 / 269		0.48 [0.12,1.90]	Z=-1.05, p=0.2949
Heterogeneity:	Q=0.62 (df=1)	p=0.4326	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 717	12 / 721	44.4	0.34 [0.11,1.03]	
FIGARO-DKD	6 / 716	10 / 736	55.6	0.62 [0.23,1.69]	
Total	10 / 1433	22 / 1457		0.46 [0.22,0.97]	Z=-2.03, p=0.0420
Heterogeneity:	Q=0.63 (df=1)	p=0.4282	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	100.0	2.68 [0.28,25.55]	
FIGARO-DKD	1 / 186	0 / 176	0.0	761E8 [761E8,761E8]	
Total	4 / 384	1 / 353		3.61 [0.41,32.12]	Z=1.15, p=0.2493
Heterogeneity:	Q=0.07 (df=1)	p=0.7956	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.91 (df=3)	p=0.2719	I^2=23.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.156.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

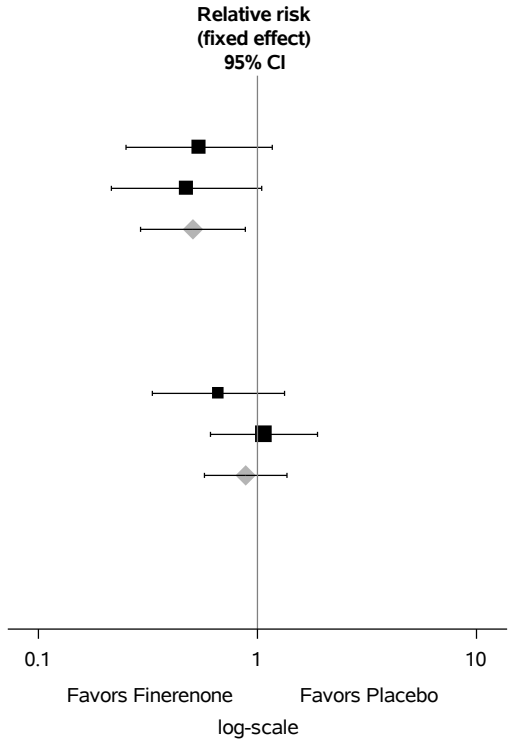
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1949	28 / 2024	43.5	0.63 [0.35,1.15]	
FIGARO-DKD	27 / 2527	28 / 2571	56.5	0.98 [0.58,1.66]	
Total	44 / 4476	56 / 4595		0.81 [0.54,1.19]	Z=-1.07, p=0.2838
Heterogeneity:	Q=1.18 (df=1)	p=0.2771	I^2=15.4%		
Female					
FIDELIO-DKD	6 / 878	10 / 807	44.6	0.55 [0.20,1.51]	
FIGARO-DKD	7 / 1156	14 / 1087	55.4	0.47 [0.19,1.16]	
Total	13 / 2034	24 / 1894		0.50 [0.26,0.99]	Z=-2.00, p=0.0459
Heterogeneity:	Q=0.05 (df=1)	p=0.8173	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.40 (df=1)	p=0.2368	I^2=28.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.156.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

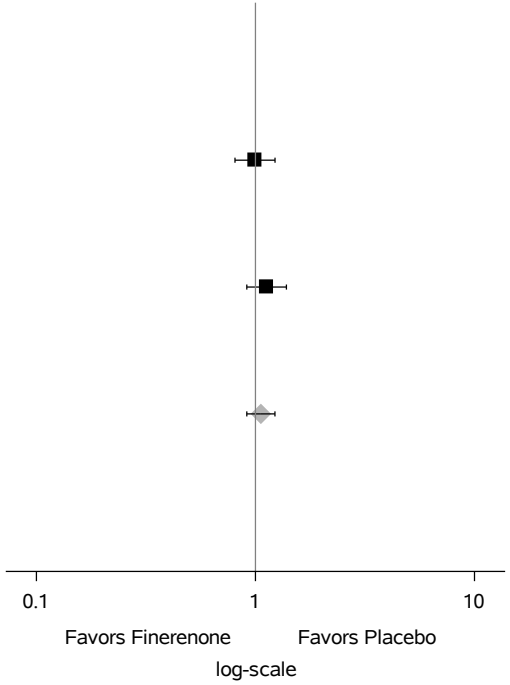
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1201	18 / 1171	51.4	0.54 [0.25,1.17]	
FIGARO-DKD	9 / 1752	19 / 1755	48.6	0.47 [0.22,1.05]	
Total	19 / 2953	37 / 2926		0.51 [0.29,0.88]	Z=-2.41, p=0.0158
Heterogeneity:	Q=0.06 (df=1)	p=0.8139	I^2=0.0%		
>= 65					
FIDELIO-DKD	13 / 1626	20 / 1660	39.6	0.66 [0.33,1.33]	
FIGARO-DKD	25 / 1931	23 / 1903	60.4	1.07 [0.61,1.88]	
Total	38 / 3557	43 / 3563		0.88 [0.57,1.36]	Z=-0.56, p=0.5767
Heterogeneity:	Q=1.10 (df=1)	p=0.2939	I^2=9.2%		
Subgroup Heterogeneity:	Q=2.40 (df=1)	p=0.1210	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.157: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

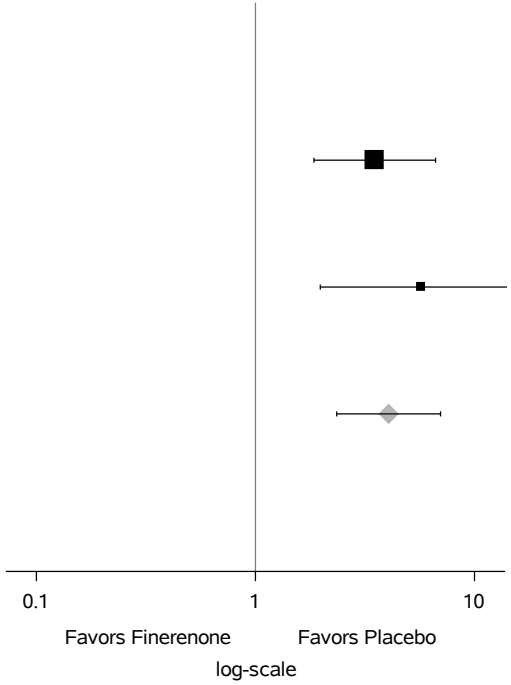
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	163 / 2827	164 / 2831	49.5	1.00 [0.81,1.23]	
FIGARO-DKD	180 / 3683	159 / 3658	50.5	1.12 [0.91,1.38]	
Total	343 / 6510	323 / 6489		1.06 [0.91,1.23]	Z=0.75, p=0.4508
Heterogeneity:	Q=0.65 (df=1)	p=0.4196	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.158: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

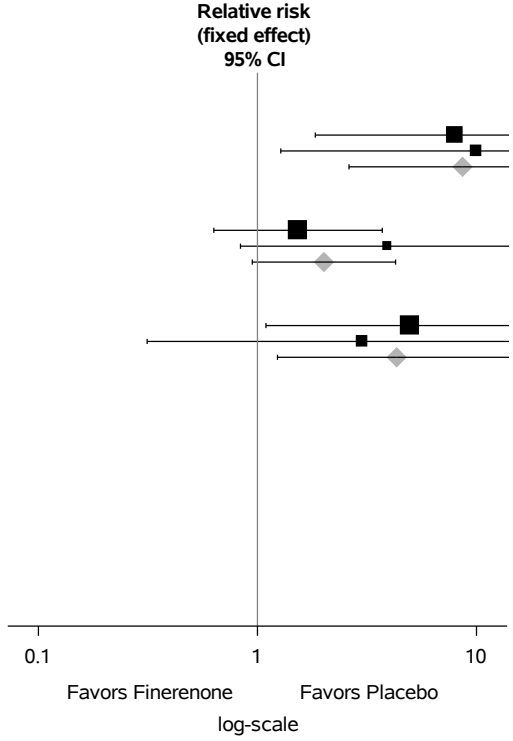
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	12 / 2831	73.3	3.50 [1.85,6.64]	
FIGARO-DKD	23 / 3683	4 / 3658	26.7	5.71 [1.98,16.50]	
Total	65 / 6510	16 / 6489		4.06 [2.35,7.00]	Z=5.03, p=<.0001
Heterogeneity:	Q=0.60 (df=1)	p=0.4386	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.158.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

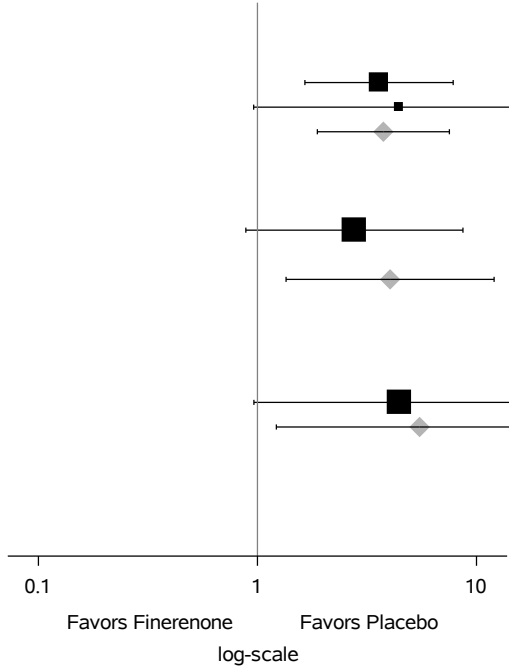
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1178	2 / 1174	66.2	7.97 [1.84,34.60]	
FIGARO-DKD	10 / 1752	1 / 1747	33.8	9.97 [1.28,77.81]	
Total	26 / 2930	3 / 2921		8.64 [2.62,28.50]	Z=3.54, p=0.0004
Heterogeneity:	Q=0.03 (df=1)	p=0.8620	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 466	8 / 476	75.3	1.53 [0.63,3.71]	
FIGARO-DKD	8 / 559	2 / 548	24.7	3.92 [0.84,18.38]	
Total	20 / 1025	10 / 1024		2.01 [0.95,4.27]	Z=1.82, p=0.0691
Heterogeneity:	Q=1.08 (df=1)	p=0.2987	I^2=7.4%		
Asia					
FIDELIO-DKD	10 / 790	2 / 786	69.0	4.97 [1.09,22.63]	
FIGARO-DKD	3 / 811	1 / 813	31.0	3.01 [0.31,28.85]	
Total	13 / 1601	3 / 1599		4.32 [1.23,15.13]	Z=2.29, p=0.0221
Heterogeneity:	Q=0.13 (df=1)	p=0.7165	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	0 / 294	0.0	964E8 [964E8,964E8]	
FIGARO-DKD	0 / 424	0 / 417	0.0	-	
Total	2 / 718	0 / 711		1.1E7 [1.1E7,1.1E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	105E9 [105E9,105E9]	
FIGARO-DKD	2 / 137	0 / 133	0.0	207E9 [207E9,207E9]	
Total	4 / 236	0 / 234		24E10 [24E10,24E10]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.33 (df=4)	p=0.3627	I^2=7.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.158.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

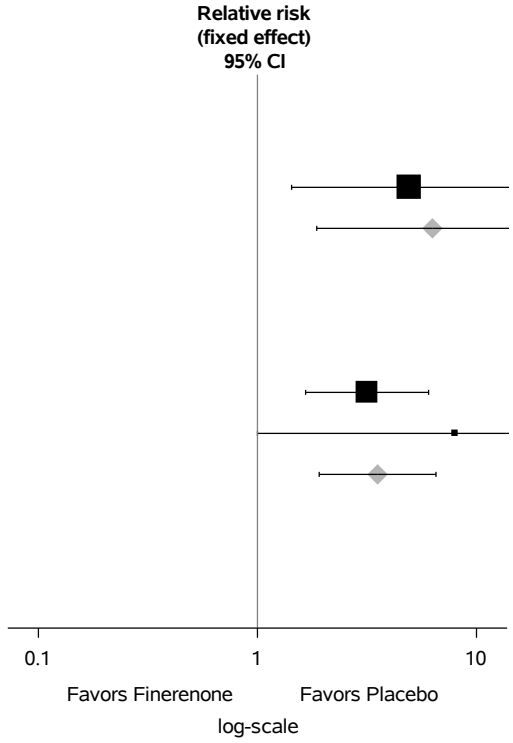
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	29 / 1556	8 / 1541	79.4	3.59 [1.65,7.83]	
FIGARO-DKD	9 / 637	2 / 627	20.6	4.43 [0.96,20.42]	
Total	38 / 2193	10 / 2168		3.76 [1.88,7.52]	Z=3.74, p=0.0002
Heterogeneity:	Q=0.06 (df=1)	p=0.8103	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	4 / 1069	100.0	2.77 [0.89,8.67]	
FIGARO-DKD	5 / 720	0 / 729	0.0	984E8 [984E8,984E8]	
Total	16 / 1781	4 / 1798		4.03 [1.35,12.03]	Z=2.50, p=0.0124
Heterogeneity:	Q=0.42 (df=1)	p=0.5193	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	0 / 221	0.0	135E9 [135E9,135E9]	
FIGARO-DKD	9 / 2326	2 / 2302	100.0	4.45 [0.96,20.59]	
Total	11 / 2536	2 / 2523		5.50 [1.22,24.78]	Z=2.22, p=0.0265
Heterogeneity:	Q=0.07 (df=1)	p=0.7875	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=2)	p=0.9038	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.158.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

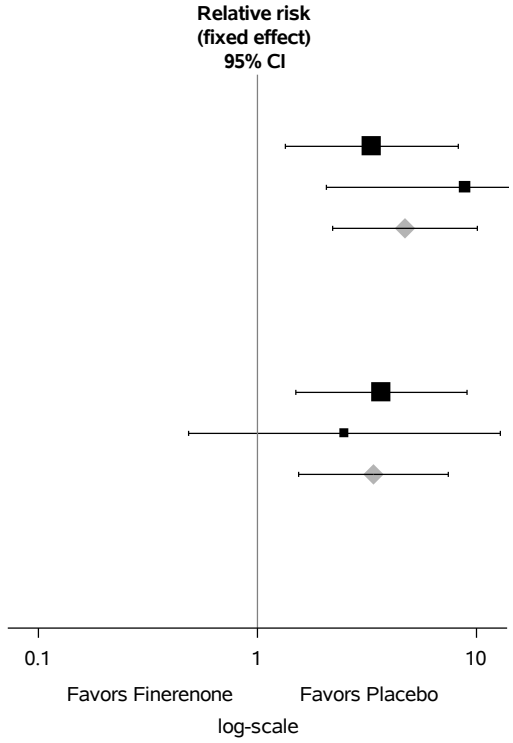
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	0 / 213	0.0	996E8 [996E8,996E8]	
FIGARO-DKD	15 / 1720	3 / 1698	100.0	4.94 [1.43,17.02]	
Total	19 / 1929	3 / 1911		6.29 [1.87,21.22]	Z=2.96, p=0.0030
Heterogeneity:	Q=0.15 (df=1)	p=0.7008	I^2=0.0%		
Very High					
FIDELIO-DKD	38 / 2618	12 / 2618	91.2	3.17 [1.66,6.05]	
FIGARO-DKD	8 / 1963	1 / 1960	8.8	7.99 [1.00,63.80]	
Total	46 / 4581	13 / 4578		3.54 [1.91,6.53]	Z=4.03, p=<.0001
Heterogeneity:	Q=0.70 (df=1)	p=0.4019	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.69 (df=1)	p=0.4070	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.158.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

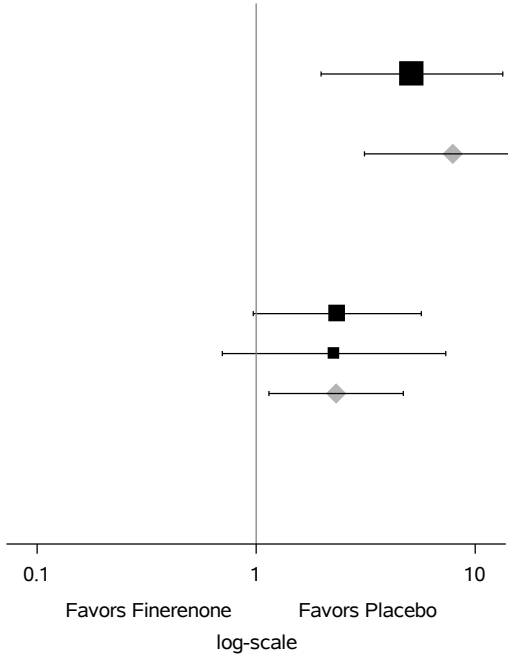
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	6 / 1299	72.0	3.33 [1.34,8.26]	
FIGARO-DKD	18 / 1673	2 / 1651	28.0	8.88 [2.06,38.22]	
Total	38 / 2974	8 / 2950		4.72 [2.20,10.09]	Z=4.00, p=<.0001
Heterogeneity:	Q=1.29 (df=1)	p=0.2565	I^2=22.3%		
Absent					
FIDELIO-DKD	22 / 1526	6 / 1532	76.8	3.68 [1.50,9.05]	
FIGARO-DKD	5 / 2010	2 / 2007	23.2	2.50 [0.48,12.85]	
Total	27 / 3536	8 / 3539		3.39 [1.54,7.44]	Z=3.04, p=0.0024
Heterogeneity:	Q=0.17 (df=1)	p=0.6836	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5528	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.158.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

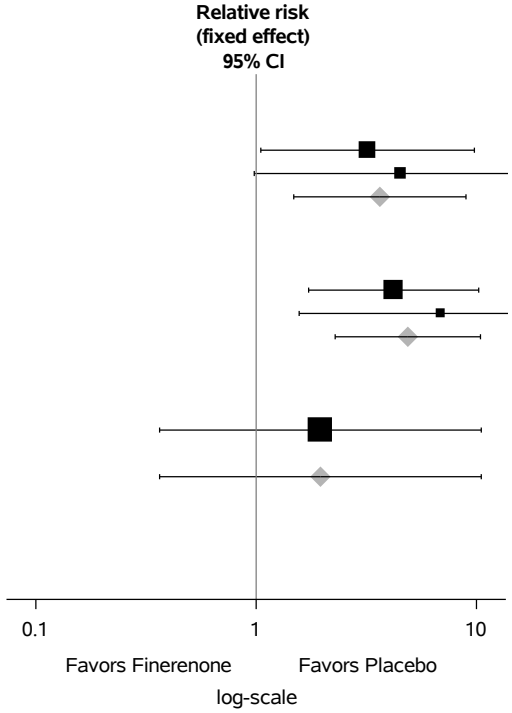
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	26 / 1879	5 / 1858	100.0	5.14 [1.98,13.36]	
FIGARO-DKD	14 / 2643	0 / 2608	0.0	751E8 [751E8,751E8]	
Total	40 / 4522	5 / 4466		7.90 [3.12,19.99]	Z=4.36, p=<.0001
Heterogeneity:	Q=0.78 (df=1)	p=0.3782	I^2=0.0%		
> 4.5					
FIDELIO-DKD	16 / 948	7 / 973	63.9	2.35 [0.97,5.68]	
FIGARO-DKD	9 / 1040	4 / 1048	36.1	2.27 [0.70,7.34]	
Total	25 / 1988	11 / 2021		2.32 [1.14,4.70]	Z=2.33, p=0.0197
Heterogeneity:	Q=0.00 (df=1)	p=0.9637	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.25 (df=1)	p=0.0394	I^2=76.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.158.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

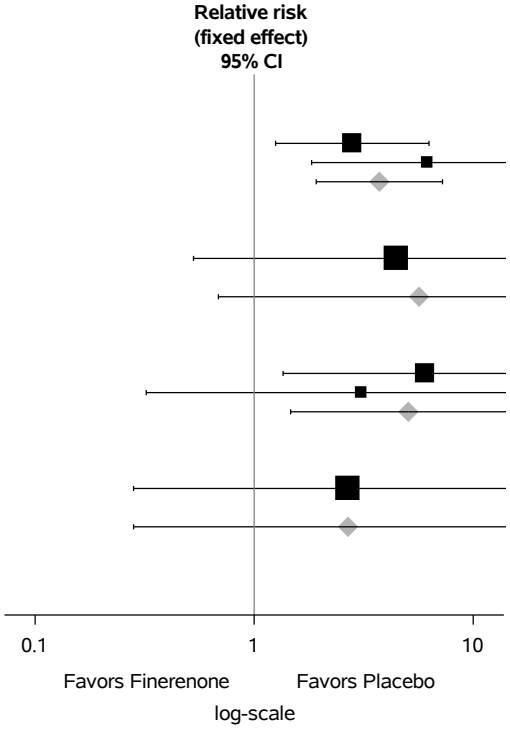
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 788	4 / 777	65.3	3.20 [1.05,9.79]	
FIGARO-DKD	9 / 1187	2 / 1194	34.7	4.53 [0.98,20.91]	
Total	22 / 1975	6 / 1971		3.64 [1.48,8.96]	Z=2.81, p=0.0049
Heterogeneity:	Q=0.13 (df=1)	p=0.7205	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	25 / 1897	6 / 1916	73.5	4.21 [1.73,10.24]	
FIGARO-DKD	14 / 2389	2 / 2351	26.5	6.89 [1.57,30.28]	
Total	39 / 4286	8 / 4267		4.88 [2.28,10.43]	Z=4.09, p=<.0001
Heterogeneity:	Q=0.31 (df=1)	p=0.5747	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	2 / 138	100.0	1.96 [0.36,10.51]	
FIGARO-DKD	0 / 107	0 / 113	0.0	-	
Total	4 / 248	2 / 251		1.96 [0.36,10.51]	Z=0.78, p=0.4336
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.00 (df=2)	p=0.6071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.158.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

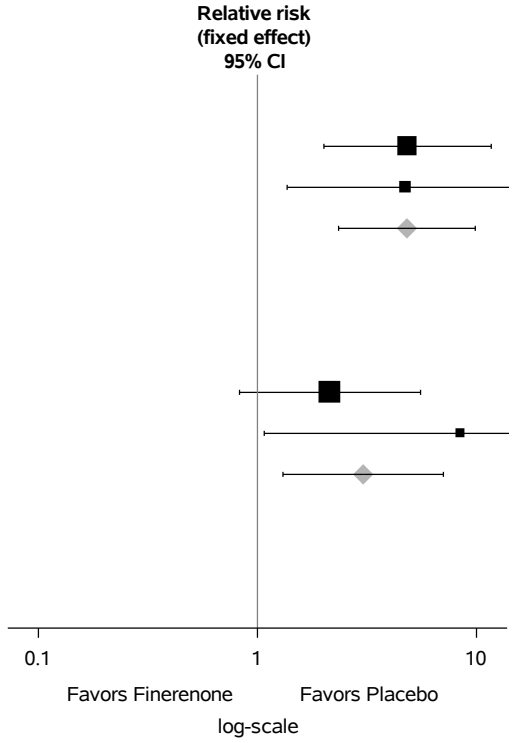
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	8 / 1809	69.5	2.81 [1.25,6.29]	
FIGARO-DKD	19 / 2668	3 / 2601	30.5	6.17 [1.83,20.84]	
Total	41 / 4441	11 / 4410		3.73 [1.92,7.24]	Z=3.88, p=0.0001
Heterogeneity:	Q=1.14 (df=1)	p=0.2861	I^2=12.1%		
Black					
FIDELIO-DKD	5 / 139	1 / 124	100.0	4.46 [0.53,37.66]	
FIGARO-DKD	1 / 113	0 / 145	0.0	125E9 [125E9,125E9]	
Total	6 / 252	1 / 269		5.66 [0.69,46.68]	Z=1.61, p=0.1073
Heterogeneity:	Q=0.05 (df=1)	p=0.8266	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 717	2 / 721	69.6	6.03 [1.36,26.86]	
FIGARO-DKD	3 / 716	1 / 736	30.4	3.08 [0.32,29.58]	
Total	15 / 1433	3 / 1457		5.06 [1.47,17.41]	Z=2.57, p=0.0102
Heterogeneity:	Q=0.24 (df=1)	p=0.6260	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	100.0	2.68 [0.28,25.55]	
FIGARO-DKD	0 / 186	0 / 176	0.0	-	
Total	3 / 384	1 / 353		2.68 [0.28,25.55]	Z=0.86, p=0.3910
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=3)	p=0.9391	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.158.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

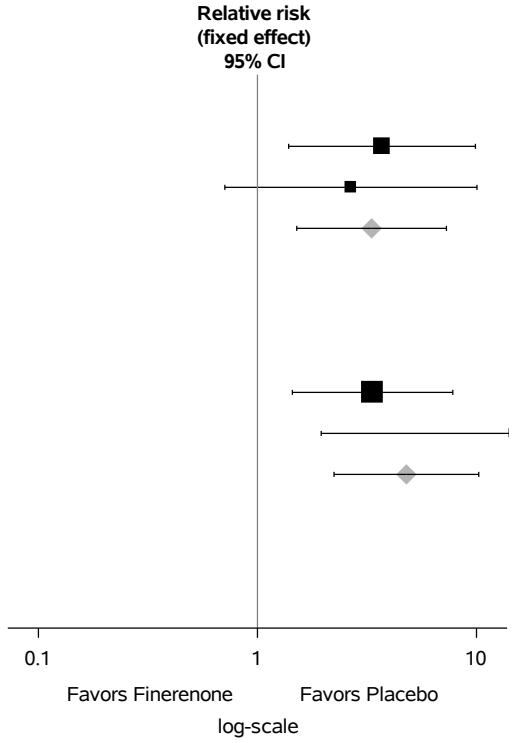
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	28 / 1949	6 / 2024	66.7	4.85 [2.01,11.68]	
FIGARO-DKD	14 / 2527	3 / 2571	33.3	4.75 [1.37,16.50]	
Total	42 / 4476	9 / 4595		4.81 [2.35,9.87]	Z=4.29, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9790	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 878	6 / 807	82.5	2.14 [0.83,5.55]	
FIGARO-DKD	9 / 1156	1 / 1087	17.5	8.46 [1.07,66.69]	
Total	23 / 2034	7 / 1894		3.04 [1.31,7.06]	Z=2.58, p=0.0098
Heterogeneity:	Q=1.46 (df=1)	p=0.2268	I^2=31.6%		
Subgroup Heterogeneity:	Q=0.66 (df=1)	p=0.4159	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.158.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

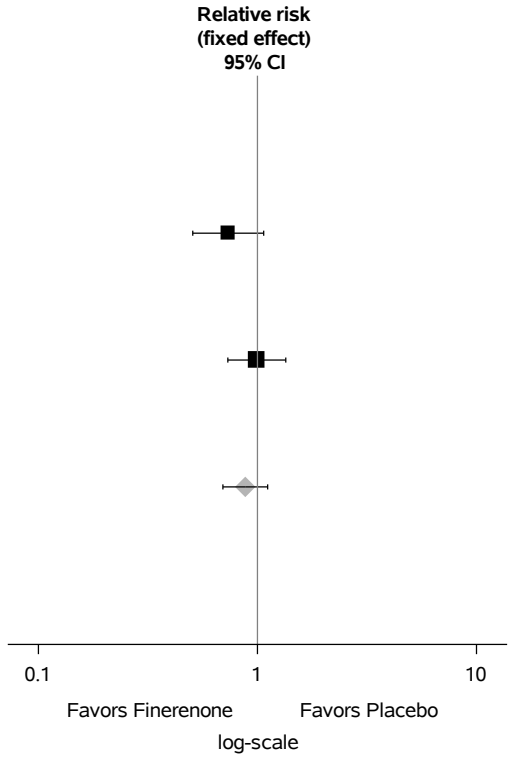
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	19 / 1201	5 / 1171	64.6	3.71 [1.39,9.89]	
FIGARO-DKD	8 / 1752	3 / 1755	35.4	2.67 [0.71,10.05]	
Total	27 / 2953	8 / 2926		3.32 [1.51,7.29]	Z=2.99, p=0.0028
Heterogeneity:	Q=0.15 (df=1)	p=0.6972	I^2=0.0%		
>= 65					
FIDELIO-DKD	23 / 1626	7 / 1660	85.2	3.35 [1.44,7.80]	
FIGARO-DKD	15 / 1931	1 / 1903	14.8	14.78 [1.95,111.80]	
Total	38 / 3557	8 / 3563		4.79 [2.24,10.24]	Z=4.03, p=<.0001
Heterogeneity:	Q=1.88 (df=1)	p=0.1708	I^2=46.7%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5123	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.159: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

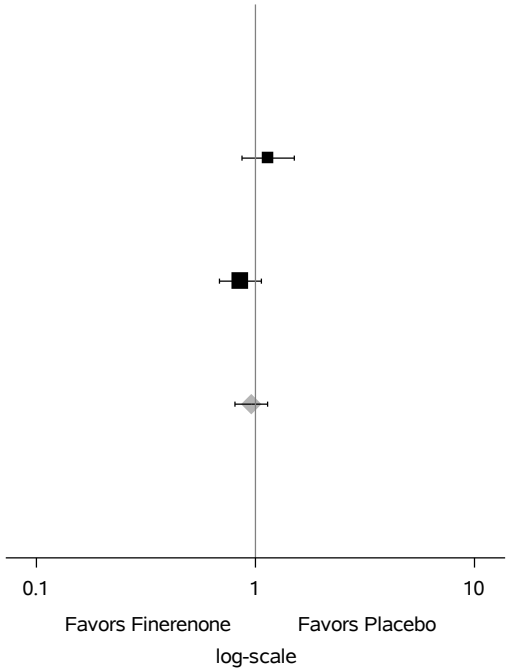
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	64 / 2831	40.0	0.74 [0.51,1.07]	
FIGARO-DKD	81 / 3683	81 / 3658	60.0	0.99 [0.73,1.35]	
Total	128 / 6510	145 / 6489		0.88 [0.70,1.11]	Z=-1.07, p=0.2862
Heterogeneity:	Q=1.50 (df=1)	p=0.2212	I^2=33.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.160: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

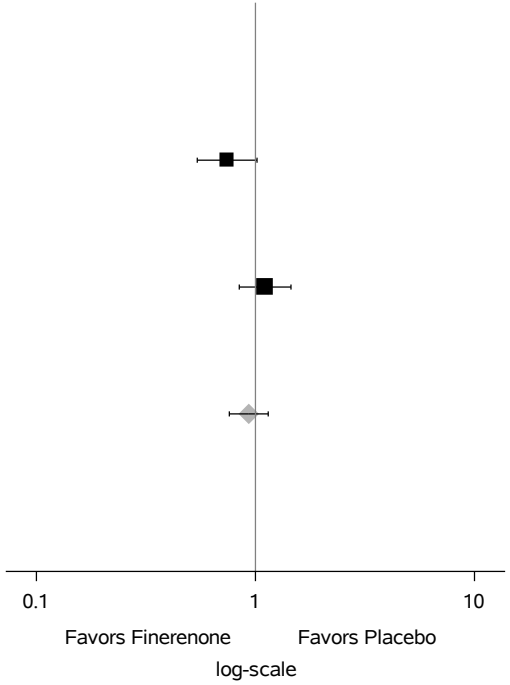
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	105 / 2827	92 / 2831	39.1	1.14 [0.87,1.50]	
FIGARO-DKD	141 / 3683	164 / 3658	60.9	0.85 [0.69,1.06]	
Total	246 / 6510	256 / 6489		0.96 [0.81,1.14]	Z=-0.50, p=0.6159
Heterogeneity:	Q=2.63 (df=1)	p=0.1050	I^2=62.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.161: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

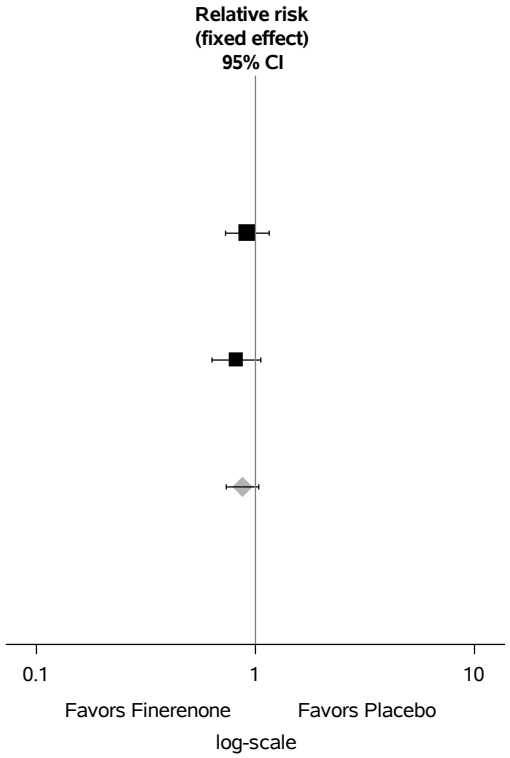
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	66 / 2827	89 / 2831	42.8	0.74 [0.54,1.02]	
FIGARO-DKD	107 / 3683	96 / 3658	57.2	1.11 [0.84,1.45]	
Total	173 / 6510	185 / 6489		0.93 [0.76,1.14]	Z=-0.67, p=0.5004
Heterogeneity:	Q=3.55 (df=1)	p=0.0595	I^2=71.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.162: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

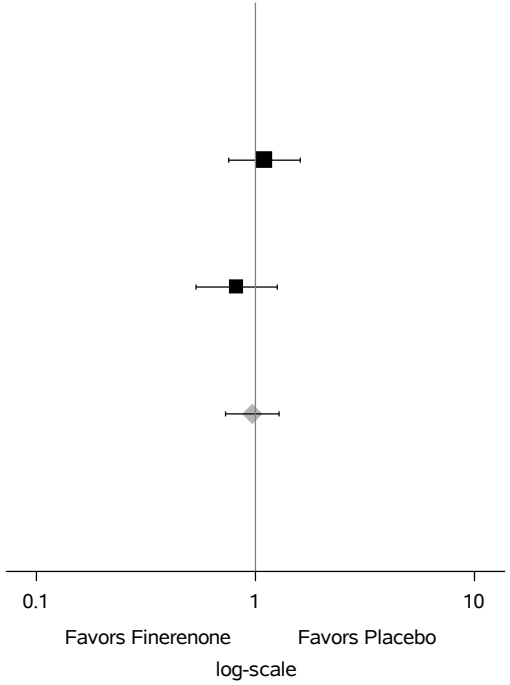
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	133 / 2827	145 / 2831	55.6	0.92 [0.73,1.16]	
FIGARO-DKD	103 / 3683	125 / 3658	44.4	0.82 [0.63,1.06]	
Total	236 / 6510	270 / 6489		0.87 [0.74,1.04]	Z=-1.56, p=0.1182
Heterogeneity:	Q=0.43 (df=1)	p=0.5112	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.163: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

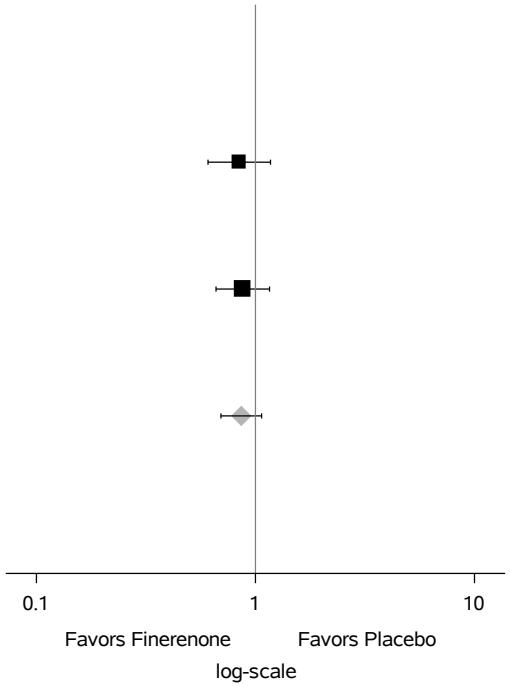
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	56 / 2827	51 / 2831	56.4	1.10 [0.76,1.60]	
FIGARO-DKD	38 / 3683	46 / 3658	43.6	0.82 [0.54,1.26]	
Total	94 / 6510	97 / 6489		0.97 [0.73,1.28]	Z=-0.23, p=0.8178
Heterogeneity:	Q=1.02 (df=1)	p=0.3131	I^2=1.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.164: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

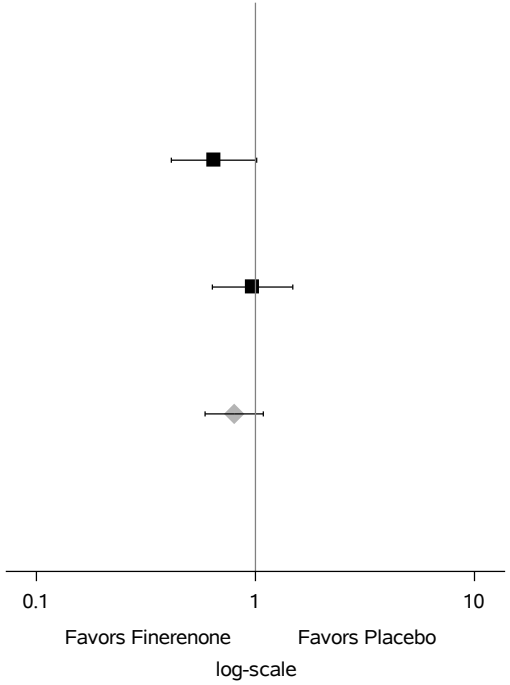
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	76 / 2831	42.3	0.84 [0.61,1.17]	
FIGARO-DKD	89 / 3683	101 / 3658	57.7	0.88 [0.66,1.16]	
Total	153 / 6510	177 / 6489		0.86 [0.70,1.07]	Z=-1.37, p=0.1715
Heterogeneity:	Q=0.03 (df=1)	p=0.8663	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.165: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

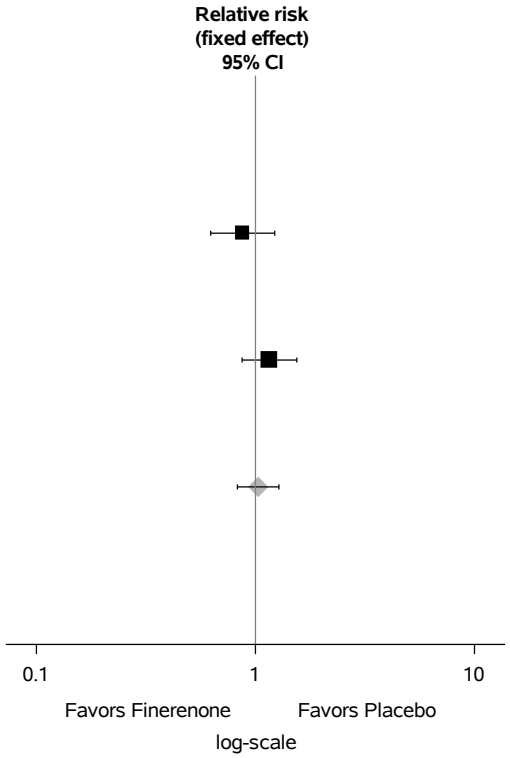
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	48 / 2831	47.0	0.65 [0.41,1.01]	
FIGARO-DKD	42 / 3683	43 / 3658	53.0	0.97 [0.64,1.48]	
Total	73 / 6510	91 / 6489		0.80 [0.59,1.09]	Z=-1.43, p=0.1523
Heterogeneity:	Q=1.66 (df=1)	p=0.1973	I^2=39.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.166: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set

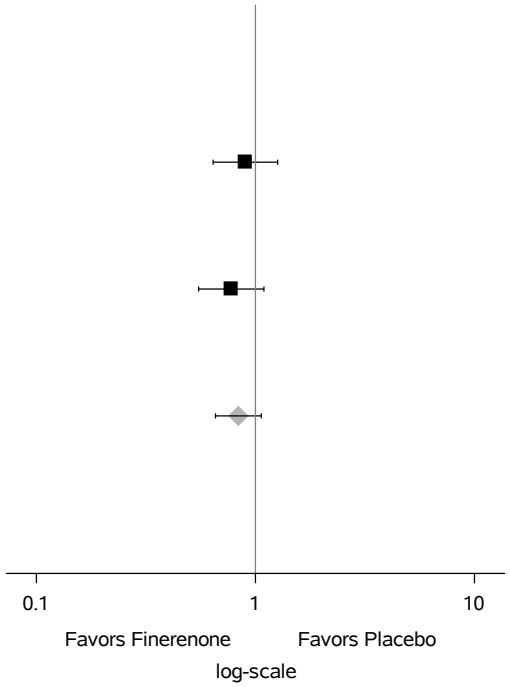
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	71 / 2831	42.2	0.87 [0.62,1.22]	
FIGARO-DKD	98 / 3683	84 / 3658	57.8	1.16 [0.87,1.55]	
Total	160 / 6510	155 / 6489		1.03 [0.83,1.28]	Z=0.26, p=0.7979
Heterogeneity:	Q=1.55 (df=1)	p=0.2129	I^2=35.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.167: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

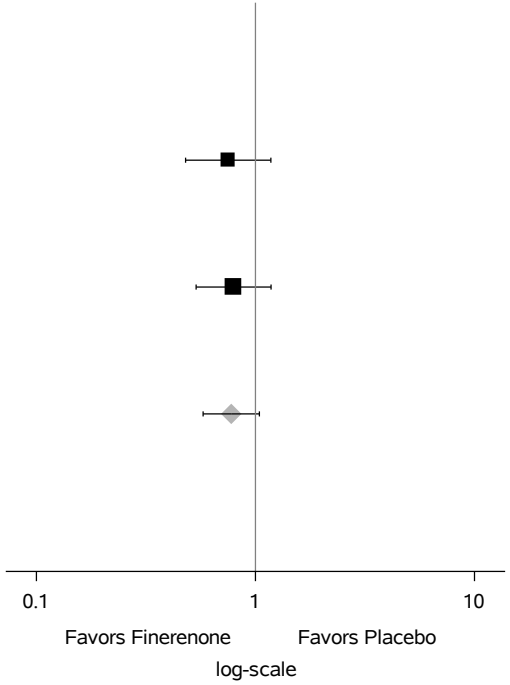
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	69 / 2831	50.6	0.90 [0.64,1.26]	
FIGARO-DKD	57 / 3683	73 / 3658	49.4	0.78 [0.55,1.09]	
Total	119 / 6510	142 / 6489		0.84 [0.66,1.06]	Z=-1.46, p=0.1452
Heterogeneity:	Q=0.36 (df=1)	p=0.5460	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.168: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

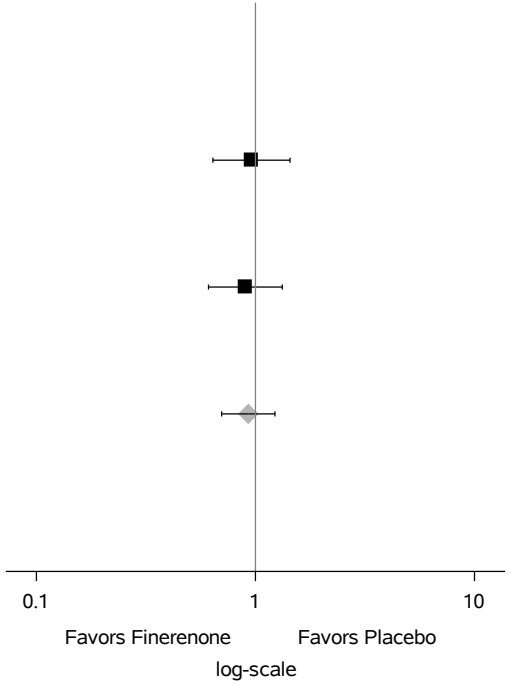
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	44 / 2831	43.5	0.75 [0.48,1.18]	
FIGARO-DKD	44 / 3683	55 / 3658	56.5	0.79 [0.54,1.18]	
Total	77 / 6510	99 / 6489		0.78 [0.58,1.04]	Z=-1.69, p=0.0917
Heterogeneity:	Q=0.03 (df=1)	p=0.8533	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.169: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

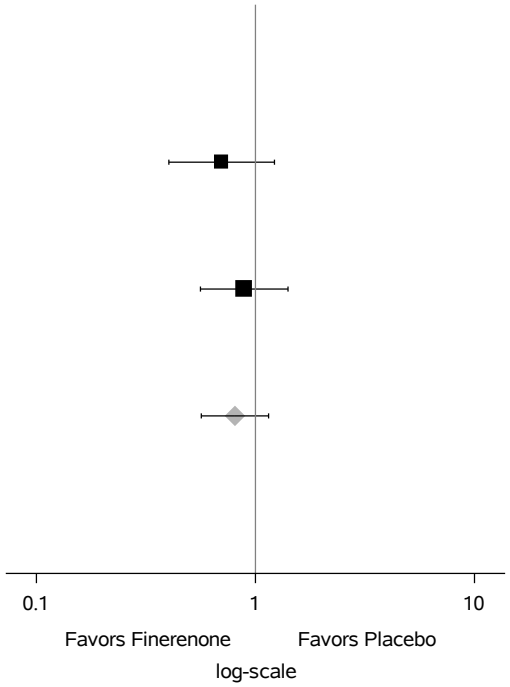
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2827	47 / 2831	47.8	0.96 [0.64,1.44]	
FIGARO-DKD	48 / 3683	53 / 3658	52.2	0.90 [0.61,1.33]	
Total	93 / 6510	100 / 6489		0.93 [0.70,1.23]	Z=-0.53, p=0.5978
Heterogeneity:	Q=0.05 (df=1)	p=0.8236	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.170: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

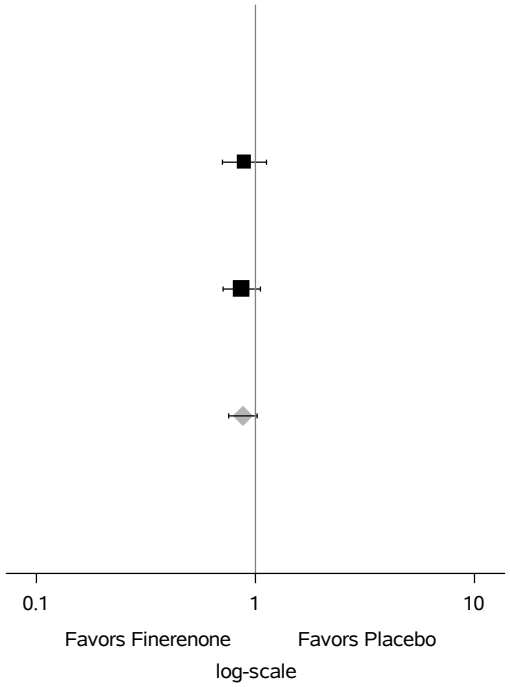
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	30 / 2831	40.7	0.70 [0.40,1.22]	
FIGARO-DKD	34 / 3683	38 / 3658	59.3	0.89 [0.56,1.41]	
Total	55 / 6510	68 / 6489		0.81 [0.57,1.15]	Z=-1.19, p=0.2324
Heterogeneity:	Q=0.42 (df=1)	p=0.5192	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.171: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

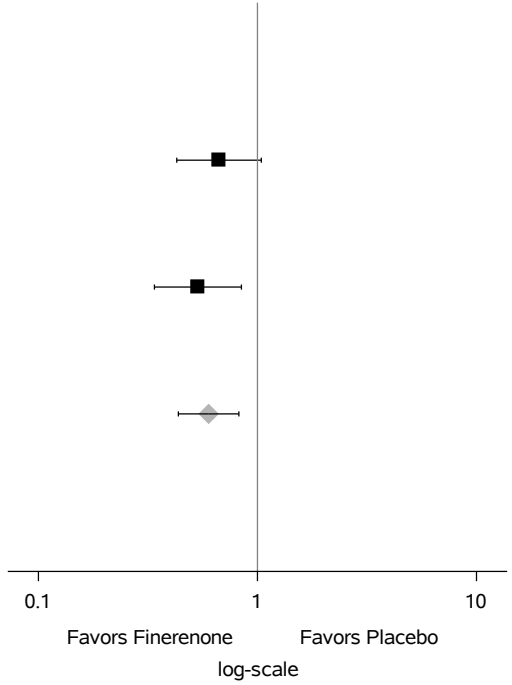
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2827	145 / 2831	41.8	0.89 [0.71,1.12]	
FIGARO-DKD	177 / 3683	203 / 3658	58.2	0.87 [0.71,1.05]	
Total	306 / 6510	348 / 6489		0.88 [0.75,1.02]	Z=-1.73, p=0.0839
Heterogeneity:	Q=0.03 (df=1)	p=0.8547	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.172: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

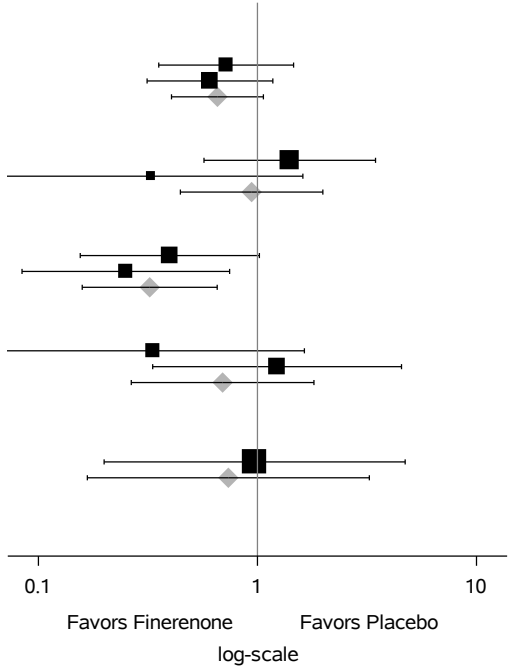
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	48 / 2831	51.4	0.67 [0.43,1.04]	
FIGARO-DKD	28 / 3683	52 / 3658	48.6	0.53 [0.34,0.84]	
Total	60 / 6510	100 / 6489		0.60 [0.44,0.82]	Z=-3.16, p=0.0016
Heterogeneity:	Q=0.47 (df=1)	p=0.4952	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.172.1: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

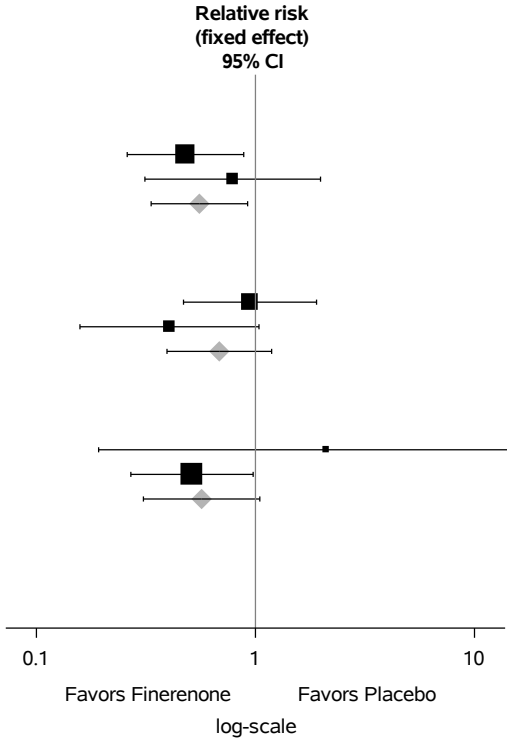
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	13 / 1178	18 / 1174	46.5	0.72 [0.35,1.46]	
FIGARO-DKD	14 / 1752	23 / 1747	53.5	0.61 [0.31,1.18]	
Total	27 / 2930	41 / 2921		0.66 [0.41,1.06]	Z=-1.71, p=0.0878
Heterogeneity:	Q=0.12 (df=1)	p=0.7303	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 466	8 / 476	75.8	1.40 [0.57,3.46]	
FIGARO-DKD	2 / 559	6 / 548	24.2	0.33 [0.07,1.61]	
Total	13 / 1025	14 / 1024		0.94 [0.44,1.99]	Z=-0.16, p=0.8724
Heterogeneity:	Q=2.45 (df=1)	p=0.1179	I^2=59.1%		
Asia					
FIDELIO-DKD	6 / 790	15 / 786	57.3	0.40 [0.16,1.02]	
FIGARO-DKD	4 / 811	16 / 813	42.7	0.25 [0.08,0.75]	
Total	10 / 1601	31 / 1599		0.32 [0.16,0.65]	Z=-3.13, p=0.0018
Heterogeneity:	Q=0.40 (df=1)	p=0.5287	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	6 / 294	40.3	0.33 [0.07,1.64]	
FIGARO-DKD	5 / 424	4 / 417	59.7	1.23 [0.33,4.55]	
Total	7 / 718	10 / 711		0.69 [0.27,1.81]	Z=-0.75, p=0.4546
Heterogeneity:	Q=1.55 (df=1)	p=0.2132	I^2=35.5%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	3 / 137	3 / 133	100.0	0.97 [0.20,4.72]	
Total	3 / 236	4 / 234		0.74 [0.17,3.24]	Z=-0.40, p=0.6857
Heterogeneity:	Q=0.12 (df=1)	p=0.7320	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.61 (df=4)	p=0.3293	I^2=13.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.172.2: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

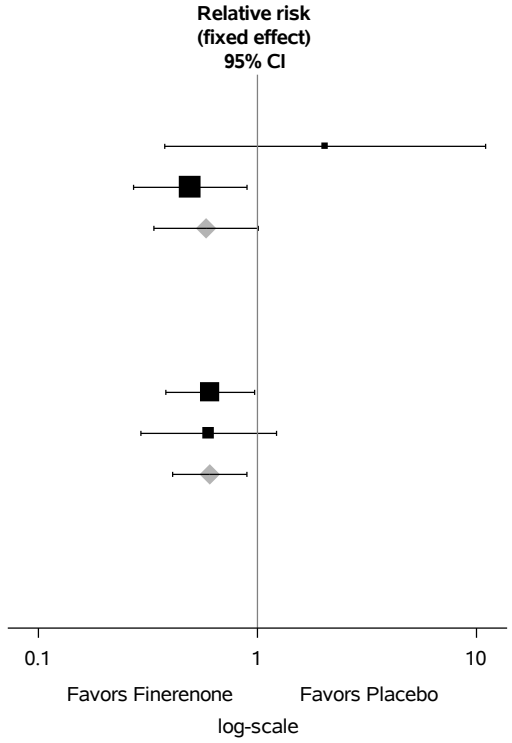
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	15 / 1556	31 / 1541	69.4	0.48 [0.26,0.88]	
FIGARO-DKD	8 / 637	10 / 627	30.6	0.79 [0.31,1.98]	
Total	23 / 2193	41 / 2168		0.55 [0.33,0.92]	Z=-2.28, p=0.0227
Heterogeneity:	Q=0.77 (df=1)	p=0.3794	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	15 / 1061	16 / 1069	64.4	0.94 [0.47,1.90]	
FIGARO-DKD	6 / 720	15 / 729	35.6	0.41 [0.16,1.04]	
Total	21 / 1781	31 / 1798		0.68 [0.39,1.19]	Z=-1.35, p=0.1758
Heterogeneity:	Q=2.01 (df=1)	p=0.1563	I^2=50.2%		
>= 60					
FIDELIO-DKD	2 / 210	1 / 221	6.7	2.10 [0.19,23.04]	
FIGARO-DKD	14 / 2326	27 / 2302	93.3	0.51 [0.27,0.98]	
Total	16 / 2536	28 / 2523		0.57 [0.31,1.05]	Z=-1.81, p=0.0698
Heterogeneity:	Q=1.25 (df=1)	p=0.2642	I^2=19.8%		
Subgroup Heterogeneity:	Q=0.34 (df=2)	p=0.8432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.172.3: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

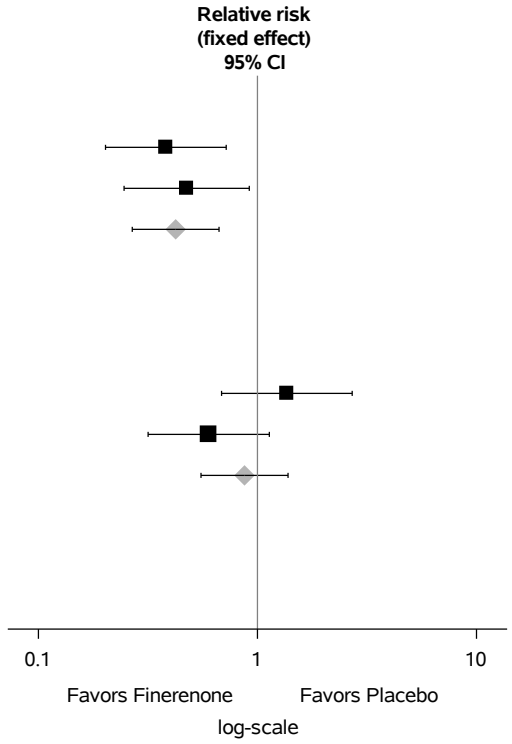
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	2 / 213	11.1	2.04 [0.38,11.01]	
FIGARO-DKD	16 / 1720	32 / 1698	88.9	0.49 [0.27,0.90]	
Total	20 / 1929	34 / 1911		0.58 [0.34,1.01]	Z=-1.93, p=0.0538
Heterogeneity:	Q=2.41 (df=1)	p=0.1202	I^2=58.6%		
Very High					
FIDELIO-DKD	28 / 2618	46 / 2618	70.0	0.61 [0.38,0.97]	
FIGARO-DKD	12 / 1963	20 / 1960	30.0	0.60 [0.29,1.22]	
Total	40 / 4581	66 / 4578		0.61 [0.41,0.90]	Z=-2.52, p=0.0119
Heterogeneity:	Q=0.00 (df=1)	p=0.9708	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9102	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.172.4: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

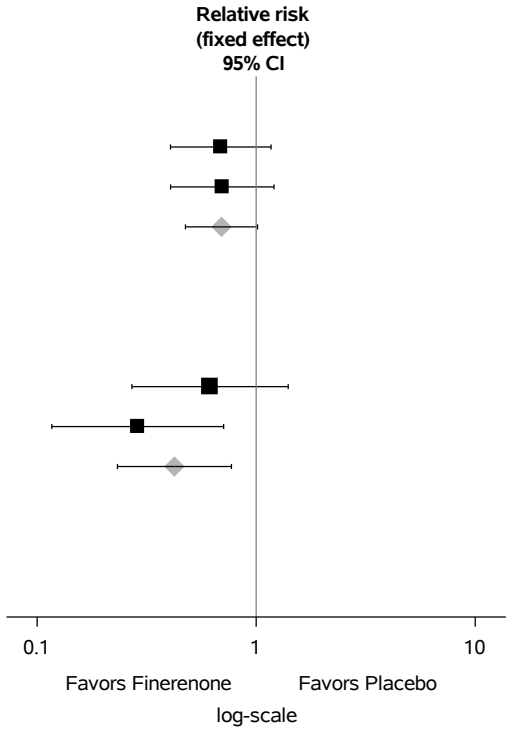
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1301	34 / 1299	51.8	0.38 [0.20,0.72]	
FIGARO-DKD	13 / 1673	27 / 1651	48.2	0.48 [0.25,0.92]	
Total	26 / 2974	61 / 2950		0.42 [0.27,0.67]	Z=-3.70, p=0.0002
Heterogeneity:	Q=0.22 (df=1)	p=0.6389	I^2=0.0%		
Absent					
FIDELIO-DKD	19 / 1526	14 / 1532	46.3	1.36 [0.69,2.71]	
FIGARO-DKD	15 / 2010	25 / 2007	53.7	0.60 [0.32,1.13]	
Total	34 / 3536	39 / 3539		0.87 [0.55,1.38]	Z=-0.58, p=0.5599
Heterogeneity:	Q=2.96 (df=1)	p=0.0856	I^2=66.2%		
Subgroup Heterogeneity:	Q=4.82 (df=1)	p=0.0281	I^2=79.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.172.5: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	33 / 1858	51.4	0.69 [0.41,1.17]	
FIGARO-DKD	22 / 2643	31 / 2608	48.6	0.70 [0.41,1.21]	
Total	45 / 4522	64 / 4466		0.69 [0.48,1.01]	Z=-1.89, p=0.0594
Heterogeneity:	Q=0.00 (df=1)	p=0.9671	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 948	15 / 973	54.7	0.62 [0.27,1.40]	
FIGARO-DKD	6 / 1040	21 / 1048	45.3	0.29 [0.12,0.71]	
Total	15 / 1988	36 / 2021		0.42 [0.23,0.77]	Z=-2.81, p=0.0049
Heterogeneity:	Q=1.50 (df=1)	p=0.2208	I^2=33.3%		
Subgroup Heterogeneity:	Q=1.87 (df=1)	p=0.1714	I^2=46.6%		

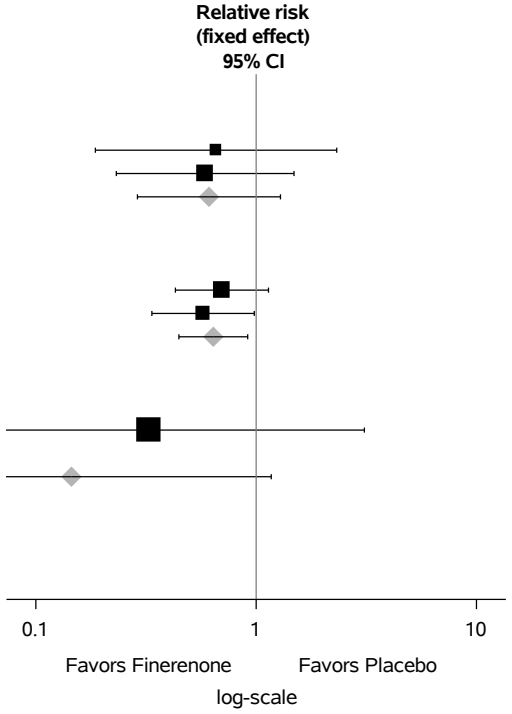


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.172.6: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)

Safety Analysis Set

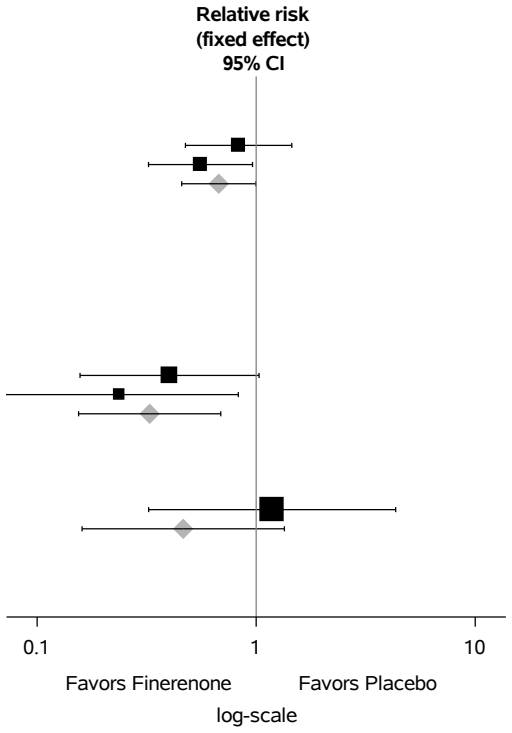
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 788	6 / 777	35.2	0.66 [0.19,2.32]	
FIGARO-DKD	7 / 1187	12 / 1194	64.8	0.59 [0.23,1.49]	
Total	11 / 1975	18 / 1971		0.61 [0.29,1.29]	Z=-1.29, p=0.1956
Heterogeneity:	Q=0.02 (df=1)	p=0.8870	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	27 / 1897	39 / 1916	54.7	0.70 [0.43,1.14]	
FIGARO-DKD	21 / 2389	36 / 2351	45.3	0.57 [0.34,0.98]	
Total	48 / 4286	75 / 4267		0.64 [0.45,0.92]	Z=-2.44, p=0.0146
Heterogeneity:	Q=0.29 (df=1)	p=0.5929	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 141	3 / 138	100.0	0.33 [0.03,3.10]	
FIGARO-DKD	0 / 107	4 / 113	0.0	0.00 [0.00,98E295]	
Total	1 / 248	7 / 251		0.15 [0.02,1.17]	Z=-1.81, p=0.0699
Heterogeneity:	Q=0.50 (df=1)	p=0.4803	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.88 (df=2)	p=0.3905	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.172.7: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

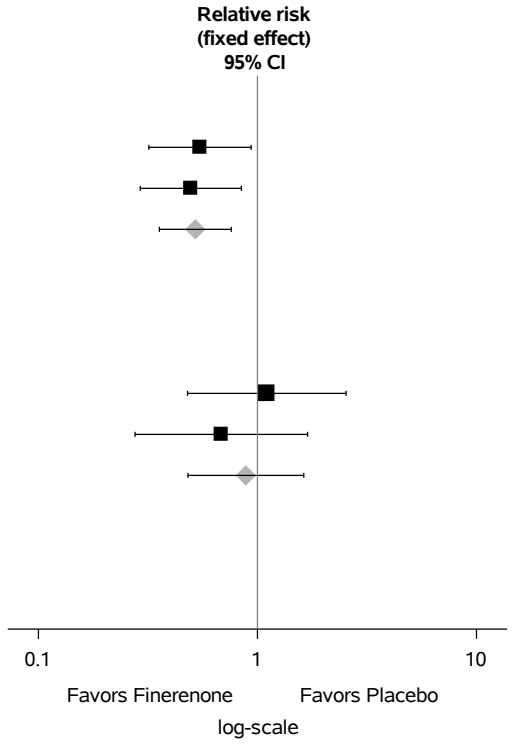
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	27 / 1809	48.9	0.83 [0.48,1.45]	
FIGARO-DKD	20 / 2668	35 / 2601	51.1	0.56 [0.32,0.96]	
Total	42 / 4441	62 / 4410		0.67 [0.46,1.00]	Z=-1.98, p=0.0478
Heterogeneity:	Q=1.01 (df=1)	p=0.3156	I^2=0.7%		
Black					
FIDELIO-DKD	4 / 139	0 / 124	0.0	15E10 [15E10,15E10]	
FIGARO-DKD	0 / 113	0 / 145	0.0	-	
Total	4 / 252	0 / 269		1.87E7 [1.87E7,1.87E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	6 / 717	15 / 721	63.9	0.40 [0.16,1.03]	
FIGARO-DKD	3 / 716	13 / 736	36.1	0.24 [0.07,0.83]	
Total	9 / 1433	28 / 1457		0.33 [0.15,0.69]	Z=-2.94, p=0.0033
Heterogeneity:	Q=0.44 (df=1)	p=0.5075	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	6 / 177	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	5 / 186	4 / 176	100.0	1.18 [0.32,4.33]	
Total	5 / 384	10 / 353		0.46 [0.16,1.35]	Z=-1.41, p=0.1577
Heterogeneity:	Q=1.99 (df=1)	p=0.1584	I^2=49.7%		
Subgroup Heterogeneity:	Q=3.00 (df=3)	p=0.3916	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.1.172.8: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

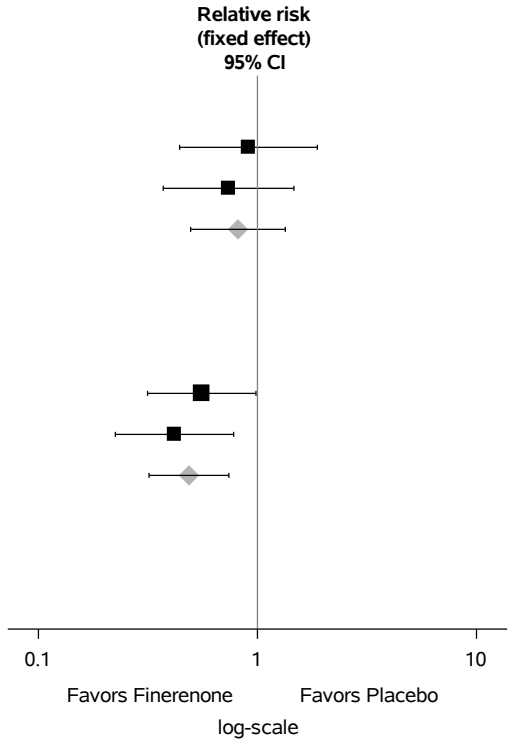
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	20 / 1949	38 / 2024	49.4	0.55 [0.32,0.94]	
FIGARO-DKD	20 / 2527	41 / 2571	50.6	0.50 [0.29,0.84]	
Total	40 / 4476	79 / 4595		0.52 [0.36,0.76]	Z=-3.39, p=0.0007
Heterogeneity:	Q=0.06 (df=1)	p=0.8026	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 878	10 / 807	54.2	1.10 [0.48,2.54]	
FIGARO-DKD	8 / 1156	11 / 1087	45.8	0.68 [0.28,1.69]	
Total	20 / 2034	21 / 1894		0.89 [0.48,1.63]	Z=-0.39, p=0.6946
Heterogeneity:	Q=0.58 (df=1)	p=0.4470	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.11 (df=1)	p=0.1463	I^2=52.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.172.9: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

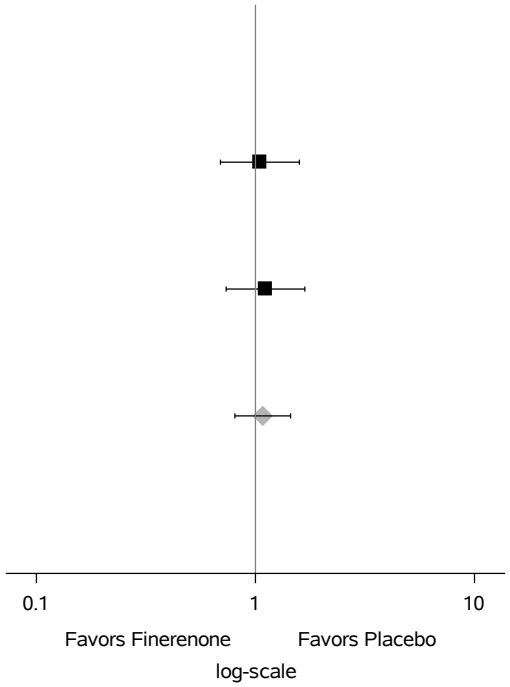
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	14 / 1201	15 / 1171	47.4	0.91 [0.44,1.88]	
FIGARO-DKD	14 / 1752	19 / 1755	52.6	0.74 [0.37,1.47]	
Total	28 / 2953	34 / 2926		0.81 [0.50,1.34]	Z=-0.81, p=0.4195
Heterogeneity:	Q=0.17 (df=1)	p=0.6809	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 1626	33 / 1660	54.3	0.56 [0.31,0.98]	
FIGARO-DKD	14 / 1931	33 / 1903	45.7	0.42 [0.22,0.78]	
Total	32 / 3557	66 / 3563		0.49 [0.32,0.74]	Z=-3.36, p=0.0008
Heterogeneity:	Q=0.44 (df=1)	p=0.5054	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.41 (df=1)	p=0.1209	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.1.173: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

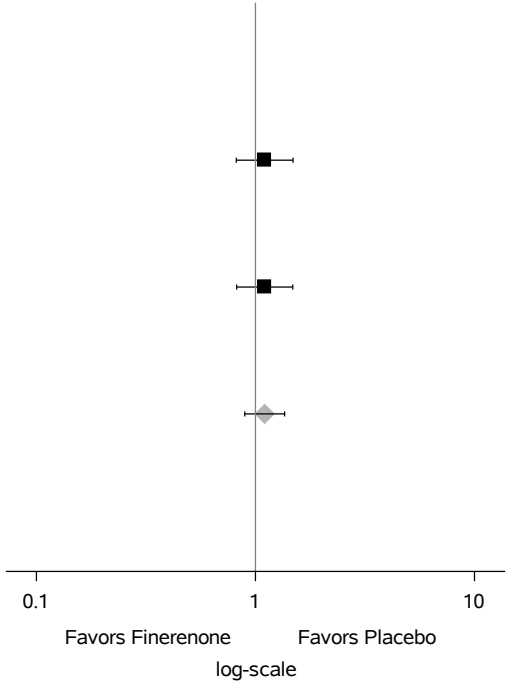
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2827	43 / 2831	49.9	1.05 [0.69,1.59]	
FIGARO-DKD	47 / 3683	42 / 3658	50.1	1.11 [0.73,1.68]	
Total	92 / 6510	85 / 6489		1.08 [0.81,1.45]	Z=0.51, p=0.6093
Heterogeneity:	Q=0.04 (df=1)	p=0.8440	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.174: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

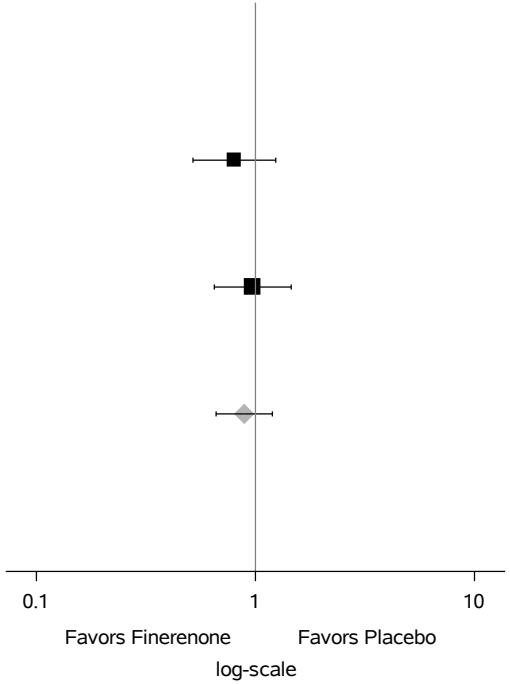
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	88 / 2827	80 / 2831	49.4	1.10 [0.82,1.48]	
FIGARO-DKD	91 / 3683	82 / 3658	50.6	1.10 [0.82,1.48]	
Total	179 / 6510	162 / 6489		1.10 [0.89,1.36]	Z=0.91, p=0.3645
Heterogeneity:	Q=0.00 (df=1)	p=0.9977	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.175: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

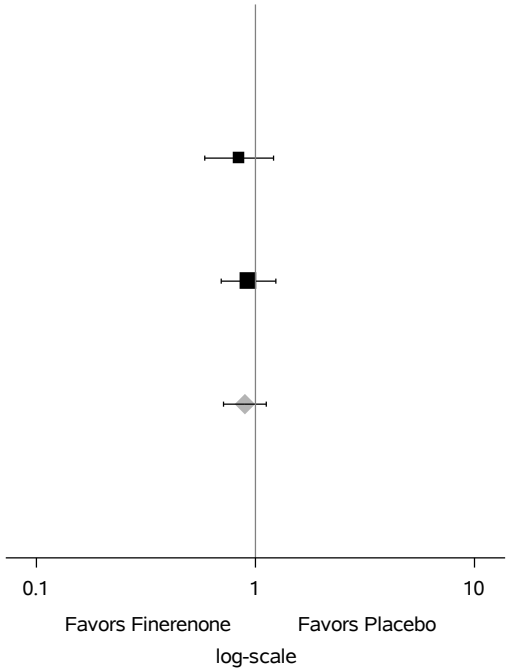
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	45 / 2831	46.3	0.80 [0.52,1.24]	
FIGARO-DKD	46 / 3683	47 / 3658	53.7	0.97 [0.65,1.46]	
Total	82 / 6510	92 / 6489		0.89 [0.66,1.19]	Z=-0.78, p=0.4336
Heterogeneity:	Q=0.41 (df=1)	p=0.5232	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.176: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

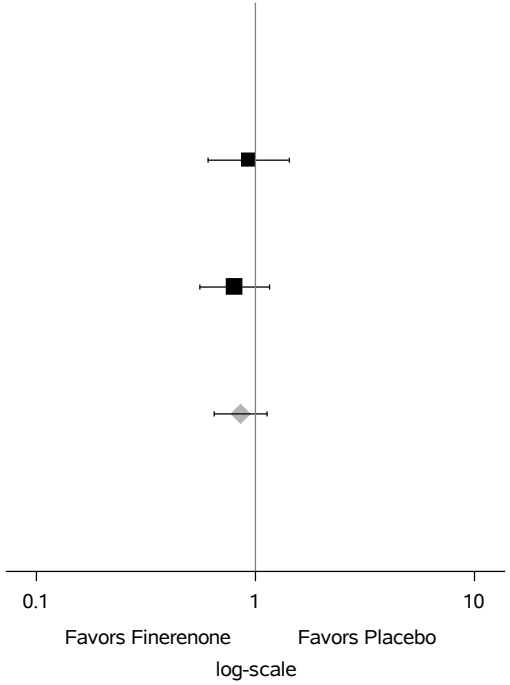
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	63 / 2831	38.7	0.84 [0.59,1.21]	
FIGARO-DKD	88 / 3683	94 / 3658	61.3	0.93 [0.70,1.24]	
Total	141 / 6510	157 / 6489		0.89 [0.71,1.12]	Z=-0.97, p=0.3331
Heterogeneity:	Q=0.18 (df=1)	p=0.6753	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.177: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

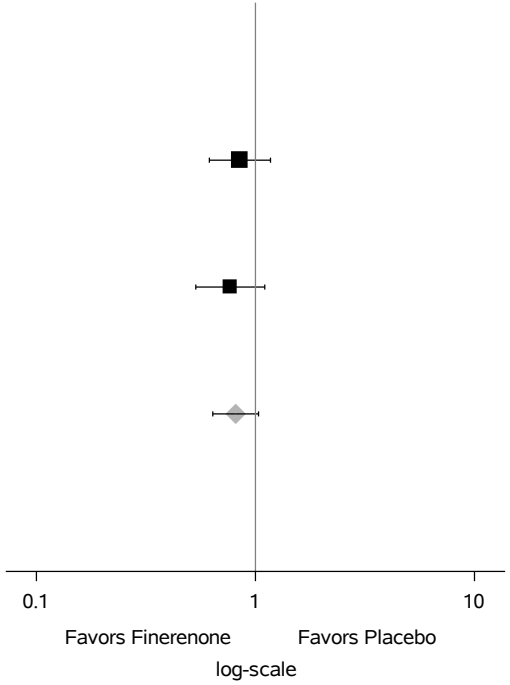
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	43 / 2831	42.4	0.93 [0.61,1.43]	
FIGARO-DKD	51 / 3683	63 / 3658	57.6	0.80 [0.56,1.16]	
Total	91 / 6510	106 / 6489		0.86 [0.65,1.13]	Z=-1.10, p=0.2715
Heterogeneity:	Q=0.26 (df=1)	p=0.6082	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.178: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

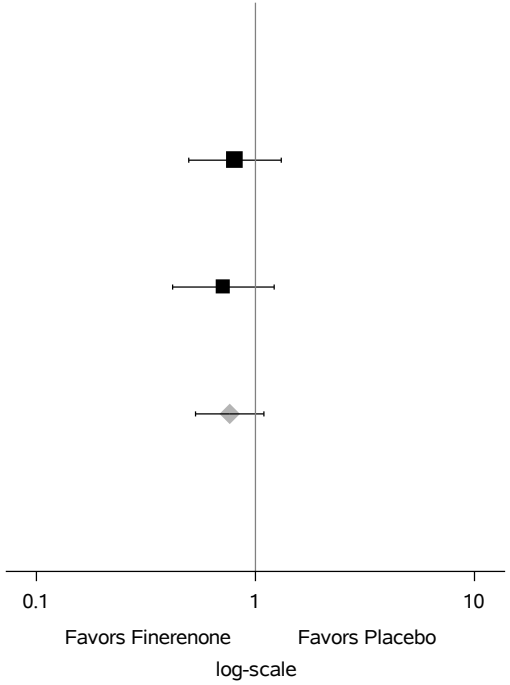
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 2827	79 / 2831	56.0	0.85 [0.62,1.17]	
FIGARO-DKD	51 / 3683	66 / 3658	44.0	0.77 [0.53,1.10]	
Total	118 / 6510	145 / 6489		0.81 [0.64,1.03]	Z=-1.70, p=0.0899
Heterogeneity:	Q=0.17 (df=1)	p=0.6819	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.179: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

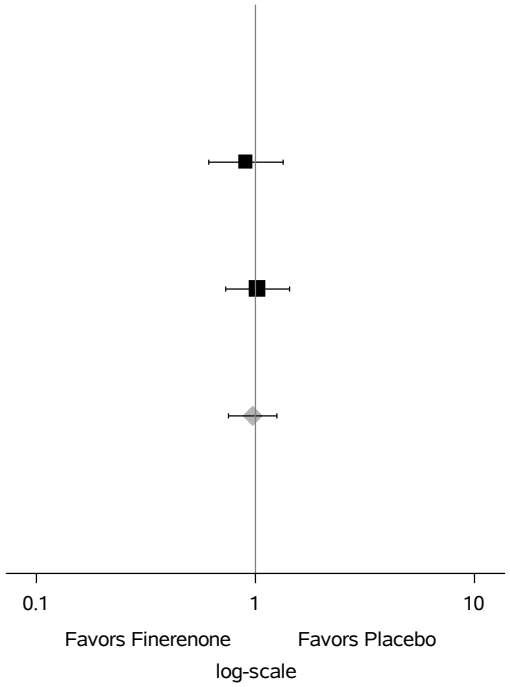
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	36 / 2831	54.7	0.81 [0.50,1.31]	
FIGARO-DKD	23 / 3683	32 / 3658	45.3	0.71 [0.42,1.22]	
Total	52 / 6510	68 / 6489		0.76 [0.53,1.09]	Z=-1.48, p=0.1401
Heterogeneity:	Q=0.11 (df=1)	p=0.7400	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.180: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

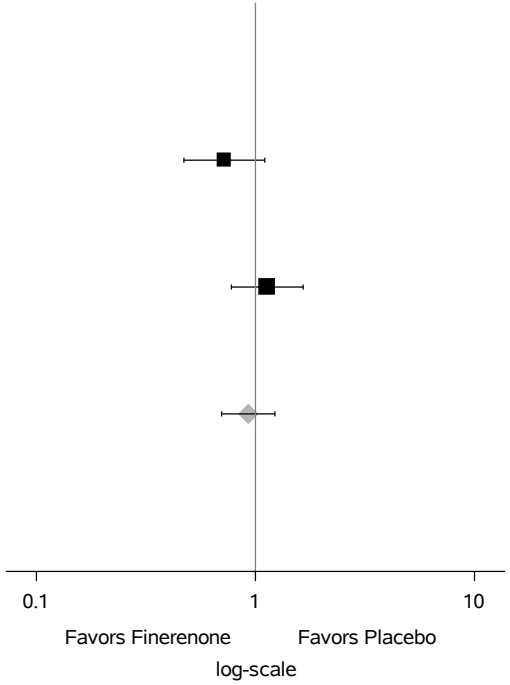
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	52 / 2831	42.4	0.91 [0.61,1.34]	
FIGARO-DKD	68 / 3683	66 / 3658	57.6	1.02 [0.73,1.43]	
Total	115 / 6510	118 / 6489		0.97 [0.75,1.25]	Z=-0.22, p=0.8230
Heterogeneity:	Q=0.22 (df=1)	p=0.6406	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.181: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

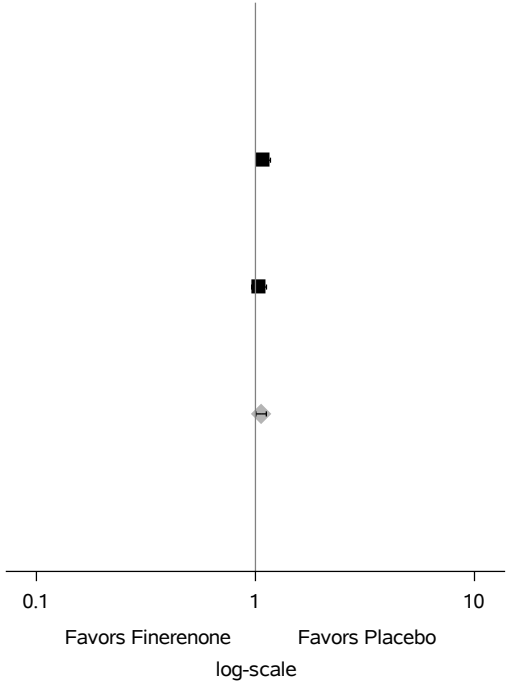
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	50 / 2831	44.0	0.72 [0.47,1.10]	
FIGARO-DKD	57 / 3683	50 / 3658	56.0	1.13 [0.78,1.65]	
Total	93 / 6510	100 / 6489		0.93 [0.70,1.23]	Z=-0.53, p=0.5961
Heterogeneity:	Q=2.42 (df=1)	p=0.1196	I^2=58.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.182: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment AEs
Safety Analysis Set

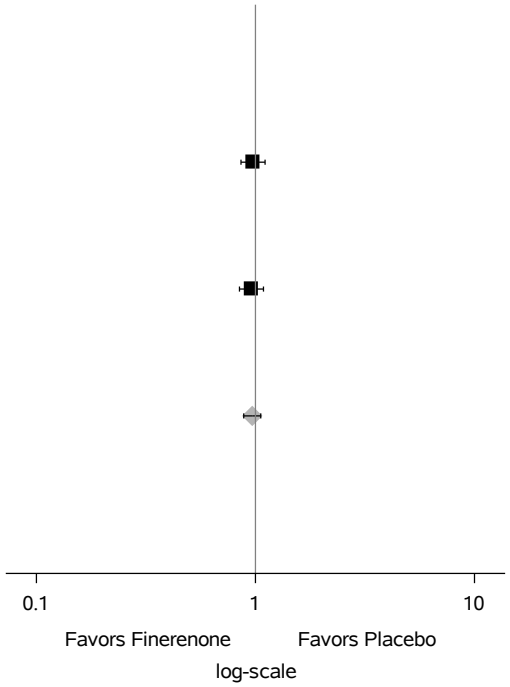
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	921 / 2827	851 / 2831	50.5	1.08 [1.00,1.17]	
FIGARO-DKD	960 / 3683	918 / 3658	49.5	1.04 [0.96,1.12]	
Total	1881 / 6510	1769 / 6489		1.06 [1.00,1.12]	Z=2.12, p=0.0339
Heterogeneity:	Q=0.58 (df=1)	p=0.4478	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.183: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment SAEs
Safety Analysis Set

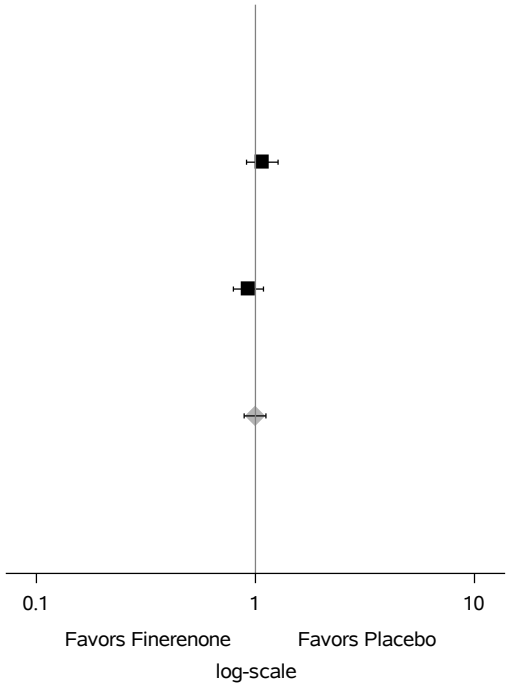
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	404 / 2827	415 / 2831	49.8	0.97 [0.86,1.11]	
FIGARO-DKD	419 / 3683	434 / 3658	50.2	0.96 [0.85,1.09]	
Total	823 / 6510	849 / 6489		0.97 [0.88,1.06]	Z=-0.74, p=0.4594
Heterogeneity:	Q=0.03 (df=1)	p=0.8562	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.1.184: Forestplot for Relative Risk of Proportion of Subjects with Severe Post-Treatment AEs
Safety Analysis Set

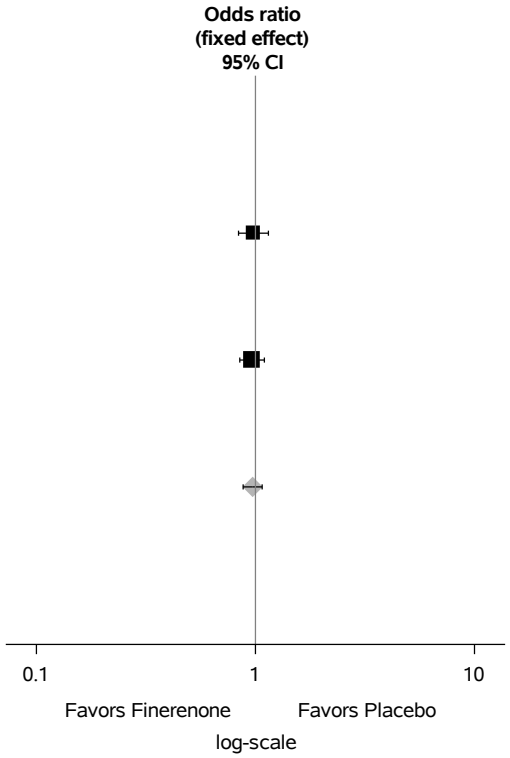
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	264 / 2827	246 / 2831	47.7	1.07 [0.91,1.27]	
FIGARO-DKD	274 / 3683	293 / 3658	52.3	0.93 [0.79,1.09]	
Total	538 / 6510	539 / 6489		1.00 [0.89,1.12]	Z=-0.07, p=0.9418
Heterogeneity:	Q=1.56 (df=1)	p=0.2120	I^2=35.8%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs
Safety Analysis Set

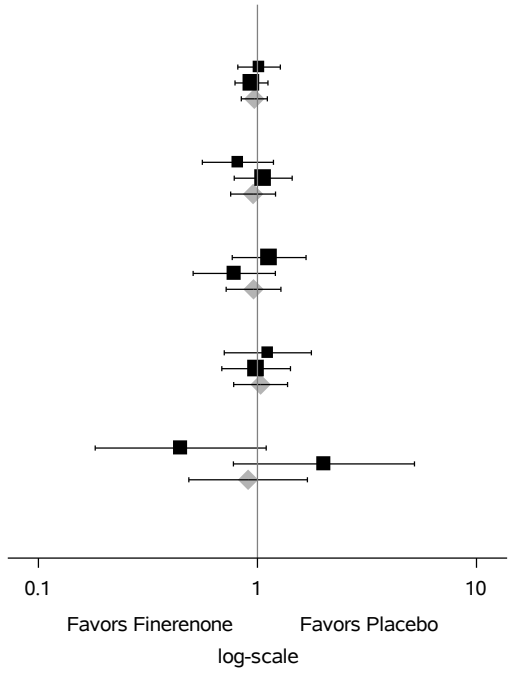
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2468 / 2827	2478 / 2831	40.4	0.98 [0.84,1.15]	
FIGARO-DKD	3134 / 3683	3129 / 3658	59.6	0.97 [0.85,1.10]	
Total	5602 / 6510	5607 / 6489		0.97 [0.88,1.07]	Z=-0.58, p=0.5610
Heterogeneity:	Q=0.02 (df=1)	p=0.8880	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.1.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Region
Safety Analysis Set

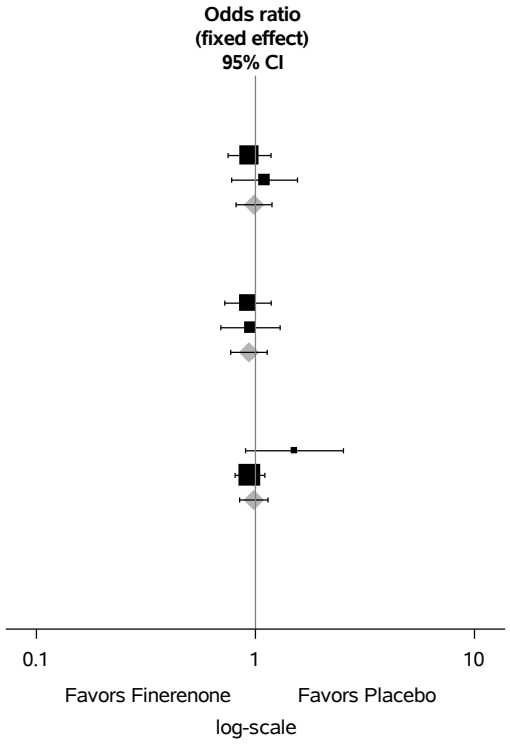
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	997 / 1178	991 / 1174	37.5	1.02 [0.81,1.27]	
FIGARO-DKD	1431 / 1752	1443 / 1747	62.5	0.94 [0.79,1.12]	
Total	2428 / 2930	2434 / 2921		0.97 [0.84,1.11]	Z=-0.47, p=0.6378
Heterogeneity:	Q=0.31 (df=1)	p=0.5801	I^2=0.0%		
North America					
FIDELIO-DKD	397 / 466	417 / 476	39.9	0.81 [0.56,1.18]	
FIGARO-DKD	459 / 559	445 / 548	60.1	1.06 [0.78,1.44]	
Total	856 / 1025	862 / 1024		0.96 [0.75,1.21]	Z=-0.38, p=0.7029
Heterogeneity:	Q=1.17 (df=1)	p=0.2790	I^2=14.7%		
Asia					
FIDELIO-DKD	738 / 790	728 / 786	55.4	1.13 [0.77,1.67]	
FIGARO-DKD	762 / 811	774 / 813	44.6	0.78 [0.51,1.21]	
Total	1500 / 1601	1502 / 1599		0.96 [0.72,1.28]	Z=-0.28, p=0.7786
Heterogeneity:	Q=1.53 (df=1)	p=0.2160	I^2=34.7%		
Latin America					
FIDELIO-DKD	253 / 294	249 / 294	38.3	1.12 [0.71,1.76]	
FIGARO-DKD	352 / 424	347 / 417	61.7	0.99 [0.69,1.41]	
Total	605 / 718	596 / 711		1.03 [0.78,1.37]	Z=0.23, p=0.8181
Heterogeneity:	Q=0.17 (df=1)	p=0.6795	I^2=0.0%		
Others					
FIDELIO-DKD	83 / 99	93 / 101	52.9	0.45 [0.18,1.10]	
FIGARO-DKD	130 / 137	120 / 133	47.1	2.01 [0.78,5.21]	
Total	213 / 236	213 / 234		0.91 [0.49,1.69]	Z=-0.31, p=0.7576
Heterogeneity:	Q=5.08 (df=1)	p=0.0241	I^2=80.3%		
Subgroup Heterogeneity:	Q=0.26 (df=4)	p=0.9921	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.1.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

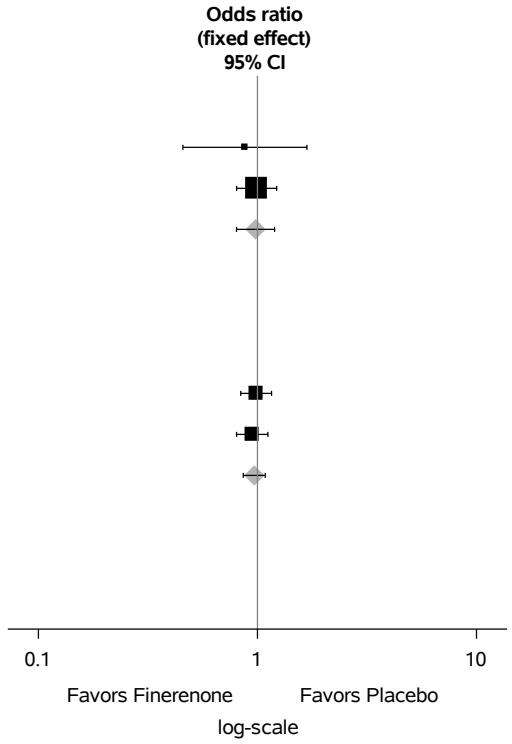
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	1381 / 1556	1377 / 1541	70.2	0.94 [0.75,1.18]	
FIGARO-DKD	567 / 637	552 / 627	29.8	1.10 [0.78,1.56]	
Total	1948 / 2193	1929 / 2168		0.99 [0.82,1.19]	Z=-0.15, p=0.8770
Heterogeneity:	Q=0.56 (df=1)	p=0.4541	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	906 / 1061	923 / 1069	62.0	0.92 [0.72,1.18]	
FIGARO-DKD	628 / 720	640 / 729	38.0	0.95 [0.70,1.30]	
Total	1534 / 1781	1563 / 1798		0.93 [0.77,1.13]	Z=-0.70, p=0.4851
Heterogeneity:	Q=0.02 (df=1)	p=0.8962	I^2=0.0%		
>= 60					
FIDELIO-DKD	181 / 210	178 / 221	8.4	1.51 [0.90,2.52]	
FIGARO-DKD	1939 / 2326	1937 / 2302	91.6	0.94 [0.81,1.10]	
Total	2120 / 2536	2115 / 2523		0.98 [0.85,1.14]	Z=-0.23, p=0.8211
Heterogeneity:	Q=2.91 (df=1)	p=0.0879	I^2=65.7%		
Subgroup Heterogeneity:	Q=0.21 (df=2)	p=0.9021	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.1.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set

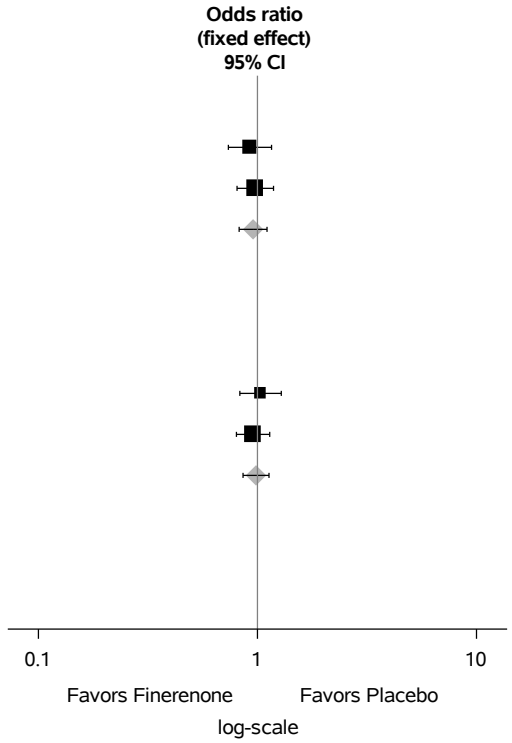
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	188 / 209	194 / 213	9.4	0.88 [0.46,1.68]	
FIGARO-DKD	1522 / 1720	1504 / 1698	90.6	0.99 [0.80,1.22]	
Total	1710 / 1929	1698 / 1911		0.98 [0.80,1.20]	Z=-0.20, p=0.8439
Heterogeneity:	Q=0.12 (df=1)	p=0.7250	I^2=0.0%		
Very High					
FIDELIO-DKD	2280 / 2618	2284 / 2618	50.9	0.99 [0.84,1.16]	
FIGARO-DKD	1612 / 1963	1625 / 1960	49.1	0.95 [0.80,1.12]	
Total	3892 / 4581	3909 / 4578		0.97 [0.86,1.09]	Z=-0.57, p=0.5661
Heterogeneity:	Q=0.12 (df=1)	p=0.7278	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9076	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.1.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set

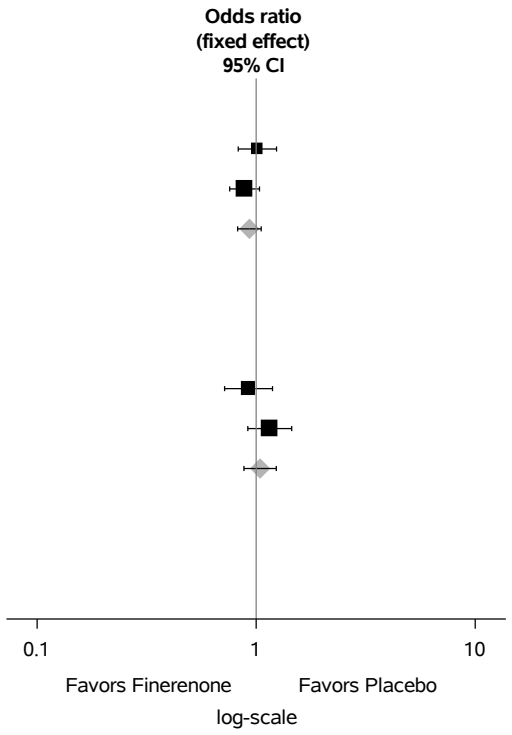
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1123 / 1301	1133 / 1299	41.7	0.92 [0.74,1.16]	
FIGARO-DKD	1424 / 1673	1410 / 1651	58.3	0.98 [0.81,1.18]	
Total	2547 / 2974	2543 / 2950		0.95 [0.82,1.11]	Z=-0.62, p=0.5378
Heterogeneity:	Q=0.14 (df=1)	p=0.7125	I^2=0.0%		
Absent					
FIDELIO-DKD	1345 / 1526	1345 / 1532	39.2	1.03 [0.83,1.28]	
FIGARO-DKD	1710 / 2010	1719 / 2007	60.8	0.95 [0.80,1.14]	
Total	3055 / 3536	3064 / 3539		0.98 [0.86,1.13]	Z=-0.22, p=0.8269
Heterogeneity:	Q=0.30 (df=1)	p=0.5811	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7627	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.1.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

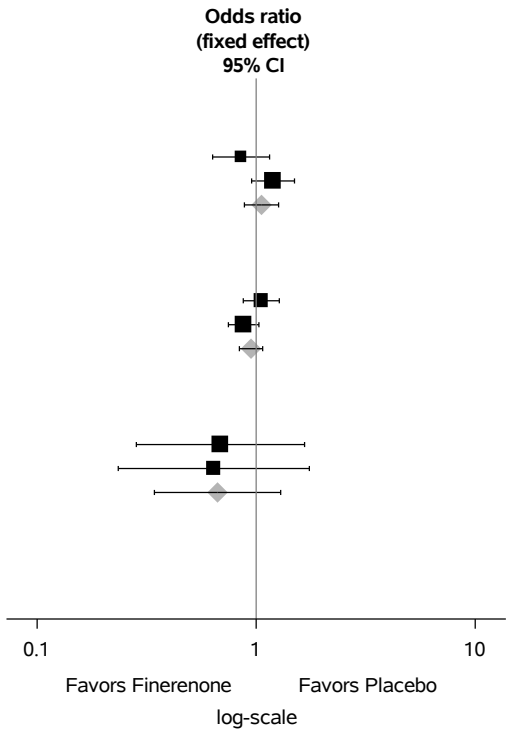
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1665 / 1879	1644 / 1858	37.7	1.01 [0.83,1.24]	
FIGARO-DKD	2257 / 2643	2265 / 2608	62.3	0.89 [0.76,1.04]	
Total	3922 / 4522	3909 / 4466		0.93 [0.82,1.05]	Z=-1.13, p=0.2601
Heterogeneity:	Q=1.06 (df=1)	p=0.3021	I^2=6.1%		
> 4.5					
FIDELIO-DKD	803 / 948	834 / 973	45.6	0.92 [0.72,1.19]	
FIGARO-DKD	877 / 1040	863 / 1048	54.4	1.15 [0.92,1.45]	
Total	1680 / 1988	1697 / 2021		1.04 [0.88,1.24]	Z=0.48, p=0.6343
Heterogeneity:	Q=1.63 (df=1)	p=0.2010	I^2=38.8%		
Subgroup Heterogeneity:	Q=1.10 (df=1)	p=0.2951	I^2=8.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.1.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

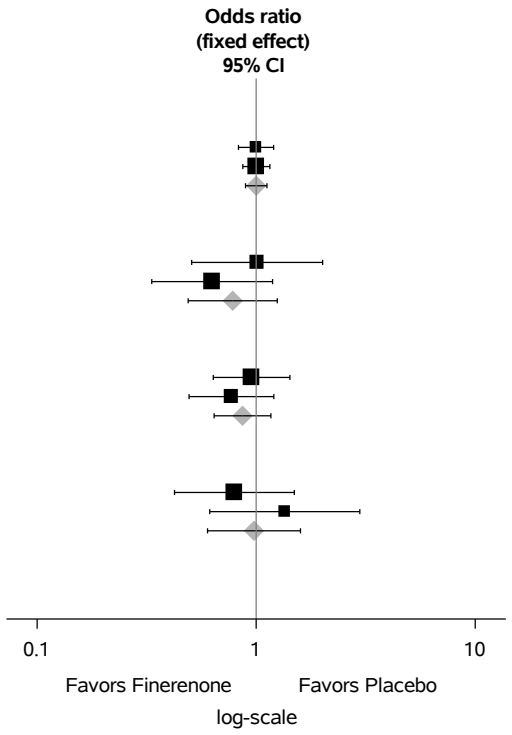
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	682 / 788	686 / 777	36.2	0.85 [0.63,1.15]	
FIGARO-DKD	1022 / 1187	1001 / 1194	63.8	1.19 [0.95,1.50]	
Total	1704 / 1975	1687 / 1971		1.06 [0.88,1.27]	Z=0.61, p=0.5413
Heterogeneity:	Q=3.09 (df=1)	p=0.0790	I^2=67.6%		
130 - < 160					
FIDELIO-DKD	1658 / 1897	1663 / 1916	41.8	1.06 [0.87,1.28]	
FIGARO-DKD	2015 / 2389	2022 / 2351	58.2	0.88 [0.75,1.03]	
Total	3673 / 4286	3685 / 4267		0.95 [0.84,1.07]	Z=-0.87, p=0.3855
Heterogeneity:	Q=2.15 (df=1)	p=0.1429	I^2=53.4%		
>= 160					
FIDELIO-DKD	128 / 141	129 / 138	56.3	0.69 [0.28,1.66]	
FIGARO-DKD	97 / 107	106 / 113	43.7	0.64 [0.23,1.75]	
Total	225 / 248	235 / 251		0.67 [0.34,1.29]	Z=-1.20, p=0.2305
Heterogeneity:	Q=0.01 (df=1)	p=0.9185	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.26 (df=2)	p=0.3228	I^2=11.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.1.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Race
Safety Analysis Set

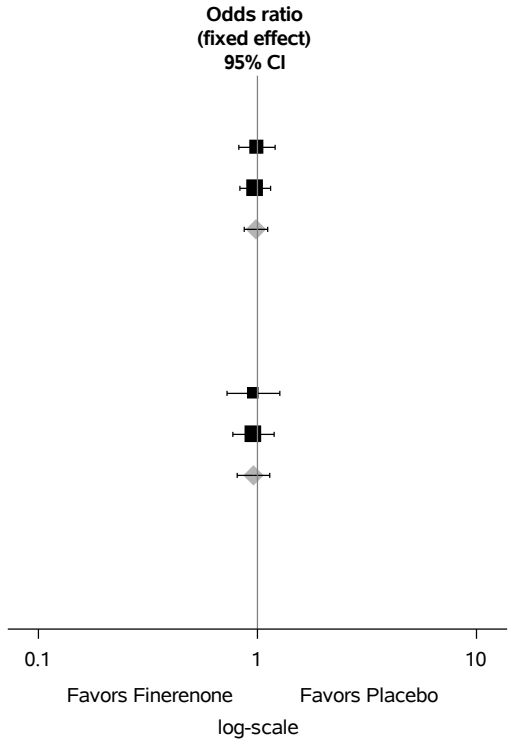
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	1512 / 1773	1543 / 1809	37.2	1.00 [0.83,1.20]	
FIGARO-DKD	2202 / 2668	2146 / 2601	62.8	1.00 [0.87,1.15]	
Total	3714 / 4441	3689 / 4410		1.00 [0.89,1.12]	Z=0.01, p=0.9905
Heterogeneity:	Q=0.00 (df=1)	p=0.9786	I^2=0.0%		
Black					
FIDELIO-DKD	119 / 139	106 / 124	46.0	1.01 [0.51,2.01]	
FIGARO-DKD	88 / 113	123 / 145	54.0	0.63 [0.33,1.19]	
Total	207 / 252	229 / 269		0.78 [0.49,1.25]	Z=-1.03, p=0.3021
Heterogeneity:	Q=0.98 (df=1)	p=0.3222	I^2=0.0%		
Asian					
FIDELIO-DKD	665 / 717	671 / 721	55.0	0.95 [0.64,1.43]	
FIGARO-DKD	670 / 716	699 / 736	45.0	0.77 [0.49,1.20]	
Total	1335 / 1433	1370 / 1457		0.87 [0.64,1.17]	Z=-0.94, p=0.3451
Heterogeneity:	Q=0.48 (df=1)	p=0.4893	I^2=0.0%		
Others					
FIDELIO-DKD	172 / 198	158 / 177	61.1	0.80 [0.42,1.49]	
FIGARO-DKD	174 / 186	161 / 176	38.9	1.35 [0.61,2.97]	
Total	346 / 384	319 / 353		0.98 [0.60,1.59]	Z=-0.09, p=0.9271
Heterogeneity:	Q=1.06 (df=1)	p=0.3038	I^2=5.4%		
Subgroup Heterogeneity:	Q=1.66 (df=3)	p=0.6449	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.1.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set

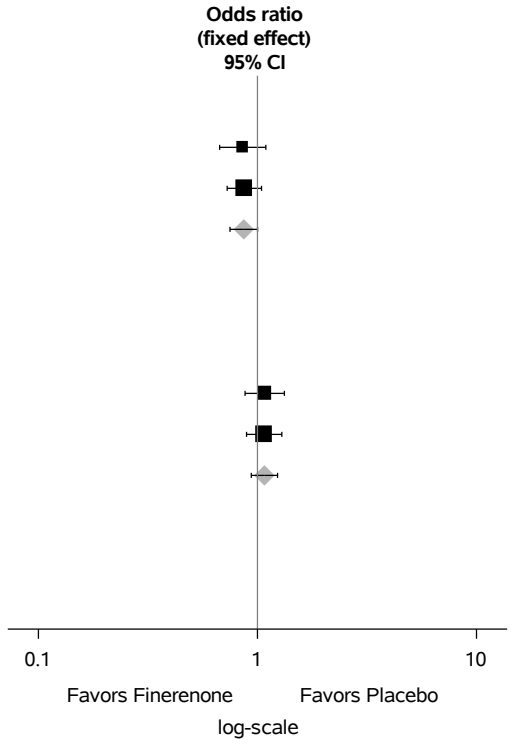
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1713 / 1949	1780 / 2024	41.7	0.99 [0.82,1.20]	
FIGARO-DKD	2186 / 2527	2231 / 2571	58.3	0.98 [0.83,1.15]	
Total	3899 / 4476	4011 / 4595		0.98 [0.87,1.11]	Z=-0.25, p=0.8029
Heterogeneity:	Q=0.02 (df=1)	p=0.8860	I^2=0.0%		
Female					
FIDELIO-DKD	755 / 878	698 / 807	37.9	0.96 [0.73,1.27]	
FIGARO-DKD	948 / 1156	898 / 1087	62.1	0.96 [0.77,1.19]	
Total	1703 / 2034	1596 / 1894		0.96 [0.81,1.14]	Z=-0.48, p=0.6312
Heterogeneity:	Q=0.00 (df=1)	p=0.9968	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8076	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.1.9: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set

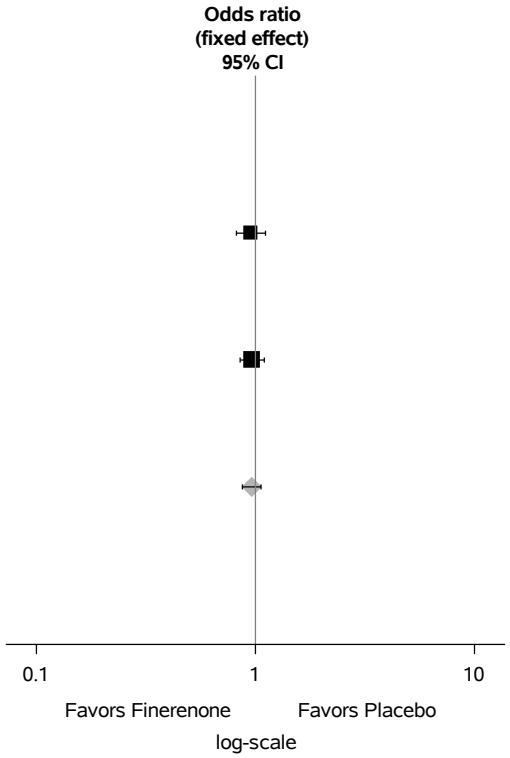
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	1039 / 1201	1033 / 1171	35.6	0.86 [0.67,1.09]	
FIGARO-DKD	1455 / 1752	1490 / 1755	64.4	0.87 [0.73,1.04]	
Total	2494 / 2953	2523 / 2926		0.87 [0.75,1.00]	Z=-1.94, p=0.0519
Heterogeneity:	Q=0.01 (df=1)	p=0.9135	I^2=0.0%		
>= 65					
FIDELIO-DKD	1429 / 1626	1445 / 1660	44.6	1.08 [0.88,1.33]	
FIGARO-DKD	1679 / 1931	1639 / 1903	55.4	1.07 [0.89,1.29]	
Total	3108 / 3557	3084 / 3563		1.08 [0.94,1.24]	Z=1.04, p=0.2990
Heterogeneity:	Q=0.00 (df=1)	p=0.9681	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.51 (df=1)	p=0.0337	I^2=77.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set

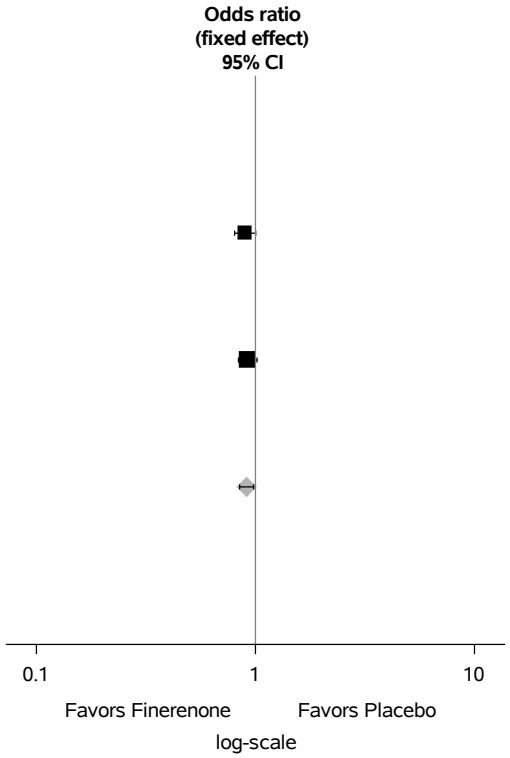
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2439 / 2827	2458 / 2831	40.9	0.95 [0.82,1.11]	
FIGARO-DKD	3112 / 3683	3107 / 3658	59.1	0.97 [0.85,1.10]	
Total	5551 / 6510	5565 / 6489		0.96 [0.87,1.06]	Z=-0.79, p=0.4292
Heterogeneity:	Q=0.02 (df=1)	p=0.8969	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs
Safety Analysis Set

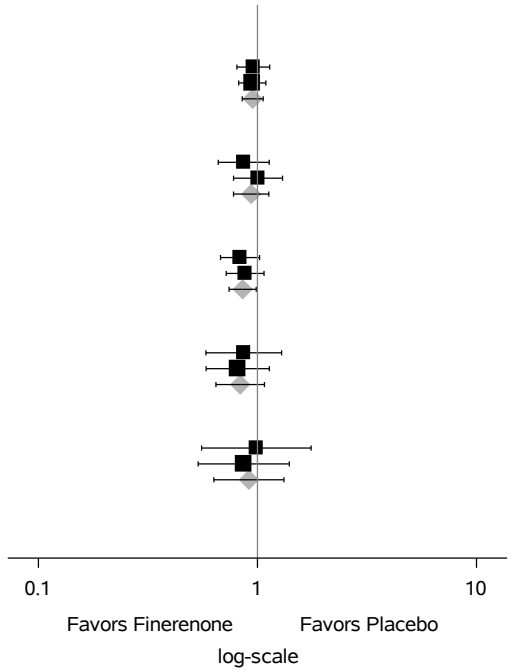
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	902 / 2827	971 / 2831	43.8	0.90 [0.80,1.00]	
FIGARO-DKD	1158 / 3683	1215 / 3658	56.2	0.92 [0.84,1.02]	
Total	2060 / 6510	2186 / 6489		0.91 [0.85,0.98]	Z=-2.48, p=0.0130
Heterogeneity:	Q=0.13 (df=1)	p=0.7204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.3.1: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Region
Safety Analysis Set

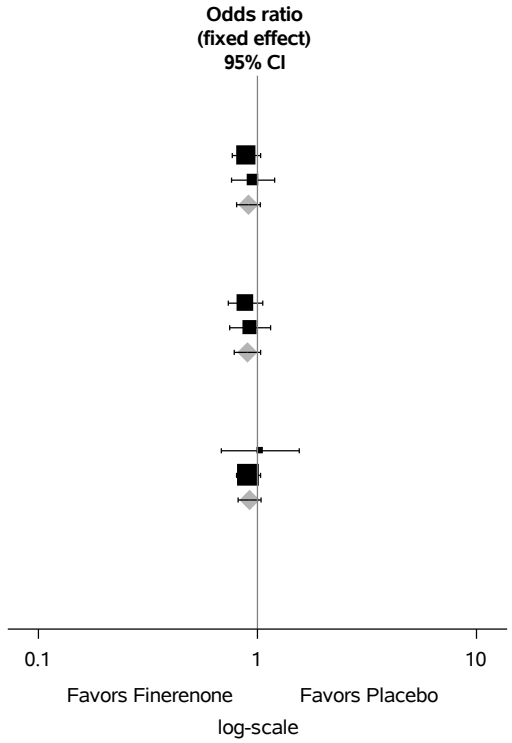
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	379 / 1178	389 / 1174	40.7	0.96 [0.81,1.14]	
FIGARO-DKD	539 / 1752	558 / 1747	59.3	0.95 [0.82,1.09]	
Total	918 / 2930	947 / 2921		0.95 [0.85,1.06]	Z=-0.89, p=0.3712
Heterogeneity:	Q=0.01 (df=1)	p=0.9239	I^2=0.0%		
North America					
FIDELIO-DKD	156 / 466	175 / 476	48.1	0.87 [0.66,1.13]	
FIGARO-DKD	167 / 559	163 / 548	51.9	1.01 [0.78,1.30]	
Total	323 / 1025	338 / 1024		0.94 [0.78,1.13]	Z=-0.70, p=0.4846
Heterogeneity:	Q=0.63 (df=1)	p=0.4269	I^2=0.0%		
Asia					
FIDELIO-DKD	273 / 790	305 / 786	48.4	0.83 [0.68,1.02]	
FIGARO-DKD	310 / 811	336 / 813	51.6	0.88 [0.72,1.07]	
Total	583 / 1601	641 / 1599		0.86 [0.74,0.99]	Z=-2.13, p=0.0328
Heterogeneity:	Q=0.13 (df=1)	p=0.7142	I^2=0.0%		
Latin America					
FIDELIO-DKD	58 / 294	65 / 294	41.1	0.87 [0.58,1.29]	
FIGARO-DKD	82 / 424	95 / 417	58.9	0.81 [0.58,1.13]	
Total	140 / 718	160 / 711		0.83 [0.65,1.08]	Z=-1.39, p=0.1634
Heterogeneity:	Q=0.06 (df=1)	p=0.8107	I^2=0.0%		
Others					
FIDELIO-DKD	36 / 99	37 / 101	40.9	0.99 [0.56,1.76]	
FIGARO-DKD	60 / 137	63 / 133	59.1	0.87 [0.54,1.40]	
Total	96 / 236	100 / 234		0.91 [0.63,1.32]	Z=-0.48, p=0.6324
Heterogeneity:	Q=0.12 (df=1)	p=0.7290	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.86 (df=4)	p=0.7615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.3.2: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

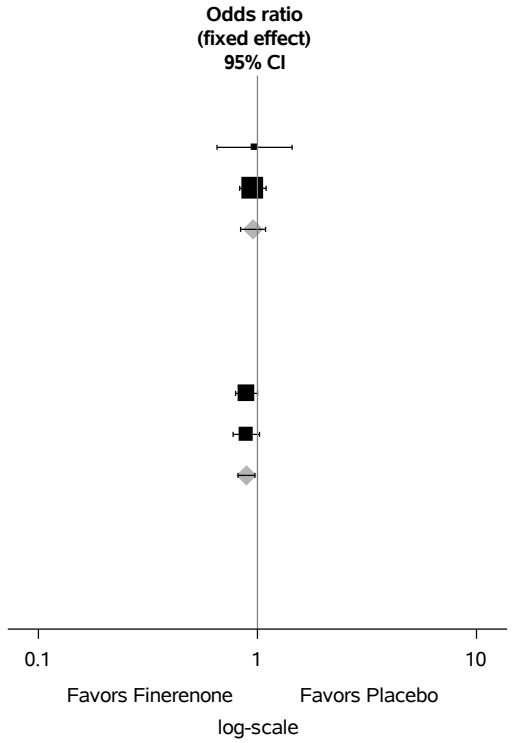
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	505 / 1556	540 / 1541	69.8	0.89 [0.77,1.03]	
FIGARO-DKD	242 / 637	245 / 627	30.2	0.96 [0.76,1.20]	
Total	747 / 2193	785 / 2168		0.91 [0.80,1.03]	Z=-1.49, p=0.1363
Heterogeneity:	Q=0.26 (df=1)	p=0.6131	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	332 / 1061	364 / 1069	58.5	0.88 [0.74,1.06]	
FIGARO-DKD	250 / 720	266 / 729	41.5	0.93 [0.75,1.15]	
Total	582 / 1781	630 / 1798		0.90 [0.78,1.03]	Z=-1.49, p=0.1361
Heterogeneity:	Q=0.11 (df=1)	p=0.7356	I^2=0.0%		
>= 60					
FIDELIO-DKD	65 / 210	67 / 221	8.7	1.03 [0.68,1.55]	
FIGARO-DKD	666 / 2326	704 / 2302	91.3	0.91 [0.80,1.03]	
Total	731 / 2536	771 / 2523		0.92 [0.82,1.04]	Z=-1.35, p=0.1784
Heterogeneity:	Q=0.32 (df=1)	p=0.5725	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=2)	p=0.9712	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.3.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set

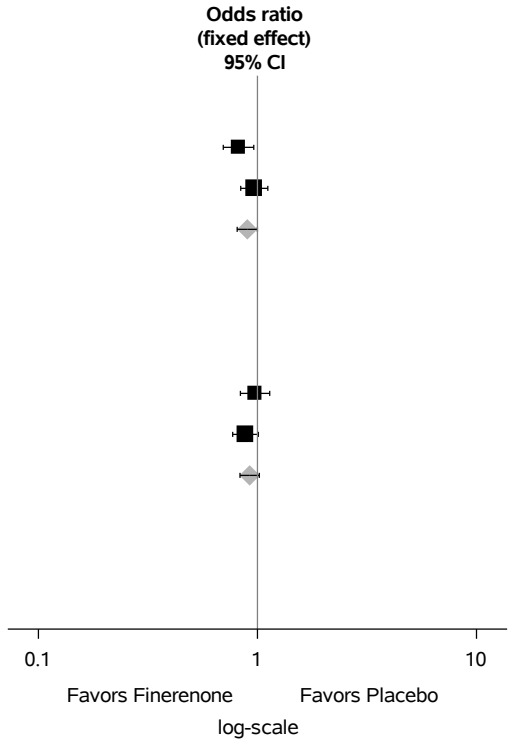
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 209	80 / 213	11.0	0.97 [0.65,1.44]	
FIGARO-DKD	623 / 1720	634 / 1698	89.0	0.95 [0.83,1.10]	
Total	700 / 1929	714 / 1911		0.95 [0.84,1.09]	Z=-0.69, p=0.4906
Heterogeneity:	Q=0.01 (df=1)	p=0.9352	I^2=0.0%		
Very High					
FIDELIO-DKD	825 / 2618	891 / 2618	59.1	0.89 [0.79,1.00]	
FIGARO-DKD	535 / 1963	581 / 1960	40.9	0.89 [0.77,1.02]	
Total	1360 / 4581	1472 / 4578		0.89 [0.82,0.97]	Z=-2.55, p=0.0107
Heterogeneity:	Q=0.00 (df=1)	p=0.9746	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.74 (df=1)	p=0.3895	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.3.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set

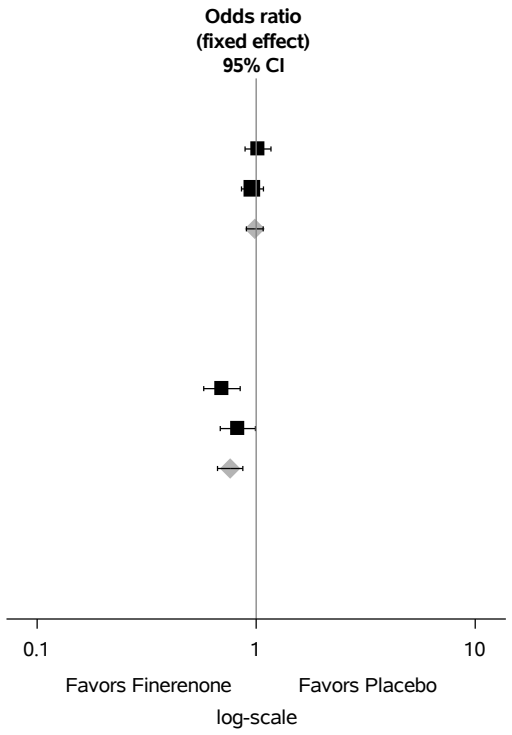
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	441 / 1301	500 / 1299	44.2	0.82 [0.70,0.96]	
FIGARO-DKD	581 / 1673	586 / 1651	55.8	0.97 [0.84,1.11]	
Total	1022 / 2974	1086 / 2950		0.90 [0.81,1.00]	Z=-1.97, p=0.0493
Heterogeneity:	Q=2.29 (df=1)	p=0.1302	I^2=56.3%		
Absent					
FIDELIO-DKD	461 / 1526	471 / 1532	43.5	0.98 [0.84,1.14]	
FIGARO-DKD	577 / 2010	629 / 2007	56.5	0.88 [0.77,1.01]	
Total	1038 / 3536	1100 / 3539		0.92 [0.83,1.02]	Z=-1.58, p=0.1139
Heterogeneity:	Q=0.92 (df=1)	p=0.3376	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7405	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.3.5: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

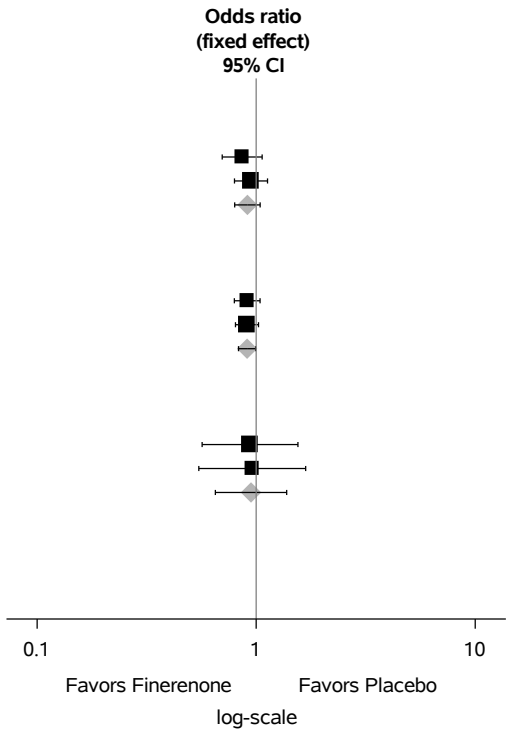
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	629 / 1879	614 / 1858	41.8	1.02 [0.89,1.17]	
FIGARO-DKD	851 / 2643	862 / 2608	58.2	0.96 [0.86,1.08]	
Total	1480 / 4522	1476 / 4466		0.99 [0.90,1.08]	Z=-0.32, p=0.7464
Heterogeneity:	Q=0.41 (df=1)	p=0.5228	I^2=0.0%		
> 4.5					
FIDELIO-DKD	273 / 948	357 / 973	48.2	0.70 [0.58,0.85]	
FIGARO-DKD	307 / 1040	353 / 1048	51.8	0.82 [0.69,0.99]	
Total	580 / 1988	710 / 2021		0.76 [0.67,0.87]	Z=-4.03, p=<.0001
Heterogeneity:	Q=1.51 (df=1)	p=0.2194	I^2=33.7%		
Subgroup Heterogeneity:	Q=10.12 (df=1)	p=0.0015	I^2=90.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.3.6: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

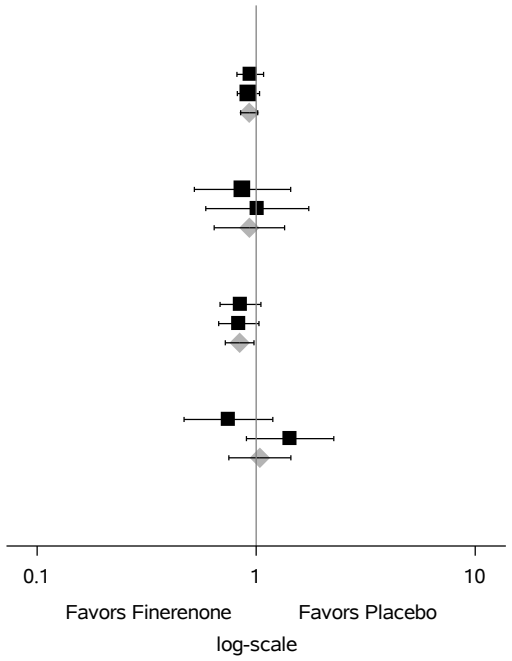
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	252 / 788	274 / 777	40.7	0.86 [0.70,1.06]	
FIGARO-DKD	361 / 1187	377 / 1194	59.3	0.95 [0.80,1.13]	
Total	613 / 1975	651 / 1971		0.91 [0.80,1.04]	Z=-1.35, p=0.1774
Heterogeneity:	Q=0.45 (df=1)	p=0.5039	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	606 / 1897	652 / 1916	44.6	0.91 [0.80,1.04]	
FIGARO-DKD	762 / 2389	800 / 2351	55.4	0.91 [0.80,1.02]	
Total	1368 / 4286	1452 / 4267		0.91 [0.83,0.99]	Z=-2.08, p=0.0379
Heterogeneity:	Q=0.00 (df=1)	p=0.9810	I^2=0.0%		
>= 160					
FIDELIO-DKD	44 / 141	45 / 138	55.4	0.94 [0.57,1.55]	
FIGARO-DKD	35 / 107	38 / 113	44.6	0.96 [0.55,1.68]	
Total	79 / 248	83 / 251		0.95 [0.65,1.38]	Z=-0.28, p=0.7767
Heterogeneity:	Q=0.00 (df=1)	p=0.9520	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=2)	p=0.9782	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.3.7: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Race
Safety Analysis Set

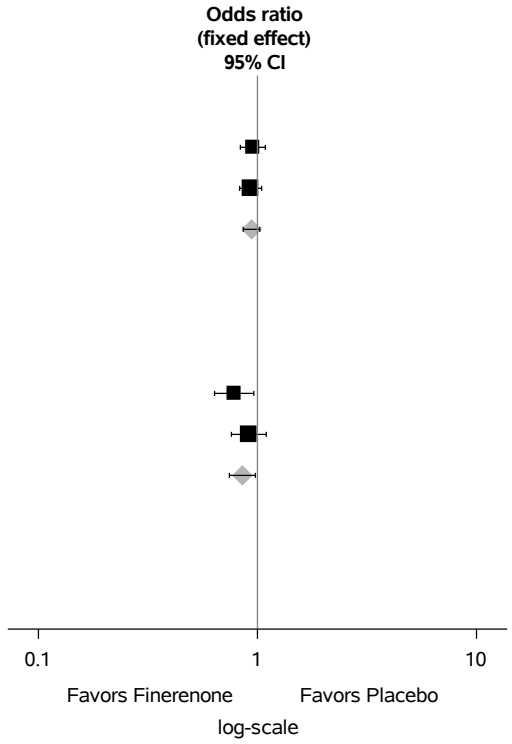
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	561 / 1773	597 / 1809	41.0	0.94 [0.82,1.08]	
FIGARO-DKD	805 / 2668	830 / 2601	59.0	0.92 [0.82,1.04]	
Total	1366 / 4441	1427 / 4410		0.93 [0.85,1.02]	Z=-1.60, p=0.1086
Heterogeneity:	Q=0.04 (df=1)	p=0.8379	I^2=0.0%		
Black					
FIDELIO-DKD	47 / 139	46 / 124	53.4	0.87 [0.52,1.44]	
FIGARO-DKD	33 / 113	42 / 145	46.6	1.01 [0.59,1.74]	
Total	80 / 252	88 / 269		0.93 [0.64,1.35]	Z=-0.38, p=0.7057
Heterogeneity:	Q=0.17 (df=1)	p=0.6817	I^2=0.0%		
Asian					
FIDELIO-DKD	249 / 717	278 / 721	49.3	0.85 [0.68,1.05]	
FIGARO-DKD	260 / 716	299 / 736	50.7	0.83 [0.67,1.03]	
Total	509 / 1433	577 / 1457		0.84 [0.72,0.98]	Z=-2.26, p=0.0239
Heterogeneity:	Q=0.01 (df=1)	p=0.9107	I^2=0.0%		
Others					
FIDELIO-DKD	45 / 198	50 / 177	49.2	0.75 [0.47,1.19]	
FIGARO-DKD	60 / 186	44 / 176	50.8	1.43 [0.90,2.26]	
Total	105 / 384	94 / 353		1.04 [0.75,1.44]	Z=0.23, p=0.8155
Heterogeneity:	Q=3.77 (df=1)	p=0.0522	I^2=73.5%		
Subgroup Heterogeneity:	Q=1.93 (df=3)	p=0.5879	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.3.8: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set

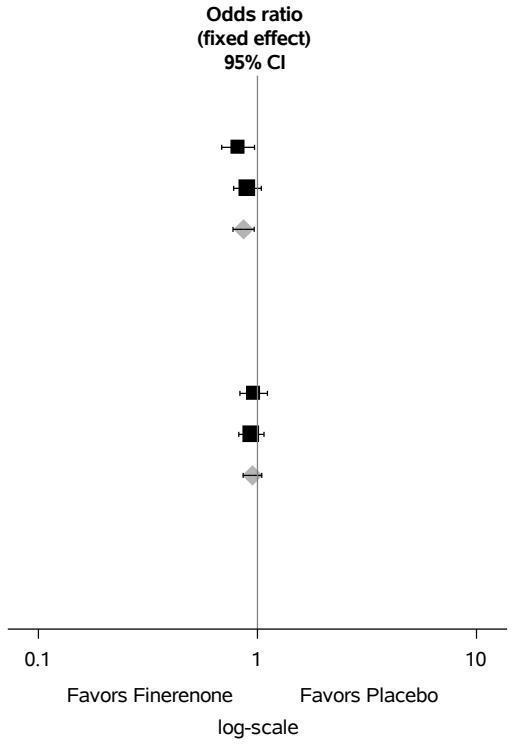
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	650 / 1949	697 / 2024	43.8	0.95 [0.84,1.09]	
FIGARO-DKD	837 / 2527	893 / 2571	56.2	0.93 [0.83,1.05]	
Total	1487 / 4476	1590 / 4595		0.94 [0.86,1.03]	Z=-1.39, p=0.1648
Heterogeneity:	Q=0.07 (df=1)	p=0.7936	I^2=0.0%		
Female					
FIDELIO-DKD	252 / 878	274 / 807	44.0	0.78 [0.64,0.96]	
FIGARO-DKD	321 / 1156	322 / 1087	56.0	0.91 [0.76,1.10]	
Total	573 / 2034	596 / 1894		0.85 [0.74,0.98]	Z=-2.27, p=0.0233
Heterogeneity:	Q=1.19 (df=1)	p=0.2744	I^2=16.3%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2421	I^2=26.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.3.9: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set

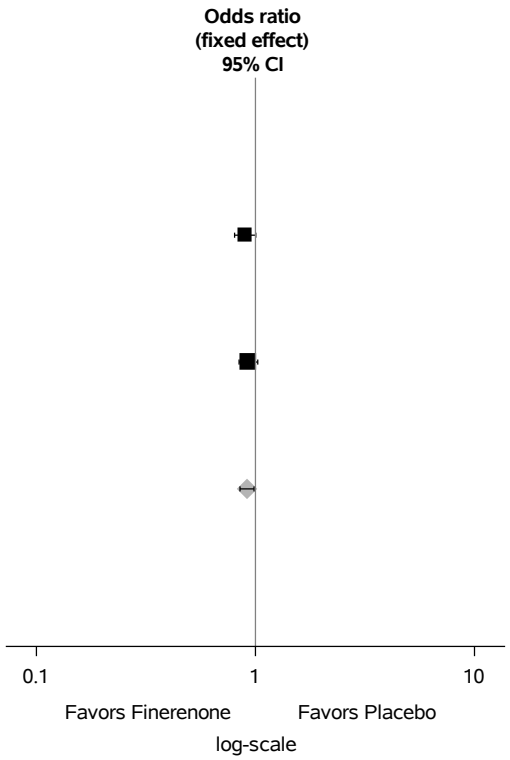
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	361 / 1201	404 / 1171	41.6	0.82 [0.69,0.97]	
FIGARO-DKD	495 / 1752	534 / 1755	58.4	0.90 [0.78,1.04]	
Total	856 / 2953	938 / 2926		0.86 [0.77,0.97]	Z=-2.57, p=0.0101
Heterogeneity:	Q=0.73 (df=1)	p=0.3918	I^2=0.0%		
>= 65					
FIDELIO-DKD	541 / 1626	567 / 1660	45.7	0.96 [0.83,1.11]	
FIGARO-DKD	663 / 1931	681 / 1903	54.3	0.94 [0.82,1.07]	
Total	1204 / 3557	1248 / 3563		0.95 [0.86,1.05]	Z=-1.06, p=0.2908
Heterogeneity:	Q=0.06 (df=1)	p=0.8095	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.52 (df=1)	p=0.2174	I^2=34.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set

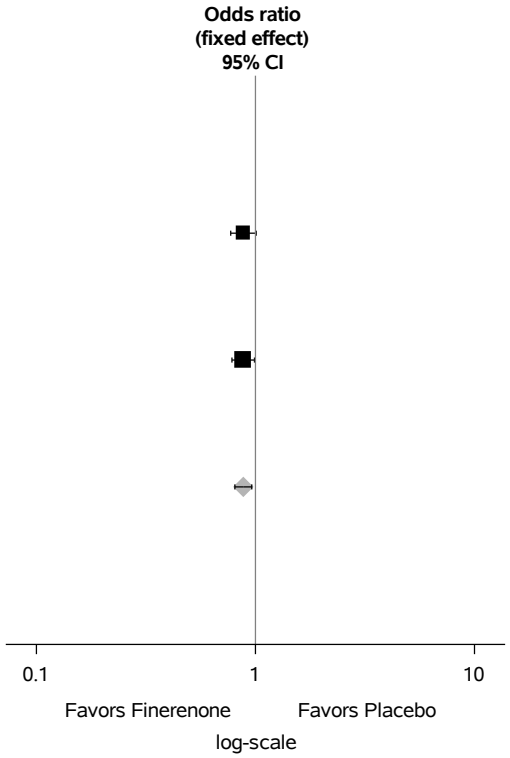
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	878 / 2827	946 / 2831	43.7	0.90 [0.80,1.00]	
FIGARO-DKD	1145 / 3683	1196 / 3658	56.3	0.93 [0.84,1.02]	
Total	2023 / 6510	2142 / 6489		0.92 [0.85,0.98]	Z=-2.36, p=0.0182
Heterogeneity:	Q=0.20 (df=1)	p=0.6538	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs
Safety Analysis Set

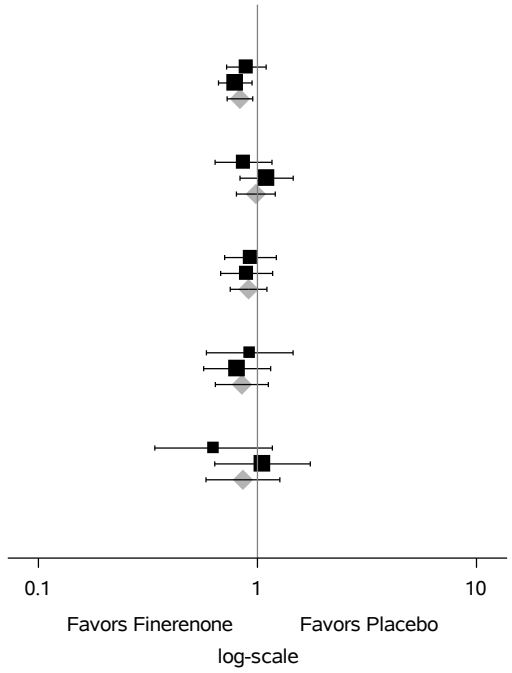
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	501 / 2827	556 / 2831	43.9	0.88 [0.77,1.01]	
FIGARO-DKD	639 / 3683	705 / 3658	56.1	0.88 [0.78,0.99]	
Total	1140 / 6510	1261 / 6489		0.88 [0.81,0.96]	Z=-2.82, p=0.0048
Heterogeneity:	Q=0.00 (df=1)	p=0.9798	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.5.1: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set

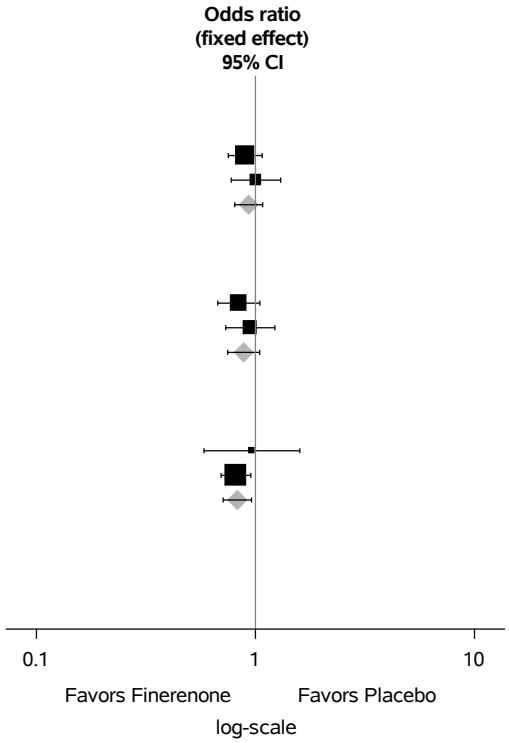
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	209 / 1178	229 / 1174	41.9	0.89 [0.72,1.10]	
FIGARO-DKD	272 / 1752	329 / 1747	58.1	0.79 [0.66,0.94]	
Total	481 / 2930	558 / 2921		0.83 [0.73,0.95]	Z=-2.69, p=0.0072
Heterogeneity:	Q=0.70 (df=1)	p=0.4018	I^2=0.0%		
North America					
FIDELIO-DKD	106 / 466	121 / 476	46.6	0.86 [0.64,1.17]	
FIGARO-DKD	134 / 559	122 / 548	53.4	1.10 [0.83,1.46]	
Total	240 / 1025	243 / 1024		0.98 [0.80,1.21]	Z=-0.16, p=0.8704
Heterogeneity:	Q=1.35 (df=1)	p=0.2458	I^2=25.8%		
Asia					
FIDELIO-DKD	120 / 790	127 / 786	50.3	0.93 [0.71,1.22]	
FIGARO-DKD	115 / 811	127 / 813	49.7	0.89 [0.68,1.17]	
Total	235 / 1601	254 / 1599		0.91 [0.75,1.10]	Z=-0.95, p=0.3424
Heterogeneity:	Q=0.04 (df=1)	p=0.8369	I^2=0.0%		
Latin America					
FIDELIO-DKD	42 / 294	45 / 294	37.4	0.92 [0.58,1.45]	
FIGARO-DKD	70 / 424	82 / 417	62.6	0.81 [0.57,1.15]	
Total	112 / 718	127 / 711		0.85 [0.64,1.12]	Z=-1.15, p=0.2488
Heterogeneity:	Q=0.20 (df=1)	p=0.6522	I^2=0.0%		
Others					
FIDELIO-DKD	24 / 99	34 / 101	39.8	0.63 [0.34,1.17]	
FIGARO-DKD	48 / 137	45 / 133	60.2	1.05 [0.64,1.74]	
Total	72 / 236	79 / 234		0.86 [0.58,1.27]	Z=-0.77, p=0.4405
Heterogeneity:	Q=1.60 (df=1)	p=0.2054	I^2=37.6%		
Subgroup Heterogeneity:	Q=2.01 (df=4)	p=0.7331	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.5.2: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

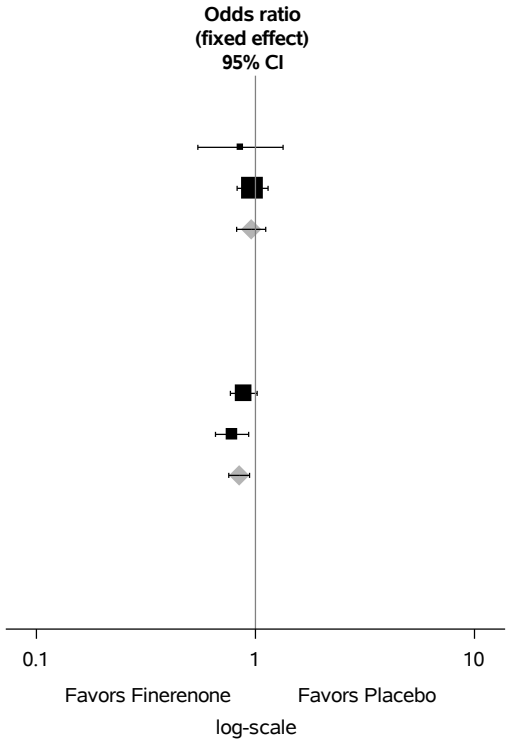
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	288 / 1556	311 / 1541	67.9	0.90 [0.75,1.07]	
FIGARO-DKD	151 / 637	148 / 627	32.1	1.01 [0.78,1.30]	
Total	439 / 2193	459 / 2168		0.93 [0.80,1.08]	Z=-0.95, p=0.3435
Heterogeneity:	Q=0.49 (df=1)	p=0.4826	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	178 / 1061	207 / 1069	57.8	0.84 [0.67,1.05]	
FIGARO-DKD	139 / 720	147 / 729	42.2	0.95 [0.73,1.23]	
Total	317 / 1781	354 / 1798		0.88 [0.75,1.05]	Z=-1.45, p=0.1481
Heterogeneity:	Q=0.48 (df=1)	p=0.4869	I^2=0.0%		
>= 60					
FIDELIO-DKD	35 / 210	38 / 221	8.8	0.96 [0.58,1.59]	
FIGARO-DKD	349 / 2326	410 / 2302	91.2	0.81 [0.70,0.95]	
Total	384 / 2536	448 / 2523		0.83 [0.71,0.96]	Z=-2.50, p=0.0123
Heterogeneity:	Q=0.39 (df=1)	p=0.5336	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.25 (df=2)	p=0.5346	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.5.3: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set

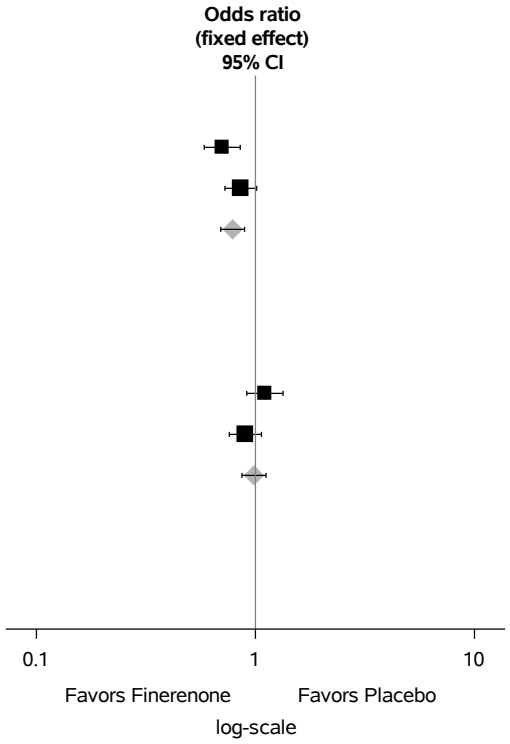
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	54 / 213	11.6	0.85 [0.55,1.34]	
FIGARO-DKD	369 / 1720	373 / 1698	88.4	0.97 [0.82,1.14]	
Total	416 / 1929	427 / 1911		0.96 [0.82,1.11]	Z=-0.58, p=0.5634
Heterogeneity:	Q=0.27 (df=1)	p=0.6006	I^2=0.0%		
Very High					
FIDELIO-DKD	454 / 2618	502 / 2618	60.7	0.88 [0.77,1.02]	
FIGARO-DKD	270 / 1963	332 / 1960	39.3	0.78 [0.66,0.93]	
Total	724 / 4581	834 / 4578		0.84 [0.76,0.94]	Z=-3.07, p=0.0021
Heterogeneity:	Q=1.16 (df=1)	p=0.2819	I^2=13.6%		
Subgroup Heterogeneity:	Q=1.73 (df=1)	p=0.1878	I^2=42.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.5.4: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set

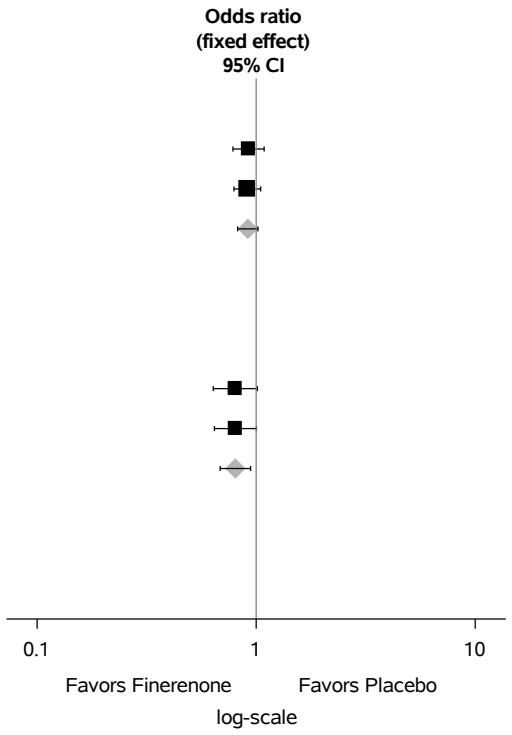
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	238 / 1301	313 / 1299	43.6	0.71 [0.58,0.85]	
FIGARO-DKD	332 / 1673	370 / 1651	56.4	0.86 [0.73,1.01]	
Total	570 / 2974	683 / 2950		0.79 [0.69,0.89]	Z=-3.75, p=0.0002
Heterogeneity:	Q=2.29 (df=1)	p=0.1301	I^2=56.4%		
Absent					
FIDELIO-DKD	263 / 1526	243 / 1532	43.9	1.10 [0.91,1.34]	
FIGARO-DKD	307 / 2010	335 / 2007	56.1	0.90 [0.76,1.07]	
Total	570 / 3536	578 / 3539		0.98 [0.87,1.12]	Z=-0.24, p=0.8092
Heterogeneity:	Q=2.49 (df=1)	p=0.1147	I^2=59.8%		
Subgroup Heterogeneity:	Q=6.09 (df=1)	p=0.0136	I^2=83.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.5.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

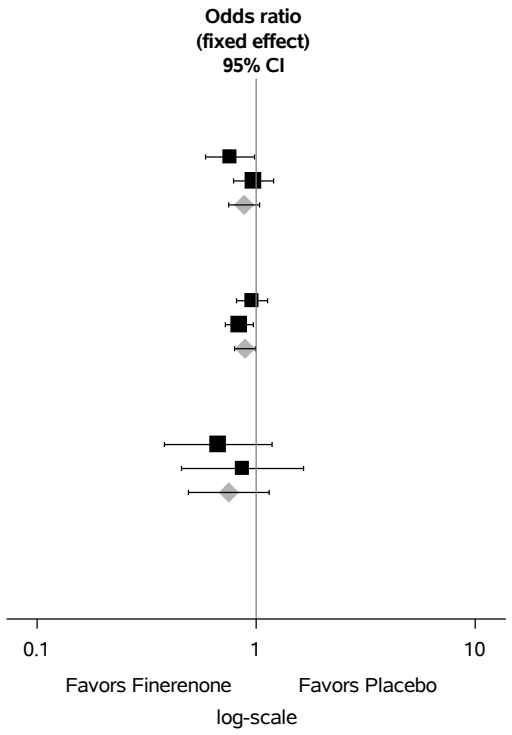
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	343 / 1879	362 / 1858	42.3	0.92 [0.78,1.09]	
FIGARO-DKD	462 / 2643	492 / 2608	57.7	0.91 [0.79,1.05]	
Total	805 / 4522	854 / 4466		0.92 [0.82,1.02]	Z=-1.61, p=0.1068
Heterogeneity:	Q=0.01 (df=1)	p=0.9069	I^2=0.0%		
> 4.5					
FIDELIO-DKD	158 / 948	194 / 973	47.5	0.80 [0.64,1.01]	
FIGARO-DKD	177 / 1040	213 / 1048	52.5	0.80 [0.64,1.00]	
Total	335 / 1988	407 / 2021		0.80 [0.68,0.94]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.00 (df=1)	p=0.9943	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.78 (df=1)	p=0.1820	I^2=43.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.5.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

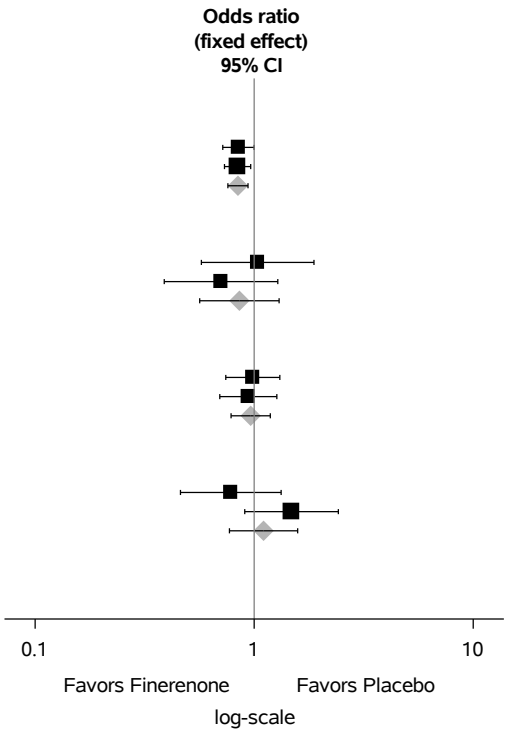
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	128 / 788	158 / 777	40.0	0.76 [0.59,0.98]	
FIGARO-DKD	208 / 1187	214 / 1194	60.0	0.97 [0.79,1.20]	
Total	336 / 1975	372 / 1971		0.88 [0.75,1.04]	Z=-1.52, p=0.1273
Heterogeneity:	Q=2.12 (df=1)	p=0.1450	I^2=52.9%		
130 - < 160					
FIDELIO-DKD	346 / 1897	362 / 1916	44.8	0.96 [0.81,1.13]	
FIGARO-DKD	409 / 2389	465 / 2351	55.2	0.84 [0.72,0.97]	
Total	755 / 4286	827 / 4267		0.89 [0.80,0.99]	Z=-2.10, p=0.0356
Heterogeneity:	Q=1.42 (df=1)	p=0.2331	I^2=29.7%		
>= 160					
FIDELIO-DKD	27 / 141	36 / 138	56.2	0.67 [0.38,1.18]	
FIGARO-DKD	22 / 107	26 / 113	43.8	0.87 [0.46,1.65]	
Total	49 / 248	62 / 251		0.75 [0.49,1.15]	Z=-1.33, p=0.1837
Heterogeneity:	Q=0.34 (df=1)	p=0.5590	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.58 (df=2)	p=0.7472	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.5.7: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set

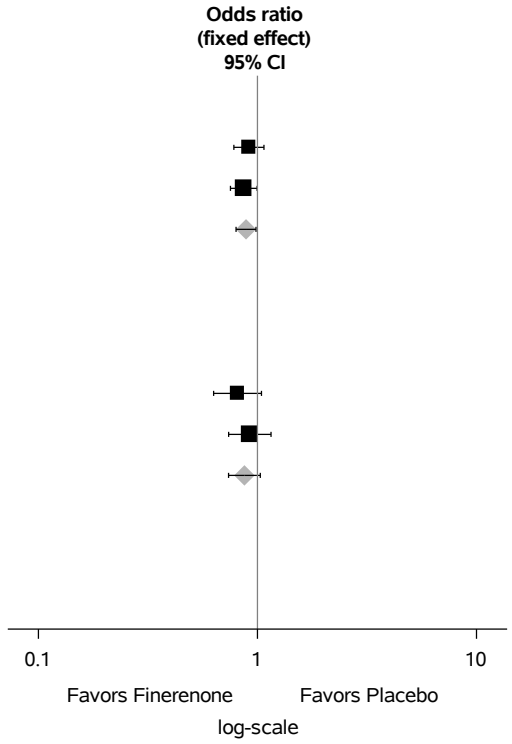
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	327 / 1773	381 / 1809	41.1	0.85 [0.72,1.00]	
FIGARO-DKD	472 / 2668	530 / 2601	58.9	0.84 [0.73,0.96]	
Total	799 / 4441	911 / 4410		0.84 [0.76,0.94]	Z=-3.17, p=0.0016
Heterogeneity:	Q=0.01 (df=1)	p=0.9335	I^2=0.0%		
Black					
FIDELIO-DKD	30 / 139	26 / 124	50.4	1.04 [0.57,1.87]	
FIGARO-DKD	22 / 113	37 / 145	49.6	0.71 [0.39,1.28]	
Total	52 / 252	63 / 269		0.86 [0.56,1.30]	Z=-0.73, p=0.4657
Heterogeneity:	Q=0.81 (df=1)	p=0.3689	I^2=0.0%		
Asian					
FIDELIO-DKD	112 / 717	114 / 721	52.7	0.99 [0.74,1.31]	
FIGARO-DKD	95 / 716	103 / 736	47.3	0.94 [0.70,1.27]	
Total	207 / 1433	217 / 1457		0.96 [0.78,1.18]	Z=-0.35, p=0.7267
Heterogeneity:	Q=0.05 (df=1)	p=0.8224	I^2=0.0%		
Others					
FIDELIO-DKD	32 / 198	35 / 177	46.4	0.78 [0.46,1.33]	
FIGARO-DKD	50 / 186	35 / 176	53.6	1.48 [0.91,2.42]	
Total	82 / 384	70 / 353		1.10 [0.77,1.58]	Z=0.54, p=0.5900
Heterogeneity:	Q=3.00 (df=1)	p=0.0832	I^2=66.7%		
Subgroup Heterogeneity:	Q=2.93 (df=3)	p=0.4027	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.5.8: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set

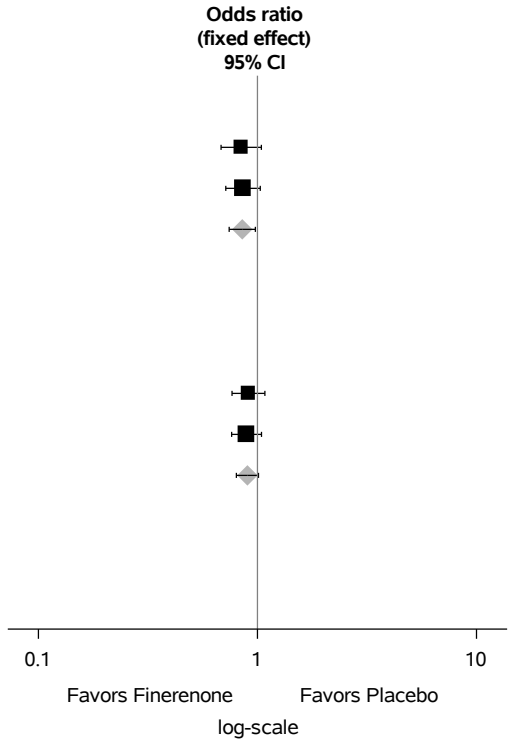
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	360 / 1949	402 / 2024	43.9	0.91 [0.78,1.07]	
FIGARO-DKD	454 / 2527	519 / 2571	56.1	0.87 [0.75,1.00]	
Total	814 / 4476	921 / 4595		0.89 [0.80,0.98]	Z=-2.25, p=0.0246
Heterogeneity:	Q=0.25 (df=1)	p=0.6150	I^2=0.0%		
Female					
FIDELIO-DKD	141 / 878	154 / 807	44.0	0.81 [0.63,1.04]	
FIGARO-DKD	185 / 1156	186 / 1087	56.0	0.92 [0.74,1.15]	
Total	326 / 2034	340 / 1894		0.87 [0.74,1.03]	Z=-1.61, p=0.1075
Heterogeneity:	Q=0.57 (df=1)	p=0.4518	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.5.9: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set

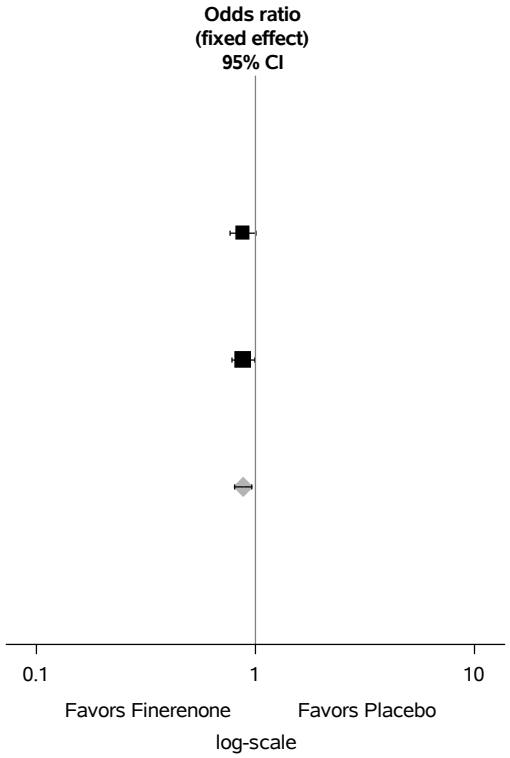
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	196 / 1201	220 / 1171	42.2	0.84 [0.68,1.04]	
FIGARO-DKD	261 / 1752	297 / 1755	57.8	0.86 [0.72,1.03]	
Total	457 / 2953	517 / 2926		0.85 [0.74,0.98]	Z=-2.27, p=0.0231
Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		
>= 65					
FIDELIO-DKD	305 / 1626	336 / 1660	45.2	0.91 [0.77,1.08]	
FIGARO-DKD	378 / 1931	408 / 1903	54.8	0.89 [0.76,1.04]	
Total	683 / 3557	744 / 3563		0.90 [0.80,1.01]	Z=-1.78, p=0.0752
Heterogeneity:	Q=0.03 (df=1)	p=0.8672	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set

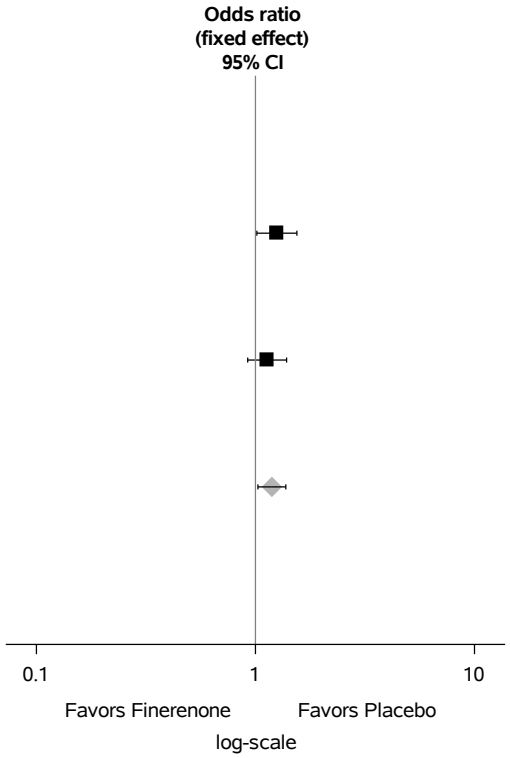
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	479 / 2827	534 / 2831	43.6	0.88 [0.77,1.01]	
FIGARO-DKD	623 / 3683	687 / 3658	56.4	0.88 [0.78,0.99]	
Total	1102 / 6510	1221 / 6489		0.88 [0.80,0.96]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.00 (df=1)	p=0.9711	I^2=0.0%		



Abbreviations: CI=confidence interval, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set

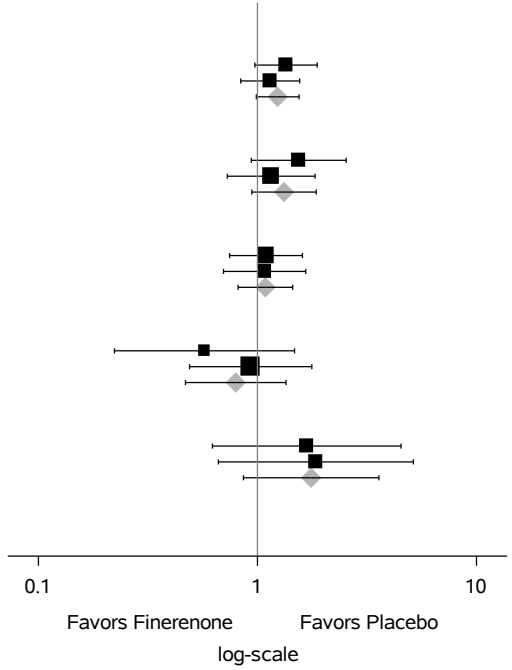
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	207 / 2827	168 / 2831	48.5	1.25 [1.01,1.55]	
FIGARO-DKD	207 / 3683	183 / 3658	51.5	1.13 [0.92,1.39]	
Total	414 / 6510	351 / 6489		1.19 [1.03,1.38]	Z=2.31, p=0.0211
Heterogeneity:	Q=0.47 (df=1)	p=0.4953	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.7.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set

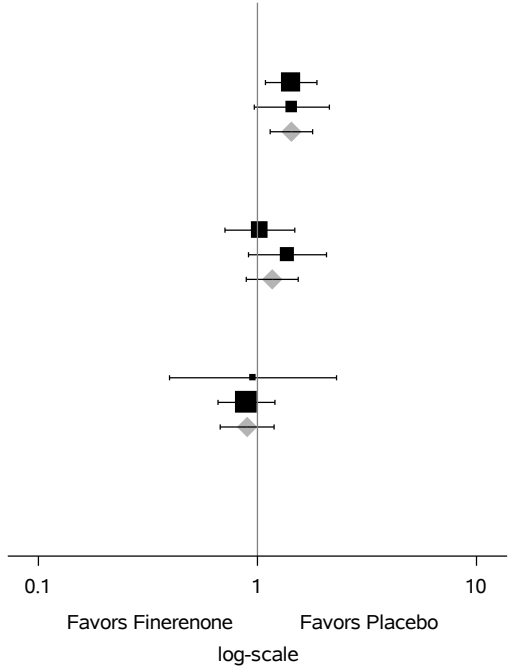
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	89 / 1178	67 / 1174	47.2	1.35 [0.97,1.87]	
FIGARO-DKD	90 / 1752	79 / 1747	52.8	1.14 [0.84,1.56]	
Total	179 / 2930	146 / 2921		1.24 [0.99,1.55]	Z=1.85, p=0.0639
Heterogeneity:	Q=0.52 (df=1)	p=0.4697	I^2=0.0%		
North America					
FIDELIO-DKD	41 / 466	28 / 476	46.2	1.54 [0.94,2.54]	
FIGARO-DKD	42 / 559	36 / 548	53.8	1.16 [0.73,1.83]	
Total	83 / 1025	64 / 1024		1.32 [0.94,1.85]	Z=1.62, p=0.1055
Heterogeneity:	Q=0.70 (df=1)	p=0.4034	I^2=0.0%		
Asia					
FIDELIO-DKD	59 / 790	54 / 786	56.0	1.09 [0.75,1.60]	
FIGARO-DKD	45 / 811	42 / 813	44.0	1.08 [0.70,1.66]	
Total	104 / 1601	96 / 1599		1.09 [0.82,1.45]	Z=0.57, p=0.5677
Heterogeneity:	Q=0.00 (df=1)	p=0.9610	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 294	12 / 294	31.6	0.57 [0.22,1.48]	
FIGARO-DKD	19 / 424	20 / 417	68.4	0.93 [0.49,1.77]	
Total	26 / 718	32 / 711		0.80 [0.47,1.35]	Z=-0.85, p=0.3971
Heterogeneity:	Q=0.69 (df=1)	p=0.4057	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 99	7 / 101	51.7	1.68 [0.62,4.52]	
FIGARO-DKD	11 / 137	6 / 133	48.3	1.85 [0.66,5.15]	
Total	22 / 236	13 / 234		1.76 [0.86,3.58]	Z=1.55, p=0.1201
Heterogeneity:	Q=0.02 (df=1)	p=0.8949	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.25 (df=4)	p=0.3731	I^2=5.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.7.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set

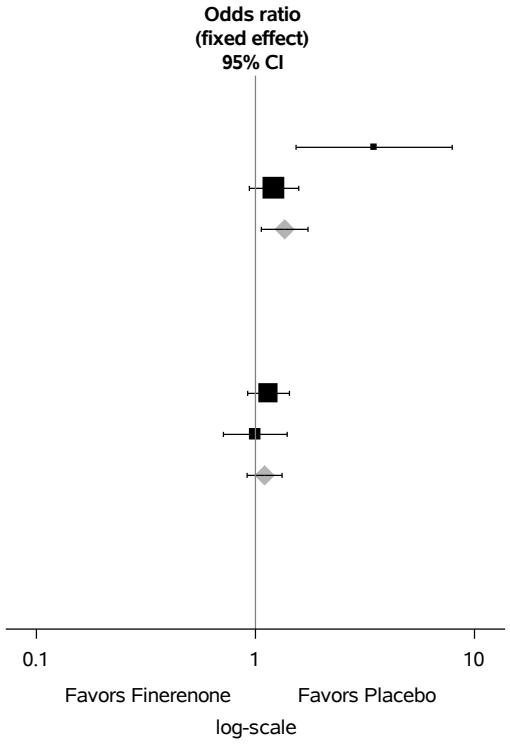
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	136 / 1556	97 / 1541	68.0	1.43 [1.09,1.87]	
FIGARO-DKD	65 / 637	46 / 627	32.0	1.44 [0.97,2.13]	
Total	201 / 2193	143 / 2168		1.43 [1.14,1.79]	Z=3.13, p=0.0017
Heterogeneity:	Q=0.00 (df=1)	p=0.9783	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	61 / 1061	60 / 1069	55.5	1.03 [0.71,1.48]	
FIGARO-DKD	57 / 720	43 / 729	44.5	1.37 [0.91,2.07]	
Total	118 / 1781	103 / 1798		1.17 [0.89,1.53]	Z=1.12, p=0.2645
Heterogeneity:	Q=1.07 (df=1)	p=0.3008	I^2=6.6%		
>= 60					
FIDELIO-DKD	10 / 210	11 / 221	10.4	0.95 [0.40,2.30]	
FIGARO-DKD	85 / 2326	94 / 2302	89.6	0.89 [0.66,1.20]	
Total	95 / 2536	105 / 2523		0.90 [0.68,1.19]	Z=-0.75, p=0.4535
Heterogeneity:	Q=0.02 (df=1)	p=0.8841	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.41 (df=2)	p=0.0405	I^2=68.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.7.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set

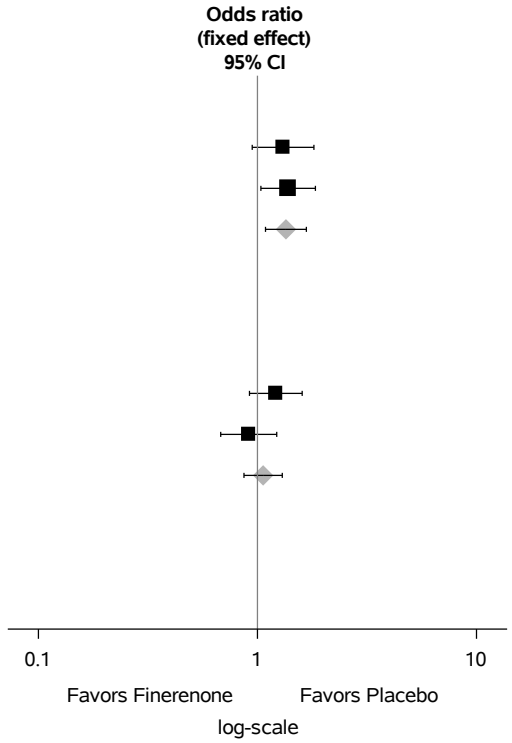
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	25 / 209	8 / 213	9.1	3.48 [1.53,7.91]	
FIGARO-DKD	136 / 1720	112 / 1698	90.9	1.22 [0.94,1.58]	
Total	161 / 1929	120 / 1911		1.36 [1.06,1.74]	Z=2.45, p=0.0141
Heterogeneity:	Q=5.76 (df=1)	p=0.0164	I^2=82.6%		
Very High					
FIDELIO-DKD	182 / 2618	160 / 2618	69.9	1.15 [0.92,1.43]	
FIGARO-DKD	71 / 1963	71 / 1960	30.1	1.00 [0.71,1.40]	
Total	253 / 4581	231 / 4578		1.10 [0.92,1.32]	Z=1.02, p=0.3057
Heterogeneity:	Q=0.47 (df=1)	p=0.4953	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.82 (df=1)	p=0.1769	I^2=45.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.7.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set

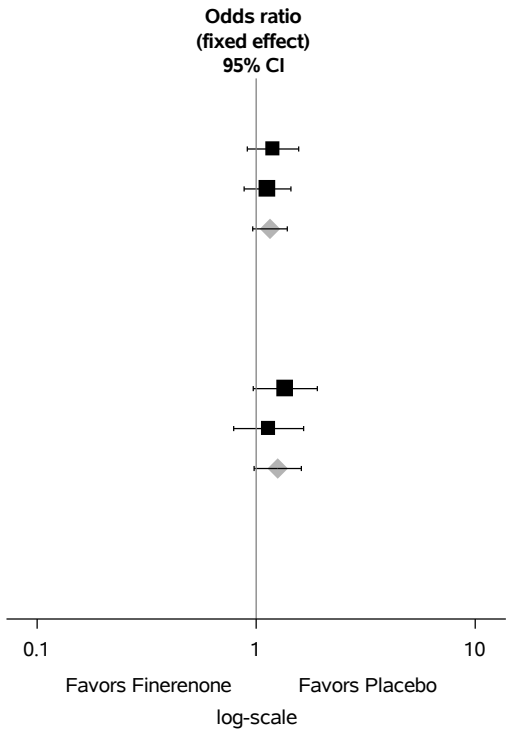
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	89 / 1301	69 / 1299	43.9	1.31 [0.95,1.81]	
FIGARO-DKD	118 / 1673	86 / 1651	56.1	1.38 [1.04,1.84]	
Total	207 / 2974	155 / 2950		1.35 [1.09,1.67]	Z=2.73, p=0.0063
Heterogeneity:	Q=0.06 (df=1)	p=0.8086	I^2=0.0%		
Absent					
FIDELIO-DKD	118 / 1526	99 / 1532	53.1	1.21 [0.92,1.60]	
FIGARO-DKD	89 / 2010	97 / 2007	46.9	0.91 [0.68,1.22]	
Total	207 / 3536	196 / 3539		1.06 [0.87,1.30]	Z=0.58, p=0.5621
Heterogeneity:	Q=1.91 (df=1)	p=0.1672	I^2=47.6%		
Subgroup Heterogeneity:	Q=2.55 (df=1)	p=0.1105	I^2=60.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.7.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set

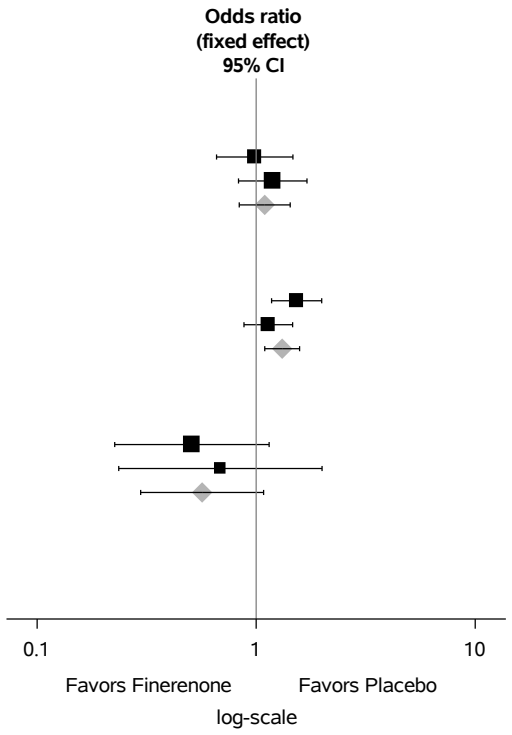
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	123 / 1879	103 / 1858	45.3	1.19 [0.91,1.56]	
FIGARO-DKD	143 / 2643	126 / 2608	54.7	1.13 [0.88,1.44]	
Total	266 / 4522	229 / 4466		1.16 [0.96,1.39]	Z=1.57, p=0.1168
Heterogeneity:	Q=0.10 (df=1)	p=0.7574	I^2=0.0%		
> 4.5					
FIDELIO-DKD	84 / 948	65 / 973	54.4	1.36 [0.97,1.90]	
FIGARO-DKD	64 / 1040	57 / 1048	45.6	1.14 [0.79,1.65]	
Total	148 / 1988	122 / 2021		1.25 [0.98,1.61]	Z=1.79, p=0.0737
Heterogeneity:	Q=0.47 (df=1)	p=0.4916	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6055	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.7.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set

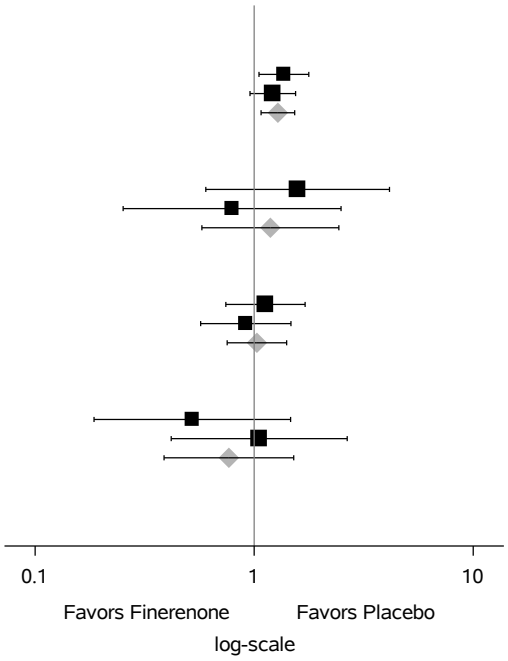
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	51 / 788	51 / 777	44.6	0.99 [0.66,1.47]	
FIGARO-DKD	68 / 1187	58 / 1194	55.4	1.19 [0.83,1.71]	
Total	119 / 1975	109 / 1971		1.09 [0.84,1.43]	Z=0.66, p=0.5101
Heterogeneity:	Q=0.47 (df=1)	p=0.4916	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	146 / 1897	99 / 1916	48.5	1.53 [1.18,1.99]	
FIGARO-DKD	133 / 2389	116 / 2351	51.5	1.14 [0.88,1.47]	
Total	279 / 4286	215 / 4267		1.31 [1.09,1.58]	Z=2.92, p=0.0035
Heterogeneity:	Q=2.53 (df=1)	p=0.1116	I^2=60.5%		
>= 160					
FIDELIO-DKD	10 / 141	18 / 138	63.4	0.51 [0.23,1.15]	
FIGARO-DKD	6 / 107	9 / 113	36.6	0.69 [0.24,2.00]	
Total	16 / 248	27 / 251		0.57 [0.30,1.08]	Z=-1.72, p=0.0849
Heterogeneity:	Q=0.19 (df=1)	p=0.6620	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.57 (df=2)	p=0.0374	I^2=69.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.7.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set

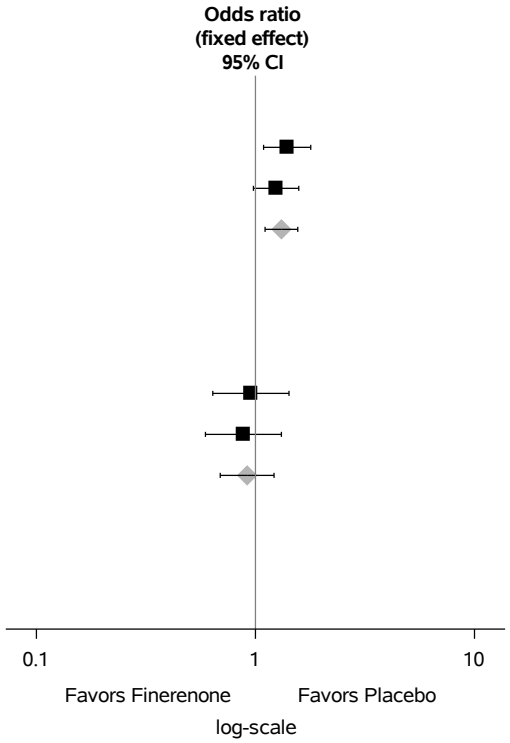
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	139 / 1773	106 / 1809	45.6	1.37 [1.05,1.78]	
FIGARO-DKD	158 / 2668	128 / 2601	54.4	1.22 [0.96,1.55]	
Total	297 / 4441	234 / 4410		1.28 [1.08,1.53]	Z=2.76, p=0.0057
Heterogeneity:	Q=0.42 (df=1)	p=0.5192	I^2=0.0%		
Black					
FIDELIO-DKD	12 / 139	7 / 124	58.5	1.58 [0.60,4.15]	
FIGARO-DKD	5 / 113	8 / 145	41.5	0.79 [0.25,2.49]	
Total	17 / 252	15 / 269		1.19 [0.58,2.44]	Z=0.46, p=0.6431
Heterogeneity:	Q=0.81 (df=1)	p=0.3672	I^2=0.0%		
Asian					
FIDELIO-DKD	50 / 717	45 / 721	56.5	1.13 [0.74,1.71]	
FIGARO-DKD	34 / 716	38 / 736	43.5	0.92 [0.57,1.47]	
Total	84 / 1433	83 / 1457		1.03 [0.75,1.41]	Z=0.18, p=0.8572
Heterogeneity:	Q=0.41 (df=1)	p=0.5210	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 198	10 / 177	44.5	0.52 [0.19,1.47]	
FIGARO-DKD	10 / 186	9 / 176	55.5	1.05 [0.42,2.66]	
Total	16 / 384	19 / 353		0.77 [0.39,1.52]	Z=-0.76, p=0.4445
Heterogeneity:	Q=0.99 (df=1)	p=0.3202	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.12 (df=3)	p=0.3730	I^2=3.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.7.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set

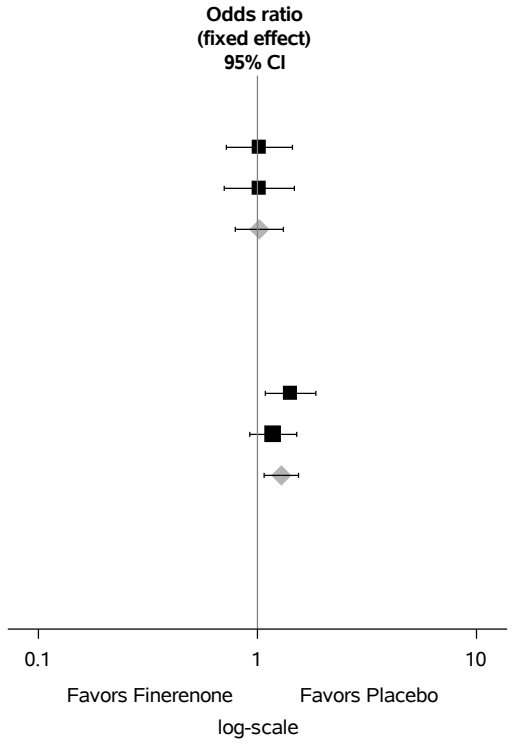
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	155 / 1949	118 / 2024	48.0	1.40 [1.09,1.79]	
FIGARO-DKD	158 / 2527	131 / 2571	52.0	1.24 [0.98,1.58]	
Total	313 / 4476	249 / 4595		1.31 [1.11,1.56]	Z=3.11, p=0.0018
Heterogeneity:	Q=0.44 (df=1)	p=0.5073	I^2=0.0%		
Female					
FIDELIO-DKD	52 / 878	50 / 807	49.8	0.95 [0.64,1.42]	
FIGARO-DKD	49 / 1156	52 / 1087	50.2	0.88 [0.59,1.31]	
Total	101 / 2034	102 / 1894		0.92 [0.69,1.22]	Z=-0.61, p=0.5443
Heterogeneity:	Q=0.07 (df=1)	p=0.7852	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.56 (df=1)	p=0.0327	I^2=78.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.7.9: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set

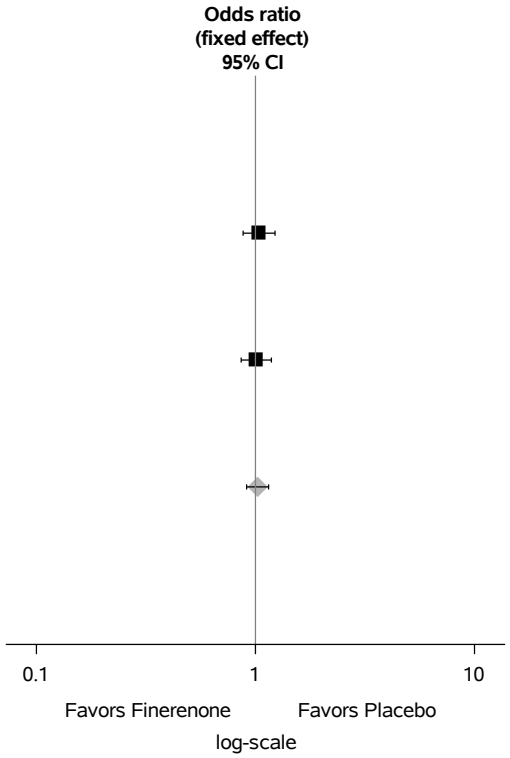
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	69 / 1201	66 / 1171	52.9	1.02 [0.72,1.44]	
FIGARO-DKD	59 / 1752	58 / 1755	47.1	1.02 [0.71,1.47]	
Total	128 / 2953	124 / 2926		1.02 [0.79,1.31]	Z=0.15, p=0.8774
Heterogeneity:	Q=0.00 (df=1)	p=0.9974	I^2=0.0%		
>= 65					
FIDELIO-DKD	138 / 1626	102 / 1660	46.4	1.42 [1.09,1.85]	
FIGARO-DKD	148 / 1931	125 / 1903	53.6	1.18 [0.92,1.51]	
Total	286 / 3557	227 / 3563		1.29 [1.07,1.54]	Z=2.72, p=0.0065
Heterogeneity:	Q=0.97 (df=1)	p=0.3249	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.12 (df=1)	p=0.1451	I^2=52.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

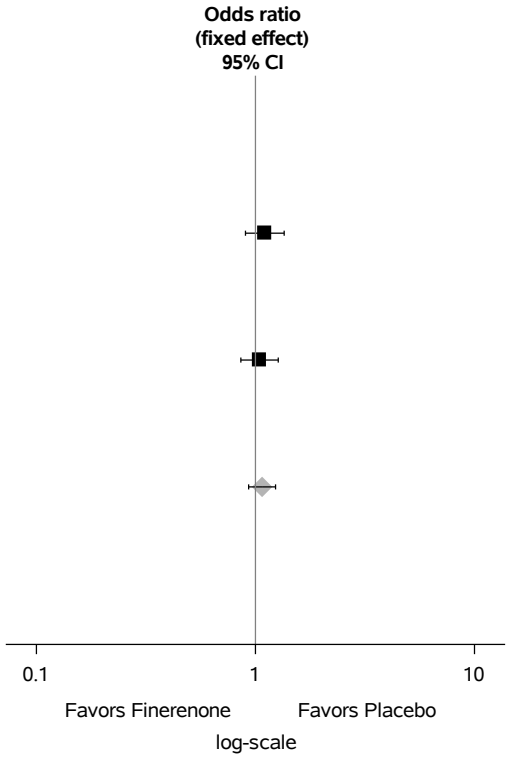
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	311 / 2827	301 / 2831	47.2	1.04 [0.88,1.23]	
FIGARO-DKD	338 / 3683	333 / 3658	52.8	1.01 [0.86,1.18]	
Total	649 / 6510	634 / 6489		1.02 [0.91,1.15]	Z=0.39, p=0.6989
Heterogeneity:	Q=0.06 (df=1)	p=0.8035	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set

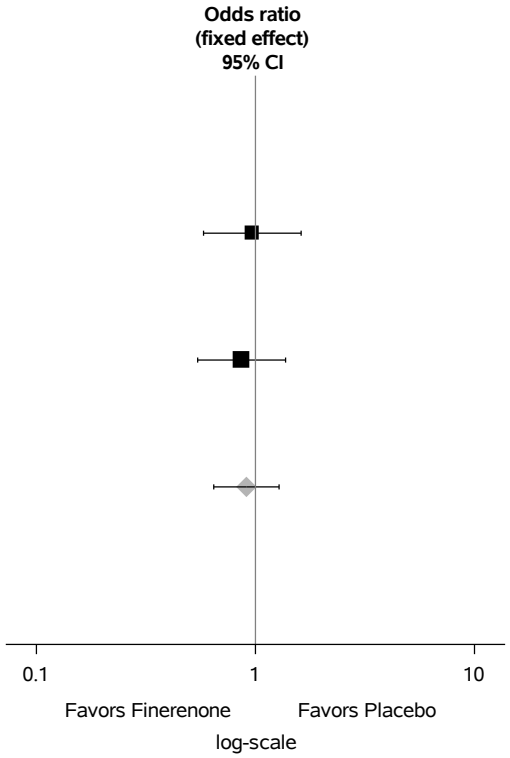
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	209 / 2827	191 / 2831	48.3	1.10 [0.90,1.35]	
FIGARO-DKD	216 / 3683	206 / 3658	51.7	1.04 [0.86,1.27]	
Total	425 / 6510	397 / 6489		1.07 [0.93,1.24]	Z=0.97, p=0.3332
Heterogeneity:	Q=0.15 (df=1)	p=0.7014	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.10: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set

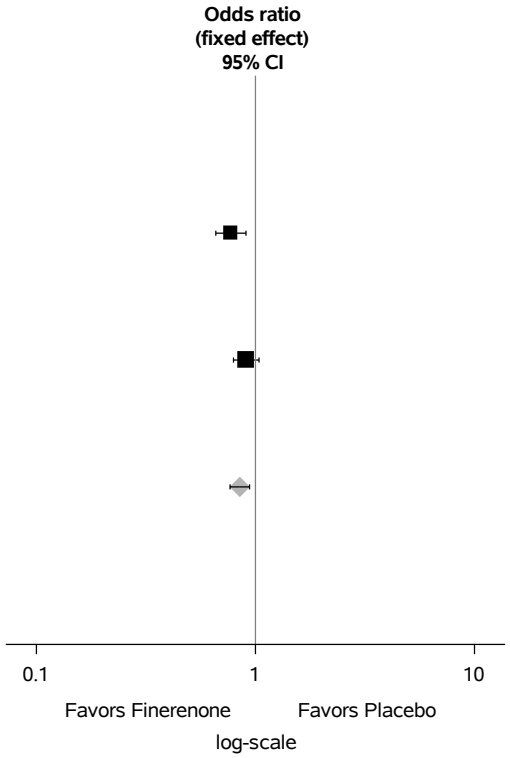
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	44.8	0.97 [0.58,1.62]	
FIGARO-DKD	34 / 3683	39 / 3658	55.2	0.86 [0.54,1.37]	
Total	63 / 6510	69 / 6489		0.91 [0.65,1.28]	Z=-0.54, p=0.5873
Heterogeneity:	Q=0.10 (df=1)	p=0.7492	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.11: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

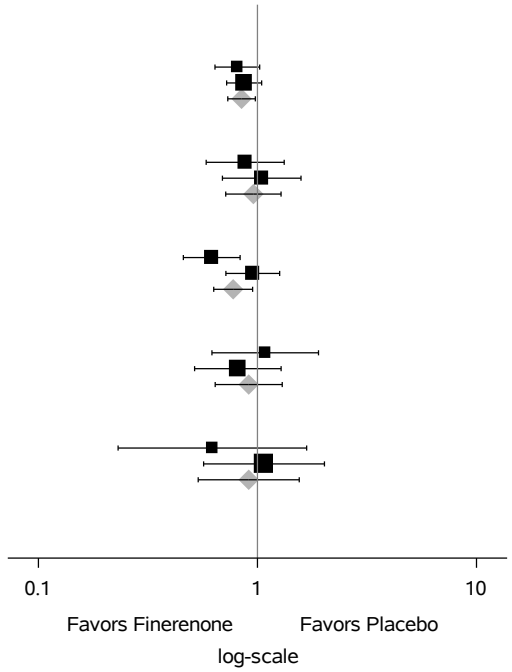
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	313 / 2827	393 / 2831	41.7	0.77 [0.66,0.91]	
FIGARO-DKD	475 / 3683	513 / 3658	58.3	0.91 [0.79,1.04]	
Total	788 / 6510	906 / 6489		0.85 [0.77,0.94]	Z=-3.15, p=0.0016
Heterogeneity:	Q=2.32 (df=1)	p=0.1275	I^2=56.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.11.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

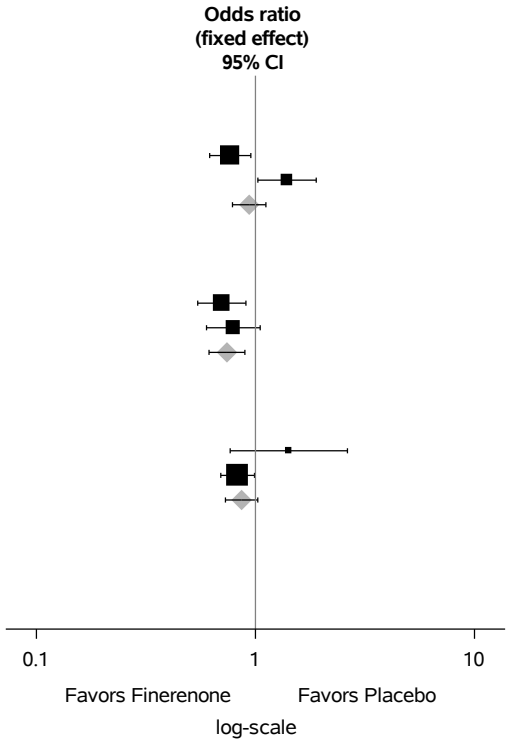
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	148 / 1178	177 / 1174	38.0	0.81 [0.64,1.02]	
FIGARO-DKD	253 / 1752	284 / 1747	62.0	0.87 [0.72,1.05]	
Total	401 / 2930	461 / 2921		0.85 [0.73,0.98]	Z=-2.26, p=0.0238
Heterogeneity:	Q=0.22 (df=1)	p=0.6383	I^2=0.0%		
North America					
FIDELIO-DKD	48 / 466	55 / 476	50.4	0.88 [0.58,1.32]	
FIGARO-DKD	51 / 559	48 / 548	49.6	1.05 [0.69,1.58]	
Total	99 / 1025	103 / 1024		0.96 [0.72,1.28]	Z=-0.29, p=0.7730
Heterogeneity:	Q=0.34 (df=1)	p=0.5585	I^2=0.0%		
Asia					
FIDELIO-DKD	82 / 790	124 / 786	47.3	0.62 [0.46,0.83]	
FIGARO-DKD	109 / 811	114 / 813	52.7	0.95 [0.72,1.26]	
Total	191 / 1601	238 / 1599		0.77 [0.63,0.95]	Z=-2.45, p=0.0144
Heterogeneity:	Q=4.24 (df=1)	p=0.0396	I^2=76.4%		
Latin America					
FIDELIO-DKD	28 / 294	26 / 294	39.7	1.09 [0.62,1.90]	
FIGARO-DKD	38 / 424	45 / 417	60.3	0.81 [0.52,1.28]	
Total	66 / 718	71 / 711		0.91 [0.64,1.30]	Z=-0.51, p=0.6092
Heterogeneity:	Q=0.61 (df=1)	p=0.4346	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 99	11 / 101	29.1	0.62 [0.23,1.68]	
FIGARO-DKD	24 / 137	22 / 133	70.9	1.07 [0.57,2.02]	
Total	31 / 236	33 / 234		0.91 [0.54,1.55]	Z=-0.34, p=0.7349
Heterogeneity:	Q=0.82 (df=1)	p=0.3658	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.67 (df=4)	p=0.7967	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.11.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

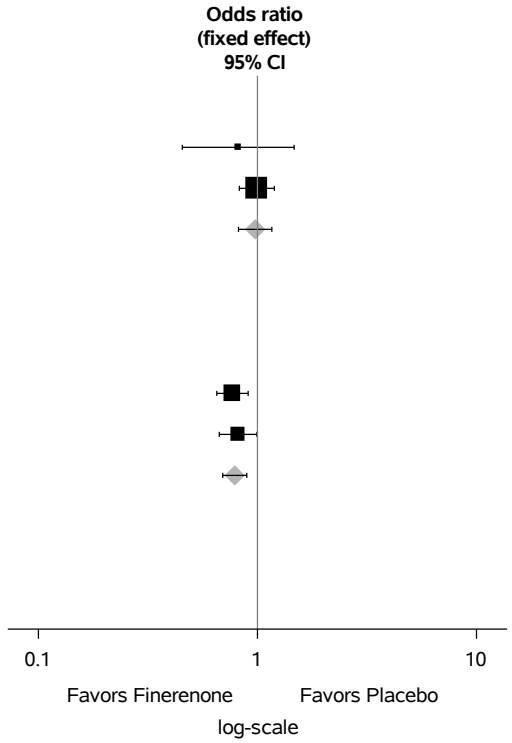
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	168 / 1556	210 / 1541	66.8	0.77 [0.62,0.95]	
FIGARO-DKD	113 / 637	84 / 627	33.2	1.39 [1.03,1.89]	
Total	281 / 2193	294 / 2168		0.94 [0.79,1.12]	Z=-0.73, p=0.4628
Heterogeneity:	Q=9.72 (df=1)	p=0.0018	I^2=89.7%		
45 - < 60					
FIDELIO-DKD	119 / 1061	163 / 1069	55.4	0.70 [0.55,0.90]	
FIGARO-DKD	104 / 720	128 / 729	44.6	0.79 [0.60,1.05]	
Total	223 / 1781	291 / 1798		0.74 [0.61,0.89]	Z=-3.12, p=0.0018
Heterogeneity:	Q=0.39 (df=1)	p=0.5306	I^2=0.0%		
>= 60					
FIDELIO-DKD	26 / 210	20 / 221	7.6	1.42 [0.77,2.63]	
FIGARO-DKD	258 / 2326	301 / 2302	92.4	0.83 [0.69,0.99]	
Total	284 / 2536	321 / 2523		0.86 [0.73,1.02]	Z=-1.68, p=0.0935
Heterogeneity:	Q=2.70 (df=1)	p=0.1002	I^2=63.0%		
Subgroup Heterogeneity:	Q=3.24 (df=2)	p=0.1983	I^2=38.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.11.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

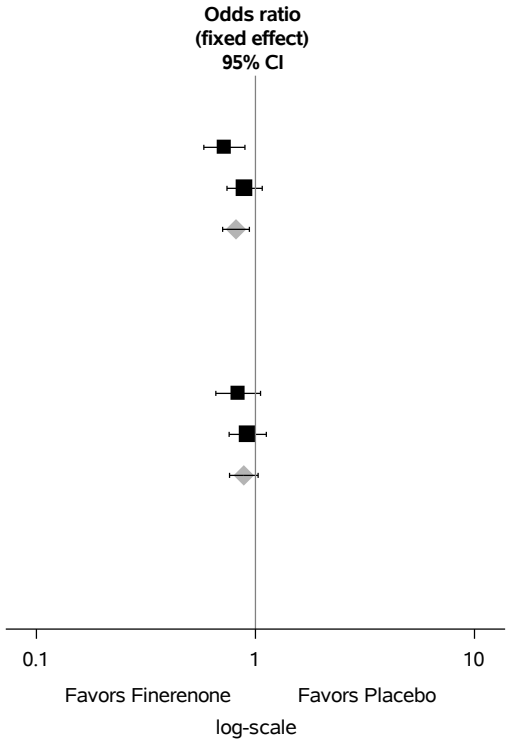
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	23 / 209	28 / 213	8.9	0.82 [0.45,1.47]	
FIGARO-DKD	271 / 1720	269 / 1698	91.1	0.99 [0.83,1.19]	
Total	294 / 1929	297 / 1911		0.98 [0.82,1.16]	Z=-0.27, p=0.7886
Heterogeneity:	Q=0.39 (df=1)	p=0.5337	I^2=0.0%		
Very High					
FIDELIO-DKD	290 / 2618	365 / 2618	59.0	0.77 [0.65,0.91]	
FIGARO-DKD	204 / 1963	244 / 1960	41.0	0.82 [0.67,0.99]	
Total	494 / 4581	609 / 4578		0.79 [0.69,0.89]	Z=-3.70, p=0.0002
Heterogeneity:	Q=0.20 (df=1)	p=0.6531	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.78 (df=1)	p=0.0517	I^2=73.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.11.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

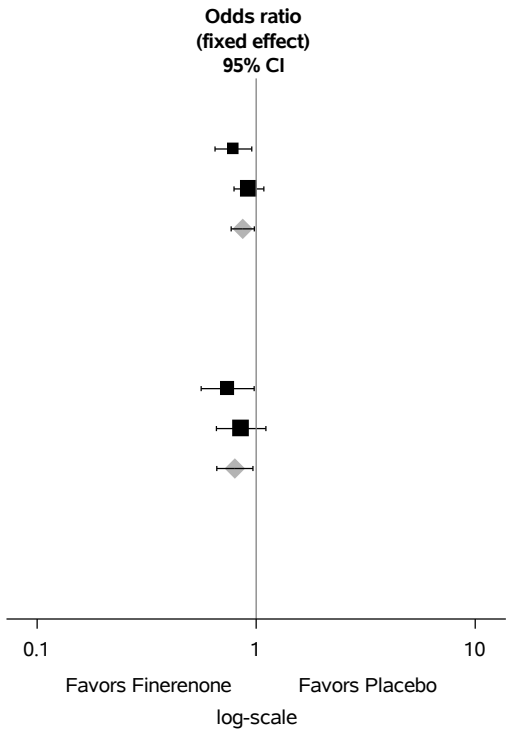
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	170 / 1301	224 / 1299	42.4	0.72 [0.58,0.90]	
FIGARO-DKD	256 / 1673	278 / 1651	57.6	0.89 [0.74,1.07]	
Total	426 / 2974	502 / 2950		0.82 [0.71,0.94]	Z=-2.85, p=0.0044
Heterogeneity:	Q=2.14 (df=1)	p=0.1432	I^2=53.3%		
Absent					
FIDELIO-DKD	143 / 1526	169 / 1532	40.9	0.83 [0.66,1.05]	
FIGARO-DKD	219 / 2010	235 / 2007	59.1	0.92 [0.76,1.12]	
Total	362 / 3536	404 / 3539		0.88 [0.76,1.03]	Z=-1.60, p=0.1105
Heterogeneity:	Q=0.41 (df=1)	p=0.5195	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4340	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.11.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	215 / 1879	262 / 1858	39.7	0.79 [0.65,0.95]	
FIGARO-DKD	354 / 2643	373 / 2608	60.3	0.93 [0.79,1.08]	
Total	569 / 4522	635 / 4466		0.87 [0.77,0.98]	Z=-2.28, p=0.0228
Heterogeneity:	Q=1.66 (df=1)	p=0.1980	I^2=39.7%		
> 4.5					
FIDELIO-DKD	98 / 948	131 / 973	46.6	0.74 [0.56,0.98]	
FIGARO-DKD	121 / 1040	140 / 1048	53.4	0.85 [0.66,1.11]	
Total	219 / 1988	271 / 2021		0.80 [0.66,0.97]	Z=-2.31, p=0.0208
Heterogeneity:	Q=0.53 (df=1)	p=0.4658	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.52 (df=1)	p=0.4710	I^2=0.0%		

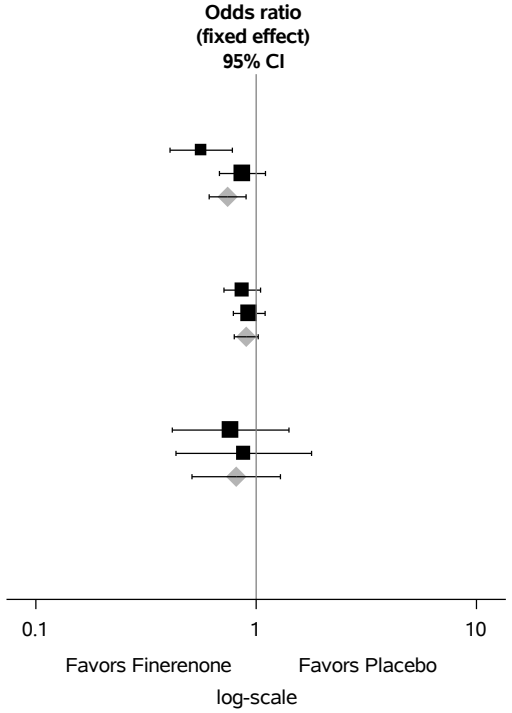


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.11.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)

Safety Analysis Set

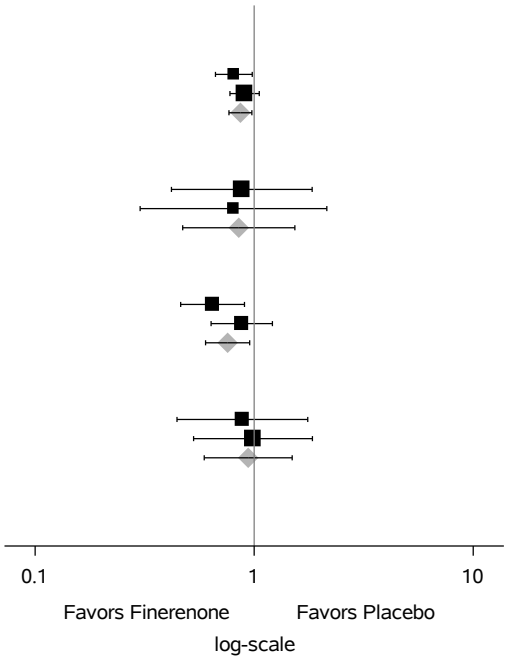
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	65 / 788	107 / 777	35.3	0.56 [0.41,0.78]	
FIGARO-DKD	143 / 1187	163 / 1194	64.7	0.87 [0.68,1.10]	
Total	208 / 1975	270 / 1971		0.74 [0.61,0.90]	Z=-3.03, p=0.0024
Heterogeneity:	Q=4.36 (df=1)	p=0.0368	I^2=77.1%		
130 - < 160					
FIDELIO-DKD	225 / 1897	258 / 1916	43.0	0.86 [0.71,1.05]	
FIGARO-DKD	315 / 2389	330 / 2351	57.0	0.93 [0.79,1.10]	
Total	540 / 4286	588 / 4267		0.90 [0.80,1.02]	Z=-1.62, p=0.1048
Heterogeneity:	Q=0.32 (df=1)	p=0.5729	I^2=0.0%		
>= 160					
FIDELIO-DKD	23 / 141	28 / 138	57.5	0.77 [0.42,1.41]	
FIGARO-DKD	17 / 107	20 / 113	42.5	0.88 [0.43,1.78]	
Total	40 / 248	48 / 251		0.81 [0.51,1.29]	Z=-0.88, p=0.3762
Heterogeneity:	Q=0.08 (df=1)	p=0.7736	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.79 (df=2)	p=0.2480	I^2=28.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.11.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

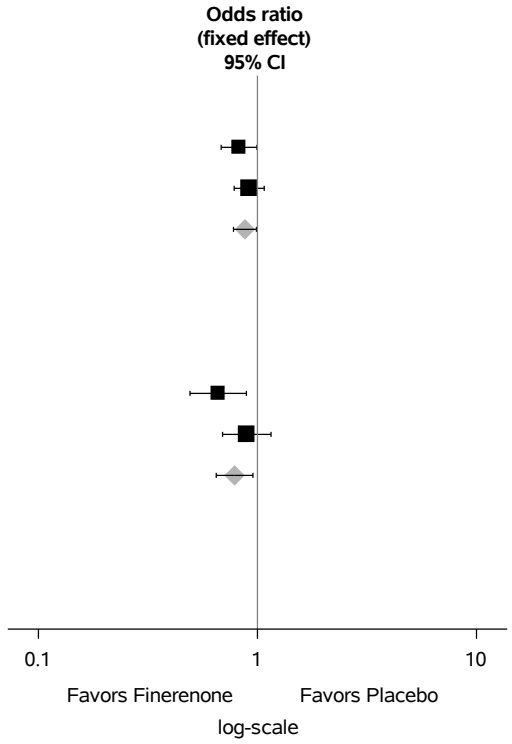
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	215 / 1773	264 / 1809	38.8	0.81 [0.67,0.98]	
FIGARO-DKD	367 / 2668	390 / 2601	61.2	0.90 [0.78,1.05]	
Total	582 / 4441	654 / 4410		0.87 [0.77,0.98]	Z=-2.35, p=0.0185
Heterogeneity:	Q=0.80 (df=1)	p=0.3702	I^2=0.0%		
Black					
FIDELIO-DKD	16 / 139	16 / 124	63.8	0.88 [0.42,1.84]	
FIGARO-DKD	7 / 113	11 / 145	36.2	0.80 [0.30,2.15]	
Total	23 / 252	27 / 269		0.85 [0.47,1.53]	Z=-0.54, p=0.5905
Heterogeneity:	Q=0.02 (df=1)	p=0.8890	I^2=0.0%		
Asian					
FIDELIO-DKD	64 / 717	95 / 721	48.0	0.65 [0.46,0.90]	
FIGARO-DKD	78 / 716	90 / 736	52.0	0.88 [0.64,1.21]	
Total	142 / 1433	185 / 1457		0.76 [0.60,0.95]	Z=-2.36, p=0.0184
Heterogeneity:	Q=1.67 (df=1)	p=0.1964	I^2=40.1%		
Others					
FIDELIO-DKD	18 / 198	18 / 177	45.2	0.88 [0.44,1.76]	
FIGARO-DKD	23 / 186	22 / 176	54.8	0.99 [0.53,1.84]	
Total	41 / 384	40 / 353		0.94 [0.59,1.49]	Z=-0.27, p=0.7898
Heterogeneity:	Q=0.06 (df=1)	p=0.8136	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.22 (df=3)	p=0.7471	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.11.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

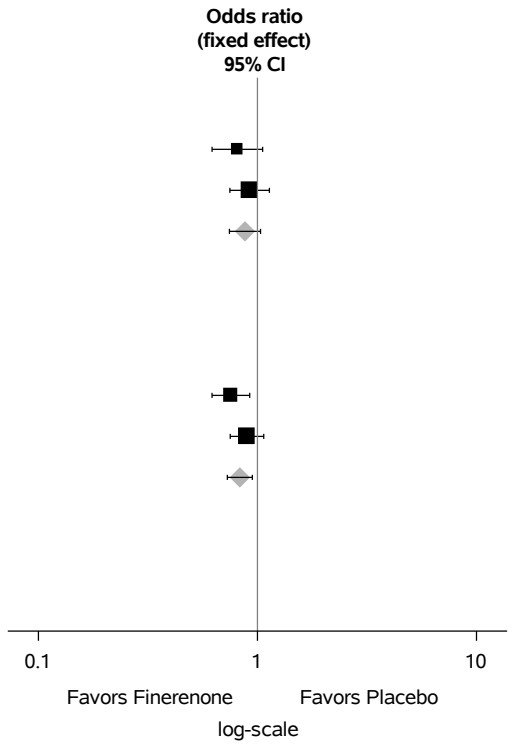
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	226 / 1949	278 / 2024	41.4	0.82 [0.68,0.99]	
FIGARO-DKD	343 / 2527	376 / 2571	58.6	0.92 [0.78,1.07]	
Total	569 / 4476	654 / 4595		0.88 [0.78,0.99]	Z=-2.13, p=0.0332
Heterogeneity:	Q=0.73 (df=1)	p=0.3926	I^2=0.0%		
Female					
FIDELIO-DKD	87 / 878	115 / 807	42.5	0.66 [0.49,0.89]	
FIGARO-DKD	132 / 1156	137 / 1087	57.5	0.89 [0.69,1.15]	
Total	219 / 2034	252 / 1894		0.79 [0.65,0.95]	Z=-2.44, p=0.0146
Heterogeneity:	Q=2.27 (df=1)	p=0.1320	I^2=55.9%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3467	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.11.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

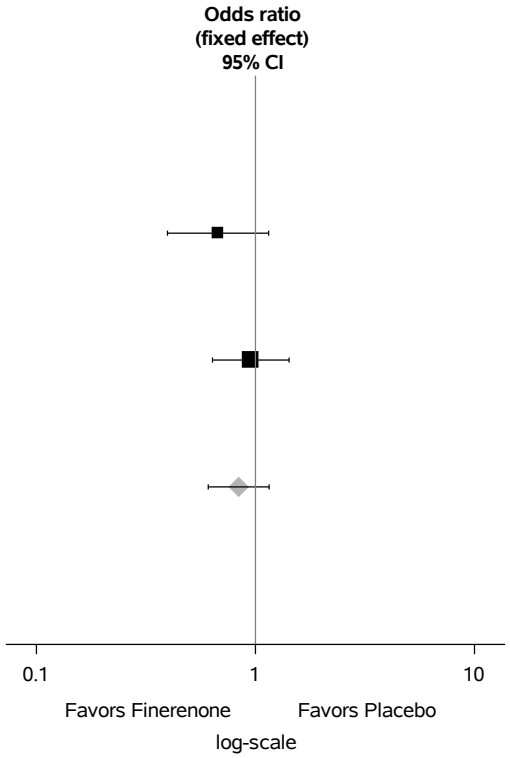
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	112 / 1201	132 / 1171	37.9	0.81 [0.62,1.06]	
FIGARO-DKD	194 / 1752	209 / 1755	62.1	0.92 [0.75,1.13]	
Total	306 / 2953	341 / 2926		0.88 [0.74,1.03]	Z=-1.57, p=0.1159
Heterogeneity:	Q=0.56 (df=1)	p=0.4531	I^2=0.0%		
>= 65					
FIDELIO-DKD	201 / 1626	261 / 1660	44.1	0.76 [0.62,0.92]	
FIGARO-DKD	281 / 1931	304 / 1903	55.9	0.90 [0.75,1.07]	
Total	482 / 3557	565 / 3563		0.83 [0.73,0.95]	Z=-2.76, p=0.0058
Heterogeneity:	Q=1.57 (df=1)	p=0.2101	I^2=36.3%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6148	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.12: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set

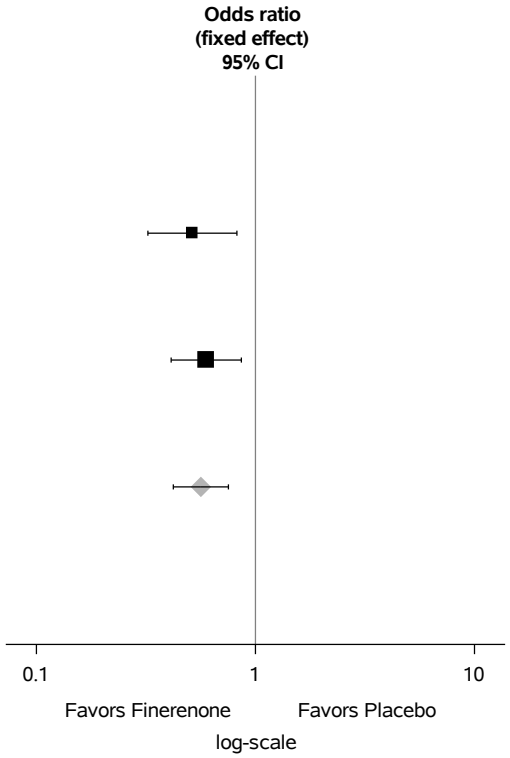
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	34 / 2831	36.5	0.67 [0.40,1.15]	
FIGARO-DKD	47 / 3683	49 / 3658	63.5	0.95 [0.64,1.42]	
Total	70 / 6510	83 / 6489		0.84 [0.61,1.15]	Z=-1.08, p=0.2805
Heterogeneity:	Q=1.02 (df=1)	p=0.3118	I^2=2.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.13: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

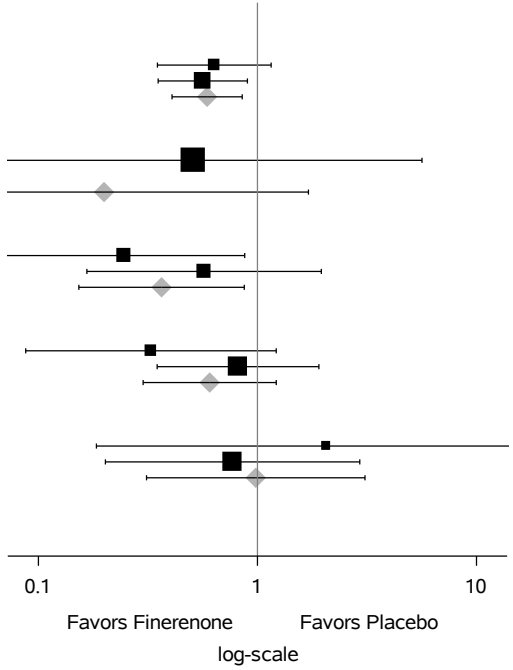
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	52 / 2831	38.4	0.52 [0.32,0.82]	
FIGARO-DKD	46 / 3683	76 / 3658	61.6	0.60 [0.41,0.86]	
Total	73 / 6510	128 / 6489		0.56 [0.42,0.75]	Z=-3.88, p=0.0001
Heterogeneity:	Q=0.23 (df=1)	p=0.6320	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.13.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

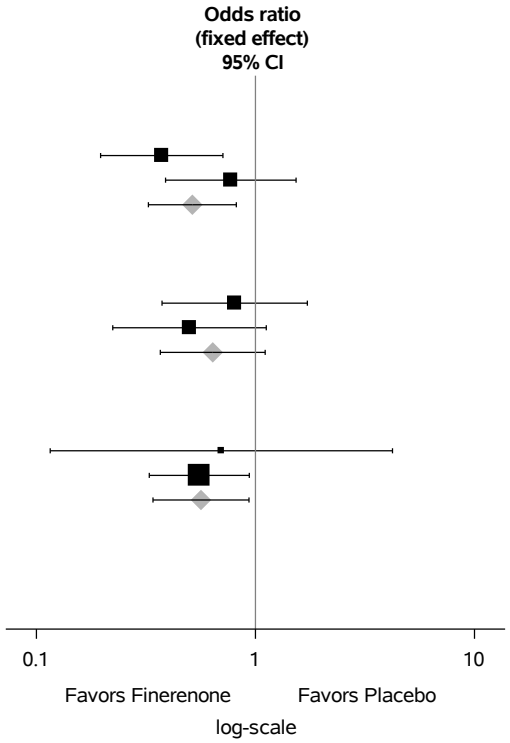
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	18 / 1178	28 / 1174	38.1	0.64 [0.35,1.15]	
FIGARO-DKD	28 / 1752	49 / 1747	61.9	0.56 [0.35,0.90]	
Total	46 / 2930	77 / 2921		0.59 [0.41,0.85]	Z=-2.81, p=0.0049
Heterogeneity:	Q=0.10 (df=1)	p=0.7553	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 466	2 / 476	100.0	0.51 [0.05,5.64]	
FIGARO-DKD	0 / 559	3 / 548	0.0	0.00 [0.00,21E296]	
Total	1 / 1025	5 / 1024		0.20 [0.02,1.71]	Z=-1.47, p=0.1413
Heterogeneity:	Q=0.59 (df=1)	p=0.4440	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 790	12 / 786	48.5	0.25 [0.07,0.87]	
FIGARO-DKD	4 / 811	7 / 813	51.5	0.57 [0.17,1.96]	
Total	7 / 1601	19 / 1599		0.36 [0.15,0.87]	Z=-2.27, p=0.0230
Heterogeneity:	Q=0.88 (df=1)	p=0.3488	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 294	9 / 294	29.4	0.33 [0.09,1.22]	
FIGARO-DKD	10 / 424	12 / 417	70.6	0.82 [0.35,1.91]	
Total	13 / 718	21 / 711		0.61 [0.30,1.22]	Z=-1.41, p=0.1595
Heterogeneity:	Q=1.32 (df=1)	p=0.2514	I^2=24.0%		
Others					
FIDELIO-DKD	2 / 99	1 / 101	23.4	2.06 [0.18,23.11]	
FIGARO-DKD	4 / 137	5 / 133	76.6	0.77 [0.20,2.93]	
Total	6 / 236	6 / 234		0.98 [0.31,3.10]	Z=-0.03, p=0.9759
Heterogeneity:	Q=0.49 (df=1)	p=0.4843	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.85 (df=4)	p=0.5830	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.13.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

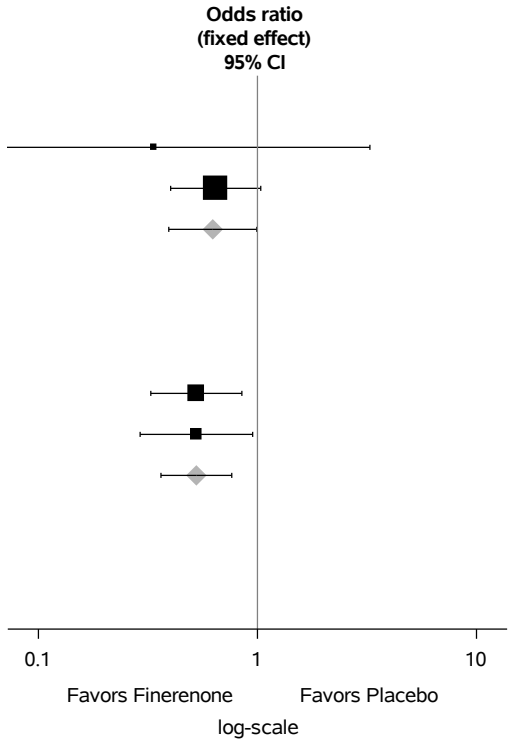
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	34 / 1541	53.2	0.37 [0.20,0.71]	
FIGARO-DKD	15 / 637	19 / 627	46.8	0.77 [0.39,1.53]	
Total	28 / 2193	53 / 2168		0.52 [0.32,0.82]	Z=-2.81, p=0.0049
Heterogeneity:	Q=2.29 (df=1)	p=0.1299	I^2=56.4%		
45 - < 60					
FIDELIO-DKD	12 / 1061	15 / 1069	52.7	0.80 [0.37,1.73]	
FIGARO-DKD	9 / 720	18 / 729	47.3	0.50 [0.22,1.12]	
Total	21 / 1781	33 / 1798		0.64 [0.37,1.11]	Z=-1.60, p=0.1104
Heterogeneity:	Q=0.70 (df=1)	p=0.4022	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	3 / 221	7.9	0.70 [0.12,4.22]	
FIGARO-DKD	22 / 2326	39 / 2302	92.1	0.55 [0.33,0.94]	
Total	24 / 2536	42 / 2523		0.56 [0.34,0.93]	Z=-2.22, p=0.0261
Heterogeneity:	Q=0.06 (df=1)	p=0.8084	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=2)	p=0.8432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.13.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

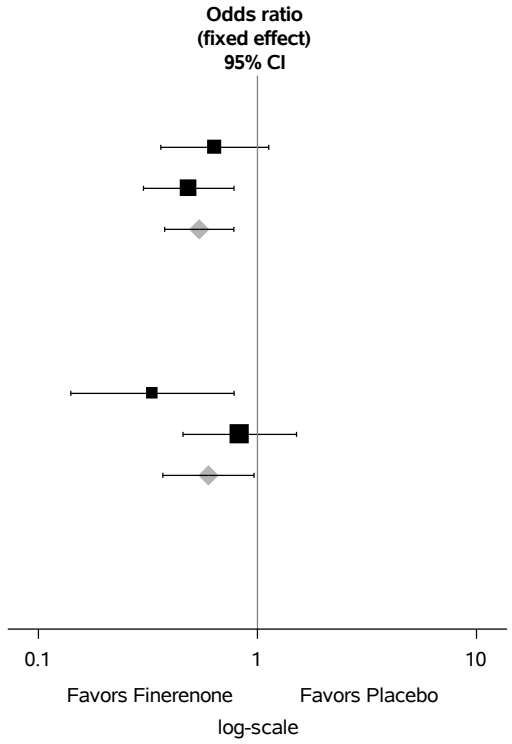
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	3 / 213	4.2	0.34 [0.03,3.26]	
FIGARO-DKD	29 / 1720	44 / 1698	95.8	0.64 [0.40,1.04]	
Total	30 / 1929	47 / 1911		0.63 [0.39,0.99]	Z=-1.99, p=0.0466
Heterogeneity:	Q=0.30 (df=1)	p=0.5828	I^2=0.0%		
Very High					
FIDELIO-DKD	26 / 2618	49 / 2618	60.4	0.53 [0.33,0.85]	
FIGARO-DKD	17 / 1963	32 / 1960	39.6	0.53 [0.29,0.95]	
Total	43 / 4581	81 / 4578		0.53 [0.36,0.76]	Z=-3.38, p=0.0007
Heterogeneity:	Q=0.00 (df=1)	p=0.9983	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.32 (df=1)	p=0.5689	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.13.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

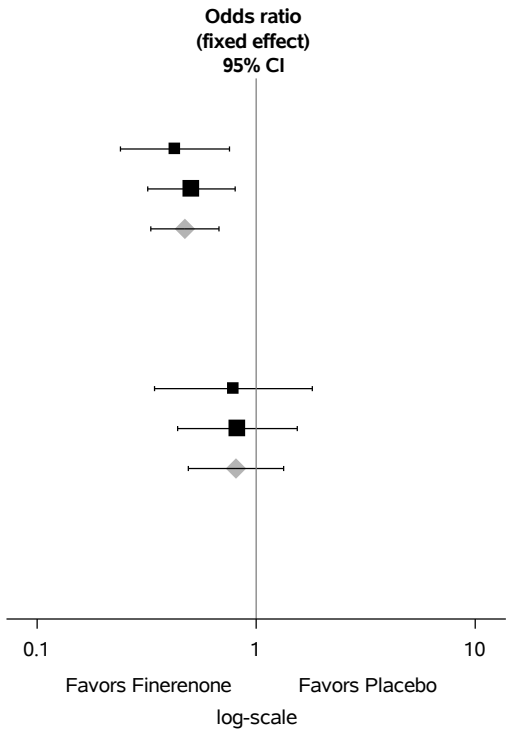
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	31 / 1299	41.3	0.64 [0.36,1.13]	
FIGARO-DKD	26 / 1673	52 / 1651	58.7	0.49 [0.30,0.78]	
Total	46 / 2974	83 / 2950		0.54 [0.38,0.78]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.53 (df=1)	p=0.4678	I^2=0.0%		
Absent					
FIDELIO-DKD	7 / 1526	21 / 1532	32.6	0.33 [0.14,0.78]	
FIGARO-DKD	20 / 2010	24 / 2007	67.4	0.83 [0.46,1.51]	
Total	27 / 3536	45 / 3539		0.60 [0.37,0.96]	Z=-2.11, p=0.0351
Heterogeneity:	Q=2.98 (df=1)	p=0.0844	I^2=66.4%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7534	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.13.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

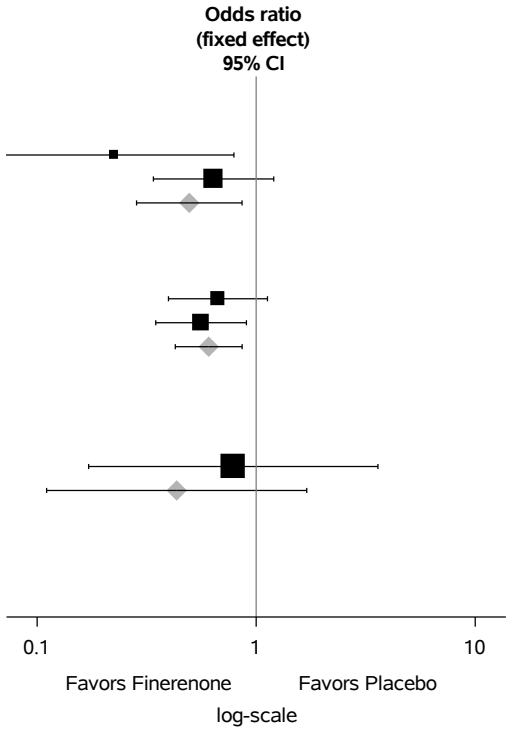
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	17 / 1879	39 / 1858	39.1	0.43 [0.24,0.76]	
FIGARO-DKD	28 / 2643	54 / 2608	60.9	0.51 [0.32,0.80]	
Total	45 / 4522	93 / 4466		0.47 [0.33,0.68]	Z=-4.10, p=<.0001
Heterogeneity:	Q=0.21 (df=1)	p=0.6438	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 948	13 / 973	36.5	0.79 [0.34,1.80]	
FIGARO-DKD	18 / 1040	22 / 1048	63.5	0.82 [0.44,1.54]	
Total	28 / 1988	35 / 2021		0.81 [0.49,1.33]	Z=-0.83, p=0.4063
Heterogeneity:	Q=0.01 (df=1)	p=0.9363	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.92 (df=1)	p=0.0874	I^2=65.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.13.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

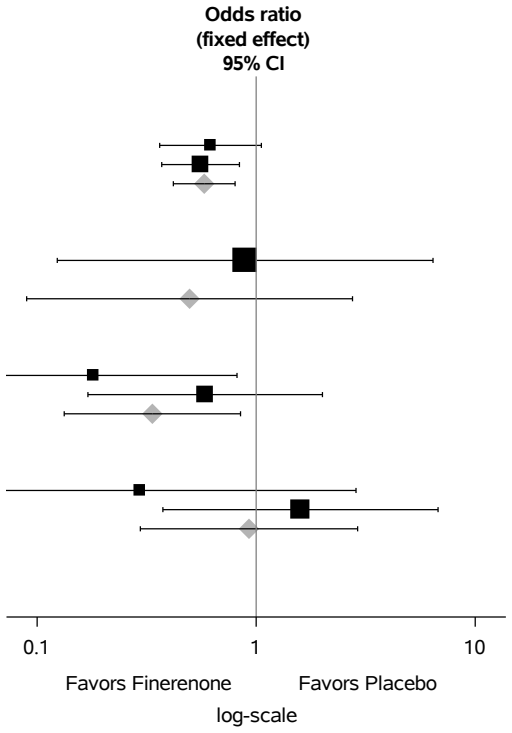
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 788	13 / 777	20.2	0.22 [0.06,0.79]	
FIGARO-DKD	16 / 1187	25 / 1194	79.8	0.64 [0.34,1.20]	
Total	19 / 1975	38 / 1971		0.50 [0.28,0.86]	Z=-2.49, p=0.0129
Heterogeneity:	Q=2.14 (df=1)	p=0.1437	I^2=53.2%		
130 - < 160					
FIDELIO-DKD	24 / 1897	36 / 1916	45.6	0.67 [0.40,1.13]	
FIGARO-DKD	27 / 2389	47 / 2351	54.4	0.56 [0.35,0.90]	
Total	51 / 4286	83 / 4267		0.61 [0.43,0.86]	Z=-2.78, p=0.0054
Heterogeneity:	Q=0.24 (df=1)	p=0.6222	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	3 / 138	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	3 / 107	4 / 113	100.0	0.79 [0.17,3.60]	
Total	3 / 248	7 / 251		0.43 [0.11,1.70]	Z=-1.20, p=0.2309
Heterogeneity:	Q=0.59 (df=1)	p=0.4432	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.52 (df=2)	p=0.7698	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.13.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

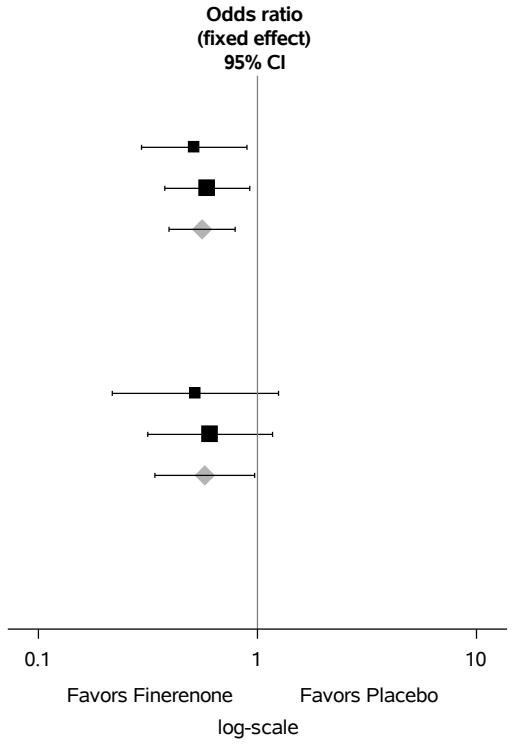
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	36 / 1809	36.9	0.62 [0.36,1.06]	
FIGARO-DKD	37 / 2668	64 / 2601	63.1	0.56 [0.37,0.84]	
Total	59 / 4441	100 / 4410		0.58 [0.42,0.80]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.09 (df=1)	p=0.7611	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	2 / 124	100.0	0.89 [0.12,6.42]	
FIGARO-DKD	0 / 113	2 / 145	0.0	0.00 [0.00,23E296]	
Total	2 / 252	4 / 269		0.50 [0.09,2.75]	Z=-0.80, p=0.4231
Heterogeneity:	Q=0.34 (df=1)	p=0.5622	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 717	11 / 721	40.0	0.18 [0.04,0.82]	
FIGARO-DKD	4 / 716	7 / 736	60.0	0.59 [0.17,2.01]	
Total	6 / 1433	18 / 1457		0.34 [0.13,0.85]	Z=-2.31, p=0.0210
Heterogeneity:	Q=1.43 (df=1)	p=0.2321	I^2=30.0%		
Others					
FIDELIO-DKD	1 / 198	3 / 177	28.8	0.29 [0.03,2.86]	
FIGARO-DKD	5 / 186	3 / 176	71.2	1.59 [0.38,6.77]	
Total	6 / 384	6 / 353		0.93 [0.30,2.91]	Z=-0.13, p=0.8968
Heterogeneity:	Q=1.52 (df=1)	p=0.2181	I^2=34.1%		
Subgroup Heterogeneity:	Q=1.98 (df=3)	p=0.5772	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.13.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

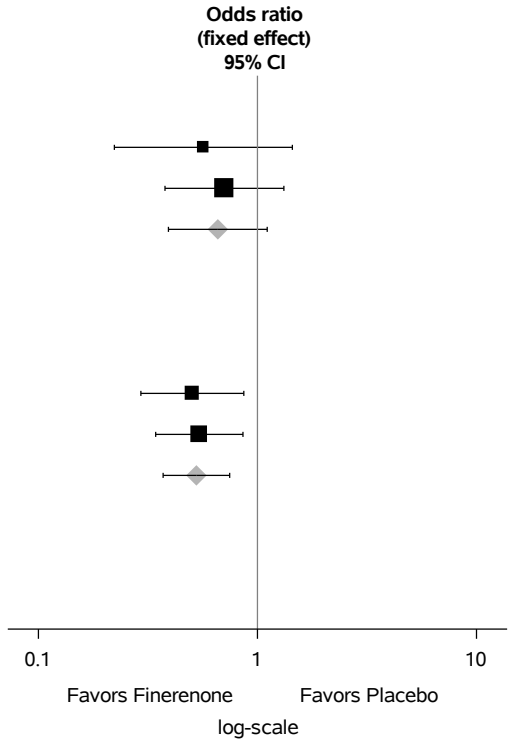
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	19 / 1949	38 / 2024	39.4	0.51 [0.30,0.90]	
FIGARO-DKD	31 / 2527	53 / 2571	60.6	0.59 [0.38,0.92]	
Total	50 / 4476	91 / 4595		0.56 [0.39,0.79]	Z=-3.28, p=0.0010
Heterogeneity:	Q=0.14 (df=1)	p=0.7060	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 878	14 / 807	36.0	0.52 [0.22,1.25]	
FIGARO-DKD	15 / 1156	23 / 1087	64.0	0.61 [0.32,1.17]	
Total	23 / 2034	37 / 1894		0.57 [0.34,0.97]	Z=-2.07, p=0.0384
Heterogeneity:	Q=0.08 (df=1)	p=0.7810	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9297	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.13.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set

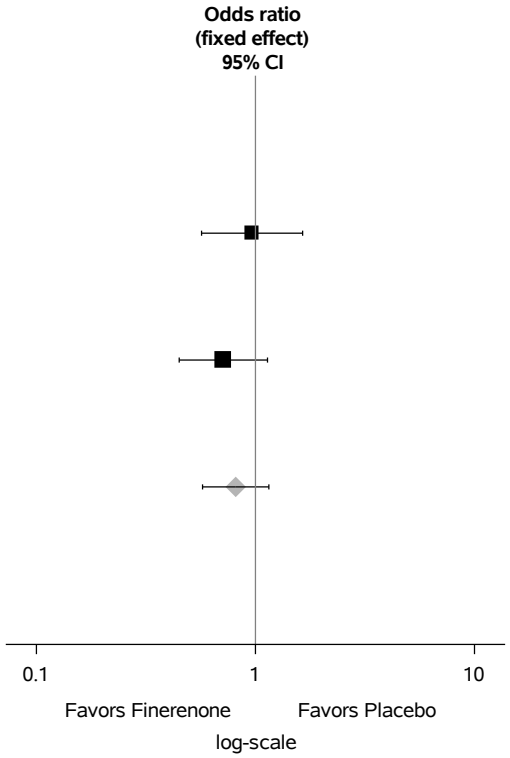
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	7 / 1201	12 / 1171	30.8	0.57 [0.22,1.44]	
FIGARO-DKD	17 / 1752	24 / 1755	69.2	0.71 [0.38,1.32]	
Total	24 / 2953	36 / 2926		0.66 [0.39,1.11]	Z=-1.57, p=0.1157
Heterogeneity:	Q=0.15 (df=1)	p=0.6995	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1626	40 / 1660	41.8	0.50 [0.29,0.87]	
FIGARO-DKD	29 / 1931	52 / 1903	58.2	0.54 [0.34,0.86]	
Total	49 / 3557	92 / 3563		0.53 [0.37,0.75]	Z=-3.60, p=0.0003
Heterogeneity:	Q=0.04 (df=1)	p=0.8394	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4805	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.14: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set

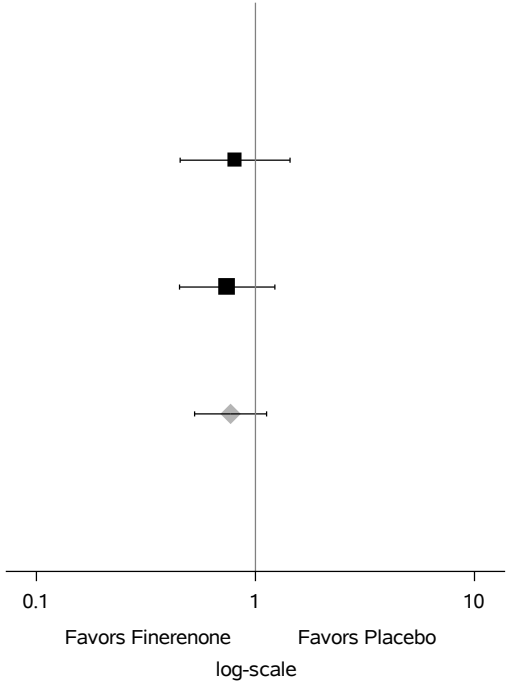
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	28 / 2831	43.3	0.97 [0.57,1.64]	
FIGARO-DKD	31 / 3683	43 / 3658	56.7	0.71 [0.45,1.14]	
Total	58 / 6510	71 / 6489		0.81 [0.57,1.15]	Z=-1.17, p=0.2432
Heterogeneity:	Q=0.70 (df=1)	p=0.4012	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.15: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set

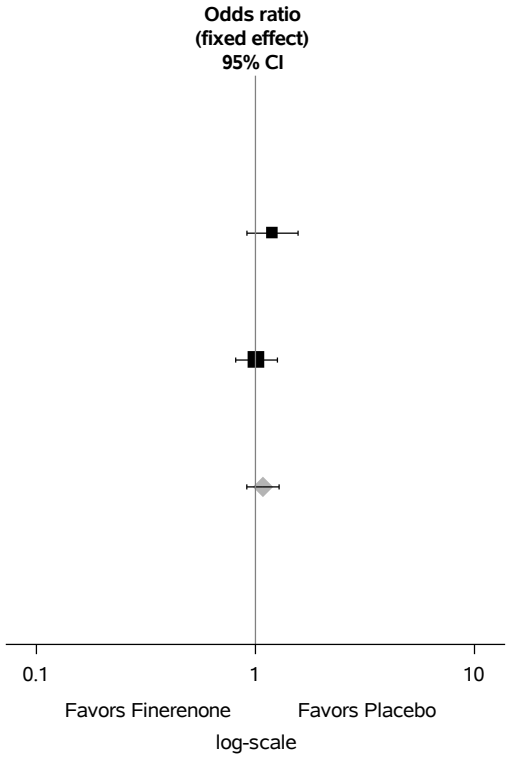
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	26 / 2831	43.0	0.81 [0.45,1.44]	
FIGARO-DKD	27 / 3683	36 / 3658	57.0	0.74 [0.45,1.23]	
Total	48 / 6510	62 / 6489		0.77 [0.53,1.12]	Z=-1.35, p=0.1757
Heterogeneity:	Q=0.05 (df=1)	p=0.8313	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.16: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set

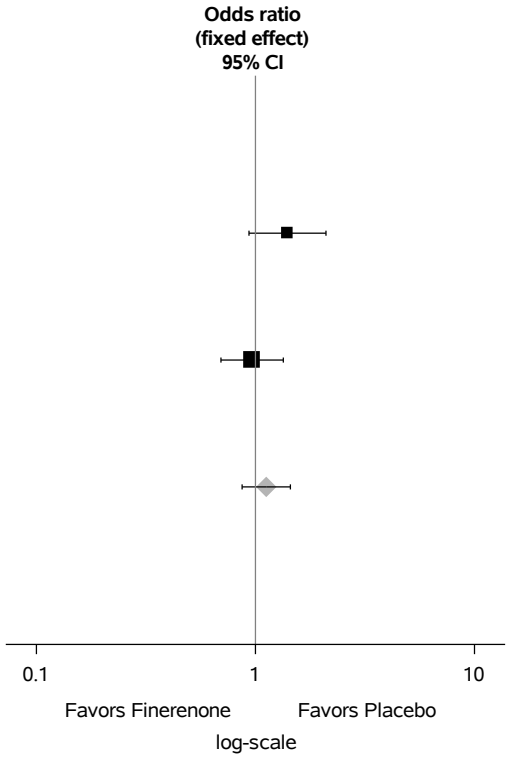
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	121 / 2827	102 / 2831	40.0	1.20 [0.91,1.57]	
FIGARO-DKD	169 / 3683	166 / 3658	60.0	1.01 [0.81,1.26]	
Total	290 / 6510	268 / 6489		1.08 [0.91,1.28]	Z=0.91, p=0.3632
Heterogeneity:	Q=0.90 (df=1)	p=0.3435	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.17: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set

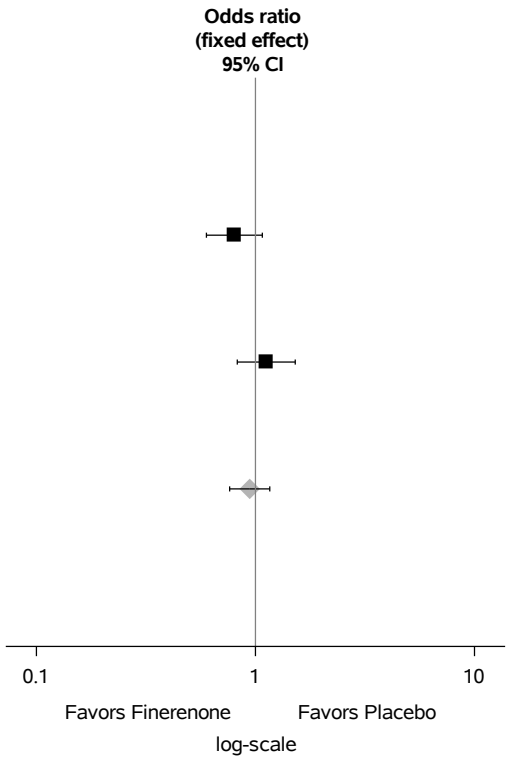
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2827	41 / 2831	39.6	1.40 [0.93,2.10]	
FIGARO-DKD	72 / 3683	74 / 3658	60.4	0.97 [0.70,1.34]	
Total	129 / 6510	115 / 6489		1.12 [0.87,1.44]	Z=0.88, p=0.3806
Heterogeneity:	Q=1.96 (df=1)	p=0.1620	I^2=48.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.18: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set

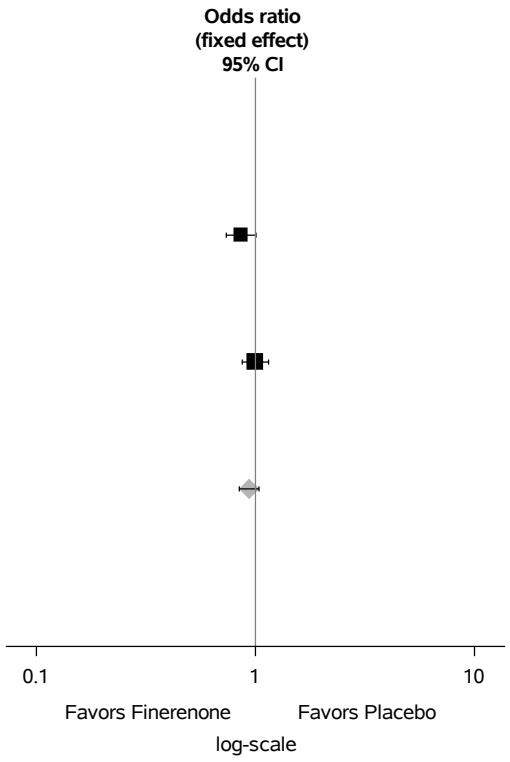
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	83 / 2827	103 / 2831	51.8	0.80 [0.60,1.07]	
FIGARO-DKD	90 / 3683	80 / 3658	48.2	1.12 [0.83,1.52]	
Total	173 / 6510	183 / 6489		0.94 [0.76,1.16]	Z=-0.56, p=0.5744
Heterogeneity:	Q=2.41 (df=1)	p=0.1206	I^2=58.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.19: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set

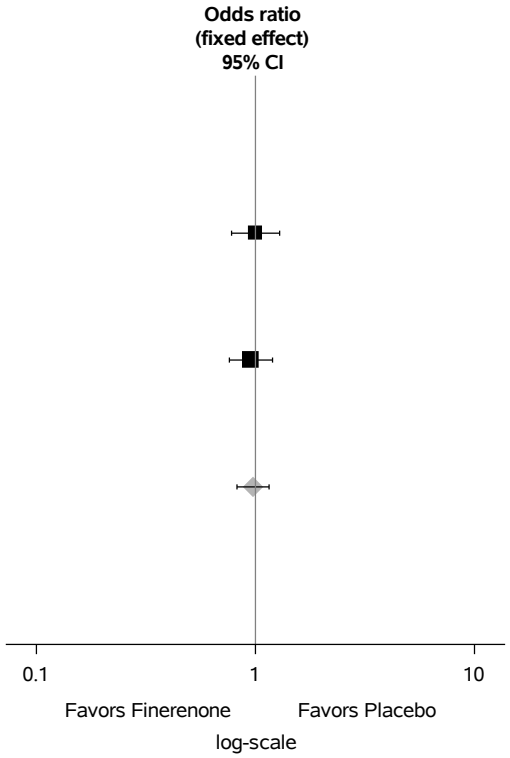
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	339 / 2827	387 / 2831	44.0	0.86 [0.74,1.01]	
FIGARO-DKD	461 / 3683	458 / 3658	56.0	1.00 [0.87,1.15]	
Total	800 / 6510	845 / 6489		0.94 [0.84,1.04]	Z=-1.26, p=0.2091
Heterogeneity:	Q=1.99 (df=1)	p=0.1587	I^2=49.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.20: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set

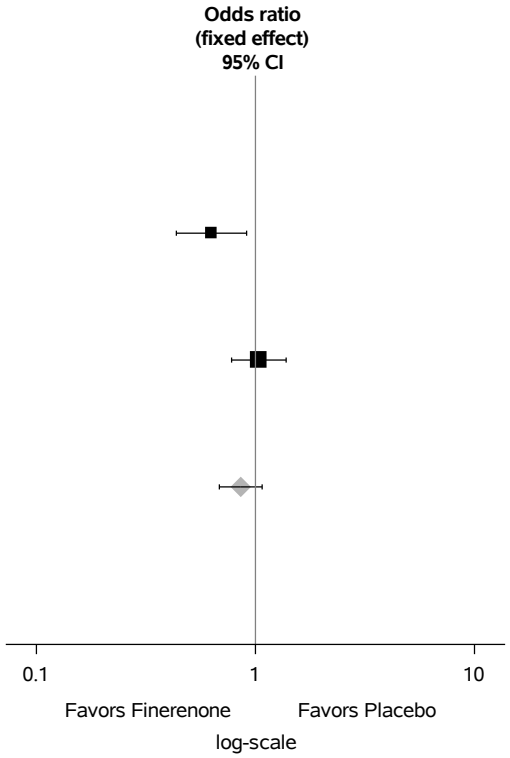
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	126 / 2831	44.6	1.00 [0.78,1.29]	
FIGARO-DKD	153 / 3683	159 / 3658	55.4	0.95 [0.76,1.20]	
Total	279 / 6510	285 / 6489		0.97 [0.82,1.15]	Z=-0.30, p=0.7669
Heterogeneity:	Q=0.08 (df=1)	p=0.7783	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.21: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set

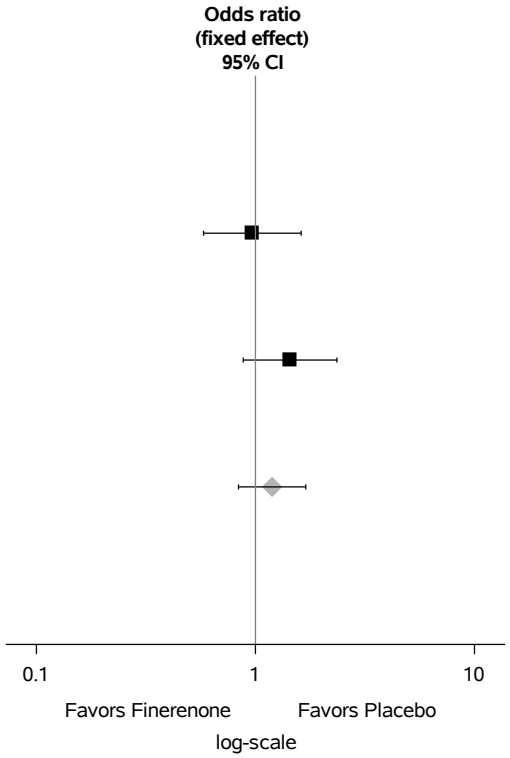
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	74 / 2831	37.6	0.63 [0.44,0.91]	
FIGARO-DKD	98 / 3683	94 / 3658	62.4	1.04 [0.78,1.38]	
Total	145 / 6510	168 / 6489		0.86 [0.68,1.07]	Z=-1.35, p=0.1778
Heterogeneity:	Q=4.36 (df=1)	p=0.0368	I^2=77.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.22: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set

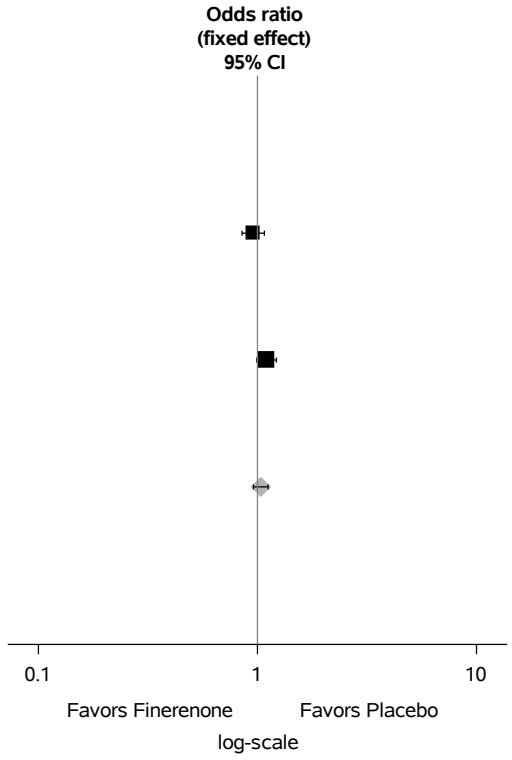
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	48.0	0.97 [0.58,1.62]	
FIGARO-DKD	39 / 3683	27 / 3658	52.0	1.44 [0.88,2.36]	
Total	68 / 6510	57 / 6489		1.19 [0.84,1.70]	Z=0.97, p=0.3315
Heterogeneity:	Q=1.20 (df=1)	p=0.2741	I^2=16.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.23: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

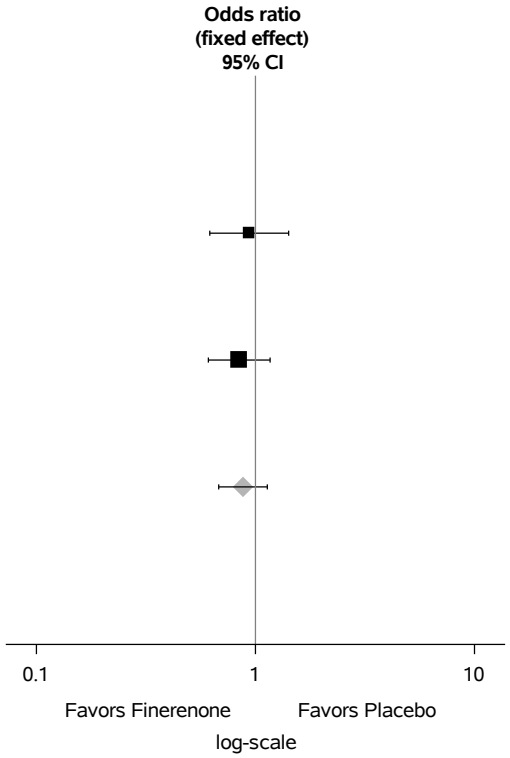
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	747 / 2827	773 / 2831	43.6	0.96 [0.85,1.08]	
FIGARO-DKD	1023 / 3683	947 / 3658	56.4	1.10 [0.99,1.22]	
Total	1770 / 6510	1720 / 6489		1.04 [0.96,1.12]	Z=0.88, p=0.3799
Heterogeneity:	Q=3.12 (df=1)	p=0.0774	I^2=67.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.24: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set

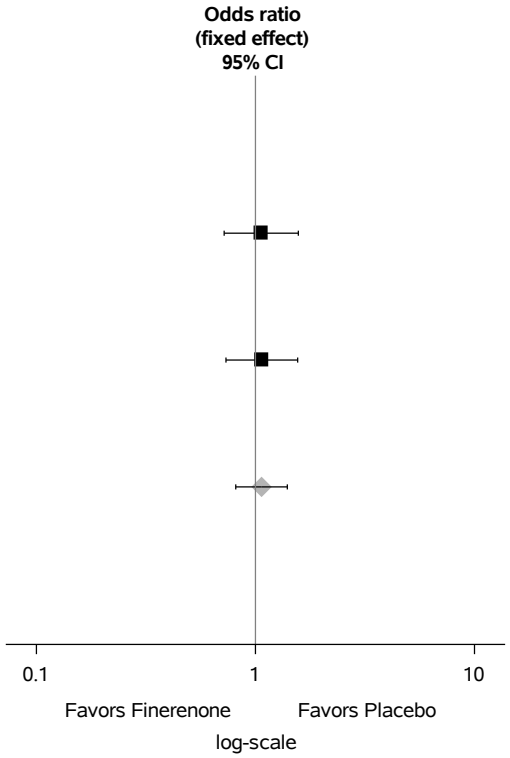
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	47 / 2831	38.0	0.94 [0.62,1.42]	
FIGARO-DKD	69 / 3683	81 / 3658	62.0	0.84 [0.61,1.17]	
Total	113 / 6510	128 / 6489		0.88 [0.68,1.13]	Z=-1.00, p=0.3155
Heterogeneity:	Q=0.15 (df=1)	p=0.6957	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.25: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set

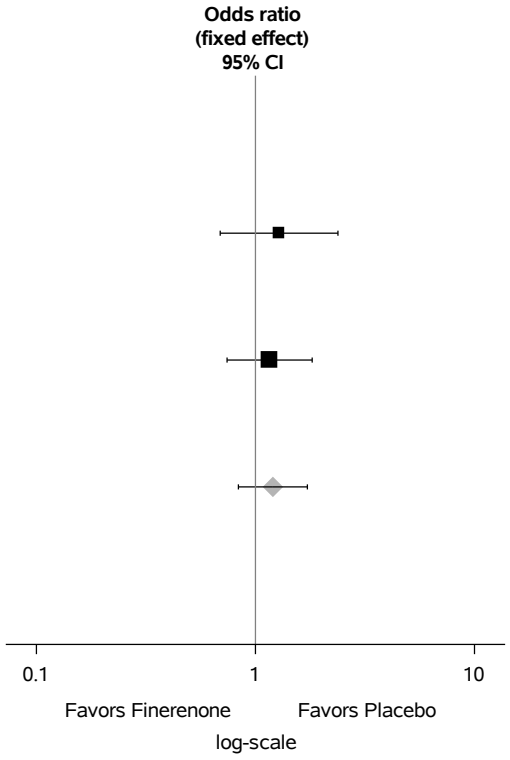
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	50 / 2831	48.3	1.06 [0.72,1.57]	
FIGARO-DKD	57 / 3683	53 / 3658	51.7	1.07 [0.73,1.56]	
Total	110 / 6510	103 / 6489		1.07 [0.81,1.40]	Z=0.46, p=0.6436
Heterogeneity:	Q=0.00 (df=1)	p=0.9822	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.26: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic gastritis (PT with Incidence >=1%)
Safety Analysis Set

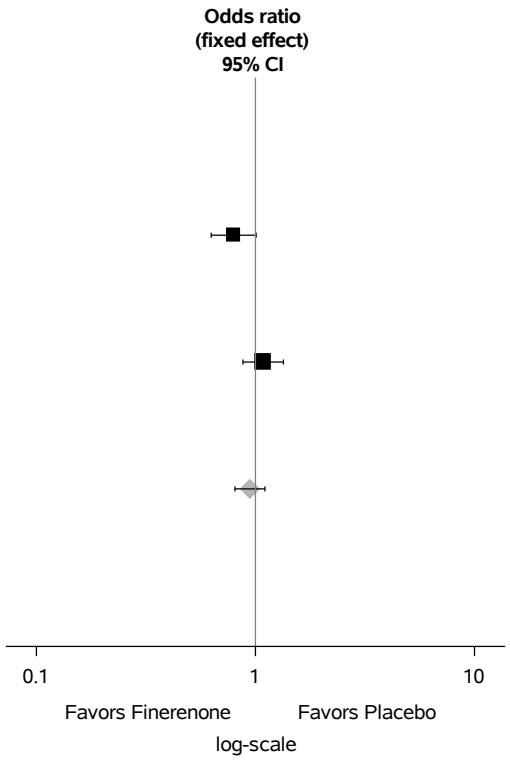
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	18 / 2831	34.3	1.28 [0.69,2.38]	
FIGARO-DKD	42 / 3683	36 / 3658	65.7	1.16 [0.74,1.82]	
Total	65 / 6510	54 / 6489		1.20 [0.84,1.73]	Z=0.99, p=0.3222
Heterogeneity:	Q=0.07 (df=1)	p=0.7987	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.27: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set

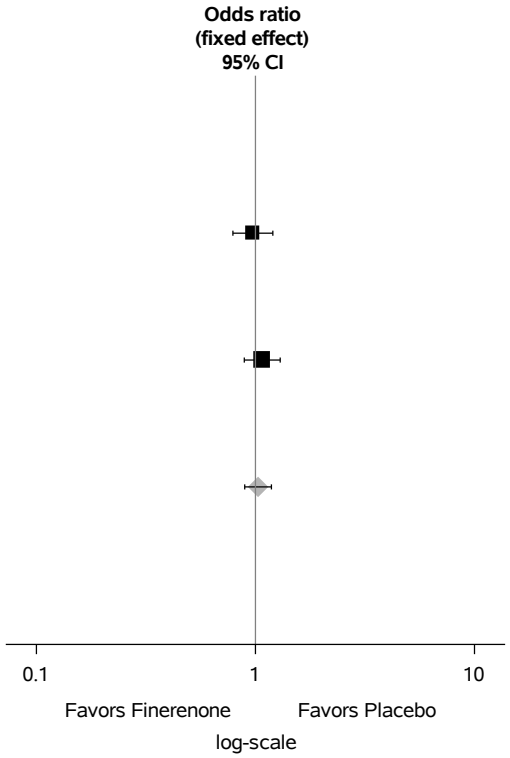
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	131 / 2827	163 / 2831	44.8	0.80 [0.63,1.01]	
FIGARO-DKD	186 / 3683	171 / 3658	55.2	1.08 [0.88,1.34]	
Total	317 / 6510	334 / 6489		0.94 [0.81,1.10]	Z=-0.72, p=0.4690
Heterogeneity:	Q=3.66 (df=1)	p=0.0558	I^2=72.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.28: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set

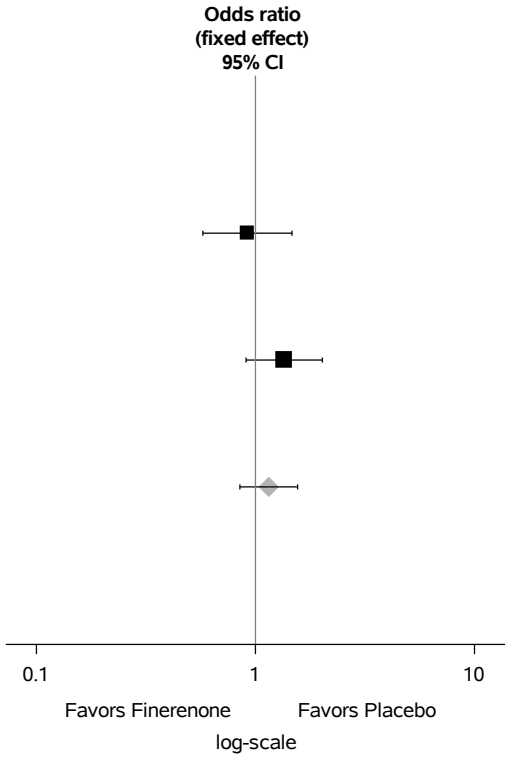
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	184 / 2827	189 / 2831	44.7	0.97 [0.79,1.20]	
FIGARO-DKD	239 / 3683	222 / 3658	55.3	1.07 [0.89,1.30]	
Total	423 / 6510	411 / 6489		1.03 [0.89,1.18]	Z=0.38, p=0.7019
Heterogeneity:	Q=0.47 (df=1)	p=0.4935	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.29: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set

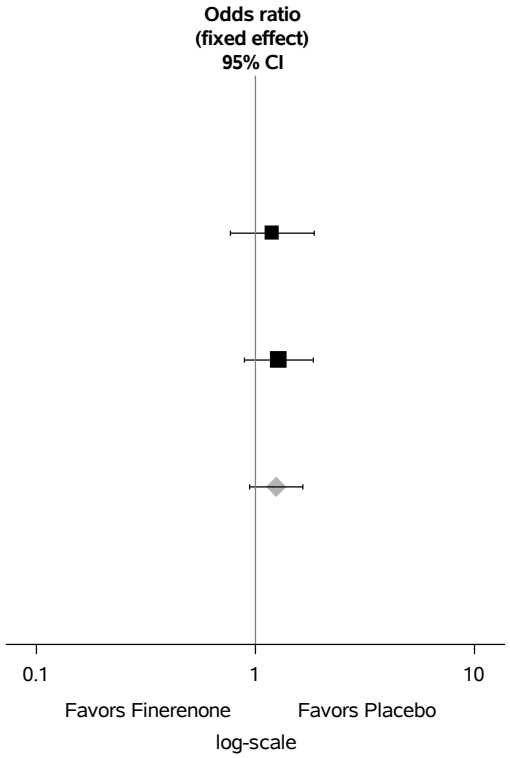
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	37 / 2831	42.3	0.92 [0.58,1.47]	
FIGARO-DKD	57 / 3683	42 / 3658	57.7	1.35 [0.91,2.02]	
Total	91 / 6510	79 / 6489		1.15 [0.85,1.56]	Z=0.90, p=0.3662
Heterogeneity:	Q=1.51 (df=1)	p=0.2191	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.30: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set

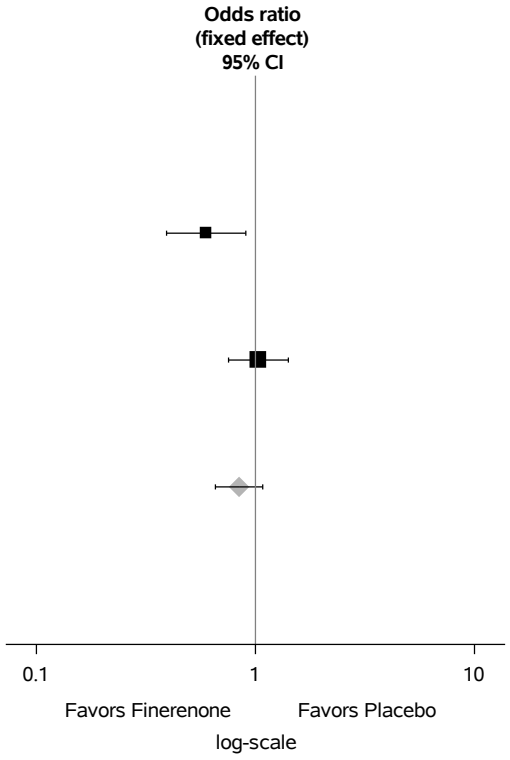
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	37 / 2831	40.3	1.19 [0.77,1.85]	
FIGARO-DKD	68 / 3683	53 / 3658	59.7	1.28 [0.89,1.84]	
Total	112 / 6510	90 / 6489		1.24 [0.94,1.65]	Z=1.53, p=0.1255
Heterogeneity:	Q=0.06 (df=1)	p=0.8119	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.31: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set

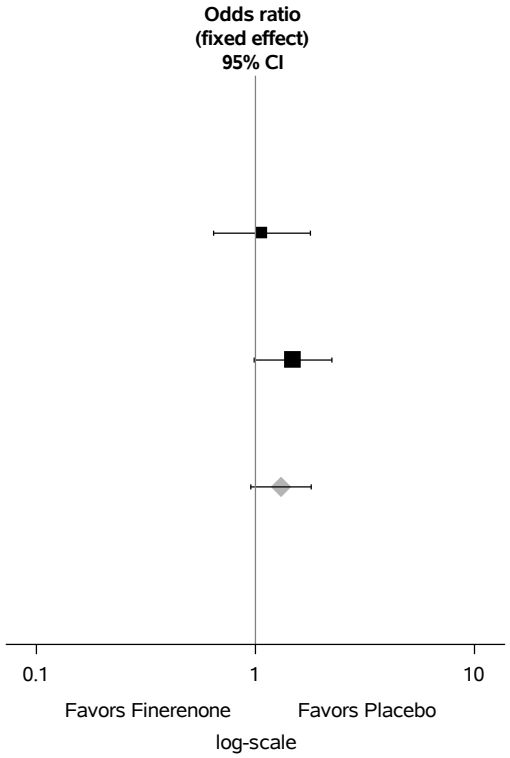
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	60 / 2831	36.3	0.60 [0.39,0.90]	
FIGARO-DKD	81 / 3683	78 / 3658	63.7	1.03 [0.75,1.41]	
Total	117 / 6510	138 / 6489		0.84 [0.66,1.08]	Z=-1.36, p=0.1749
Heterogeneity:	Q=4.26 (df=1)	p=0.0390	I^2=76.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.32: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set

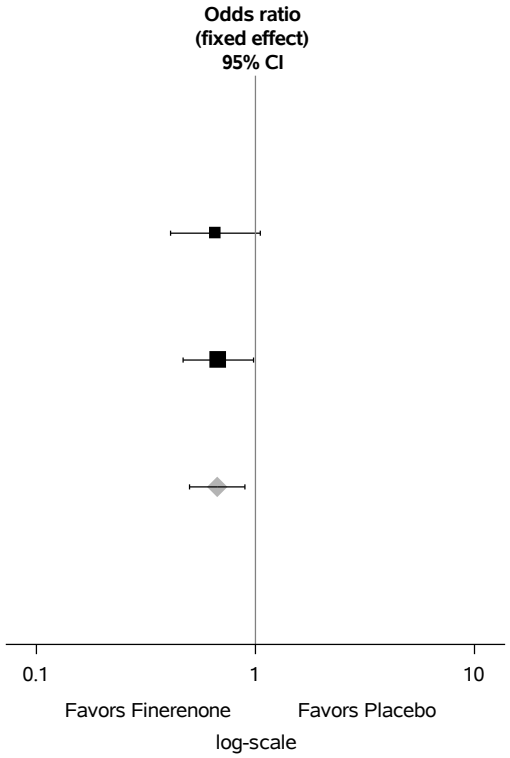
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	29 / 2831	39.2	1.07 [0.64,1.78]	
FIGARO-DKD	58 / 3683	39 / 3658	60.8	1.48 [0.99,2.23]	
Total	89 / 6510	68 / 6489		1.31 [0.95,1.80]	Z=1.66, p=0.0972
Heterogeneity:	Q=0.96 (df=1)	p=0.3270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.33: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

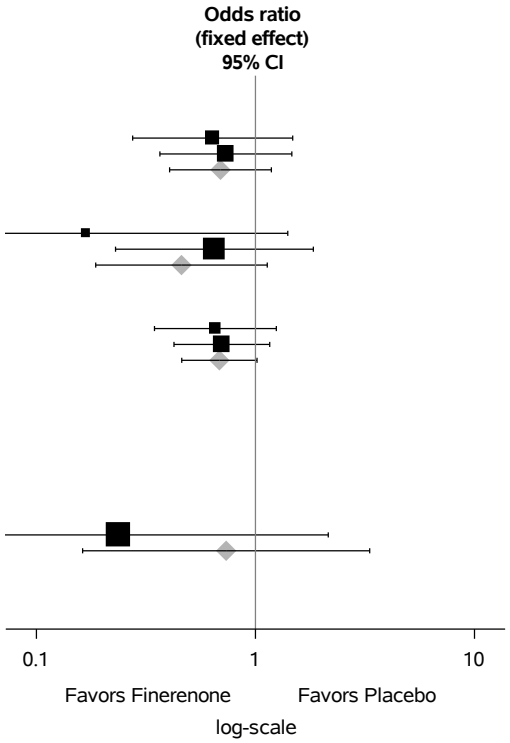
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	44 / 2831	38.1	0.66 [0.41,1.05]	
FIGARO-DKD	48 / 3683	70 / 3658	61.9	0.68 [0.47,0.98]	
Total	77 / 6510	114 / 6489		0.67 [0.50,0.90]	Z=-2.71, p=0.0068
Heterogeneity:	Q=0.01 (df=1)	p=0.9205	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.33.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

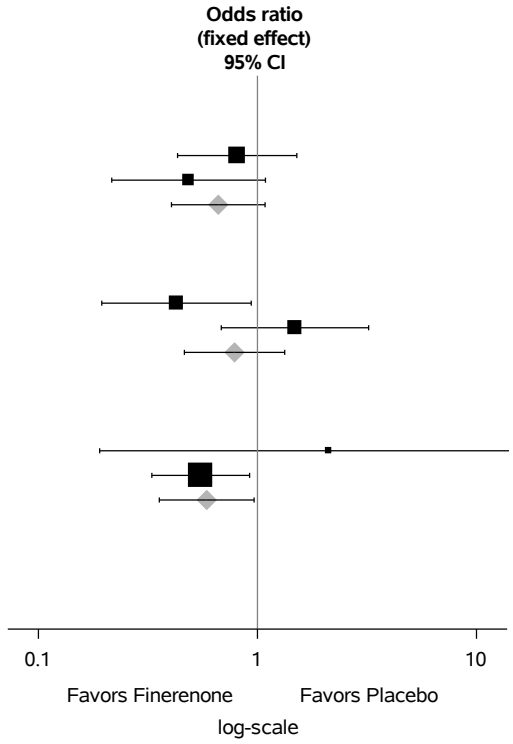
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1178	14 / 1174	40.5	0.64 [0.28,1.48]	
FIGARO-DKD	14 / 1752	19 / 1747	59.5	0.73 [0.37,1.47]	
Total	23 / 2930	33 / 2921		0.69 [0.41,1.18]	Z=-1.35, p=0.1780
Heterogeneity:	Q=0.06 (df=1)	p=0.8035	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 466	6 / 476	19.4	0.17 [0.02,1.40]	
FIGARO-DKD	6 / 559	9 / 548	80.6	0.65 [0.23,1.84]	
Total	7 / 1025	15 / 1024		0.46 [0.19,1.13]	Z=-1.69, p=0.0910
Heterogeneity:	Q=1.29 (df=1)	p=0.2567	I^2=22.3%		
Asia					
FIDELIO-DKD	16 / 790	24 / 786	38.2	0.66 [0.35,1.25]	
FIGARO-DKD	27 / 811	38 / 813	61.8	0.70 [0.42,1.16]	
Total	43 / 1601	62 / 1599		0.68 [0.46,1.02]	Z=-1.88, p=0.0603
Heterogeneity:	Q=0.03 (df=1)	p=0.8704	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	0 / 294	0.0	143E9 [143E9,143E9]	
FIGARO-DKD	0 / 424	0 / 417	0.0	-	
Total	1 / 718	0 / 711		351E9 [351E9,351E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	117E9 [117E9,117E9]	
FIGARO-DKD	1 / 137	4 / 133	100.0	0.24 [0.03,2.15]	
Total	3 / 236	4 / 234		0.73 [0.16,3.32]	Z=-0.40, p=0.6890
Heterogeneity:	Q=1.01 (df=1)	p=0.3146	I^2=1.1%		
Subgroup Heterogeneity:	Q=0.70 (df=4)	p=0.9511	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.33.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

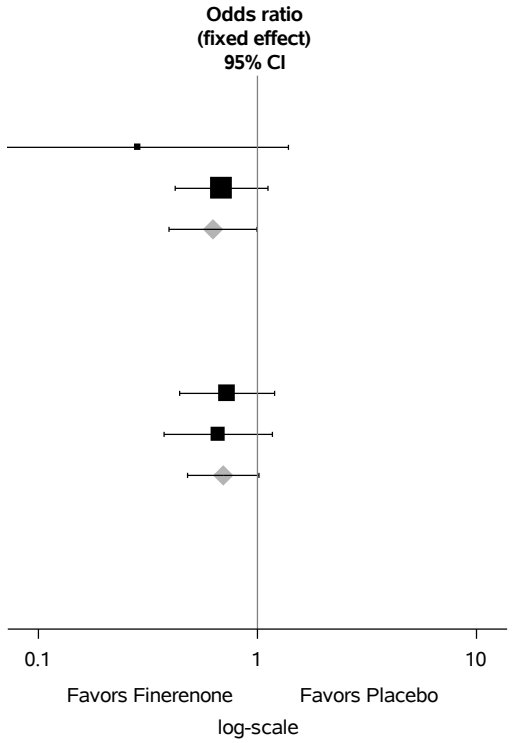
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	18 / 1556	22 / 1541	62.4	0.81 [0.43,1.51]	
FIGARO-DKD	9 / 637	18 / 627	37.6	0.48 [0.22,1.09]	
Total	27 / 2193	40 / 2168		0.66 [0.40,1.08]	Z=-1.64, p=0.1009
Heterogeneity:	Q=0.96 (df=1)	p=0.3274	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	21 / 1069	49.3	0.43 [0.19,0.94]	
FIGARO-DKD	16 / 720	11 / 729	50.7	1.48 [0.68,3.22]	
Total	25 / 1781	32 / 1798		0.79 [0.46,1.33]	Z=-0.90, p=0.3706
Heterogeneity:	Q=4.90 (df=1)	p=0.0268	I^2=79.6%		
>= 60					
FIDELIO-DKD	2 / 210	1 / 221	4.4	2.12 [0.19,23.50]	
FIGARO-DKD	23 / 2326	41 / 2302	95.6	0.55 [0.33,0.92]	
Total	25 / 2536	42 / 2523		0.59 [0.36,0.97]	Z=-2.10, p=0.0359
Heterogeneity:	Q=1.15 (df=1)	p=0.2840	I^2=12.9%		
Subgroup Heterogeneity:	Q=0.63 (df=2)	p=0.7307	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.33.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

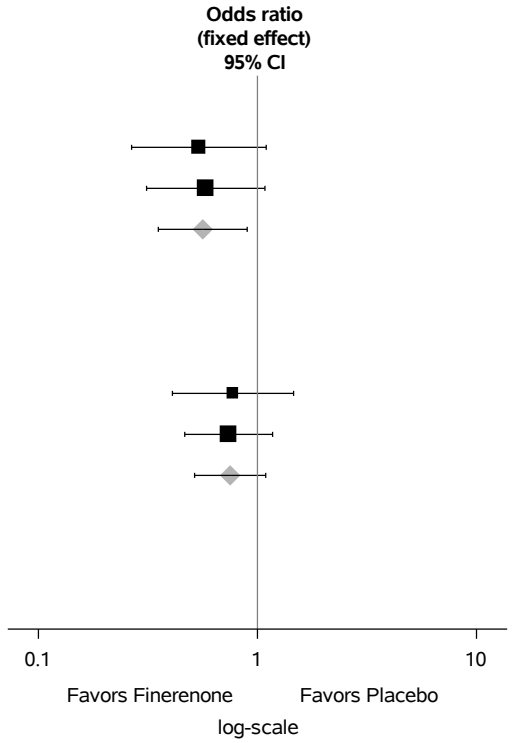
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	7 / 213	8.7	0.28 [0.06,1.38]	
FIGARO-DKD	28 / 1720	40 / 1698	91.3	0.69 [0.42,1.12]	
Total	30 / 1929	47 / 1911		0.63 [0.39,1.00]	Z=-1.98, p=0.0476
Heterogeneity:	Q=1.09 (df=1)	p=0.2967	I^2=8.2%		
Very High					
FIDELIO-DKD	27 / 2618	37 / 2618	56.5	0.73 [0.44,1.20]	
FIGARO-DKD	20 / 1963	30 / 1960	43.5	0.66 [0.37,1.17]	
Total	47 / 4581	67 / 4578		0.70 [0.48,1.02]	Z=-1.88, p=0.0603
Heterogeneity:	Q=0.06 (df=1)	p=0.8093	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7230	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.33.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

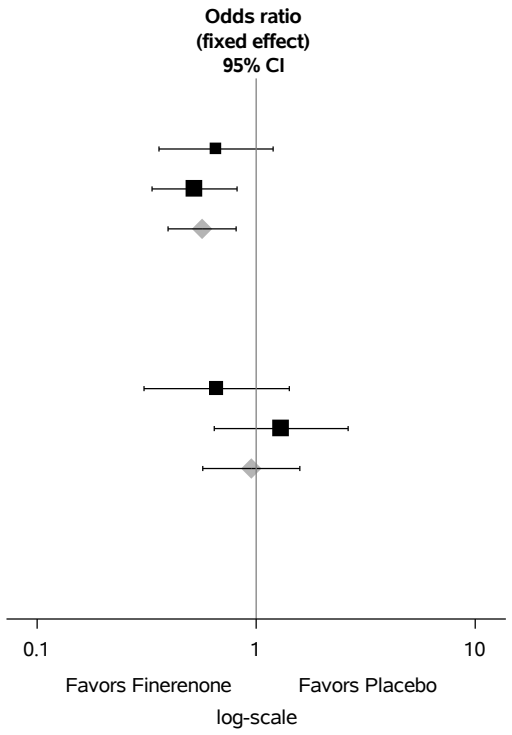
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	12 / 1301	22 / 1299	43.6	0.54 [0.27,1.10]	
FIGARO-DKD	16 / 1673	27 / 1651	56.4	0.58 [0.31,1.08]	
Total	28 / 2974	49 / 2950		0.56 [0.35,0.90]	Z=-2.41, p=0.0158
Heterogeneity:	Q=0.02 (df=1)	p=0.8807	I^2=0.0%		
Absent					
FIDELIO-DKD	17 / 1526	22 / 1532	34.5	0.77 [0.41,1.46]	
FIGARO-DKD	32 / 2010	43 / 2007	65.5	0.74 [0.47,1.17]	
Total	49 / 3536	65 / 3539		0.75 [0.52,1.09]	Z=-1.50, p=0.1325
Heterogeneity:	Q=0.01 (df=1)	p=0.9099	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3454	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.33.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

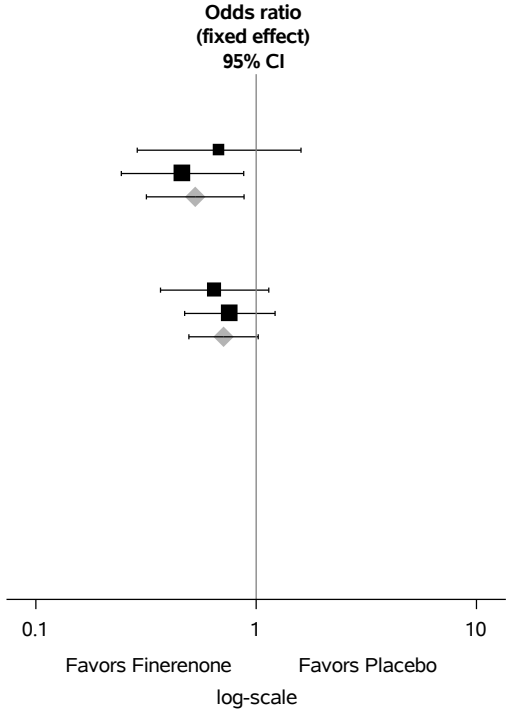
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	18 / 1879	27 / 1858	35.7	0.66 [0.36,1.20]	
FIGARO-DKD	30 / 2643	56 / 2608	64.3	0.52 [0.33,0.82]	
Total	48 / 4522	83 / 4466		0.57 [0.40,0.81]	Z=-3.11, p=0.0018
Heterogeneity:	Q=0.35 (df=1)	p=0.5536	I^2=0.0%		
> 4.5					
FIDELIO-DKD	11 / 948	17 / 973	45.9	0.66 [0.31,1.42]	
FIGARO-DKD	18 / 1040	14 / 1048	54.1	1.30 [0.64,2.63]	
Total	29 / 1988	31 / 2021		0.95 [0.57,1.58]	Z=-0.20, p=0.8440
Heterogeneity:	Q=1.64 (df=1)	p=0.2005	I^2=39.0%		
Subgroup Heterogeneity:	Q=2.65 (df=1)	p=0.1038	I^2=62.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.33.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

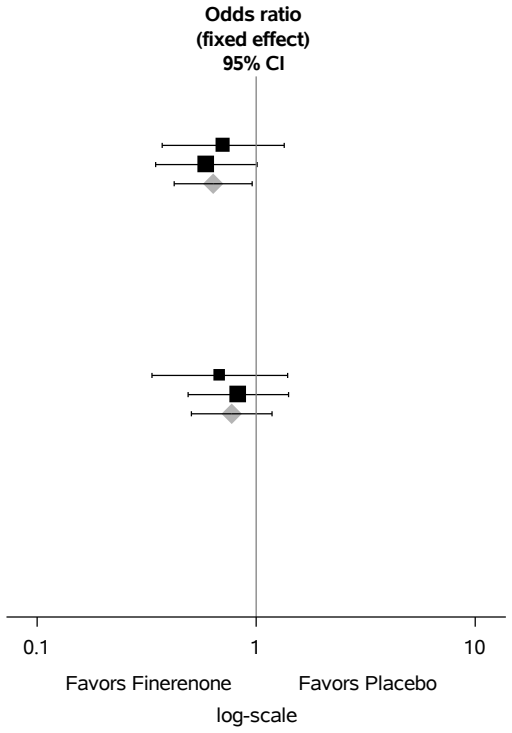
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 788	13 / 777	35.8	0.68 [0.29,1.60]	
FIGARO-DKD	14 / 1187	30 / 1194	64.2	0.46 [0.24,0.88]	
Total	23 / 1975	43 / 1971		0.53 [0.32,0.88]	Z=-2.45, p=0.0144
Heterogeneity:	Q=0.49 (df=1)	p=0.4825	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	20 / 1897	31 / 1916	41.1	0.65 [0.37,1.14]	
FIGARO-DKD	31 / 2389	40 / 2351	58.9	0.76 [0.47,1.22]	
Total	51 / 4286	71 / 4267		0.71 [0.50,1.02]	Z=-1.84, p=0.0652
Heterogeneity:	Q=0.18 (df=1)	p=0.6725	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	0 / 138	0.0	-	
FIGARO-DKD	3 / 107	0 / 113	0.0	163E9 [163E9,163E9]	
Total	3 / 248	0 / 251		443E9 [443E9,443E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.86 (df=2)	p=0.6505	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.33.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

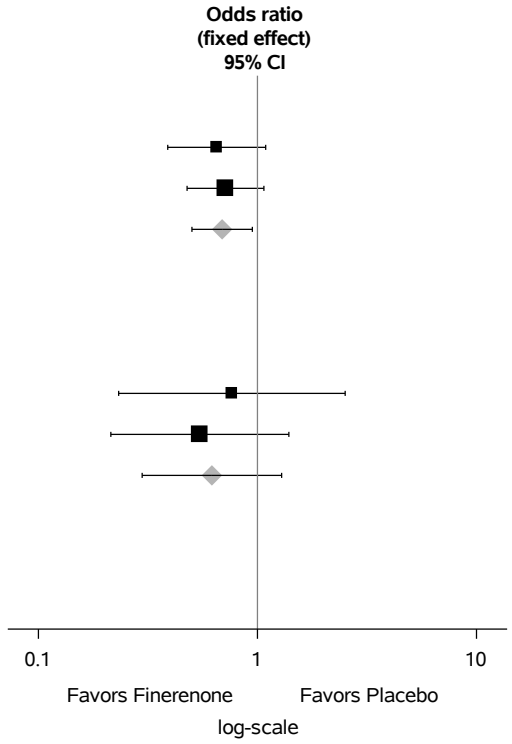
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	16 / 1773	23 / 1809	40.9	0.71 [0.37,1.34]	
FIGARO-DKD	22 / 2668	36 / 2601	59.1	0.59 [0.35,1.01]	
Total	38 / 4441	59 / 4410		0.64 [0.42,0.96]	Z=-2.16, p=0.0307
Heterogeneity:	Q=0.17 (df=1)	p=0.6774	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 139	1 / 124	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	0 / 113	1 / 145	0.0	0.00 [0.00,17E296]	
Total	0 / 252	2 / 269		0.00 [0.00,15E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	13 / 717	19 / 721	35.4	0.68 [0.33,1.39]	
FIGARO-DKD	26 / 716	32 / 736	64.6	0.83 [0.49,1.41]	
Total	39 / 1433	51 / 1457		0.77 [0.51,1.18]	Z=-1.19, p=0.2346
Heterogeneity:	Q=0.19 (df=1)	p=0.6670	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	1 / 177	0.0	0.00 [0.00,21E296]	
FIGARO-DKD	0 / 186	1 / 176	0.0	0.00 [0.00,2E297]	
Total	0 / 384	2 / 353		0.00 [0.00,2E297]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.42 (df=3)	p=0.9362	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.33.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

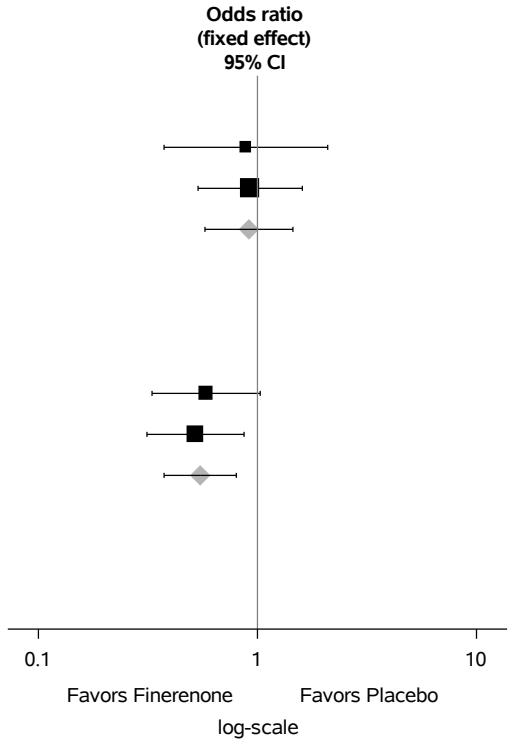
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 1949	38 / 2024	38.1	0.65 [0.39,1.09]	
FIGARO-DKD	41 / 2527	58 / 2571	61.9	0.71 [0.48,1.07]	
Total	65 / 4476	96 / 4595		0.69 [0.50,0.95]	Z=-2.29, p=0.0219
Heterogeneity:	Q=0.08 (df=1)	p=0.7822	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 878	6 / 807	38.2	0.76 [0.23,2.52]	
FIGARO-DKD	7 / 1156	12 / 1087	61.8	0.55 [0.21,1.39]	
Total	12 / 2034	18 / 1894		0.62 [0.30,1.29]	Z=-1.28, p=0.2003
Heterogeneity:	Q=0.19 (df=1)	p=0.6625	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7917	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.33.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set

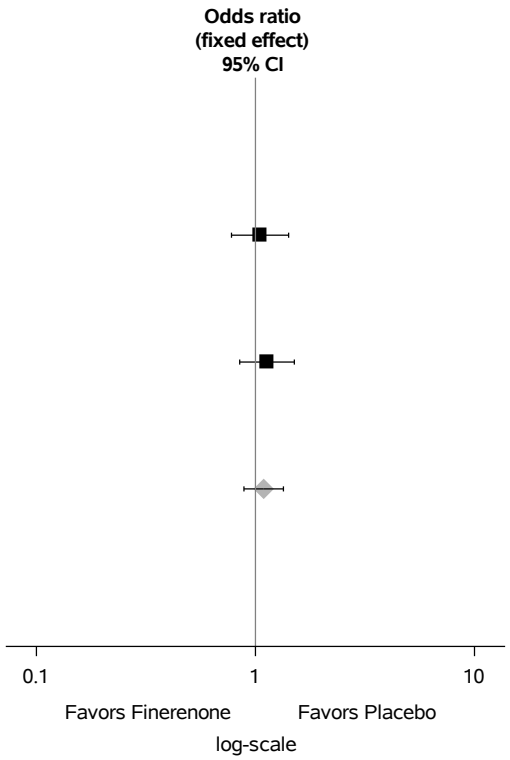
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1201	11 / 1171	28.9	0.89 [0.37,2.09]	
FIGARO-DKD	25 / 1752	27 / 1755	71.1	0.93 [0.54,1.60]	
Total	35 / 2953	38 / 2926		0.91 [0.58,1.45]	Z=-0.38, p=0.7044
Heterogeneity:	Q=0.01 (df=1)	p=0.9306	I^2=0.0%		
>= 65					
FIDELIO-DKD	19 / 1626	33 / 1660	44.6	0.58 [0.33,1.03]	
FIGARO-DKD	23 / 1931	43 / 1903	55.4	0.52 [0.31,0.87]	
Total	42 / 3557	76 / 3563		0.55 [0.37,0.80]	Z=-3.11, p=0.0019
Heterogeneity:	Q=0.08 (df=1)	p=0.7749	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.82 (df=1)	p=0.0932	I^2=64.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.34: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set

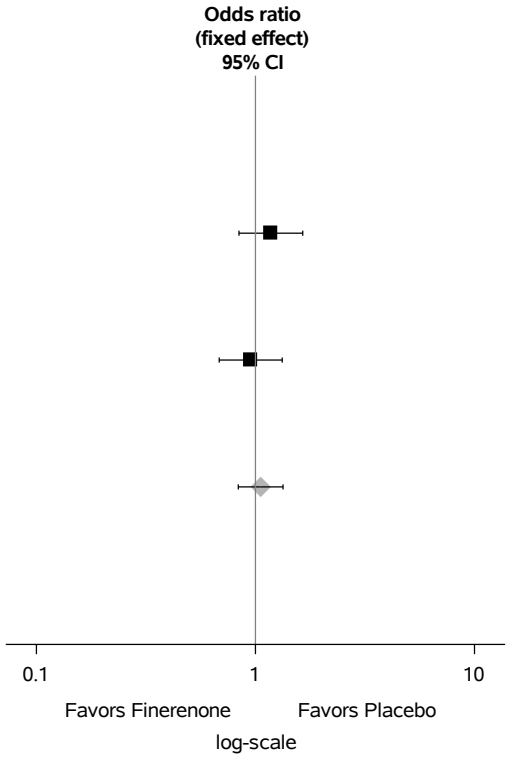
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	90 / 2827	86 / 2831	47.8	1.05 [0.78,1.42]	
FIGARO-DKD	102 / 3683	90 / 3658	52.2	1.13 [0.85,1.50]	
Total	192 / 6510	176 / 6489		1.09 [0.89,1.34]	Z=0.82, p=0.4134
Heterogeneity:	Q=0.12 (df=1)	p=0.7301	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.35: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set

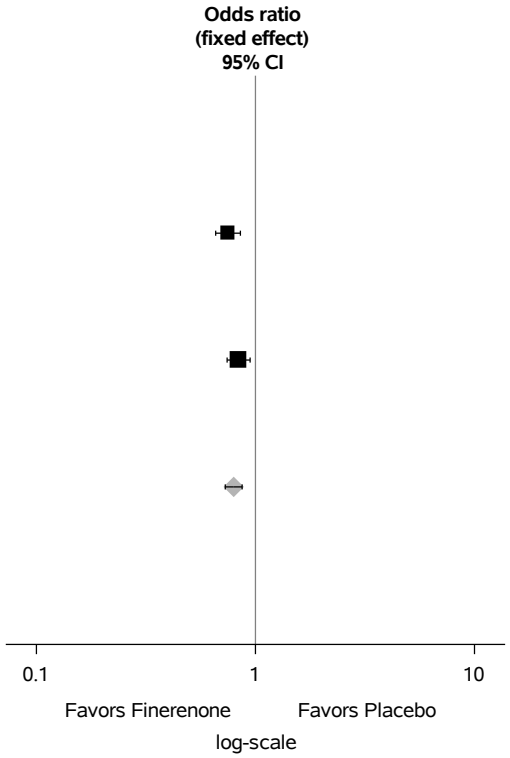
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	76 / 2827	65 / 2831	49.4	1.18 [0.84,1.64]	
FIGARO-DKD	70 / 3683	73 / 3658	50.6	0.95 [0.68,1.32]	
Total	146 / 6510	138 / 6489		1.06 [0.83,1.34]	Z=0.46, p=0.6478
Heterogeneity:	Q=0.77 (df=1)	p=0.3790	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.36: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

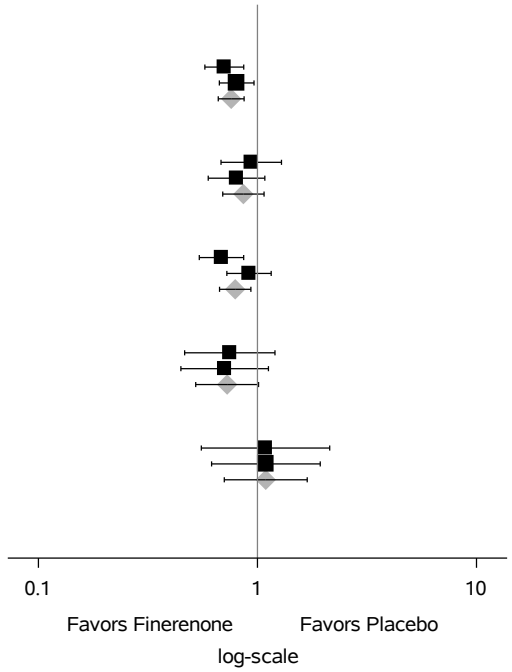
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	512 / 2827	645 / 2831	46.4	0.75 [0.66,0.85]	
FIGARO-DKD	595 / 3683	684 / 3658	53.6	0.84 [0.74,0.95]	
Total	1107 / 6510	1329 / 6489		0.80 [0.73,0.87]	Z=-5.07, p=<.0001
Heterogeneity:	Q=1.51 (df=1)	p=0.2191	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.36.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

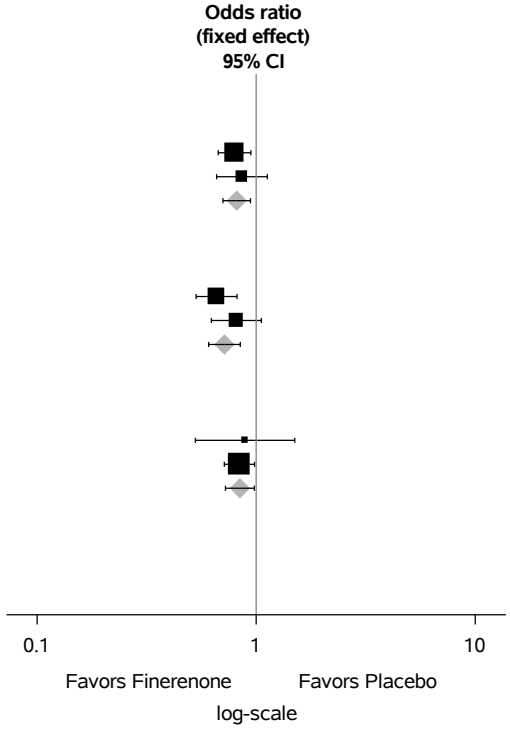
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	201 / 1178	265 / 1174	44.3	0.71 [0.58,0.87]	
FIGARO-DKD	252 / 1752	302 / 1747	55.7	0.80 [0.67,0.96]	
Total	453 / 2930	567 / 2921		0.76 [0.66,0.87]	Z=-3.98, p=<.0001
Heterogeneity:	Q=0.87 (df=1)	p=0.3512	I^2=0.0%		
North America					
FIDELIO-DKD	92 / 466	99 / 476	46.7	0.94 [0.68,1.29]	
FIGARO-DKD	100 / 559	117 / 548	53.3	0.80 [0.60,1.08]	
Total	192 / 1025	216 / 1024		0.86 [0.69,1.07]	Z=-1.33, p=0.1821
Heterogeneity:	Q=0.48 (df=1)	p=0.4864	I^2=0.0%		
Asia					
FIDELIO-DKD	162 / 790	215 / 786	50.0	0.69 [0.54,0.87]	
FIGARO-DKD	176 / 811	189 / 813	50.0	0.92 [0.72,1.16]	
Total	338 / 1601	404 / 1599		0.79 [0.67,0.93]	Z=-2.78, p=0.0054
Heterogeneity:	Q=2.96 (df=1)	p=0.0854	I^2=66.2%		
Latin America					
FIDELIO-DKD	35 / 294	45 / 294	48.4	0.75 [0.47,1.20]	
FIGARO-DKD	35 / 424	47 / 417	51.6	0.71 [0.45,1.12]	
Total	70 / 718	92 / 711		0.73 [0.52,1.01]	Z=-1.89, p=0.0587
Heterogeneity:	Q=0.03 (df=1)	p=0.8724	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 99	21 / 101	41.7	1.09 [0.55,2.14]	
FIGARO-DKD	32 / 137	29 / 133	58.3	1.09 [0.62,1.93]	
Total	54 / 236	50 / 234		1.09 [0.71,1.69]	Z=0.39, p=0.6952
Heterogeneity:	Q=0.00 (df=1)	p=0.9927	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.30 (df=4)	p=0.5082	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.36.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

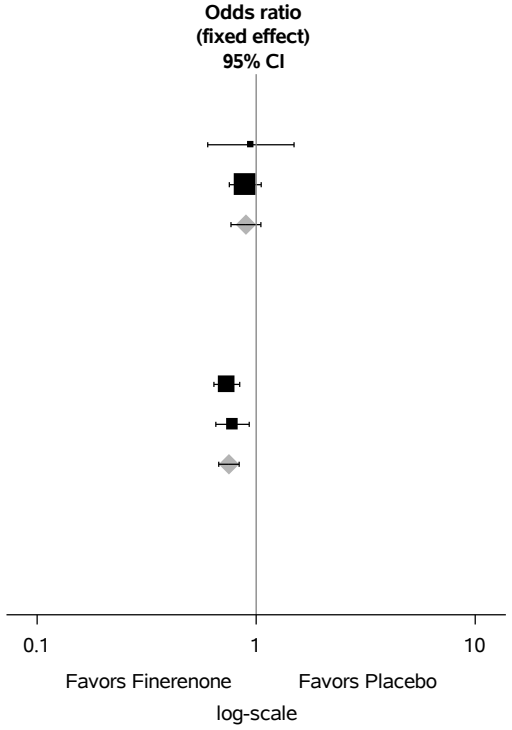
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	304 / 1556	360 / 1541	70.6	0.80 [0.67,0.95]	
FIGARO-DKD	132 / 637	146 / 627	29.4	0.86 [0.66,1.12]	
Total	436 / 2193	506 / 2168		0.82 [0.71,0.94]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.23 (df=1)	p=0.6300	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	177 / 1061	249 / 1069	59.9	0.66 [0.53,0.82]	
FIGARO-DKD	126 / 720	151 / 729	40.1	0.81 [0.62,1.06]	
Total	303 / 1781	400 / 1798		0.72 [0.61,0.85]	Z=-3.93, p=<.0001
Heterogeneity:	Q=1.44 (df=1)	p=0.2294	I^2=30.8%		
>= 60					
FIDELIO-DKD	31 / 210	36 / 221	8.5	0.89 [0.53,1.50]	
FIGARO-DKD	337 / 2326	387 / 2302	91.5	0.84 [0.72,0.98]	
Total	368 / 2536	423 / 2523		0.84 [0.72,0.98]	Z=-2.21, p=0.0273
Heterogeneity:	Q=0.05 (df=1)	p=0.8303	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.18 (df=2)	p=0.3358	I^2=8.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.36.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

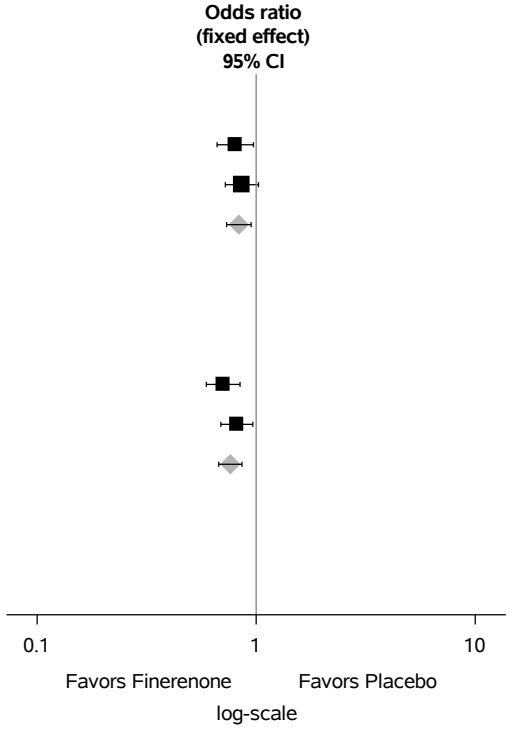
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	50 / 213	12.0	0.95 [0.60,1.49]	
FIGARO-DKD	329 / 1720	356 / 1698	88.0	0.89 [0.75,1.05]	
Total	376 / 1929	406 / 1911		0.90 [0.77,1.05]	Z=-1.34, p=0.1796
Heterogeneity:	Q=0.06 (df=1)	p=0.8110	I^2=0.0%		
Very High					
FIDELIO-DKD	465 / 2618	595 / 2618	62.6	0.73 [0.64,0.84]	
FIGARO-DKD	266 / 1963	328 / 1960	37.4	0.78 [0.65,0.93]	
Total	731 / 4581	923 / 4578		0.75 [0.67,0.84]	Z=-5.23, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5945	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.38 (df=1)	p=0.0658	I^2=70.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.36.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

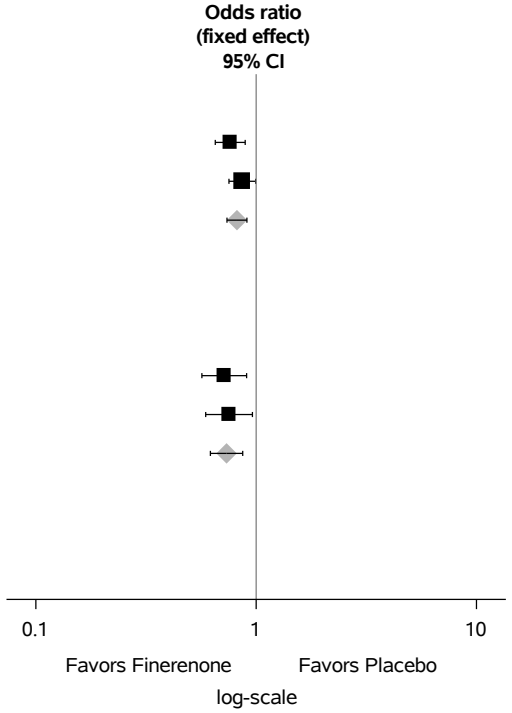
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	243 / 1301	289 / 1299	45.3	0.80 [0.66,0.97]	
FIGARO-DKD	296 / 1673	330 / 1651	54.7	0.86 [0.72,1.02]	
Total	539 / 2974	619 / 2950		0.83 [0.73,0.95]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.28 (df=1)	p=0.5981	I^2=0.0%		
Absent					
FIDELIO-DKD	269 / 1526	356 / 1532	47.4	0.71 [0.59,0.84]	
FIGARO-DKD	299 / 2010	354 / 2007	52.6	0.82 [0.69,0.97]	
Total	568 / 3536	710 / 3539		0.76 [0.67,0.86]	Z=-4.36, p=<.0001
Heterogeneity:	Q=1.33 (df=1)	p=0.2496	I^2=24.6%		
Subgroup Heterogeneity:	Q=0.98 (df=1)	p=0.3214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.36.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

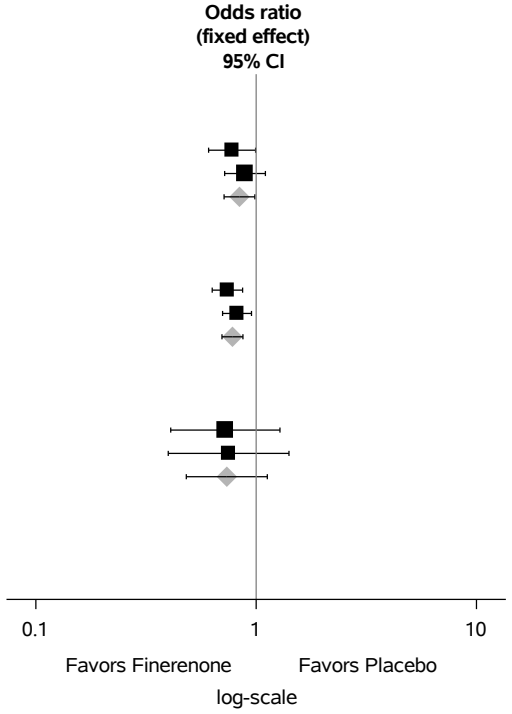
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	363 / 1879	444 / 1858	44.2	0.76 [0.65,0.89]	
FIGARO-DKD	461 / 2643	512 / 2608	55.8	0.86 [0.75,0.99]	
Total	824 / 4522	956 / 4466		0.82 [0.74,0.91]	Z=-3.78, p=0.0002
Heterogeneity:	Q=1.39 (df=1)	p=0.2389	I^2=27.9%		
> 4.5					
FIDELIO-DKD	149 / 948	201 / 973	52.2	0.72 [0.57,0.90]	
FIGARO-DKD	134 / 1040	172 / 1048	47.8	0.75 [0.59,0.96]	
Total	283 / 1988	373 / 2021		0.73 [0.62,0.87]	Z=-3.59, p=0.0003
Heterogeneity:	Q=0.09 (df=1)	p=0.7701	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.15 (df=1)	p=0.2828	I^2=13.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.36.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

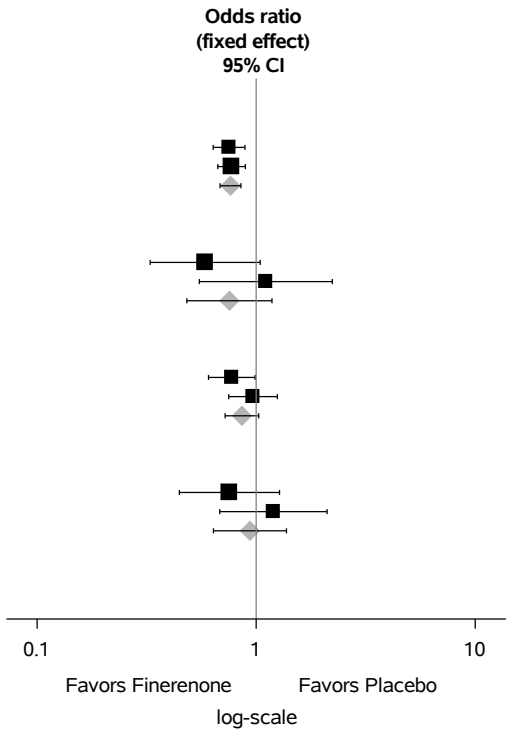
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	147 / 788	177 / 777	42.9	0.78 [0.61,0.99]	
FIGARO-DKD	195 / 1187	216 / 1194	57.1	0.89 [0.72,1.10]	
Total	342 / 1975	393 / 1971		0.84 [0.72,0.99]	Z=-2.13, p=0.0332
Heterogeneity:	Q=0.67 (df=1)	p=0.4142	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	338 / 1897	434 / 1916	47.5	0.74 [0.63,0.87]	
FIGARO-DKD	378 / 2389	439 / 2351	52.5	0.82 [0.70,0.95]	
Total	716 / 4286	873 / 4267		0.78 [0.70,0.87]	Z=-4.44, p=<.0001
Heterogeneity:	Q=0.81 (df=1)	p=0.3688	I^2=0.0%		
>= 160					
FIDELIO-DKD	27 / 141	34 / 138	55.0	0.72 [0.41,1.28]	
FIGARO-DKD	22 / 107	29 / 113	45.0	0.75 [0.40,1.41]	
Total	49 / 248	63 / 251		0.74 [0.48,1.12]	Z=-1.42, p=0.1553
Heterogeneity:	Q=0.01 (df=1)	p=0.9371	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.68 (df=2)	p=0.7107	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.36.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

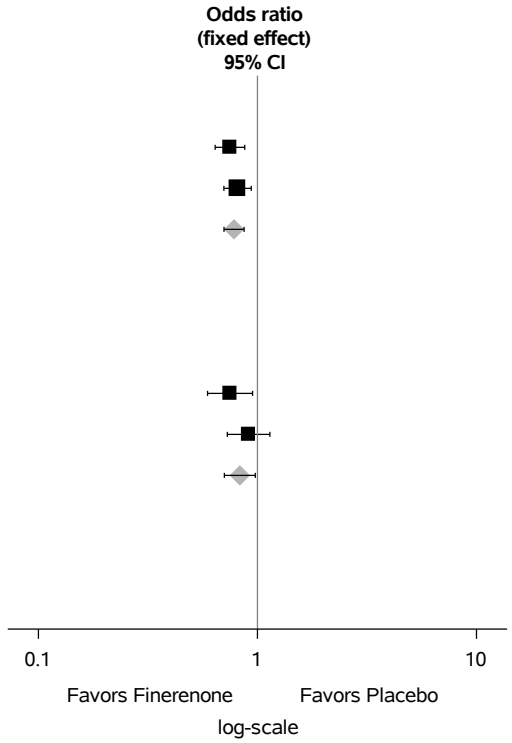
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	302 / 1773	388 / 1809	42.9	0.75 [0.64,0.89]	
FIGARO-DKD	402 / 2668	486 / 2601	57.1	0.77 [0.67,0.89]	
Total	704 / 4441	874 / 4410		0.76 [0.68,0.85]	Z=-4.84, p=<.0001
Heterogeneity:	Q=0.05 (df=1)	p=0.8147	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 139	35 / 124	59.4	0.59 [0.33,1.04]	
FIGARO-DKD	17 / 113	20 / 145	40.6	1.11 [0.55,2.23]	
Total	43 / 252	55 / 269		0.75 [0.48,1.18]	Z=-1.23, p=0.2181
Heterogeneity:	Q=1.90 (df=1)	p=0.1685	I^2=47.3%		
Asian					
FIDELIO-DKD	152 / 717	186 / 721	52.1	0.77 [0.61,0.99]	
FIGARO-DKD	144 / 716	152 / 736	47.9	0.97 [0.75,1.25]	
Total	296 / 1433	338 / 1457		0.86 [0.72,1.03]	Z=-1.66, p=0.0963
Heterogeneity:	Q=1.53 (df=1)	p=0.2164	I^2=34.6%		
Others					
FIDELIO-DKD	32 / 198	36 / 177	53.5	0.76 [0.45,1.28]	
FIGARO-DKD	32 / 186	26 / 176	46.5	1.20 [0.68,2.11]	
Total	64 / 384	62 / 353		0.94 [0.64,1.37]	Z=-0.33, p=0.7383
Heterogeneity:	Q=1.38 (df=1)	p=0.2403	I^2=27.5%		
Subgroup Heterogeneity:	Q=2.06 (df=3)	p=0.5597	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.36.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

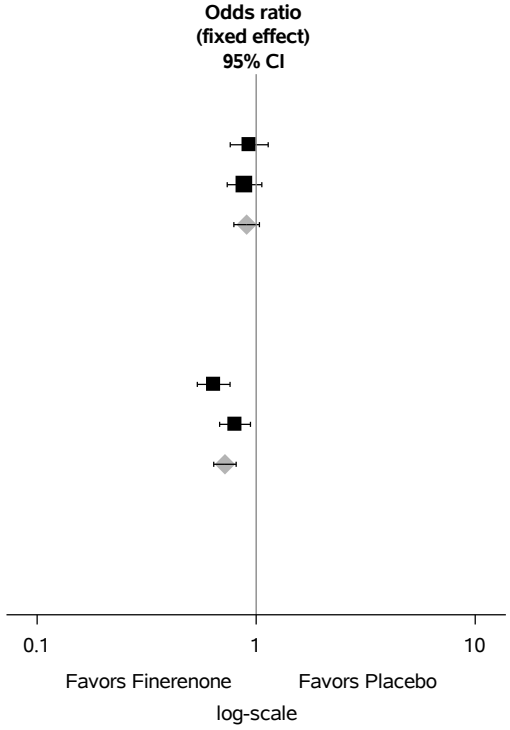
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	351 / 1949	459 / 2024	46.1	0.75 [0.64,0.87]	
FIGARO-DKD	413 / 2527	499 / 2571	53.9	0.81 [0.70,0.94]	
Total	764 / 4476	958 / 4595		0.78 [0.70,0.87]	Z=-4.57, p=<.0001
Heterogeneity:	Q=0.55 (df=1)	p=0.4596	I^2=0.0%		
Female					
FIDELIO-DKD	161 / 878	186 / 807	47.2	0.75 [0.59,0.95]	
FIGARO-DKD	182 / 1156	185 / 1087	52.8	0.91 [0.73,1.14]	
Total	343 / 2034	371 / 1894		0.83 [0.71,0.98]	Z=-2.23, p=0.0255
Heterogeneity:	Q=1.38 (df=1)	p=0.2409	I^2=27.3%		
Subgroup Heterogeneity:	Q=0.38 (df=1)	p=0.5383	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.36.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

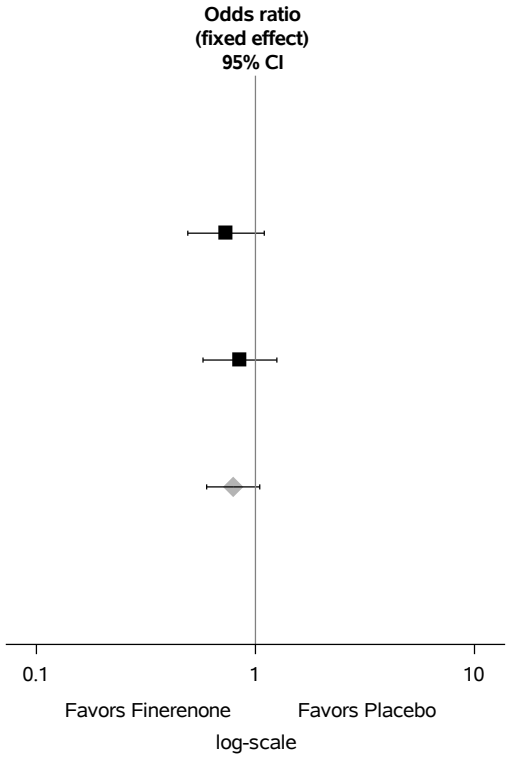
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	239 / 1201	247 / 1171	45.4	0.93 [0.76,1.13]	
FIGARO-DKD	262 / 1752	291 / 1755	54.6	0.88 [0.74,1.06]	
Total	501 / 2953	538 / 2926		0.90 [0.79,1.03]	Z=-1.46, p=0.1439
Heterogeneity:	Q=0.13 (df=1)	p=0.7200	I^2=0.0%		
>= 65					
FIDELIO-DKD	273 / 1626	398 / 1660	47.0	0.64 [0.54,0.76]	
FIGARO-DKD	333 / 1931	393 / 1903	53.0	0.80 [0.68,0.94]	
Total	606 / 3557	791 / 3563		0.72 [0.64,0.81]	Z=-5.46, p=<.0001
Heterogeneity:	Q=3.46 (df=1)	p=0.0629	I^2=71.1%		
Subgroup Heterogeneity:	Q=6.26 (df=1)	p=0.0124	I^2=84.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.37: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set

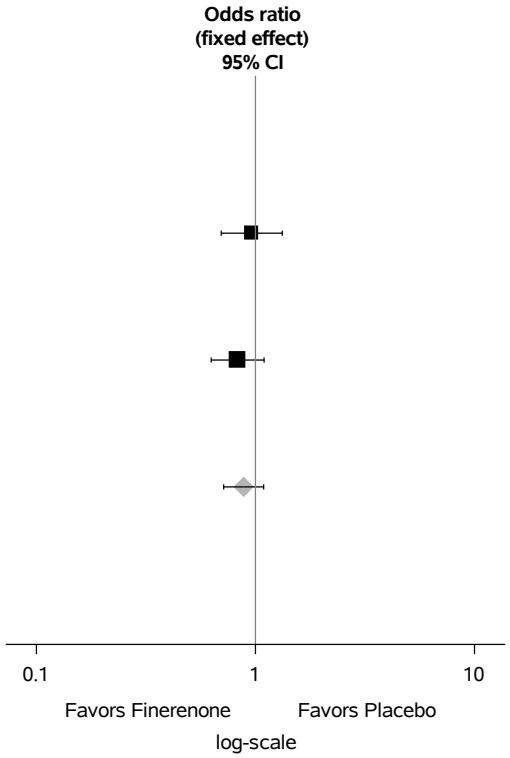
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	57 / 2831	48.3	0.73 [0.49,1.10]	
FIGARO-DKD	48 / 3683	56 / 3658	51.7	0.85 [0.58,1.25]	
Total	90 / 6510	113 / 6489		0.79 [0.60,1.05]	Z=-1.64, p=0.1002
Heterogeneity:	Q=0.26 (df=1)	p=0.6085	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.38: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set

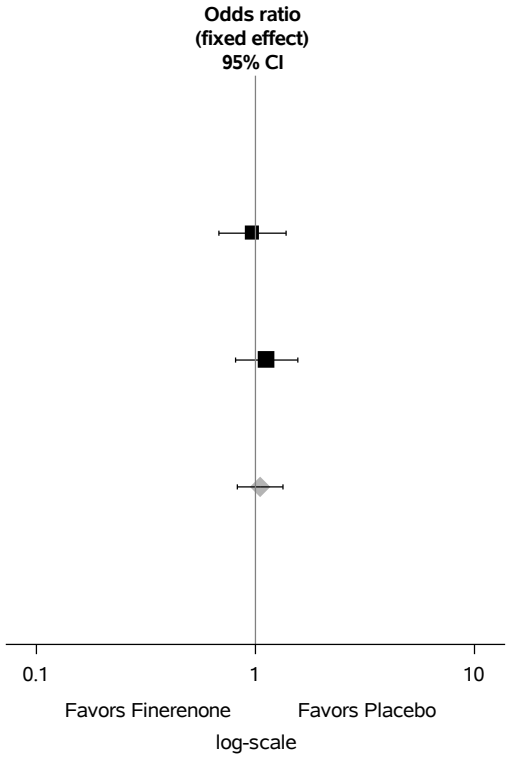
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	78 / 2831	42.8	0.96 [0.70,1.33]	
FIGARO-DKD	94 / 3683	112 / 3658	57.2	0.83 [0.63,1.10]	
Total	169 / 6510	190 / 6489		0.88 [0.72,1.09]	Z=-1.16, p=0.2481
Heterogeneity:	Q=0.47 (df=1)	p=0.4937	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.39: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set

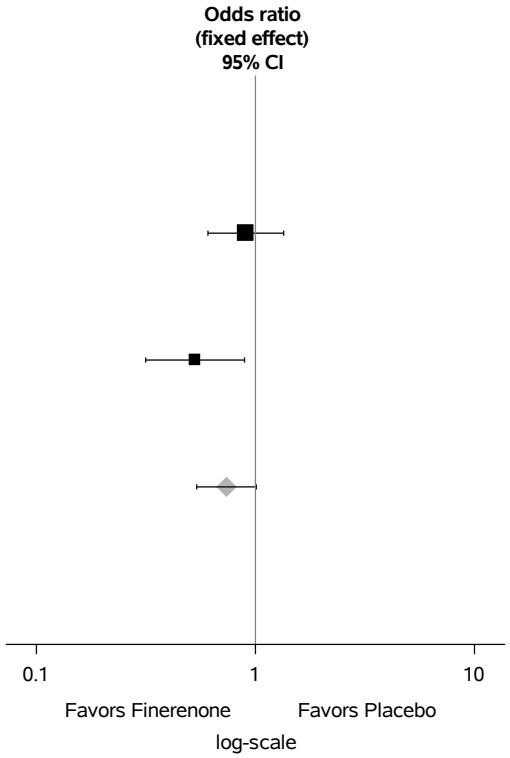
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	64 / 2831	46.2	0.97 [0.68,1.38]	
FIGARO-DKD	78 / 3683	69 / 3658	53.8	1.13 [0.81,1.56]	
Total	140 / 6510	133 / 6489		1.05 [0.83,1.34]	Z=0.40, p=0.6870
Heterogeneity:	Q=0.37 (df=1)	p=0.5437	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.40: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set

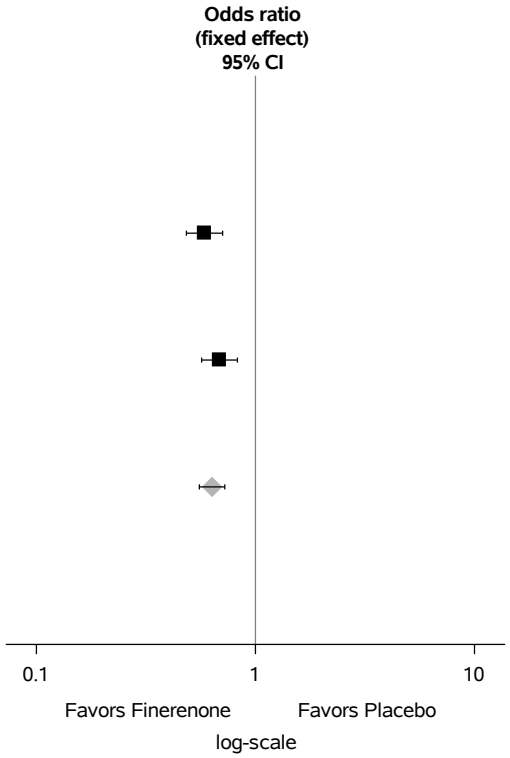
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	52 / 2831	63.1	0.90 [0.61,1.35]	
FIGARO-DKD	22 / 3683	41 / 3658	36.9	0.53 [0.32,0.89]	
Total	69 / 6510	93 / 6489		0.74 [0.54,1.01]	Z=-1.90, p=0.0570
Heterogeneity:	Q=2.55 (df=1)	p=0.1104	I^2=60.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.41: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

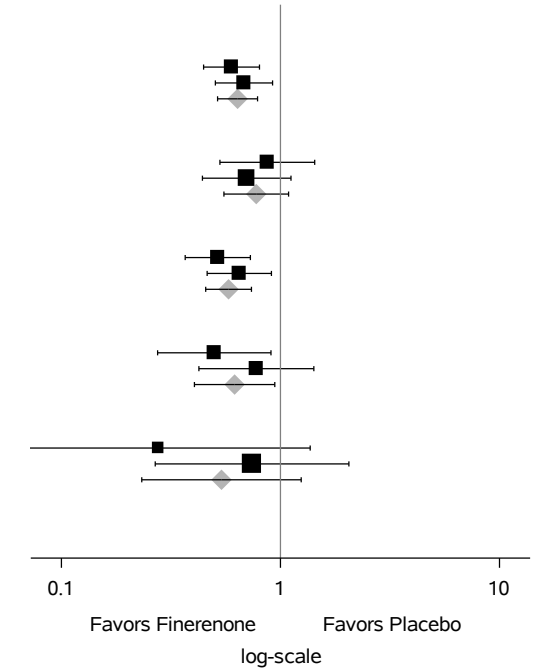
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	186 / 2827	304 / 2831	49.4	0.59 [0.48,0.71]	
FIGARO-DKD	198 / 3683	280 / 3658	50.6	0.69 [0.57,0.83]	
Total	384 / 6510	584 / 6489		0.63 [0.55,0.72]	Z=-6.68, p=<.0001
Heterogeneity:	Q=1.33 (df=1)	p=0.2481	I^2=25.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.41.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

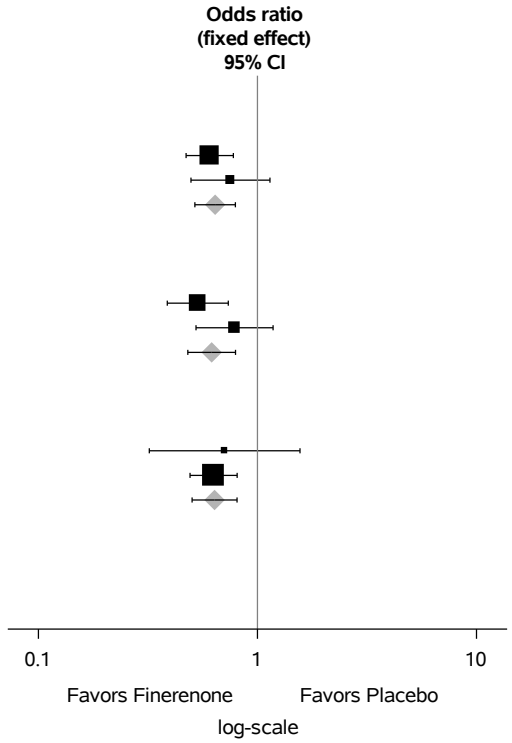
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	79 / 1178	126 / 1174	51.2	0.60 [0.45,0.80]	
FIGARO-DKD	76 / 1752	109 / 1747	48.8	0.68 [0.50,0.92]	
Total	155 / 2930	235 / 2921		0.64 [0.52,0.79]	Z=-4.21, p=<.0001
Heterogeneity:	Q=0.37 (df=1)	p=0.5419	I^2=0.0%		
North America					
FIDELIO-DKD	31 / 466	36 / 476	46.6	0.87 [0.53,1.43]	
FIGARO-DKD	33 / 559	45 / 548	53.4	0.70 [0.44,1.12]	
Total	64 / 1025	81 / 1024		0.78 [0.55,1.09]	Z=-1.47, p=0.1424
Heterogeneity:	Q=0.39 (df=1)	p=0.5332	I^2=0.0%		
Asia					
FIDELIO-DKD	56 / 790	101 / 786	49.3	0.52 [0.37,0.73]	
FIGARO-DKD	62 / 811	92 / 813	50.7	0.65 [0.46,0.91]	
Total	118 / 1601	193 / 1599		0.58 [0.46,0.74]	Z=-4.45, p=<.0001
Heterogeneity:	Q=0.85 (df=1)	p=0.3571	I^2=0.0%		
Latin America					
FIDELIO-DKD	18 / 294	34 / 294	50.7	0.50 [0.27,0.91]	
FIGARO-DKD	20 / 424	25 / 417	49.3	0.78 [0.42,1.42]	
Total	38 / 718	59 / 711		0.62 [0.40,0.94]	Z=-2.24, p=0.0254
Heterogeneity:	Q=1.04 (df=1)	p=0.3068	I^2=4.3%		
Others					
FIDELIO-DKD	2 / 99	7 / 101	28.9	0.28 [0.06,1.37]	
FIGARO-DKD	7 / 137	9 / 133	71.1	0.74 [0.27,2.05]	
Total	9 / 236	16 / 234		0.54 [0.23,1.24]	Z=-1.45, p=0.1471
Heterogeneity:	Q=1.05 (df=1)	p=0.3061	I^2=4.5%		
Subgroup Heterogeneity:	Q=2.05 (df=4)	p=0.7271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.41.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

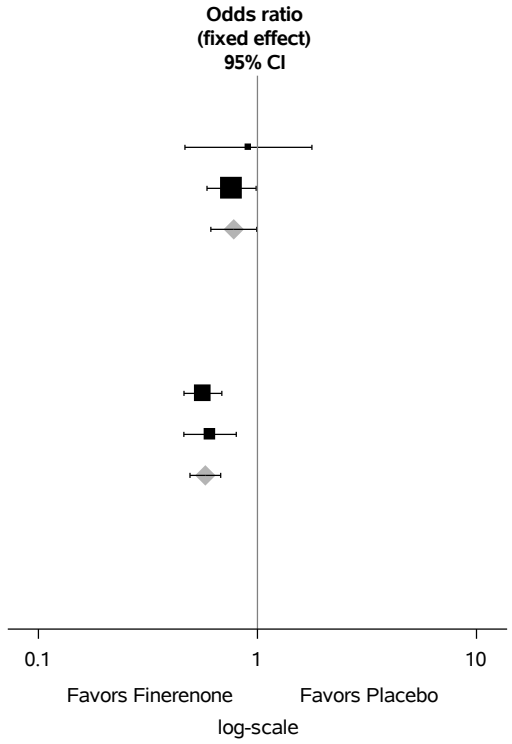
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	112 / 1556	175 / 1541	73.6	0.61 [0.47,0.78]	
FIGARO-DKD	43 / 637	55 / 627	26.4	0.75 [0.50,1.14]	
Total	155 / 2193	230 / 2168		0.64 [0.52,0.79]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.78 (df=1)	p=0.3773	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	63 / 1061	113 / 1069	61.5	0.53 [0.39,0.74]	
FIGARO-DKD	45 / 720	57 / 729	38.5	0.79 [0.52,1.18]	
Total	108 / 1781	170 / 1798		0.62 [0.48,0.79]	Z=-3.76, p=0.0002
Heterogeneity:	Q=2.15 (df=1)	p=0.1427	I^2=53.5%		
>= 60					
FIDELIO-DKD	11 / 210	16 / 221	8.9	0.71 [0.32,1.56]	
FIGARO-DKD	110 / 2326	168 / 2302	91.1	0.63 [0.49,0.81]	
Total	121 / 2536	184 / 2523		0.64 [0.50,0.81]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.08 (df=1)	p=0.7837	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=2)	p=0.9748	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.41.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

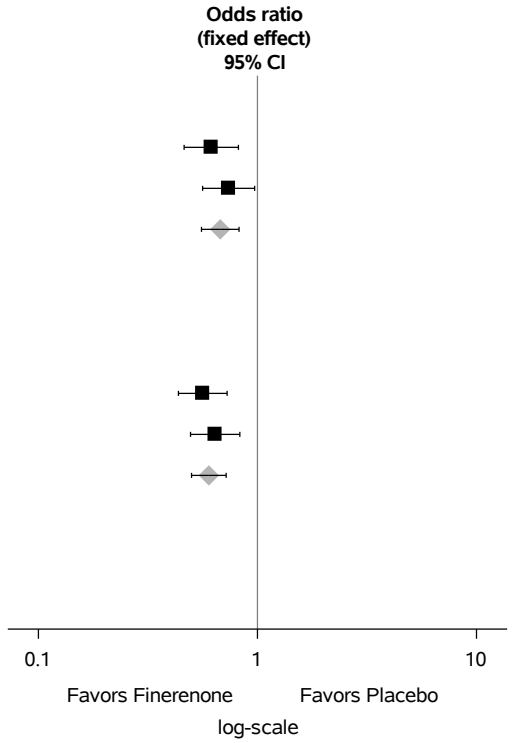
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	18 / 209	20 / 213	13.0	0.91 [0.47,1.77]	
FIGARO-DKD	111 / 1720	141 / 1698	87.0	0.76 [0.59,0.99]	
Total	129 / 1929	161 / 1911		0.78 [0.61,0.99]	Z=-2.03, p=0.0426
Heterogeneity:	Q=0.24 (df=1)	p=0.6276	I^2=0.0%		
Very High					
FIDELIO-DKD	168 / 2618	284 / 2618	65.7	0.56 [0.46,0.69]	
FIGARO-DKD	87 / 1963	139 / 1960	34.3	0.61 [0.46,0.80]	
Total	255 / 4581	423 / 4578		0.58 [0.49,0.68]	Z=-6.66, p=<.0001
Heterogeneity:	Q=0.19 (df=1)	p=0.6646	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.08 (df=1)	p=0.0434	I^2=75.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.41.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

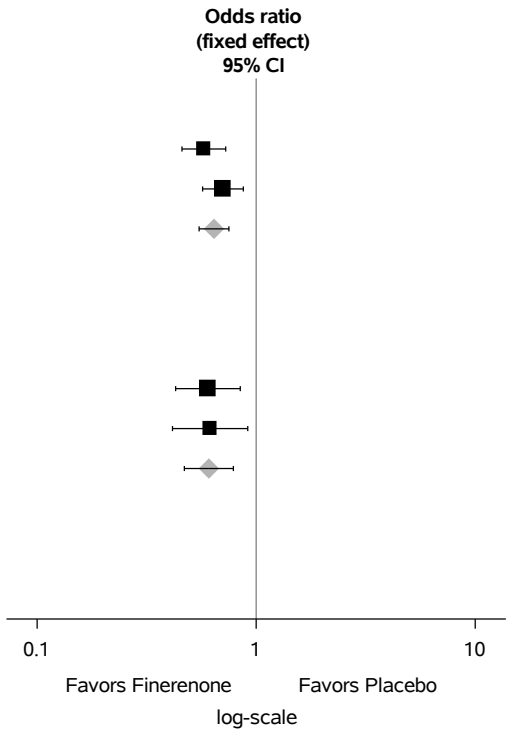
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	84 / 1301	131 / 1299	47.9	0.62 [0.46,0.82]	
FIGARO-DKD	97 / 1673	127 / 1651	52.1	0.74 [0.56,0.97]	
Total	181 / 2974	258 / 2950		0.68 [0.56,0.82]	Z=-3.88, p=0.0001
Heterogeneity:	Q=0.82 (df=1)	p=0.3657	I^2=0.0%		
Absent					
FIDELIO-DKD	102 / 1526	173 / 1532	50.7	0.56 [0.44,0.73]	
FIGARO-DKD	101 / 2010	153 / 2007	49.3	0.64 [0.49,0.83]	
Total	203 / 3536	326 / 3539		0.60 [0.50,0.72]	Z=-5.50, p=<.0001
Heterogeneity:	Q=0.49 (df=1)	p=0.4825	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3804	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.41.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	128 / 1879	209 / 1858	46.4	0.58 [0.46,0.73]	
FIGARO-DKD	156 / 2643	213 / 2608	53.6	0.71 [0.57,0.87]	
Total	284 / 4522	422 / 4466		0.64 [0.55,0.75]	Z=-5.55, p=<.0001
Heterogeneity:	Q=1.58 (df=1)	p=0.2095	I^2=36.5%		
> 4.5					
FIDELIO-DKD	58 / 948	95 / 973	57.6	0.60 [0.43,0.85]	
FIGARO-DKD	42 / 1040	67 / 1048	42.4	0.62 [0.41,0.92]	
Total	100 / 1988	162 / 2021		0.61 [0.47,0.79]	Z=-3.78, p=0.0002
Heterogeneity:	Q=0.01 (df=1)	p=0.9317	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7256	I^2=0.0%		

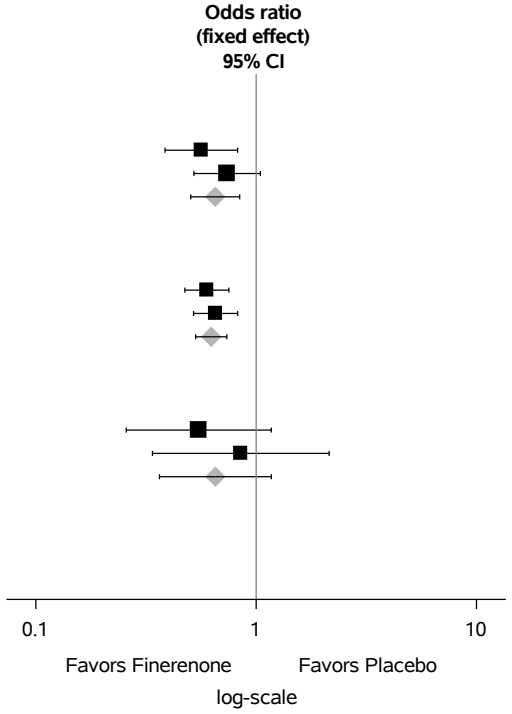


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.41.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set

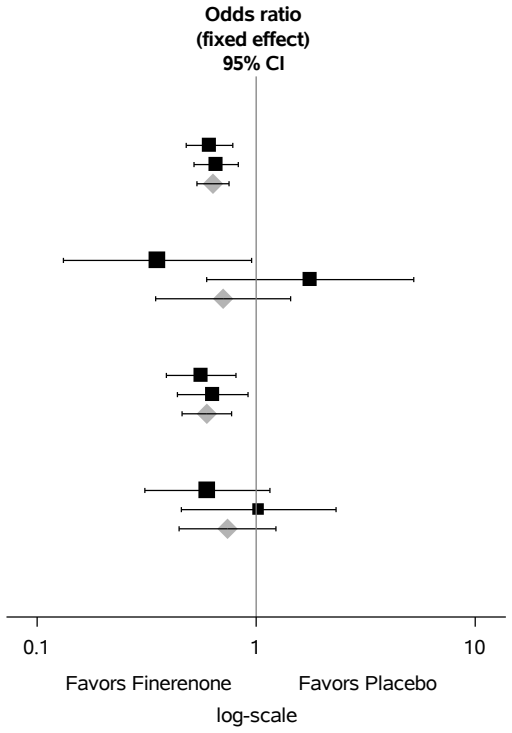
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	46 / 788	77 / 777	45.6	0.56 [0.39,0.82]	
FIGARO-DKD	59 / 1187	79 / 1194	54.4	0.74 [0.52,1.04]	
Total	105 / 1975	156 / 1971		0.65 [0.50,0.84]	Z=-3.28, p=0.0010
Heterogeneity:	Q=1.06 (df=1)	p=0.3037	I^2=5.5%		
130 - < 160					
FIDELIO-DKD	128 / 1897	207 / 1916	50.1	0.60 [0.47,0.75]	
FIGARO-DKD	130 / 2389	190 / 2351	49.9	0.65 [0.52,0.82]	
Total	258 / 4286	397 / 4267		0.63 [0.53,0.74]	Z=-5.65, p=<.0001
Heterogeneity:	Q=0.30 (df=1)	p=0.5828	I^2=0.0%		
>= 160					
FIDELIO-DKD	12 / 141	20 / 138	59.8	0.55 [0.26,1.17]	
FIGARO-DKD	9 / 107	11 / 113	40.2	0.85 [0.34,2.14]	
Total	21 / 248	31 / 251		0.65 [0.36,1.17]	Z=-1.43, p=0.1529
Heterogeneity:	Q=0.52 (df=1)	p=0.4711	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=2)	p=0.9592	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.41.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

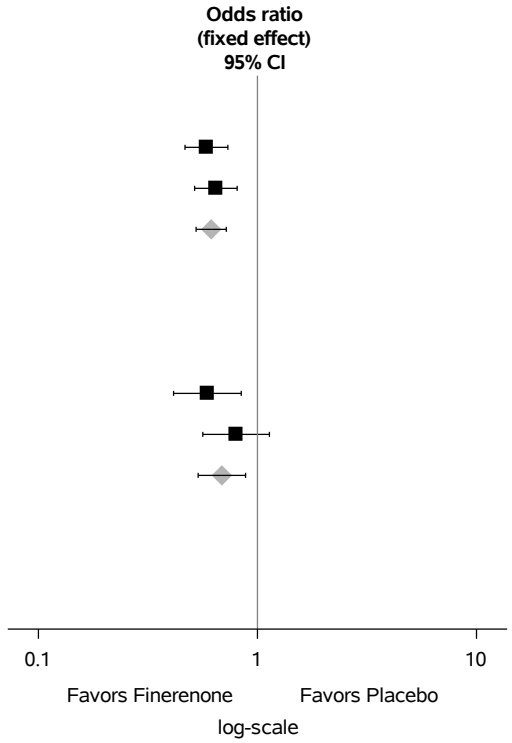
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	113 / 1773	181 / 1809	47.5	0.61 [0.48,0.78]	
FIGARO-DKD	127 / 2668	184 / 2601	52.5	0.66 [0.52,0.83]	
Total	240 / 4441	365 / 4410		0.64 [0.54,0.75]	Z=-5.28, p=<.0001
Heterogeneity:	Q=0.16 (df=1)	p=0.6855	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	14 / 124	54.8	0.35 [0.13,0.95]	
FIGARO-DKD	8 / 113	6 / 145	45.2	1.77 [0.59,5.24]	
Total	14 / 252	20 / 269		0.71 [0.35,1.44]	Z=-0.96, p=0.3372
Heterogeneity:	Q=4.59 (df=1)	p=0.0322	I^2=78.2%		
Asian					
FIDELIO-DKD	50 / 717	85 / 721	50.7	0.56 [0.39,0.81]	
FIGARO-DKD	50 / 716	78 / 736	49.3	0.63 [0.44,0.92]	
Total	100 / 1433	163 / 1457		0.60 [0.46,0.77]	Z=-3.90, p=<.0001
Heterogeneity:	Q=0.21 (df=1)	p=0.6478	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 198	24 / 177	60.5	0.60 [0.31,1.16]	
FIGARO-DKD	13 / 186	12 / 176	39.5	1.03 [0.46,2.32]	
Total	30 / 384	36 / 353		0.74 [0.44,1.23]	Z=-1.16, p=0.2460
Heterogeneity:	Q=1.02 (df=1)	p=0.3119	I^2=2.2%		
Subgroup Heterogeneity:	Q=0.67 (df=3)	p=0.8808	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.41.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

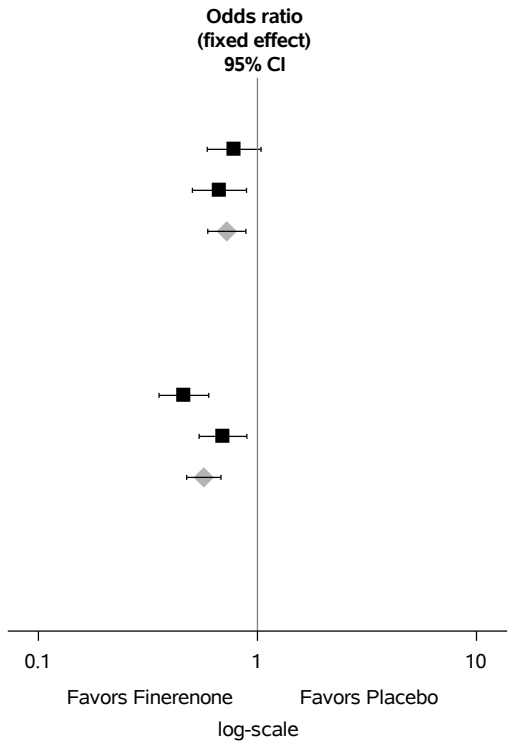
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	131 / 1949	222 / 2024	49.5	0.58 [0.47,0.73]	
FIGARO-DKD	136 / 2527	208 / 2571	50.5	0.65 [0.52,0.81]	
Total	267 / 4476	430 / 4595		0.61 [0.52,0.72]	Z=-6.00, p=<.0001
Heterogeneity:	Q=0.38 (df=1)	p=0.5384	I^2=0.0%		
Female					
FIDELIO-DKD	55 / 878	82 / 807	49.2	0.59 [0.41,0.84]	
FIGARO-DKD	62 / 1156	72 / 1087	50.8	0.80 [0.56,1.13]	
Total	117 / 2034	154 / 1894		0.69 [0.54,0.88]	Z=-2.94, p=0.0032
Heterogeneity:	Q=1.40 (df=1)	p=0.2363	I^2=28.7%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4572	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.41.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set

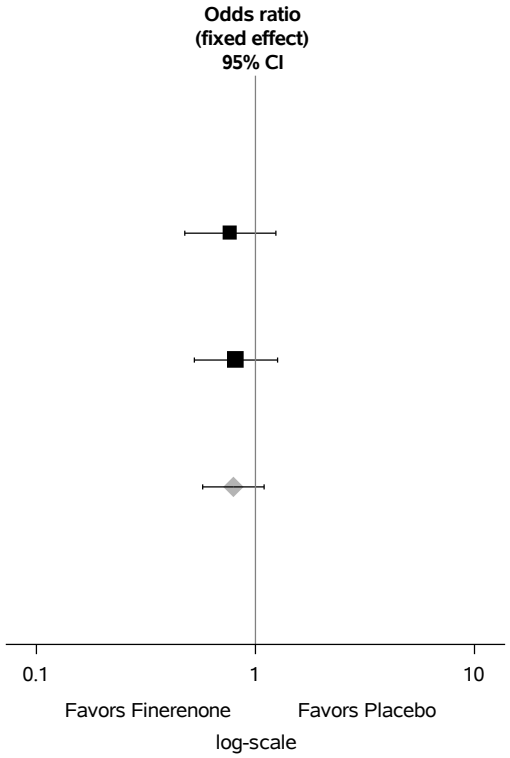
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	96 / 1201	117 / 1171	50.3	0.78 [0.59,1.04]	
FIGARO-DKD	85 / 1752	124 / 1755	49.7	0.67 [0.50,0.89]	
Total	181 / 2953	241 / 2926		0.72 [0.59,0.89]	Z=-3.15, p=0.0016
Heterogeneity:	Q=0.57 (df=1)	p=0.4505	I^2=0.0%		
>= 65					
FIDELIO-DKD	90 / 1626	187 / 1660	47.9	0.46 [0.36,0.60]	
FIGARO-DKD	113 / 1931	156 / 1903	52.1	0.70 [0.54,0.89]	
Total	203 / 3557	343 / 3563		0.57 [0.48,0.68]	Z=-6.13, p=<.0001
Heterogeneity:	Q=4.94 (df=1)	p=0.0262	I^2=79.8%		
Subgroup Heterogeneity:	Q=3.09 (df=1)	p=0.0787	I^2=67.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.42: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set

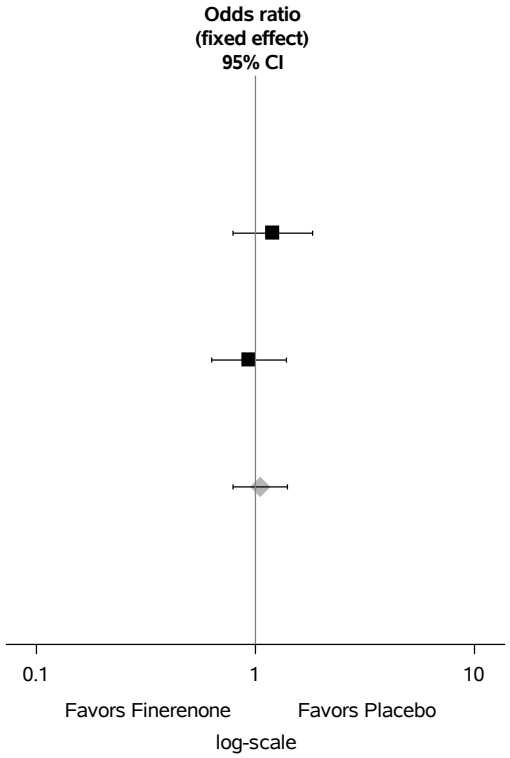
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2827	39 / 2831	45.5	0.77 [0.48,1.24]	
FIGARO-DKD	37 / 3683	45 / 3658	54.5	0.81 [0.53,1.26]	
Total	67 / 6510	84 / 6489		0.79 [0.57,1.10]	Z=-1.41, p=0.1593
Heterogeneity:	Q=0.03 (df=1)	p=0.8577	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.43: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set

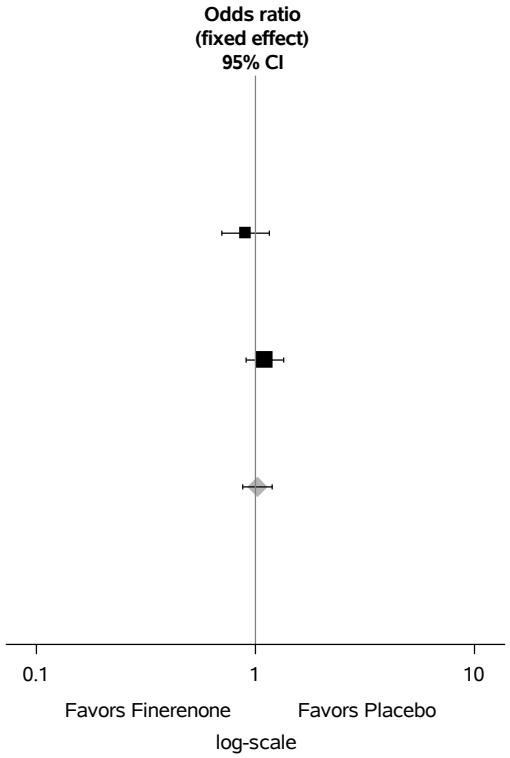
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2827	41 / 2831	46.9	1.20 [0.79,1.82]	
FIGARO-DKD	49 / 3683	52 / 3658	53.1	0.94 [0.63,1.39]	
Total	98 / 6510	93 / 6489		1.05 [0.79,1.40]	Z=0.34, p=0.7308
Heterogeneity:	Q=0.73 (df=1)	p=0.3937	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.44: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

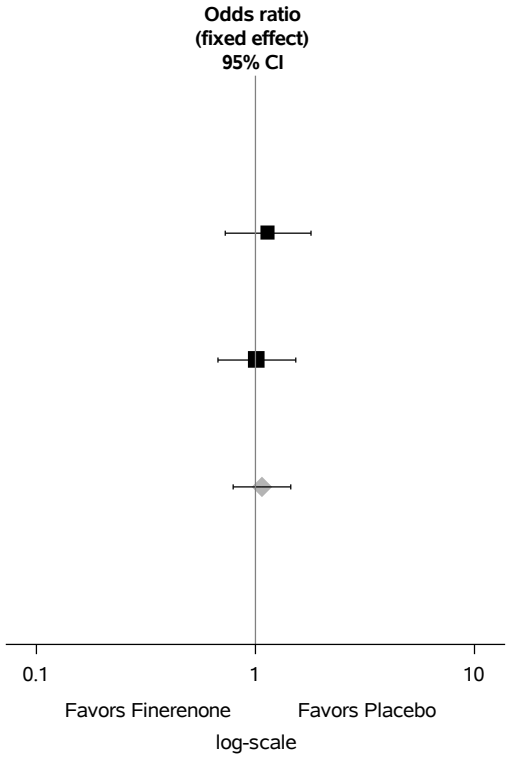
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	123 / 2827	136 / 2831	38.5	0.90 [0.70,1.16]	
FIGARO-DKD	220 / 3683	199 / 3658	61.5	1.10 [0.91,1.35]	
Total	343 / 6510	335 / 6489		1.02 [0.87,1.19]	Z=0.27, p=0.7898
Heterogeneity:	Q=1.56 (df=1)	p=0.2114	I^2=36.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.45: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set

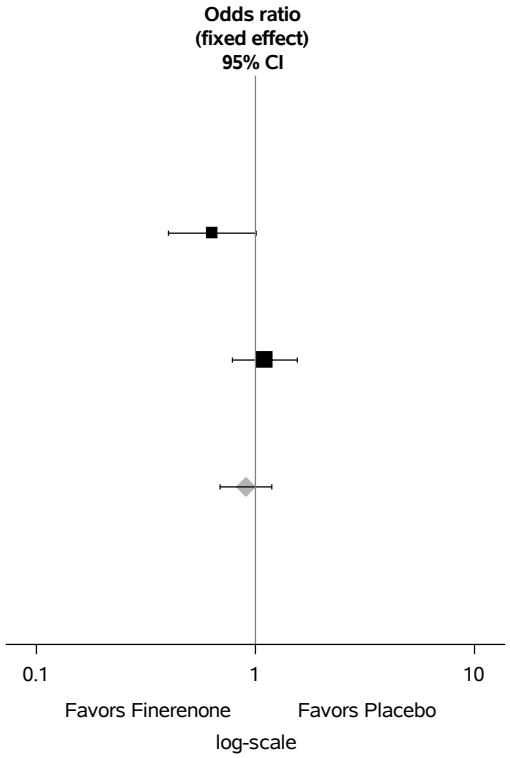
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2827	36 / 2831	45.2	1.14 [0.73,1.79]	
FIGARO-DKD	47 / 3683	46 / 3658	54.8	1.01 [0.67,1.53]	
Total	88 / 6510	82 / 6489		1.07 [0.79,1.45]	Z=0.44, p=0.6578
Heterogeneity:	Q=0.15 (df=1)	p=0.7030	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.46: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set

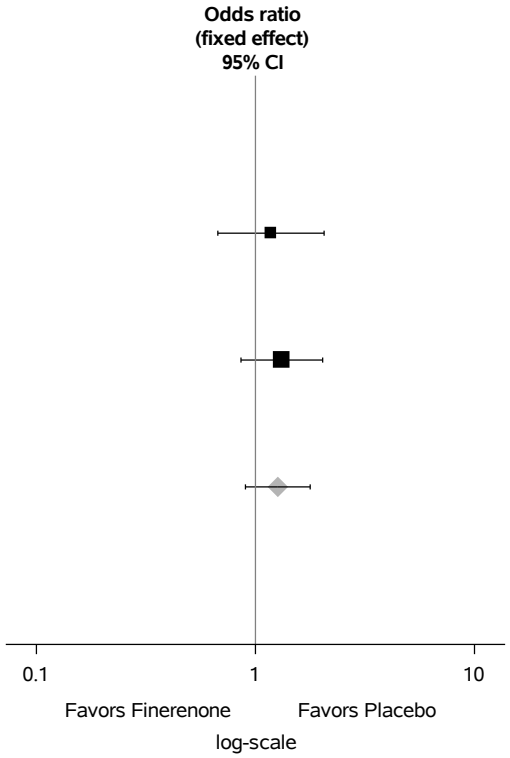
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2827	47 / 2831	35.4	0.64 [0.40,1.01]	
FIGARO-DKD	71 / 3683	64 / 3658	64.6	1.10 [0.78,1.55]	
Total	101 / 6510	111 / 6489		0.90 [0.69,1.19]	Z=-0.72, p=0.4713
Heterogeneity:	Q=3.57 (df=1)	p=0.0590	I^2=72.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.47: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

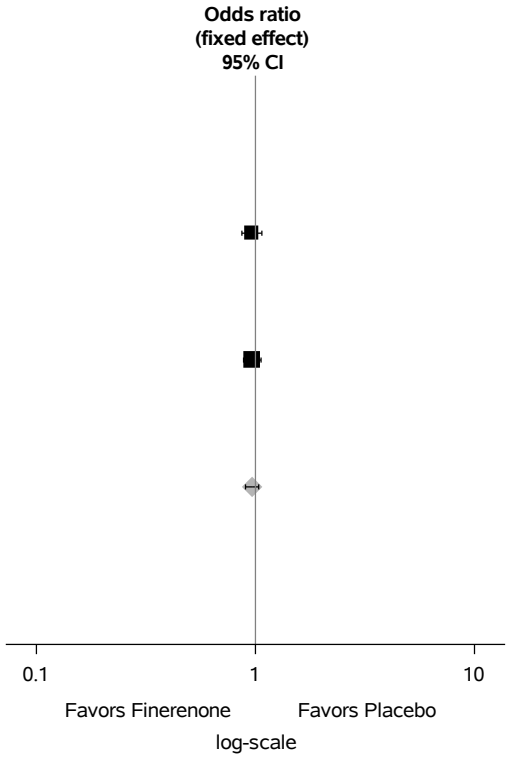
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	23 / 2831	37.1	1.18 [0.67,2.06]	
FIGARO-DKD	49 / 3683	37 / 3658	62.9	1.32 [0.86,2.03]	
Total	76 / 6510	60 / 6489		1.27 [0.90,1.78]	Z=1.35, p=0.1757
Heterogeneity:	Q=0.10 (df=1)	p=0.7509	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.48: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

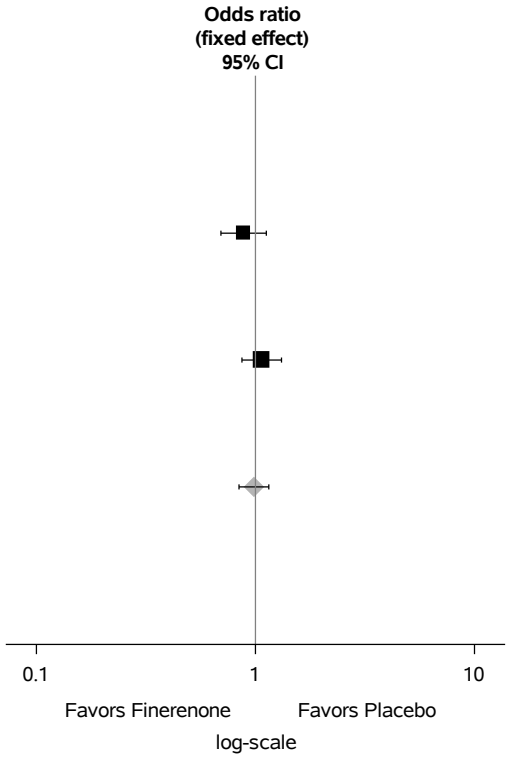
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1227 / 2827	1255 / 2831	43.4	0.96 [0.87,1.07]	
FIGARO-DKD	1637 / 3683	1656 / 3658	56.6	0.97 [0.88,1.06]	
Total	2864 / 6510	2911 / 6489		0.97 [0.90,1.03]	Z=-1.00, p=0.3189
Heterogeneity:	Q=0.00 (df=1)	p=0.9508	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.49: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set

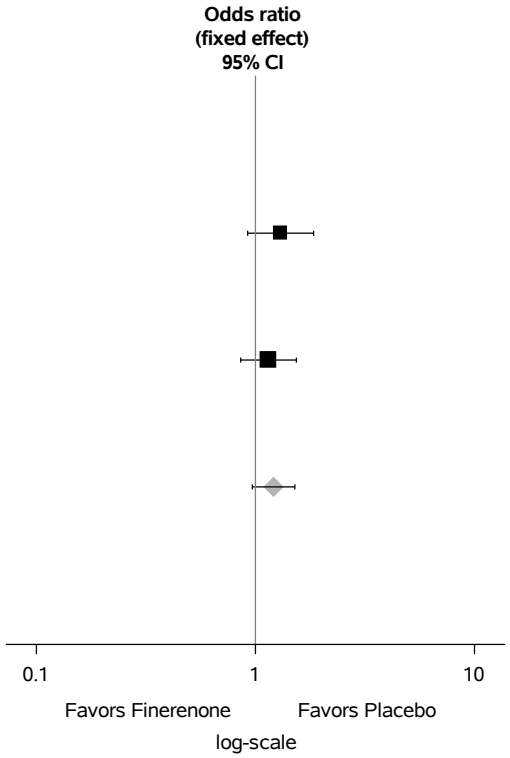
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	134 / 2827	151 / 2831	43.1	0.88 [0.70,1.12]	
FIGARO-DKD	194 / 3683	181 / 3658	56.9	1.07 [0.87,1.31]	
Total	328 / 6510	332 / 6489		0.98 [0.84,1.15]	Z=-0.20, p=0.8393
Heterogeneity:	Q=1.39 (df=1)	p=0.2389	I^2=27.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.50: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set

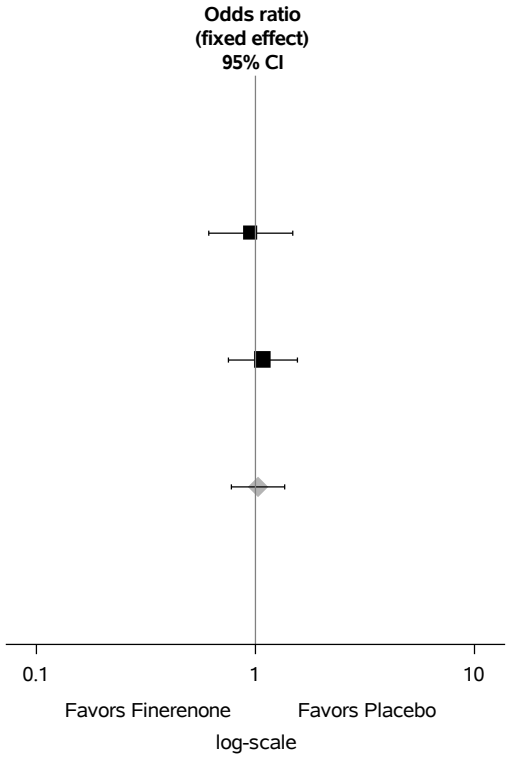
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	58 / 2831	41.6	1.30 [0.92,1.84]	
FIGARO-DKD	99 / 3683	86 / 3658	58.4	1.15 [0.86,1.54]	
Total	174 / 6510	144 / 6489		1.21 [0.97,1.51]	Z=1.67, p=0.0948
Heterogeneity:	Q=0.30 (df=1)	p=0.5826	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.51: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set

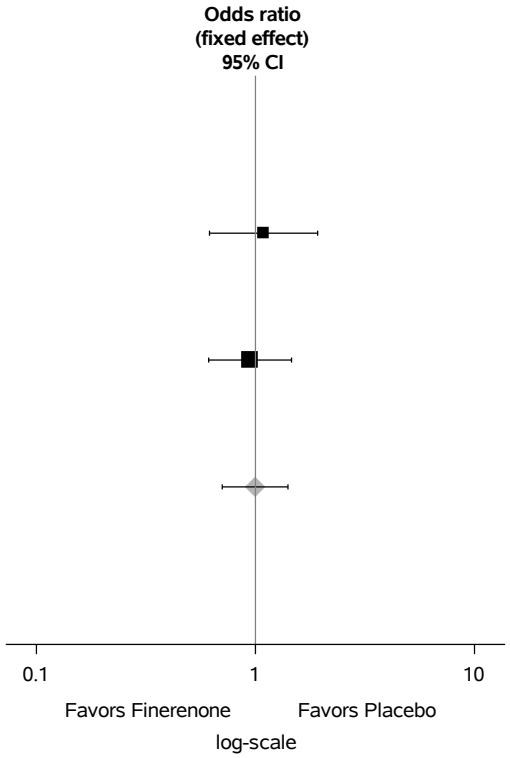
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	41 / 2831	40.3	0.95 [0.61,1.48]	
FIGARO-DKD	62 / 3683	57 / 3658	59.7	1.08 [0.75,1.55]	
Total	101 / 6510	98 / 6489		1.03 [0.78,1.36]	Z=0.19, p=0.8498
Heterogeneity:	Q=0.19 (df=1)	p=0.6610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.52: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cystitis (PT with Incidence >=1%)
Safety Analysis Set

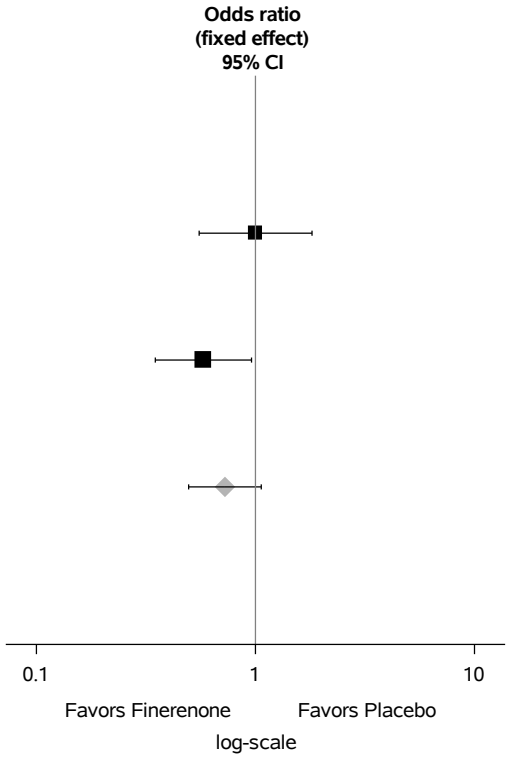
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2827	23 / 2831	37.0	1.09 [0.62,1.92]	
FIGARO-DKD	40 / 3683	42 / 3658	63.0	0.95 [0.61,1.46]	
Total	65 / 6510	65 / 6489		1.00 [0.71,1.41]	Z=-0.02, p=0.9827
Heterogeneity:	Q=0.15 (df=1)	p=0.6981	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.53: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set

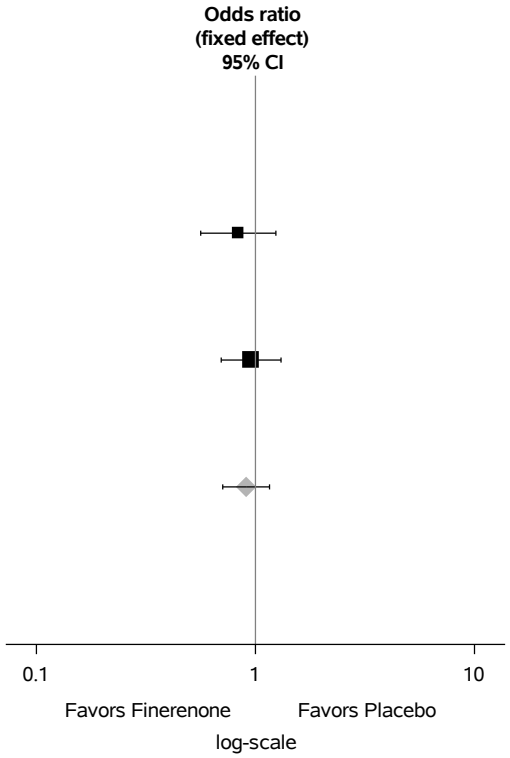
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	22 / 2827	22 / 2831	42.1	1.00 [0.55,1.81]	
FIGARO-DKD	24 / 3683	41 / 3658	57.9	0.58 [0.35,0.96]	
Total	46 / 6510	63 / 6489		0.73 [0.50,1.06]	Z=-1.65, p=0.0996
Heterogeneity:	Q=1.90 (df=1)	p=0.1679	I^2=47.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.54: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set

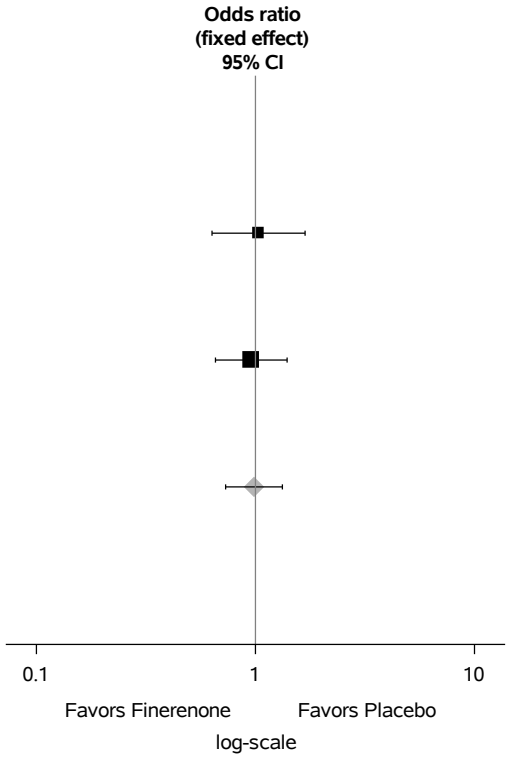
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2827	55 / 2831	38.8	0.83 [0.56,1.24]	
FIGARO-DKD	78 / 3683	81 / 3658	61.2	0.96 [0.70,1.31]	
Total	124 / 6510	136 / 6489		0.91 [0.71,1.16]	Z=-0.78, p=0.4348
Heterogeneity:	Q=0.27 (df=1)	p=0.6004	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.55: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set

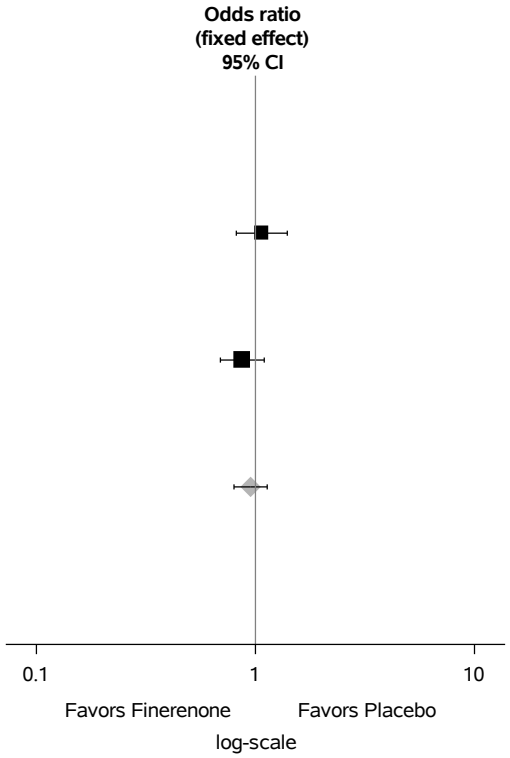
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	32 / 2831	37.2	1.03 [0.63,1.68]	
FIGARO-DKD	54 / 3683	56 / 3658	62.8	0.96 [0.66,1.39]	
Total	87 / 6510	88 / 6489		0.98 [0.73,1.33]	Z=-0.10, p=0.9194
Heterogeneity:	Q=0.06 (df=1)	p=0.8084	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.56: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set

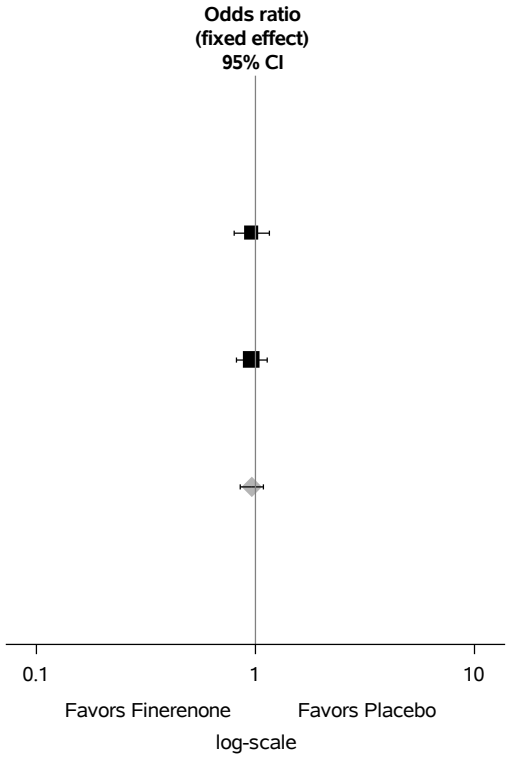
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	115 / 2827	108 / 2831	42.5	1.07 [0.82,1.40]	
FIGARO-DKD	142 / 3683	161 / 3658	57.5	0.87 [0.69,1.10]	
Total	257 / 6510	269 / 6489		0.95 [0.80,1.13]	Z=-0.57, p=0.5666
Heterogeneity:	Q=1.29 (df=1)	p=0.2557	I^2=22.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.57: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set

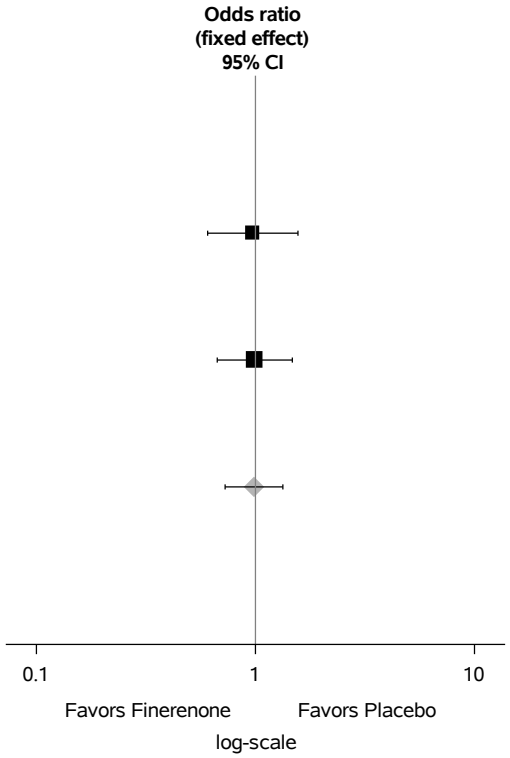
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	241 / 2827	250 / 2831	43.2	0.96 [0.80,1.16]	
FIGARO-DKD	318 / 3683	327 / 3658	56.8	0.96 [0.82,1.13]	
Total	559 / 6510	577 / 6489		0.96 [0.85,1.09]	Z=-0.62, p=0.5376
Heterogeneity:	Q=0.00 (df=1)	p=0.9966	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.58: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set

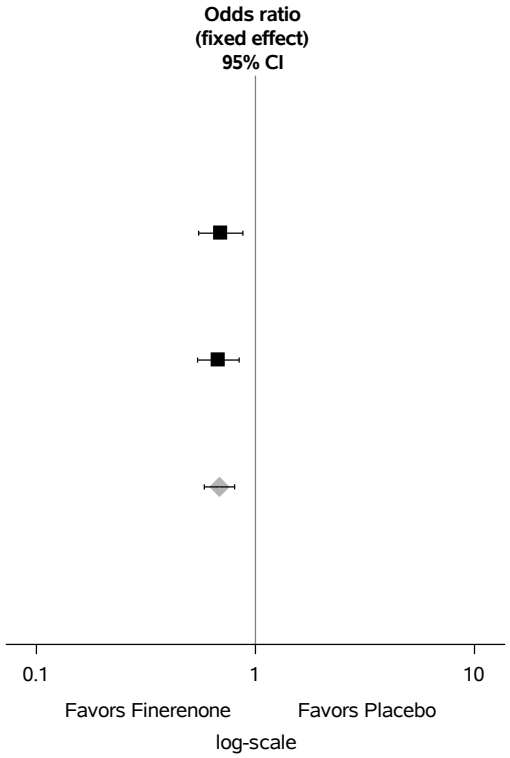
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	35 / 2831	40.9	0.97 [0.60,1.56]	
FIGARO-DKD	50 / 3683	50 / 3658	59.1	0.99 [0.67,1.47]	
Total	84 / 6510	85 / 6489		0.98 [0.73,1.33]	Z=-0.10, p=0.9203
Heterogeneity:	Q=0.00 (df=1)	p=0.9468	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.59: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

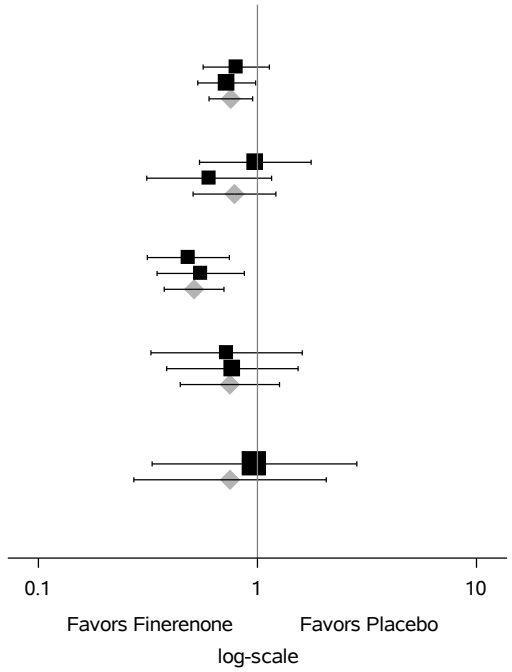
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	128 / 2827	181 / 2831	46.9	0.69 [0.55,0.88]	
FIGARO-DKD	143 / 3683	206 / 3658	53.1	0.68 [0.54,0.84]	
Total	271 / 6510	387 / 6489		0.69 [0.58,0.80]	Z=-4.66, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8760	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.59.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

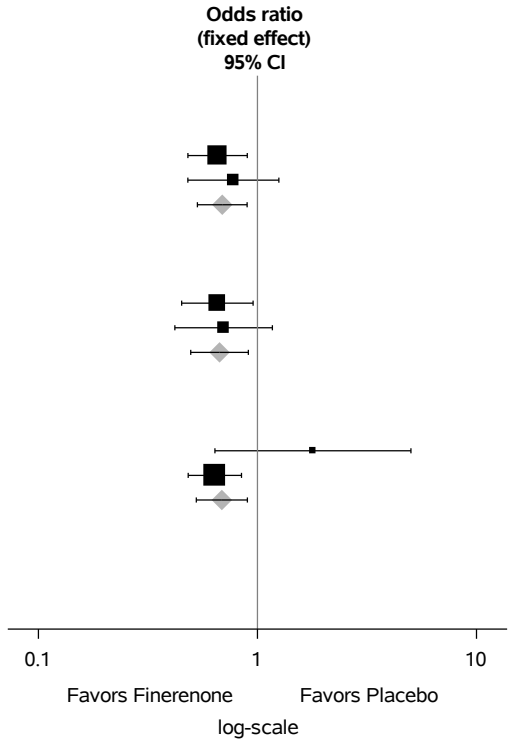
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	61 / 1178	75 / 1174	43.3	0.80 [0.57,1.13]	
FIGARO-DKD	76 / 1752	103 / 1747	56.7	0.72 [0.53,0.98]	
Total	137 / 2930	178 / 2921		0.76 [0.60,0.95]	Z=-2.40, p=0.0165
Heterogeneity:	Q=0.18 (df=1)	p=0.6702	I^2=0.0%		
North America					
FIDELIO-DKD	23 / 466	24 / 476	55.6	0.98 [0.54,1.76]	
FIGARO-DKD	15 / 559	24 / 548	44.4	0.60 [0.31,1.16]	
Total	38 / 1025	48 / 1024		0.79 [0.51,1.21]	Z=-1.09, p=0.2766
Heterogeneity:	Q=1.17 (df=1)	p=0.2801	I^2=14.3%		
Asia					
FIDELIO-DKD	33 / 790	65 / 786	53.1	0.48 [0.31,0.74]	
FIGARO-DKD	30 / 811	53 / 813	46.9	0.55 [0.35,0.87]	
Total	63 / 1601	118 / 1599		0.51 [0.38,0.70]	Z=-4.16, p=<.0001
Heterogeneity:	Q=0.16 (df=1)	p=0.6851	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 294	15 / 294	43.0	0.72 [0.33,1.60]	
FIGARO-DKD	15 / 424	19 / 417	57.0	0.77 [0.38,1.53]	
Total	26 / 718	34 / 711		0.75 [0.44,1.26]	Z=-1.09, p=0.2761
Heterogeneity:	Q=0.01 (df=1)	p=0.9100	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	2 / 101	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	7 / 137	7 / 133	100.0	0.97 [0.33,2.84]	
Total	7 / 236	9 / 234		0.75 [0.27,2.06]	Z=-0.56, p=0.5765
Heterogeneity:	Q=0.22 (df=1)	p=0.6398	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.45 (df=4)	p=0.3481	I^2=10.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.59.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

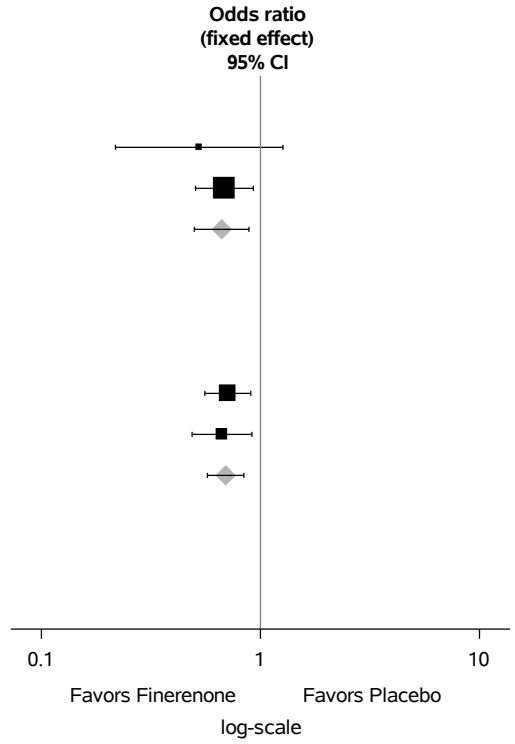
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	70 / 1556	103 / 1541	70.2	0.66 [0.48,0.90]	
FIGARO-DKD	32 / 637	40 / 627	29.8	0.78 [0.48,1.25]	
Total	102 / 2193	143 / 2168		0.69 [0.53,0.90]	Z=-2.78, p=0.0055
Heterogeneity:	Q=0.32 (df=1)	p=0.5697	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	48 / 1061	72 / 1069	65.1	0.66 [0.45,0.96]	
FIGARO-DKD	26 / 720	37 / 729	34.9	0.70 [0.42,1.17]	
Total	74 / 1781	109 / 1798		0.67 [0.50,0.91]	Z=-2.58, p=0.0099
Heterogeneity:	Q=0.04 (df=1)	p=0.8394	I^2=0.0%		
>= 60					
FIDELIO-DKD	10 / 210	6 / 221	6.9	1.79 [0.64,5.02]	
FIGARO-DKD	85 / 2326	129 / 2302	93.1	0.64 [0.48,0.85]	
Total	95 / 2536	135 / 2523		0.69 [0.53,0.90]	Z=-2.73, p=0.0063
Heterogeneity:	Q=3.58 (df=1)	p=0.0584	I^2=72.1%		
Subgroup Heterogeneity:	Q=0.02 (df=2)	p=0.9892	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.59.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

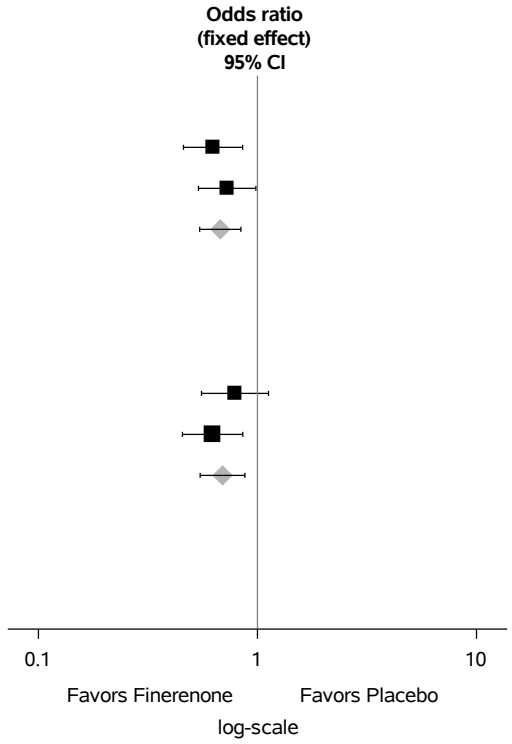
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	15 / 213	10.6	0.53 [0.22,1.27]	
FIGARO-DKD	75 / 1720	106 / 1698	89.4	0.68 [0.51,0.93]	
Total	83 / 1929	121 / 1911		0.67 [0.50,0.89]	Z=-2.79, p=0.0053
Heterogeneity:	Q=0.31 (df=1)	p=0.5770	I^2=0.0%		
Very High					
FIDELIO-DKD	120 / 2618	166 / 2618	63.0	0.71 [0.56,0.90]	
FIGARO-DKD	68 / 1963	100 / 1960	37.0	0.67 [0.49,0.91]	
Total	188 / 4581	266 / 4578		0.69 [0.57,0.84]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.09 (df=1)	p=0.7622	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8120	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.59.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

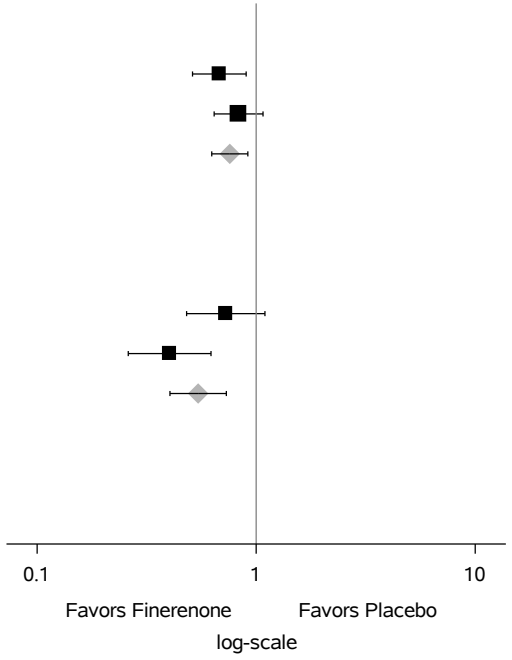
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	70 / 1301	108 / 1299	48.5	0.63 [0.46,0.86]	
FIGARO-DKD	78 / 1673	104 / 1651	51.5	0.73 [0.54,0.98]	
Total	148 / 2974	212 / 2950		0.68 [0.54,0.84]	Z=-3.54, p=0.0004
Heterogeneity:	Q=0.45 (df=1)	p=0.5021	I^2=0.0%		
Absent					
FIDELIO-DKD	58 / 1526	73 / 1532	44.8	0.79 [0.56,1.12]	
FIGARO-DKD	65 / 2010	102 / 2007	55.2	0.62 [0.45,0.86]	
Total	123 / 3536	175 / 3539		0.69 [0.55,0.88]	Z=-3.05, p=0.0023
Heterogeneity:	Q=0.95 (df=1)	p=0.3310	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8850	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.59.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

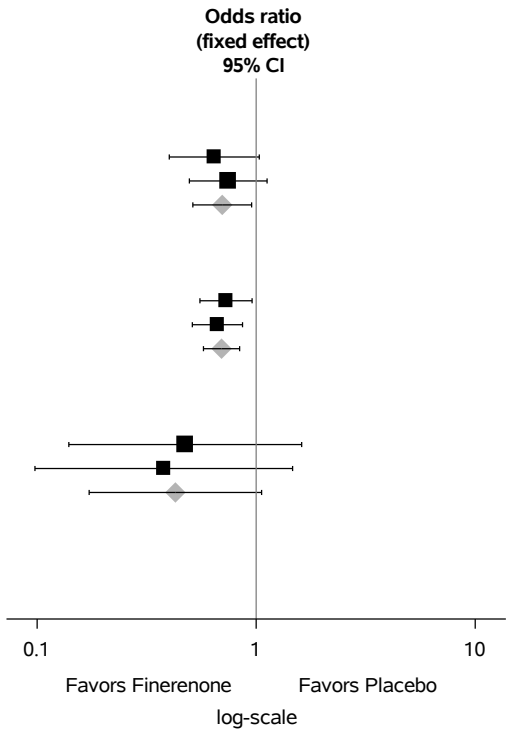
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	87 / 1879	124 / 1858	45.3	0.68 [0.51,0.90]	
FIGARO-DKD	113 / 2643	133 / 2608	54.7	0.83 [0.64,1.07]	
Total	200 / 4522	257 / 4466		0.76 [0.63,0.92]	Z=-2.87, p=0.0042
Heterogeneity:	Q=1.08 (df=1)	p=0.2984	I^2=7.5%		
> 4.5					
FIDELIO-DKD	41 / 948	57 / 973	52.7	0.73 [0.48,1.10]	
FIGARO-DKD	30 / 1040	72 / 1048	47.3	0.40 [0.26,0.62]	
Total	71 / 1988	129 / 2021		0.54 [0.40,0.73]	Z=-4.03, p=<.0001
Heterogeneity:	Q=3.74 (df=1)	p=0.0533	I^2=73.2%		
Subgroup Heterogeneity:	Q=3.43 (df=1)	p=0.0639	I^2=70.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.59.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

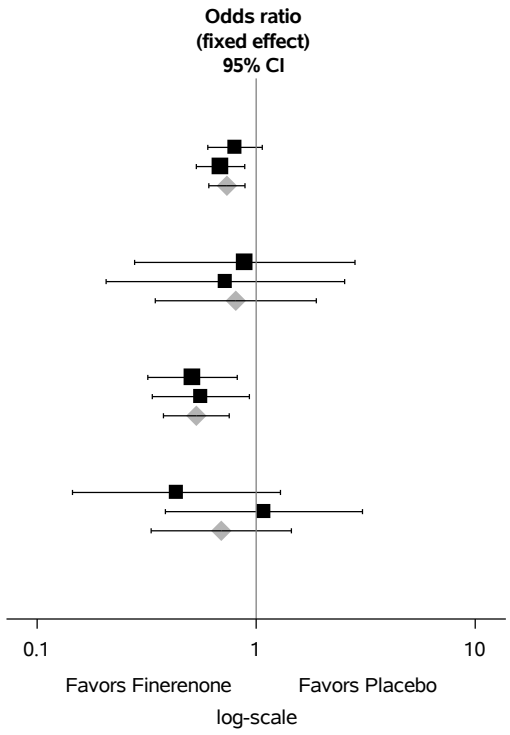
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	30 / 788	45 / 777	42.7	0.64 [0.40,1.03]	
FIGARO-DKD	42 / 1187	56 / 1194	57.3	0.75 [0.50,1.12]	
Total	72 / 1975	101 / 1971		0.70 [0.51,0.95]	Z=-2.26, p=0.0236
Heterogeneity:	Q=0.21 (df=1)	p=0.6458	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	94 / 1897	128 / 1916	48.1	0.73 [0.55,0.96]	
FIGARO-DKD	98 / 2389	142 / 2351	51.9	0.67 [0.51,0.87]	
Total	192 / 4286	270 / 4267		0.69 [0.57,0.84]	Z=-3.75, p=0.0002
Heterogeneity:	Q=0.22 (df=1)	p=0.6422	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	8 / 138	55.0	0.47 [0.14,1.61]	
FIGARO-DKD	3 / 107	8 / 113	45.0	0.38 [0.10,1.47]	
Total	7 / 248	16 / 251		0.43 [0.17,1.06]	Z=-1.84, p=0.0663
Heterogeneity:	Q=0.06 (df=1)	p=0.8085	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=2)	p=0.5835	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.59.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

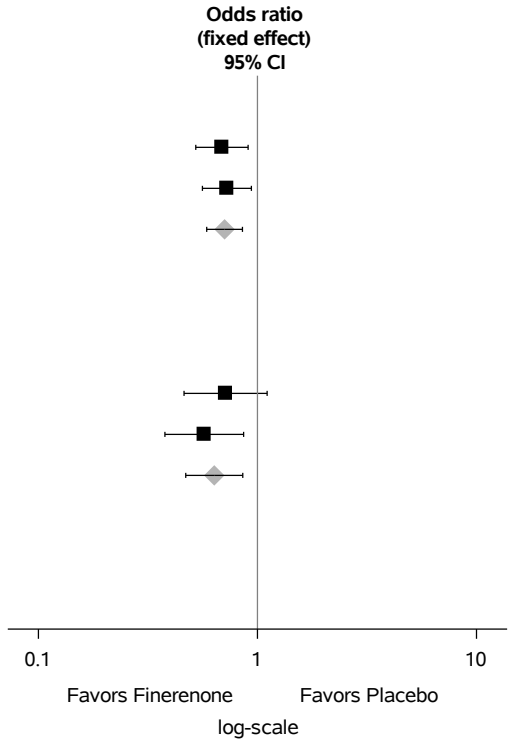
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	89 / 1773	112 / 1809	44.1	0.80 [0.60,1.07]	
FIGARO-DKD	107 / 2668	149 / 2601	55.9	0.69 [0.53,0.89]	
Total	196 / 4441	261 / 4410		0.74 [0.61,0.89]	Z=-3.17, p=0.0015
Heterogeneity:	Q=0.61 (df=1)	p=0.4354	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	6 / 124	54.0	0.89 [0.28,2.83]	
FIGARO-DKD	4 / 113	7 / 145	46.0	0.72 [0.21,2.53]	
Total	10 / 252	13 / 269		0.81 [0.35,1.88]	Z=-0.50, p=0.6197
Heterogeneity:	Q=0.05 (df=1)	p=0.8148	I^2=0.0%		
Asian					
FIDELIO-DKD	28 / 717	53 / 721	54.1	0.51 [0.32,0.82]	
FIGARO-DKD	24 / 716	43 / 736	45.9	0.56 [0.34,0.93]	
Total	52 / 1433	96 / 1457		0.53 [0.38,0.75]	Z=-3.57, p=0.0004
Heterogeneity:	Q=0.06 (df=1)	p=0.8051	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 198	10 / 177	47.3	0.43 [0.14,1.29]	
FIGARO-DKD	8 / 186	7 / 176	52.7	1.09 [0.39,3.06]	
Total	13 / 384	17 / 353		0.69 [0.33,1.45]	Z=-0.98, p=0.3293
Heterogeneity:	Q=1.43 (df=1)	p=0.2313	I^2=30.2%		
Subgroup Heterogeneity:	Q=2.70 (df=3)	p=0.4409	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.59.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

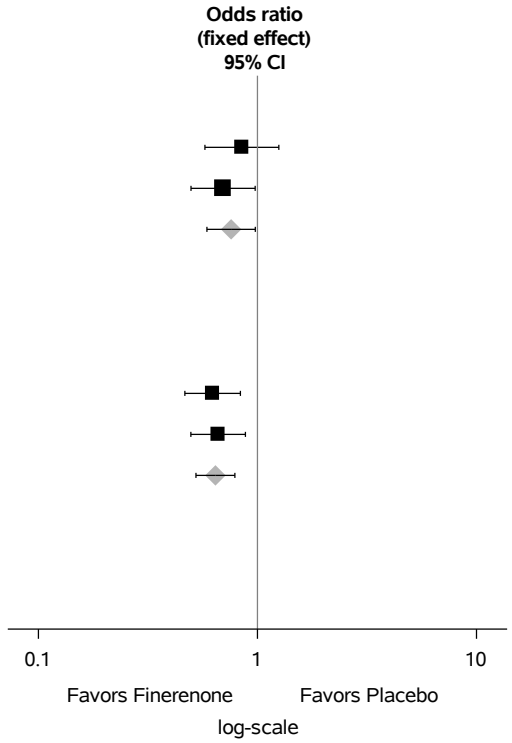
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	90 / 1949	133 / 2024	46.7	0.69 [0.52,0.91]	
FIGARO-DKD	105 / 2527	145 / 2571	53.3	0.73 [0.56,0.94]	
Total	195 / 4476	278 / 4595		0.71 [0.59,0.85]	Z=-3.60, p=0.0003
Heterogeneity:	Q=0.07 (df=1)	p=0.7853	I^2=0.0%		
Female					
FIDELIO-DKD	38 / 878	48 / 807	47.3	0.72 [0.46,1.11]	
FIGARO-DKD	38 / 1156	61 / 1087	52.7	0.57 [0.38,0.86]	
Total	76 / 2034	109 / 1894		0.64 [0.47,0.86]	Z=-2.97, p=0.0030
Heterogeneity:	Q=0.53 (df=1)	p=0.4653	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5479	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.59.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

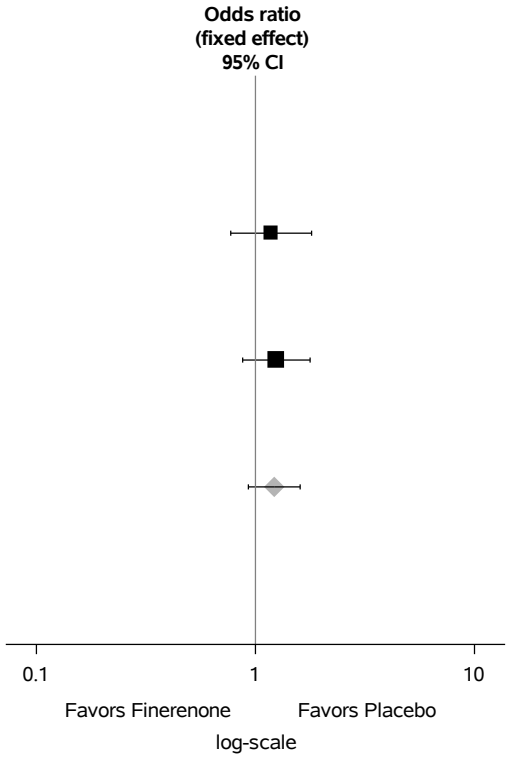
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	50 / 1201	57 / 1171	43.0	0.85 [0.58,1.25]	
FIGARO-DKD	60 / 1752	85 / 1755	57.0	0.70 [0.50,0.98]	
Total	110 / 2953	142 / 2926		0.76 [0.59,0.98]	Z=-2.13, p=0.0329
Heterogeneity:	Q=0.57 (df=1)	p=0.4515	I^2=0.0%		
>= 65					
FIDELIO-DKD	78 / 1626	124 / 1660	49.1	0.62 [0.47,0.84]	
FIGARO-DKD	83 / 1931	121 / 1903	50.9	0.66 [0.50,0.88]	
Total	161 / 3557	245 / 3563		0.64 [0.52,0.79]	Z=-4.23, p=<.0001
Heterogeneity:	Q=0.08 (df=1)	p=0.7810	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.98 (df=1)	p=0.3220	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.60: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set

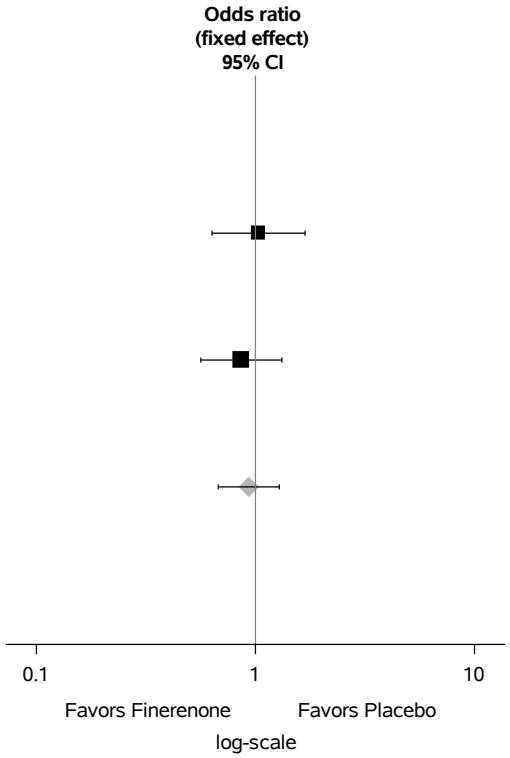
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	40 / 2831	41.0	1.18 [0.77,1.80]	
FIGARO-DKD	70 / 3683	56 / 3658	59.0	1.25 [0.87,1.78]	
Total	117 / 6510	96 / 6489		1.22 [0.93,1.60]	Z=1.42, p=0.1547
Heterogeneity:	Q=0.04 (df=1)	p=0.8459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.61: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set

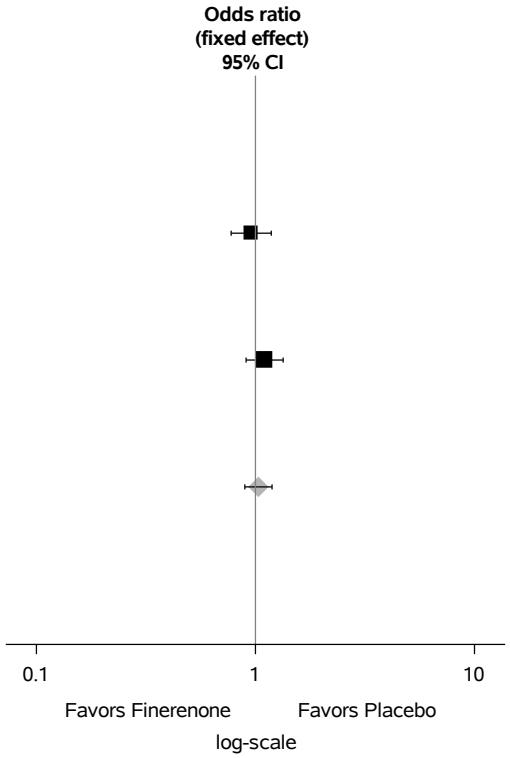
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	32 / 2831	43.2	1.03 [0.63,1.68]	
FIGARO-DKD	40 / 3683	46 / 3658	56.8	0.86 [0.56,1.32]	
Total	73 / 6510	78 / 6489		0.93 [0.68,1.28]	Z=-0.43, p=0.6676
Heterogeneity:	Q=0.30 (df=1)	p=0.5848	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.62: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set

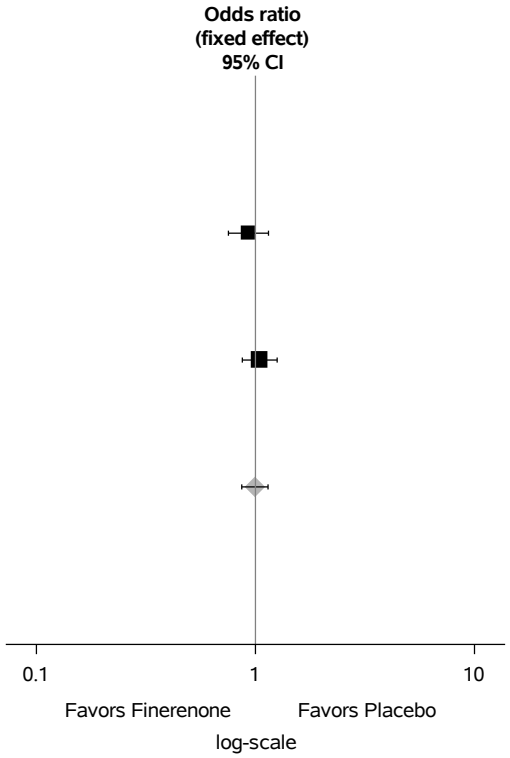
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 2827	189 / 2831	46.1	0.96 [0.77,1.18]	
FIGARO-DKD	226 / 3683	205 / 3658	53.9	1.10 [0.91,1.34]	
Total	407 / 6510	394 / 6489		1.03 [0.89,1.19]	Z=0.43, p=0.6670
Heterogeneity:	Q=0.93 (df=1)	p=0.3353	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.63: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set

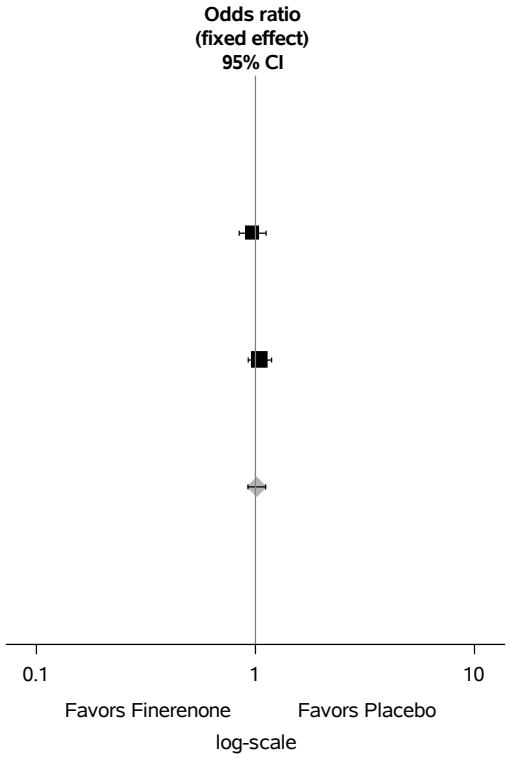
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	179 / 2827	192 / 2831	43.0	0.93 [0.75,1.15]	
FIGARO-DKD	252 / 3683	240 / 3658	57.0	1.05 [0.87,1.26]	
Total	431 / 6510	432 / 6489		0.99 [0.87,1.14]	Z=-0.09, p=0.9322
Heterogeneity:	Q=0.69 (df=1)	p=0.4052	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.64: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

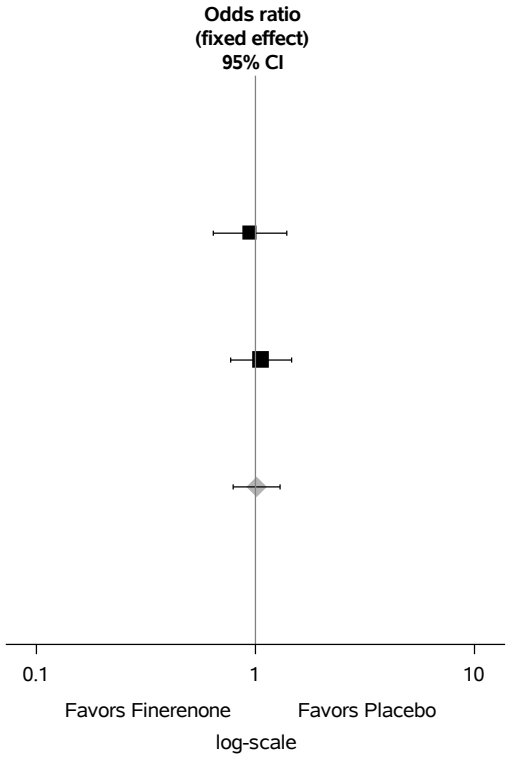
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	455 / 2827	467 / 2831	43.1	0.97 [0.84,1.12]	
FIGARO-DKD	626 / 3683	598 / 3658	56.9	1.05 [0.93,1.18]	
Total	1081 / 6510	1065 / 6489		1.01 [0.92,1.11]	Z=0.29, p=0.7681
Heterogeneity:	Q=0.64 (df=1)	p=0.4249	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.65: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set

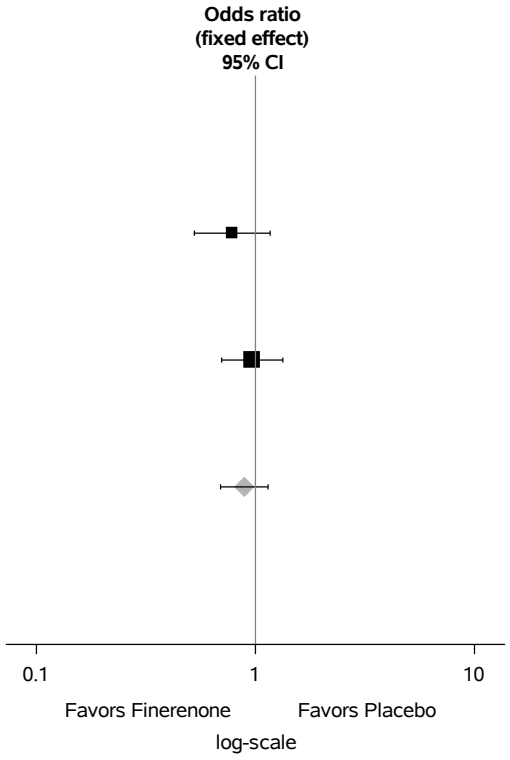
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2827	54 / 2831	40.8	0.94 [0.64,1.39]	
FIGARO-DKD	79 / 3683	74 / 3658	59.2	1.06 [0.77,1.46]	
Total	130 / 6510	128 / 6489		1.01 [0.79,1.30]	Z=0.10, p=0.9222
Heterogeneity:	Q=0.21 (df=1)	p=0.6488	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.66: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set

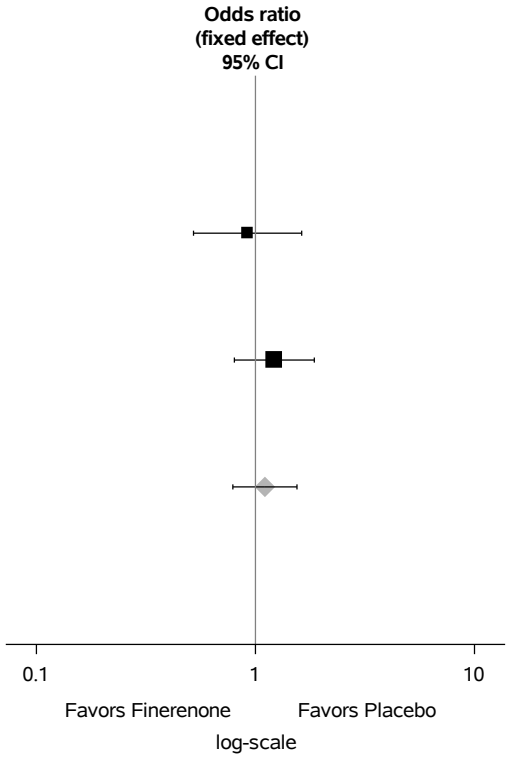
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2827	56 / 2831	39.4	0.78 [0.53,1.17]	
FIGARO-DKD	75 / 3683	77 / 3658	60.6	0.97 [0.70,1.33]	
Total	119 / 6510	133 / 6489		0.89 [0.69,1.14]	Z=-0.92, p=0.3583
Heterogeneity:	Q=0.65 (df=1)	p=0.4208	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.67: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set

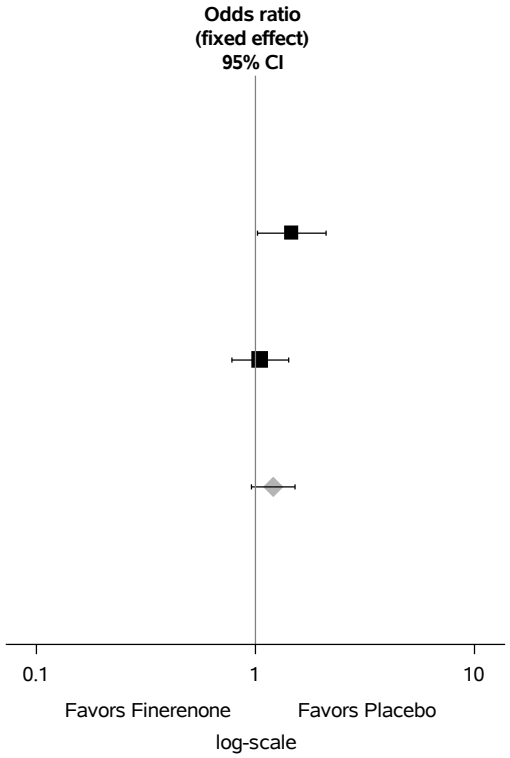
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	25 / 2831	35.3	0.92 [0.52,1.63]	
FIGARO-DKD	49 / 3683	40 / 3658	64.7	1.22 [0.80,1.86]	
Total	72 / 6510	65 / 6489		1.10 [0.79,1.55]	Z=0.58, p=0.5633
Heterogeneity:	Q=0.61 (df=1)	p=0.4357	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.68: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set

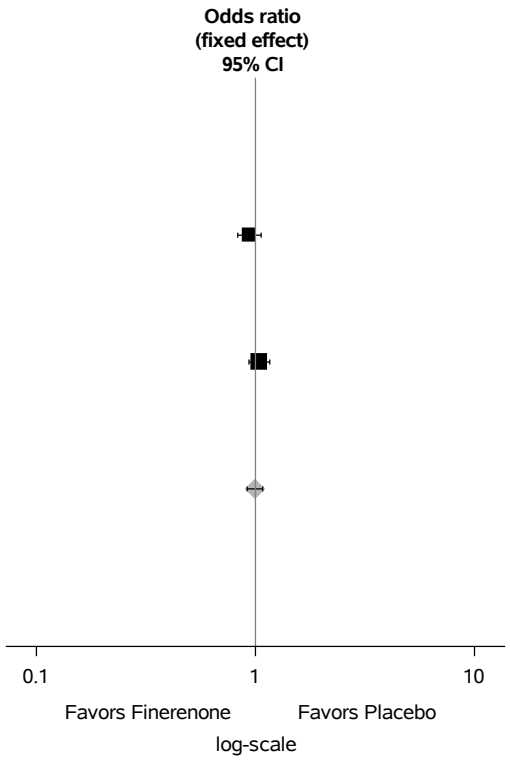
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	74 / 2827	51 / 2831	40.6	1.47 [1.02,2.10]	
FIGARO-DKD	91 / 3683	86 / 3658	59.4	1.05 [0.78,1.42]	
Total	165 / 6510	137 / 6489		1.21 [0.96,1.52]	Z=1.60, p=0.1100
Heterogeneity:	Q=1.92 (df=1)	p=0.1656	I^2=48.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.69: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

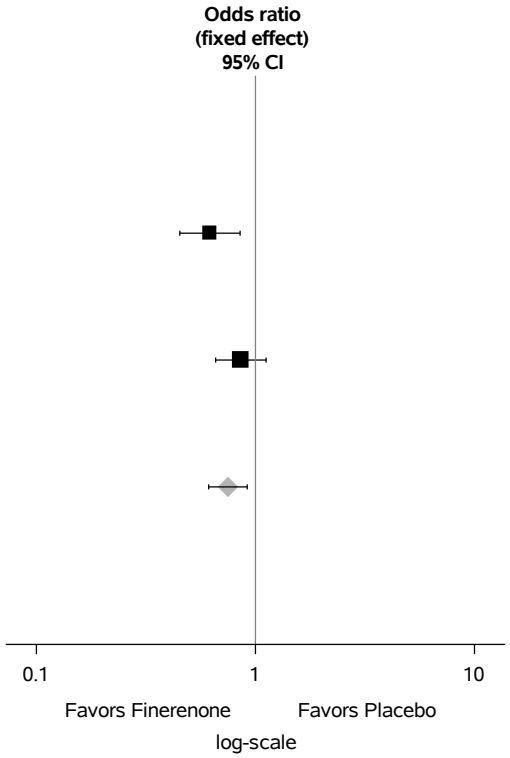
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	649 / 2827	682 / 2831	44.2	0.94 [0.83,1.06]	
FIGARO-DKD	845 / 3683	813 / 3658	55.8	1.04 [0.93,1.16]	
Total	1494 / 6510	1495 / 6489		1.00 [0.92,1.08]	Z=-0.12, p=0.9053
Heterogeneity:	Q=1.54 (df=1)	p=0.2151	I^2=34.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.70: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

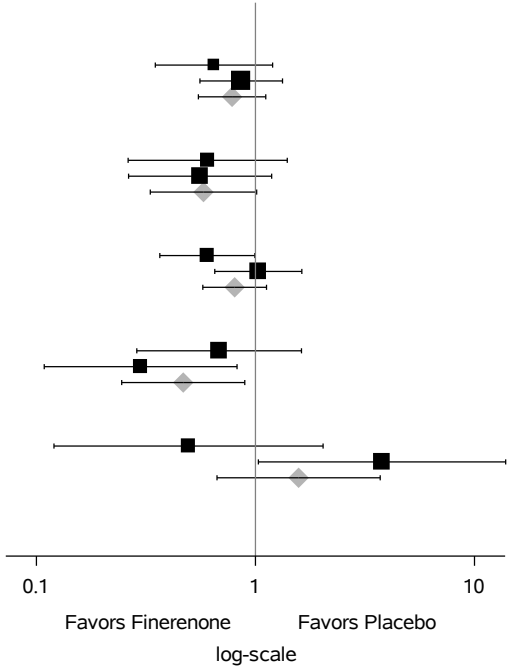
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	102 / 2831	41.2	0.62 [0.45,0.85]	
FIGARO-DKD	105 / 3683	121 / 3658	58.8	0.86 [0.66,1.12]	
Total	169 / 6510	223 / 6489		0.75 [0.61,0.92]	Z=-2.79, p=0.0052
Heterogeneity:	Q=2.38 (df=1)	p=0.1233	I^2=57.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.70.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

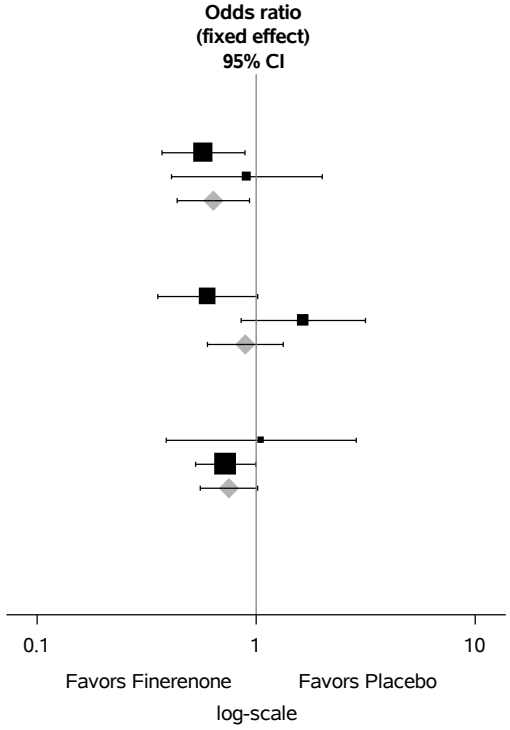
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	17 / 1178	26 / 1174	33.1	0.65 [0.35,1.20]	
FIGARO-DKD	39 / 1752	45 / 1747	66.9	0.86 [0.56,1.33]	
Total	56 / 2930	71 / 2921		0.78 [0.55,1.11]	Z=-1.36, p=0.1738
Heterogeneity:	Q=0.55 (df=1)	p=0.4563	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 466	15 / 476	44.7	0.61 [0.26,1.40]	
FIGARO-DKD	11 / 559	19 / 548	55.3	0.56 [0.26,1.19]	
Total	20 / 1025	34 / 1024		0.58 [0.33,1.01]	Z=-1.91, p=0.0555
Heterogeneity:	Q=0.02 (df=1)	p=0.8895	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 790	42 / 786	45.7	0.60 [0.37,0.99]	
FIGARO-DKD	39 / 811	38 / 813	54.3	1.03 [0.65,1.63]	
Total	65 / 1601	80 / 1599		0.80 [0.57,1.12]	Z=-1.28, p=0.2008
Heterogeneity:	Q=2.40 (df=1)	p=0.1210	I^2=58.4%		
Latin America					
FIDELIO-DKD	9 / 294	13 / 294	57.8	0.68 [0.29,1.62]	
FIGARO-DKD	5 / 424	16 / 417	42.2	0.30 [0.11,0.82]	
Total	14 / 718	29 / 711		0.47 [0.25,0.89]	Z=-2.30, p=0.0214
Heterogeneity:	Q=1.48 (df=1)	p=0.2238	I^2=32.4%		
Others					
FIDELIO-DKD	3 / 99	6 / 101	45.8	0.49 [0.12,2.04]	
FIGARO-DKD	11 / 137	3 / 133	54.2	3.78 [1.03,13.88]	
Total	14 / 236	9 / 234		1.57 [0.67,3.71]	Z=1.04, p=0.3000
Heterogeneity:	Q=4.32 (df=1)	p=0.0377	I^2=76.8%		
Subgroup Heterogeneity:	Q=5.95 (df=4)	p=0.2030	I^2=32.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.70.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

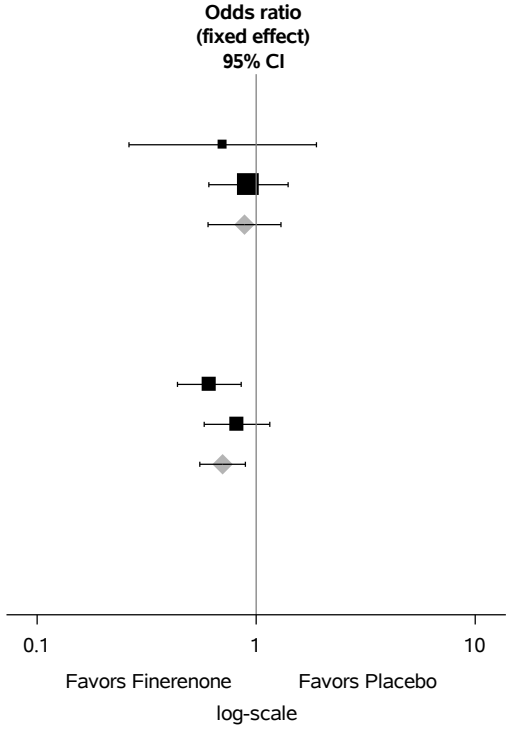
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	33 / 1556	56 / 1541	76.8	0.57 [0.37,0.89]	
FIGARO-DKD	12 / 637	13 / 627	23.2	0.91 [0.41,2.00]	
Total	45 / 2193	69 / 2168		0.64 [0.44,0.93]	Z=-2.32, p=0.0203
Heterogeneity:	Q=0.98 (df=1)	p=0.3227	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	23 / 1061	38 / 1069	60.8	0.60 [0.36,1.02]	
FIGARO-DKD	24 / 720	15 / 729	39.2	1.64 [0.85,3.16]	
Total	47 / 1781	53 / 1798		0.89 [0.60,1.33]	Z=-0.56, p=0.5751
Heterogeneity:	Q=5.52 (df=1)	p=0.0188	I^2=81.9%		
>= 60					
FIDELIO-DKD	8 / 210	8 / 221	9.1	1.05 [0.39,2.86]	
FIGARO-DKD	69 / 2326	93 / 2302	90.9	0.73 [0.53,1.00]	
Total	77 / 2536	101 / 2523		0.75 [0.56,1.02]	Z=-1.86, p=0.0631
Heterogeneity:	Q=0.49 (df=1)	p=0.4853	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=2)	p=0.4883	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.70.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

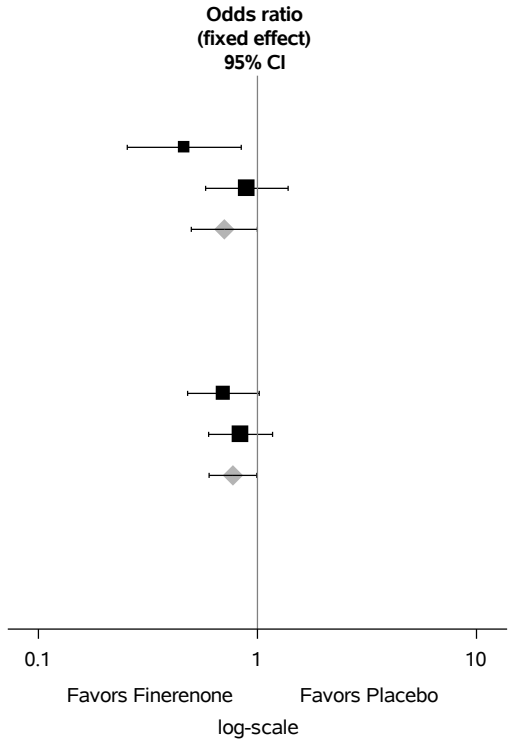
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	10 / 213	15.2	0.70 [0.26,1.88]	
FIGARO-DKD	44 / 1720	47 / 1698	84.8	0.92 [0.61,1.40]	
Total	51 / 1929	57 / 1911		0.88 [0.60,1.30]	Z=-0.63, p=0.5307
Heterogeneity:	Q=0.25 (df=1)	p=0.6199	I^2=0.0%		
Very High					
FIDELIO-DKD	57 / 2618	92 / 2618	51.5	0.61 [0.44,0.85]	
FIGARO-DKD	61 / 1963	74 / 1960	48.5	0.82 [0.58,1.15]	
Total	118 / 4581	166 / 4578		0.70 [0.55,0.89]	Z=-2.89, p=0.0039
Heterogeneity:	Q=1.41 (df=1)	p=0.2357	I^2=28.9%		
Subgroup Heterogeneity:	Q=1.00 (df=1)	p=0.3179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.70.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

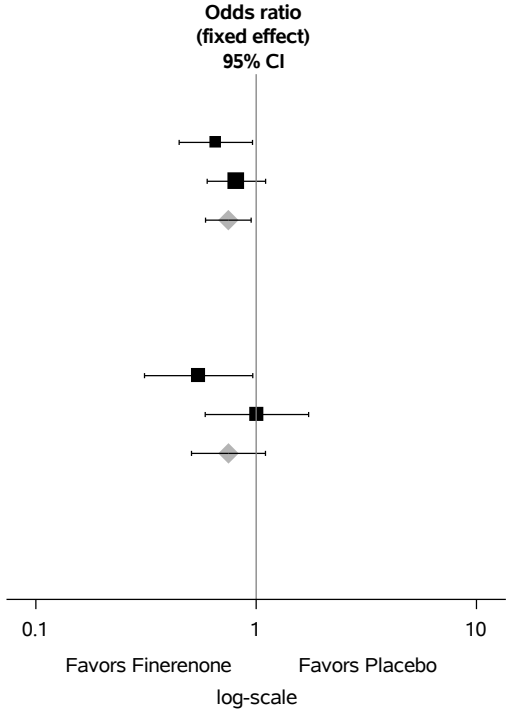
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	16 / 1301	34 / 1299	34.4	0.46 [0.25,0.84]	
FIGARO-DKD	40 / 1673	44 / 1651	65.6	0.89 [0.58,1.38]	
Total	56 / 2974	78 / 2950		0.71 [0.50,1.00]	Z=-1.97, p=0.0494
Heterogeneity:	Q=3.04 (df=1)	p=0.0810	I^2=67.1%		
Absent					
FIDELIO-DKD	48 / 1526	68 / 1532	44.3	0.70 [0.48,1.02]	
FIGARO-DKD	65 / 2010	77 / 2007	55.7	0.84 [0.60,1.17]	
Total	113 / 3536	145 / 3539		0.77 [0.60,0.99]	Z=-2.02, p=0.0437
Heterogeneity:	Q=0.49 (df=1)	p=0.4829	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6790	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.70.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

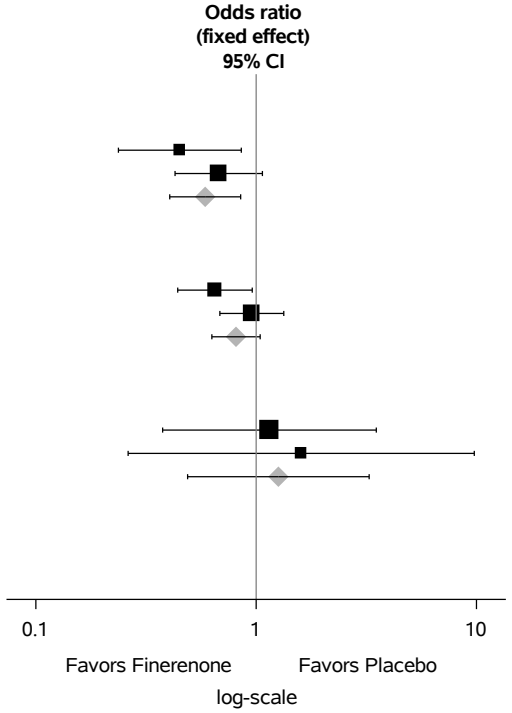
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	45 / 1879	67 / 1858	38.8	0.66 [0.45,0.96]	
FIGARO-DKD	78 / 2643	94 / 2608	61.2	0.81 [0.60,1.10]	
Total	123 / 4522	161 / 4466		0.75 [0.59,0.95]	Z=-2.39, p=0.0168
Heterogeneity:	Q=0.74 (df=1)	p=0.3896	I^2=0.0%		
> 4.5					
FIDELIO-DKD	19 / 948	35 / 973	47.7	0.55 [0.31,0.97]	
FIGARO-DKD	27 / 1040	27 / 1048	52.3	1.01 [0.59,1.73]	
Total	46 / 1988	62 / 2021		0.75 [0.51,1.10]	Z=-1.47, p=0.1423
Heterogeneity:	Q=2.33 (df=1)	p=0.1270	I^2=57.1%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.70.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

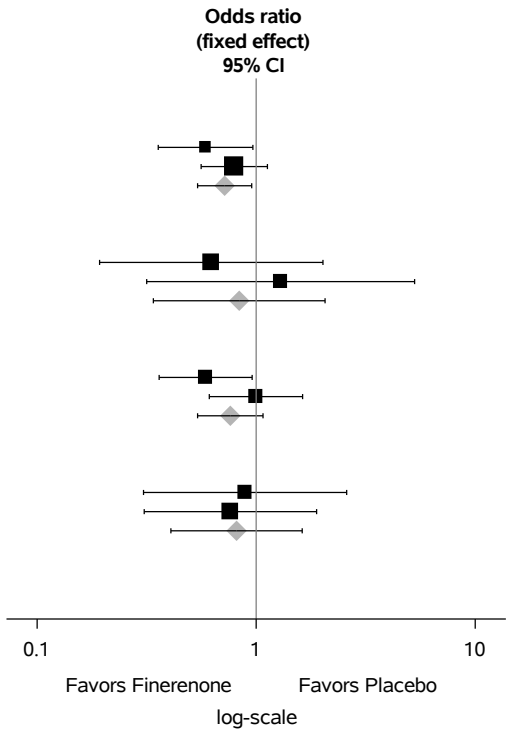
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 788	30 / 777	33.6	0.45 [0.24,0.86]	
FIGARO-DKD	32 / 1187	47 / 1194	66.4	0.68 [0.43,1.07]	
Total	46 / 1975	77 / 1971		0.59 [0.41,0.85]	Z=-2.82, p=0.0049
Heterogeneity:	Q=1.02 (df=1)	p=0.3121	I^2=2.1%		
130 - < 160					
FIDELIO-DKD	43 / 1897	66 / 1916	42.4	0.65 [0.44,0.96]	
FIGARO-DKD	70 / 2389	72 / 2351	57.6	0.96 [0.68,1.33]	
Total	113 / 4286	138 / 4267		0.81 [0.63,1.04]	Z=-1.64, p=0.1016
Heterogeneity:	Q=2.16 (df=1)	p=0.1413	I^2=53.8%		
>= 160					
FIDELIO-DKD	7 / 141	6 / 138	72.4	1.15 [0.38,3.51]	
FIGARO-DKD	3 / 107	2 / 113	27.6	1.60 [0.26,9.77]	
Total	10 / 248	8 / 251		1.26 [0.49,3.26]	Z=0.48, p=0.6316
Heterogeneity:	Q=0.09 (df=1)	p=0.7599	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.19 (df=2)	p=0.2030	I^2=37.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.70.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

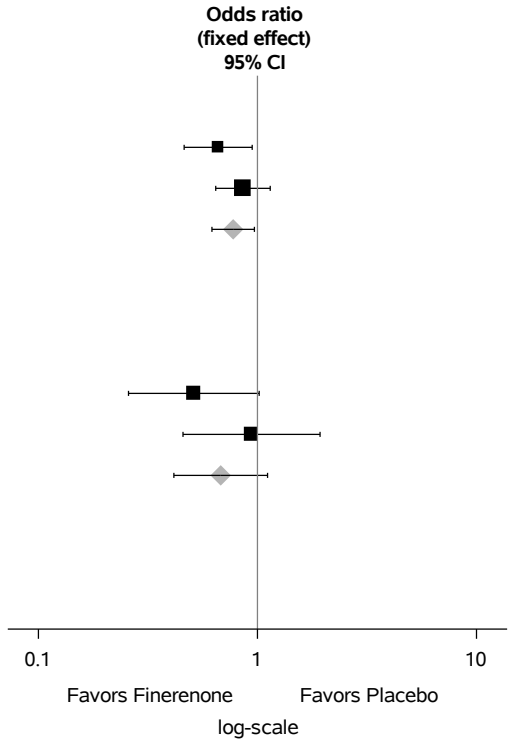
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	25 / 1773	43 / 1809	32.9	0.59 [0.36,0.97]	
FIGARO-DKD	59 / 2668	72 / 2601	67.1	0.79 [0.56,1.13]	
Total	84 / 4441	115 / 4410		0.72 [0.54,0.95]	Z=-2.28, p=0.0224
Heterogeneity:	Q=0.95 (df=1)	p=0.3300	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	7 / 124	59.0	0.62 [0.19,2.02]	
FIGARO-DKD	4 / 113	4 / 145	41.0	1.29 [0.32,5.29]	
Total	9 / 252	11 / 269		0.84 [0.34,2.06]	Z=-0.39, p=0.6986
Heterogeneity:	Q=0.61 (df=1)	p=0.4354	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 717	45 / 721	50.2	0.59 [0.36,0.96]	
FIGARO-DKD	33 / 716	34 / 736	49.8	1.00 [0.61,1.63]	
Total	60 / 1433	79 / 1457		0.76 [0.54,1.07]	Z=-1.55, p=0.1211
Heterogeneity:	Q=2.24 (df=1)	p=0.1343	I^2=55.4%		
Others					
FIDELIO-DKD	7 / 198	7 / 177	41.9	0.89 [0.31,2.59]	
FIGARO-DKD	9 / 186	11 / 176	58.1	0.76 [0.31,1.89]	
Total	16 / 384	18 / 353		0.81 [0.41,1.62]	Z=-0.59, p=0.5579
Heterogeneity:	Q=0.05 (df=1)	p=0.8289	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=3)	p=0.9764	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.70.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

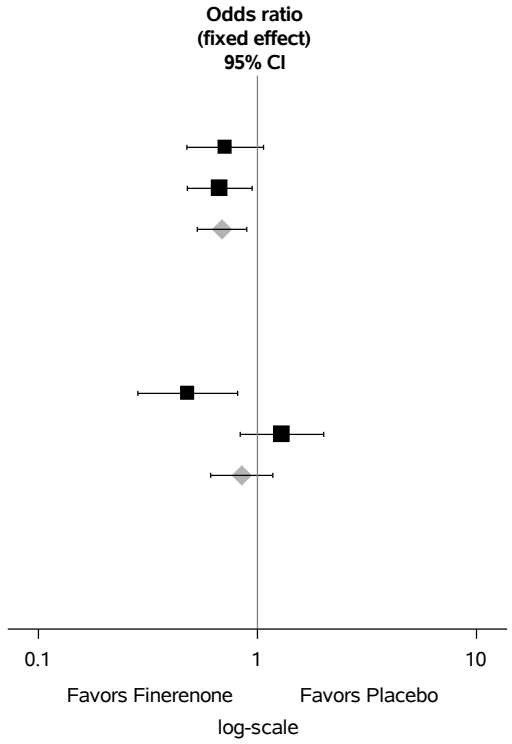
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 1949	79 / 2024	39.1	0.66 [0.46,0.95]	
FIGARO-DKD	90 / 2527	106 / 2571	60.9	0.86 [0.64,1.14]	
Total	141 / 4476	185 / 4595		0.77 [0.62,0.97]	Z=-2.24, p=0.0249
Heterogeneity:	Q=1.25 (df=1)	p=0.2644	I^2=19.7%		
Female					
FIDELIO-DKD	13 / 878	23 / 807	52.4	0.51 [0.26,1.02]	
FIGARO-DKD	15 / 1156	15 / 1087	47.6	0.94 [0.46,1.93]	
Total	28 / 2034	38 / 1894		0.68 [0.42,1.11]	Z=-1.54, p=0.1243
Heterogeneity:	Q=1.43 (df=1)	p=0.2324	I^2=29.9%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6353	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.70.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set

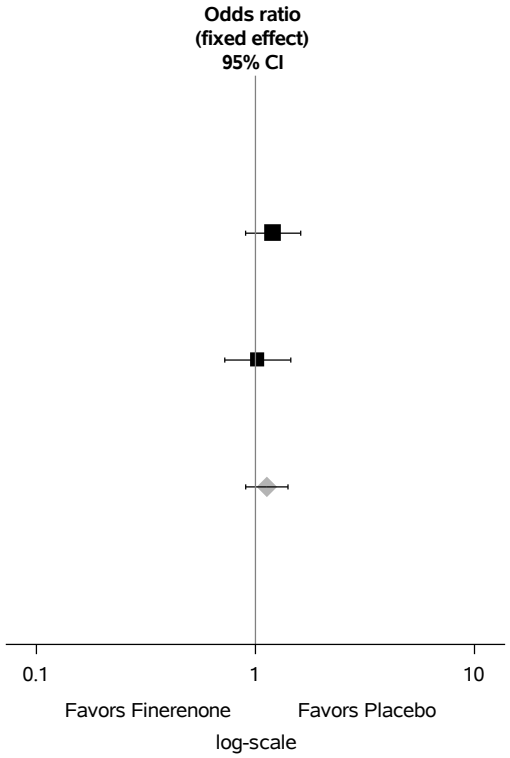
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	43 / 1201	58 / 1171	41.7	0.71 [0.48,1.07]	
FIGARO-DKD	58 / 1752	85 / 1755	58.3	0.67 [0.48,0.95]	
Total	101 / 2953	143 / 2926		0.69 [0.53,0.89]	Z=-2.81, p=0.0050
Heterogeneity:	Q=0.05 (df=1)	p=0.8306	I^2=0.0%		
>= 65					
FIDELIO-DKD	21 / 1626	44 / 1660	41.2	0.48 [0.28,0.81]	
FIGARO-DKD	47 / 1931	36 / 1903	58.8	1.29 [0.83,2.01]	
Total	68 / 3557	80 / 3563		0.85 [0.61,1.18]	Z=-0.99, p=0.3220
Heterogeneity:	Q=8.07 (df=1)	p=0.0045	I^2=87.6%		
Subgroup Heterogeneity:	Q=0.95 (df=1)	p=0.3301	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.71: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set

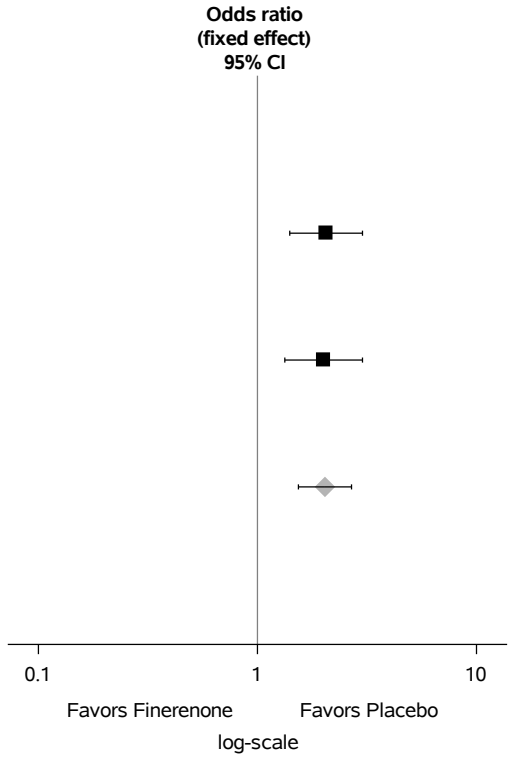
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	87 / 2831	58.9	1.20 [0.90,1.61]	
FIGARO-DKD	66 / 3683	64 / 3658	41.1	1.02 [0.72,1.45]	
Total	170 / 6510	151 / 6489		1.13 [0.90,1.41]	Z=1.06, p=0.2904
Heterogeneity:	Q=0.49 (df=1)	p=0.4830	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.72: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

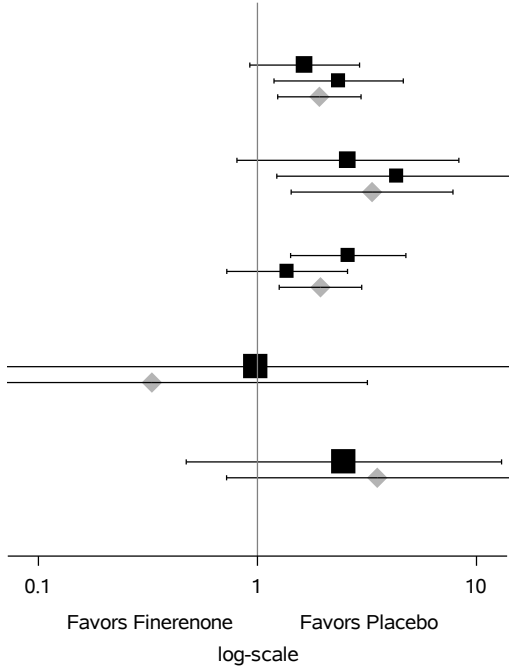
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	81 / 2827	40 / 2831	53.3	2.06 [1.40,3.02]	
FIGARO-DKD	70 / 3683	35 / 3658	46.7	2.01 [1.33,3.02]	
Total	151 / 6510	75 / 6489		2.03 [1.54,2.69]	Z=4.98, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9277	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.72.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

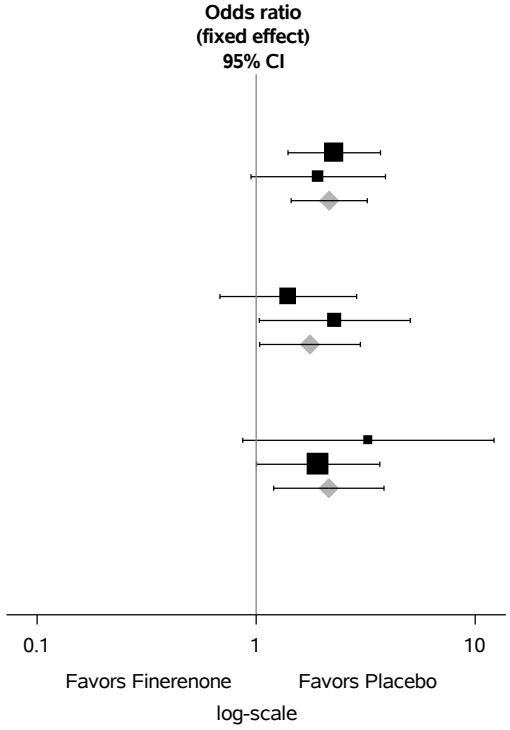
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	31 / 1178	19 / 1174	58.1	1.64 [0.92,2.93]	
FIGARO-DKD	28 / 1752	12 / 1747	41.9	2.35 [1.19,4.63]	
Total	59 / 2930	31 / 2921		1.92 [1.24,2.97]	Z=2.91, p=0.0036
Heterogeneity:	Q=0.62 (df=1)	p=0.4321	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	4 / 476	53.9	2.59 [0.81,8.31]	
FIGARO-DKD	13 / 559	3 / 548	46.1	4.33 [1.23,15.26]	
Total	23 / 1025	7 / 1024		3.34 [1.43,7.81]	Z=2.78, p=0.0055
Heterogeneity:	Q=0.35 (df=1)	p=0.5569	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	15 / 786	52.3	2.60 [1.42,4.76]	
FIGARO-DKD	23 / 811	17 / 813	47.7	1.37 [0.72,2.58]	
Total	61 / 1601	32 / 1599		1.94 [1.26,2.99]	Z=2.99, p=0.0028
Heterogeneity:	Q=2.06 (df=1)	p=0.1511	I^2=51.5%		
Latin America					
FIDELIO-DKD	0 / 294	2 / 294	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	1 / 424	1 / 417	100.0	0.98 [0.06,15.77]	
Total	1 / 718	3 / 711		0.33 [0.03,3.18]	Z=-0.96, p=0.3370
Heterogeneity:	Q=0.60 (df=1)	p=0.4401	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	117E9 [117E9,117E9]	
FIGARO-DKD	5 / 137	2 / 133	100.0	2.48 [0.47,13.02]	
Total	7 / 236	2 / 234		3.52 [0.72,17.17]	Z=1.56, p=0.1192
Heterogeneity:	Q=0.17 (df=1)	p=0.6785	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.36 (df=4)	p=0.3599	I^2=8.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.72.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

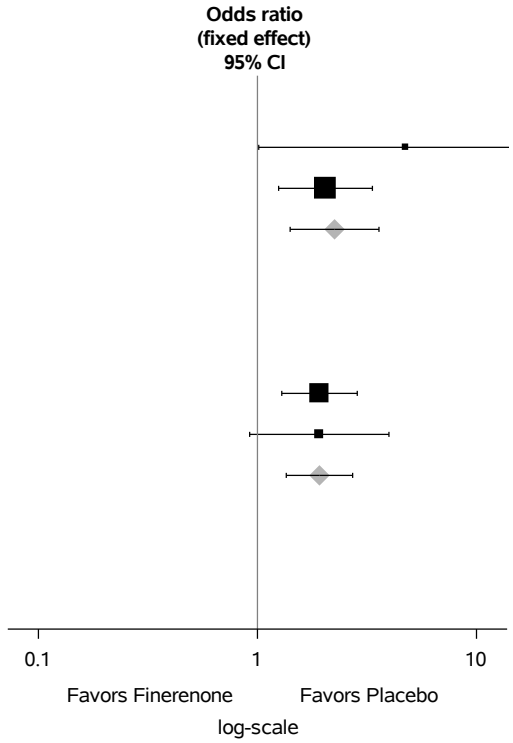
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	54 / 1556	24 / 1541	67.9	2.27 [1.40,3.69]	
FIGARO-DKD	23 / 637	12 / 627	32.1	1.92 [0.95,3.89]	
Total	77 / 2193	36 / 2168		2.15 [1.44,3.22]	Z=3.76, p=0.0002
Heterogeneity:	Q=0.15 (df=1)	p=0.7000	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	18 / 1061	13 / 1069	55.0	1.40 [0.68,2.88]	
FIGARO-DKD	20 / 720	9 / 729	45.0	2.29 [1.03,5.05]	
Total	38 / 1781	22 / 1798		1.76 [1.04,2.99]	Z=2.10, p=0.0361
Heterogeneity:	Q=0.80 (df=1)	p=0.3705	I^2=0.0%		
>= 60					
FIDELIO-DKD	9 / 210	3 / 221	19.4	3.25 [0.87,12.19]	
FIGARO-DKD	27 / 2326	14 / 2302	80.6	1.92 [1.00,3.67]	
Total	36 / 2536	17 / 2523		2.15 [1.20,3.83]	Z=2.58, p=0.0099
Heterogeneity:	Q=0.50 (df=1)	p=0.4815	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=2)	p=0.8198	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.72.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

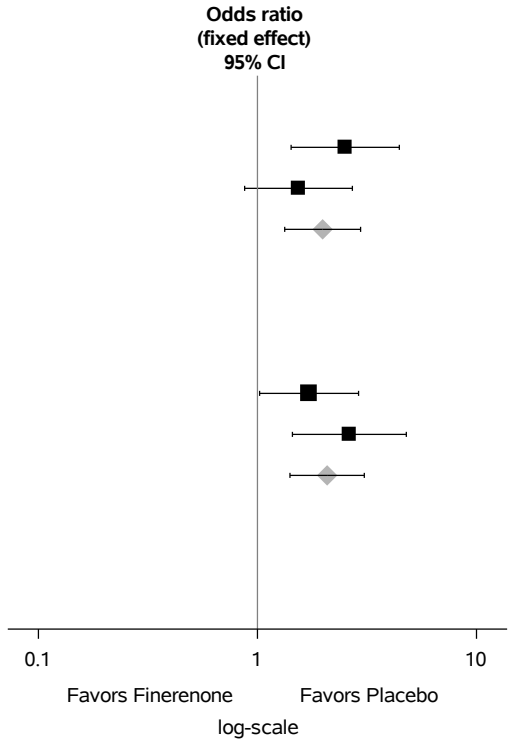
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	9 / 209	2 / 213	9.2	4.75 [1.01,22.24]	
FIGARO-DKD	49 / 1720	24 / 1698	90.8	2.05 [1.25,3.35]	
Total	58 / 1929	26 / 1911		2.25 [1.41,3.59]	Z=3.40, p=0.0007
Heterogeneity:	Q=1.04 (df=1)	p=0.3075	I^2=4.0%		
Very High					
FIDELIO-DKD	72 / 2618	38 / 2618	77.3	1.92 [1.29,2.86]	
FIGARO-DKD	21 / 1963	11 / 1960	22.7	1.92 [0.92,3.98]	
Total	93 / 4581	49 / 4578		1.92 [1.35,2.72]	Z=3.66, p=0.0002
Heterogeneity:	Q=0.00 (df=1)	p=0.9960	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5936	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.72.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

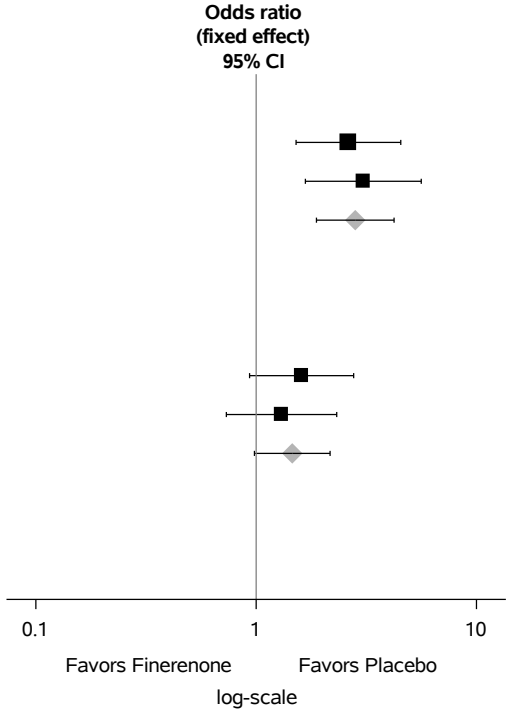
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	42 / 1301	17 / 1299	49.8	2.52 [1.42,4.44]	
FIGARO-DKD	31 / 1673	20 / 1651	50.2	1.54 [0.87,2.71]	
Total	73 / 2974	37 / 2950		1.98 [1.33,2.96]	Z=3.37, p=0.0008
Heterogeneity:	Q=1.44 (df=1)	p=0.2302	I^2=30.6%		
Absent					
FIDELIO-DKD	39 / 1526	23 / 1532	57.0	1.72 [1.02,2.90]	
FIGARO-DKD	39 / 2010	15 / 2007	43.0	2.63 [1.44,4.78]	
Total	78 / 3536	38 / 3539		2.08 [1.41,3.07]	Z=3.67, p=0.0002
Heterogeneity:	Q=1.10 (df=1)	p=0.2952	I^2=8.7%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.72.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

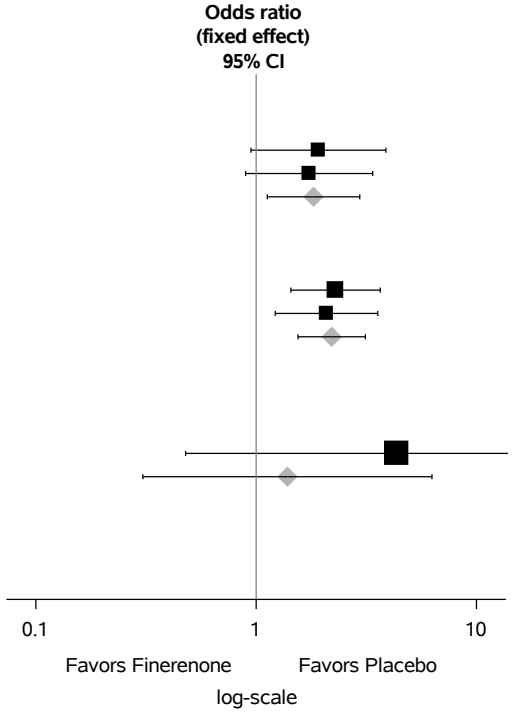
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	47 / 1879	18 / 1858	55.1	2.62 [1.52,4.53]	
FIGARO-DKD	43 / 2643	14 / 2608	44.9	3.06 [1.67,5.61]	
Total	90 / 4522	32 / 4466		2.82 [1.88,4.23]	Z=5.00, p=<.0001
Heterogeneity:	Q=0.14 (df=1)	p=0.7084	I^2=0.0%		
> 4.5					
FIDELIO-DKD	34 / 948	22 / 973	52.9	1.61 [0.93,2.77]	
FIGARO-DKD	27 / 1040	21 / 1048	47.1	1.30 [0.73,2.32]	
Total	61 / 1988	43 / 2021		1.46 [0.98,2.17]	Z=1.87, p=0.0616
Heterogeneity:	Q=0.27 (df=1)	p=0.6037	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.19 (df=1)	p=0.0227	I^2=80.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.72.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

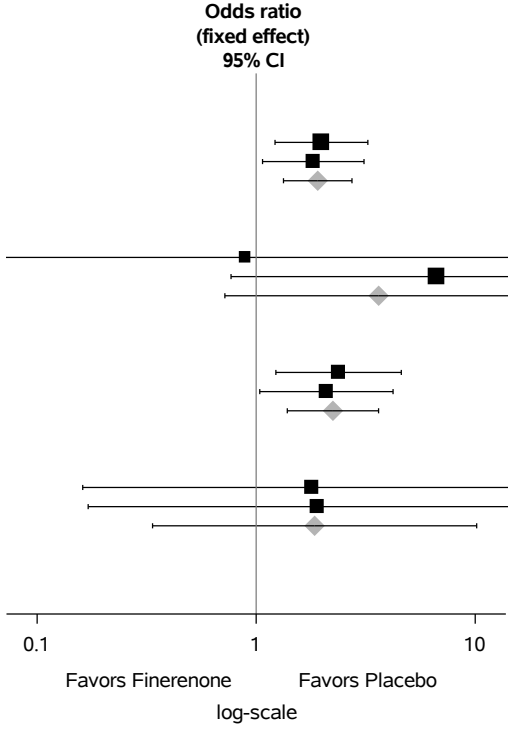
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	23 / 788	12 / 777	47.0	1.92 [0.95,3.88]	
FIGARO-DKD	24 / 1187	14 / 1194	53.0	1.74 [0.90,3.38]	
Total	47 / 1975	26 / 1971		1.82 [1.12,2.95]	Z=2.43, p=0.0151
Heterogeneity:	Q=0.04 (df=1)	p=0.8443	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	58 / 1897	26 / 1916	56.8	2.29 [1.44,3.66]	
FIGARO-DKD	42 / 2389	20 / 2351	43.2	2.09 [1.22,3.56]	
Total	100 / 4286	46 / 4267		2.20 [1.55,3.13]	Z=4.39, p=<.0001
Heterogeneity:	Q=0.07 (df=1)	p=0.7941	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	2 / 138	0.0	0.00 [0.00,79E295]	
FIGARO-DKD	4 / 107	1 / 113	100.0	4.35 [0.48,39.55]	
Total	4 / 248	3 / 251		1.39 [0.31,6.28]	Z=0.42, p=0.6718
Heterogeneity:	Q=1.03 (df=1)	p=0.3100	I^2=3.0%		
Subgroup Heterogeneity:	Q=0.64 (df=2)	p=0.7251	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.72.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

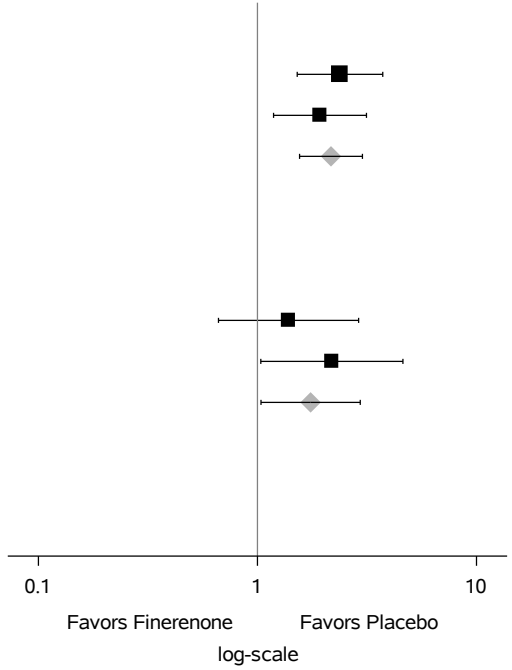
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	48 / 1773	25 / 1809	54.4	1.99 [1.22,3.23]	
FIGARO-DKD	39 / 2668	21 / 2601	45.6	1.82 [1.07,3.11]	
Total	87 / 4441	46 / 4410		1.91 [1.33,2.74]	Z=3.52, p=0.0004
Heterogeneity:	Q=0.05 (df=1)	p=0.8162	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	1 / 124	37.6	0.89 [0.06,14.40]	
FIGARO-DKD	5 / 113	1 / 145	62.4	6.67 [0.77,57.89]	
Total	6 / 252	2 / 269		3.62 [0.72,18.25]	Z=1.56, p=0.1185
Heterogeneity:	Q=1.28 (df=1)	p=0.2576	I^2=22.0%		
Asian					
FIDELIO-DKD	30 / 717	13 / 721	53.1	2.38 [1.23,4.60]	
FIGARO-DKD	24 / 716	12 / 736	46.9	2.09 [1.04,4.22]	
Total	54 / 1433	25 / 1457		2.24 [1.39,3.62]	Z=3.30, p=0.0010
Heterogeneity:	Q=0.07 (df=1)	p=0.7943	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	1 / 177	50.0	1.80 [0.16,19.98]	
FIGARO-DKD	2 / 186	1 / 176	50.0	1.90 [0.17,21.17]	
Total	4 / 384	2 / 353		1.85 [0.34,10.16]	Z=0.71, p=0.4797
Heterogeneity:	Q=0.00 (df=1)	p=0.9736	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=3)	p=0.8562	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.72.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

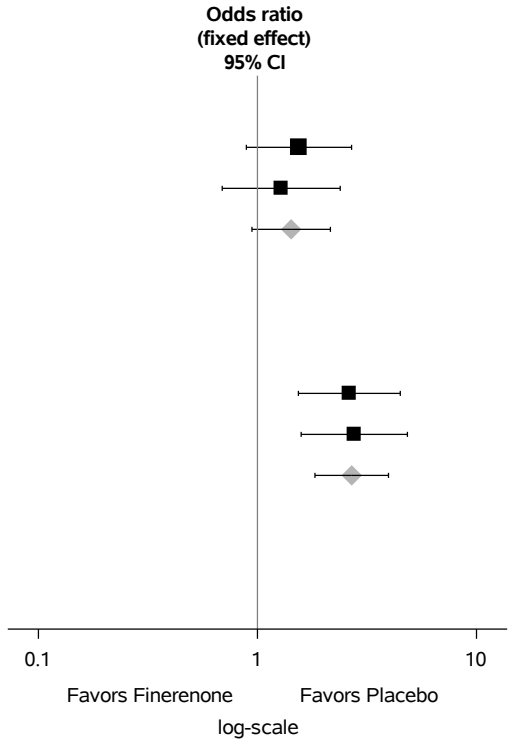
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	63 / 1949	28 / 2024	54.1	2.38 [1.52,3.73]	
FIGARO-DKD	47 / 2527	25 / 2571	45.9	1.93 [1.18,3.15]	
Total	110 / 4476	53 / 4595		2.17 [1.56,3.01]	Z=4.58, p=<.0001
Heterogeneity:	Q=0.38 (df=1)	p=0.5350	I^2=0.0%		
Female					
FIDELIO-DKD	18 / 878	12 / 807	50.7	1.39 [0.66,2.90]	
FIGARO-DKD	23 / 1156	10 / 1087	49.3	2.19 [1.04,4.61]	
Total	41 / 2034	22 / 1894		1.75 [1.04,2.95]	Z=2.10, p=0.0358
Heterogeneity:	Q=0.72 (df=1)	p=0.3948	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4968	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.72.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set

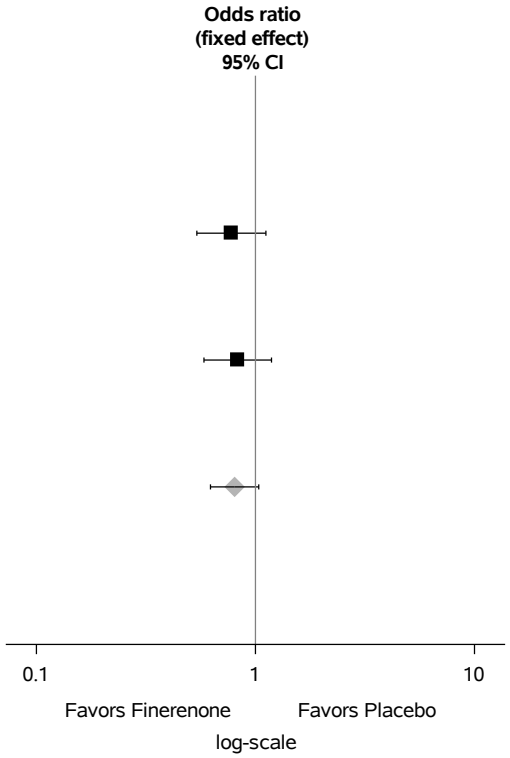
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	33 / 1201	21 / 1171	55.7	1.55 [0.89,2.69]	
FIGARO-DKD	23 / 1752	18 / 1755	44.3	1.28 [0.69,2.39]	
Total	56 / 2953	39 / 2926		1.43 [0.94,2.15]	Z=1.68, p=0.0920
Heterogeneity:	Q=0.19 (df=1)	p=0.6597	I^2=0.0%		
>= 65					
FIDELIO-DKD	48 / 1626	19 / 1660	52.1	2.63 [1.54,4.49]	
FIGARO-DKD	47 / 1931	17 / 1903	47.9	2.77 [1.58,4.84]	
Total	95 / 3557	36 / 3563		2.69 [1.83,3.97]	Z=5.03, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8950	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.87 (df=1)	p=0.0273	I^2=79.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.73: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set

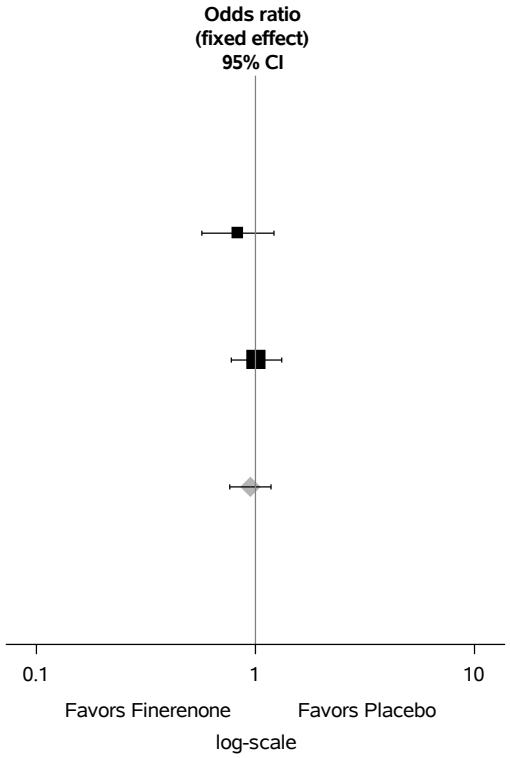
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	68 / 2831	48.9	0.78 [0.54,1.12]	
FIGARO-DKD	57 / 3683	68 / 3658	51.1	0.83 [0.58,1.18]	
Total	110 / 6510	136 / 6489		0.80 [0.62,1.04]	Z=-1.69, p=0.0905
Heterogeneity:	Q=0.07 (df=1)	p=0.7966	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.74: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set

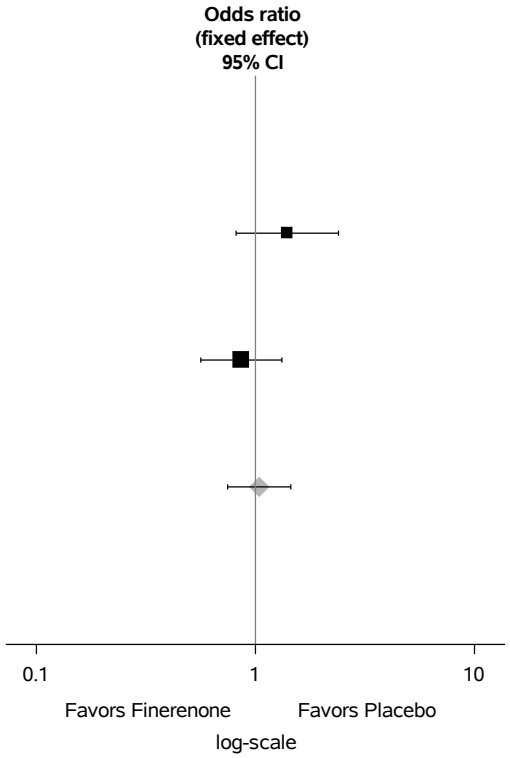
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	50 / 2827	60 / 2831	32.8	0.83 [0.57,1.21]	
FIGARO-DKD	114 / 3683	112 / 3658	67.2	1.01 [0.78,1.32]	
Total	164 / 6510	172 / 6489		0.95 [0.76,1.18]	Z=-0.48, p=0.6307
Heterogeneity:	Q=0.69 (df=1)	p=0.4067	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.75: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set

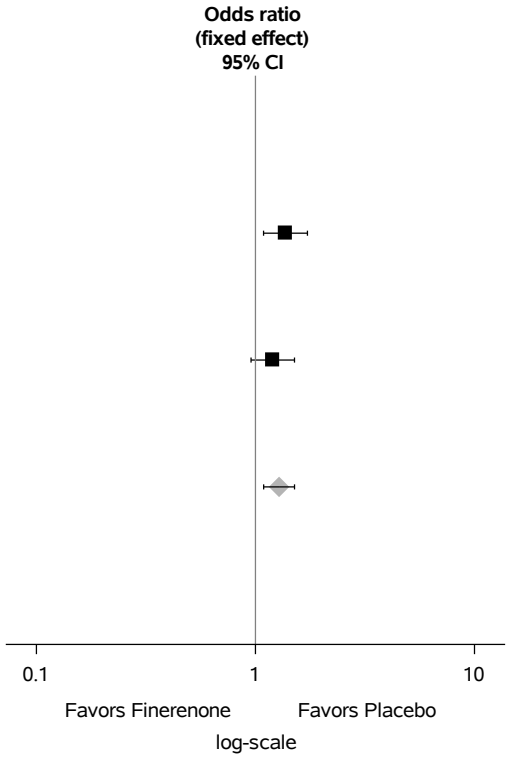
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	23 / 2831	38.5	1.40 [0.82,2.39]	
FIGARO-DKD	40 / 3683	46 / 3658	61.5	0.86 [0.56,1.32]	
Total	72 / 6510	69 / 6489		1.04 [0.75,1.45]	Z=0.23, p=0.8161
Heterogeneity:	Q=1.90 (df=1)	p=0.1678	I^2=47.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.76: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

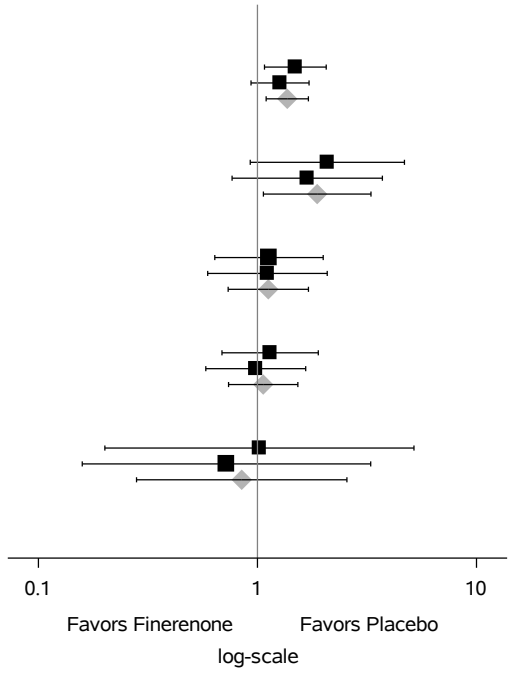
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	179 / 2827	133 / 2831	49.5	1.37 [1.09,1.73]	
FIGARO-DKD	169 / 3683	141 / 3658	50.5	1.20 [0.95,1.51]	
Total	348 / 6510	274 / 6489		1.28 [1.09,1.51]	Z=3.00, p=0.0027
Heterogeneity:	Q=0.65 (df=1)	p=0.4193	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.76.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

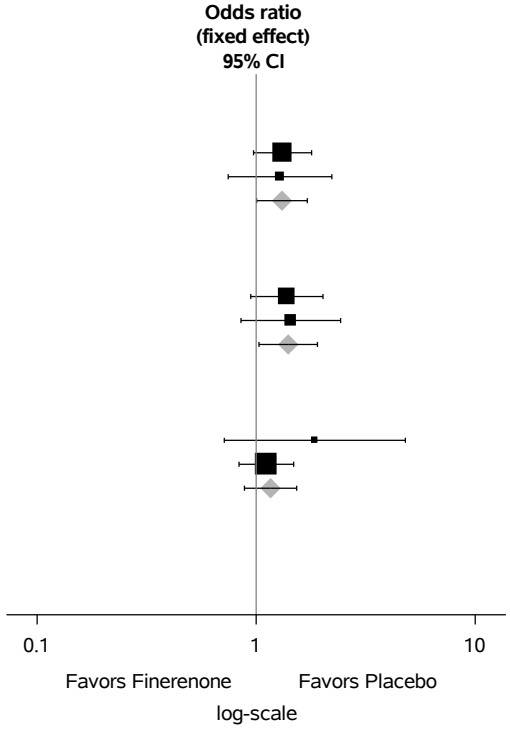
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	96 / 1178	66 / 1174	46.9	1.49 [1.08,2.06]	
FIGARO-DKD	98 / 1752	78 / 1747	53.1	1.27 [0.93,1.72]	
Total	194 / 2930	144 / 2921		1.37 [1.10,1.71]	Z=2.76, p=0.0057
Heterogeneity:	Q=0.50 (df=1)	p=0.4781	I^2=0.0%		
North America					
FIDELIO-DKD	18 / 466	9 / 476	48.7	2.08 [0.93,4.69]	
FIGARO-DKD	17 / 559	10 / 548	51.3	1.69 [0.77,3.72]	
Total	35 / 1025	19 / 1024		1.87 [1.06,3.30]	Z=2.18, p=0.0295
Heterogeneity:	Q=0.13 (df=1)	p=0.7142	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 790	23 / 786	54.9	1.13 [0.64,2.00]	
FIGARO-DKD	21 / 811	19 / 813	45.1	1.11 [0.59,2.08]	
Total	47 / 1601	42 / 1599		1.12 [0.73,1.71]	Z=0.53, p=0.5966
Heterogeneity:	Q=0.00 (df=1)	p=0.9702	I^2=0.0%		
Latin America					
FIDELIO-DKD	36 / 294	32 / 294	51.8	1.14 [0.69,1.90]	
FIGARO-DKD	30 / 424	30 / 417	48.2	0.98 [0.58,1.66]	
Total	66 / 718	62 / 711		1.06 [0.74,1.53]	Z=0.33, p=0.7450
Heterogeneity:	Q=0.16 (df=1)	p=0.6848	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 99	3 / 101	46.5	1.02 [0.20,5.18]	
FIGARO-DKD	3 / 137	4 / 133	53.5	0.72 [0.16,3.29]	
Total	6 / 236	7 / 234		0.85 [0.28,2.56]	Z=-0.29, p=0.7693
Heterogeneity:	Q=0.09 (df=1)	p=0.7600	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.01 (df=4)	p=0.4050	I^2=0.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.76.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

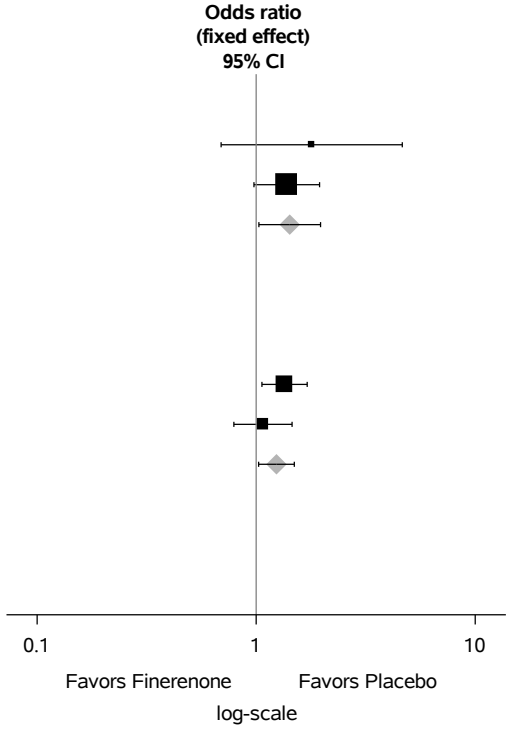
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	101 / 1556	77 / 1541	76.1	1.32 [0.97,1.79]	
FIGARO-DKD	31 / 637	24 / 627	23.9	1.29 [0.75,2.22]	
Total	132 / 2193	101 / 2168		1.31 [1.00,1.71]	Z=2.00, p=0.0460
Heterogeneity:	Q=0.01 (df=1)	p=0.9337	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	66 / 1061	49 / 1069	65.6	1.38 [0.94,2.02]	
FIGARO-DKD	35 / 720	25 / 729	34.4	1.44 [0.85,2.43]	
Total	101 / 1781	74 / 1798		1.40 [1.03,1.90]	Z=2.15, p=0.0318
Heterogeneity:	Q=0.02 (df=1)	p=0.9007	I^2=0.0%		
>= 60					
FIDELIO-DKD	12 / 210	7 / 221	8.3	1.85 [0.72,4.80]	
FIGARO-DKD	103 / 2326	92 / 2302	91.7	1.11 [0.84,1.48]	
Total	115 / 2536	99 / 2523		1.16 [0.88,1.53]	Z=1.08, p=0.2801
Heterogeneity:	Q=1.01 (df=1)	p=0.3151	I^2=0.9%		
Subgroup Heterogeneity:	Q=0.83 (df=2)	p=0.6615	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.76.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

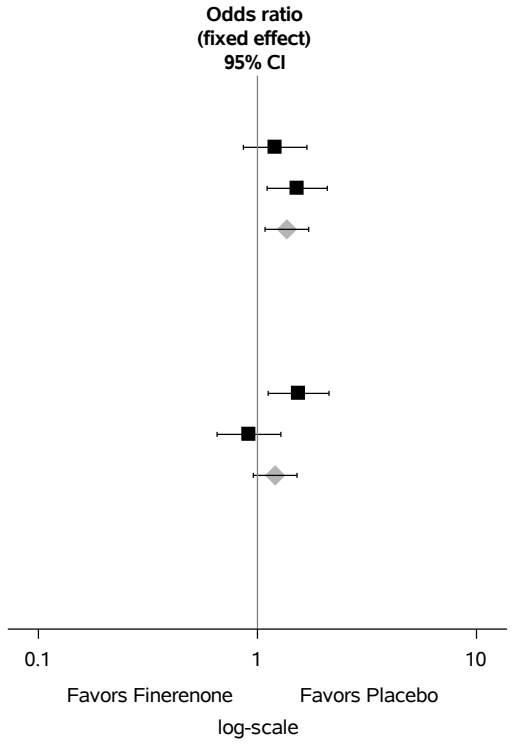
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	12 / 209	7 / 213	11.6	1.79 [0.69,4.65]	
FIGARO-DKD	80 / 1720	58 / 1698	88.4	1.38 [0.98,1.95]	
Total	92 / 1929	65 / 1911		1.42 [1.03,1.97]	Z=2.13, p=0.0329
Heterogeneity:	Q=0.26 (df=1)	p=0.6120	I^2=0.0%		
Very High					
FIDELIO-DKD	167 / 2618	126 / 2618	62.3	1.35 [1.06,1.71]	
FIGARO-DKD	89 / 1963	83 / 1960	37.7	1.07 [0.79,1.46]	
Total	256 / 4581	209 / 4578		1.24 [1.03,1.49]	Z=2.23, p=0.0259
Heterogeneity:	Q=1.32 (df=1)	p=0.2511	I^2=24.1%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4654	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.76.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

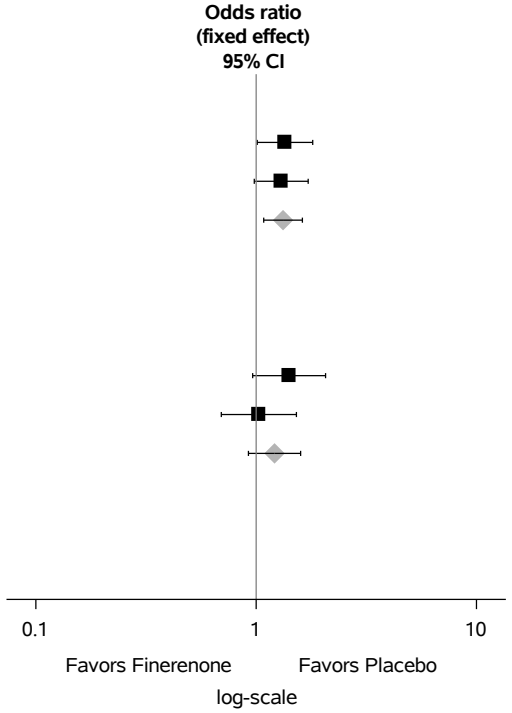
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	80 / 1301	67 / 1299	47.3	1.20 [0.86,1.68]	
FIGARO-DKD	101 / 1673	67 / 1651	52.7	1.52 [1.11,2.08]	
Total	181 / 2974	134 / 2950		1.36 [1.08,1.71]	Z=2.64, p=0.0082
Heterogeneity:	Q=0.97 (df=1)	p=0.3238	I^2=0.0%		
Absent					
FIDELIO-DKD	99 / 1526	66 / 1532	52.3	1.54 [1.12,2.12]	
FIGARO-DKD	68 / 2010	74 / 2007	47.7	0.91 [0.65,1.28]	
Total	167 / 3536	140 / 3539		1.20 [0.96,1.52]	Z=1.59, p=0.1123
Heterogeneity:	Q=4.87 (df=1)	p=0.0273	I^2=79.5%		
Subgroup Heterogeneity:	Q=0.55 (df=1)	p=0.4576	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.76.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

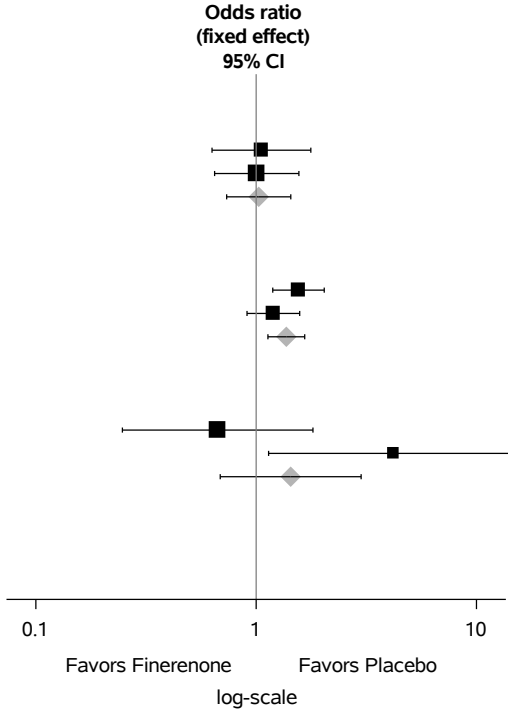
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	113 / 1879	84 / 1858	48.5	1.35 [1.01,1.81]	
FIGARO-DKD	116 / 2643	89 / 2608	51.5	1.30 [0.98,1.72]	
Total	229 / 4522	173 / 4466		1.32 [1.08,1.62]	Z=2.73, p=0.0064
Heterogeneity:	Q=0.04 (df=1)	p=0.8488	I^2=0.0%		
> 4.5					
FIDELIO-DKD	66 / 948	49 / 973	51.5	1.41 [0.96,2.07]	
FIGARO-DKD	53 / 1040	52 / 1048	48.5	1.03 [0.69,1.52]	
Total	119 / 1988	101 / 2021		1.21 [0.92,1.59]	Z=1.38, p=0.1680
Heterogeneity:	Q=1.28 (df=1)	p=0.2572	I^2=22.1%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6072	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.76.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

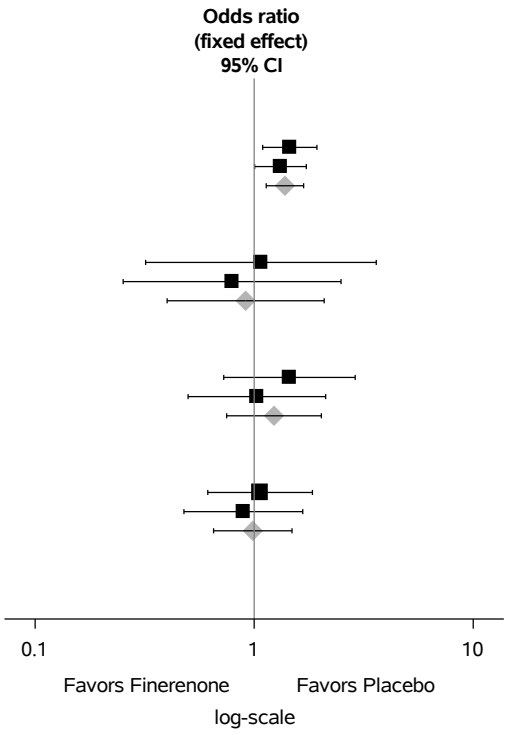
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	31 / 788	29 / 777	42.1	1.06 [0.63,1.77]	
FIGARO-DKD	41 / 1187	41 / 1194	57.9	1.01 [0.65,1.56]	
Total	72 / 1975	70 / 1971		1.03 [0.73,1.44]	Z=0.16, p=0.8764
Heterogeneity:	Q=0.02 (df=1)	p=0.8883	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	141 / 1897	94 / 1916	51.2	1.56 [1.19,2.04]	
FIGARO-DKD	117 / 2389	97 / 2351	48.8	1.20 [0.91,1.58]	
Total	258 / 4286	191 / 4267		1.37 [1.13,1.66]	Z=3.21, p=0.0013
Heterogeneity:	Q=1.79 (df=1)	p=0.1809	I^2=44.2%		
>= 160					
FIDELIO-DKD	7 / 141	10 / 138	63.2	0.67 [0.25,1.81]	
FIGARO-DKD	11 / 107	3 / 113	36.8	4.20 [1.14,15.50]	
Total	18 / 248	13 / 251		1.43 [0.69,2.99]	Z=0.96, p=0.3370
Heterogeneity:	Q=4.86 (df=1)	p=0.0275	I^2=79.4%		
Subgroup Heterogeneity:	Q=2.23 (df=2)	p=0.3271	I^2=10.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.76.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

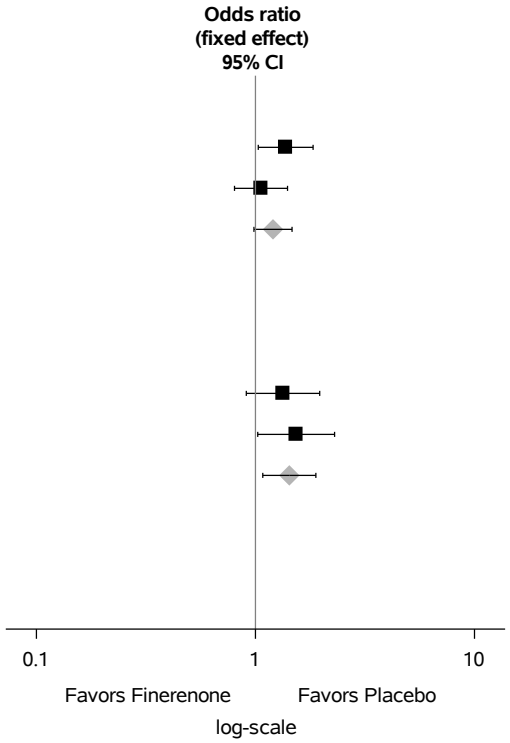
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	120 / 1773	86 / 1809	47.6	1.45 [1.09,1.93]	
FIGARO-DKD	127 / 2668	95 / 2601	52.4	1.32 [1.00,1.73]	
Total	247 / 4441	181 / 4410		1.38 [1.14,1.68]	Z=3.22, p=0.0013
Heterogeneity:	Q=0.24 (df=1)	p=0.6250	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 139	5 / 124	47.2	1.07 [0.32,3.61]	
FIGARO-DKD	5 / 113	8 / 145	52.8	0.79 [0.25,2.49]	
Total	11 / 252	13 / 269		0.91 [0.40,2.09]	Z=-0.21, p=0.8312
Heterogeneity:	Q=0.13 (df=1)	p=0.7216	I^2=0.0%		
Asian					
FIDELIO-DKD	20 / 717	14 / 721	52.3	1.45 [0.73,2.89]	
FIGARO-DKD	15 / 716	15 / 736	47.7	1.03 [0.50,2.12]	
Total	35 / 1433	29 / 1457		1.23 [0.75,2.03]	Z=0.82, p=0.4115
Heterogeneity:	Q=0.45 (df=1)	p=0.5018	I^2=0.0%		
Others					
FIDELIO-DKD	33 / 198	28 / 177	56.3	1.06 [0.61,1.84]	
FIGARO-DKD	22 / 186	23 / 176	43.7	0.89 [0.48,1.67]	
Total	55 / 384	51 / 353		0.99 [0.65,1.49]	Z=-0.07, p=0.9447
Heterogeneity:	Q=0.17 (df=1)	p=0.6782	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.78 (df=3)	p=0.4265	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.76.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

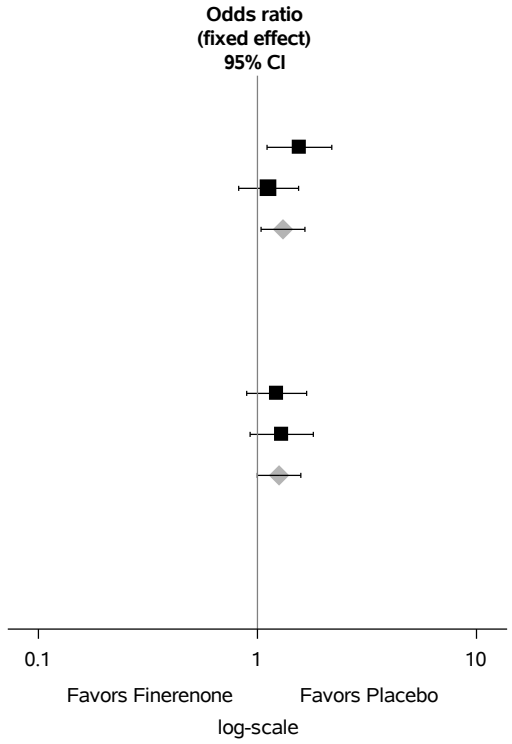
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	112 / 1949	86 / 2024	48.4	1.37 [1.03,1.83]	
FIGARO-DKD	105 / 2527	101 / 2571	51.6	1.06 [0.80,1.40]	
Total	217 / 4476	187 / 4595		1.20 [0.98,1.47]	Z=1.81, p=0.0709
Heterogeneity:	Q=1.61 (df=1)	p=0.2052	I^2=37.7%		
Female					
FIDELIO-DKD	67 / 878	47 / 807	52.3	1.34 [0.91,1.96]	
FIGARO-DKD	64 / 1156	40 / 1087	47.7	1.53 [1.02,2.30]	
Total	131 / 2034	87 / 1894		1.43 [1.08,1.89]	Z=2.50, p=0.0124
Heterogeneity:	Q=0.24 (df=1)	p=0.6275	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.96 (df=1)	p=0.3271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.76.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set

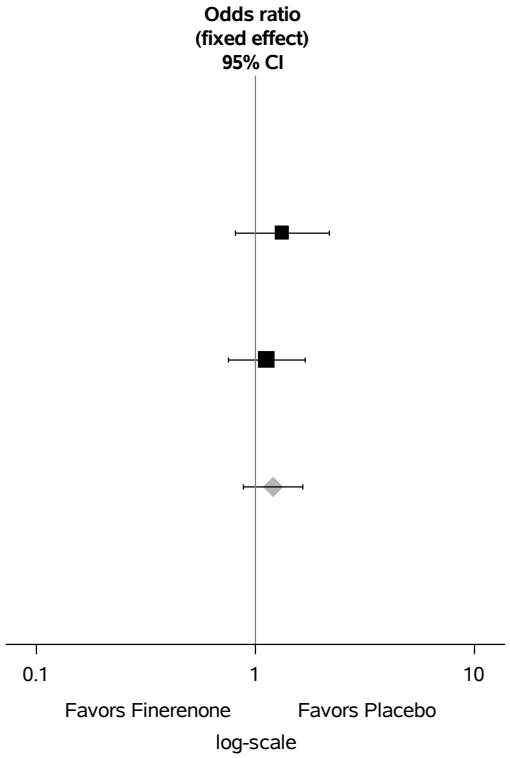
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	90 / 1201	58 / 1171	46.1	1.55 [1.11,2.18]	
FIGARO-DKD	86 / 1752	77 / 1755	53.9	1.12 [0.82,1.54]	
Total	176 / 2953	135 / 2926		1.31 [1.04,1.65]	Z=2.28, p=0.0224
Heterogeneity:	Q=1.87 (df=1)	p=0.1715	I^2=46.5%		
>= 65					
FIDELIO-DKD	89 / 1626	75 / 1660	52.7	1.22 [0.89,1.68]	
FIGARO-DKD	83 / 1931	64 / 1903	47.3	1.29 [0.93,1.80]	
Total	172 / 3557	139 / 3563		1.25 [1.00,1.58]	Z=1.95, p=0.0516
Heterogeneity:	Q=0.05 (df=1)	p=0.8200	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8026	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.77: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set

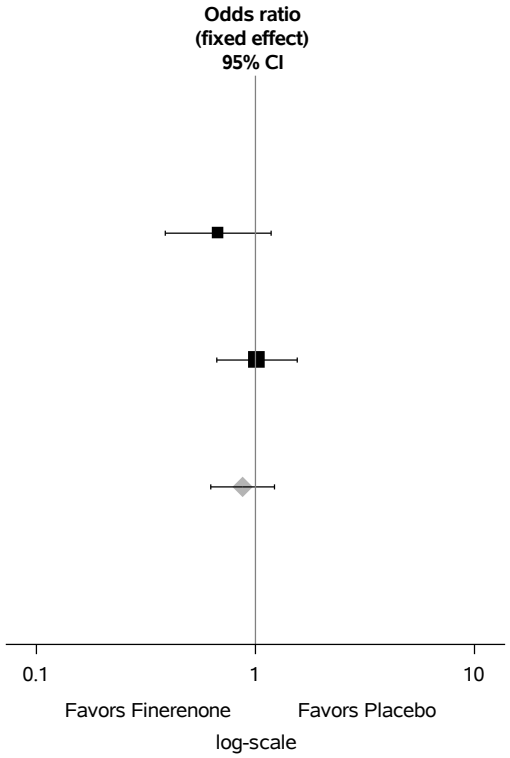
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2827	28 / 2831	40.0	1.33 [0.81,2.18]	
FIGARO-DKD	51 / 3683	45 / 3658	60.0	1.13 [0.75,1.69]	
Total	88 / 6510	73 / 6489		1.20 [0.88,1.65]	Z=1.17, p=0.2437
Heterogeneity:	Q=0.25 (df=1)	p=0.6154	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.78: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set

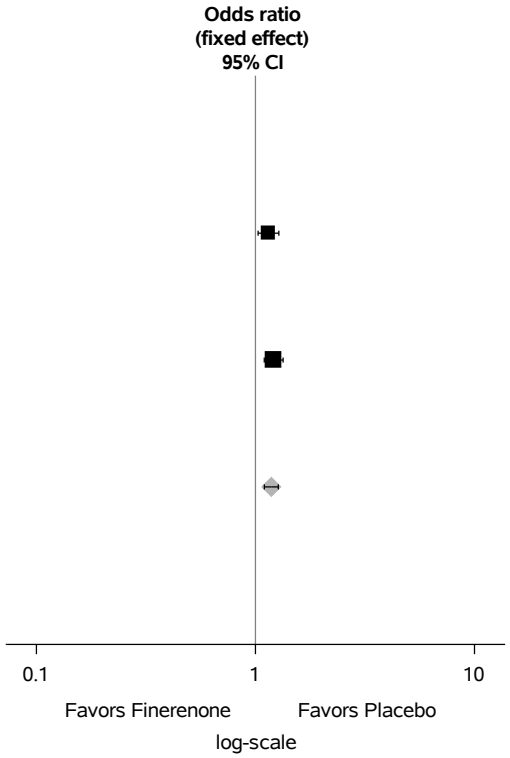
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	31 / 2831	36.6	0.68 [0.39,1.18]	
FIGARO-DKD	44 / 3683	43 / 3658	63.4	1.02 [0.67,1.55]	
Total	65 / 6510	74 / 6489		0.87 [0.63,1.22]	Z=-0.79, p=0.4301
Heterogeneity:	Q=1.31 (df=1)	p=0.2525	I^2=23.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.79: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

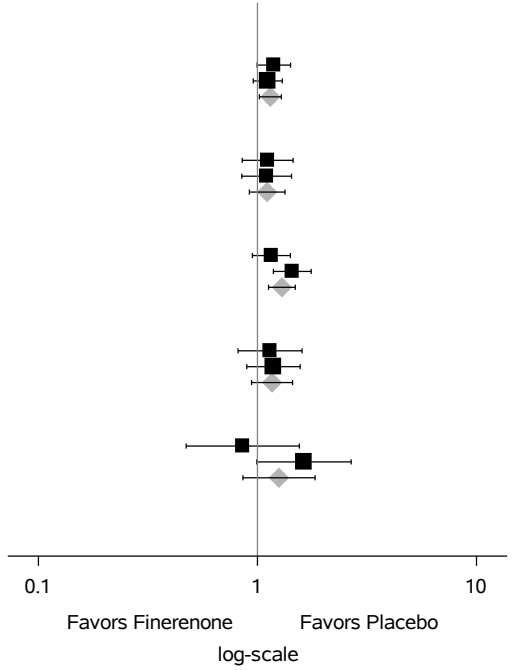
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1045 / 2827	958 / 2831	45.2	1.15 [1.03,1.28]	
FIGARO-DKD	1218 / 3683	1060 / 3658	54.8	1.21 [1.10,1.34]	
Total	2263 / 6510	2018 / 6489		1.18 [1.10,1.27]	Z=4.46, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4663	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.79.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

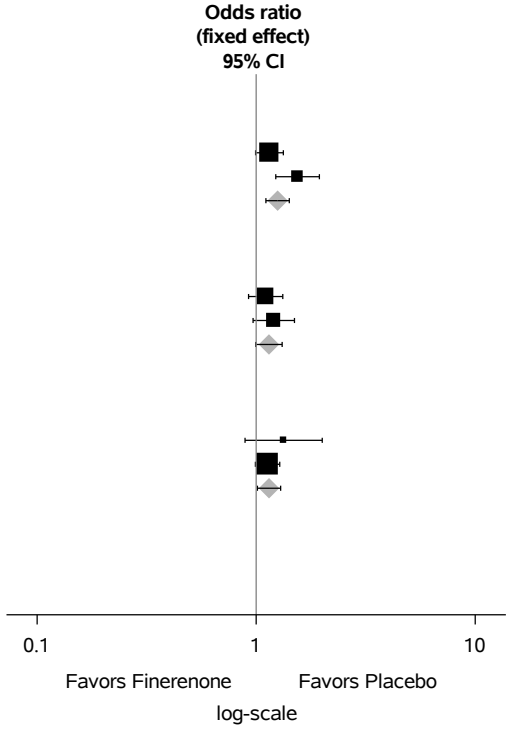
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	380 / 1178	336 / 1174	43.0	1.19 [1.00,1.42]	
FIGARO-DKD	460 / 1752	423 / 1747	57.0	1.11 [0.96,1.30]	
Total	840 / 2930	759 / 2921		1.15 [1.02,1.29]	Z=2.31, p=0.0211
Heterogeneity:	Q=0.29 (df=1)	p=0.5922	I^2=0.0%		
North America					
FIDELIO-DKD	170 / 466	162 / 476	48.9	1.11 [0.85,1.45]	
FIGARO-DKD	164 / 559	150 / 548	51.1	1.10 [0.85,1.43]	
Total	334 / 1025	312 / 1024		1.11 [0.92,1.33]	Z=1.07, p=0.2855
Heterogeneity:	Q=0.00 (df=1)	p=0.9564	I^2=0.0%		
Asia					
FIDELIO-DKD	354 / 790	324 / 786	49.7	1.16 [0.95,1.41]	
FIGARO-DKD	370 / 811	299 / 813	50.3	1.44 [1.18,1.76]	
Total	724 / 1601	623 / 1599		1.29 [1.12,1.49]	Z=3.58, p=0.0003
Heterogeneity:	Q=2.34 (df=1)	p=0.1260	I^2=57.3%		
Latin America					
FIDELIO-DKD	111 / 294	102 / 294	41.0	1.14 [0.82,1.60]	
FIGARO-DKD	164 / 424	145 / 417	59.0	1.18 [0.89,1.57]	
Total	275 / 718	247 / 711		1.17 [0.94,1.45]	Z=1.40, p=0.1625
Heterogeneity:	Q=0.03 (df=1)	p=0.8732	I^2=0.0%		
Others					
FIDELIO-DKD	30 / 99	34 / 101	41.0	0.86 [0.47,1.55]	
FIGARO-DKD	60 / 137	43 / 133	59.0	1.63 [0.99,2.68]	
Total	90 / 236	77 / 234		1.25 [0.86,1.83]	Z=1.17, p=0.2423
Heterogeneity:	Q=2.65 (df=1)	p=0.1033	I^2=62.3%		
Subgroup Heterogeneity:	Q=2.43 (df=4)	p=0.6572	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.79.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

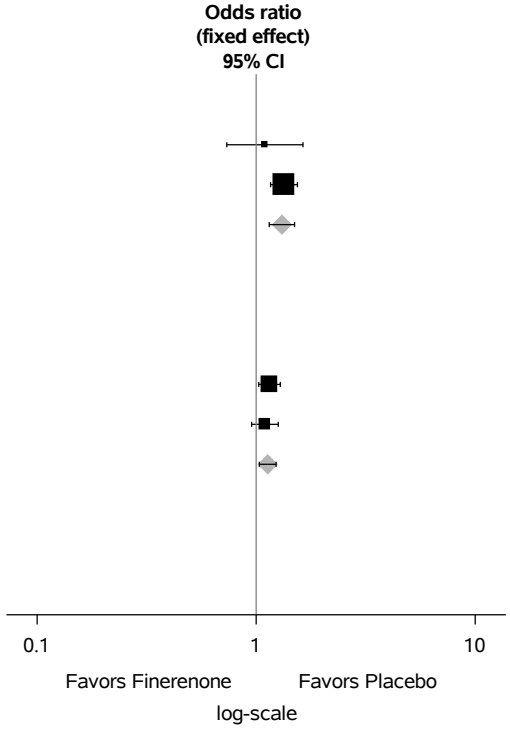
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	603 / 1556	547 / 1541	71.2	1.15 [0.99,1.33]	
FIGARO-DKD	272 / 637	204 / 627	28.8	1.55 [1.23,1.94]	
Total	875 / 2193	751 / 2168		1.25 [1.11,1.42]	Z=3.59, p=0.0003
Heterogeneity:	Q=4.54 (df=1)	p=0.0330	I^2=78.0%		
45 - < 60					
FIDELIO-DKD	368 / 1061	347 / 1069	59.4	1.10 [0.92,1.32]	
FIGARO-DKD	260 / 720	233 / 729	40.6	1.20 [0.97,1.50]	
Total	628 / 1781	580 / 1798		1.14 [1.00,1.31]	Z=1.90, p=0.0575
Heterogeneity:	Q=0.35 (df=1)	p=0.5541	I^2=0.0%		
>= 60					
FIDELIO-DKD	74 / 210	64 / 221	9.1	1.33 [0.89,2.00]	
FIGARO-DKD	686 / 2326	623 / 2302	90.9	1.13 [0.99,1.28]	
Total	760 / 2536	687 / 2523		1.14 [1.01,1.29]	Z=2.17, p=0.0300
Heterogeneity:	Q=0.61 (df=1)	p=0.4365	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=2)	p=0.5132	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.79.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

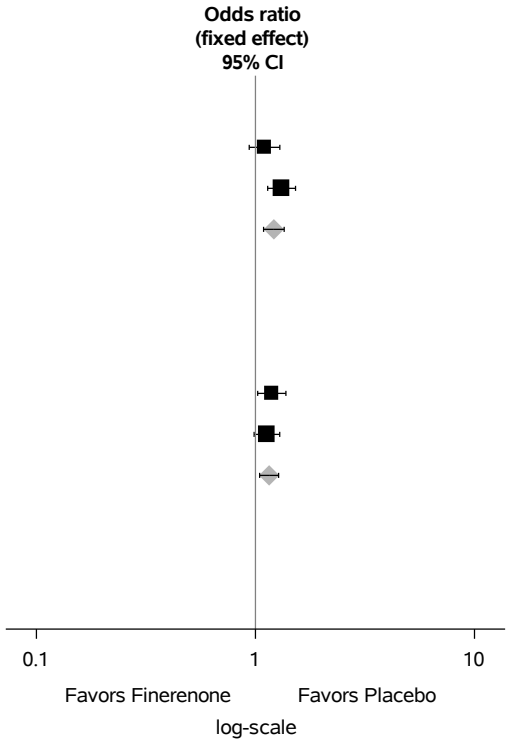
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	75 / 209	72 / 213	11.0	1.10 [0.73,1.64]	
FIGARO-DKD	657 / 1720	536 / 1698	89.0	1.34 [1.16,1.54]	
Total	732 / 1929	608 / 1911		1.31 [1.15,1.50]	Z=3.98, p=<.0001
Heterogeneity:	Q=0.86 (df=1)	p=0.3540	I^2=0.0%		
Very High					
FIDELIO-DKD	970 / 2618	886 / 2618	60.4	1.15 [1.03,1.29]	
FIGARO-DKD	561 / 1963	524 / 1960	39.6	1.10 [0.95,1.26]	
Total	1531 / 4581	1410 / 4578		1.13 [1.03,1.23]	Z=2.70, p=0.0070
Heterogeneity:	Q=0.27 (df=1)	p=0.6007	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.36 (df=1)	p=0.0670	I^2=70.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.79.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

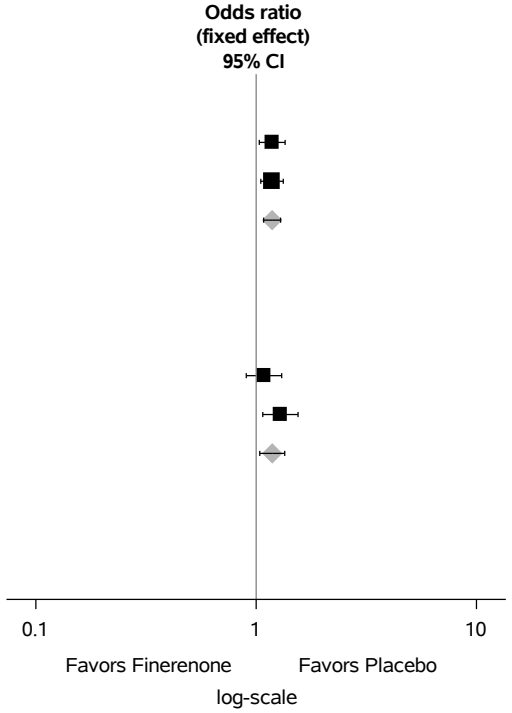
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	473 / 1301	444 / 1299	45.3	1.10 [0.94,1.29]	
FIGARO-DKD	583 / 1673	477 / 1651	54.7	1.32 [1.14,1.52]	
Total	1056 / 2974	921 / 2950		1.21 [1.09,1.35]	Z=3.51, p=0.0005
Heterogeneity:	Q=2.62 (df=1)	p=0.1058	I^2=61.8%		
Absent					
FIDELIO-DKD	572 / 1526	514 / 1532	45.2	1.19 [1.02,1.38]	
FIGARO-DKD	635 / 2010	583 / 2007	54.8	1.13 [0.99,1.29]	
Total	1207 / 3536	1097 / 3539		1.15 [1.04,1.28]	Z=2.83, p=0.0047
Heterogeneity:	Q=0.25 (df=1)	p=0.6150	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.44 (df=1)	p=0.5051	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.79.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

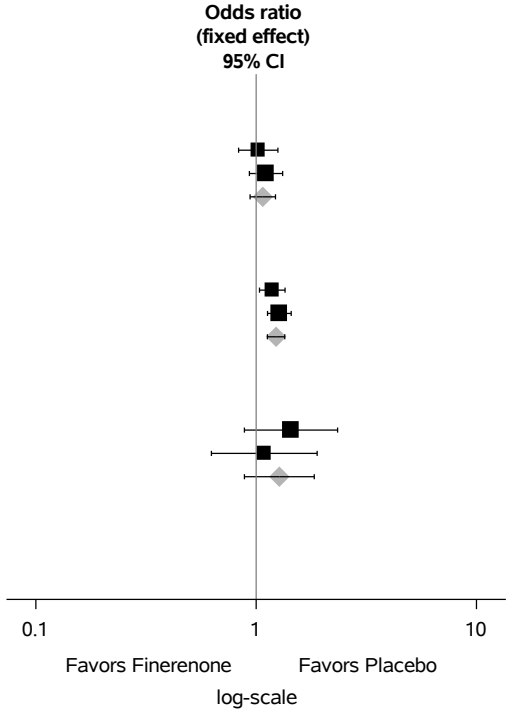
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	684 / 1879	606 / 1858	43.1	1.18 [1.03,1.35]	
FIGARO-DKD	855 / 2643	752 / 2608	56.9	1.18 [1.05,1.33]	
Total	1539 / 4522	1358 / 4466		1.18 [1.08,1.29]	Z=3.68, p=0.0002
Heterogeneity:	Q=0.00 (df=1)	p=0.9827	I^2=0.0%		
> 4.5					
FIDELIO-DKD	361 / 948	352 / 973	49.7	1.08 [0.90,1.31]	
FIGARO-DKD	363 / 1040	308 / 1048	50.3	1.29 [1.07,1.55]	
Total	724 / 1988	660 / 2021		1.18 [1.04,1.35]	Z=2.52, p=0.0117
Heterogeneity:	Q=1.66 (df=1)	p=0.1975	I^2=39.8%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9859	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.79.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

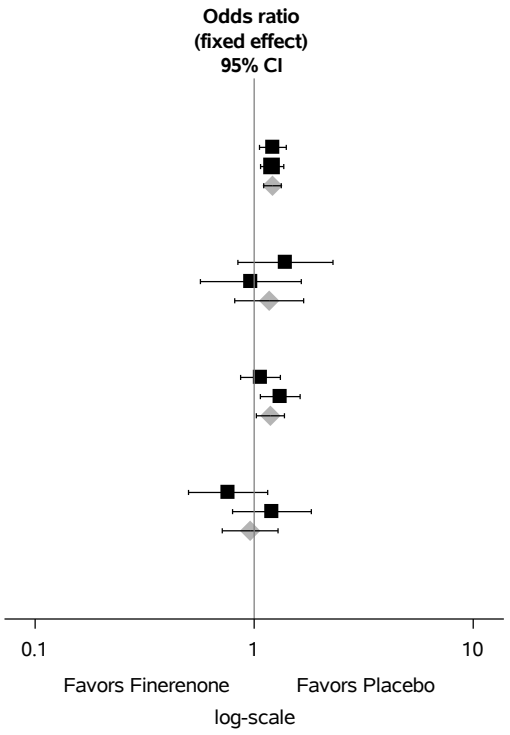
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	292 / 788	284 / 777	41.7	1.02 [0.83,1.26]	
FIGARO-DKD	380 / 1187	356 / 1194	58.3	1.11 [0.93,1.32]	
Total	672 / 1975	640 / 1971		1.07 [0.94,1.22]	Z=1.02, p=0.3080
Heterogeneity:	Q=0.35 (df=1)	p=0.5543	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	694 / 1897	628 / 1916	46.2	1.18 [1.04,1.35]	
FIGARO-DKD	799 / 2389	665 / 2351	53.8	1.27 [1.13,1.44]	
Total	1493 / 4286	1293 / 4267		1.23 [1.12,1.35]	Z=4.50, p=<.0001
Heterogeneity:	Q=0.64 (df=1)	p=0.4254	I^2=0.0%		
>= 160					
FIDELIO-DKD	59 / 141	46 / 138	56.3	1.44 [0.88,2.34]	
FIGARO-DKD	39 / 107	39 / 113	43.7	1.09 [0.63,1.89]	
Total	98 / 248	85 / 251		1.27 [0.88,1.84]	Z=1.30, p=0.1936
Heterogeneity:	Q=0.55 (df=1)	p=0.4572	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.04 (df=2)	p=0.2184	I^2=34.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.79.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

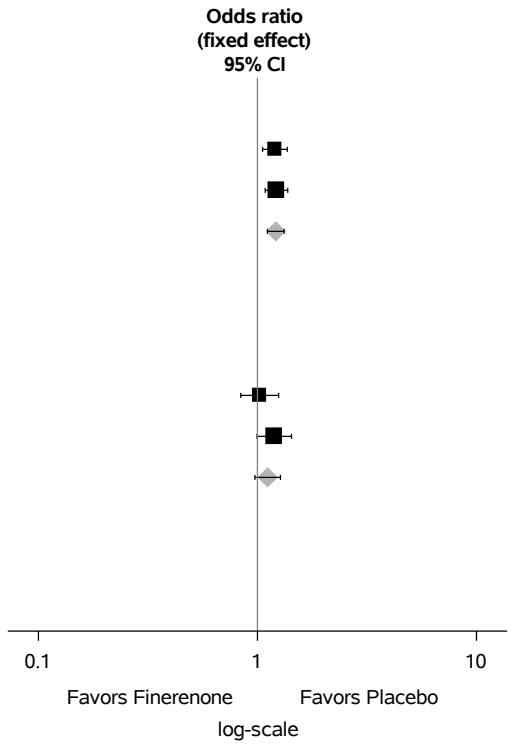
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	603 / 1773	538 / 1809	42.9	1.22 [1.06,1.40]	
FIGARO-DKD	768 / 2668	652 / 2601	57.1	1.21 [1.07,1.37]	
Total	1371 / 4441	1190 / 4410		1.21 [1.11,1.33]	Z=4.09, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9358	I^2=0.0%		
Black					
FIDELIO-DKD	59 / 139	43 / 124	53.0	1.39 [0.84,2.29]	
FIGARO-DKD	35 / 113	46 / 145	47.0	0.97 [0.57,1.64]	
Total	94 / 252	89 / 269		1.17 [0.81,1.68]	Z=0.85, p=0.3936
Heterogeneity:	Q=0.96 (df=1)	p=0.3281	I^2=0.0%		
Asian					
FIDELIO-DKD	312 / 717	302 / 721	50.0	1.07 [0.87,1.32]	
FIGARO-DKD	325 / 716	285 / 736	50.0	1.32 [1.07,1.62]	
Total	637 / 1433	587 / 1457		1.19 [1.02,1.37]	Z=2.26, p=0.0237
Heterogeneity:	Q=1.89 (df=1)	p=0.1687	I^2=47.2%		
Others					
FIDELIO-DKD	71 / 198	75 / 177	49.7	0.76 [0.50,1.15]	
FIGARO-DKD	90 / 186	77 / 176	50.3	1.21 [0.80,1.82]	
Total	161 / 384	152 / 353		0.96 [0.71,1.29]	Z=-0.28, p=0.7769
Heterogeneity:	Q=2.37 (df=1)	p=0.1239	I^2=57.8%		
Subgroup Heterogeneity:	Q=2.25 (df=3)	p=0.5223	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.79.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

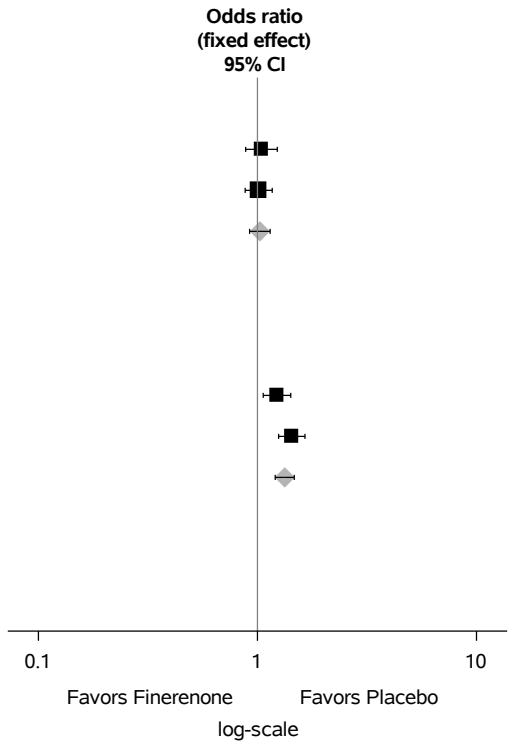
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	728 / 1949	671 / 2024	45.2	1.20 [1.06,1.37]	
FIGARO-DKD	852 / 2527	756 / 2571	54.8	1.22 [1.08,1.37]	
Total	1580 / 4476	1427 / 4595		1.21 [1.11,1.32]	Z=4.31, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8618	I^2=0.0%		
Female					
FIDELIO-DKD	317 / 878	287 / 807	45.3	1.02 [0.84,1.25]	
FIGARO-DKD	366 / 1156	304 / 1087	54.7	1.19 [1.00,1.43]	
Total	683 / 2034	591 / 1894		1.11 [0.97,1.27]	Z=1.57, p=0.1165
Heterogeneity:	Q=1.24 (df=1)	p=0.2653	I^2=19.4%		
Subgroup Heterogeneity:	Q=1.09 (df=1)	p=0.2964	I^2=8.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.79.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

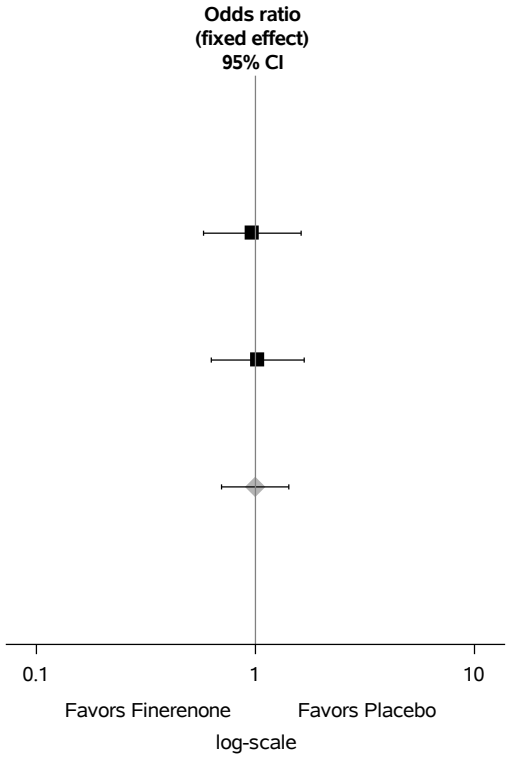
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	457 / 1201	434 / 1171	42.2	1.04 [0.88,1.23]	
FIGARO-DKD	560 / 1752	556 / 1755	57.8	1.01 [0.88,1.17]	
Total	1017 / 2953	990 / 2926		1.03 [0.92,1.14]	Z=0.46, p=0.6457
Heterogeneity:	Q=0.07 (df=1)	p=0.7938	I^2=0.0%		
>= 65					
FIDELIO-DKD	588 / 1626	524 / 1660	47.9	1.23 [1.06,1.42]	
FIGARO-DKD	658 / 1931	504 / 1903	52.1	1.43 [1.25,1.65]	
Total	1246 / 3557	1028 / 3563		1.33 [1.21,1.47]	Z=5.62, p=<.0001
Heterogeneity:	Q=2.31 (df=1)	p=0.1282	I^2=56.8%		
Subgroup Heterogeneity:	Q=12.10 (df=1)	p=0.0005	I^2=91.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.80: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set

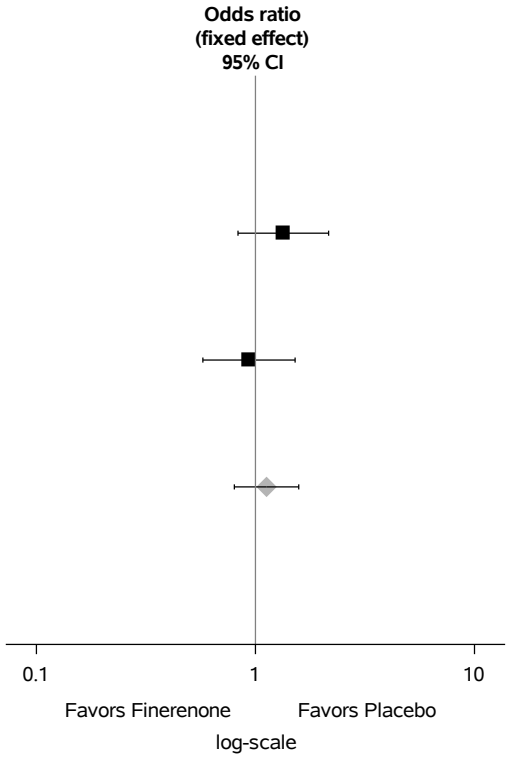
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	47.5	0.97 [0.58,1.62]	
FIGARO-DKD	33 / 3683	32 / 3658	52.5	1.02 [0.63,1.67]	
Total	62 / 6510	62 / 6489		1.00 [0.70,1.42]	Z=-0.02, p=0.9871
Heterogeneity:	Q=0.02 (df=1)	p=0.8747	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.81: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set

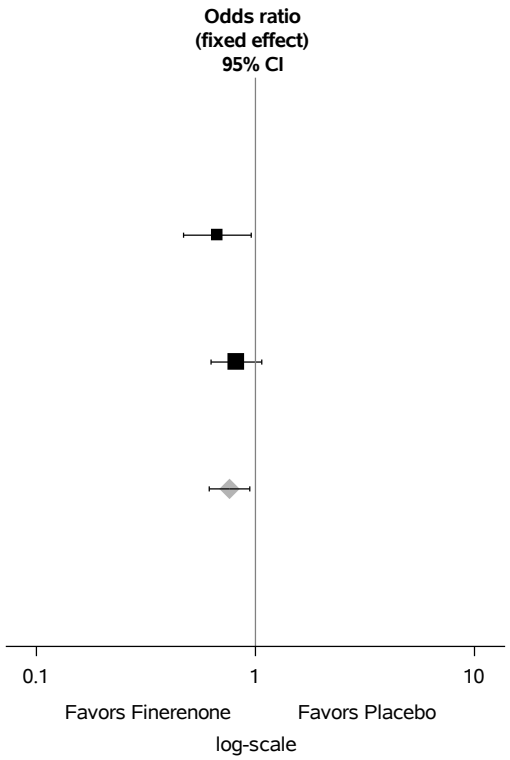
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	30 / 2831	50.9	1.34 [0.83,2.16]	
FIGARO-DKD	32 / 3683	34 / 3658	49.1	0.93 [0.58,1.52]	
Total	72 / 6510	64 / 6489		1.12 [0.80,1.58]	Z=0.67, p=0.5002
Heterogeneity:	Q=1.08 (df=1)	p=0.2982	I^2=7.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.82: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

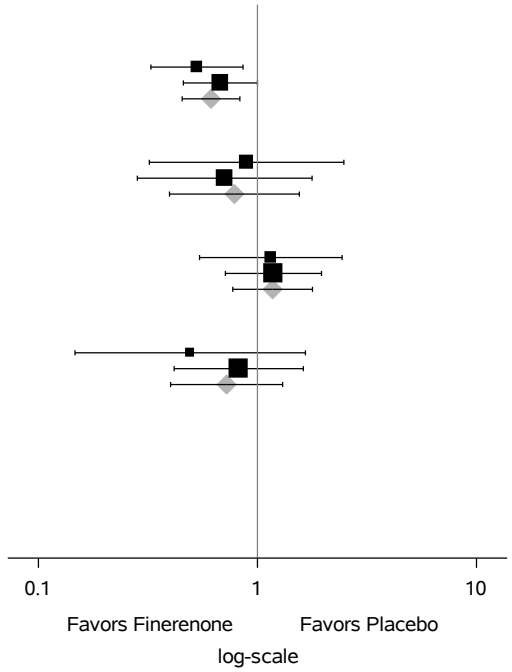
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 2827	77 / 2831	36.0	0.67 [0.47,0.96]	
FIGARO-DKD	102 / 3683	123 / 3658	64.0	0.82 [0.63,1.07]	
Total	154 / 6510	200 / 6489		0.76 [0.62,0.94]	Z=-2.51, p=0.0121
Heterogeneity:	Q=0.78 (df=1)	p=0.3778	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.82.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

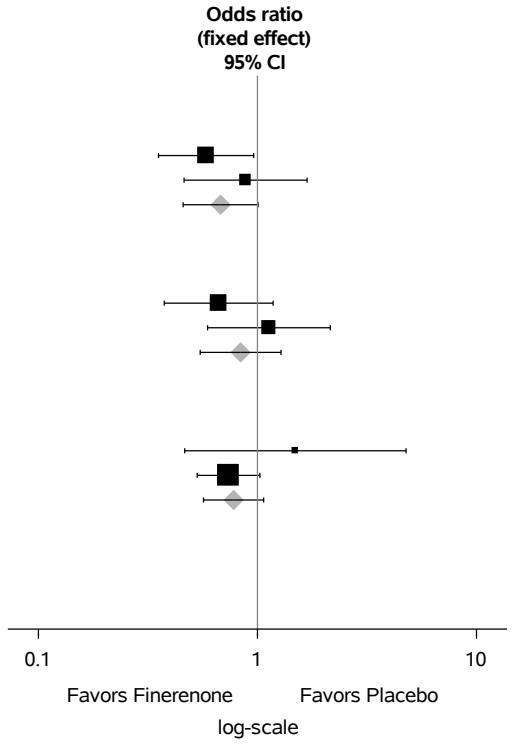
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 1178	48 / 1174	39.3	0.53 [0.33,0.86]	
FIGARO-DKD	44 / 1752	64 / 1747	60.7	0.68 [0.46,1.00]	
Total	70 / 2930	112 / 2921		0.61 [0.45,0.83]	Z=-3.16, p=0.0016
Heterogeneity:	Q=0.60 (df=1)	p=0.4370	I^2=0.0%		
North America					
FIDELIO-DKD	7 / 466	8 / 476	44.7	0.89 [0.32,2.48]	
FIGARO-DKD	8 / 559	11 / 548	55.3	0.71 [0.28,1.78]	
Total	15 / 1025	19 / 1024		0.78 [0.40,1.55]	Z=-0.70, p=0.4869
Heterogeneity:	Q=0.11 (df=1)	p=0.7428	I^2=0.0%		
Asia					
FIDELIO-DKD	15 / 790	13 / 786	31.3	1.15 [0.54,2.43]	
FIGARO-DKD	34 / 811	29 / 813	68.7	1.18 [0.71,1.96]	
Total	49 / 1601	42 / 1599		1.17 [0.77,1.78]	Z=0.75, p=0.4557
Heterogeneity:	Q=0.00 (df=1)	p=0.9524	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 294	8 / 294	23.9	0.49 [0.15,1.66]	
FIGARO-DKD	16 / 424	19 / 417	76.1	0.82 [0.42,1.62]	
Total	20 / 718	27 / 711		0.72 [0.40,1.30]	Z=-1.08, p=0.2805
Heterogeneity:	Q=0.52 (df=1)	p=0.4712	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	0 / 137	0 / 133	0.0	-	
Total	0 / 236	0 / 234		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=6.06 (df=4)	p=0.1946	I^2=34.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.82.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

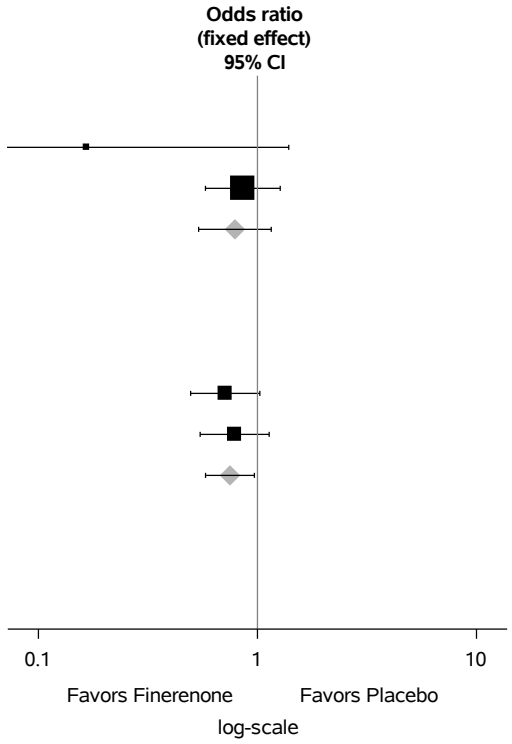
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	25 / 1556	42 / 1541	62.6	0.58 [0.35,0.96]	
FIGARO-DKD	18 / 637	20 / 627	37.4	0.88 [0.46,1.68]	
Total	43 / 2193	62 / 2168		0.68 [0.46,1.01]	Z=-1.93, p=0.0538
Heterogeneity:	Q=0.99 (df=1)	p=0.3197	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	20 / 1061	30 / 1069	56.0	0.67 [0.38,1.18]	
FIGARO-DKD	20 / 720	18 / 729	44.0	1.13 [0.59,2.15]	
Total	40 / 1781	48 / 1798		0.84 [0.55,1.28]	Z=-0.82, p=0.4140
Heterogeneity:	Q=1.44 (df=1)	p=0.2299	I^2=30.6%		
>= 60					
FIDELIO-DKD	7 / 210	5 / 221	7.4	1.49 [0.47,4.77]	
FIGARO-DKD	64 / 2326	85 / 2302	92.6	0.74 [0.53,1.03]	
Total	71 / 2536	90 / 2523		0.78 [0.57,1.07]	Z=-1.56, p=0.1198
Heterogeneity:	Q=1.30 (df=1)	p=0.2549	I^2=22.8%		
Subgroup Heterogeneity:	Q=0.54 (df=2)	p=0.7639	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.82.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

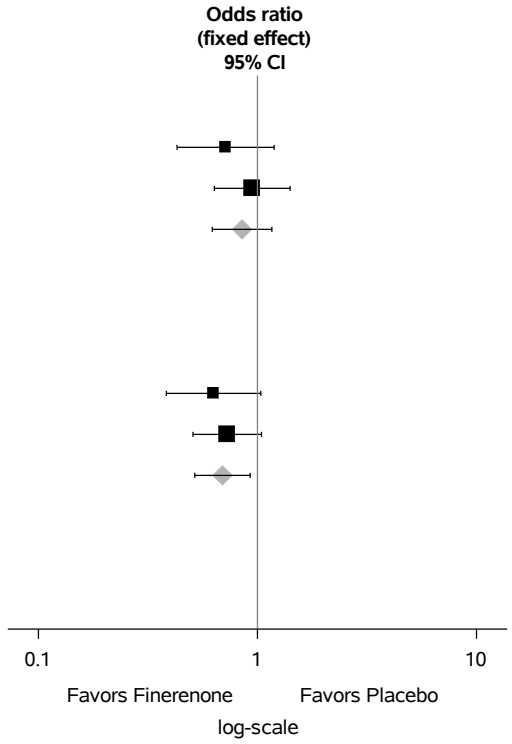
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	6 / 213	3.3	0.17 [0.02,1.39]	
FIGARO-DKD	48 / 1720	55 / 1698	96.7	0.86 [0.58,1.27]	
Total	49 / 1929	61 / 1911		0.79 [0.54,1.16]	Z=-1.22, p=0.2238
Heterogeneity:	Q=2.24 (df=1)	p=0.1345	I^2=55.4%		
Very High					
FIDELIO-DKD	51 / 2618	71 / 2618	49.9	0.71 [0.50,1.03]	
FIGARO-DKD	54 / 1963	68 / 1960	50.1	0.79 [0.55,1.13]	
Total	105 / 4581	139 / 4578		0.75 [0.58,0.97]	Z=-2.21, p=0.0274
Heterogeneity:	Q=0.14 (df=1)	p=0.7052	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8237	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.82.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

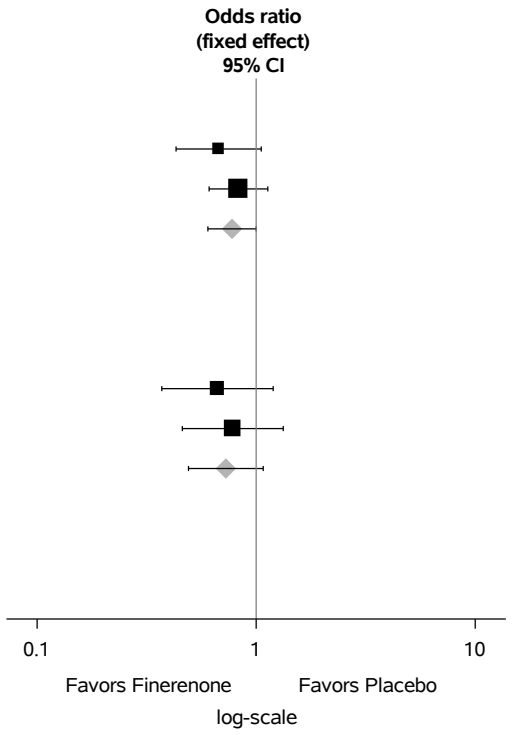
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 1301	36 / 1299	37.8	0.72 [0.43,1.19]	
FIGARO-DKD	49 / 1673	51 / 1651	62.2	0.95 [0.64,1.41]	
Total	75 / 2974	87 / 2950		0.85 [0.62,1.16]	Z=-1.01, p=0.3117
Heterogeneity:	Q=0.72 (df=1)	p=0.3966	I^2=0.0%		
Absent					
FIDELIO-DKD	26 / 1526	41 / 1532	34.5	0.63 [0.38,1.04]	
FIGARO-DKD	53 / 2010	72 / 2007	65.5	0.73 [0.51,1.04]	
Total	79 / 3536	113 / 3539		0.69 [0.52,0.93]	Z=-2.47, p=0.0134
Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3451	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.82.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

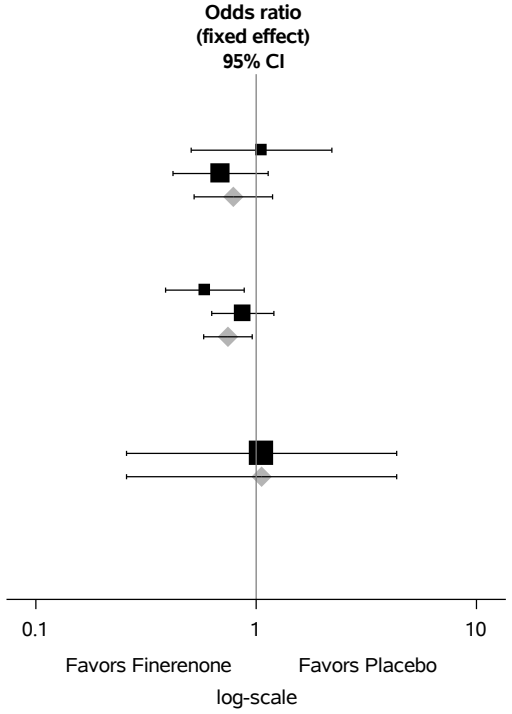
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	33 / 1879	48 / 1858	32.2	0.67 [0.43,1.06]	
FIGARO-DKD	77 / 2643	91 / 2608	67.8	0.83 [0.61,1.13]	
Total	110 / 4522	139 / 4466		0.78 [0.60,1.00]	Z=-1.96, p=0.0499
Heterogeneity:	Q=0.56 (df=1)	p=0.4534	I^2=0.0%		
> 4.5					
FIDELIO-DKD	19 / 948	29 / 973	45.1	0.67 [0.37,1.20]	
FIGARO-DKD	25 / 1040	32 / 1048	54.9	0.78 [0.46,1.33]	
Total	44 / 1988	61 / 2021		0.73 [0.49,1.08]	Z=-1.59, p=0.1115
Heterogeneity:	Q=0.16 (df=1)	p=0.6896	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7851	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.82.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

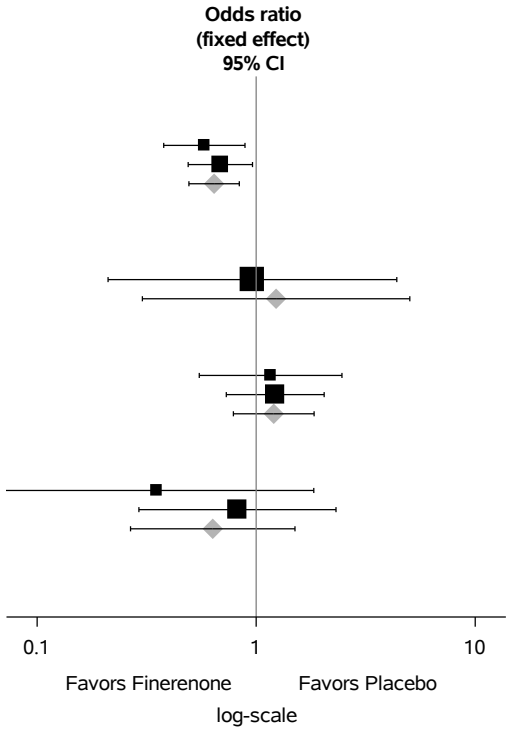
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	14 / 777	31.4	1.06 [0.51,2.21]	
FIGARO-DKD	27 / 1187	39 / 1194	68.6	0.69 [0.42,1.13]	
Total	42 / 1975	53 / 1971		0.79 [0.52,1.19]	Z=-1.14, p=0.2537
Heterogeneity:	Q=0.89 (df=1)	p=0.3446	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	37 / 1897	63 / 1916	38.4	0.59 [0.39,0.88]	
FIGARO-DKD	71 / 2389	80 / 2351	61.6	0.87 [0.63,1.20]	
Total	108 / 4286	143 / 4267		0.74 [0.58,0.96]	Z=-2.28, p=0.0226
Heterogeneity:	Q=2.20 (df=1)	p=0.1382	I^2=54.5%		
>= 160					
FIDELIO-DKD	0 / 141	0 / 138	0.0	-	
FIGARO-DKD	4 / 107	4 / 113	100.0	1.06 [0.26,4.34]	
Total	4 / 248	4 / 251		1.06 [0.26,4.34]	Z=0.08, p=0.9374
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=2)	p=0.8758	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.82.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

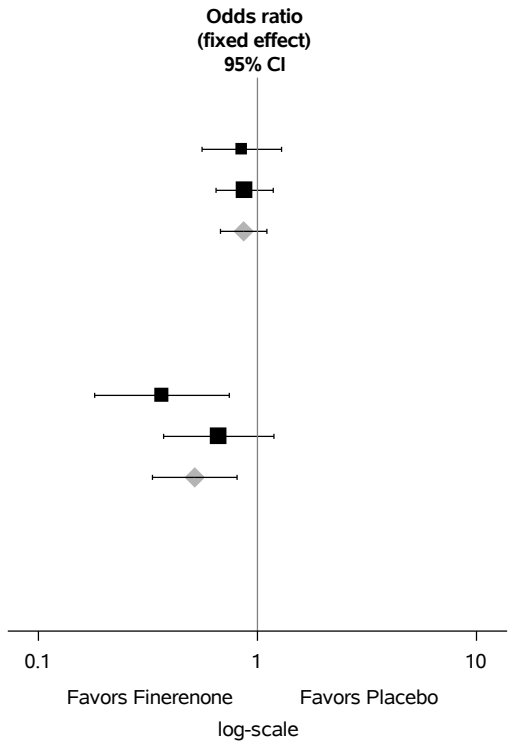
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	34 / 1773	59 / 1809	38.5	0.58 [0.38,0.89]	
FIGARO-DKD	59 / 2668	83 / 2601	61.5	0.69 [0.49,0.96]	
Total	93 / 4441	142 / 4410		0.64 [0.49,0.84]	Z=-3.27, p=0.0011
Heterogeneity:	Q=0.37 (df=1)	p=0.5455	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	0 / 124	0.0	112E9 [112E9,112E9]	
FIGARO-DKD	3 / 113	4 / 145	100.0	0.96 [0.21,4.38]	
Total	4 / 252	4 / 269		1.23 [0.30,5.03]	Z=0.29, p=0.7704
Heterogeneity:	Q=0.10 (df=1)	p=0.7480	I^2=0.0%		
Asian					
FIDELIO-DKD	15 / 717	13 / 721	32.0	1.16 [0.55,2.46]	
FIGARO-DKD	33 / 716	28 / 736	68.0	1.22 [0.73,2.04]	
Total	48 / 1433	41 / 1457		1.20 [0.79,1.84]	Z=0.85, p=0.3935
Heterogeneity:	Q=0.01 (df=1)	p=0.9165	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	5 / 177	28.2	0.35 [0.07,1.83]	
FIGARO-DKD	7 / 186	8 / 176	71.8	0.82 [0.29,2.31]	
Total	9 / 384	13 / 353		0.63 [0.27,1.50]	Z=-1.04, p=0.3005
Heterogeneity:	Q=0.73 (df=1)	p=0.3924	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.66 (df=3)	p=0.0834	I^2=55.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.82.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

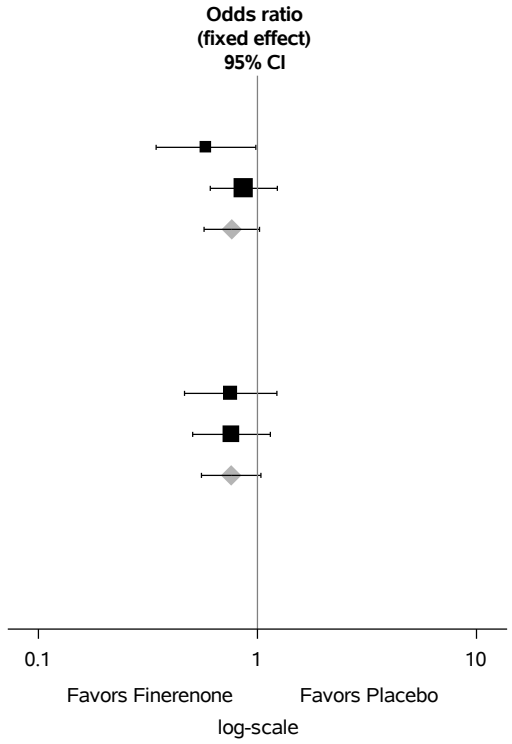
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	41 / 1949	50 / 2024	34.1	0.85 [0.56,1.29]	
FIGARO-DKD	82 / 2527	95 / 2571	65.9	0.87 [0.65,1.18]	
Total	123 / 4476	145 / 4595		0.87 [0.68,1.10]	Z=-1.16, p=0.2449
Heterogeneity:	Q=0.01 (df=1)	p=0.9094	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 878	27 / 807	40.2	0.37 [0.18,0.74]	
FIGARO-DKD	20 / 1156	28 / 1087	59.8	0.67 [0.37,1.19]	
Total	31 / 2034	55 / 1894		0.52 [0.33,0.81]	Z=-2.90, p=0.0037
Heterogeneity:	Q=1.64 (df=1)	p=0.2005	I^2=39.0%		
Subgroup Heterogeneity:	Q=3.95 (df=1)	p=0.0469	I^2=74.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.82.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

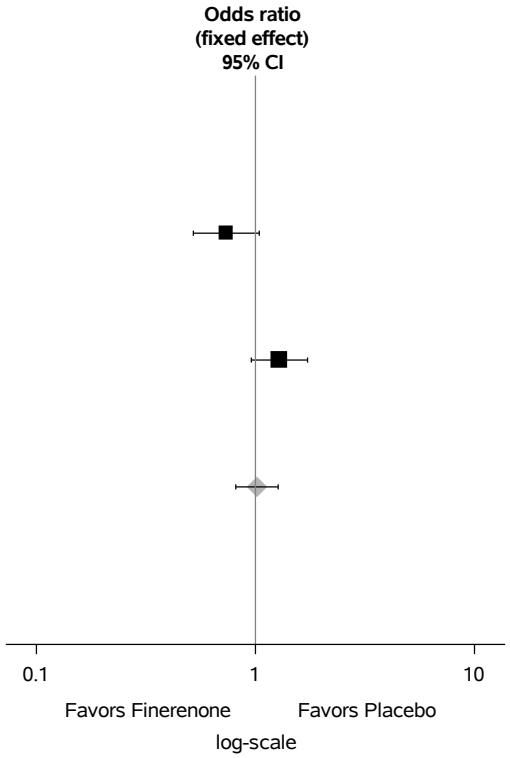
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	23 / 1201	38 / 1171	31.1	0.58 [0.34,0.98]	
FIGARO-DKD	60 / 1752	69 / 1755	68.9	0.87 [0.61,1.23]	
Total	83 / 2953	107 / 2926		0.76 [0.57,1.02]	Z=-1.81, p=0.0696
Heterogeneity:	Q=1.52 (df=1)	p=0.2171	I^2=34.4%		
>= 65					
FIDELIO-DKD	29 / 1626	39 / 1660	41.4	0.75 [0.46,1.23]	
FIGARO-DKD	42 / 1931	54 / 1903	58.6	0.76 [0.51,1.15]	
Total	71 / 3557	93 / 3563		0.76 [0.56,1.04]	Z=-1.73, p=0.0831
Heterogeneity:	Q=0.00 (df=1)	p=0.9787	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9765	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.83: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set

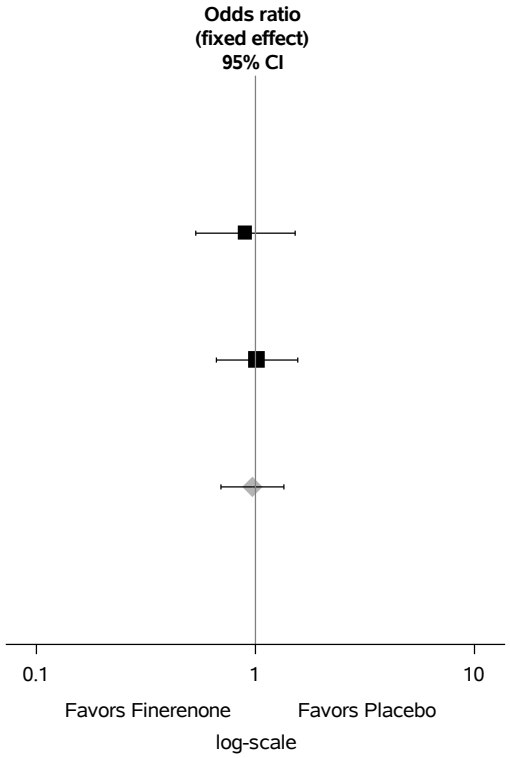
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2827	77 / 2831	42.1	0.74 [0.52,1.04]	
FIGARO-DKD	103 / 3683	80 / 3658	57.9	1.29 [0.96,1.73]	
Total	160 / 6510	157 / 6489		1.02 [0.81,1.27]	Z=0.14, p=0.8882
Heterogeneity:	Q=5.78 (df=1)	p=0.0162	I^2=82.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.84: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set

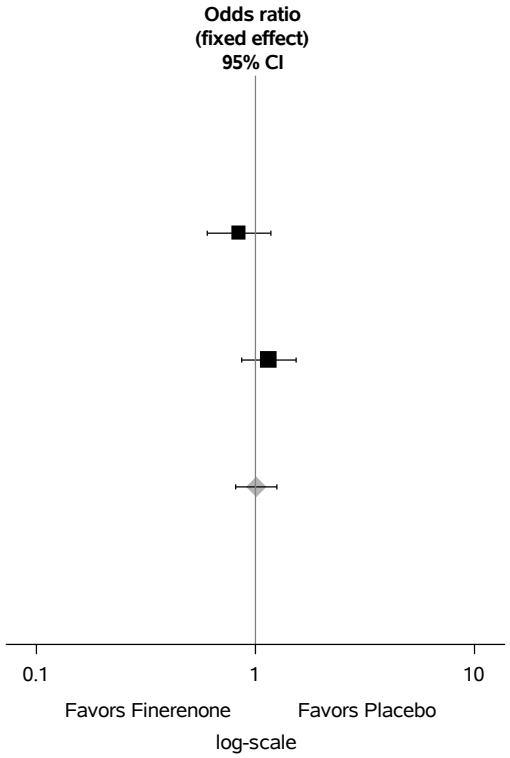
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	30 / 2831	40.1	0.90 [0.53,1.52]	
FIGARO-DKD	43 / 3683	42 / 3658	59.9	1.02 [0.66,1.56]	
Total	70 / 6510	72 / 6489		0.97 [0.70,1.35]	Z=-0.19, p=0.8495
Heterogeneity:	Q=0.13 (df=1)	p=0.7234	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.85: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set

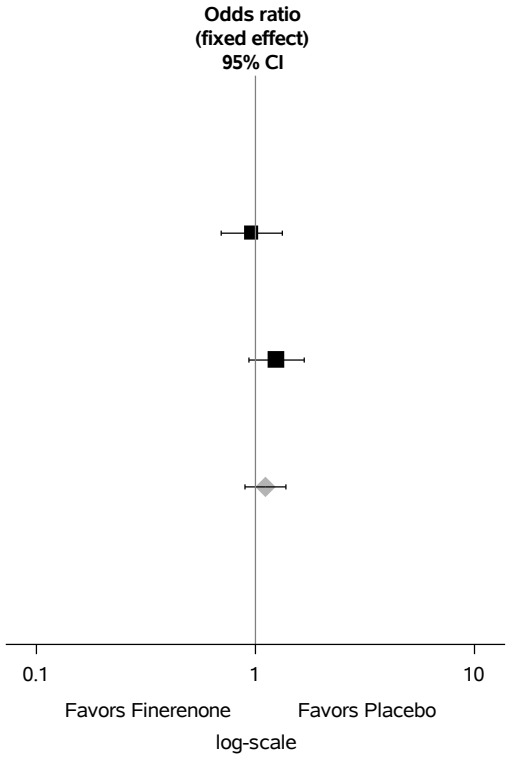
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 2827	77 / 2831	42.2	0.84 [0.60,1.18]	
FIGARO-DKD	104 / 3683	90 / 3658	57.8	1.15 [0.87,1.53]	
Total	169 / 6510	167 / 6489		1.01 [0.81,1.25]	Z=0.08, p=0.9366
Heterogeneity:	Q=1.95 (df=1)	p=0.1621	I^2=48.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.86: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set

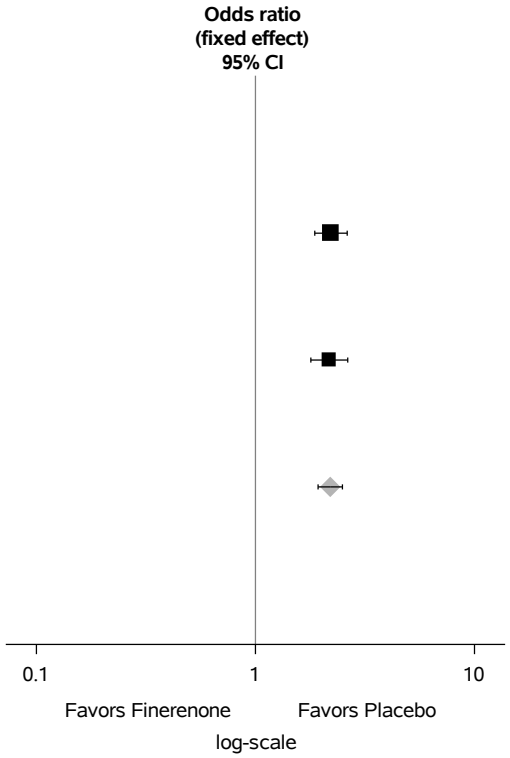
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	75 / 2827	78 / 2831	45.0	0.96 [0.70,1.33]	
FIGARO-DKD	105 / 3683	84 / 3658	55.0	1.25 [0.93,1.67]	
Total	180 / 6510	162 / 6489		1.11 [0.90,1.38]	Z=0.96, p=0.3387
Heterogeneity:	Q=1.39 (df=1)	p=0.2379	I^2=28.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.87: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

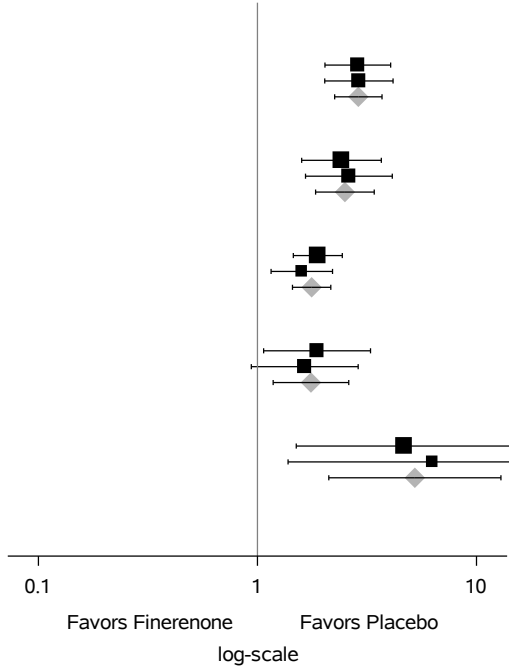
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	446 / 2827	221 / 2831	56.4	2.21 [1.87,2.62]	
FIGARO-DKD	335 / 3683	161 / 3658	43.6	2.17 [1.79,2.64]	
Total	781 / 6510	382 / 6489		2.20 [1.93,2.50]	Z=12.04, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.87.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

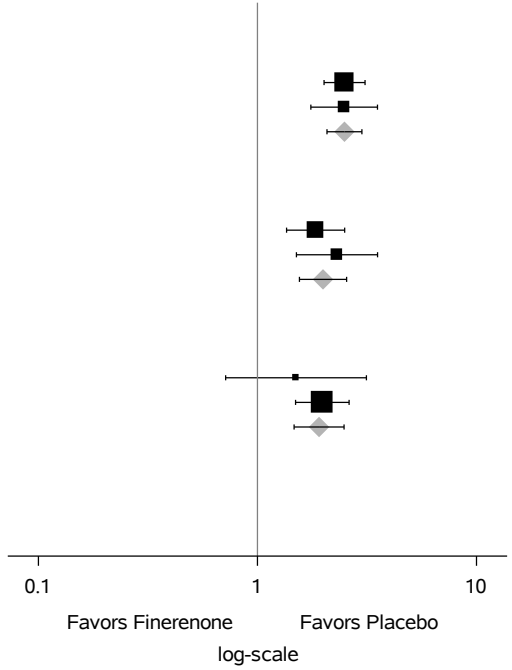
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	126 / 1178	47 / 1174	51.9	2.87 [2.03,4.06]	
FIGARO-DKD	117 / 1752	42 / 1747	48.1	2.90 [2.03,4.16]	
Total	243 / 2930	89 / 2921		2.89 [2.25,3.70]	Z=8.35, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9641	I^2=0.0%		
North America					
FIDELIO-DKD	77 / 466	36 / 476	54.3	2.42 [1.59,3.68]	
FIGARO-DKD	69 / 559	28 / 548	45.7	2.62 [1.66,4.13]	
Total	146 / 1025	64 / 1024		2.51 [1.84,3.41]	Z=5.85, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.8053	I^2=0.0%		
Asia					
FIDELIO-DKD	190 / 790	113 / 786	61.1	1.89 [1.46,2.44]	
FIGARO-DKD	103 / 811	68 / 813	38.9	1.59 [1.15,2.20]	
Total	293 / 1601	181 / 1599		1.77 [1.45,2.16]	Z=5.54, p=<.0001
Heterogeneity:	Q=0.64 (df=1)	p=0.4246	I^2=0.0%		
Latin America					
FIDELIO-DKD	37 / 294	21 / 294	50.0	1.87 [1.07,3.28]	
FIGARO-DKD	34 / 424	21 / 417	50.0	1.64 [0.94,2.88]	
Total	71 / 718	42 / 711		1.75 [1.18,2.61]	Z=2.77, p=0.0055
Heterogeneity:	Q=0.10 (df=1)	p=0.7490	I^2=0.0%		
Others					
FIDELIO-DKD	16 / 99	4 / 101	64.1	4.67 [1.50,14.53]	
FIGARO-DKD	12 / 137	2 / 133	35.9	6.29 [1.38,28.66]	
Total	28 / 236	6 / 234		5.23 [2.12,12.93]	Z=3.58, p=0.0003
Heterogeneity:	Q=0.09 (df=1)	p=0.7588	I^2=0.0%		
Subgroup Heterogeneity:	Q=14.58 (df=4)	p=0.0057	I^2=72.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.87.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

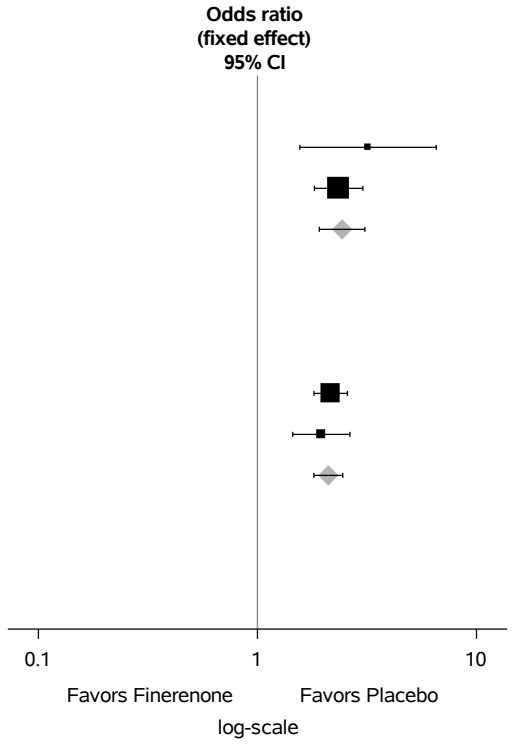
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	305 / 1556	137 / 1541	72.6	2.50 [2.01,3.10]	
FIGARO-DKD	115 / 637	51 / 627	27.4	2.49 [1.75,3.53]	
Total	420 / 2193	188 / 2168		2.50 [2.08,3.00]	Z=9.77, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9842	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	123 / 1061	71 / 1069	66.1	1.84 [1.36,2.50]	
FIGARO-DKD	71 / 720	33 / 729	33.9	2.31 [1.51,3.53]	
Total	194 / 1781	104 / 1798		1.99 [1.55,2.55]	Z=5.45, p=<.0001
Heterogeneity:	Q=0.70 (df=1)	p=0.4014	I^2=0.0%		
>= 60					
FIDELIO-DKD	18 / 210	13 / 221	12.6	1.50 [0.72,3.14]	
FIGARO-DKD	149 / 2326	77 / 2302	87.4	1.98 [1.49,2.62]	
Total	167 / 2536	90 / 2523		1.91 [1.47,2.49]	Z=4.83, p=<.0001
Heterogeneity:	Q=0.47 (df=1)	p=0.4936	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.53 (df=2)	p=0.1712	I^2=43.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.87.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

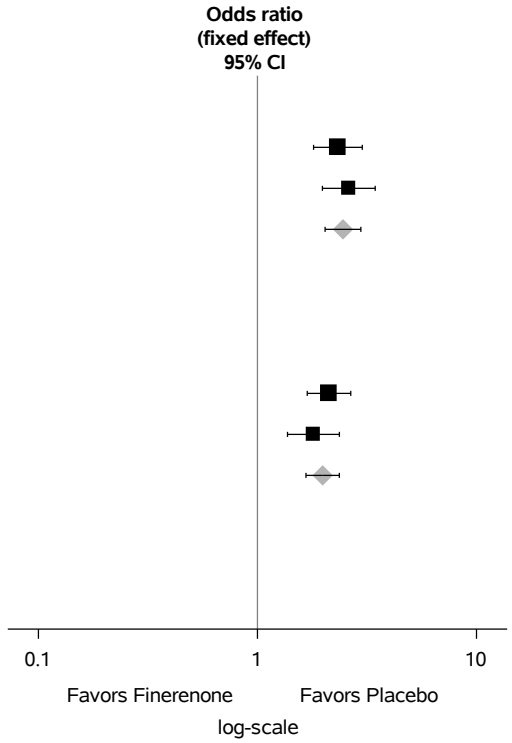
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	31 / 209	11 / 213	11.2	3.20 [1.56,6.55]	
FIGARO-DKD	206 / 1720	93 / 1698	88.8	2.35 [1.82,3.03]	
Total	237 / 1929	104 / 1911		2.44 [1.92,3.10]	Z=7.27, p=<.0001
Heterogeneity:	Q=0.63 (df=1)	p=0.4260	I^2=0.0%		
Very High					
FIDELIO-DKD	415 / 2618	210 / 2618	74.5	2.16 [1.81,2.58]	
FIGARO-DKD	129 / 1963	68 / 1960	25.5	1.96 [1.45,2.64]	
Total	544 / 4581	278 / 4578		2.11 [1.81,2.45]	Z=9.62, p=<.0001
Heterogeneity:	Q=0.31 (df=1)	p=0.5785	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.00 (df=1)	p=0.3174	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.87.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

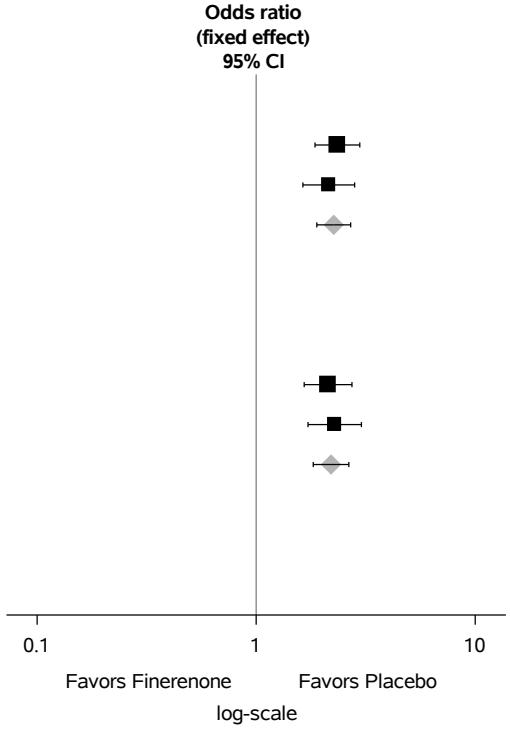
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	204 / 1301	96 / 1299	54.0	2.33 [1.80,3.01]	
FIGARO-DKD	185 / 1673	75 / 1651	46.0	2.61 [1.98,3.45]	
Total	389 / 2974	171 / 2950		2.46 [2.04,2.97]	Z=9.37, p=<.0001
Heterogeneity:	Q=0.35 (df=1)	p=0.5529	I^2=0.0%		
Absent					
FIDELIO-DKD	242 / 1526	125 / 1532	58.7	2.12 [1.69,2.67]	
FIGARO-DKD	150 / 2010	86 / 2007	41.3	1.80 [1.37,2.37]	
Total	392 / 3536	211 / 3539		1.98 [1.67,2.36]	Z=7.66, p=<.0001
Heterogeneity:	Q=0.81 (df=1)	p=0.3678	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.66 (df=1)	p=0.1031	I^2=62.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.87.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

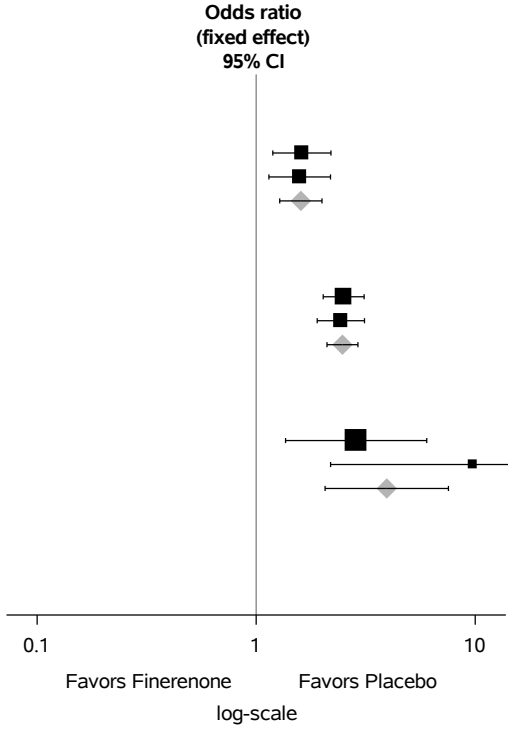
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	242 / 1879	110 / 1858	57.2	2.35 [1.86,2.97]	
FIGARO-DKD	168 / 2643	80 / 2608	42.8	2.14 [1.63,2.82]	
Total	410 / 4522	190 / 4466		2.26 [1.89,2.70]	Z=8.98, p=<.0001
Heterogeneity:	Q=0.25 (df=1)	p=0.6201	I^2=0.0%		
> 4.5					
FIDELIO-DKD	204 / 948	111 / 973	55.5	2.13 [1.66,2.74]	
FIGARO-DKD	167 / 1040	81 / 1048	44.5	2.28 [1.72,3.02]	
Total	371 / 1988	192 / 2021		2.20 [1.82,2.65]	Z=8.25, p=<.0001
Heterogeneity:	Q=0.13 (df=1)	p=0.7156	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8293	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.87.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

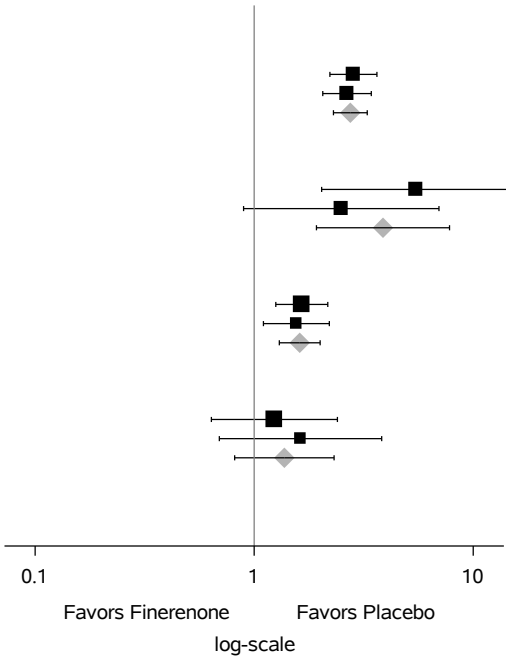
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	119 / 788	77 / 777	52.9	1.62 [1.19,2.20]	
FIGARO-DKD	99 / 1187	65 / 1194	47.1	1.58 [1.14,2.18]	
Total	218 / 1975	142 / 1971		1.60 [1.28,2.00]	Z=4.14, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9197	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	299 / 1897	133 / 1916	57.2	2.51 [2.02,3.11]	
FIGARO-DKD	220 / 2389	94 / 2351	42.8	2.44 [1.90,3.12]	
Total	519 / 4286	227 / 4267		2.48 [2.10,2.91]	Z=10.93, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8602	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 141	11 / 138	80.3	2.86 [1.36,6.01]	
FIGARO-DKD	16 / 107	2 / 113	19.7	9.76 [2.19,43.55]	
Total	44 / 248	13 / 251		3.95 [2.06,7.55]	Z=4.15, p=<.0001
Heterogeneity:	Q=2.13 (df=1)	p=0.1445	I^2=53.0%		
Subgroup Heterogeneity:	Q=13.03 (df=2)	p=0.0015	I^2=84.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.87.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

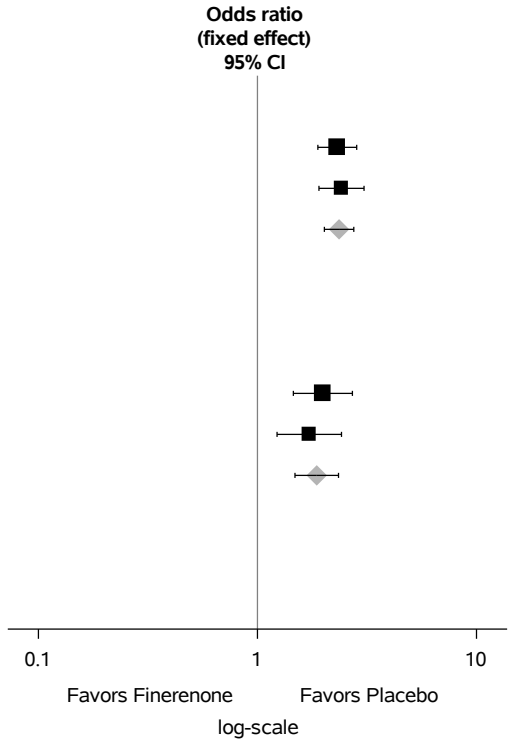
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	241 / 1773	95 / 1809	51.6	2.84 [2.22,3.63]	
FIGARO-DKD	222 / 2668	86 / 2601	48.4	2.65 [2.06,3.43]	
Total	463 / 4441	181 / 4410		2.75 [2.30,3.28]	Z=11.16, p=<.0001
Heterogeneity:	Q=0.14 (df=1)	p=0.7115	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 139	5 / 124	51.8	5.48 [2.03,14.75]	
FIGARO-DKD	11 / 113	6 / 145	48.2	2.50 [0.89,6.98]	
Total	37 / 252	11 / 269		3.87 [1.92,7.80]	Z=3.79, p=0.0001
Heterogeneity:	Q=1.17 (df=1)	p=0.2796	I^2=14.5%		
Asian					
FIDELIO-DKD	156 / 717	104 / 721	61.6	1.65 [1.26,2.17]	
FIGARO-DKD	87 / 716	60 / 736	38.4	1.56 [1.10,2.20]	
Total	243 / 1433	164 / 1457		1.61 [1.30,2.00]	Z=4.37, p=<.0001
Heterogeneity:	Q=0.06 (df=1)	p=0.8001	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 198	17 / 177	62.4	1.24 [0.64,2.40]	
FIGARO-DKD	15 / 186	9 / 176	37.6	1.63 [0.69,3.82]	
Total	38 / 384	26 / 353		1.37 [0.81,2.32]	Z=1.19, p=0.2338
Heterogeneity:	Q=0.25 (df=1)	p=0.6185	I^2=0.0%		
Subgroup Heterogeneity:	Q=19.66 (df=3)	p=0.0002	I^2=84.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.87.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

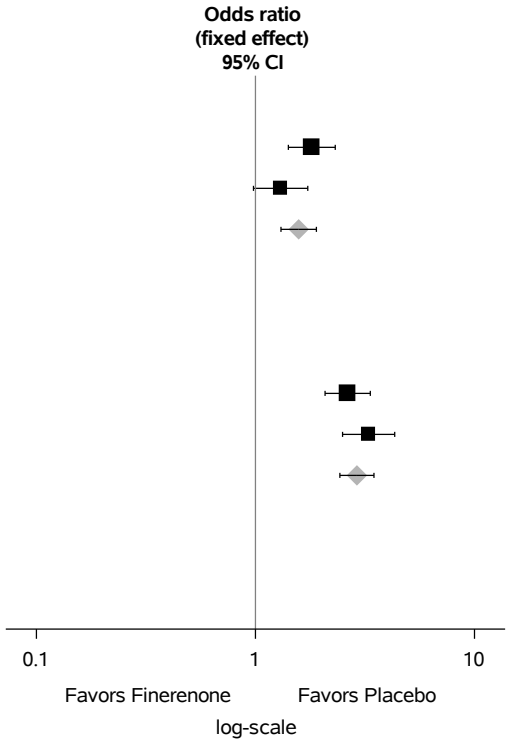
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	312 / 1949	154 / 2024	57.4	2.31 [1.89,2.84]	
FIGARO-DKD	236 / 2527	105 / 2571	42.6	2.42 [1.91,3.07]	
Total	548 / 4476	259 / 4595		2.36 [2.02,2.75]	Z=10.88, p=<.0001
Heterogeneity:	Q=0.08 (df=1)	p=0.7810	I^2=0.0%		
Female					
FIDELIO-DKD	134 / 878	67 / 807	54.4	1.99 [1.46,2.71]	
FIGARO-DKD	99 / 1156	56 / 1087	45.6	1.72 [1.23,2.42]	
Total	233 / 2034	123 / 1894		1.86 [1.48,2.34]	Z=5.34, p=<.0001
Heterogeneity:	Q=0.37 (df=1)	p=0.5422	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.78 (df=1)	p=0.0955	I^2=64.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.87.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

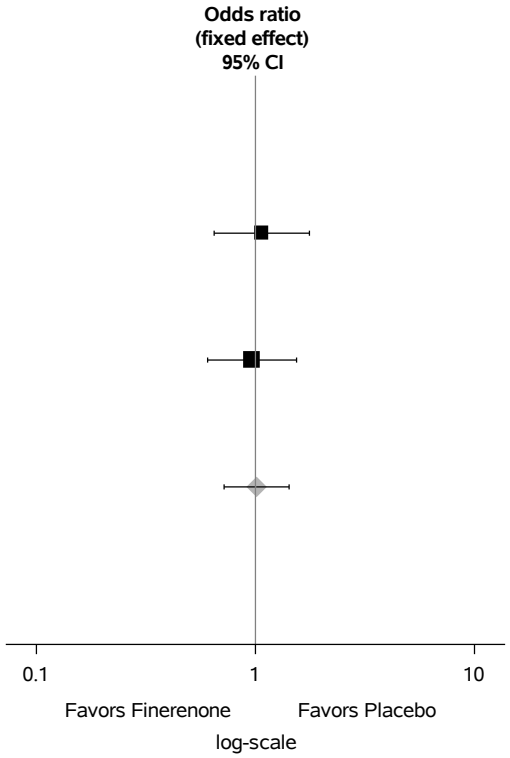
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	196 / 1201	114 / 1171	57.3	1.81 [1.41,2.31]	
FIGARO-DKD	114 / 1752	89 / 1755	42.7	1.30 [0.98,1.73]	
Total	310 / 2953	203 / 2926		1.58 [1.31,1.90]	Z=4.78, p=<.0001
Heterogeneity:	Q=2.90 (df=1)	p=0.0884	I^2=65.6%		
>= 65					
FIDELIO-DKD	250 / 1626	107 / 1660	57.0	2.64 [2.08,3.34]	
FIGARO-DKD	221 / 1931	72 / 1903	43.0	3.29 [2.50,4.32]	
Total	471 / 3557	179 / 3563		2.91 [2.43,3.48]	Z=11.67, p=<.0001
Heterogeneity:	Q=1.42 (df=1)	p=0.2340	I^2=29.4%		
Subgroup Heterogeneity:	Q=21.54 (df=1)	p=<.0001	I^2=95.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.88: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set

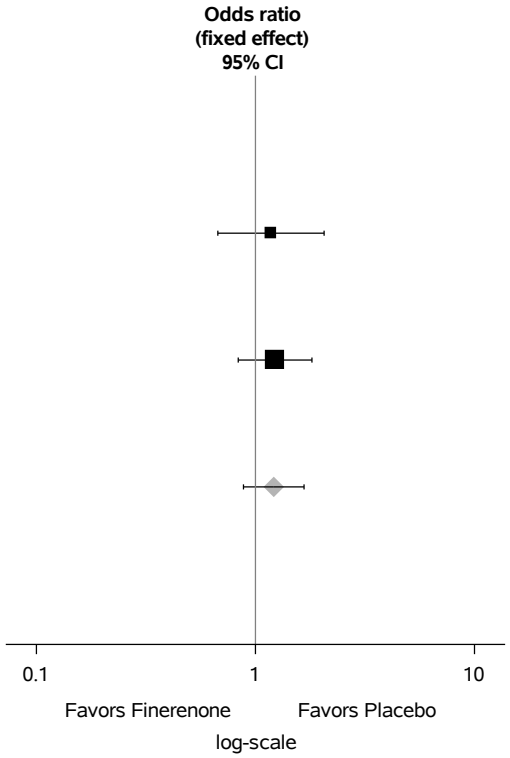
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	30 / 2831	46.6	1.07 [0.65,1.76]	
FIGARO-DKD	35 / 3683	36 / 3658	53.4	0.97 [0.60,1.54]	
Total	67 / 6510	66 / 6489		1.01 [0.72,1.42]	Z=0.07, p=0.9443
Heterogeneity:	Q=0.09 (df=1)	p=0.7704	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.89: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set

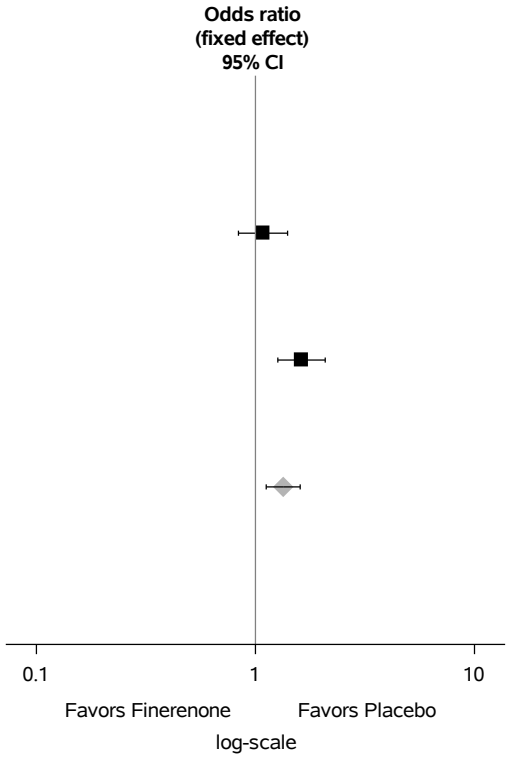
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	23 / 2831	32.5	1.18 [0.67,2.06]	
FIGARO-DKD	58 / 3683	47 / 3658	67.5	1.23 [0.83,1.81]	
Total	85 / 6510	70 / 6489		1.21 [0.88,1.67]	Z=1.18, p=0.2362
Heterogeneity:	Q=0.02 (df=1)	p=0.9008	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.90: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

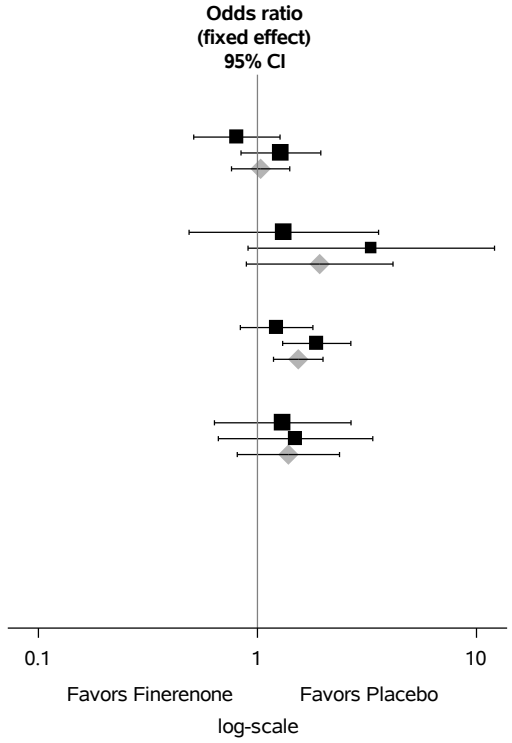
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	125 / 2827	116 / 2831	48.2	1.08 [0.84,1.40]	
FIGARO-DKD	167 / 3683	104 / 3658	51.8	1.62 [1.27,2.08]	
Total	292 / 6510	220 / 6489		1.34 [1.12,1.60]	Z=3.20, p=0.0014
Heterogeneity:	Q=4.89 (df=1)	p=0.0270	I^2=79.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.90.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

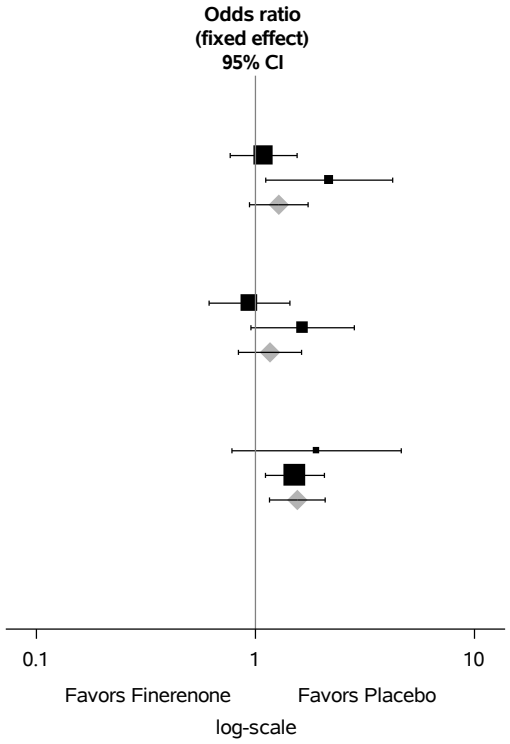
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	35 / 1178	43 / 1174	46.1	0.81 [0.51,1.27]	
FIGARO-DKD	51 / 1752	40 / 1747	53.9	1.28 [0.84,1.95]	
Total	86 / 2930	83 / 2921		1.03 [0.76,1.40]	Z=0.21, p=0.8308
Heterogeneity:	Q=2.16 (df=1)	p=0.1420	I^2=53.6%		
North America					
FIDELIO-DKD	9 / 466	7 / 476	62.9	1.32 [0.49,3.57]	
FIGARO-DKD	10 / 559	3 / 548	37.1	3.31 [0.91,12.09]	
Total	19 / 1025	10 / 1024		1.92 [0.89,4.16]	Z=1.66, p=0.0964
Heterogeneity:	Q=1.22 (df=1)	p=0.2687	I^2=18.3%		
Asia					
FIDELIO-DKD	63 / 790	52 / 786	46.9	1.22 [0.84,1.79]	
FIGARO-DKD	90 / 811	51 / 813	53.1	1.87 [1.30,2.67]	
Total	153 / 1601	103 / 1599		1.54 [1.18,1.99]	Z=3.23, p=0.0012
Heterogeneity:	Q=2.50 (df=1)	p=0.1140	I^2=60.0%		
Latin America					
FIDELIO-DKD	18 / 294	14 / 294	56.1	1.30 [0.64,2.67]	
FIGARO-DKD	15 / 424	10 / 417	43.9	1.49 [0.66,3.36]	
Total	33 / 718	24 / 711		1.38 [0.81,2.37]	Z=1.19, p=0.2355
Heterogeneity:	Q=0.06 (df=1)	p=0.8073	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	1 / 137	0 / 133	0.0	113E9 [113E9,113E9]	
Total	1 / 236	0 / 234		151E9 [151E9,151E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.67 (df=4)	p=0.3230	I^2=14.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.90.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

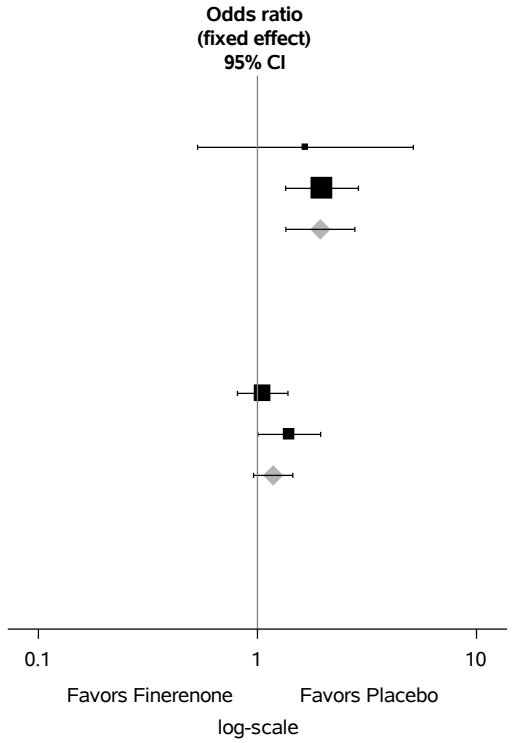
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	68 / 1556	62 / 1541	78.3	1.09 [0.77,1.55]	
FIGARO-DKD	28 / 637	13 / 627	21.7	2.17 [1.11,4.23]	
Total	96 / 2193	75 / 2168		1.28 [0.94,1.74]	Z=1.56, p=0.1186
Heterogeneity:	Q=3.21 (df=1)	p=0.0732	I^2=68.8%		
45 - < 60					
FIDELIO-DKD	43 / 1061	46 / 1069	62.1	0.94 [0.61,1.44]	
FIGARO-DKD	35 / 720	22 / 729	37.9	1.64 [0.95,2.83]	
Total	78 / 1781	68 / 1798		1.17 [0.84,1.62]	Z=0.90, p=0.3668
Heterogeneity:	Q=2.52 (df=1)	p=0.1125	I^2=60.3%		
>= 60					
FIDELIO-DKD	14 / 210	8 / 221	10.8	1.90 [0.78,4.63]	
FIGARO-DKD	104 / 2326	69 / 2302	89.2	1.51 [1.11,2.07]	
Total	118 / 2536	77 / 2523		1.55 [1.16,2.08]	Z=2.95, p=0.0032
Heterogeneity:	Q=0.22 (df=1)	p=0.6360	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.75 (df=2)	p=0.4168	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.90.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

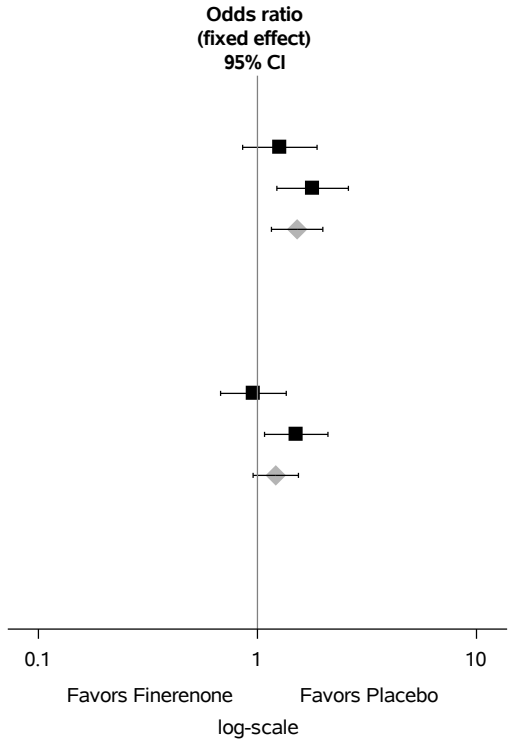
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	5 / 213	10.2	1.66 [0.53,5.15]	
FIGARO-DKD	80 / 1720	41 / 1698	89.8	1.97 [1.34,2.89]	
Total	88 / 1929	46 / 1911		1.94 [1.35,2.78]	Z=3.58, p=0.0003
Heterogeneity:	Q=0.08 (df=1)	p=0.7750	I^2=0.0%		
Very High					
FIDELIO-DKD	117 / 2618	111 / 2618	60.8	1.06 [0.81,1.38]	
FIGARO-DKD	87 / 1963	63 / 1960	39.2	1.40 [1.00,1.94]	
Total	204 / 4581	174 / 4578		1.18 [0.96,1.45]	Z=1.57, p=0.1168
Heterogeneity:	Q=1.66 (df=1)	p=0.1973	I^2=39.8%		
Subgroup Heterogeneity:	Q=5.43 (df=1)	p=0.0198	I^2=81.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.90.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

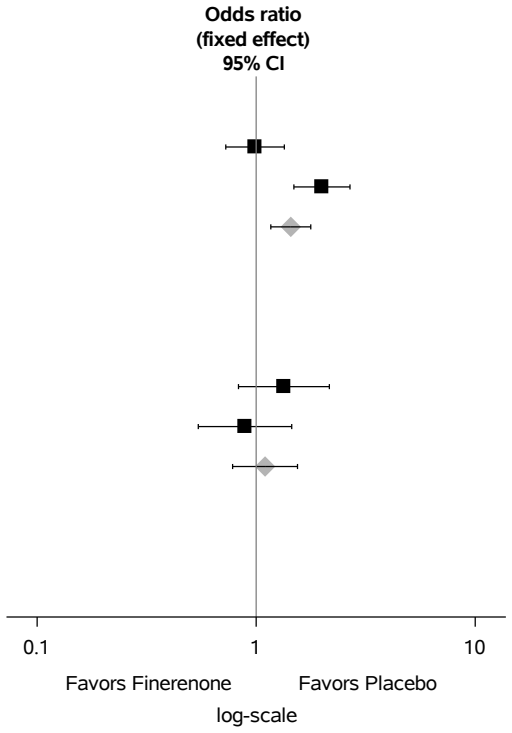
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	59 / 1301	47 / 1299	48.0	1.27 [0.86,1.87]	
FIGARO-DKD	78 / 1673	44 / 1651	52.0	1.79 [1.23,2.60]	
Total	137 / 2974	91 / 2950		1.52 [1.16,1.99]	Z=3.03, p=0.0025
Heterogeneity:	Q=1.55 (df=1)	p=0.2131	I^2=35.5%		
Absent					
FIDELIO-DKD	66 / 1526	69 / 1532	48.3	0.96 [0.68,1.35]	
FIGARO-DKD	89 / 2010	60 / 2007	51.7	1.50 [1.08,2.10]	
Total	155 / 3536	129 / 3539		1.21 [0.96,1.54]	Z=1.58, p=0.1136
Heterogeneity:	Q=3.38 (df=1)	p=0.0660	I^2=70.4%		
Subgroup Heterogeneity:	Q=1.49 (df=1)	p=0.2214	I^2=33.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.90.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

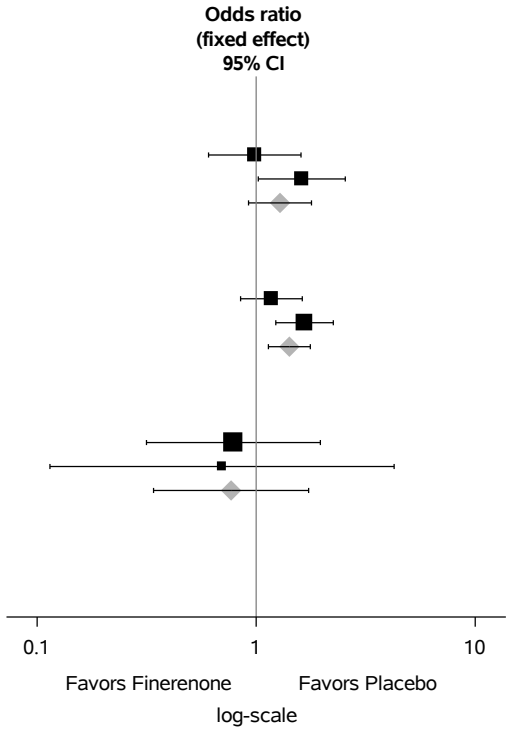
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	85 / 1879	85 / 1858	47.9	0.99 [0.73,1.34]	
FIGARO-DKD	136 / 2643	69 / 2608	52.1	2.00 [1.49,2.68]	
Total	221 / 4522	154 / 4466		1.44 [1.17,1.78]	Z=3.40, p=0.0007
Heterogeneity:	Q=10.46 (df=1)	p=0.0012	I^2=90.4%		
> 4.5					
FIDELIO-DKD	40 / 948	31 / 973	51.4	1.34 [0.83,2.16]	
FIGARO-DKD	31 / 1040	35 / 1048	48.6	0.89 [0.54,1.45]	
Total	71 / 1988	66 / 2021		1.10 [0.78,1.54]	Z=0.54, p=0.5913
Heterogeneity:	Q=1.37 (df=1)	p=0.2420	I^2=27.0%		
Subgroup Heterogeneity:	Q=1.75 (df=1)	p=0.1856	I^2=42.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.90.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

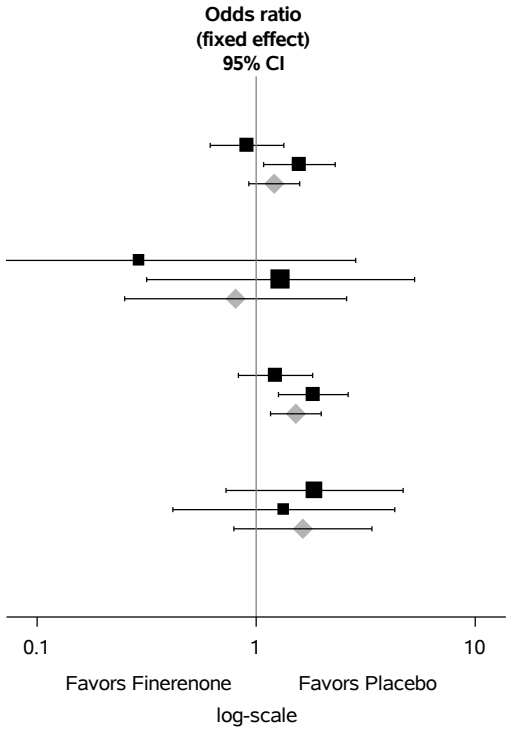
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	34 / 788	34 / 777	46.9	0.99 [0.61,1.60]	
FIGARO-DKD	49 / 1187	31 / 1194	53.1	1.62 [1.02,2.55]	
Total	83 / 1975	65 / 1971		1.28 [0.92,1.79]	Z=1.48, p=0.1376
Heterogeneity:	Q=2.11 (df=1)	p=0.1465	I^2=52.6%		
130 - < 160					
FIDELIO-DKD	82 / 1897	71 / 1916	46.5	1.17 [0.85,1.62]	
FIGARO-DKD	116 / 2389	70 / 2351	53.5	1.66 [1.23,2.25]	
Total	198 / 4286	141 / 4267		1.42 [1.14,1.77]	Z=3.10, p=0.0019
Heterogeneity:	Q=2.37 (df=1)	p=0.1237	I^2=57.8%		
>= 160					
FIDELIO-DKD	9 / 141	11 / 138	79.7	0.79 [0.32,1.96]	
FIGARO-DKD	2 / 107	3 / 113	20.3	0.70 [0.11,4.26]	
Total	11 / 248	14 / 251		0.77 [0.34,1.74]	Z=-0.63, p=0.5259
Heterogeneity:	Q=0.01 (df=1)	p=0.9079	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.10 (df=2)	p=0.3496	I^2=4.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.90.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

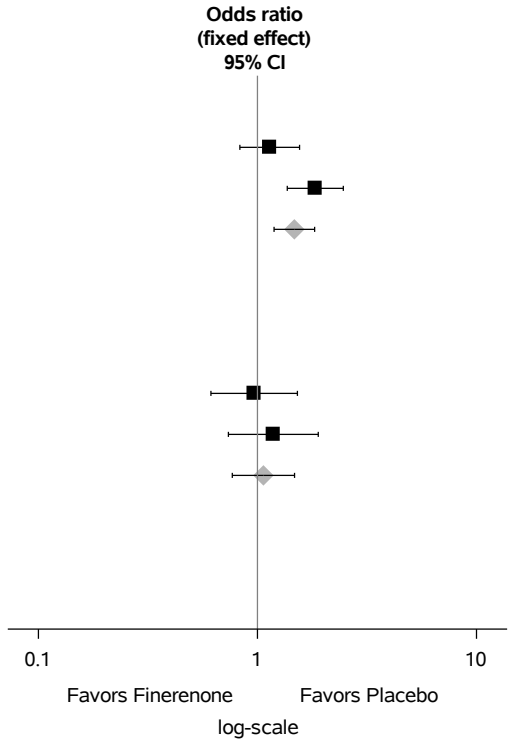
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	50 / 1773	56 / 1809	48.6	0.91 [0.62,1.34]	
FIGARO-DKD	72 / 2668	45 / 2601	51.4	1.58 [1.08,2.30]	
Total	122 / 4441	101 / 4410		1.21 [0.93,1.58]	Z=1.39, p=0.1633
Heterogeneity:	Q=3.99 (df=1)	p=0.0457	I^2=75.0%		
Black					
FIDELIO-DKD	1 / 139	3 / 124	27.7	0.29 [0.03,2.85]	
FIGARO-DKD	4 / 113	4 / 145	72.3	1.29 [0.32,5.29]	
Total	5 / 252	7 / 269		0.81 [0.25,2.59]	Z=-0.36, p=0.7167
Heterogeneity:	Q=1.20 (df=1)	p=0.2740	I^2=16.4%		
Asian					
FIDELIO-DKD	60 / 717	50 / 721	46.8	1.23 [0.83,1.81]	
FIGARO-DKD	84 / 716	50 / 736	53.2	1.82 [1.26,2.63]	
Total	144 / 1433	100 / 1457		1.52 [1.16,1.98]	Z=3.07, p=0.0021
Heterogeneity:	Q=2.12 (df=1)	p=0.1457	I^2=52.8%		
Others					
FIDELIO-DKD	14 / 198	7 / 177	61.1	1.85 [0.73,4.69]	
FIGARO-DKD	7 / 186	5 / 176	38.9	1.34 [0.42,4.29]	
Total	21 / 384	12 / 353		1.63 [0.79,3.38]	Z=1.33, p=0.1847
Heterogeneity:	Q=0.18 (df=1)	p=0.6712	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.42 (df=3)	p=0.4907	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.90.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

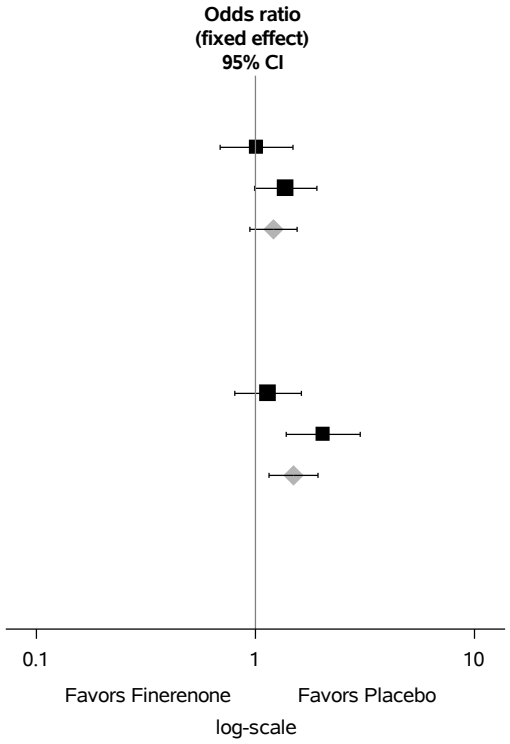
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	85 / 1949	78 / 2024	46.8	1.14 [0.83,1.56]	
FIGARO-DKD	127 / 2527	72 / 2571	53.2	1.84 [1.37,2.47]	
Total	212 / 4476	150 / 4595		1.47 [1.19,1.82]	Z=3.56, p=0.0004
Heterogeneity:	Q=4.76 (df=1)	p=0.0291	I^2=79.0%		
Female					
FIDELIO-DKD	40 / 878	38 / 807	51.9	0.97 [0.61,1.52]	
FIGARO-DKD	40 / 1156	32 / 1087	48.1	1.18 [0.74,1.90]	
Total	80 / 2034	70 / 1894		1.06 [0.77,1.48]	Z=0.37, p=0.7077
Heterogeneity:	Q=0.36 (df=1)	p=0.5468	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.66 (df=1)	p=0.1028	I^2=62.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.90.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set

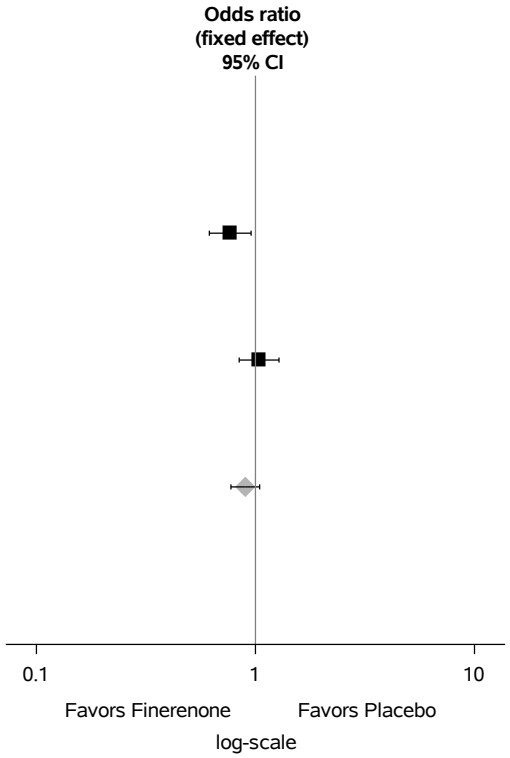
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	56 / 1201	54 / 1171	42.3	1.01 [0.69,1.48]	
FIGARO-DKD	88 / 1752	65 / 1755	57.7	1.37 [0.99,1.91]	
Total	144 / 2953	119 / 2926		1.21 [0.94,1.55]	Z=1.50, p=0.1347
Heterogeneity:	Q=1.42 (df=1)	p=0.2326	I^2=29.8%		
>= 65					
FIDELIO-DKD	69 / 1626	62 / 1660	55.3	1.14 [0.80,1.62]	
FIGARO-DKD	79 / 1931	39 / 1903	44.7	2.04 [1.38,3.01]	
Total	148 / 3557	101 / 3563		1.49 [1.15,1.93]	Z=3.05, p=0.0023
Heterogeneity:	Q=4.71 (df=1)	p=0.0299	I^2=78.8%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2486	I^2=24.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.91: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set

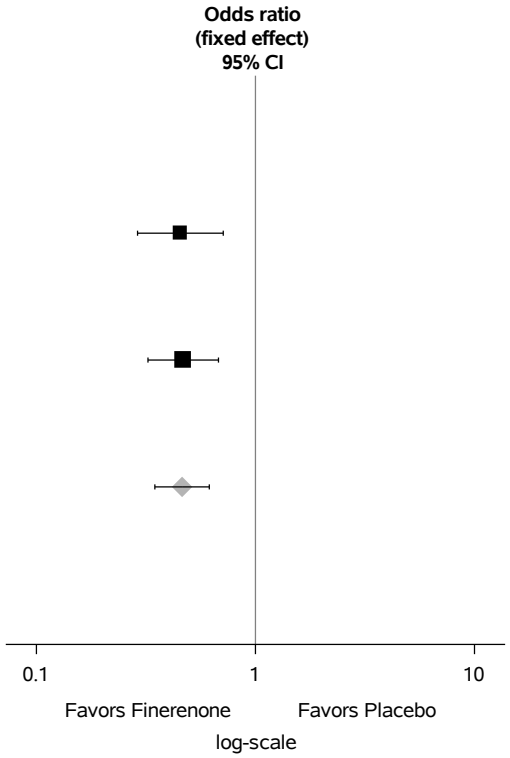
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	151 / 2827	194 / 2831	47.6	0.77 [0.62,0.96]	
FIGARO-DKD	189 / 3683	181 / 3658	52.4	1.04 [0.84,1.28]	
Total	340 / 6510	375 / 6489		0.90 [0.77,1.05]	Z=-1.39, p=0.1659
Heterogeneity:	Q=3.85 (df=1)	p=0.0496	I^2=74.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.92: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

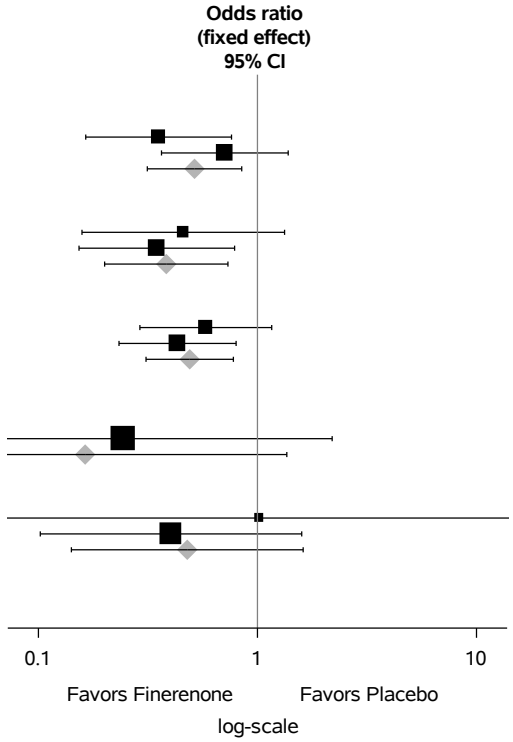
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2827	61 / 2831	40.3	0.45 [0.29,0.71]	
FIGARO-DKD	42 / 3683	88 / 3658	59.7	0.47 [0.32,0.68]	
Total	70 / 6510	149 / 6489		0.46 [0.35,0.62]	Z=-5.28, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.92.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

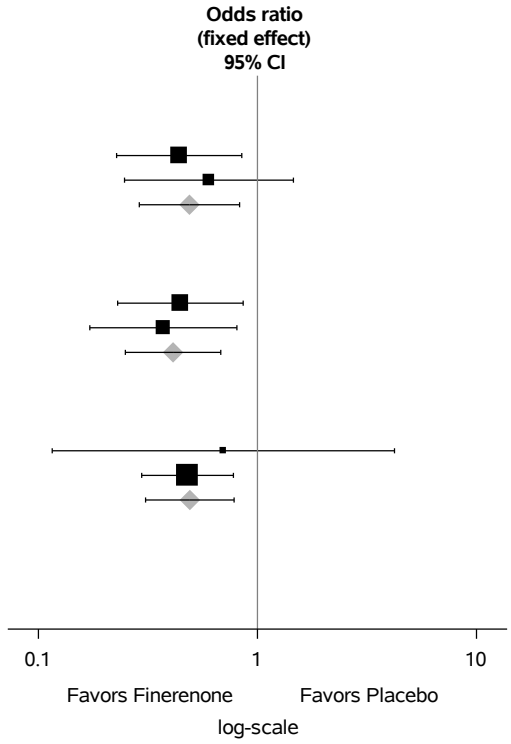
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1178	25 / 1174	43.0	0.35 [0.16,0.76]	
FIGARO-DKD	15 / 1752	21 / 1747	57.0	0.71 [0.36,1.38]	
Total	24 / 2930	46 / 2921		0.52 [0.31,0.85]	Z=-2.61, p=0.0090
Heterogeneity:	Q=1.81 (df=1)	p=0.1783	I^2=44.8%		
North America					
FIDELIO-DKD	5 / 466	11 / 476	37.1	0.46 [0.16,1.33]	
FIGARO-DKD	8 / 559	22 / 548	62.9	0.35 [0.15,0.79]	
Total	13 / 1025	33 / 1024		0.38 [0.20,0.73]	Z=-2.90, p=0.0038
Heterogeneity:	Q=0.17 (df=1)	p=0.6846	I^2=0.0%		
Asia					
FIDELIO-DKD	13 / 790	22 / 786	44.1	0.58 [0.29,1.16]	
FIGARO-DKD	15 / 811	34 / 813	55.9	0.43 [0.23,0.80]	
Total	28 / 1601	56 / 1599		0.49 [0.31,0.78]	Z=-3.04, p=0.0024
Heterogeneity:	Q=0.39 (df=1)	p=0.5299	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 294	2 / 294	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	1 / 424	4 / 417	100.0	0.24 [0.03,2.19]	
Total	1 / 718	6 / 711		0.16 [0.02,1.36]	Z=-1.67, p=0.0940
Heterogeneity:	Q=0.13 (df=1)	p=0.7203	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 99	1 / 101	19.6	1.02 [0.06,16.54]	
FIGARO-DKD	3 / 137	7 / 133	80.4	0.40 [0.10,1.59]	
Total	4 / 236	8 / 234		0.48 [0.14,1.62]	Z=-1.19, p=0.2352
Heterogeneity:	Q=0.34 (df=1)	p=0.5576	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.50 (df=4)	p=0.8271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.92.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

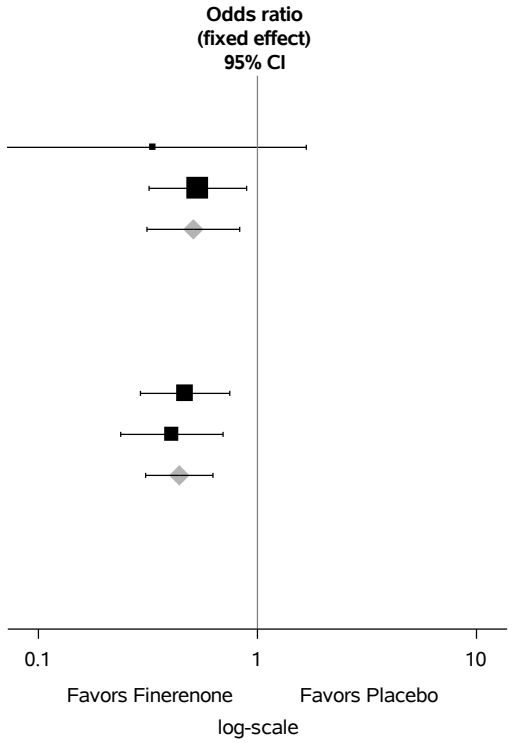
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	29 / 1541	64.5	0.44 [0.23,0.85]	
FIGARO-DKD	8 / 637	13 / 627	35.5	0.60 [0.25,1.46]	
Total	21 / 2193	42 / 2168		0.49 [0.29,0.83]	Z=-2.66, p=0.0079
Heterogeneity:	Q=0.31 (df=1)	p=0.5787	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	13 / 1061	29 / 1069	57.9	0.44 [0.23,0.86]	
FIGARO-DKD	9 / 720	24 / 729	42.1	0.37 [0.17,0.81]	
Total	22 / 1781	53 / 1798		0.41 [0.25,0.68]	Z=-3.47, p=0.0005
Heterogeneity:	Q=0.12 (df=1)	p=0.7295	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	3 / 221	6.7	0.70 [0.12,4.22]	
FIGARO-DKD	25 / 2326	51 / 2302	93.3	0.48 [0.30,0.78]	
Total	27 / 2536	54 / 2523		0.49 [0.31,0.78]	Z=-2.99, p=0.0028
Heterogeneity:	Q=0.16 (df=1)	p=0.6920	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.31 (df=2)	p=0.8548	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.92.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

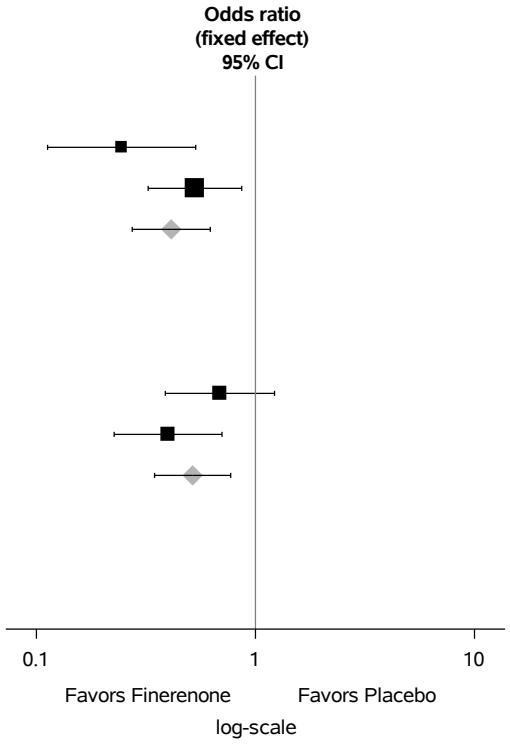
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	6 / 213	9.2	0.33 [0.07,1.67]	
FIGARO-DKD	23 / 1720	42 / 1698	90.8	0.53 [0.32,0.89]	
Total	25 / 1929	48 / 1911		0.51 [0.31,0.83]	Z=-2.71, p=0.0067
Heterogeneity:	Q=0.30 (df=1)	p=0.5843	I^2=0.0%		
Very High					
FIDELIO-DKD	26 / 2618	55 / 2618	56.8	0.47 [0.29,0.75]	
FIGARO-DKD	19 / 1963	46 / 1960	43.2	0.41 [0.24,0.70]	
Total	45 / 4581	101 / 4578		0.44 [0.31,0.63]	Z=-4.55, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.7023	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6314	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.92.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

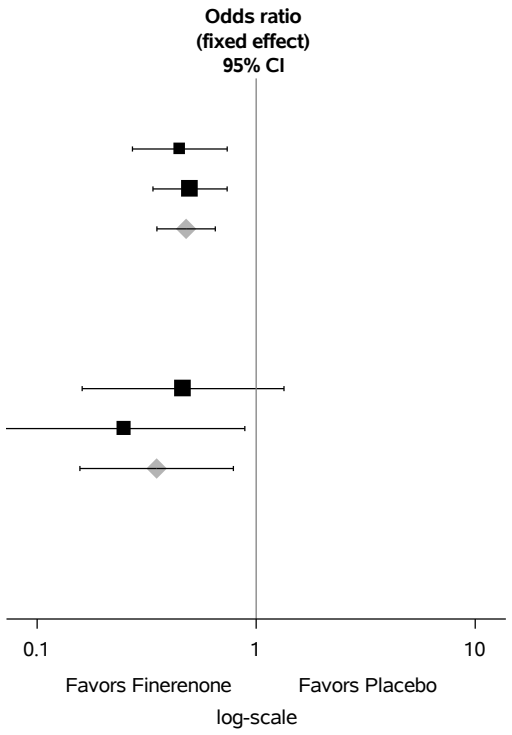
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	8 / 1301	32 / 1299	28.5	0.24 [0.11,0.53]	
FIGARO-DKD	25 / 1673	46 / 1651	71.5	0.53 [0.32,0.87]	
Total	33 / 2974	78 / 2950		0.41 [0.27,0.62]	Z=-4.23, p=<.0001
Heterogeneity:	Q=2.71 (df=1)	p=0.0999	I^2=63.1%		
Absent					
FIDELIO-DKD	20 / 1526	29 / 1532	49.4	0.69 [0.39,1.22]	
FIGARO-DKD	17 / 2010	42 / 2007	50.6	0.40 [0.23,0.70]	
Total	37 / 3536	71 / 3539		0.52 [0.35,0.77]	Z=-3.24, p=0.0012
Heterogeneity:	Q=1.76 (df=1)	p=0.1851	I^2=43.1%		
Subgroup Heterogeneity:	Q=0.59 (df=1)	p=0.4422	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.92.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

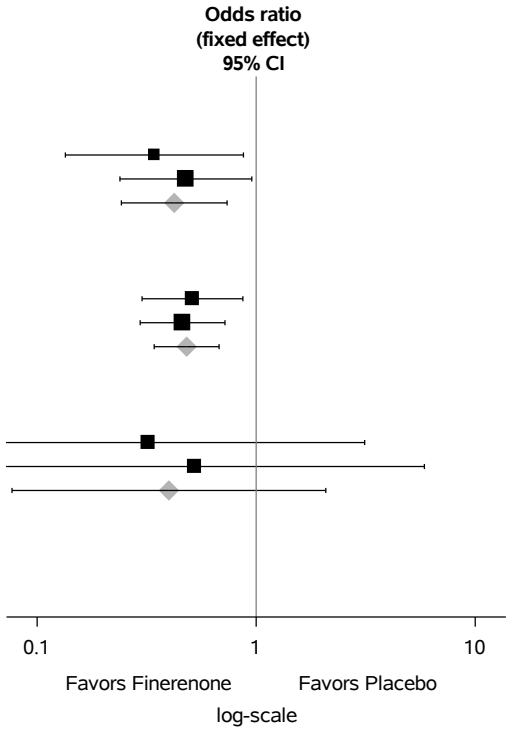
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	50 / 1858	38.0	0.45 [0.27,0.74]	
FIGARO-DKD	39 / 2643	76 / 2608	62.0	0.50 [0.34,0.74]	
Total	62 / 4522	126 / 4466		0.48 [0.35,0.65]	Z=-4.70, p=<.0001
Heterogeneity:	Q=0.11 (df=1)	p=0.7390	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 948	11 / 973	58.8	0.46 [0.16,1.34]	
FIGARO-DKD	3 / 1040	12 / 1048	41.2	0.25 [0.07,0.89]	
Total	8 / 1988	23 / 2021		0.35 [0.16,0.79]	Z=-2.54, p=0.0110
Heterogeneity:	Q=0.54 (df=1)	p=0.4620	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.49 (df=1)	p=0.4818	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.92.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

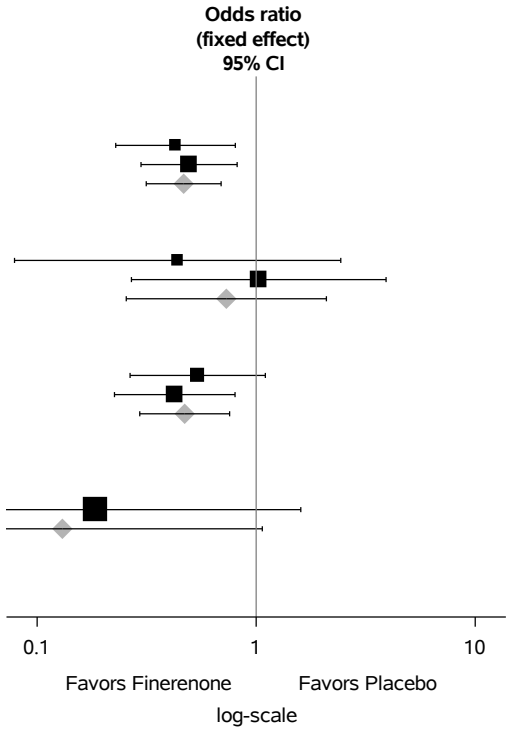
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	6 / 788	17 / 777	35.4	0.34 [0.13,0.87]	
FIGARO-DKD	12 / 1187	25 / 1194	64.6	0.48 [0.24,0.96]	
Total	18 / 1975	42 / 1971		0.42 [0.24,0.74]	Z=-3.04, p=0.0024
Heterogeneity:	Q=0.31 (df=1)	p=0.5774	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	21 / 1897	41 / 1916	41.5	0.51 [0.30,0.87]	
FIGARO-DKD	29 / 2389	61 / 2351	58.5	0.46 [0.30,0.72]	
Total	50 / 4286	102 / 4267		0.48 [0.34,0.68]	Z=-4.20, p=<.0001
Heterogeneity:	Q=0.09 (df=1)	p=0.7682	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 141	3 / 138	53.0	0.32 [0.03,3.13]	
FIGARO-DKD	1 / 107	2 / 113	47.0	0.52 [0.05,5.86]	
Total	2 / 248	5 / 251		0.40 [0.08,2.08]	Z=-1.09, p=0.2756
Heterogeneity:	Q=0.08 (df=1)	p=0.7729	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=2)	p=0.9116	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.92.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

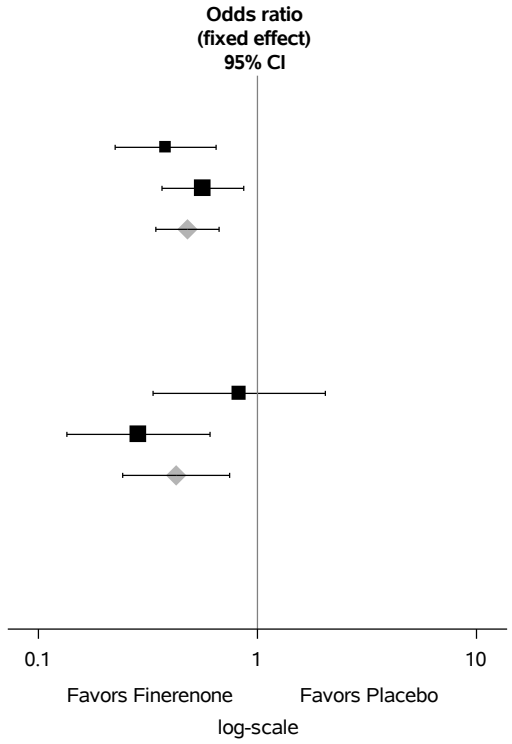
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1773	33 / 1809	39.3	0.43 [0.23,0.80]	
FIGARO-DKD	23 / 2668	45 / 2601	60.7	0.49 [0.30,0.82]	
Total	37 / 4441	78 / 4410		0.47 [0.31,0.69]	Z=-3.80, p=0.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7292	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	4 / 124	37.9	0.44 [0.08,2.43]	
FIGARO-DKD	4 / 113	5 / 145	62.1	1.03 [0.27,3.92]	
Total	6 / 252	9 / 269		0.73 [0.26,2.09]	Z=-0.58, p=0.5589
Heterogeneity:	Q=0.59 (df=1)	p=0.4419	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 717	22 / 721	44.3	0.54 [0.27,1.10]	
FIGARO-DKD	14 / 716	33 / 736	55.7	0.42 [0.23,0.80]	
Total	26 / 1433	55 / 1457		0.47 [0.29,0.76]	Z=-3.12, p=0.0018
Heterogeneity:	Q=0.25 (df=1)	p=0.6194	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	2 / 177	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	1 / 186	5 / 176	100.0	0.18 [0.02,1.60]	
Total	1 / 384	7 / 353		0.13 [0.02,1.07]	Z=-1.90, p=0.0574
Heterogeneity:	Q=0.10 (df=1)	p=0.7510	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.11 (df=3)	p=0.5508	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.92.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

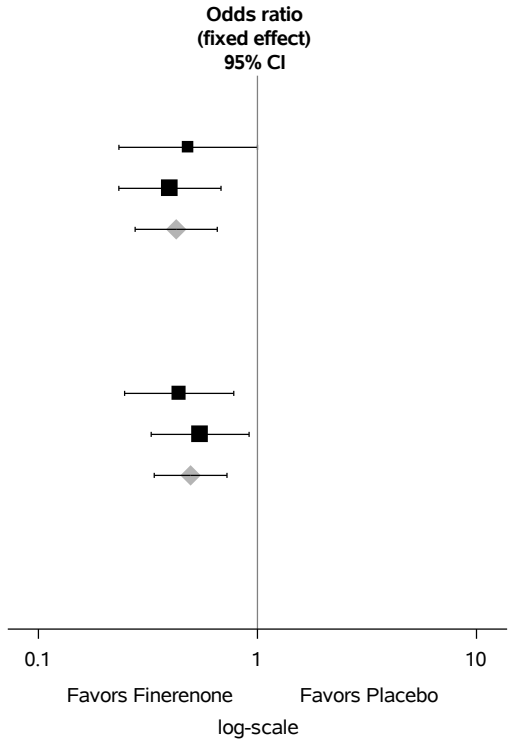
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	19 / 1949	51 / 2024	39.6	0.38 [0.22,0.65]	
FIGARO-DKD	33 / 2527	59 / 2571	60.4	0.56 [0.37,0.87]	
Total	52 / 4476	110 / 4595		0.48 [0.34,0.67]	Z=-4.34, p=<.0001
Heterogeneity:	Q=1.27 (df=1)	p=0.2607	I^2=21.0%		
Female					
FIDELIO-DKD	9 / 878	10 / 807	40.8	0.83 [0.33,2.04]	
FIGARO-DKD	9 / 1156	29 / 1087	59.2	0.29 [0.13,0.61]	
Total	18 / 2034	39 / 1894		0.43 [0.24,0.75]	Z=-2.98, p=0.0029
Heterogeneity:	Q=3.12 (df=1)	p=0.0772	I^2=68.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7210	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.92.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set

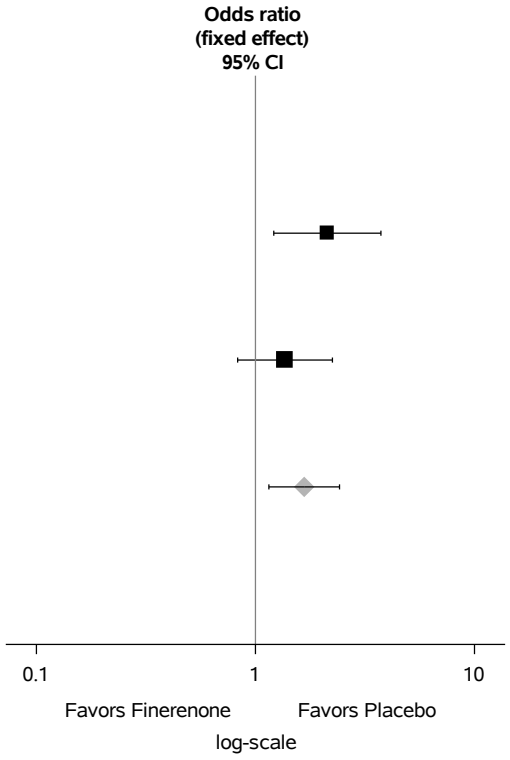
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1201	22 / 1171	35.2	0.48 [0.23,1.00]	
FIGARO-DKD	19 / 1752	47 / 1755	64.8	0.40 [0.23,0.68]	
Total	30 / 2953	69 / 2926		0.43 [0.28,0.66]	Z=-3.88, p=0.0001
Heterogeneity:	Q=0.17 (df=1)	p=0.6774	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 1626	39 / 1660	44.6	0.44 [0.25,0.78]	
FIGARO-DKD	23 / 1931	41 / 1903	55.4	0.55 [0.33,0.92]	
Total	40 / 3557	80 / 3563		0.50 [0.34,0.73]	Z=-3.60, p=0.0003
Heterogeneity:	Q=0.31 (df=1)	p=0.5750	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6069	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

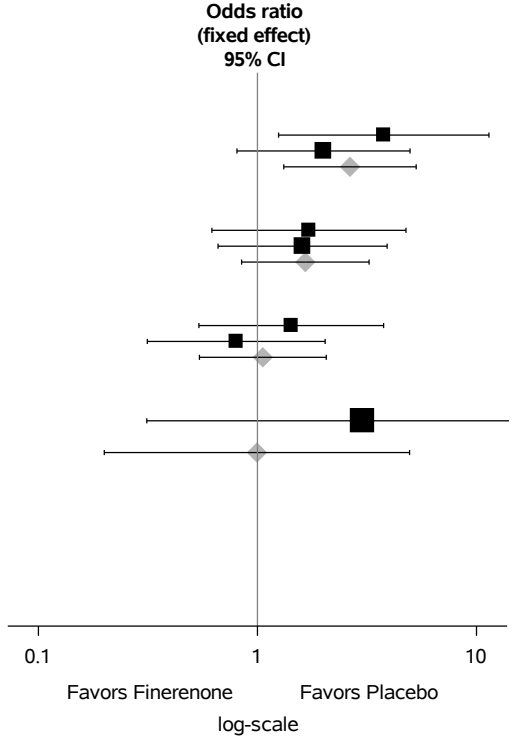
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2827	18 / 2831	43.9	2.13 [1.21,3.74]	
FIGARO-DKD	37 / 3683	27 / 3658	56.1	1.36 [0.83,2.25]	
Total	75 / 6510	45 / 6489		1.67 [1.15,2.42]	Z=2.71, p=0.0068
Heterogeneity:	Q=1.35 (df=1)	p=0.2461	I^2=25.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.93.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

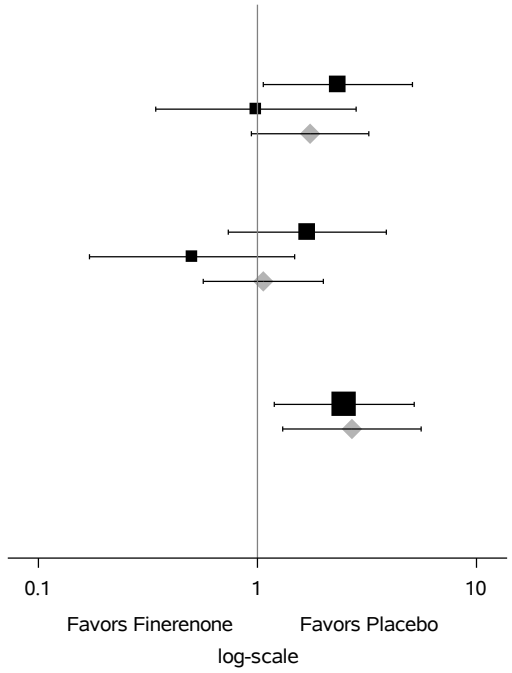
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1178	4 / 1174	40.4	3.77 [1.25,11.40]	
FIGARO-DKD	14 / 1752	7 / 1747	59.6	2.00 [0.81,4.97]	
Total	29 / 2930	11 / 2921		2.64 [1.32,5.30]	Z=2.74, p=0.0062
Heterogeneity:	Q=0.76 (df=1)	p=0.3847	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	6 / 476	43.1	1.72 [0.62,4.77]	
FIGARO-DKD	13 / 559	8 / 548	56.9	1.61 [0.66,3.91]	
Total	23 / 1025	14 / 1024		1.65 [0.85,3.23]	Z=1.47, p=0.1410
Heterogeneity:	Q=0.01 (df=1)	p=0.9231	I^2=0.0%		
Asia					
FIDELIO-DKD	10 / 790	7 / 786	48.1	1.43 [0.54,3.77]	
FIGARO-DKD	8 / 811	10 / 813	51.9	0.80 [0.31,2.04]	
Total	18 / 1601	17 / 1599		1.06 [0.54,2.06]	Z=0.17, p=0.8679
Heterogeneity:	Q=0.71 (df=1)	p=0.4002	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 294	1 / 294	100.0	3.02 [0.31,29.21]	
FIGARO-DKD	0 / 424	2 / 417	0.0	0.00 [0.00,24E296]	
Total	3 / 718	3 / 711		0.99 [0.20,4.95]	Z=-0.01, p=0.9946
Heterogeneity:	Q=0.92 (df=1)	p=0.3372	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	0 / 101	0.0	-	
FIGARO-DKD	2 / 137	0 / 133	0.0	228E9 [228E9,228E9]	
Total	2 / 236	0 / 234		303E9 [303E9,303E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.83 (df=4)	p=0.4298	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

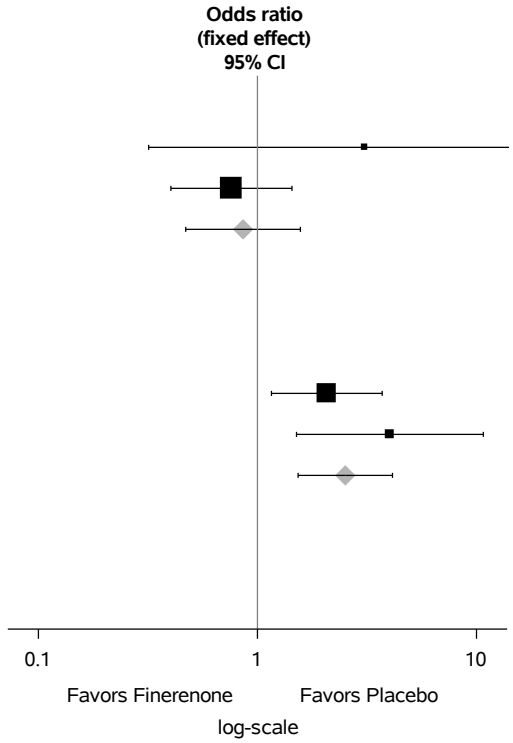
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	21 / 1556	9 / 1541	64.4	2.33 [1.06,5.10]	
FIGARO-DKD	7 / 637	7 / 627	35.6	0.98 [0.34,2.82]	
Total	28 / 2193	16 / 2168		1.74 [0.94,3.22]	Z=1.76, p=0.0788
Heterogeneity:	Q=1.65 (df=1)	p=0.1983	I^2=39.6%		
45 - < 60					
FIDELIO-DKD	15 / 1061	9 / 1069	62.8	1.69 [0.74,3.88]	
FIGARO-DKD	5 / 720	10 / 729	37.2	0.50 [0.17,1.48]	
Total	20 / 1781	19 / 1798		1.06 [0.57,2.00]	Z=0.19, p=0.8489
Heterogeneity:	Q=3.04 (df=1)	p=0.0810	I^2=67.2%		
>= 60					
FIDELIO-DKD	2 / 210	0 / 221	0.0	148E9 [148E9,148E9]	
FIGARO-DKD	25 / 2326	10 / 2302	100.0	2.49 [1.19,5.20]	
Total	27 / 2536	10 / 2523		2.70 [1.30,5.59]	Z=2.67, p=0.0075
Heterogeneity:	Q=0.05 (df=1)	p=0.8298	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.65 (df=2)	p=0.1615	I^2=45.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

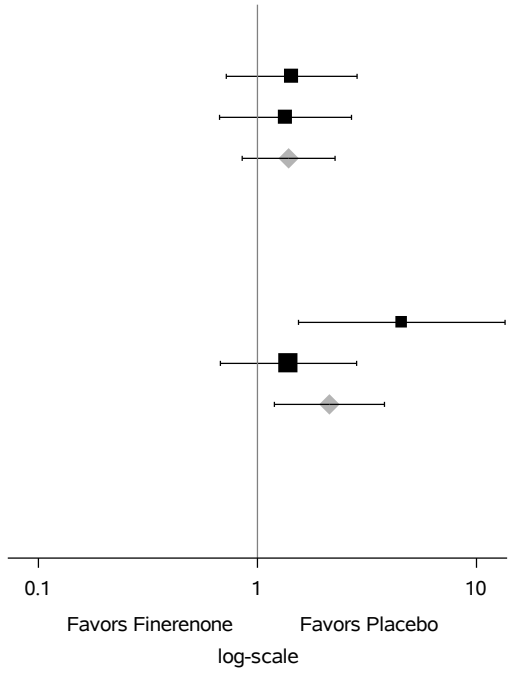
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	1 / 213	7.3	3.09 [0.32,29.92]	
FIGARO-DKD	17 / 1720	22 / 1698	92.7	0.76 [0.40,1.44]	
Total	20 / 1929	23 / 1911		0.86 [0.47,1.57]	Z=-0.49, p=0.6225
Heterogeneity:	Q=1.36 (df=1)	p=0.2436	I^2=26.5%		
Very High					
FIDELIO-DKD	35 / 2618	17 / 2618	74.0	2.07 [1.16,3.71]	
FIGARO-DKD	20 / 1963	5 / 1960	26.0	4.02 [1.51,10.75]	
Total	55 / 4581	22 / 4578		2.52 [1.53,4.14]	Z=3.65, p=0.0003
Heterogeneity:	Q=1.30 (df=1)	p=0.2534	I^2=23.4%		
Subgroup Heterogeneity:	Q=7.28 (df=1)	p=0.0070	I^2=86.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

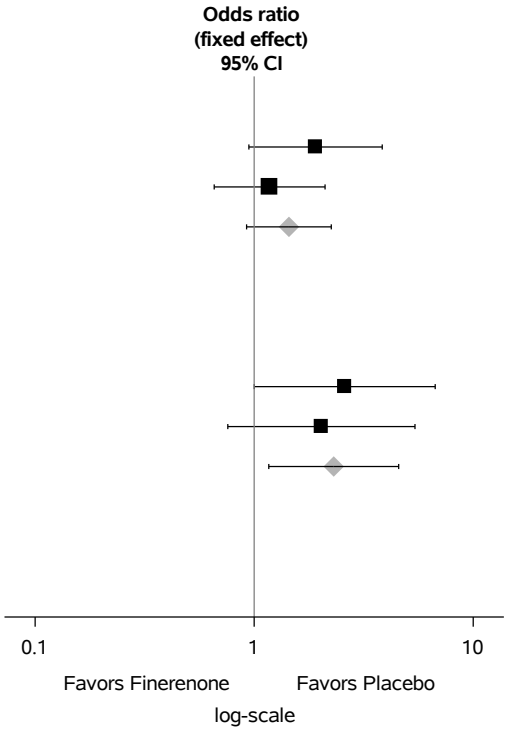
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	14 / 1299	50.5	1.43 [0.72,2.85]	
FIGARO-DKD	19 / 1673	14 / 1651	49.5	1.34 [0.67,2.69]	
Total	39 / 2974	28 / 2950		1.39 [0.85,2.26]	Z=1.32, p=0.1882
Heterogeneity:	Q=0.02 (df=1)	p=0.8966	I^2=0.0%		
Absent					
FIDELIO-DKD	18 / 1526	4 / 1532	30.3	4.56 [1.54,13.50]	
FIGARO-DKD	18 / 2010	13 / 2007	69.7	1.39 [0.68,2.84]	
Total	36 / 3536	17 / 3539		2.13 [1.19,3.80]	Z=2.56, p=0.0104
Heterogeneity:	Q=3.27 (df=1)	p=0.0705	I^2=69.4%		
Subgroup Heterogeneity:	Q=1.23 (df=1)	p=0.2671	I^2=18.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

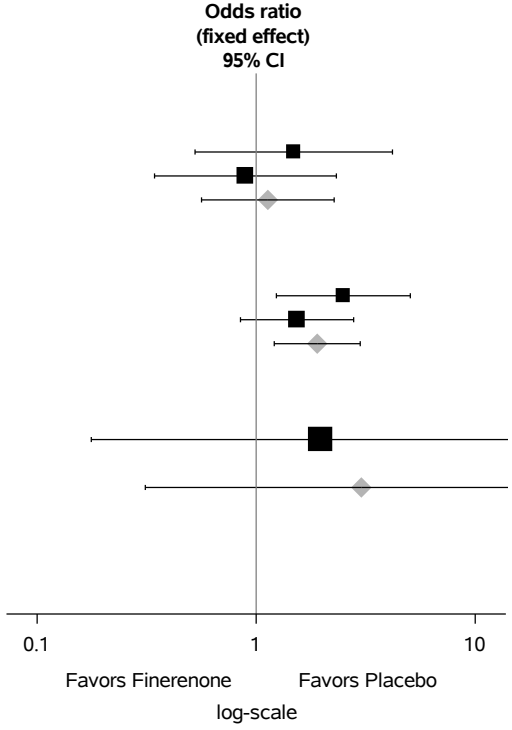
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	12 / 1858	40.9	1.91 [0.95,3.84]	
FIGARO-DKD	25 / 2643	21 / 2608	59.1	1.18 [0.66,2.11]	
Total	48 / 4522	33 / 4466		1.44 [0.92,2.25]	Z=1.61, p=0.1075
Heterogeneity:	Q=1.08 (df=1)	p=0.2991	I^2=7.2%		
> 4.5					
FIDELIO-DKD	15 / 948	6 / 973	51.7	2.59 [1.00,6.71]	
FIGARO-DKD	12 / 1040	6 / 1048	48.3	2.03 [0.76,5.42]	
Total	27 / 1988	12 / 2021		2.31 [1.17,4.57]	Z=2.40, p=0.0164
Heterogeneity:	Q=0.12 (df=1)	p=0.7251	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=1)	p=0.2576	I^2=22.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.93.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

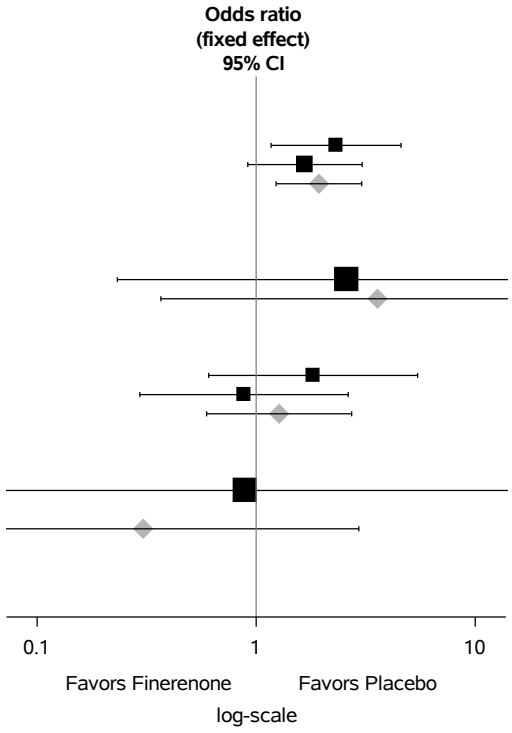
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 788	6 / 777	45.9	1.48 [0.53,4.19]	
FIGARO-DKD	8 / 1187	9 / 1194	54.1	0.89 [0.34,2.32]	
Total	17 / 1975	15 / 1971		1.13 [0.56,2.27]	Z=0.34, p=0.7301
Heterogeneity:	Q=0.50 (df=1)	p=0.4805	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	27 / 1897	11 / 1916	41.7	2.50 [1.24,5.06]	
FIGARO-DKD	28 / 2389	18 / 2351	58.3	1.54 [0.85,2.79]	
Total	55 / 4286	29 / 4267		1.90 [1.21,2.99]	Z=2.78, p=0.0054
Heterogeneity:	Q=1.07 (df=1)	p=0.3004	I^2=6.7%		
>= 160					
FIDELIO-DKD	2 / 141	1 / 138	100.0	1.97 [0.18,21.99]	
FIGARO-DKD	1 / 107	0 / 113	0.0	145E9 [145E9,145E9]	
Total	3 / 248	1 / 251		3.02 [0.31,29.28]	Z=0.95, p=0.3400
Heterogeneity:	Q=0.12 (df=1)	p=0.7286	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.78 (df=2)	p=0.4114	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.93.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

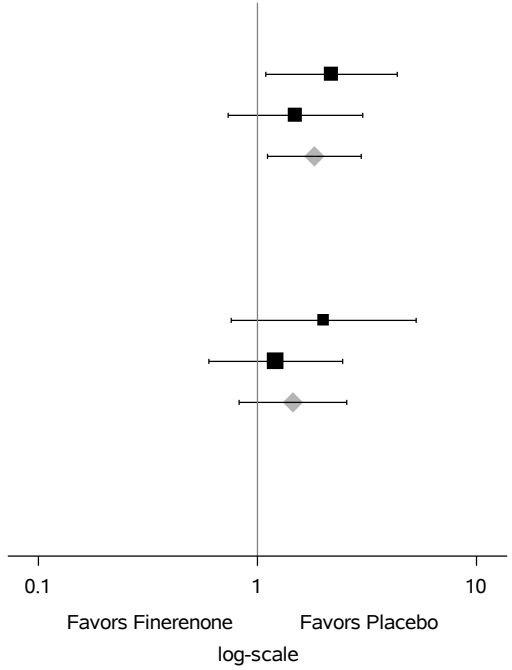
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	27 / 1773	12 / 1809	43.6	2.32 [1.17,4.59]	
FIGARO-DKD	29 / 2668	17 / 2601	56.4	1.67 [0.92,3.05]	
Total	56 / 4441	29 / 4410		1.93 [1.23,3.03]	Z=2.87, p=0.0041
Heterogeneity:	Q=0.50 (df=1)	p=0.4815	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	0 / 124	0.0	112E9 [112E9,112E9]	
FIGARO-DKD	2 / 113	1 / 145	100.0	2.59 [0.23,28.98]	
Total	3 / 252	1 / 269		3.58 [0.37,34.90]	Z=1.10, p=0.2723
Heterogeneity:	Q=0.07 (df=1)	p=0.7937	I^2=0.0%		
Asian					
FIDELIO-DKD	9 / 717	5 / 721	49.9	1.82 [0.61,5.46]	
FIGARO-DKD	6 / 716	7 / 736	50.1	0.88 [0.29,2.63]	
Total	15 / 1433	12 / 1457		1.27 [0.59,2.73]	Z=0.62, p=0.5347
Heterogeneity:	Q=0.84 (df=1)	p=0.3583	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 198	1 / 177	100.0	0.89 [0.06,14.39]	
FIGARO-DKD	0 / 186	2 / 176	0.0	0.00 [0.00,1E297]	
Total	1 / 384	3 / 353		0.30 [0.03,2.94]	Z=-1.03, p=0.3044
Heterogeneity:	Q=0.58 (df=1)	p=0.4481	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.48 (df=3)	p=0.3228	I^2=13.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.93.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

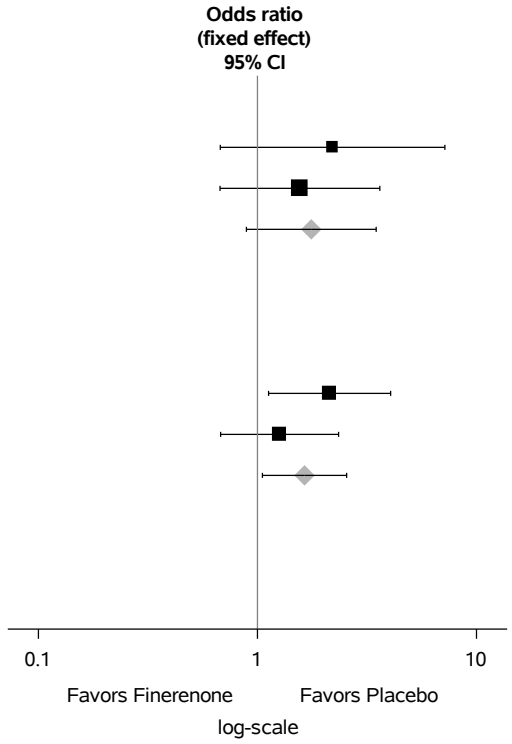
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1949	12 / 2024	51.2	2.18 [1.09,4.35]	
FIGARO-DKD	19 / 2527	13 / 2571	48.8	1.49 [0.73,3.02]	
Total	44 / 4476	25 / 4595		1.82 [1.11,2.98]	Z=2.38, p=0.0173
Heterogeneity:	Q=0.57 (df=1)	p=0.4520	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 878	6 / 807	34.4	2.01 [0.76,5.30]	
FIGARO-DKD	18 / 1156	14 / 1087	65.6	1.21 [0.60,2.45]	
Total	31 / 2034	20 / 1894		1.45 [0.82,2.56]	Z=1.29, p=0.1962
Heterogeneity:	Q=0.68 (df=1)	p=0.4103	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=1)	p=0.5564	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.93.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set

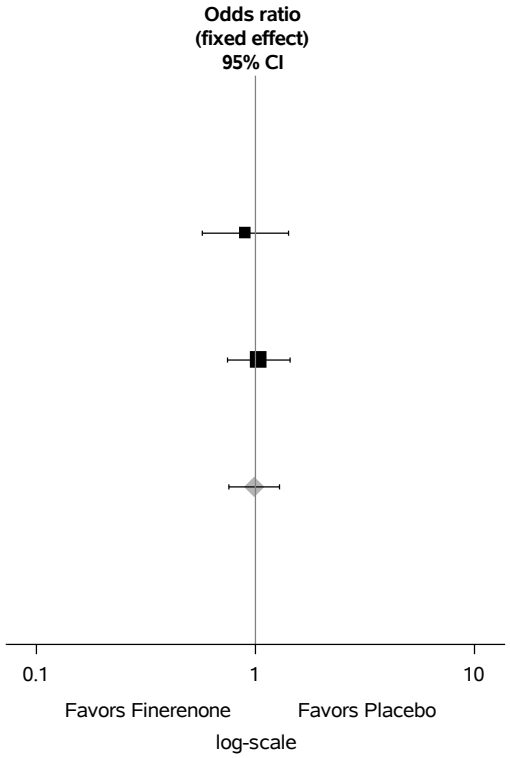
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1201	4 / 1171	33.6	2.20 [0.68,7.17]	
FIGARO-DKD	14 / 1752	9 / 1755	66.4	1.56 [0.67,3.62]	
Total	23 / 2953	13 / 2926		1.76 [0.89,3.48]	Z=1.63, p=0.1039
Heterogeneity:	Q=0.22 (df=1)	p=0.6423	I^2=0.0%		
>= 65					
FIDELIO-DKD	29 / 1626	14 / 1660	48.3	2.13 [1.12,4.06]	
FIGARO-DKD	23 / 1931	18 / 1903	51.7	1.26 [0.68,2.35]	
Total	52 / 3557	32 / 3563		1.64 [1.05,2.55]	Z=2.19, p=0.0285
Heterogeneity:	Q=1.33 (df=1)	p=0.2482	I^2=25.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8639	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.94: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set

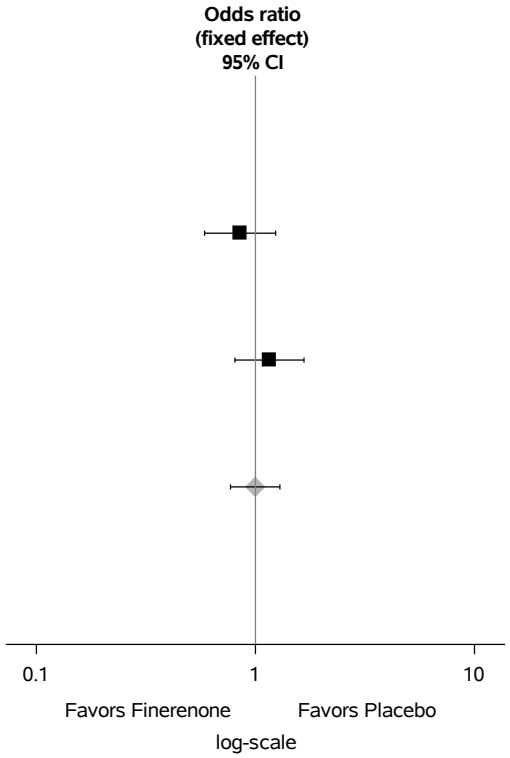
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	40 / 2831	34.5	0.90 [0.57,1.42]	
FIGARO-DKD	74 / 3683	71 / 3658	65.5	1.04 [0.75,1.44]	
Total	110 / 6510	111 / 6489		0.99 [0.76,1.29]	Z=-0.10, p=0.9221
Heterogeneity:	Q=0.24 (df=1)	p=0.6226	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.95: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set

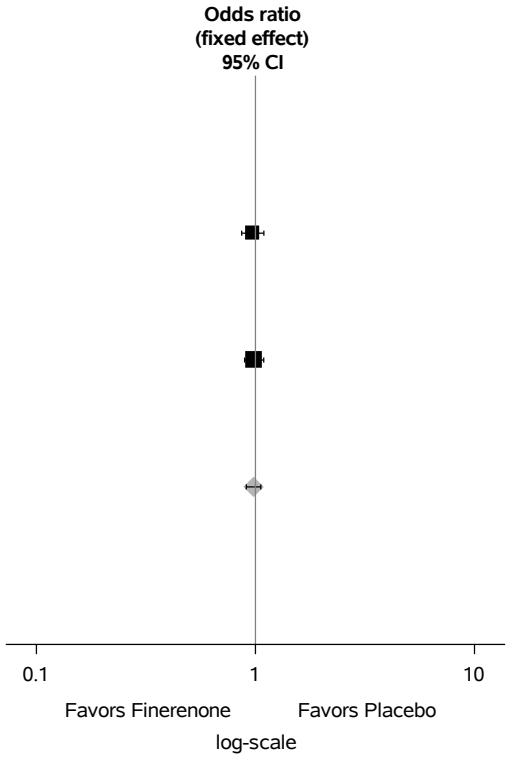
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	52 / 2827	61 / 2831	48.6	0.85 [0.59,1.24]	
FIGARO-DKD	64 / 3683	55 / 3658	51.4	1.16 [0.81,1.67]	
Total	116 / 6510	116 / 6489		1.00 [0.77,1.29]	Z=-0.02, p=0.9828
Heterogeneity:	Q=1.35 (df=1)	p=0.2459	I^2=25.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.96: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

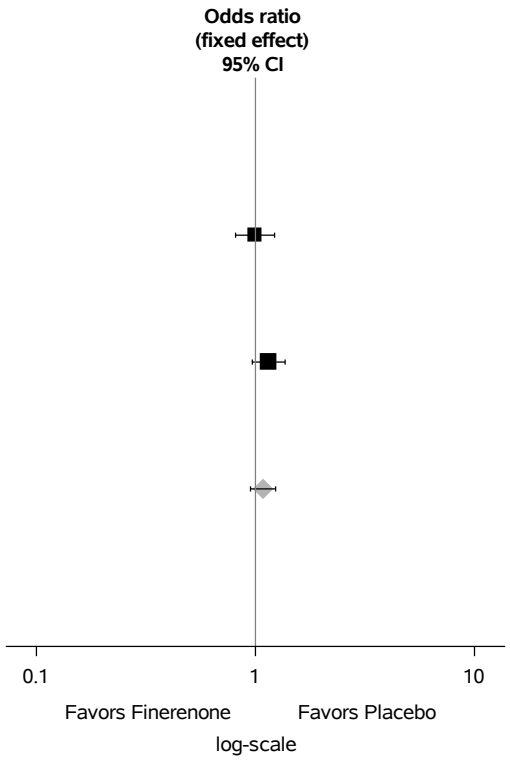
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	773 / 2827	790 / 2831	42.8	0.97 [0.87,1.09]	
FIGARO-DKD	1065 / 3683	1068 / 3658	57.2	0.99 [0.89,1.09]	
Total	1838 / 6510	1858 / 6489		0.98 [0.91,1.06]	Z=-0.51, p=0.6110
Heterogeneity:	Q=0.03 (df=1)	p=0.8533	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.97: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set

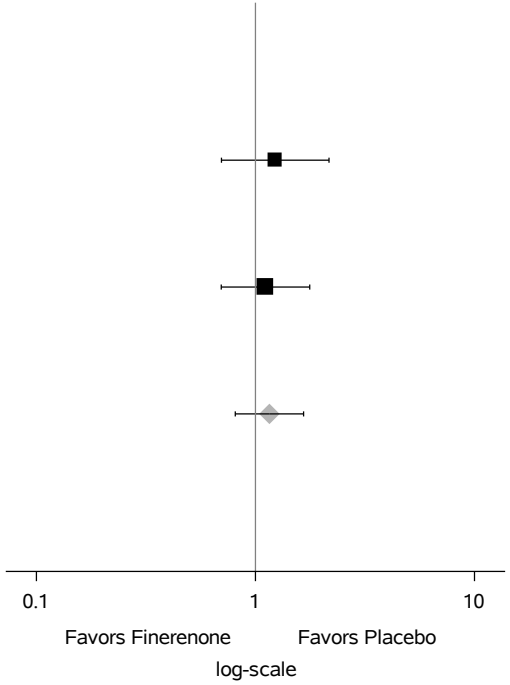
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	196 / 2827	197 / 2831	41.4	1.00 [0.81,1.22]	
FIGARO-DKD	300 / 3683	262 / 3658	58.6	1.15 [0.97,1.37]	
Total	496 / 6510	459 / 6489		1.08 [0.95,1.24]	Z=1.19, p=0.2346
Heterogeneity:	Q=1.10 (df=1)	p=0.2947	I^2=8.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.98: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set

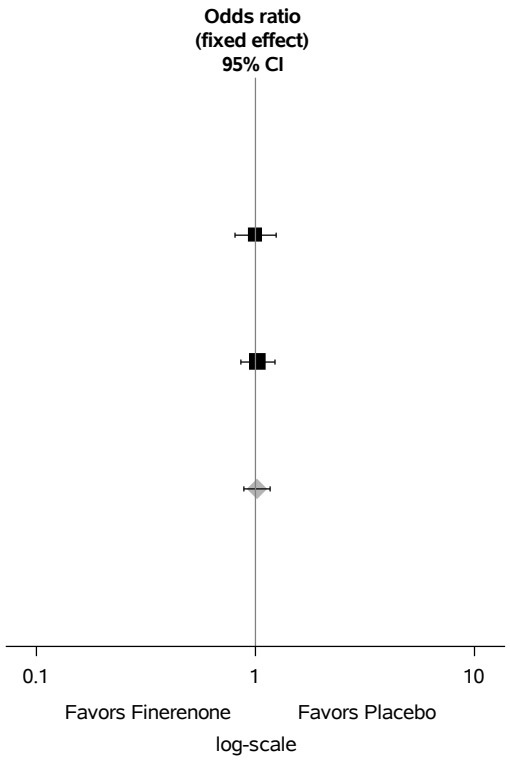
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	22 / 2831	40.3	1.23 [0.70,2.17]	
FIGARO-DKD	38 / 3683	34 / 3658	59.7	1.11 [0.70,1.77]	
Total	65 / 6510	56 / 6489		1.16 [0.81,1.66]	Z=0.80, p=0.4225
Heterogeneity:	Q=0.08 (df=1)	p=0.7836	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.99: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set

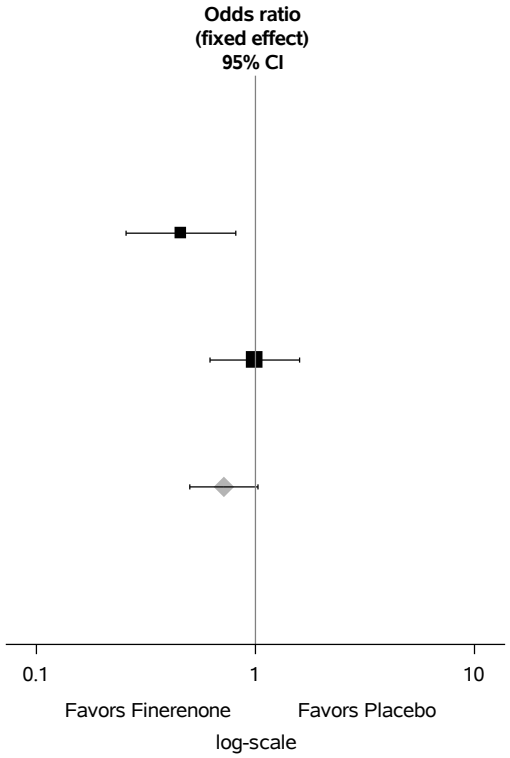
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	175 / 2827	175 / 2831	40.7	1.00 [0.81,1.24]	
FIGARO-DKD	261 / 3683	253 / 3658	59.3	1.03 [0.86,1.23]	
Total	436 / 6510	428 / 6489		1.02 [0.89,1.17]	Z=0.23, p=0.8190
Heterogeneity:	Q=0.03 (df=1)	p=0.8635	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.100: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set

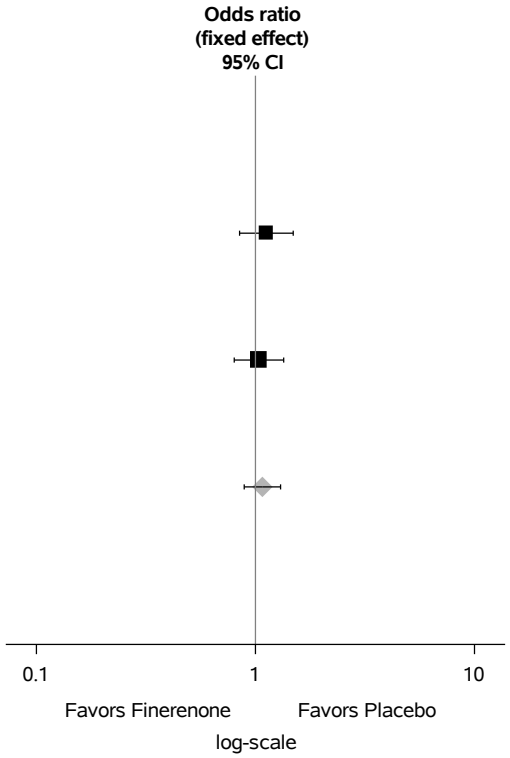
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 2827	37 / 2831	40.0	0.46 [0.26,0.81]	
FIGARO-DKD	35 / 3683	35 / 3658	60.0	0.99 [0.62,1.59]	
Total	52 / 6510	72 / 6489		0.72 [0.50,1.03]	Z=-1.81, p=0.0696
Heterogeneity:	Q=4.19 (df=1)	p=0.0408	I^2=76.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.101: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set

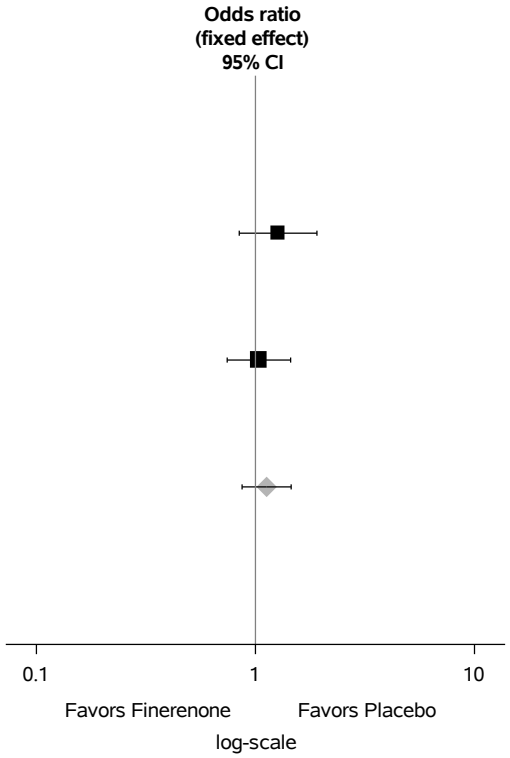
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	106 / 2827	95 / 2831	45.9	1.12 [0.85,1.49]	
FIGARO-DKD	120 / 3683	115 / 3658	54.1	1.04 [0.80,1.35]	
Total	226 / 6510	210 / 6489		1.08 [0.89,1.30]	Z=0.75, p=0.4549
Heterogeneity:	Q=0.16 (df=1)	p=0.6897	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.102: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set

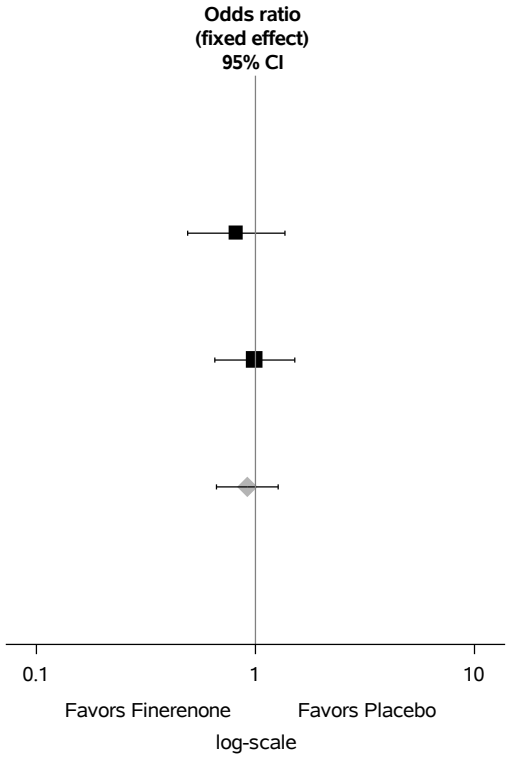
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	42 / 2831	40.0	1.27 [0.84,1.91]	
FIGARO-DKD	72 / 3683	69 / 3658	60.0	1.04 [0.74,1.45]	
Total	125 / 6510	111 / 6489		1.12 [0.87,1.46]	Z=0.89, p=0.3723
Heterogeneity:	Q=0.56 (df=1)	p=0.4536	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.103: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set

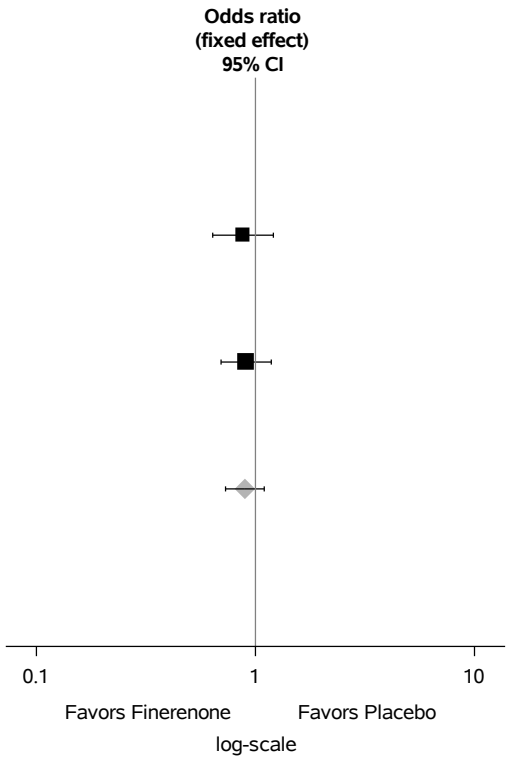
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2827	33 / 2831	40.3	0.82 [0.49,1.36]	
FIGARO-DKD	44 / 3683	44 / 3658	59.7	0.99 [0.65,1.51]	
Total	71 / 6510	77 / 6489		0.92 [0.66,1.27]	Z=-0.52, p=0.6050
Heterogeneity:	Q=0.33 (df=1)	p=0.5647	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.104: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set

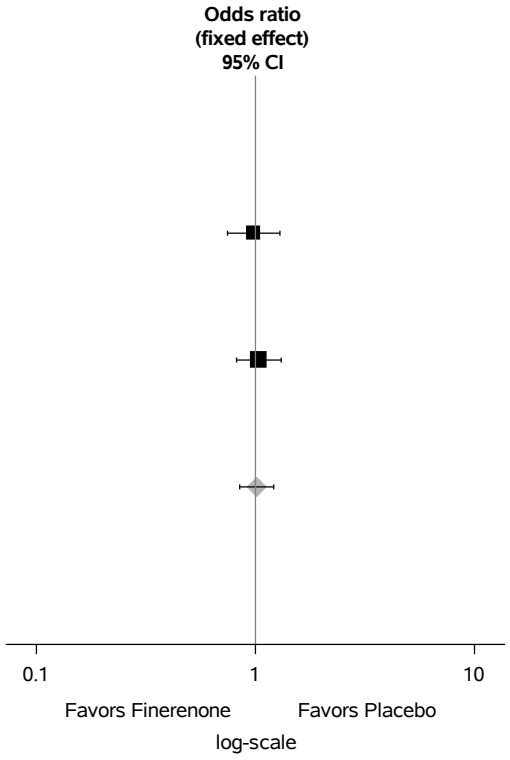
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	73 / 2827	83 / 2831	40.7	0.88 [0.64,1.21]	
FIGARO-DKD	109 / 3683	119 / 3658	59.3	0.91 [0.70,1.18]	
Total	182 / 6510	202 / 6489		0.89 [0.73,1.10]	Z=-1.07, p=0.2846
Heterogeneity:	Q=0.02 (df=1)	p=0.8761	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.105: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set

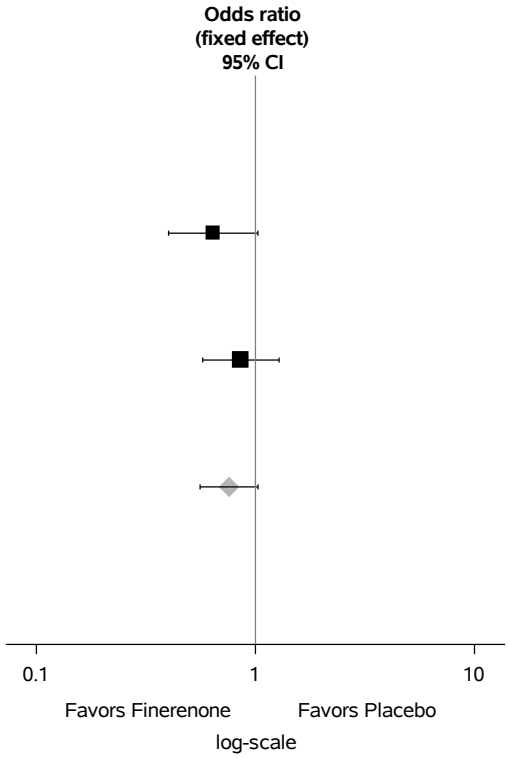
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	106 / 2831	42.1	0.98 [0.75,1.29]	
FIGARO-DKD	148 / 3683	142 / 3658	57.9	1.04 [0.82,1.31]	
Total	252 / 6510	248 / 6489		1.01 [0.85,1.21]	Z=0.14, p=0.8854
Heterogeneity:	Q=0.09 (df=1)	p=0.7688	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.106: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set

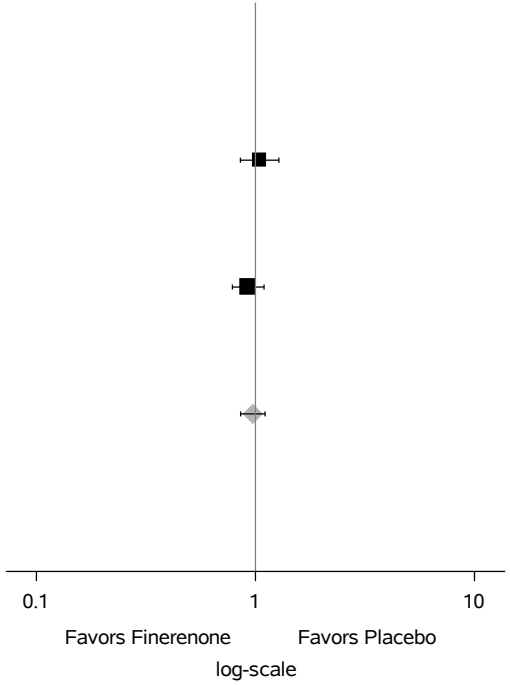
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	45 / 2831	42.2	0.64 [0.40,1.03]	
FIGARO-DKD	45 / 3683	52 / 3658	57.8	0.86 [0.57,1.28]	
Total	74 / 6510	97 / 6489		0.76 [0.56,1.03]	Z=-1.79, p=0.0740
Heterogeneity:	Q=0.85 (df=1)	p=0.3573	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.107: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

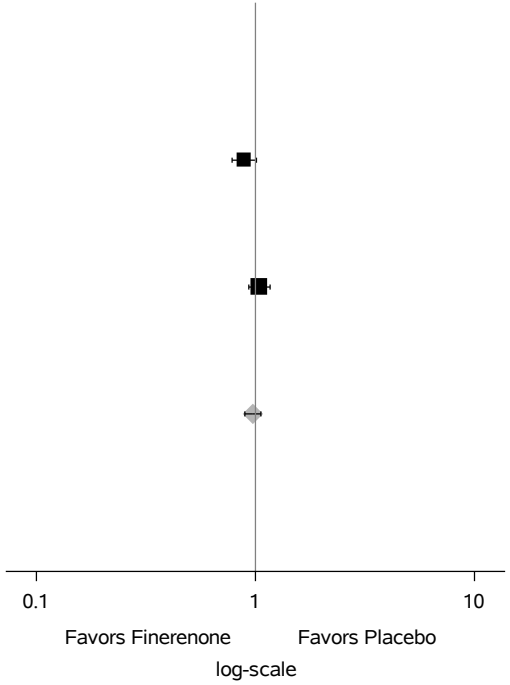
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	206 / 2827	198 / 2831	40.3	1.05 [0.85,1.28]	
FIGARO-DKD	293 / 3683	312 / 3658	59.7	0.93 [0.78,1.09]	
Total	499 / 6510	510 / 6489		0.97 [0.86,1.11]	Z=-0.42, p=0.6753
Heterogeneity:	Q=0.81 (df=1)	p=0.3692	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.108: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

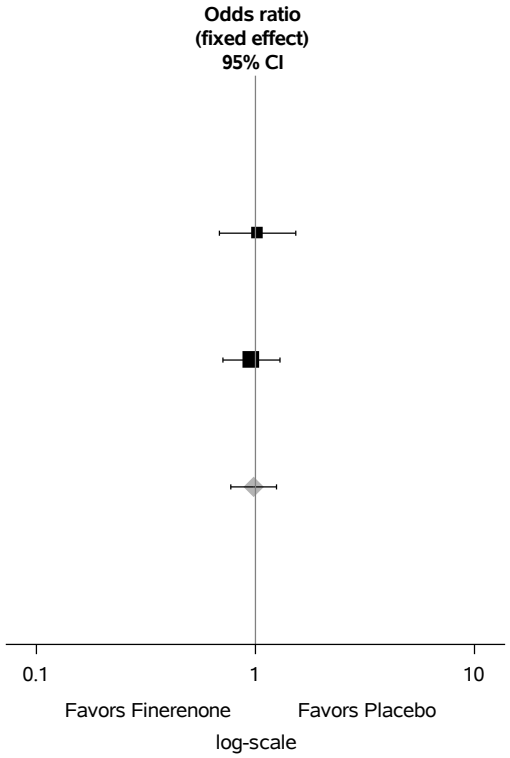
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	567 / 2827	623 / 2831	43.3	0.89 [0.78,1.01]	
FIGARO-DKD	795 / 3683	764 / 3658	56.7	1.04 [0.93,1.17]	
Total	1362 / 6510	1387 / 6489		0.97 [0.89,1.06]	Z=-0.63, p=0.5268
Heterogeneity:	Q=3.37 (df=1)	p=0.0662	I^2=70.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.109: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set

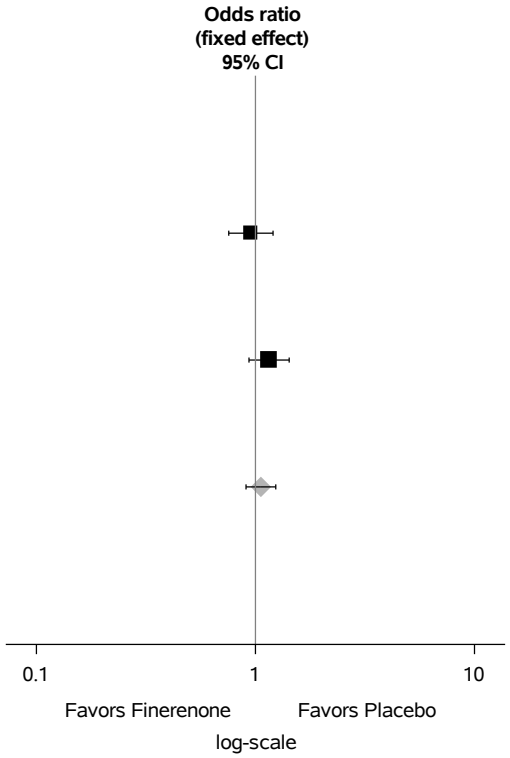
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2827	48 / 2831	35.8	1.02 [0.68,1.53]	
FIGARO-DKD	86 / 3683	89 / 3658	64.2	0.96 [0.71,1.29]	
Total	135 / 6510	137 / 6489		0.98 [0.77,1.25]	Z=-0.15, p=0.8769
Heterogeneity:	Q=0.06 (df=1)	p=0.8008	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.110: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set

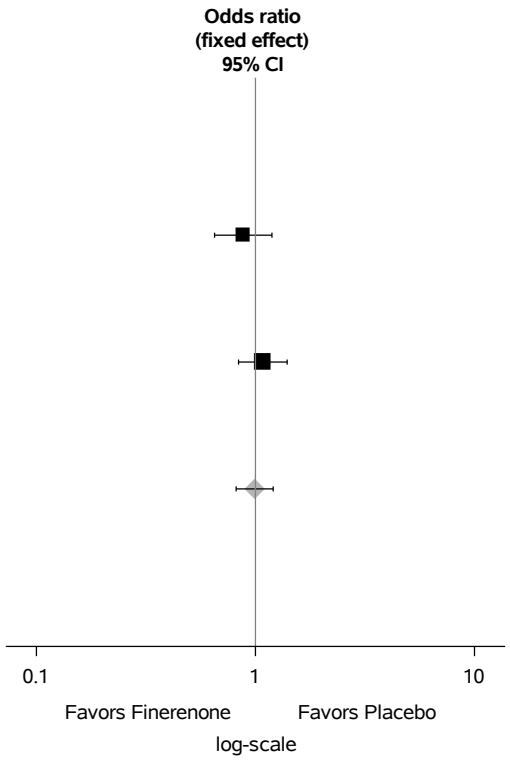
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	146 / 2827	153 / 2831	45.1	0.95 [0.76,1.20]	
FIGARO-DKD	195 / 3683	169 / 3658	54.9	1.15 [0.93,1.43]	
Total	341 / 6510	322 / 6489		1.06 [0.91,1.24]	Z=0.72, p=0.4737
Heterogeneity:	Q=1.42 (df=1)	p=0.2331	I^2=29.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.111: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set

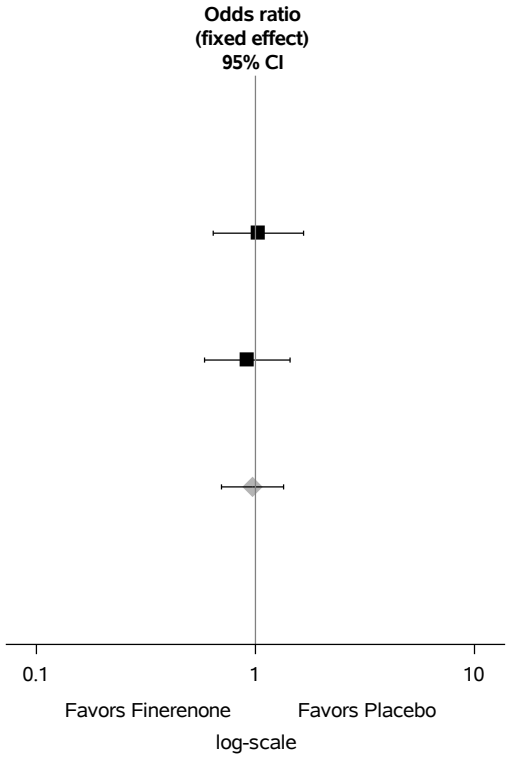
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	82 / 2827	93 / 2831	41.8	0.88 [0.65,1.19]	
FIGARO-DKD	127 / 3683	117 / 3658	58.2	1.08 [0.84,1.40]	
Total	209 / 6510	210 / 6489		0.99 [0.82,1.20]	Z=-0.08, p=0.9324
Heterogeneity:	Q=1.05 (df=1)	p=0.3065	I^2=4.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.112: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set

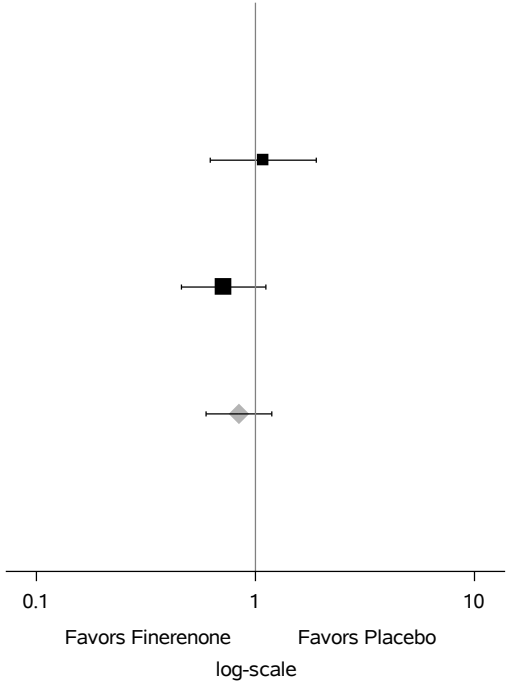
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2827	34 / 2831	47.2	1.03 [0.64,1.66]	
FIGARO-DKD	37 / 3683	40 / 3658	52.8	0.92 [0.59,1.44]	
Total	72 / 6510	74 / 6489		0.97 [0.70,1.34]	Z=-0.18, p=0.8538
Heterogeneity:	Q=0.12 (df=1)	p=0.7270	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.113: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set

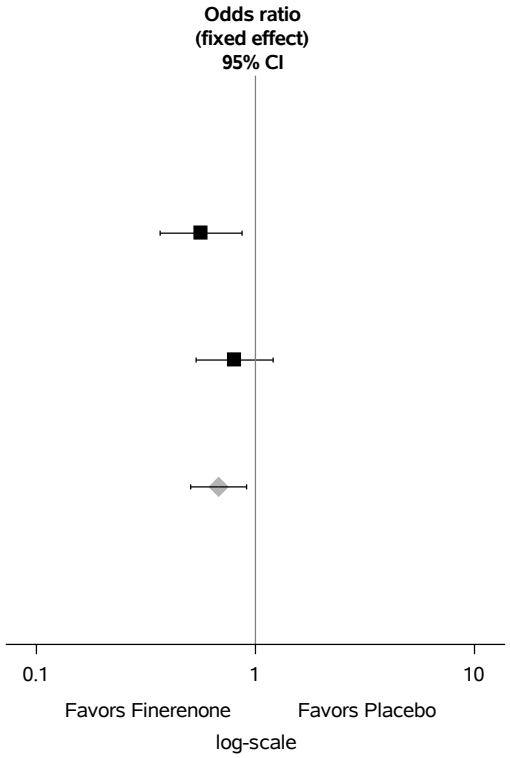
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2827	24 / 2831	38.8	1.09 [0.62,1.90]	
FIGARO-DKD	34 / 3683	47 / 3658	61.2	0.72 [0.46,1.12]	
Total	60 / 6510	71 / 6489		0.84 [0.59,1.19]	Z=-0.99, p=0.3242
Heterogeneity:	Q=1.31 (df=1)	p=0.2518	I^2=23.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.114: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set

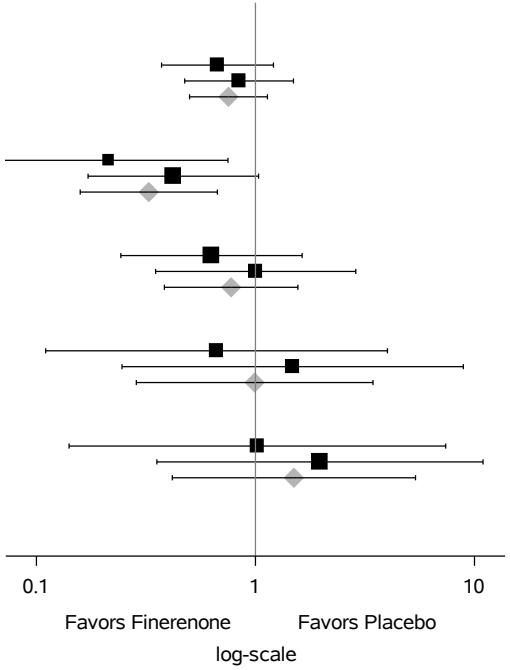
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	58 / 2831	46.9	0.56 [0.37,0.87]	
FIGARO-DKD	43 / 3683	53 / 3658	53.1	0.80 [0.54,1.20]	
Total	76 / 6510	111 / 6489		0.68 [0.51,0.91]	Z=-2.58, p=0.0098
Heterogeneity:	Q=1.37 (df=1)	p=0.2421	I^2=26.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.114.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Syncope (PT with Incidence >=1%)
Safety Analysis Set

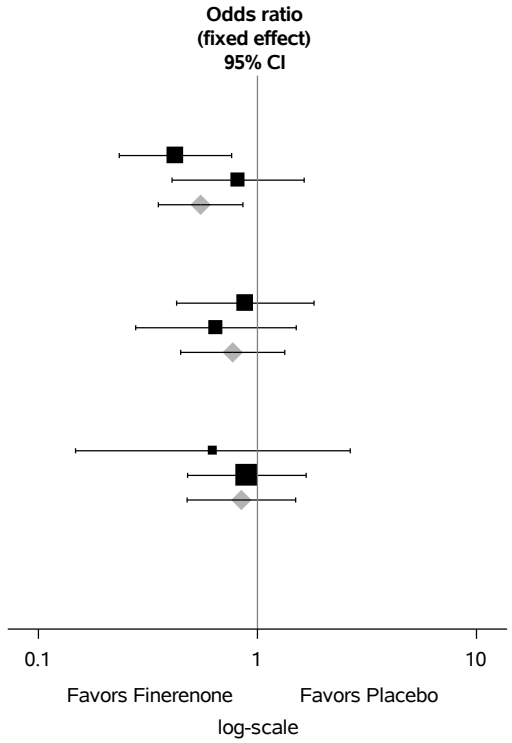
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	19 / 1178	28 / 1174	48.6	0.67 [0.37,1.21]	
FIGARO-DKD	22 / 1752	26 / 1747	51.4	0.84 [0.48,1.49]	
Total	41 / 2930	54 / 2921		0.75 [0.50,1.13]	Z=-1.36, p=0.1750
Heterogeneity:	Q=0.29 (df=1)	p=0.5879	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 466	14 / 476	33.8	0.21 [0.06,0.75]	
FIGARO-DKD	7 / 559	16 / 548	66.2	0.42 [0.17,1.03]	
Total	10 / 1025	30 / 1024		0.33 [0.16,0.67]	Z=-3.05, p=0.0023
Heterogeneity:	Q=0.75 (df=1)	p=0.3860	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 790	11 / 786	54.9	0.63 [0.24,1.63]	
FIGARO-DKD	7 / 811	7 / 813	45.1	1.00 [0.35,2.87]	
Total	14 / 1601	18 / 1599		0.77 [0.38,1.56]	Z=-0.71, p=0.4753
Heterogeneity:	Q=0.41 (df=1)	p=0.5210	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	3 / 294	49.9	0.66 [0.11,4.01]	
FIGARO-DKD	3 / 424	2 / 417	50.1	1.48 [0.25,8.89]	
Total	5 / 718	5 / 711		0.99 [0.29,3.44]	Z=-0.01, p=0.9895
Heterogeneity:	Q=0.38 (df=1)	p=0.5369	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	2 / 101	42.9	1.02 [0.14,7.39]	
FIGARO-DKD	4 / 137	2 / 133	57.1	1.97 [0.35,10.94]	
Total	6 / 236	4 / 234		1.50 [0.42,5.38]	Z=0.62, p=0.5354
Heterogeneity:	Q=0.24 (df=1)	p=0.6225	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.18 (df=4)	p=0.1863	I^2=35.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.114.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set

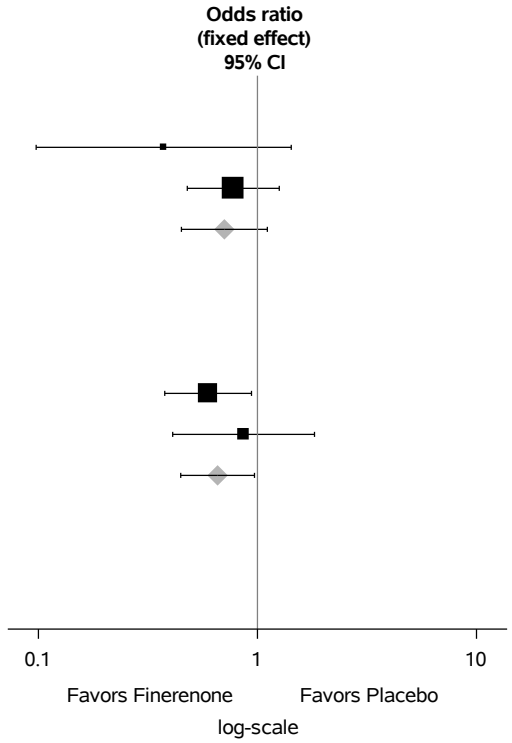
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	16 / 1556	37 / 1541	58.0	0.42 [0.23,0.76]	
FIGARO-DKD	15 / 637	18 / 627	42.0	0.82 [0.41,1.63]	
Total	31 / 2193	55 / 2168		0.55 [0.35,0.86]	Z=-2.63, p=0.0084
Heterogeneity:	Q=2.01 (df=1)	p=0.1565	I^2=50.2%		
45 - < 60					
FIDELIO-DKD	14 / 1061	16 / 1069	57.7	0.88 [0.43,1.81]	
FIGARO-DKD	9 / 720	14 / 729	42.3	0.65 [0.28,1.50]	
Total	23 / 1781	30 / 1798		0.77 [0.45,1.33]	Z=-0.93, p=0.3519
Heterogeneity:	Q=0.30 (df=1)	p=0.5863	I^2=0.0%		
>= 60					
FIDELIO-DKD	3 / 210	5 / 221	15.7	0.63 [0.15,2.65]	
FIGARO-DKD	19 / 2326	21 / 2302	84.3	0.89 [0.48,1.67]	
Total	22 / 2536	26 / 2523		0.84 [0.48,1.49]	Z=-0.58, p=0.5618
Heterogeneity:	Q=0.20 (df=1)	p=0.6565	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.63 (df=2)	p=0.4430	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.114.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set

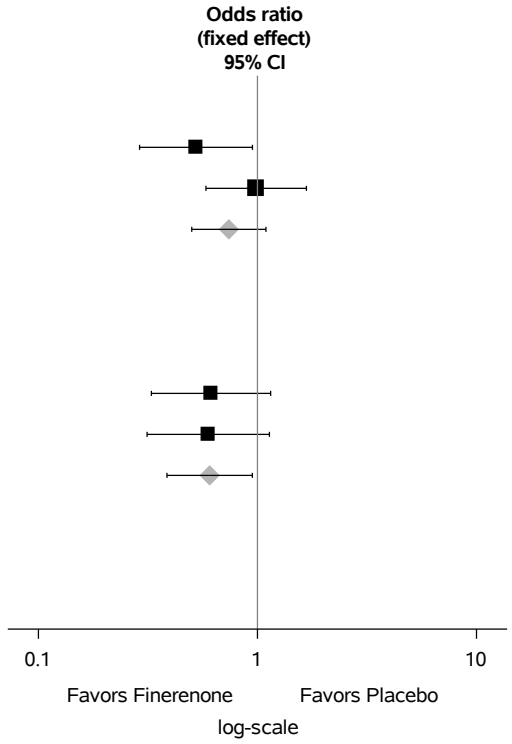
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	8 / 213	11.5	0.37 [0.10,1.43]	
FIGARO-DKD	30 / 1720	38 / 1698	88.5	0.78 [0.48,1.26]	
Total	33 / 1929	46 / 1911		0.71 [0.45,1.11]	Z=-1.51, p=0.1313
Heterogeneity:	Q=1.01 (df=1)	p=0.3142	I^2=1.3%		
Very High					
FIDELIO-DKD	30 / 2618	50 / 2618	72.8	0.60 [0.38,0.94]	
FIGARO-DKD	13 / 1963	15 / 1960	27.2	0.86 [0.41,1.82]	
Total	43 / 4581	65 / 4578		0.66 [0.45,0.97]	Z=-2.12, p=0.0342
Heterogeneity:	Q=0.70 (df=1)	p=0.4028	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8144	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.114.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Syncope (PT with Incidence >=1%)
Safety Analysis Set

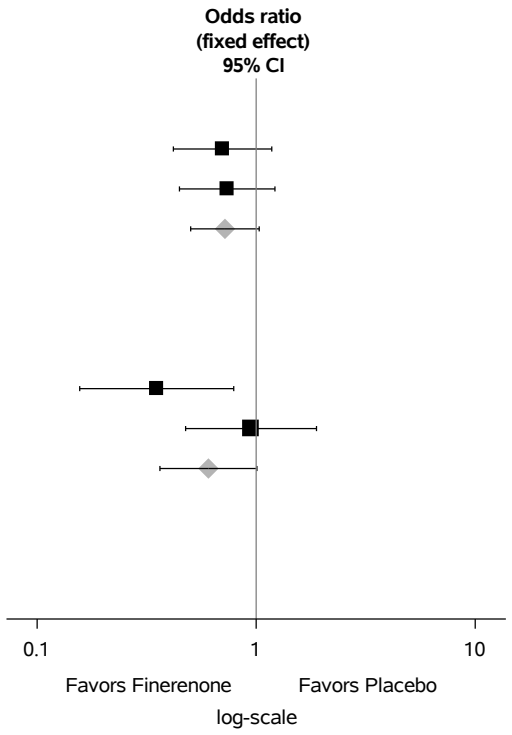
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 1301	32 / 1299	44.2	0.52 [0.29,0.95]	
FIGARO-DKD	28 / 1673	28 / 1651	55.8	0.99 [0.58,1.67]	
Total	45 / 2974	60 / 2950		0.74 [0.50,1.09]	Z=-1.51, p=0.1306
Heterogeneity:	Q=2.44 (df=1)	p=0.1186	I^2=58.9%		
Absent					
FIDELIO-DKD	16 / 1526	26 / 1532	51.3	0.61 [0.33,1.15]	
FIGARO-DKD	15 / 2010	25 / 2007	48.7	0.60 [0.31,1.13]	
Total	31 / 3536	51 / 3539		0.61 [0.39,0.95]	Z=-2.19, p=0.0283
Heterogeneity:	Q=0.00 (df=1)	p=0.9492	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.44 (df=1)	p=0.5063	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.114.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set

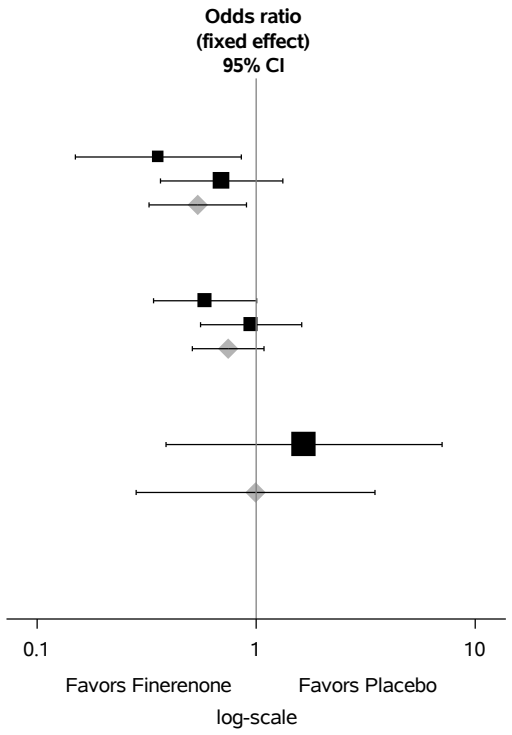
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1879	35 / 1858	48.5	0.70 [0.42,1.18]	
FIGARO-DKD	27 / 2643	36 / 2608	51.5	0.74 [0.45,1.22]	
Total	52 / 4522	71 / 4466		0.72 [0.50,1.03]	Z=-1.79, p=0.0740
Heterogeneity:	Q=0.02 (df=1)	p=0.8947	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 948	23 / 973	41.9	0.35 [0.16,0.79]	
FIGARO-DKD	16 / 1040	17 / 1048	58.1	0.95 [0.48,1.89]	
Total	24 / 1988	40 / 2021		0.61 [0.36,1.01]	Z=-1.93, p=0.0536
Heterogeneity:	Q=3.36 (df=1)	p=0.0668	I^2=70.2%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5853	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.114.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set

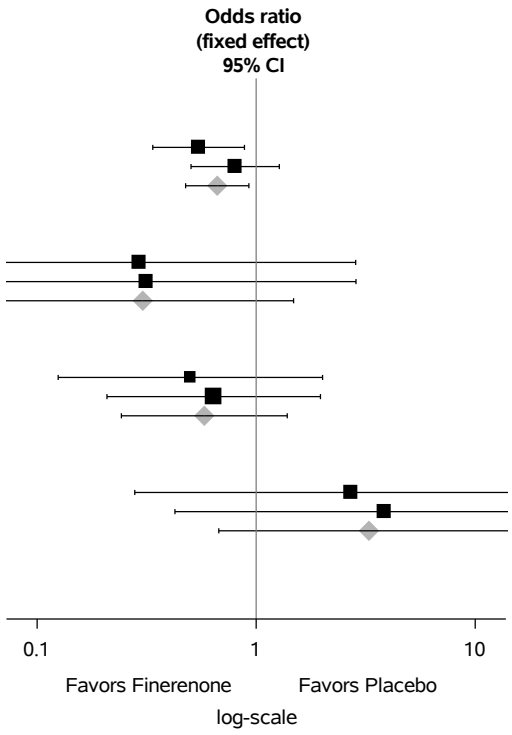
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 788	19 / 777	35.2	0.36 [0.15,0.86]	
FIGARO-DKD	16 / 1187	23 / 1194	64.8	0.70 [0.37,1.32]	
Total	23 / 1975	42 / 1971		0.54 [0.32,0.90]	Z=-2.35, p=0.0188
Heterogeneity:	Q=1.45 (df=1)	p=0.2281	I^2=31.2%		
130 - < 160					
FIDELIO-DKD	21 / 1897	36 / 1916	49.0	0.58 [0.34,1.01]	
FIGARO-DKD	27 / 2389	28 / 2351	51.0	0.95 [0.56,1.61]	
Total	48 / 4286	64 / 4267		0.74 [0.51,1.09]	Z=-1.53, p=0.1256
Heterogeneity:	Q=1.56 (df=1)	p=0.2116	I^2=35.9%		
>= 160					
FIDELIO-DKD	5 / 141	3 / 138	100.0	1.65 [0.39,7.06]	
FIGARO-DKD	0 / 107	2 / 113	0.0	0.00 [0.00,18E296]	
Total	5 / 248	5 / 251		0.99 [0.28,3.49]	Z=-0.01, p=0.9920
Heterogeneity:	Q=0.47 (df=1)	p=0.4910	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=2)	p=0.5117	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.114.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Syncope (PT with Incidence >=1%)
Safety Analysis Set

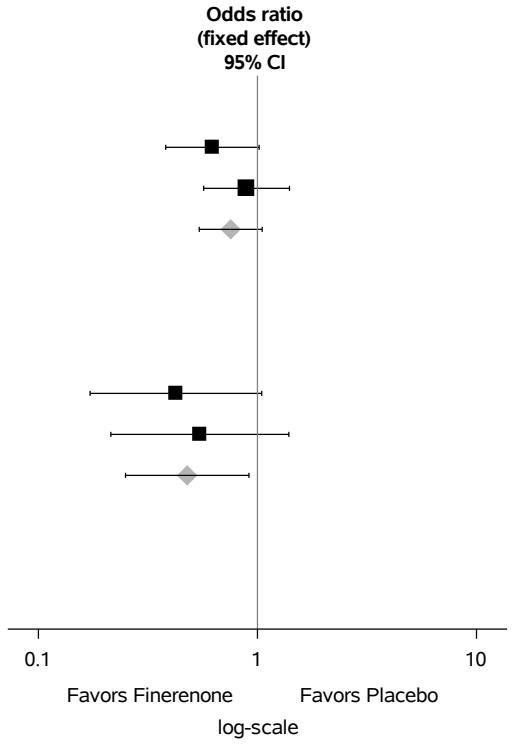
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	26 / 1773	48 / 1809	48.1	0.55 [0.34,0.88]	
FIGARO-DKD	33 / 2668	40 / 2601	51.9	0.80 [0.50,1.28]	
Total	59 / 4441	88 / 4410		0.66 [0.48,0.93]	Z=-2.41, p=0.0159
Heterogeneity:	Q=1.27 (df=1)	p=0.2602	I^2=21.1%		
Black					
FIDELIO-DKD	1 / 139	3 / 124	48.4	0.29 [0.03,2.85]	
FIGARO-DKD	1 / 113	4 / 145	51.6	0.31 [0.03,2.86]	
Total	2 / 252	7 / 269		0.30 [0.06,1.48]	Z=-1.47, p=0.1405
Heterogeneity:	Q=0.00 (df=1)	p=0.9635	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 717	6 / 721	39.5	0.50 [0.12,2.01]	
FIGARO-DKD	5 / 716	8 / 736	60.5	0.64 [0.21,1.97]	
Total	8 / 1433	14 / 1457		0.58 [0.24,1.39]	Z=-1.23, p=0.2203
Heterogeneity:	Q=0.07 (df=1)	p=0.7877	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	48.4	2.71 [0.28,26.27]	
FIGARO-DKD	4 / 186	1 / 176	51.6	3.85 [0.43,34.75]	
Total	7 / 384	2 / 353		3.27 [0.68,15.86]	Z=1.47, p=0.1410
Heterogeneity:	Q=0.05 (df=1)	p=0.8277	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.94 (df=3)	p=0.1760	I^2=39.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.114.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Syncope (PT with Incidence >=1%)
Safety Analysis Set

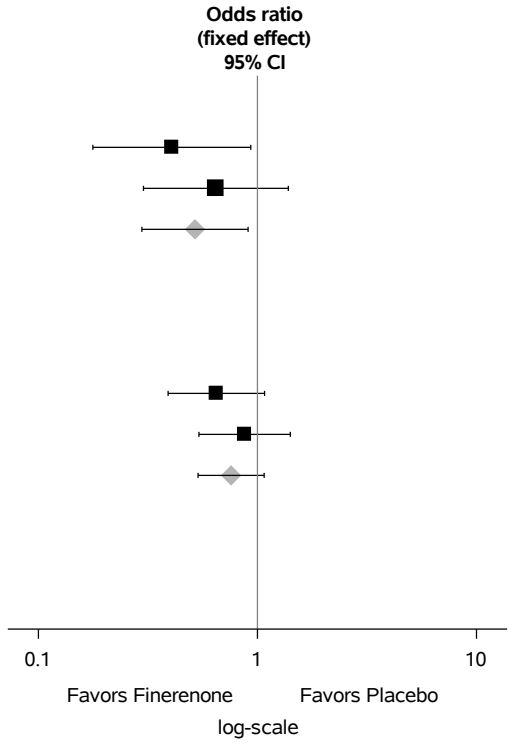
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 1949	43 / 2024	45.8	0.62 [0.38,1.02]	
FIGARO-DKD	36 / 2527	41 / 2571	54.2	0.89 [0.57,1.40]	
Total	62 / 4476	84 / 4595		0.75 [0.54,1.05]	Z=-1.67, p=0.0956
Heterogeneity:	Q=1.11 (df=1)	p=0.2914	I^2=10.2%		
Female					
FIDELIO-DKD	7 / 878	15 / 807	51.8	0.42 [0.17,1.05]	
FIGARO-DKD	7 / 1156	12 / 1087	48.2	0.55 [0.21,1.39]	
Total	14 / 2034	27 / 1894		0.48 [0.25,0.91]	Z=-2.23, p=0.0257
Heterogeneity:	Q=0.14 (df=1)	p=0.7043	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.51 (df=1)	p=0.2185	I^2=34.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.114.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Syncope (PT with Incidence >=1%)
Safety Analysis Set

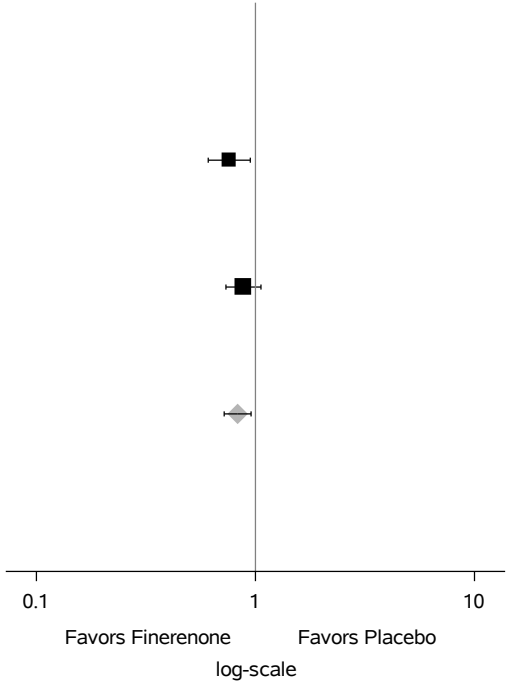
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	8 / 1201	19 / 1171	45.7	0.41 [0.18,0.93]	
FIGARO-DKD	11 / 1752	17 / 1755	54.3	0.65 [0.30,1.38]	
Total	19 / 2953	36 / 2926		0.52 [0.30,0.91]	Z=-2.31, p=0.0211
Heterogeneity:	Q=0.65 (df=1)	p=0.4202	I^2=0.0%		
>= 65					
FIDELIO-DKD	25 / 1626	39 / 1660	47.3	0.65 [0.39,1.08]	
FIGARO-DKD	32 / 1931	36 / 1903	52.7	0.87 [0.54,1.41]	
Total	57 / 3557	75 / 3563		0.76 [0.54,1.07]	Z=-1.56, p=0.1182
Heterogeneity:	Q=0.70 (df=1)	p=0.4038	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.28 (df=1)	p=0.2577	I^2=21.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

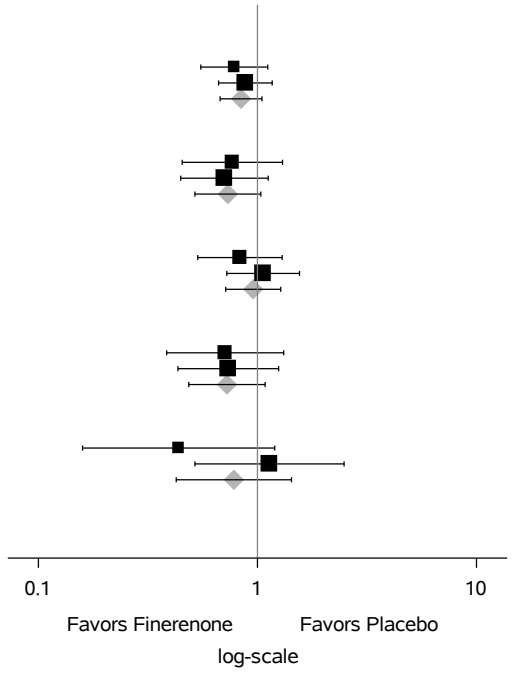
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	148 / 2827	192 / 2831	41.0	0.76 [0.61,0.95]	
FIGARO-DKD	230 / 3683	257 / 3658	59.0	0.88 [0.73,1.06]	
Total	378 / 6510	449 / 6489		0.83 [0.72,0.95]	Z=-2.60, p=0.0093
Heterogeneity:	Q=1.03 (df=1)	p=0.3095	I^2=3.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.115.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

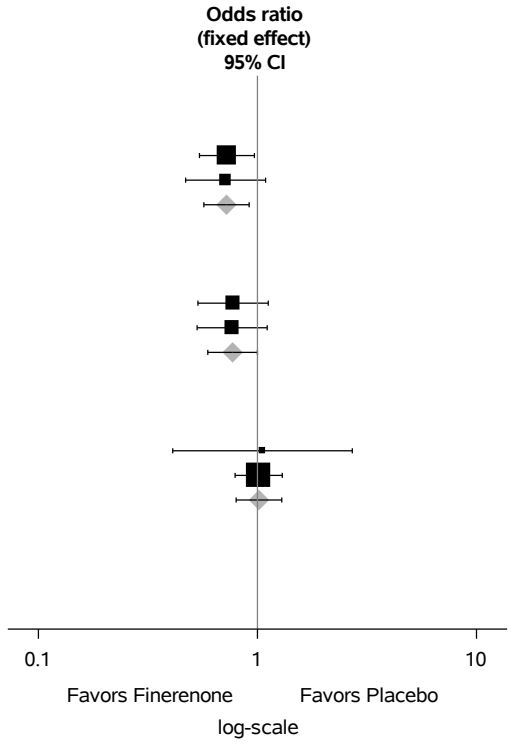
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	59 / 1178	74 / 1174	39.1	0.78 [0.55,1.11]	
FIGARO-DKD	97 / 1752	109 / 1747	60.9	0.88 [0.66,1.17]	
Total	156 / 2930	183 / 2921		0.84 [0.68,1.05]	Z=-1.54, p=0.1239
Heterogeneity:	Q=0.26 (df=1)	p=0.6121	I^2=0.0%		
North America					
FIDELIO-DKD	26 / 466	34 / 476	43.2	0.77 [0.45,1.30]	
FIGARO-DKD	34 / 559	46 / 548	56.8	0.71 [0.45,1.12]	
Total	60 / 1025	80 / 1024		0.73 [0.52,1.04]	Z=-1.76, p=0.0785
Heterogeneity:	Q=0.05 (df=1)	p=0.8154	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	45 / 786	42.6	0.83 [0.53,1.30]	
FIGARO-DKD	58 / 811	55 / 813	57.4	1.06 [0.72,1.56]	
Total	96 / 1601	100 / 1599		0.96 [0.72,1.28]	Z=-0.30, p=0.7639
Heterogeneity:	Q=0.66 (df=1)	p=0.4151	I^2=0.0%		
Latin America					
FIDELIO-DKD	19 / 294	26 / 294	42.6	0.71 [0.39,1.32]	
FIGARO-DKD	26 / 424	34 / 417	57.4	0.74 [0.43,1.25]	
Total	45 / 718	60 / 711		0.73 [0.49,1.08]	Z=-1.57, p=0.1173
Heterogeneity:	Q=0.01 (df=1)	p=0.9369	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 99	13 / 101	37.6	0.44 [0.16,1.20]	
FIGARO-DKD	15 / 137	13 / 133	62.4	1.13 [0.52,2.49]	
Total	21 / 236	26 / 234		0.78 [0.43,1.43]	Z=-0.80, p=0.4226
Heterogeneity:	Q=2.14 (df=1)	p=0.1431	I^2=53.4%		
Subgroup Heterogeneity:	Q=1.91 (df=4)	p=0.7525	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

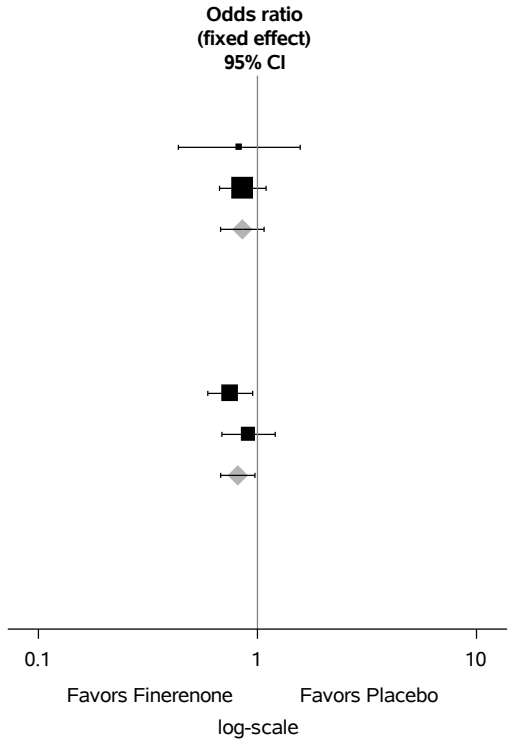
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	86 / 1556	115 / 1541	67.9	0.73 [0.54,0.97]	
FIGARO-DKD	41 / 637	55 / 627	32.1	0.72 [0.47,1.09]	
Total	127 / 2193	170 / 2168		0.72 [0.57,0.92]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.00 (df=1)	p=0.9574	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	53 / 1061	68 / 1069	49.8	0.77 [0.53,1.12]	
FIGARO-DKD	55 / 720	71 / 729	50.2	0.77 [0.53,1.11]	
Total	108 / 1781	139 / 1798		0.77 [0.59,1.00]	Z=-1.96, p=0.0498
Heterogeneity:	Q=0.00 (df=1)	p=0.9708	I^2=0.0%		
>= 60					
FIDELIO-DKD	9 / 210	9 / 221	6.5	1.05 [0.41,2.71]	
FIGARO-DKD	134 / 2326	131 / 2302	93.5	1.01 [0.79,1.30]	
Total	143 / 2536	140 / 2523		1.02 [0.80,1.29]	Z=0.13, p=0.8985
Heterogeneity:	Q=0.01 (df=1)	p=0.9355	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.35 (df=2)	p=0.1136	I^2=54.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

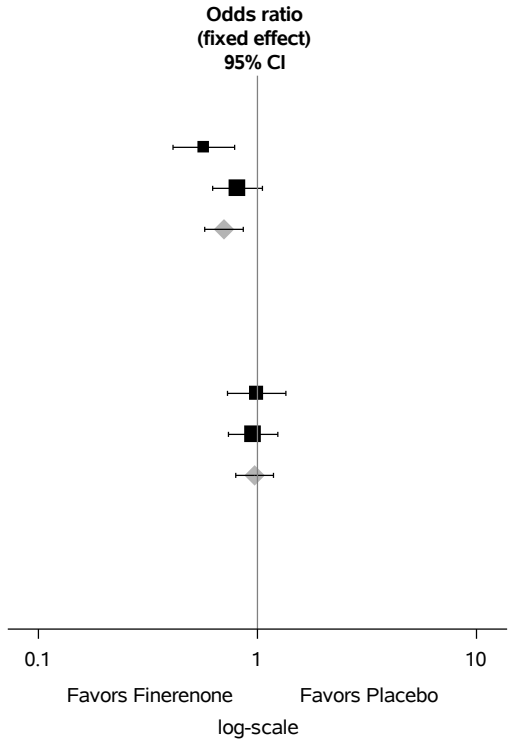
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	19 / 209	23 / 213	12.8	0.83 [0.44,1.57]	
FIGARO-DKD	131 / 1720	149 / 1698	87.2	0.86 [0.67,1.09]	
Total	150 / 1929	172 / 1911		0.85 [0.68,1.07]	Z=-1.36, p=0.1732
Heterogeneity:	Q=0.01 (df=1)	p=0.9162	I^2=0.0%		
Very High					
FIDELIO-DKD	129 / 2618	169 / 2618	58.5	0.75 [0.59,0.95]	
FIGARO-DKD	99 / 1963	108 / 1960	41.5	0.91 [0.69,1.21]	
Total	228 / 4581	277 / 4578		0.81 [0.68,0.97]	Z=-2.25, p=0.0246
Heterogeneity:	Q=1.06 (df=1)	p=0.3021	I^2=6.1%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7481	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

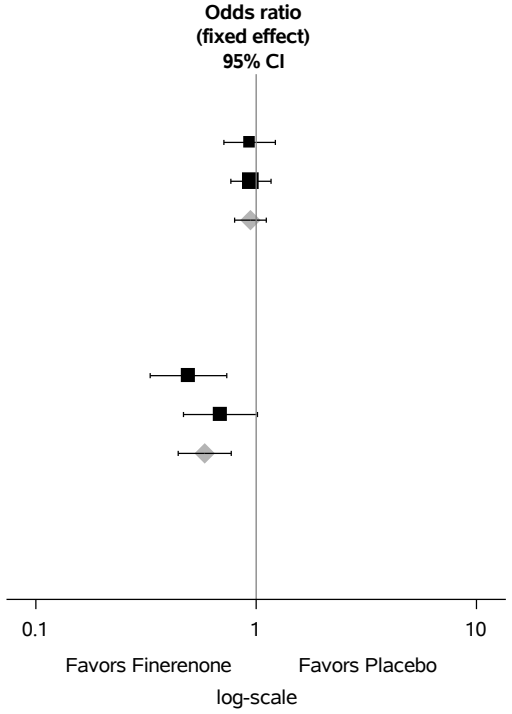
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	62 / 1301	105 / 1299	39.5	0.57 [0.41,0.79]	
FIGARO-DKD	111 / 1673	133 / 1651	60.5	0.81 [0.62,1.05]	
Total	173 / 2974	238 / 2950		0.70 [0.57,0.86]	Z=-3.40, p=0.0007
Heterogeneity:	Q=2.78 (df=1)	p=0.0952	I^2=64.1%		
Absent					
FIDELIO-DKD	86 / 1526	87 / 1532	41.7	0.99 [0.73,1.35]	
FIGARO-DKD	119 / 2010	124 / 2007	58.3	0.96 [0.74,1.24]	
Total	205 / 3536	211 / 3539		0.97 [0.80,1.18]	Z=-0.30, p=0.7678
Heterogeneity:	Q=0.03 (df=1)	p=0.8556	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.95 (df=1)	p=0.0261	I^2=79.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

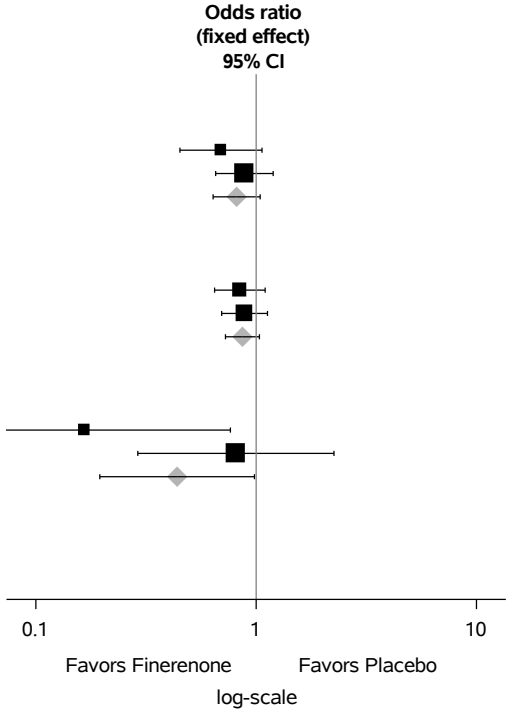
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	110 / 1879	116 / 1858	37.9	0.93 [0.71,1.22]	
FIGARO-DKD	184 / 2643	191 / 2608	62.1	0.95 [0.77,1.17]	
Total	294 / 4522	307 / 4466		0.94 [0.80,1.11]	Z=-0.71, p=0.4788
Heterogeneity:	Q=0.01 (df=1)	p=0.9363	I^2=0.0%		
> 4.5					
FIDELIO-DKD	38 / 948	76 / 973	48.3	0.49 [0.33,0.74]	
FIGARO-DKD	46 / 1040	66 / 1048	51.7	0.69 [0.47,1.01]	
Total	84 / 1988	142 / 2021		0.58 [0.44,0.77]	Z=-3.80, p=0.0001
Heterogeneity:	Q=1.39 (df=1)	p=0.2388	I^2=27.9%		
Subgroup Heterogeneity:	Q=8.42 (df=1)	p=0.0037	I^2=88.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.115.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

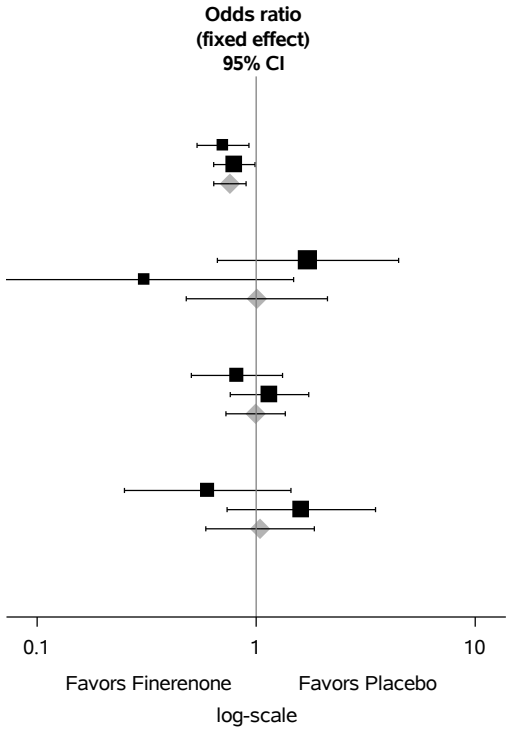
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	38 / 788	53 / 777	32.9	0.69 [0.45,1.06]	
FIGARO-DKD	87 / 1187	98 / 1194	67.1	0.88 [0.65,1.19]	
Total	125 / 1975	151 / 1971		0.82 [0.64,1.04]	Z=-1.63, p=0.1036
Heterogeneity:	Q=0.84 (df=1)	p=0.3587	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	108 / 1897	128 / 1916	45.1	0.84 [0.65,1.10]	
FIGARO-DKD	136 / 2389	150 / 2351	54.9	0.89 [0.70,1.13]	
Total	244 / 4286	278 / 4267		0.87 [0.73,1.03]	Z=-1.59, p=0.1129
Heterogeneity:	Q=0.07 (df=1)	p=0.7872	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 141	11 / 138	31.1	0.17 [0.04,0.76]	
FIGARO-DKD	7 / 107	9 / 113	68.9	0.81 [0.29,2.25]	
Total	9 / 248	20 / 251		0.44 [0.20,0.98]	Z=-2.00, p=0.0452
Heterogeneity:	Q=2.93 (df=1)	p=0.0871	I^2=65.8%		
Subgroup Heterogeneity:	Q=2.65 (df=2)	p=0.2657	I^2=24.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.115.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

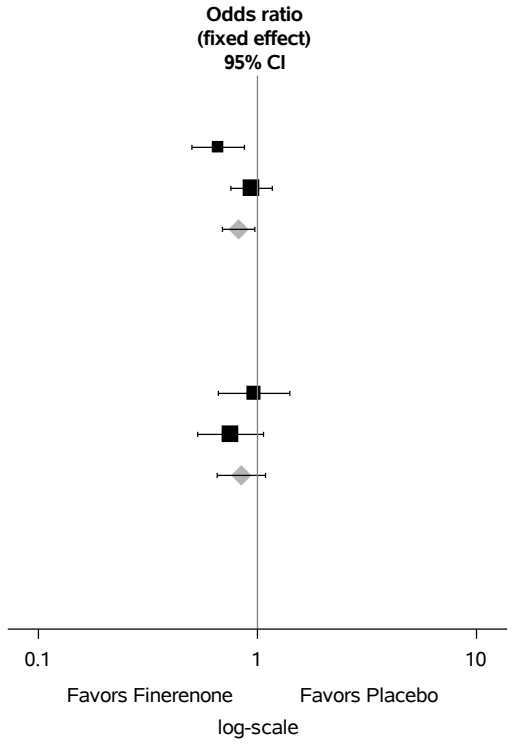
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	94 / 1773	133 / 1809	38.9	0.71 [0.54,0.93]	
FIGARO-DKD	159 / 2668	192 / 2601	61.1	0.80 [0.64,0.99]	
Total	253 / 4441	325 / 4410		0.76 [0.64,0.90]	Z=-3.18, p=0.0015
Heterogeneity:	Q=0.45 (df=1)	p=0.5016	I^2=0.0%		
Black					
FIDELIO-DKD	13 / 139	7 / 124	73.1	1.72 [0.67,4.47]	
FIGARO-DKD	2 / 113	8 / 145	26.9	0.31 [0.06,1.48]	
Total	15 / 252	15 / 269		1.01 [0.48,2.12]	Z=0.02, p=0.9849
Heterogeneity:	Q=3.41 (df=1)	p=0.0649	I^2=70.6%		
Asian					
FIDELIO-DKD	32 / 717	39 / 721	42.5	0.82 [0.51,1.32]	
FIGARO-DKD	51 / 716	46 / 736	57.5	1.15 [0.76,1.74]	
Total	83 / 1433	85 / 1457		0.99 [0.73,1.36]	Z=-0.04, p=0.9704
Heterogeneity:	Q=1.13 (df=1)	p=0.2888	I^2=11.1%		
Others					
FIDELIO-DKD	9 / 198	13 / 177	44.3	0.60 [0.25,1.44]	
FIGARO-DKD	18 / 186	11 / 176	55.7	1.61 [0.74,3.51]	
Total	27 / 384	24 / 353		1.04 [0.59,1.84]	Z=0.14, p=0.8882
Heterogeneity:	Q=2.71 (df=1)	p=0.1000	I^2=63.0%		
Subgroup Heterogeneity:	Q=3.22 (df=3)	p=0.3586	I^2=6.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.115.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

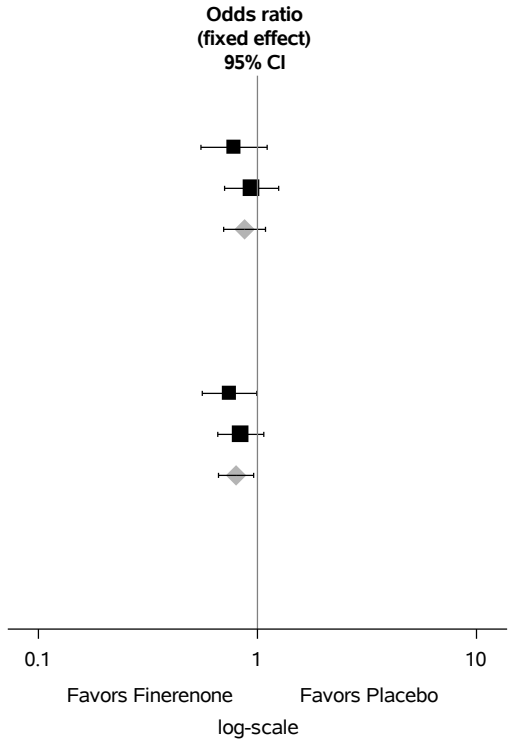
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	88 / 1949	135 / 2024	38.3	0.66 [0.50,0.87]	
FIGARO-DKD	168 / 2527	181 / 2571	61.7	0.94 [0.76,1.17]	
Total	256 / 4476	316 / 4595		0.82 [0.69,0.97]	Z=-2.28, p=0.0227
Heterogeneity:	Q=3.84 (df=1)	p=0.0500	I^2=74.0%		
Female					
FIDELIO-DKD	60 / 878	57 / 807	45.9	0.97 [0.66,1.41]	
FIGARO-DKD	62 / 1156	76 / 1087	54.1	0.75 [0.53,1.07]	
Total	122 / 2034	133 / 1894		0.84 [0.65,1.09]	Z=-1.31, p=0.1915
Heterogeneity:	Q=0.90 (df=1)	p=0.3434	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8551	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.115.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set

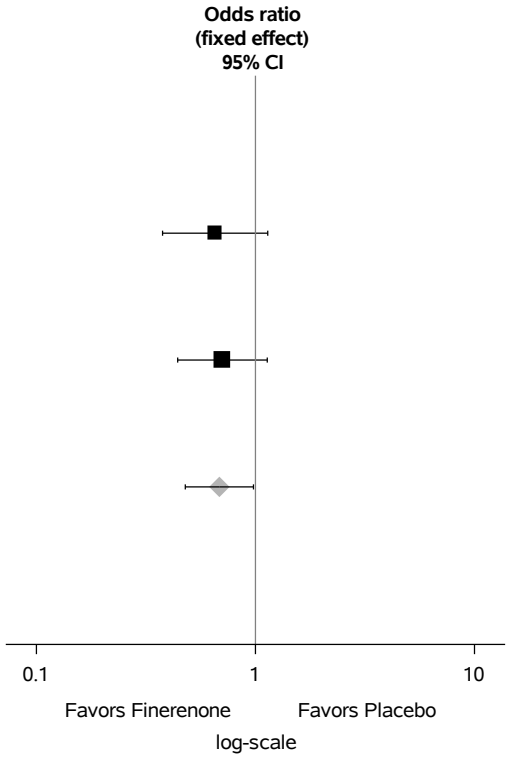
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	61 / 1201	75 / 1171	40.0	0.78 [0.55,1.11]	
FIGARO-DKD	98 / 1752	104 / 1755	60.0	0.94 [0.71,1.25]	
Total	159 / 2953	179 / 2926		0.87 [0.70,1.09]	Z=-1.21, p=0.2276
Heterogeneity:	Q=0.65 (df=1)	p=0.4203	I^2=0.0%		
>= 65					
FIDELIO-DKD	87 / 1626	117 / 1660	41.7	0.75 [0.56,0.99]	
FIGARO-DKD	132 / 1931	153 / 1903	58.3	0.84 [0.66,1.07]	
Total	219 / 3557	270 / 3563		0.80 [0.66,0.96]	Z=-2.39, p=0.0171
Heterogeneity:	Q=0.38 (df=1)	p=0.5358	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5421	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

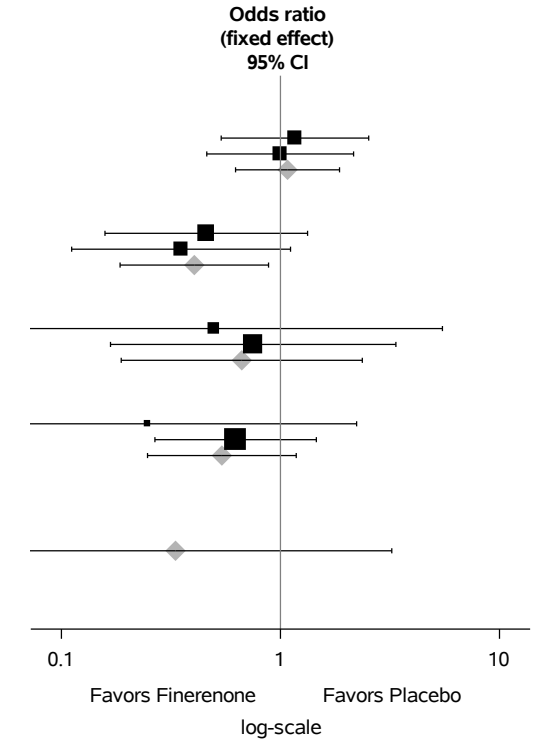
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	32 / 2831	42.0	0.65 [0.38,1.14]	
FIGARO-DKD	30 / 3683	42 / 3658	58.0	0.71 [0.44,1.13]	
Total	51 / 6510	74 / 6489		0.68 [0.48,0.98]	Z=-2.07, p=0.0381
Heterogeneity:	Q=0.04 (df=1)	p=0.8352	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.116.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

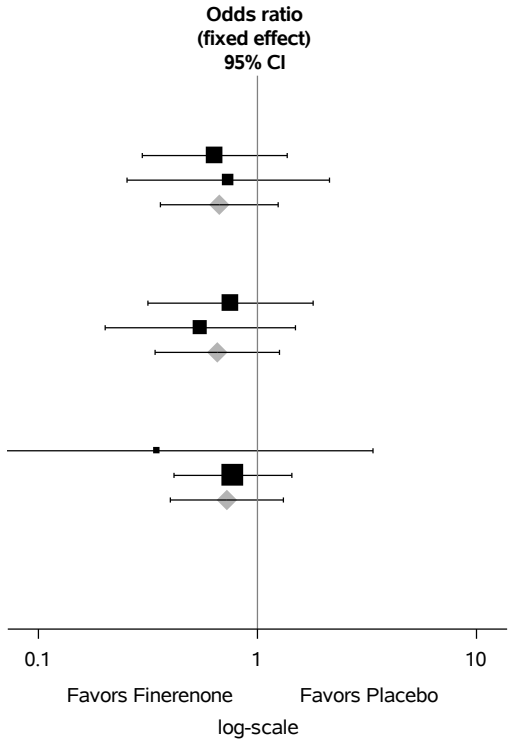
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	14 / 1178	12 / 1174	49.8	1.16 [0.54,2.53]	
FIGARO-DKD	13 / 1752	13 / 1747	50.2	1.00 [0.46,2.16]	
Total	27 / 2930	25 / 2921		1.08 [0.62,1.86]	Z=0.27, p=0.7893
Heterogeneity:	Q=0.08 (df=1)	p=0.7808	I^2=0.0%		
North America					
FIDELIO-DKD	5 / 466	11 / 476	53.9	0.46 [0.16,1.33]	
FIGARO-DKD	4 / 559	11 / 548	46.1	0.35 [0.11,1.11]	
Total	9 / 1025	22 / 1024		0.40 [0.19,0.88]	Z=-2.27, p=0.0230
Heterogeneity:	Q=0.11 (df=1)	p=0.7406	I^2=0.0%		
Asia					
FIDELIO-DKD	1 / 790	2 / 786	28.1	0.50 [0.04,5.49]	
FIGARO-DKD	3 / 811	4 / 813	71.9	0.75 [0.17,3.37]	
Total	4 / 1601	6 / 1599		0.67 [0.19,2.36]	Z=-0.63, p=0.5294
Heterogeneity:	Q=0.08 (df=1)	p=0.7749	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	4 / 294	13.0	0.25 [0.03,2.23]	
FIGARO-DKD	9 / 424	14 / 417	87.0	0.62 [0.27,1.46]	
Total	10 / 718	18 / 711		0.54 [0.25,1.18]	Z=-1.54, p=0.1226
Heterogeneity:	Q=0.60 (df=1)	p=0.4399	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	3 / 101	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	1 / 137	0 / 133	0.0	113E9 [113E9,113E9]	
Total	1 / 236	3 / 234		0.33 [0.03,3.22]	Z=-0.95, p=0.3416
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=5.13 (df=4)	p=0.2740	I^2=22.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

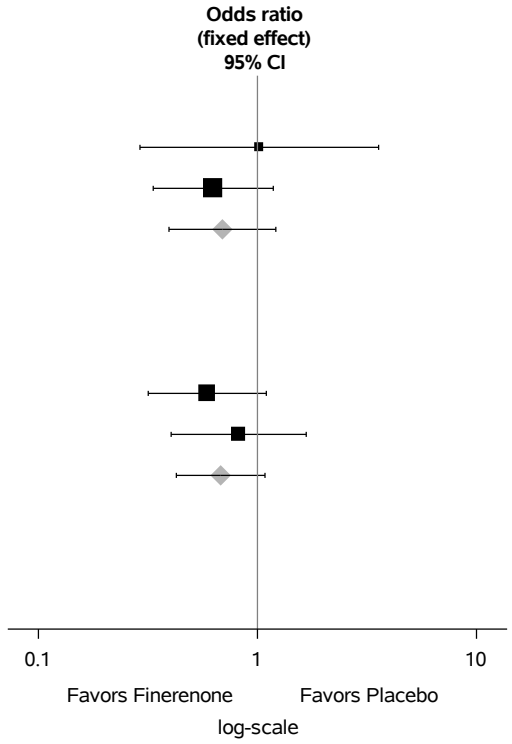
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	11 / 1556	17 / 1541	66.1	0.64 [0.30,1.37]	
FIGARO-DKD	6 / 637	8 / 627	33.9	0.74 [0.25,2.13]	
Total	17 / 2193	25 / 2168		0.67 [0.36,1.24]	Z=-1.27, p=0.2039
Heterogeneity:	Q=0.05 (df=1)	p=0.8315	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	12 / 1069	57.0	0.75 [0.32,1.80]	
FIGARO-DKD	6 / 720	11 / 729	43.0	0.55 [0.20,1.49]	
Total	15 / 1781	23 / 1798		0.66 [0.34,1.26]	Z=-1.27, p=0.2057
Heterogeneity:	Q=0.22 (df=1)	p=0.6383	I^2=0.0%		
>= 60					
FIDELIO-DKD	1 / 210	3 / 221	6.9	0.35 [0.04,3.37]	
FIGARO-DKD	18 / 2326	23 / 2302	93.1	0.77 [0.42,1.44]	
Total	19 / 2536	26 / 2523		0.73 [0.40,1.31]	Z=-1.06, p=0.2890
Heterogeneity:	Q=0.44 (df=1)	p=0.5057	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=2)	p=0.9715	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

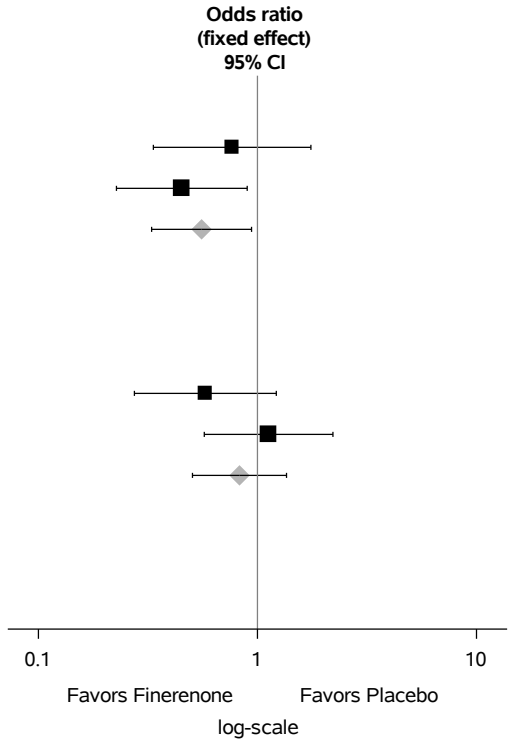
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	5 / 209	5 / 213	20.2	1.02 [0.29,3.57]	
FIGARO-DKD	16 / 1720	25 / 1698	79.8	0.63 [0.33,1.18]	
Total	21 / 1929	30 / 1911		0.69 [0.39,1.21]	Z=-1.29, p=0.1984
Heterogeneity:	Q=0.46 (df=1)	p=0.4993	I^2=0.0%		
Very High					
FIDELIO-DKD	16 / 2618	27 / 2618	56.7	0.59 [0.32,1.10]	
FIGARO-DKD	14 / 1963	17 / 1960	43.3	0.82 [0.40,1.67]	
Total	30 / 4581	44 / 4578		0.68 [0.43,1.08]	Z=-1.63, p=0.1038
Heterogeneity:	Q=0.47 (df=1)	p=0.4925	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

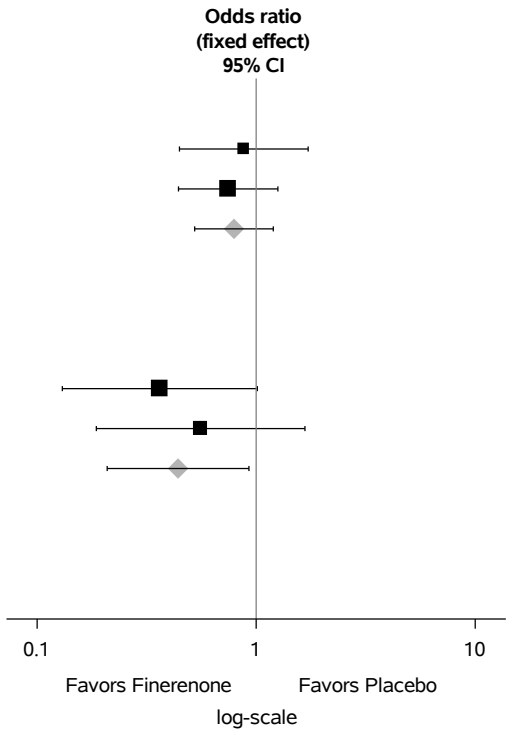
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	10 / 1301	13 / 1299	40.8	0.77 [0.33,1.75]	
FIGARO-DKD	12 / 1673	26 / 1651	59.2	0.45 [0.23,0.90]	
Total	22 / 2974	39 / 2950		0.56 [0.33,0.94]	Z=-2.19, p=0.0284
Heterogeneity:	Q=0.93 (df=1)	p=0.3352	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	19 / 1532	45.1	0.58 [0.27,1.22]	
FIGARO-DKD	18 / 2010	16 / 2007	54.9	1.12 [0.57,2.21]	
Total	29 / 3536	35 / 3539		0.83 [0.51,1.36]	Z=-0.75, p=0.4544
Heterogeneity:	Q=1.68 (df=1)	p=0.1953	I^2=40.4%		
Subgroup Heterogeneity:	Q=1.17 (df=1)	p=0.2787	I^2=14.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

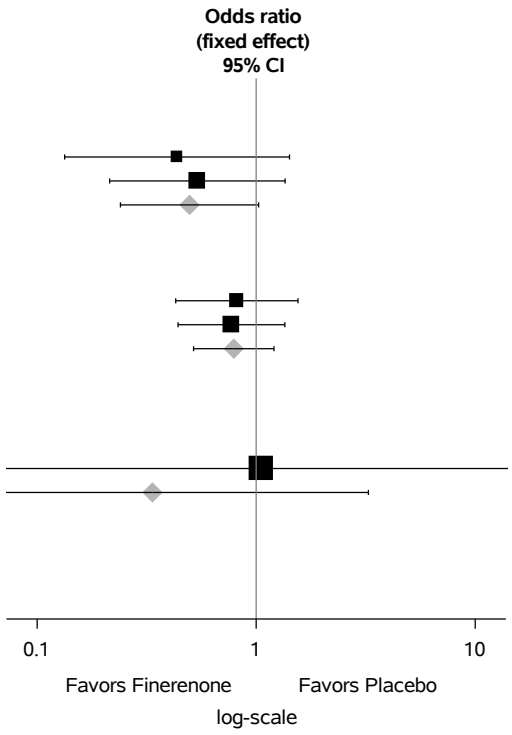
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1879	18 / 1858	37.4	0.88 [0.45,1.73]	
FIGARO-DKD	25 / 2643	33 / 2608	62.6	0.75 [0.44,1.26]	
Total	41 / 4522	51 / 4466		0.79 [0.52,1.20]	Z=-1.11, p=0.2687
Heterogeneity:	Q=0.14 (df=1)	p=0.7069	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 948	14 / 973	53.4	0.36 [0.13,1.01]	
FIGARO-DKD	5 / 1040	9 / 1048	46.6	0.56 [0.19,1.67]	
Total	10 / 1988	23 / 2021		0.44 [0.21,0.93]	Z=-2.16, p=0.0307
Heterogeneity:	Q=0.31 (df=1)	p=0.5752	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1761	I^2=45.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.116.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

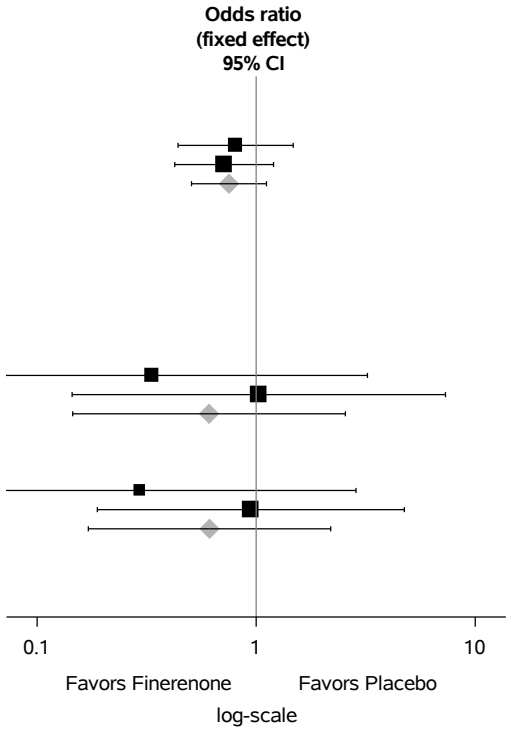
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 788	9 / 777	37.8	0.44 [0.13,1.42]	
FIGARO-DKD	7 / 1187	13 / 1194	62.2	0.54 [0.21,1.36]	
Total	11 / 1975	22 / 1971		0.50 [0.24,1.03]	Z=-1.89, p=0.0587
Heterogeneity:	Q=0.08 (df=1)	p=0.7803	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	17 / 1897	21 / 1916	43.3	0.82 [0.43,1.55]	
FIGARO-DKD	22 / 2389	28 / 2351	56.7	0.77 [0.44,1.35]	
Total	39 / 4286	49 / 4267		0.79 [0.52,1.21]	Z=-1.09, p=0.2749
Heterogeneity:	Q=0.02 (df=1)	p=0.8966	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	2 / 138	0.0	0.00 [0.00,79E295]	
FIGARO-DKD	1 / 107	1 / 113	100.0	1.06 [0.07,17.11]	
Total	1 / 248	3 / 251		0.34 [0.03,3.25]	Z=-0.94, p=0.3465
Heterogeneity:	Q=0.65 (df=1)	p=0.4201	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.57 (df=2)	p=0.4557	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.116.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

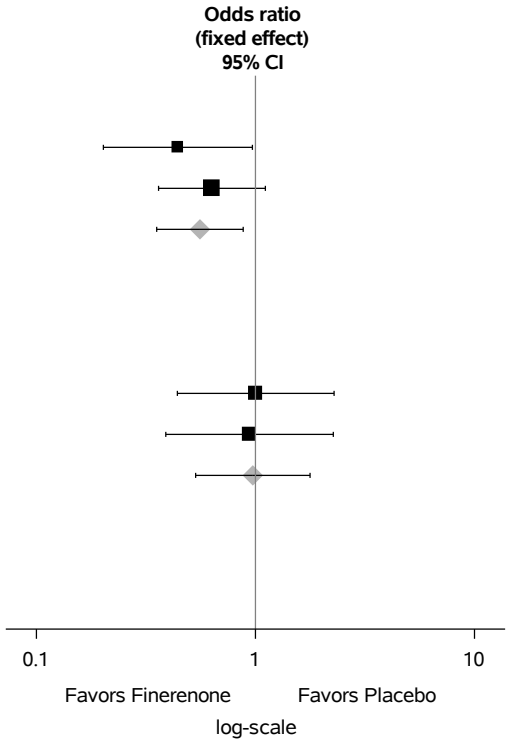
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	19 / 1773	24 / 1809	42.4	0.81 [0.44,1.48]	
FIGARO-DKD	25 / 2668	34 / 2601	57.6	0.71 [0.42,1.20]	
Total	44 / 4441	58 / 4410		0.75 [0.51,1.11]	Z=-1.42, p=0.1552
Heterogeneity:	Q=0.09 (df=1)	p=0.7670	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 139	2 / 124	0.0	0.00 [0.00,71E295]	
FIGARO-DKD	0 / 113	3 / 145	0.0	0.00 [0.00,15E296]	
Total	0 / 252	5 / 269		0.00 [0.00,17E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	1 / 717	3 / 721	42.9	0.33 [0.03,3.22]	
FIGARO-DKD	2 / 716	2 / 736	57.1	1.03 [0.14,7.32]	
Total	3 / 1433	5 / 1457		0.61 [0.15,2.55]	Z=-0.68, p=0.4979
Heterogeneity:	Q=0.54 (df=1)	p=0.4613	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 198	3 / 177	33.5	0.29 [0.03,2.86]	
FIGARO-DKD	3 / 186	3 / 176	66.5	0.95 [0.19,4.75]	
Total	4 / 384	6 / 353		0.61 [0.17,2.19]	Z=-0.75, p=0.4505
Heterogeneity:	Q=0.68 (df=1)	p=0.4106	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=3)	p=0.9845	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.116.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

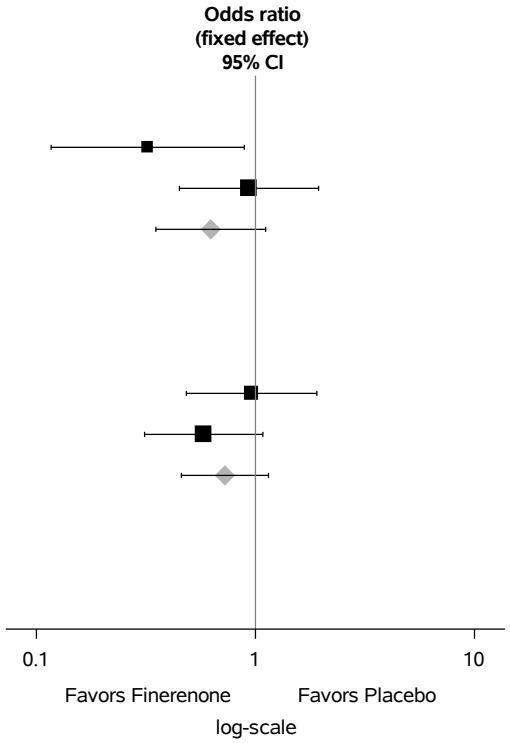
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	9 / 1949	21 / 2024	33.9	0.44 [0.20,0.97]	
FIGARO-DKD	20 / 2527	32 / 2571	66.1	0.63 [0.36,1.11]	
Total	29 / 4476	53 / 4595		0.56 [0.35,0.88]	Z=-2.52, p=0.0119
Heterogeneity:	Q=0.53 (df=1)	p=0.4664	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 878	11 / 807	53.3	1.00 [0.44,2.29]	
FIGARO-DKD	10 / 1156	10 / 1087	46.7	0.94 [0.39,2.27]	
Total	22 / 2034	21 / 1894		0.97 [0.53,1.78]	Z=-0.09, p=0.9285
Heterogeneity:	Q=0.01 (df=1)	p=0.9161	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1484	I^2=52.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.116.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Anxiety (PT with Incidence >=1%)
Safety Analysis Set

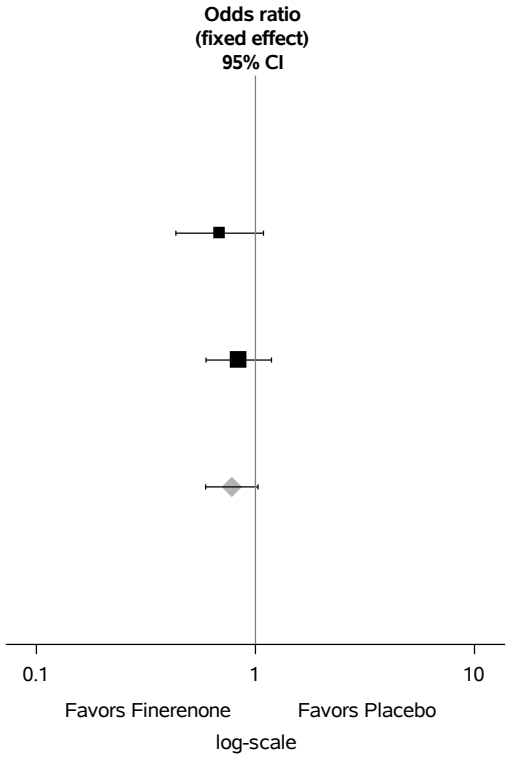
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	5 / 1201	15 / 1171	34.2	0.32 [0.12,0.89]	
FIGARO-DKD	14 / 1752	15 / 1755	65.8	0.93 [0.45,1.94]	
Total	19 / 2953	30 / 2926		0.63 [0.35,1.11]	Z=-1.60, p=0.1104
Heterogeneity:	Q=2.80 (df=1)	p=0.0944	I^2=64.3%		
>= 65					
FIDELIO-DKD	16 / 1626	17 / 1660	45.1	0.96 [0.48,1.91]	
FIGARO-DKD	16 / 1931	27 / 1903	54.9	0.58 [0.31,1.08]	
Total	32 / 3557	44 / 3563		0.73 [0.46,1.15]	Z=-1.38, p=0.1691
Heterogeneity:	Q=1.14 (df=1)	p=0.2864	I^2=12.0%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6922	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.117: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set

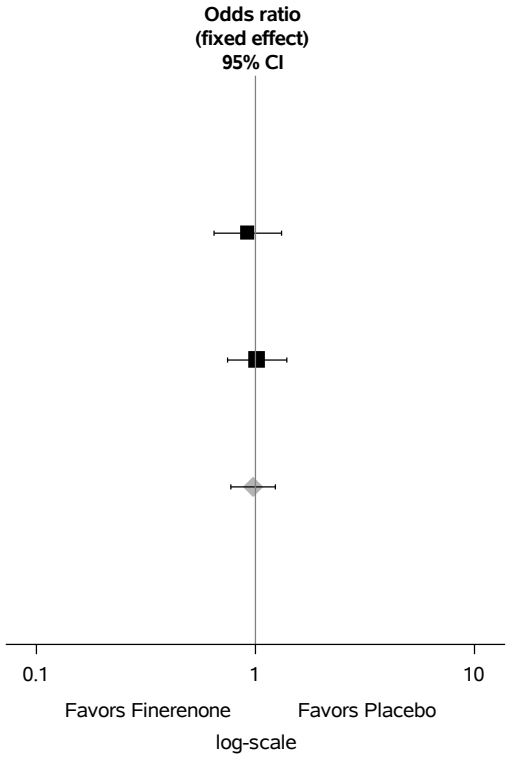
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	45 / 2831	35.8	0.69 [0.43,1.09]	
FIGARO-DKD	61 / 3683	72 / 3658	64.2	0.84 [0.59,1.18]	
Total	92 / 6510	117 / 6489		0.78 [0.59,1.03]	Z=-1.77, p=0.0772
Heterogeneity:	Q=0.47 (df=1)	p=0.4943	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.118: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set

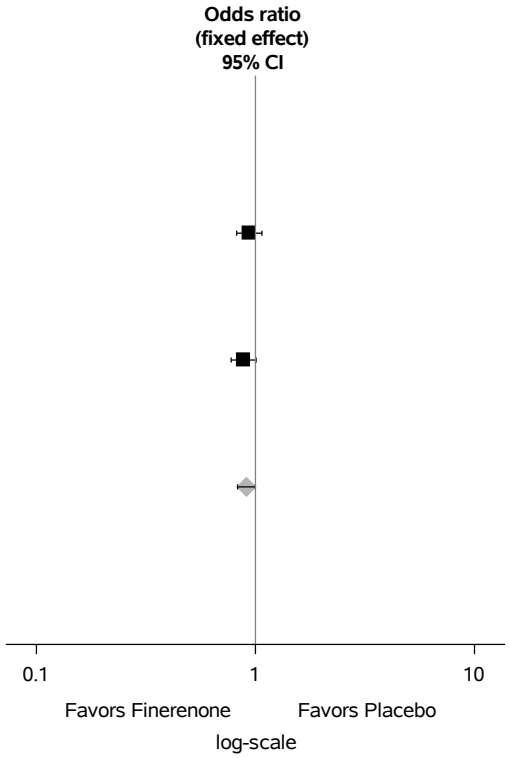
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	60 / 2827	65 / 2831	43.5	0.92 [0.65,1.32]	
FIGARO-DKD	82 / 3683	80 / 3658	56.5	1.02 [0.75,1.39]	
Total	142 / 6510	145 / 6489		0.98 [0.77,1.23]	Z=-0.21, p=0.8362
Heterogeneity:	Q=0.17 (df=1)	p=0.6820	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.119: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

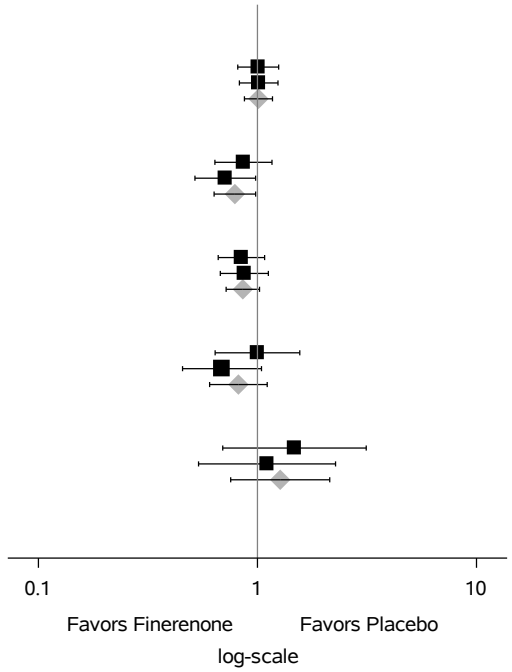
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	524 / 2827	553 / 2831	49.4	0.94 [0.82,1.07]	
FIGARO-DKD	495 / 3683	547 / 3658	50.6	0.88 [0.77,1.01]	
Total	1019 / 6510	1100 / 6489		0.91 [0.83,1.00]	Z=-1.99, p=0.0462
Heterogeneity:	Q=0.39 (df=1)	p=0.5318	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.119.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	201 / 1178	199 / 1174	47.1	1.01 [0.81,1.25]	
FIGARO-DKD	214 / 1752	211 / 1747	52.9	1.01 [0.83,1.24]	
Total	415 / 2930	410 / 2921		1.01 [0.87,1.17]	Z=0.14, p=0.8888
Heterogeneity:	Q=0.00 (df=1)	p=0.9743	I^2=0.0%		
North America					
FIDELIO-DKD	105 / 466	120 / 476	53.0	0.86 [0.64,1.16]	
FIGARO-DKD	80 / 559	104 / 548	47.0	0.71 [0.52,0.98]	
Total	185 / 1025	224 / 1024		0.79 [0.63,0.98]	Z=-2.13, p=0.0331
Heterogeneity:	Q=0.73 (df=1)	p=0.3931	I^2=0.0%		
Asia					
FIDELIO-DKD	153 / 790	174 / 786	51.8	0.84 [0.66,1.08]	
FIGARO-DKD	139 / 811	156 / 813	48.2	0.87 [0.68,1.12]	
Total	292 / 1601	330 / 1599		0.86 [0.72,1.02]	Z=-1.72, p=0.0857
Heterogeneity:	Q=0.03 (df=1)	p=0.8640	I^2=0.0%		
Latin America					
FIDELIO-DKD	46 / 294	46 / 294	46.5	1.00 [0.64,1.56]	
FIGARO-DKD	44 / 424	60 / 417	53.5	0.69 [0.45,1.04]	
Total	90 / 718	106 / 711		0.82 [0.60,1.11]	Z=-1.30, p=0.1946
Heterogeneity:	Q=1.44 (df=1)	p=0.2300	I^2=30.6%		
Others					
FIDELIO-DKD	19 / 99	14 / 101	47.7	1.48 [0.69,3.14]	
FIGARO-DKD	18 / 137	16 / 133	52.3	1.11 [0.54,2.27]	
Total	37 / 236	30 / 234		1.27 [0.75,2.14]	Z=0.90, p=0.3677
Heterogeneity:	Q=0.29 (df=1)	p=0.5877	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.08 (df=4)	p=0.1934	I^2=34.2%		

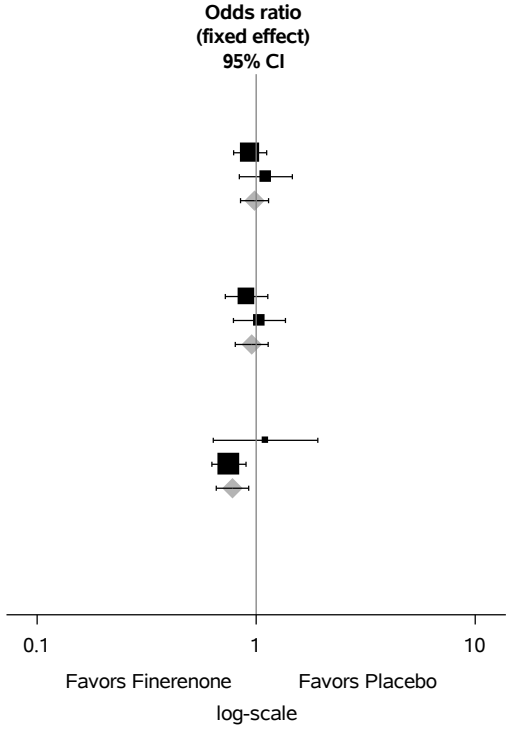


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.119.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)

Safety Analysis Set

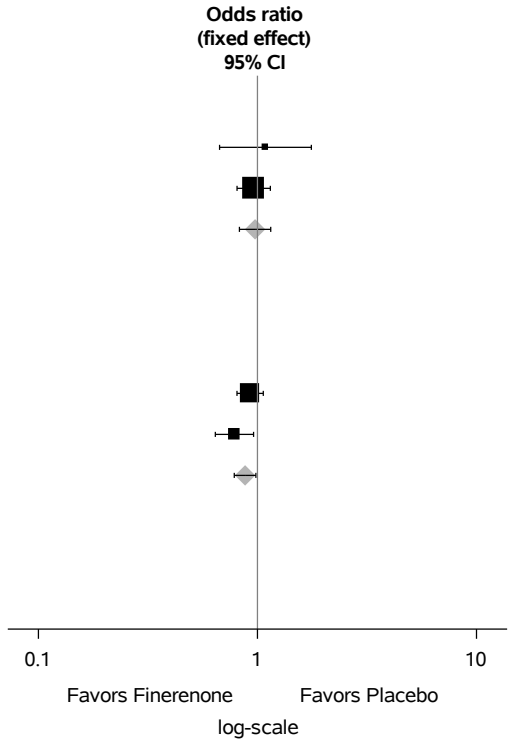
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	315 / 1556	328 / 1541	72.0	0.94 [0.79,1.12]	
FIGARO-DKD	129 / 637	117 / 627	28.0	1.11 [0.84,1.46]	
Total	444 / 2193	445 / 2168		0.98 [0.85,1.14]	Z=-0.23, p=0.8198
Heterogeneity:	Q=0.97 (df=1)	p=0.3253	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	179 / 1061	196 / 1069	60.0	0.90 [0.72,1.13]	
FIGARO-DKD	125 / 720	123 / 729	40.0	1.04 [0.79,1.36]	
Total	304 / 1781	319 / 1798		0.95 [0.80,1.13]	Z=-0.53, p=0.5952
Heterogeneity:	Q=0.57 (df=1)	p=0.4520	I^2=0.0%		
>= 60					
FIDELIO-DKD	30 / 210	29 / 221	9.6	1.10 [0.64,1.91]	
FIGARO-DKD	241 / 2326	307 / 2302	90.4	0.75 [0.63,0.90]	
Total	271 / 2536	336 / 2523		0.78 [0.66,0.92]	Z=-2.87, p=0.0042
Heterogeneity:	Q=1.70 (df=1)	p=0.1922	I^2=41.2%		
Subgroup Heterogeneity:	Q=4.52 (df=2)	p=0.1046	I^2=55.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.119.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

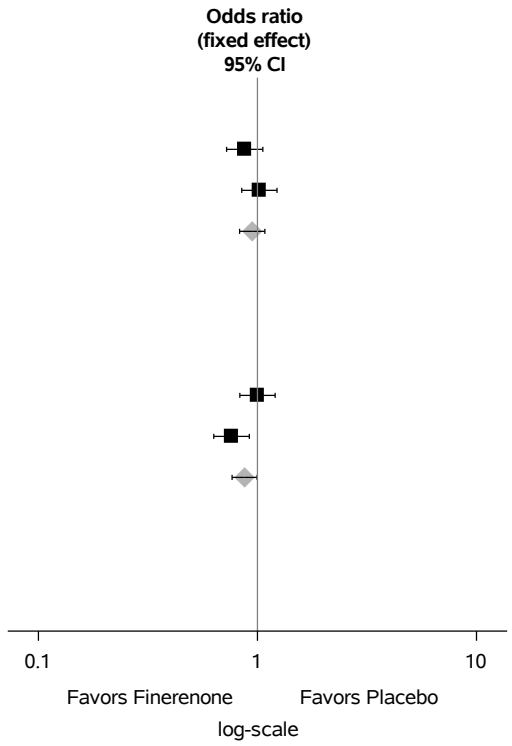
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 209	40 / 213	11.6	1.09 [0.67,1.76]	
FIGARO-DKD	302 / 1720	308 / 1698	88.4	0.96 [0.81,1.15]	
Total	344 / 1929	348 / 1911		0.98 [0.83,1.15]	Z=-0.30, p=0.7640
Heterogeneity:	Q=0.22 (df=1)	p=0.6366	I^2=0.0%		
Very High					
FIDELIO-DKD	482 / 2618	513 / 2618	67.9	0.93 [0.81,1.06]	
FIGARO-DKD	193 / 1963	239 / 1960	32.1	0.79 [0.64,0.96]	
Total	675 / 4581	752 / 4578		0.88 [0.78,0.98]	Z=-2.24, p=0.0251
Heterogeneity:	Q=1.76 (df=1)	p=0.1850	I^2=43.1%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3045	I^2=5.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.119.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

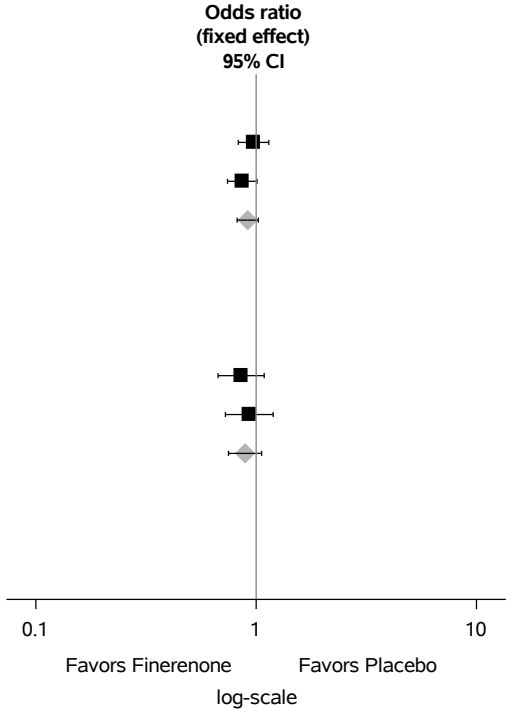
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	253 / 1301	281 / 1299	48.7	0.87 [0.72,1.06]	
FIGARO-DKD	270 / 1673	262 / 1651	51.3	1.02 [0.85,1.23]	
Total	523 / 2974	543 / 2950		0.95 [0.83,1.08]	Z=-0.81, p=0.4175
Heterogeneity:	Q=1.29 (df=1)	p=0.2561	I^2=22.5%		
Absent					
FIDELIO-DKD	271 / 1526	272 / 1532	50.4	1.00 [0.83,1.20]	
FIGARO-DKD	225 / 2010	285 / 2007	49.6	0.76 [0.63,0.92]	
Total	496 / 3536	557 / 3539		0.87 [0.77,1.00]	Z=-2.02, p=0.0435
Heterogeneity:	Q=4.12 (df=1)	p=0.0425	I^2=75.7%		
Subgroup Heterogeneity:	Q=0.71 (df=1)	p=0.3988	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.119.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

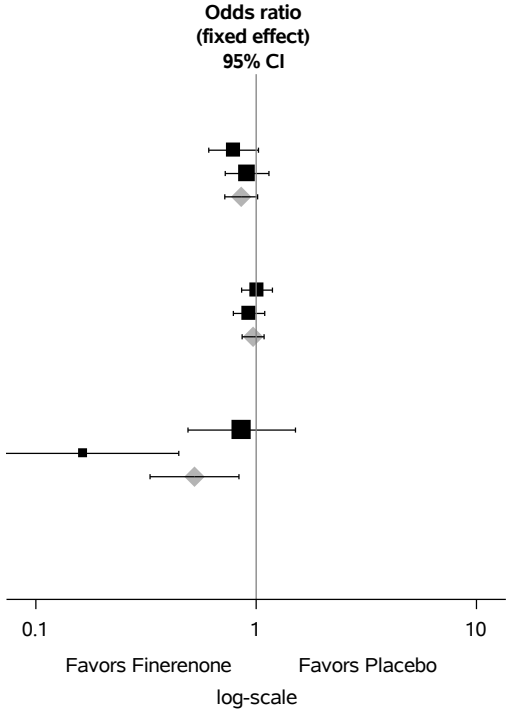
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	377 / 1879	381 / 1858	48.4	0.97 [0.83,1.14]	
FIGARO-DKD	357 / 2643	399 / 2608	51.6	0.86 [0.74,1.01]	
Total	734 / 4522	780 / 4466		0.92 [0.82,1.02]	Z=-1.56, p=0.1181
Heterogeneity:	Q=1.09 (df=1)	p=0.2967	I^2=8.2%		
> 4.5					
FIDELIO-DKD	147 / 948	172 / 973	51.8	0.85 [0.67,1.09]	
FIGARO-DKD	138 / 1040	148 / 1048	48.2	0.93 [0.72,1.19]	
Total	285 / 1988	320 / 2021		0.89 [0.75,1.06]	Z=-1.31, p=0.1890
Heterogeneity:	Q=0.23 (df=1)	p=0.6316	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7914	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.119.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

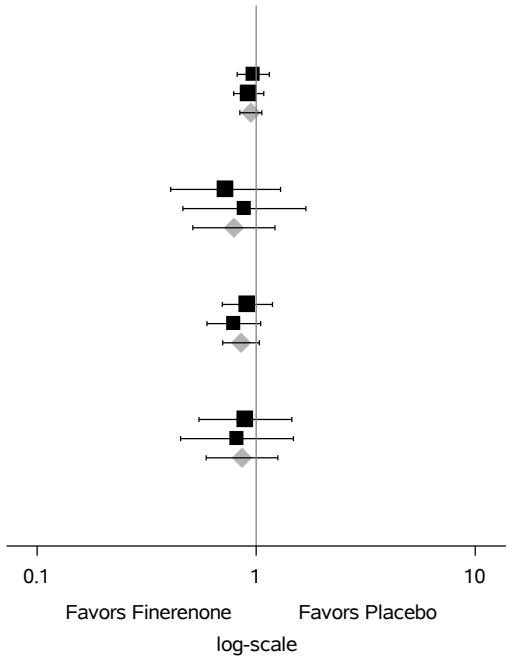
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	127 / 788	152 / 777	43.6	0.79 [0.61,1.02]	
FIGARO-DKD	165 / 1187	180 / 1194	56.4	0.91 [0.72,1.14]	
Total	292 / 1975	332 / 1971		0.86 [0.72,1.02]	Z=-1.79, p=0.0739
Heterogeneity:	Q=0.64 (df=1)	p=0.4249	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	367 / 1897	368 / 1916	50.9	1.01 [0.86,1.19]	
FIGARO-DKD	325 / 2389	341 / 2351	49.1	0.93 [0.79,1.09]	
Total	692 / 4286	709 / 4267		0.97 [0.86,1.09]	Z=-0.55, p=0.5844
Heterogeneity:	Q=0.51 (df=1)	p=0.4759	I^2=0.0%		
>= 160					
FIDELIO-DKD	30 / 141	33 / 138	76.0	0.86 [0.49,1.51]	
FIGARO-DKD	5 / 107	26 / 113	24.0	0.16 [0.06,0.45]	
Total	35 / 248	59 / 251		0.52 [0.33,0.84]	Z=-2.72, p=0.0065
Heterogeneity:	Q=8.17 (df=1)	p=0.0042	I^2=87.8%		
Subgroup Heterogeneity:	Q=7.02 (df=2)	p=0.0299	I^2=71.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.119.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

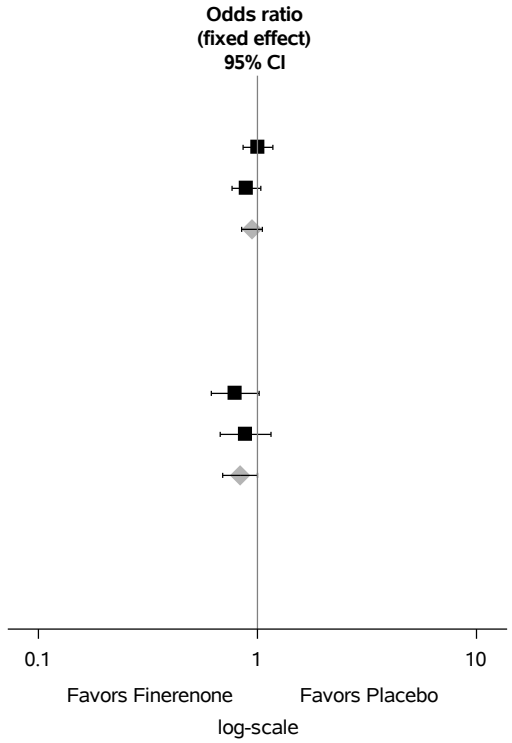
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	323 / 1773	338 / 1809	46.6	0.97 [0.82,1.15]	
FIGARO-DKD	349 / 2668	364 / 2601	53.4	0.92 [0.79,1.08]	
Total	672 / 4441	702 / 4410		0.95 [0.84,1.06]	Z=-0.95, p=0.3402
Heterogeneity:	Q=0.16 (df=1)	p=0.6899	I^2=0.0%		
Black					
FIDELIO-DKD	28 / 139	32 / 124	55.6	0.73 [0.41,1.29]	
FIGARO-DKD	19 / 113	27 / 145	44.4	0.88 [0.46,1.69]	
Total	47 / 252	59 / 269		0.79 [0.51,1.22]	Z=-1.06, p=0.2878
Heterogeneity:	Q=0.20 (df=1)	p=0.6556	I^2=0.0%		
Asian					
FIDELIO-DKD	131 / 717	142 / 721	53.4	0.91 [0.70,1.19]	
FIGARO-DKD	103 / 716	129 / 736	46.6	0.79 [0.60,1.05]	
Total	234 / 1433	271 / 1457		0.85 [0.70,1.03]	Z=-1.62, p=0.1054
Heterogeneity:	Q=0.52 (df=1)	p=0.4704	I^2=0.0%		
Others					
FIDELIO-DKD	42 / 198	41 / 177	59.6	0.89 [0.55,1.45]	
FIGARO-DKD	24 / 186	27 / 176	40.4	0.82 [0.45,1.48]	
Total	66 / 384	68 / 353		0.86 [0.59,1.26]	Z=-0.77, p=0.4389
Heterogeneity:	Q=0.05 (df=1)	p=0.8217	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=3)	p=0.7199	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.119.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

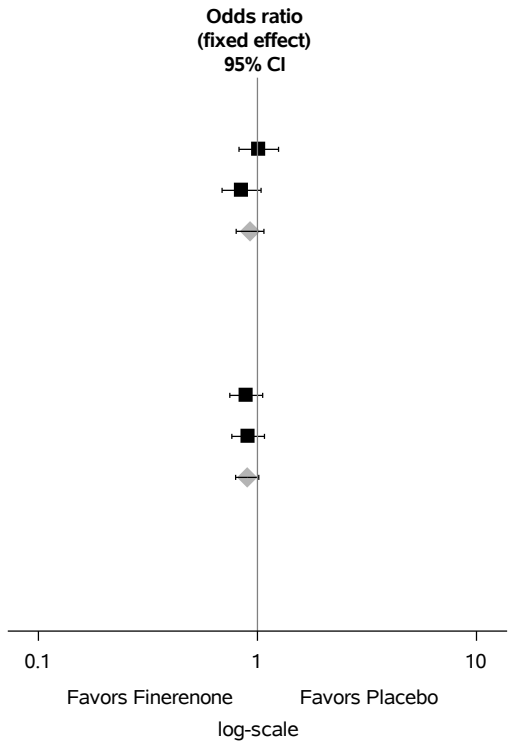
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	384 / 1949	397 / 2024	48.3	1.01 [0.86,1.18]	
FIGARO-DKD	377 / 2527	423 / 2571	51.7	0.89 [0.77,1.04]	
Total	761 / 4476	820 / 4595		0.94 [0.85,1.05]	Z=-1.04, p=0.3006
Heterogeneity:	Q=1.20 (df=1)	p=0.2733	I^2=16.7%		
Female					
FIDELIO-DKD	140 / 878	156 / 807	53.0	0.79 [0.62,1.02]	
FIGARO-DKD	118 / 1156	124 / 1087	47.0	0.88 [0.68,1.15]	
Total	258 / 2034	280 / 1894		0.83 [0.69,1.00]	Z=-1.95, p=0.0507
Heterogeneity:	Q=0.34 (df=1)	p=0.5599	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2496	I^2=24.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.119.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

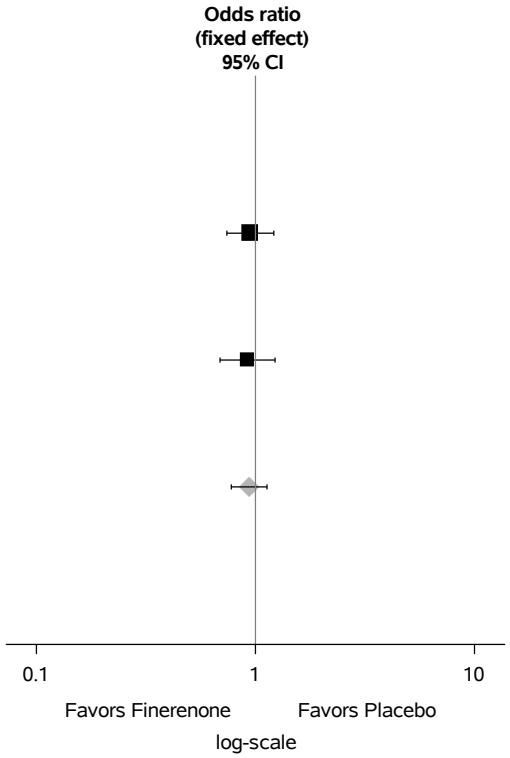
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	222 / 1201	214 / 1171	49.3	1.01 [0.82,1.25]	
FIGARO-DKD	193 / 1752	224 / 1755	50.7	0.85 [0.69,1.04]	
Total	415 / 2953	438 / 2926		0.93 [0.80,1.07]	Z=-1.05, p=0.2952
Heterogeneity:	Q=1.48 (df=1)	p=0.2241	I^2=32.3%		
>= 65					
FIDELIO-DKD	302 / 1626	339 / 1660	49.6	0.89 [0.75,1.06]	
FIGARO-DKD	302 / 1931	323 / 1903	50.4	0.91 [0.76,1.08]	
Total	604 / 3557	662 / 3563		0.90 [0.79,1.01]	Z=-1.73, p=0.0828
Heterogeneity:	Q=0.03 (df=1)	p=0.8716	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7581	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.120: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

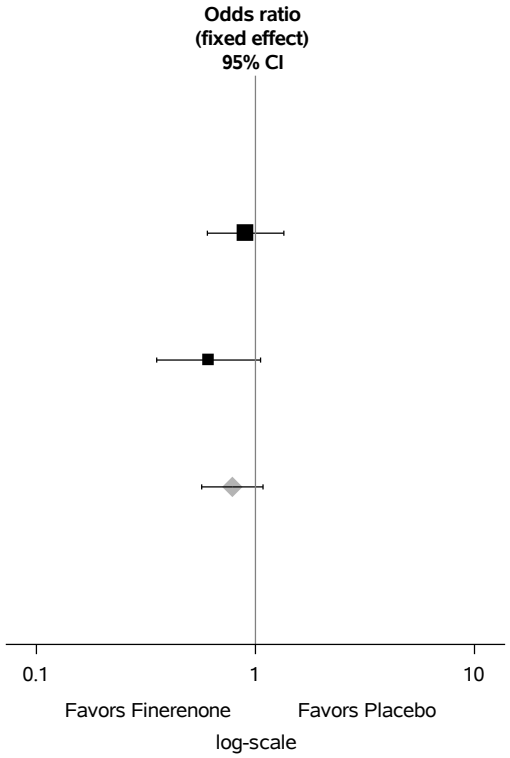
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2827	136 / 2831	57.9	0.95 [0.74,1.21]	
FIGARO-DKD	91 / 3683	98 / 3658	42.1	0.92 [0.69,1.23]	
Total	220 / 6510	234 / 6489		0.94 [0.78,1.13]	Z=-0.69, p=0.4892
Heterogeneity:	Q=0.02 (df=1)	p=0.8807	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.121: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set

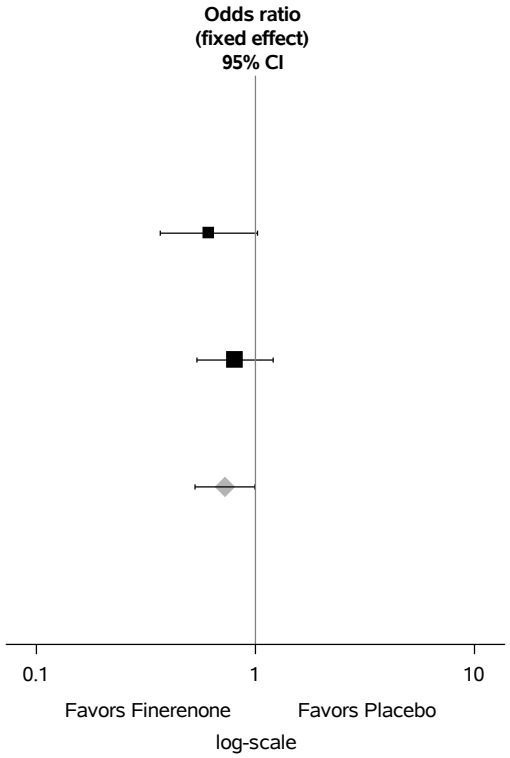
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2827	51 / 2831	64.8	0.90 [0.60,1.35]	
FIGARO-DKD	21 / 3683	34 / 3658	35.2	0.61 [0.35,1.06]	
Total	67 / 6510	85 / 6489		0.78 [0.57,1.08]	Z=-1.48, p=0.1399
Heterogeneity:	Q=1.26 (df=1)	p=0.2610	I^2=20.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.122: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

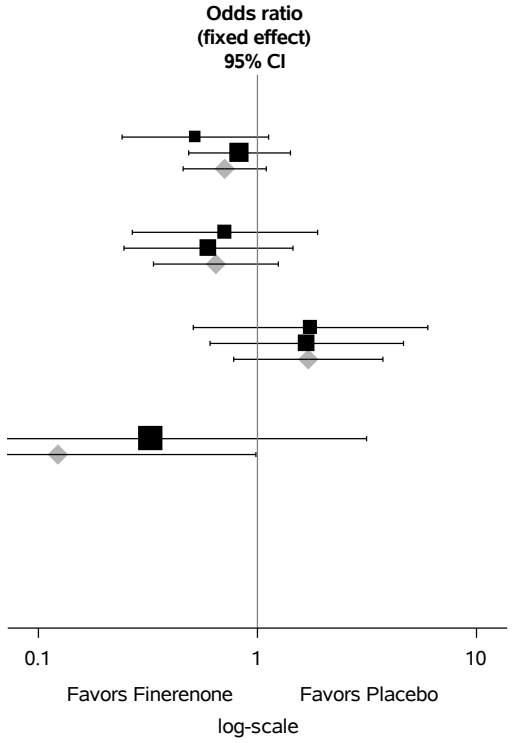
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2827	39 / 2831	38.1	0.61 [0.37,1.02]	
FIGARO-DKD	44 / 3683	54 / 3658	61.9	0.81 [0.54,1.20]	
Total	68 / 6510	93 / 6489		0.73 [0.53,0.99]	Z=-2.00, p=0.0458
Heterogeneity:	Q=0.69 (df=1)	p=0.4066	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.122.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

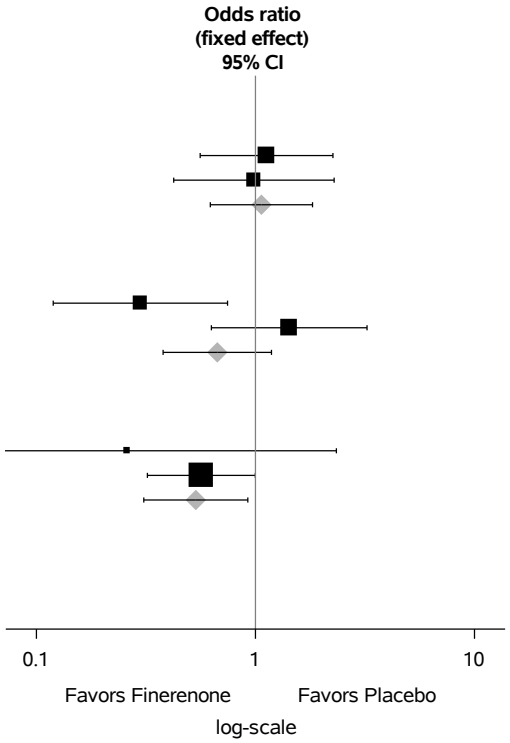
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 1178	19 / 1174	32.6	0.52 [0.24,1.12]	
FIGARO-DKD	25 / 1752	30 / 1747	67.4	0.83 [0.49,1.41]	
Total	35 / 2930	49 / 2921		0.71 [0.46,1.10]	Z=-1.55, p=0.1222
Heterogeneity:	Q=0.95 (df=1)	p=0.3310	I^2=0.0%		
North America					
FIDELIO-DKD	7 / 466	10 / 476	45.4	0.71 [0.27,1.88]	
FIGARO-DKD	8 / 559	13 / 548	54.6	0.60 [0.25,1.45]	
Total	15 / 1025	23 / 1024		0.65 [0.34,1.25]	Z=-1.30, p=0.1920
Heterogeneity:	Q=0.07 (df=1)	p=0.7966	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 790	4 / 786	40.5	1.75 [0.51,5.99]	
FIGARO-DKD	10 / 811	6 / 813	59.5	1.68 [0.61,4.64]	
Total	17 / 1601	10 / 1599		1.71 [0.78,3.74]	Z=1.34, p=0.1816
Heterogeneity:	Q=0.00 (df=1)	p=0.9608	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 294	5 / 294	0.0	0.00 [0.00,18E296]	
FIGARO-DKD	1 / 424	3 / 417	100.0	0.33 [0.03,3.15]	
Total	1 / 718	8 / 711		0.12 [0.02,0.98]	Z=-1.97, p=0.0483
Heterogeneity:	Q=0.71 (df=1)	p=0.3981	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	0 / 137	2 / 133	0.0	0.00 [0.00,76E295]	
Total	0 / 236	3 / 234		0.00 [0.00,9E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=7.36 (df=4)	p=0.1181	I^2=45.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.122.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

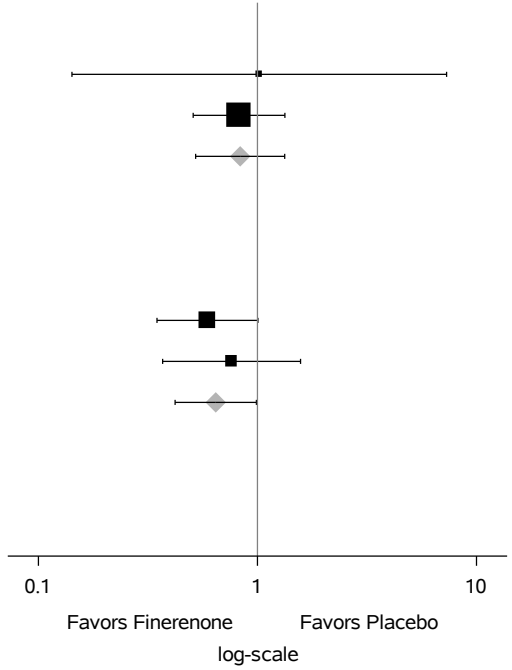
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	17 / 1556	15 / 1541	59.3	1.12 [0.56,2.26]	
FIGARO-DKD	11 / 637	11 / 627	40.7	0.98 [0.42,2.29]	
Total	28 / 2193	26 / 2168		1.06 [0.62,1.82]	Z=0.23, p=0.8190
Heterogeneity:	Q=0.06 (df=1)	p=0.8120	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	6 / 1061	20 / 1069	44.4	0.30 [0.12,0.75]	
FIGARO-DKD	14 / 720	10 / 729	55.6	1.43 [0.63,3.23]	
Total	20 / 1781	30 / 1798		0.67 [0.38,1.18]	Z=-1.38, p=0.1675
Heterogeneity:	Q=6.27 (df=1)	p=0.0123	I^2=84.1%		
>= 60					
FIDELIO-DKD	1 / 210	4 / 221	6.2	0.26 [0.03,2.34]	
FIGARO-DKD	19 / 2326	33 / 2302	93.8	0.57 [0.32,1.00]	
Total	20 / 2536	37 / 2523		0.53 [0.31,0.92]	Z=-2.25, p=0.0246
Heterogeneity:	Q=0.45 (df=1)	p=0.5003	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.24 (df=2)	p=0.1981	I^2=38.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.122.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

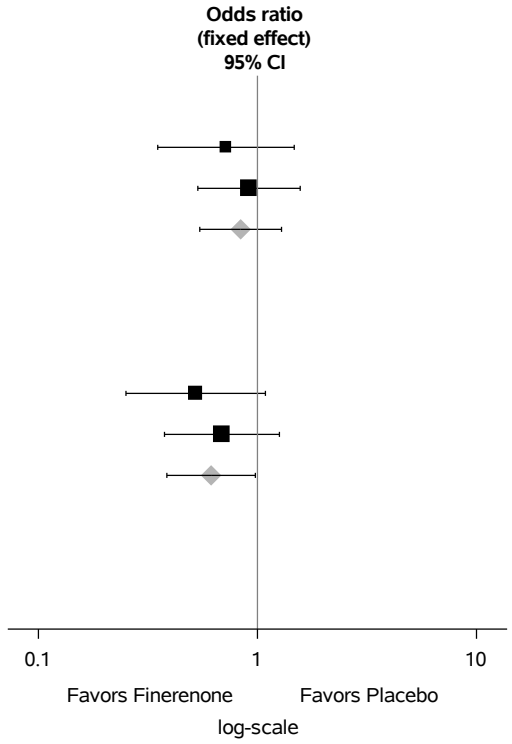
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	2 / 213	5.7	1.02 [0.14,7.30]	
FIGARO-DKD	31 / 1720	37 / 1698	94.3	0.82 [0.51,1.33]	
Total	33 / 1929	39 / 1911		0.83 [0.52,1.33]	Z=-0.76, p=0.4469
Heterogeneity:	Q=0.04 (df=1)	p=0.8370	I^2=0.0%		
Very High					
FIDELIO-DKD	22 / 2618	37 / 2618	65.1	0.59 [0.35,1.00]	
FIGARO-DKD	13 / 1963	17 / 1960	34.9	0.76 [0.37,1.57]	
Total	35 / 4581	54 / 4578		0.65 [0.42,0.99]	Z=-2.01, p=0.0443
Heterogeneity:	Q=0.31 (df=1)	p=0.5797	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=1)	p=0.4271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.122.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

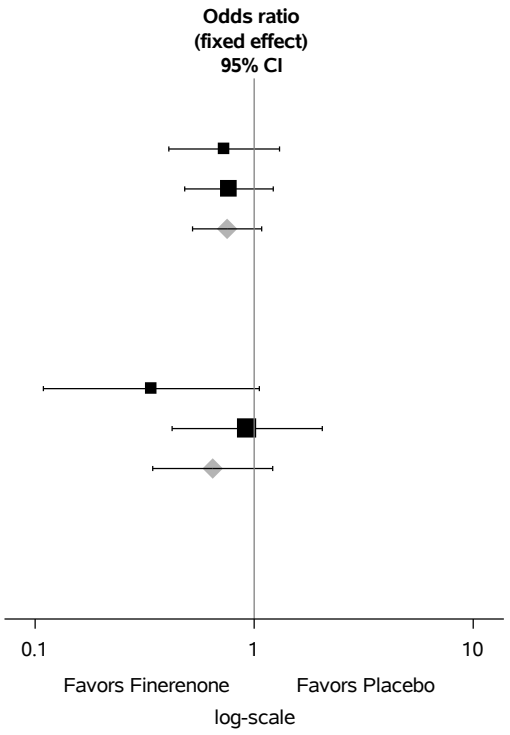
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1301	18 / 1299	36.0	0.72 [0.35,1.47]	
FIGARO-DKD	26 / 1673	28 / 1651	64.0	0.92 [0.53,1.57]	
Total	39 / 2974	46 / 2950		0.84 [0.55,1.29]	Z=-0.81, p=0.4205
Heterogeneity:	Q=0.28 (df=1)	p=0.5968	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	21 / 1532	40.5	0.52 [0.25,1.09]	
FIGARO-DKD	18 / 2010	26 / 2007	59.5	0.69 [0.38,1.26]	
Total	29 / 3536	47 / 3539		0.61 [0.39,0.98]	Z=-2.05, p=0.0401
Heterogeneity:	Q=0.32 (df=1)	p=0.5690	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3365	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.122.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

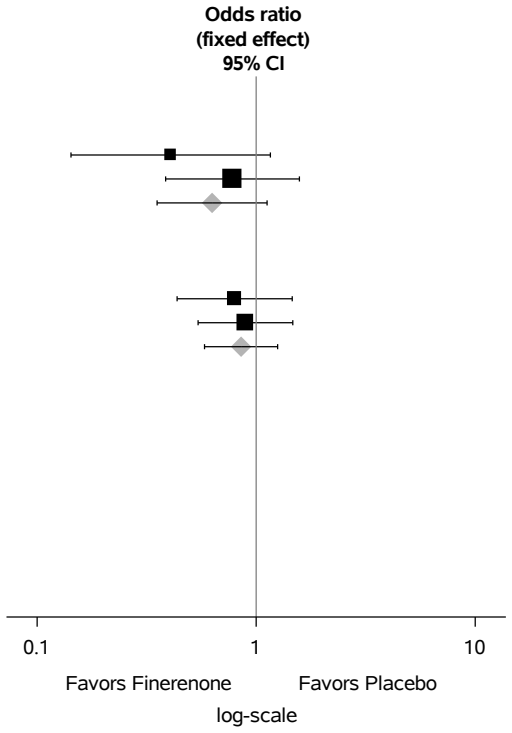
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	20 / 1879	27 / 1858	39.0	0.73 [0.41,1.31]	
FIGARO-DKD	32 / 2643	41 / 2608	61.0	0.77 [0.48,1.22]	
Total	52 / 4522	68 / 4466		0.75 [0.52,1.08]	Z=-1.53, p=0.1249
Heterogeneity:	Q=0.02 (df=1)	p=0.8944	I^2=0.0%		
> 4.5					
FIDELIO-DKD	4 / 948	12 / 973	32.6	0.34 [0.11,1.06]	
FIGARO-DKD	12 / 1040	13 / 1048	67.4	0.93 [0.42,2.05]	
Total	16 / 1988	25 / 2021		0.65 [0.34,1.21]	Z=-1.35, p=0.1754
Heterogeneity:	Q=2.05 (df=1)	p=0.1521	I^2=51.2%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6835	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.122.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

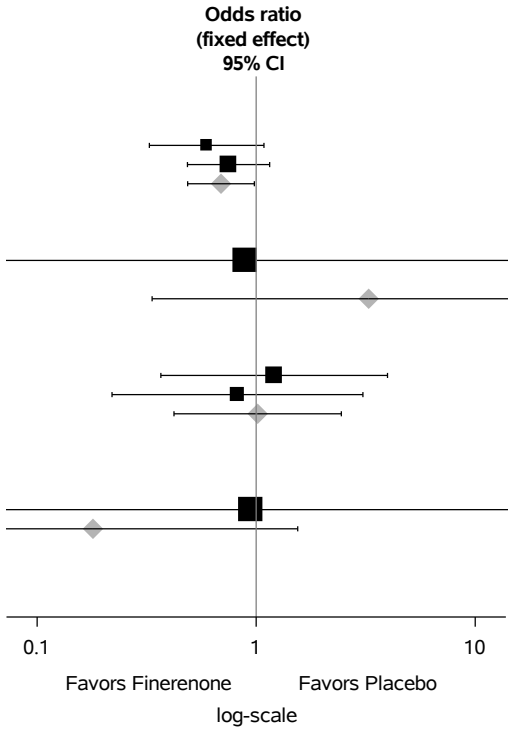
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 788	12 / 777	31.0	0.41 [0.14,1.16]	
FIGARO-DKD	14 / 1187	18 / 1194	69.0	0.78 [0.39,1.58]	
Total	19 / 1975	30 / 1971		0.63 [0.35,1.12]	Z=-1.57, p=0.1161
Heterogeneity:	Q=1.02 (df=1)	p=0.3123	I^2=2.0%		
130 - < 160					
FIDELIO-DKD	19 / 1897	24 / 1916	40.3	0.80 [0.44,1.46]	
FIGARO-DKD	30 / 2389	33 / 2351	59.7	0.89 [0.54,1.47]	
Total	49 / 4286	57 / 4267		0.85 [0.58,1.25]	Z=-0.81, p=0.4182
Heterogeneity:	Q=0.08 (df=1)	p=0.7768	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 141	3 / 138	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	0 / 107	3 / 113	0.0	0.00 [0.00,11E296]	
Total	0 / 248	6 / 251		0.00 [0.00,13E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.74 (df=2)	p=0.6905	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.122.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

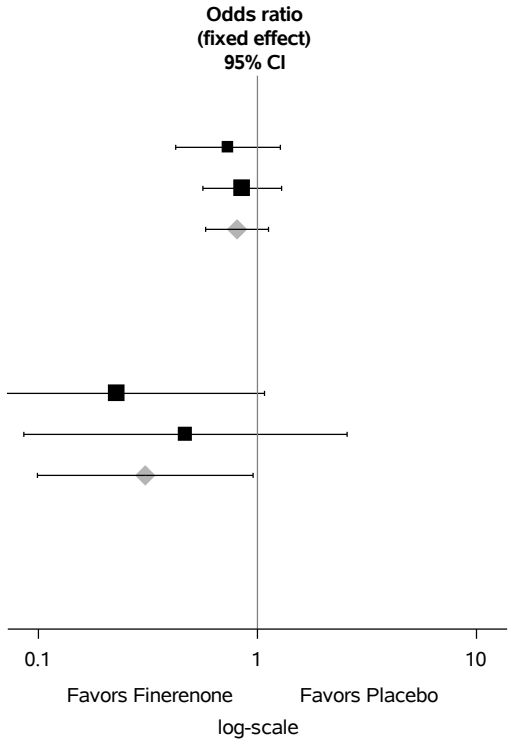
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 1773	29 / 1809	34.0	0.59 [0.33,1.09]	
FIGARO-DKD	37 / 2668	48 / 2601	66.0	0.75 [0.49,1.15]	
Total	54 / 4441	77 / 4410		0.69 [0.49,0.98]	Z=-2.07, p=0.0386
Heterogeneity:	Q=0.37 (df=1)	p=0.5429	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 139	1 / 124	100.0	0.89 [0.06,14.40]	
FIGARO-DKD	2 / 113	0 / 145	0.0	277E9 [277E9,277E9]	
Total	3 / 252	1 / 269		3.26 [0.33,31.81]	Z=1.02, p=0.3086
Heterogeneity:	Q=0.84 (df=1)	p=0.3606	I^2=0.0%		
Asian					
FIDELIO-DKD	6 / 717	5 / 721	55.1	1.21 [0.37,3.98]	
FIGARO-DKD	4 / 716	5 / 736	44.9	0.82 [0.22,3.07]	
Total	10 / 1433	10 / 1457		1.02 [0.42,2.45]	Z=0.03, p=0.9723
Heterogeneity:	Q=0.18 (df=1)	p=0.6702	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	4 / 177	0.0	0.00 [0.00,14E296]	
FIGARO-DKD	1 / 186	1 / 176	100.0	0.95 [0.06,15.24]	
Total	1 / 384	5 / 353		0.18 [0.02,1.55]	Z=-1.56, p=0.1182
Heterogeneity:	Q=1.37 (df=1)	p=0.2417	I^2=27.0%		
Subgroup Heterogeneity:	Q=3.93 (df=3)	p=0.2696	I^2=23.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.122.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

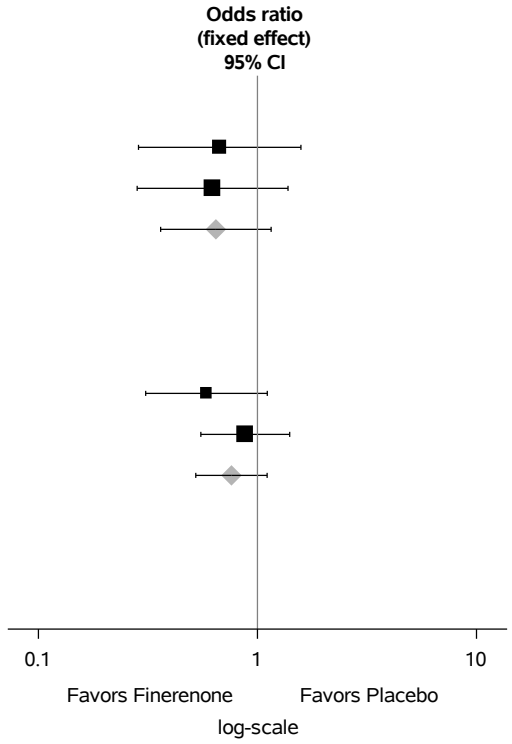
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	22 / 1949	31 / 2024	36.2	0.73 [0.42,1.27]	
FIGARO-DKD	42 / 2527	50 / 2571	63.8	0.85 [0.56,1.29]	
Total	64 / 4476	81 / 4595		0.81 [0.58,1.12]	Z=-1.27, p=0.2037
Heterogeneity:	Q=0.18 (df=1)	p=0.6708	I^2=0.0%		
Female					
FIDELIO-DKD	2 / 878	8 / 807	54.5	0.23 [0.05,1.08]	
FIGARO-DKD	2 / 1156	4 / 1087	45.5	0.47 [0.09,2.57]	
Total	4 / 2034	12 / 1894		0.31 [0.10,0.96]	Z=-2.04, p=0.0414
Heterogeneity:	Q=0.38 (df=1)	p=0.5375	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.57 (df=1)	p=0.1091	I^2=61.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.122.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Haematuria (PT with Incidence >=1%)
Safety Analysis Set

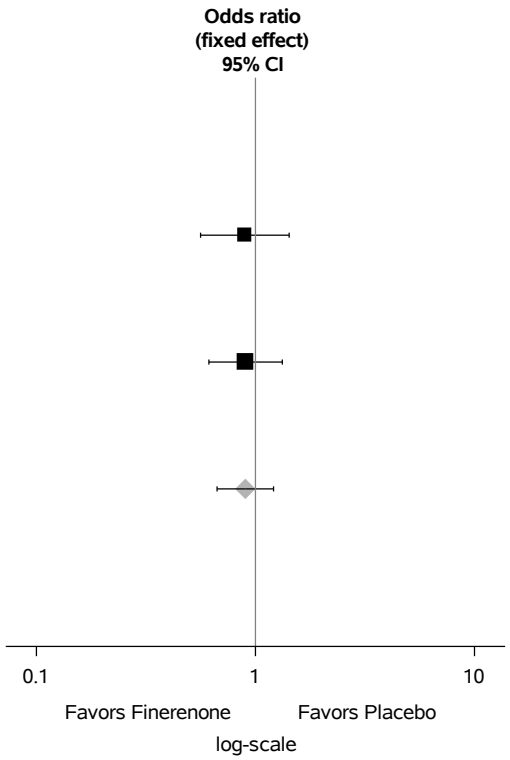
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1201	13 / 1171	46.3	0.67 [0.29,1.58]	
FIGARO-DKD	10 / 1752	16 / 1755	53.7	0.62 [0.28,1.38]	
Total	19 / 2953	29 / 2926		0.65 [0.36,1.15]	Z=-1.48, p=0.1402
Heterogeneity:	Q=0.02 (df=1)	p=0.8995	I^2=0.0%		
>= 65					
FIDELIO-DKD	15 / 1626	26 / 1660	34.8	0.59 [0.31,1.11]	
FIGARO-DKD	34 / 1931	38 / 1903	65.2	0.88 [0.55,1.40]	
Total	49 / 3557	64 / 3563		0.76 [0.52,1.11]	Z=-1.43, p=0.1532
Heterogeneity:	Q=1.02 (df=1)	p=0.3128	I^2=1.8%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6425	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.123: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set

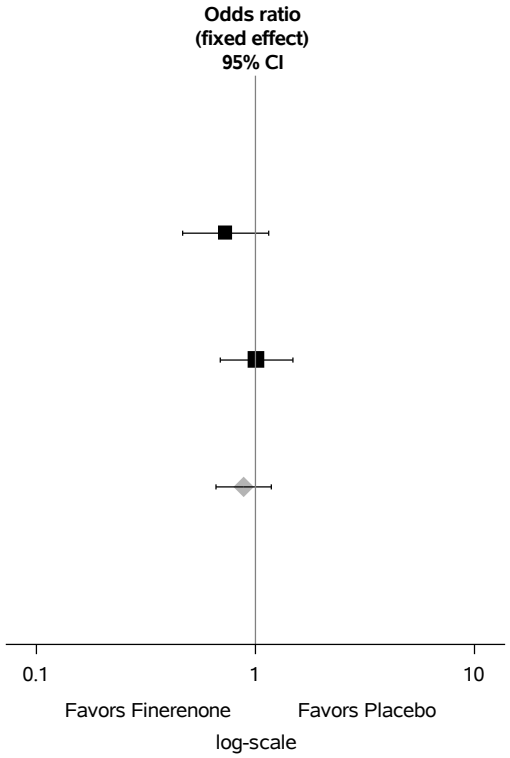
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2827	38 / 2831	40.7	0.89 [0.56,1.43]	
FIGARO-DKD	50 / 3683	55 / 3658	59.3	0.90 [0.61,1.33]	
Total	84 / 6510	93 / 6489		0.90 [0.67,1.21]	Z=-0.70, p=0.4814
Heterogeneity:	Q=0.00 (df=1)	p=0.9803	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.124: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set

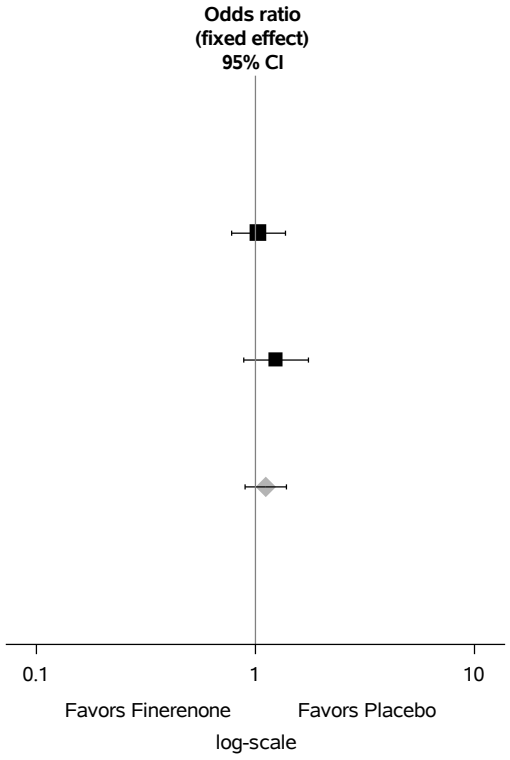
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	45 / 2831	41.6	0.73 [0.47,1.15]	
FIGARO-DKD	54 / 3683	53 / 3658	58.4	1.01 [0.69,1.48]	
Total	87 / 6510	98 / 6489		0.88 [0.66,1.18]	Z=-0.84, p=0.4026
Heterogeneity:	Q=1.16 (df=1)	p=0.2817	I^2=13.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.125: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set

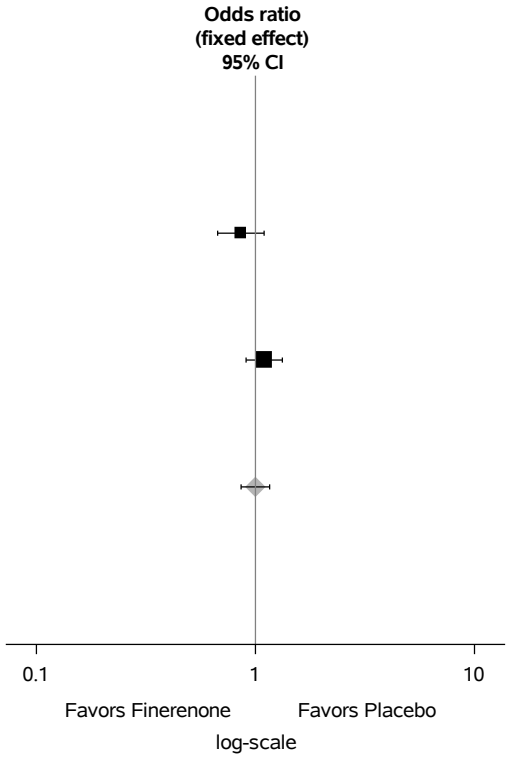
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	101 / 2827	98 / 2831	59.1	1.03 [0.78,1.37]	
FIGARO-DKD	76 / 3683	61 / 3658	40.9	1.24 [0.88,1.75]	
Total	177 / 6510	159 / 6489		1.11 [0.90,1.38]	Z=0.98, p=0.3282
Heterogeneity:	Q=0.67 (df=1)	p=0.4140	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.126: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set

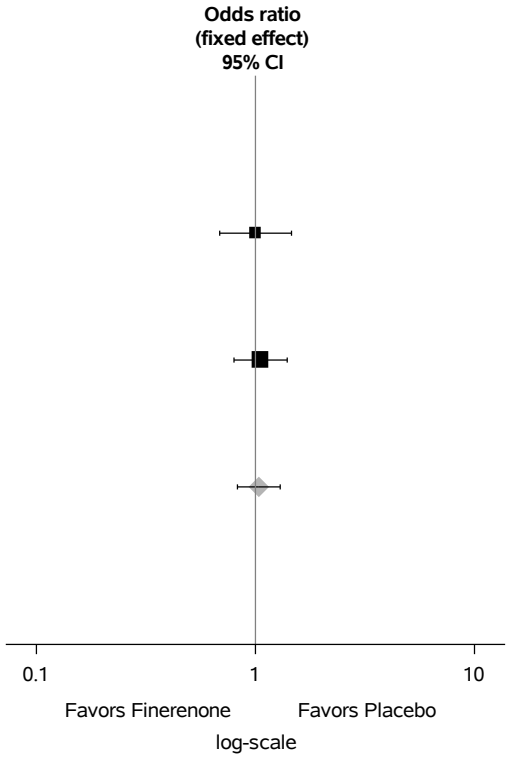
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	146 / 2831	37.9	0.86 [0.67,1.10]	
FIGARO-DKD	236 / 3683	215 / 3658	62.1	1.10 [0.91,1.33]	
Total	362 / 6510	361 / 6489		1.00 [0.86,1.16]	Z=-0.01, p=0.9895
Heterogeneity:	Q=2.41 (df=1)	p=0.1208	I^2=58.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.127: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set

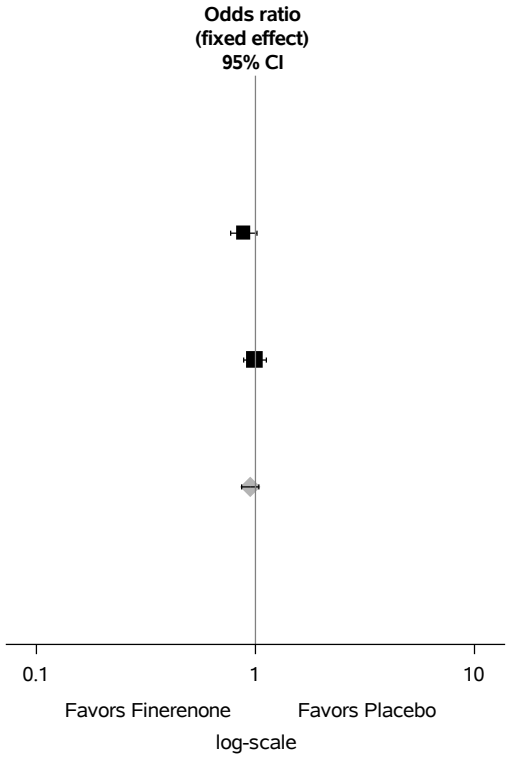
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	55 / 2827	55 / 2831	35.5	1.00 [0.69,1.46]	
FIGARO-DKD	104 / 3683	98 / 3658	64.5	1.06 [0.80,1.40]	
Total	159 / 6510	153 / 6489		1.04 [0.83,1.30]	Z=0.31, p=0.7574
Heterogeneity:	Q=0.05 (df=1)	p=0.8261	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.128: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

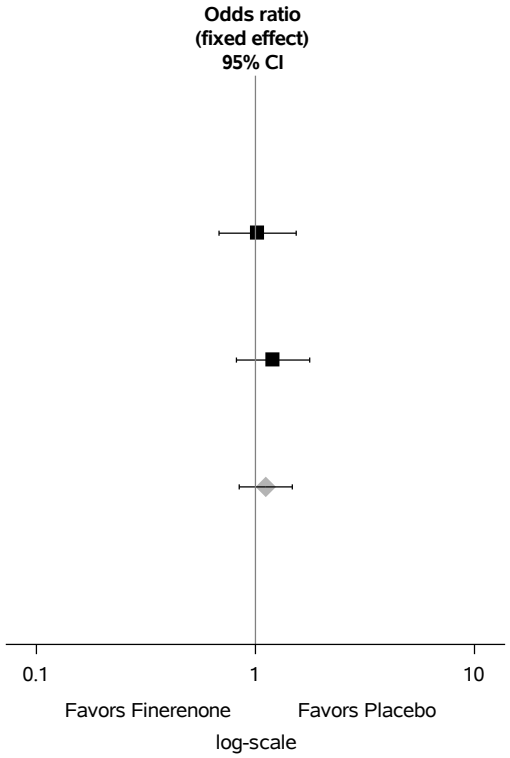
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	462 / 2827	512 / 2831	42.7	0.88 [0.77,1.02]	
FIGARO-DKD	660 / 3683	658 / 3658	57.3	1.00 [0.88,1.12]	
Total	1122 / 6510	1170 / 6489		0.95 [0.86,1.04]	Z=-1.19, p=0.2332
Heterogeneity:	Q=1.60 (df=1)	p=0.2058	I^2=37.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.129: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set

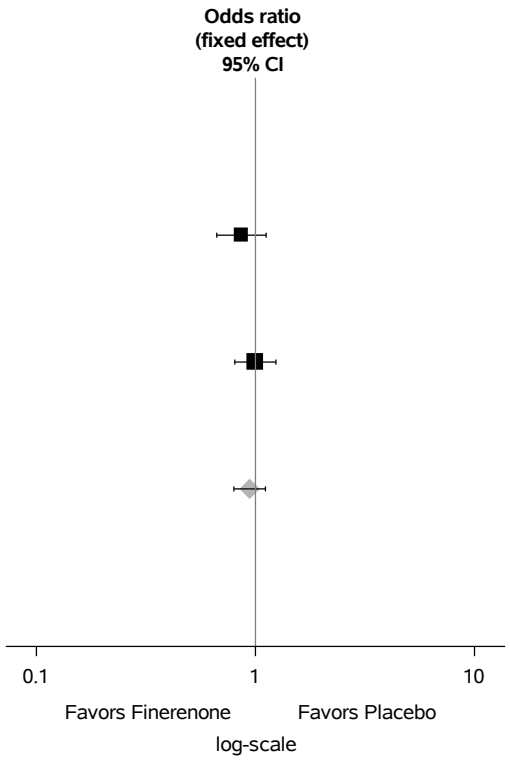
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 2827	47 / 2831	47.4	1.02 [0.68,1.53]	
FIGARO-DKD	58 / 3683	48 / 3658	52.6	1.20 [0.82,1.77]	
Total	106 / 6510	95 / 6489		1.11 [0.84,1.47]	Z=0.76, p=0.4468
Heterogeneity:	Q=0.32 (df=1)	p=0.5697	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.130: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set

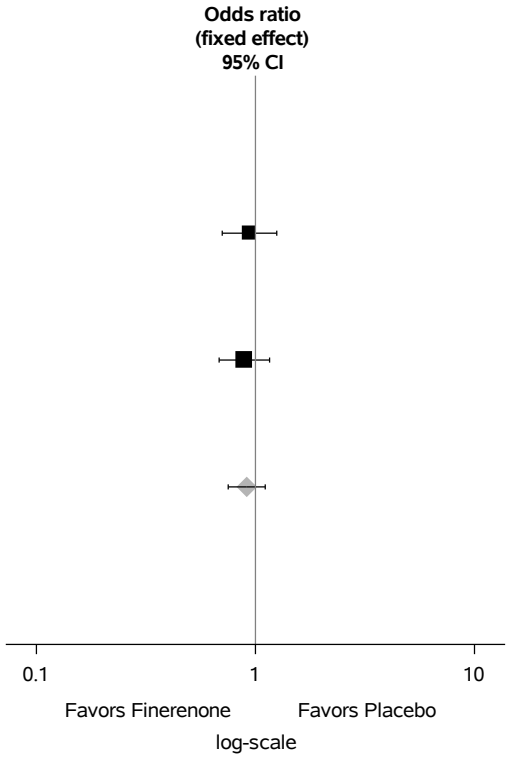
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2827	128 / 2831	40.9	0.86 [0.67,1.12]	
FIGARO-DKD	173 / 3683	172 / 3658	59.1	1.00 [0.80,1.24]	
Total	284 / 6510	300 / 6489		0.94 [0.80,1.11]	Z=-0.72, p=0.4715
Heterogeneity:	Q=0.72 (df=1)	p=0.3963	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.131: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set

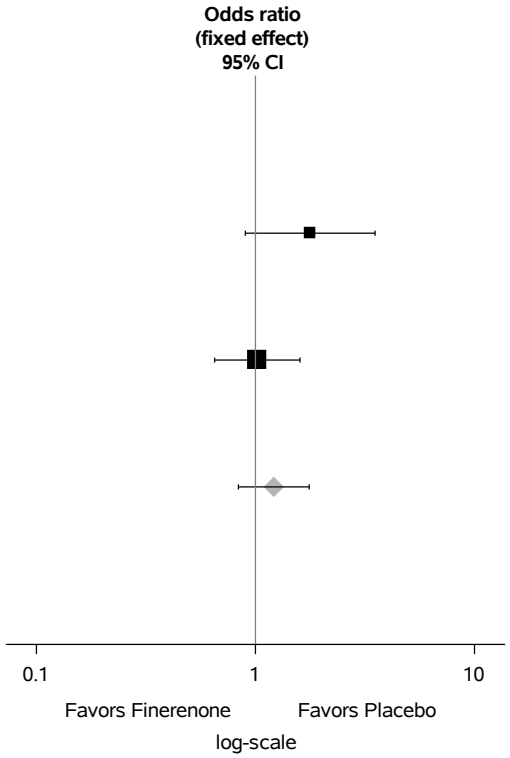
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2827	100 / 2831	46.1	0.94 [0.71,1.25]	
FIGARO-DKD	107 / 3683	119 / 3658	53.9	0.89 [0.68,1.16]	
Total	201 / 6510	219 / 6489		0.91 [0.75,1.11]	Z=-0.92, p=0.3555
Heterogeneity:	Q=0.07 (df=1)	p=0.7860	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.132: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oropharyngeal pain (PT with Incidence >=1%)
Safety Analysis Set

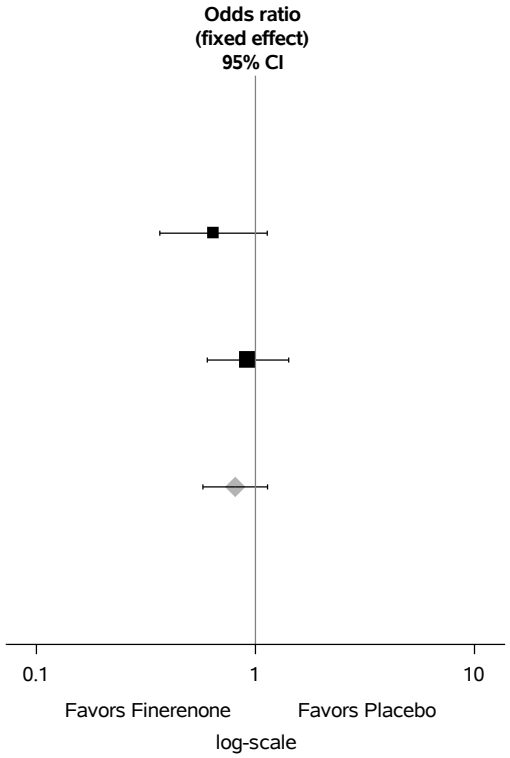
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	13 / 2831	30.2	1.78 [0.90,3.52]	
FIGARO-DKD	39 / 3683	38 / 3658	69.8	1.02 [0.65,1.60]	
Total	62 / 6510	51 / 6489		1.21 [0.84,1.76]	Z=1.02, p=0.3098
Heterogeneity:	Q=1.78 (df=1)	p=0.1819	I^2=43.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.133: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set

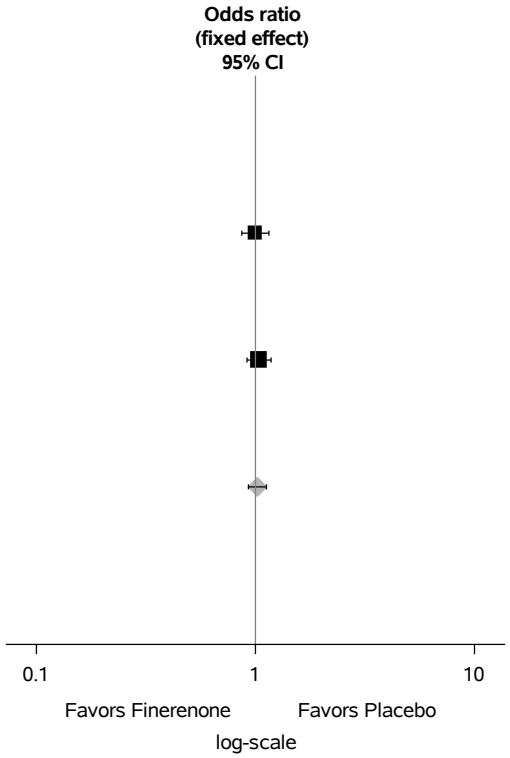
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2827	31 / 2831	36.5	0.64 [0.37,1.13]	
FIGARO-DKD	41 / 3683	44 / 3658	63.5	0.92 [0.60,1.42]	
Total	61 / 6510	75 / 6489		0.81 [0.58,1.14]	Z=-1.23, p=0.2200
Heterogeneity:	Q=1.01 (df=1)	p=0.3160	I^2=0.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.134: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

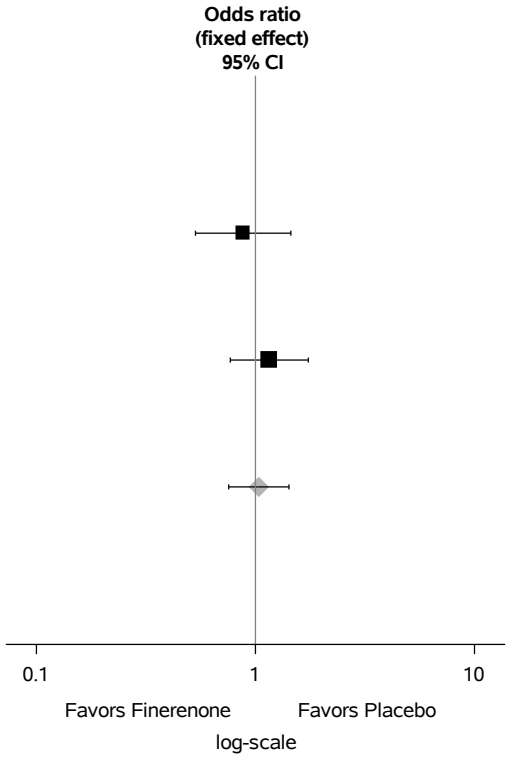
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	450 / 2827	451 / 2831	44.1	1.00 [0.87,1.15]	
FIGARO-DKD	578 / 3683	556 / 3658	55.9	1.04 [0.92,1.18]	
Total	1028 / 6510	1007 / 6489		1.02 [0.93,1.12]	Z=0.43, p=0.6679
Heterogeneity:	Q=0.16 (df=1)	p=0.6899	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.135: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set

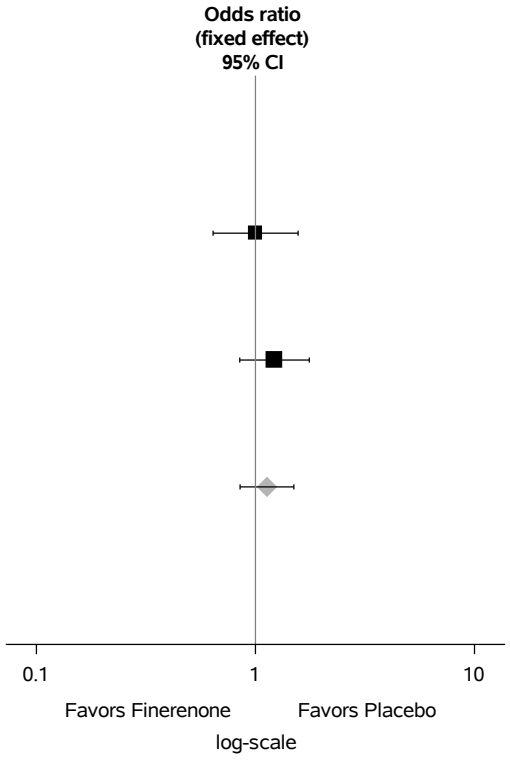
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	33 / 2831	40.1	0.88 [0.53,1.45]	
FIGARO-DKD	50 / 3683	43 / 3658	59.9	1.16 [0.77,1.74]	
Total	79 / 6510	76 / 6489		1.04 [0.75,1.42]	Z=0.22, p=0.8256
Heterogeneity:	Q=0.69 (df=1)	p=0.4054	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.136: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set

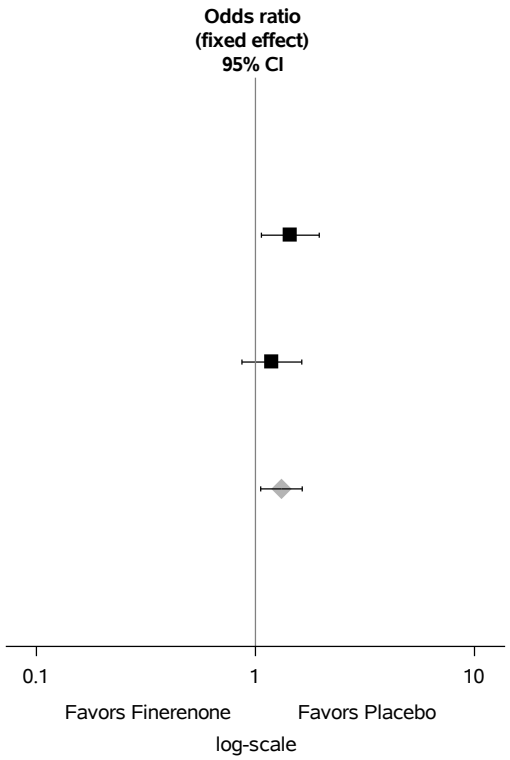
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	39 / 2831	40.1	1.00 [0.64,1.57]	
FIGARO-DKD	65 / 3683	53 / 3658	59.9	1.22 [0.85,1.76]	
Total	104 / 6510	92 / 6489		1.13 [0.85,1.50]	Z=0.84, p=0.4019
Heterogeneity:	Q=0.46 (df=1)	p=0.4993	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.137: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

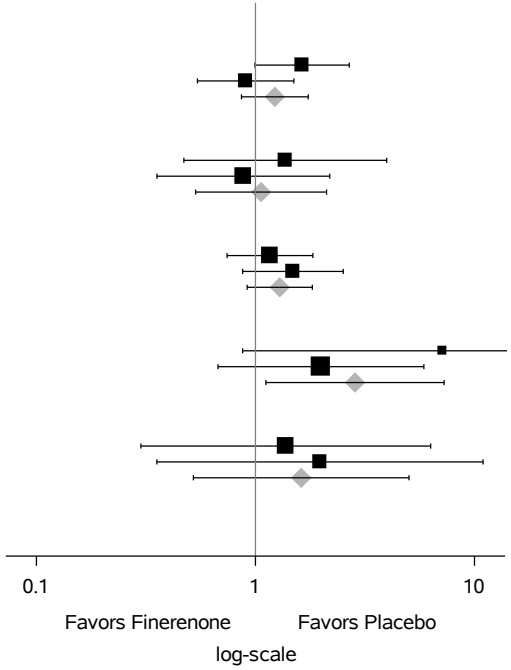
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2827	73 / 2831	51.7	1.44 [1.06,1.96]	
FIGARO-DKD	87 / 3683	73 / 3658	48.3	1.19 [0.87,1.63]	
Total	191 / 6510	146 / 6489		1.31 [1.06,1.64]	Z=2.45, p=0.0141
Heterogeneity:	Q=0.76 (df=1)	p=0.3838	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.137.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

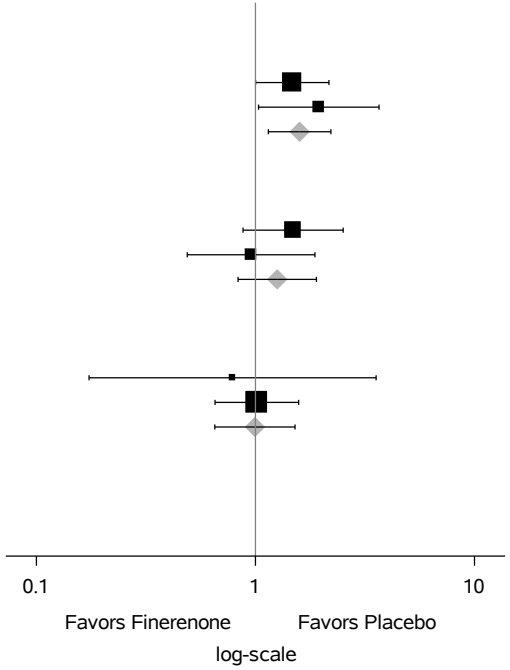
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	42 / 1178	26 / 1174	51.1	1.63 [0.99,2.68]	
FIGARO-DKD	29 / 1752	32 / 1747	48.9	0.90 [0.54,1.50]	
Total	71 / 2930	58 / 2921		1.23 [0.86,1.74]	Z=1.14, p=0.2550
Heterogeneity:	Q=2.69 (df=1)	p=0.1011	I^2=62.8%		
North America					
FIDELIO-DKD	8 / 466	6 / 476	42.1	1.37 [0.47,3.97]	
FIGARO-DKD	9 / 559	10 / 548	57.9	0.88 [0.35,2.18]	
Total	17 / 1025	16 / 1024		1.06 [0.53,2.11]	Z=0.17, p=0.8662
Heterogeneity:	Q=0.38 (df=1)	p=0.5372	I^2=0.0%		
Asia					
FIDELIO-DKD	43 / 790	37 / 786	57.9	1.17 [0.74,1.83]	
FIGARO-DKD	35 / 811	24 / 813	42.1	1.48 [0.87,2.52]	
Total	78 / 1601	61 / 1599		1.29 [0.92,1.82]	Z=1.46, p=0.1442
Heterogeneity:	Q=0.46 (df=1)	p=0.4968	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 294	1 / 294	21.0	7.15 [0.87,58.45]	
FIGARO-DKD	10 / 424	5 / 417	79.0	1.99 [0.67,5.87]	
Total	17 / 718	6 / 711		2.85 [1.12,7.26]	Z=2.19, p=0.0286
Heterogeneity:	Q=1.16 (df=1)	p=0.2821	I^2=13.6%		
Others					
FIDELIO-DKD	4 / 99	3 / 101	55.9	1.38 [0.30,6.31]	
FIGARO-DKD	4 / 137	2 / 133	44.1	1.97 [0.35,10.94]	
Total	8 / 236	5 / 234		1.62 [0.52,5.02]	Z=0.83, p=0.4055
Heterogeneity:	Q=0.09 (df=1)	p=0.7588	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.28 (df=4)	p=0.5128	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.137.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

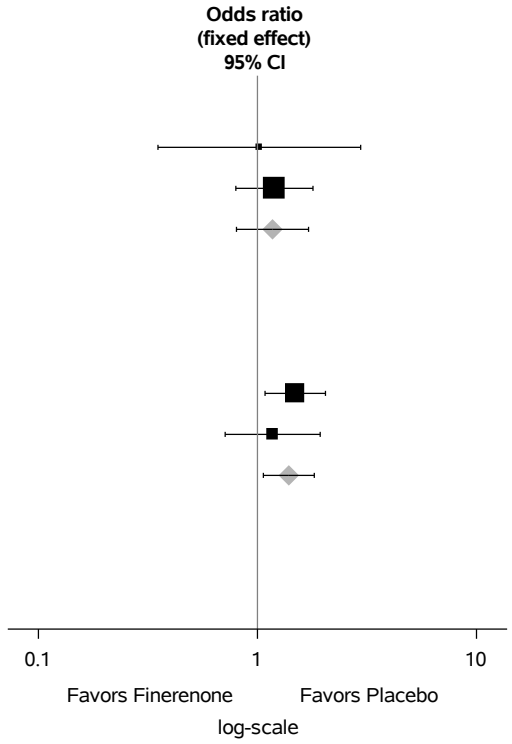
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	66 / 1556	45 / 1541	73.0	1.47 [1.00,2.17]	
FIGARO-DKD	29 / 637	15 / 627	27.0	1.95 [1.03,3.67]	
Total	95 / 2193	60 / 2168		1.59 [1.15,2.21]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.54 (df=1)	p=0.4611	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	24 / 1069	61.9	1.49 [0.88,2.51]	
FIGARO-DKD	17 / 720	18 / 729	38.1	0.96 [0.49,1.87]	
Total	52 / 1781	42 / 1798		1.26 [0.83,1.90]	Z=1.09, p=0.2762
Heterogeneity:	Q=1.03 (df=1)	p=0.3103	I^2=2.8%		
>= 60					
FIDELIO-DKD	3 / 210	4 / 221	7.8	0.79 [0.17,3.56]	
FIGARO-DKD	41 / 2326	40 / 2302	92.2	1.01 [0.65,1.57]	
Total	44 / 2536	44 / 2523		0.99 [0.65,1.52]	Z=-0.03, p=0.9793
Heterogeneity:	Q=0.10 (df=1)	p=0.7504	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.02 (df=2)	p=0.2207	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.137.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

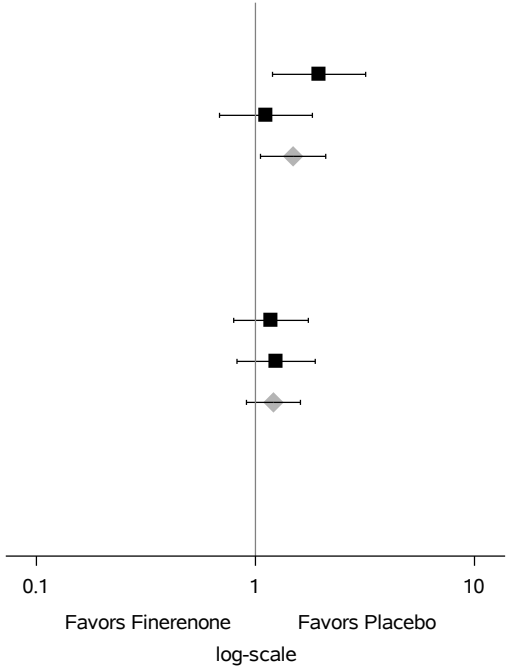
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	7 / 213	12.7	1.02 [0.35,2.96]	
FIGARO-DKD	53 / 1720	44 / 1698	87.3	1.20 [0.80,1.79]	
Total	60 / 1929	51 / 1911		1.17 [0.80,1.71]	Z=0.82, p=0.4129
Heterogeneity:	Q=0.07 (df=1)	p=0.7850	I^2=0.0%		
Very High					
FIDELIO-DKD	97 / 2618	66 / 2618	71.2	1.49 [1.08,2.04]	
FIGARO-DKD	34 / 1963	29 / 1960	28.8	1.17 [0.71,1.93]	
Total	131 / 4581	95 / 4578		1.39 [1.06,1.82]	Z=2.41, p=0.0158
Heterogeneity:	Q=0.62 (df=1)	p=0.4322	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.52 (df=1)	p=0.4687	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.137.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

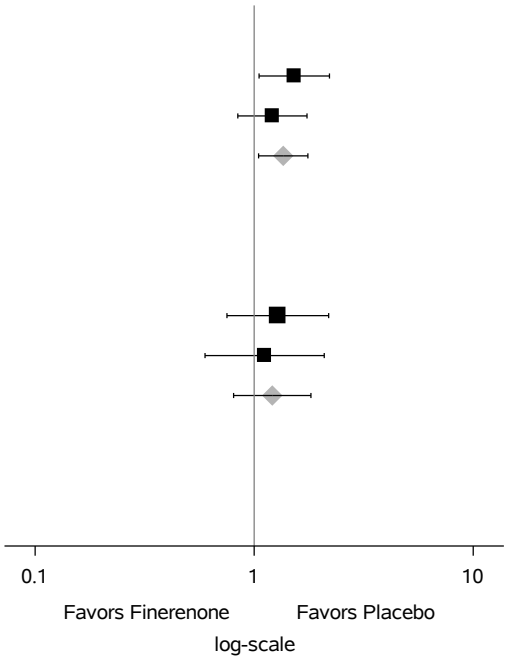
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	48 / 1301	25 / 1299	49.9	1.95 [1.20,3.19]	
FIGARO-DKD	35 / 1673	31 / 1651	50.1	1.12 [0.69,1.82]	
Total	83 / 2974	56 / 2950		1.49 [1.05,2.09]	Z=2.26, p=0.0237
Heterogeneity:	Q=2.51 (df=1)	p=0.1132	I^2=60.1%		
Absent					
FIDELIO-DKD	56 / 1526	48 / 1532	52.4	1.18 [0.80,1.74]	
FIGARO-DKD	52 / 2010	42 / 2007	47.6	1.24 [0.82,1.87]	
Total	108 / 3536	90 / 3539		1.21 [0.91,1.60]	Z=1.31, p=0.1915
Heterogeneity:	Q=0.03 (df=1)	p=0.8536	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3628	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.137.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

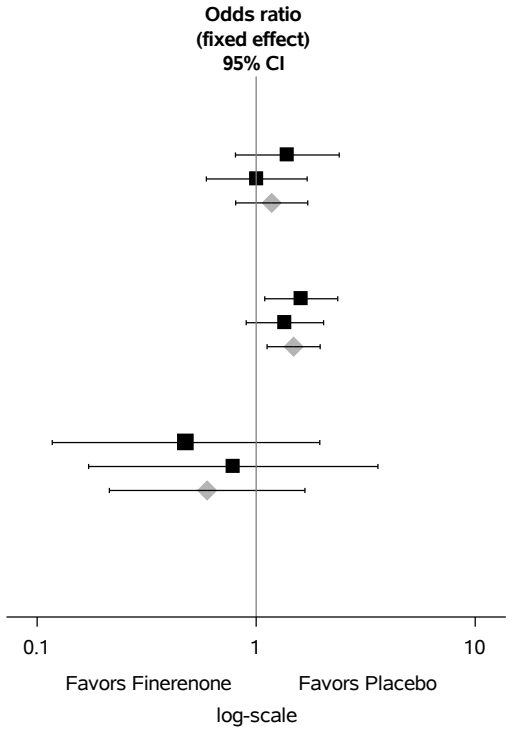
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	73 / 1879	48 / 1858	49.2	1.52 [1.05,2.21]	
FIGARO-DKD	66 / 2643	54 / 2608	50.8	1.21 [0.84,1.74]	
Total	139 / 4522	102 / 4466		1.36 [1.05,1.76]	Z=2.31, p=0.0208
Heterogeneity:	Q=0.75 (df=1)	p=0.3854	I^2=0.0%		
> 4.5					
FIDELIO-DKD	31 / 948	25 / 973	57.9	1.28 [0.75,2.19]	
FIGARO-DKD	21 / 1040	19 / 1048	42.1	1.12 [0.60,2.09]	
Total	52 / 1988	44 / 2021		1.21 [0.81,1.82]	Z=0.92, p=0.3592
Heterogeneity:	Q=0.11 (df=1)	p=0.7417	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6389	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.137.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

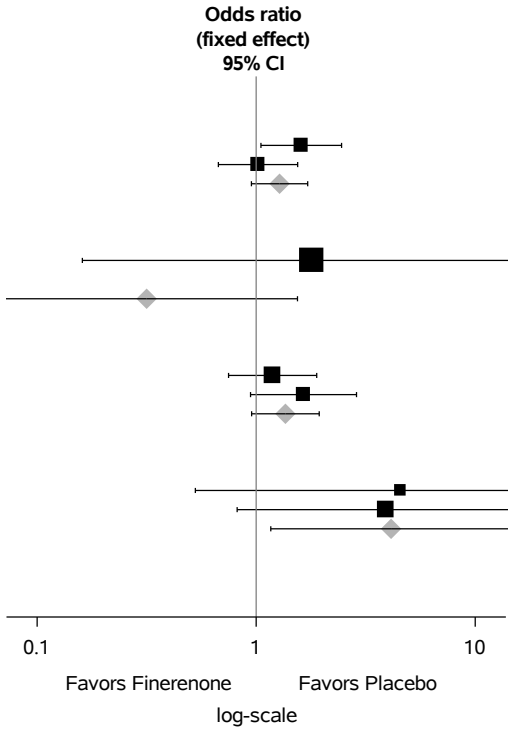
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	32 / 788	23 / 777	48.6	1.39 [0.80,2.39]	
FIGARO-DKD	28 / 1187	28 / 1194	51.4	1.01 [0.59,1.71]	
Total	60 / 1975	51 / 1971		1.18 [0.81,1.72]	Z=0.84, p=0.3982
Heterogeneity:	Q=0.69 (df=1)	p=0.4072	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	69 / 1897	44 / 1916	53.0	1.61 [1.09,2.36]	
FIGARO-DKD	56 / 2389	41 / 2351	47.0	1.35 [0.90,2.03]	
Total	125 / 4286	85 / 4267		1.48 [1.12,1.96]	Z=2.76, p=0.0057
Heterogeneity:	Q=0.36 (df=1)	p=0.5470	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 141	6 / 138	53.9	0.48 [0.12,1.95]	
FIGARO-DKD	3 / 107	4 / 113	46.1	0.79 [0.17,3.60]	
Total	6 / 248	10 / 251		0.60 [0.21,1.67]	Z=-0.98, p=0.3257
Heterogeneity:	Q=0.22 (df=1)	p=0.6381	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.30 (df=2)	p=0.1922	I^2=39.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.137.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

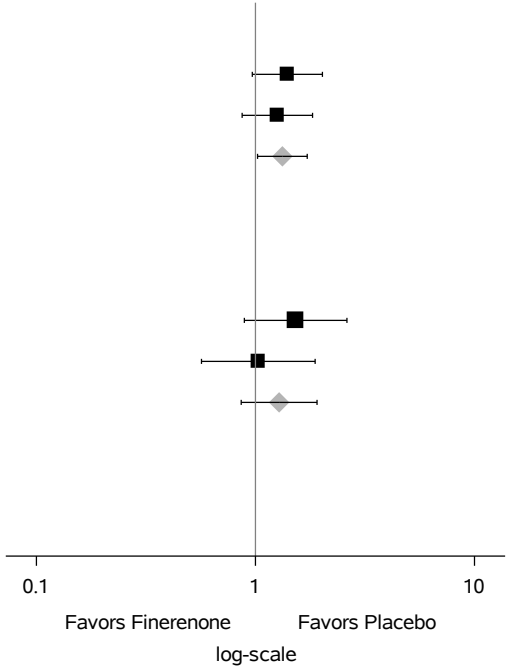
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	56 / 1773	36 / 1809	49.2	1.61 [1.05,2.45]	
FIGARO-DKD	46 / 2668	44 / 2601	50.8	1.02 [0.67,1.55]	
Total	102 / 4441	80 / 4410		1.28 [0.95,1.72]	Z=1.63, p=0.1035
Heterogeneity:	Q=2.25 (df=1)	p=0.1340	I^2=55.5%		
Black					
FIDELIO-DKD	2 / 139	1 / 124	100.0	1.80 [0.16,20.05]	
FIGARO-DKD	0 / 113	6 / 145	0.0	0.00 [0.00,2E297]	
Total	2 / 252	7 / 269		0.32 [0.06,1.54]	Z=-1.42, p=0.1546
Heterogeneity:	Q=1.99 (df=1)	p=0.1583	I^2=49.8%		
Asian					
FIDELIO-DKD	41 / 717	35 / 721	59.1	1.19 [0.75,1.89]	
FIGARO-DKD	33 / 716	21 / 736	40.9	1.65 [0.94,2.87]	
Total	74 / 1433	56 / 1457		1.36 [0.95,1.94]	Z=1.70, p=0.0898
Heterogeneity:	Q=0.77 (df=1)	p=0.3795	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 198	1 / 177	34.4	4.56 [0.53,39.41]	
FIGARO-DKD	8 / 186	2 / 176	65.6	3.91 [0.82,18.67]	
Total	13 / 384	3 / 353		4.13 [1.17,14.63]	Z=2.20, p=0.0280
Heterogeneity:	Q=0.01 (df=1)	p=0.9100	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.32 (df=3)	p=0.0972	I^2=52.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.137.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

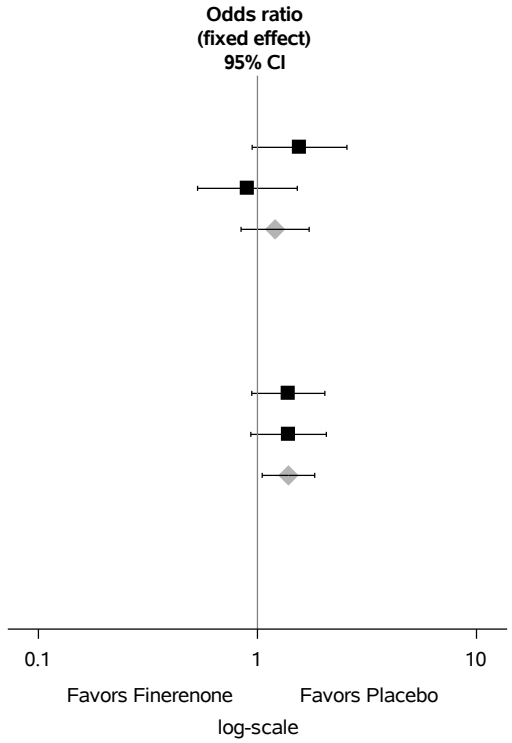
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	68 / 1949	51 / 2024	50.2	1.40 [0.97,2.02]	
FIGARO-DKD	64 / 2527	52 / 2571	49.8	1.26 [0.87,1.82]	
Total	132 / 4476	103 / 4595		1.33 [1.02,1.72]	Z=2.13, p=0.0335
Heterogeneity:	Q=0.16 (df=1)	p=0.6927	I^2=0.0%		
Female					
FIDELIO-DKD	36 / 878	22 / 807	55.1	1.53 [0.89,2.62]	
FIGARO-DKD	23 / 1156	21 / 1087	44.9	1.03 [0.57,1.87]	
Total	59 / 2034	43 / 1894		1.28 [0.86,1.91]	Z=1.22, p=0.2211
Heterogeneity:	Q=0.91 (df=1)	p=0.3393	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8874	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.137.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Pruritus (PT with Incidence >=1%)
Safety Analysis Set

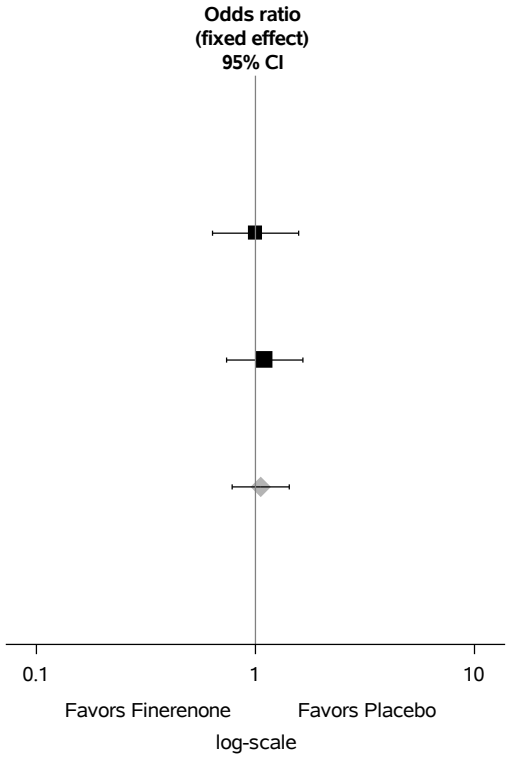
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	41 / 1201	26 / 1171	52.6	1.56 [0.95,2.56]	
FIGARO-DKD	27 / 1752	30 / 1755	47.4	0.90 [0.53,1.52]	
Total	68 / 2953	56 / 2926		1.20 [0.84,1.72]	Z=1.02, p=0.3095
Heterogeneity:	Q=2.21 (df=1)	p=0.1376	I^2=54.6%		
>= 65					
FIDELIO-DKD	63 / 1626	47 / 1660	51.6	1.38 [0.94,2.03]	
FIGARO-DKD	60 / 1931	43 / 1903	48.4	1.39 [0.93,2.06]	
Total	123 / 3557	90 / 3563		1.39 [1.05,1.83]	Z=2.31, p=0.0207
Heterogeneity:	Q=0.00 (df=1)	p=0.9922	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5427	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.138: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set

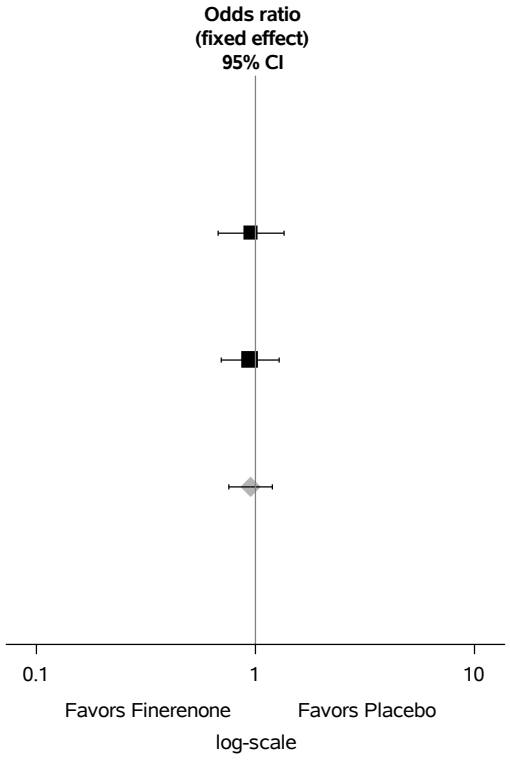
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2827	38 / 2831	44.0	1.00 [0.64,1.57]	
FIGARO-DKD	51 / 3683	46 / 3658	56.0	1.10 [0.74,1.65]	
Total	89 / 6510	84 / 6489		1.06 [0.78,1.43]	Z=0.36, p=0.7177
Heterogeneity:	Q=0.10 (df=1)	p=0.7552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.139: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set

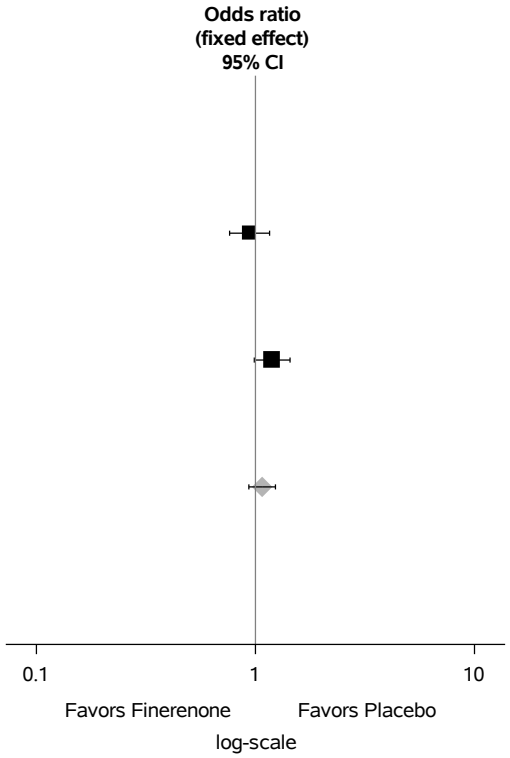
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	67 / 2831	43.5	0.96 [0.68,1.35]	
FIGARO-DKD	83 / 3683	87 / 3658	56.5	0.95 [0.70,1.28]	
Total	147 / 6510	154 / 6489		0.95 [0.76,1.19]	Z=-0.44, p=0.6624
Heterogeneity:	Q=0.00 (df=1)	p=0.9671	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.140: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set

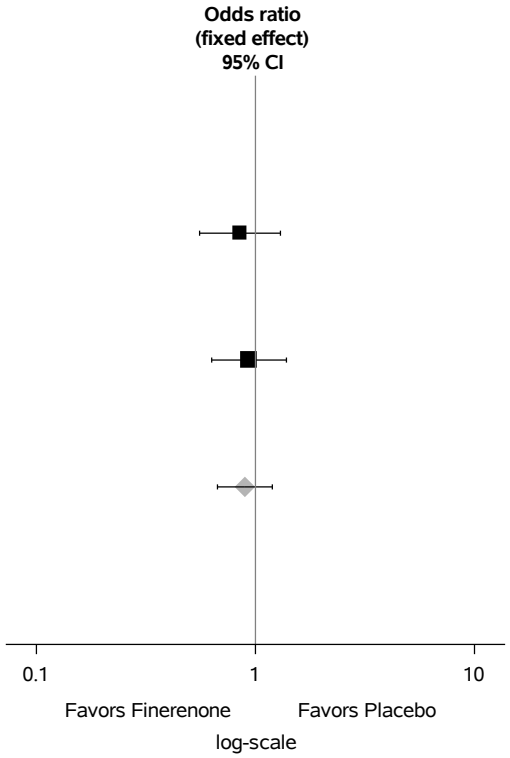
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	181 / 2827	192 / 2831	44.4	0.94 [0.76,1.16]	
FIGARO-DKD	254 / 3683	214 / 3658	55.6	1.19 [0.99,1.44]	
Total	435 / 6510	406 / 6489		1.07 [0.93,1.23]	Z=0.99, p=0.3239
Heterogeneity:	Q=2.72 (df=1)	p=0.0988	I^2=63.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.141: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set

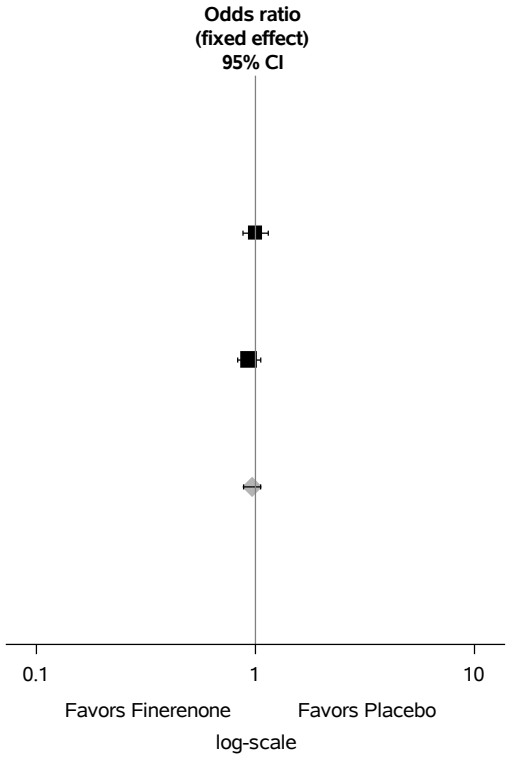
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	47 / 2831	46.1	0.85 [0.56,1.30]	
FIGARO-DKD	49 / 3683	52 / 3658	53.9	0.94 [0.63,1.39]	
Total	89 / 6510	99 / 6489		0.89 [0.67,1.19]	Z=-0.76, p=0.4502
Heterogeneity:	Q=0.10 (df=1)	p=0.7472	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.142: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

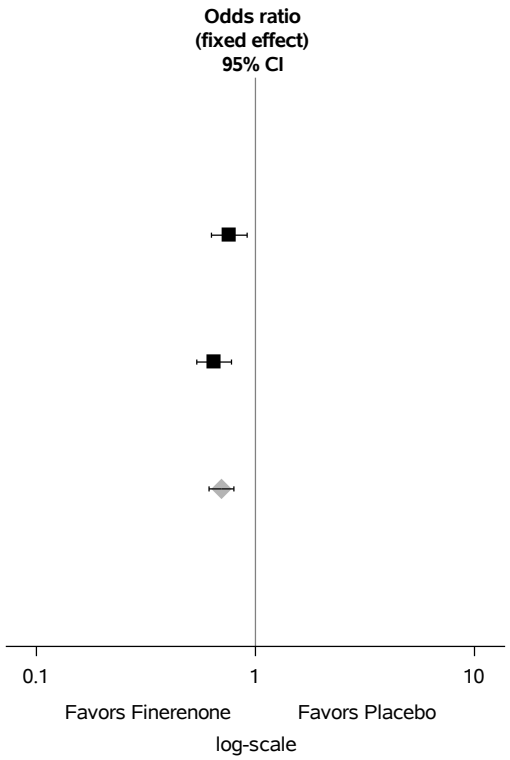
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	537 / 2827	537 / 2831	45.4	1.00 [0.88,1.14]	
FIGARO-DKD	616 / 3683	646 / 3658	54.6	0.94 [0.83,1.06]	
Total	1153 / 6510	1183 / 6489		0.97 [0.88,1.06]	Z=-0.77, p=0.4435
Heterogeneity:	Q=0.54 (df=1)	p=0.4628	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.143: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

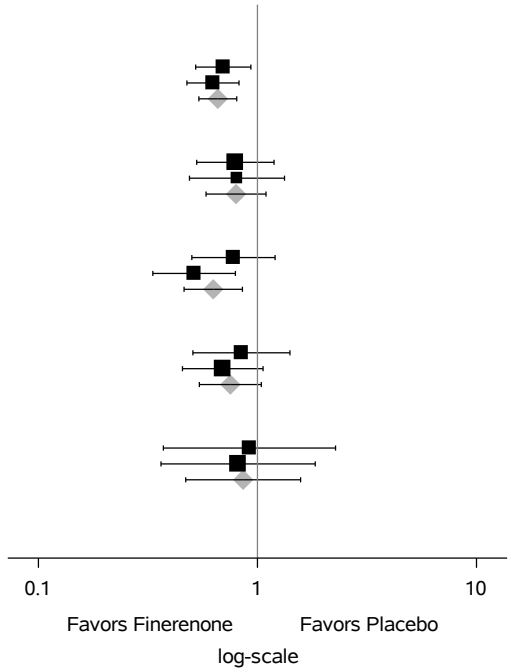
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	212 / 2827	273 / 2831	48.6	0.76 [0.63,0.92]	
FIGARO-DKD	207 / 3683	308 / 3658	51.4	0.65 [0.54,0.78]	
Total	419 / 6510	581 / 6489		0.70 [0.61,0.80]	Z=-5.36, p=<.0001
Heterogeneity:	Q=1.43 (df=1)	p=0.2325	I^2=29.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.143.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

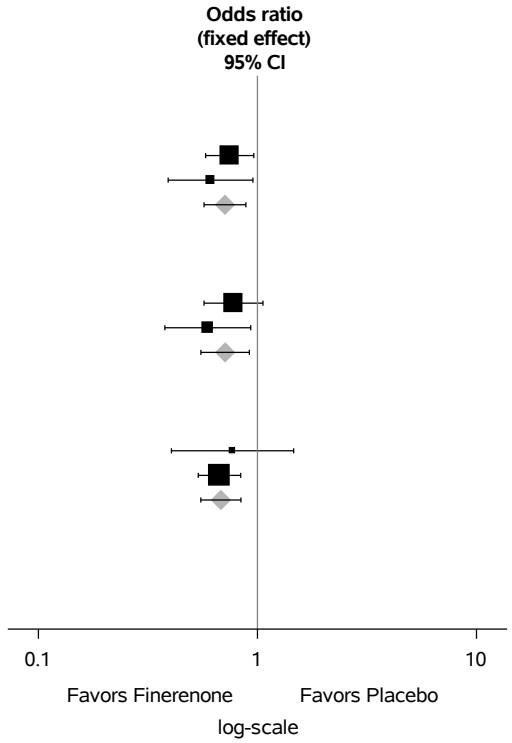
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	86 / 1178	119 / 1174	47.1	0.70 [0.52,0.93]	
FIGARO-DKD	90 / 1752	139 / 1747	52.9	0.63 [0.48,0.82]	
Total	176 / 2930	258 / 2921		0.66 [0.54,0.80]	Z=-4.10, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5941	I^2=0.0%		
North America					
FIDELIO-DKD	47 / 466	59 / 476	60.2	0.79 [0.53,1.19]	
FIGARO-DKD	30 / 559	36 / 548	39.8	0.81 [0.49,1.33]	
Total	77 / 1025	95 / 1024		0.80 [0.58,1.09]	Z=-1.40, p=0.1613
Heterogeneity:	Q=0.00 (df=1)	p=0.9583	I^2=0.0%		
Asia					
FIDELIO-DKD	38 / 790	48 / 786	49.6	0.78 [0.50,1.20]	
FIGARO-DKD	33 / 811	62 / 813	50.4	0.51 [0.33,0.79]	
Total	71 / 1601	110 / 1599		0.63 [0.46,0.85]	Z=-2.97, p=0.0030
Heterogeneity:	Q=1.73 (df=1)	p=0.1884	I^2=42.2%		
Latin America					
FIDELIO-DKD	31 / 294	36 / 294	40.8	0.84 [0.51,1.41]	
FIGARO-DKD	42 / 424	57 / 417	59.2	0.69 [0.45,1.06]	
Total	73 / 718	93 / 711		0.75 [0.54,1.04]	Z=-1.72, p=0.0863
Heterogeneity:	Q=0.34 (df=1)	p=0.5624	I^2=0.0%		
Others					
FIDELIO-DKD	10 / 99	11 / 101	44.5	0.92 [0.37,2.27]	
FIGARO-DKD	12 / 137	14 / 133	55.5	0.82 [0.36,1.84]	
Total	22 / 236	25 / 234		0.86 [0.47,1.57]	Z=-0.49, p=0.6256
Heterogeneity:	Q=0.04 (df=1)	p=0.8475	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.13 (df=4)	p=0.7122	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.143.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

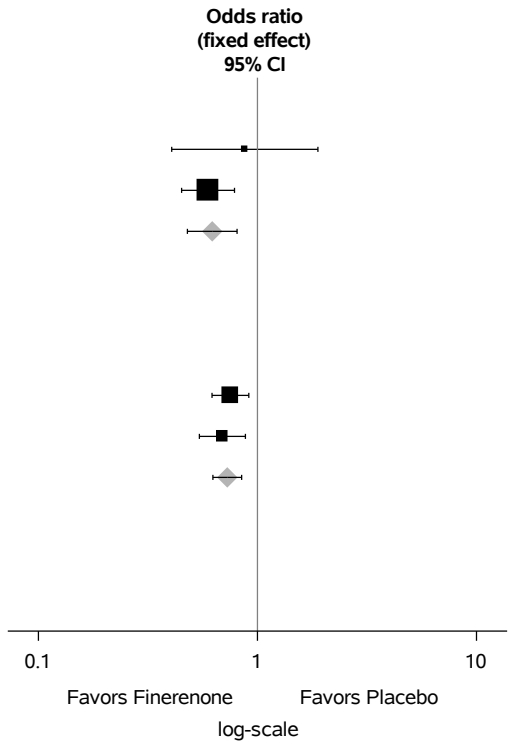
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	116 / 1556	150 / 1541	75.6	0.75 [0.58,0.96]	
FIGARO-DKD	34 / 637	53 / 627	24.4	0.61 [0.39,0.95]	
Total	150 / 2193	203 / 2168		0.71 [0.57,0.89]	Z=-3.04, p=0.0023
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	78 / 1061	99 / 1069	68.0	0.78 [0.57,1.06]	
FIGARO-DKD	32 / 720	53 / 729	32.0	0.59 [0.38,0.93]	
Total	110 / 1781	152 / 1798		0.71 [0.55,0.92]	Z=-2.61, p=0.0090
Heterogeneity:	Q=0.94 (df=1)	p=0.3329	I^2=0.0%		
>= 60					
FIDELIO-DKD	18 / 210	24 / 221	10.8	0.77 [0.40,1.46]	
FIGARO-DKD	141 / 2326	202 / 2302	89.2	0.67 [0.54,0.84]	
Total	159 / 2536	226 / 2523		0.68 [0.55,0.84]	Z=-3.57, p=0.0004
Heterogeneity:	Q=0.16 (df=1)	p=0.6926	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=2)	p=0.9501	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.143.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

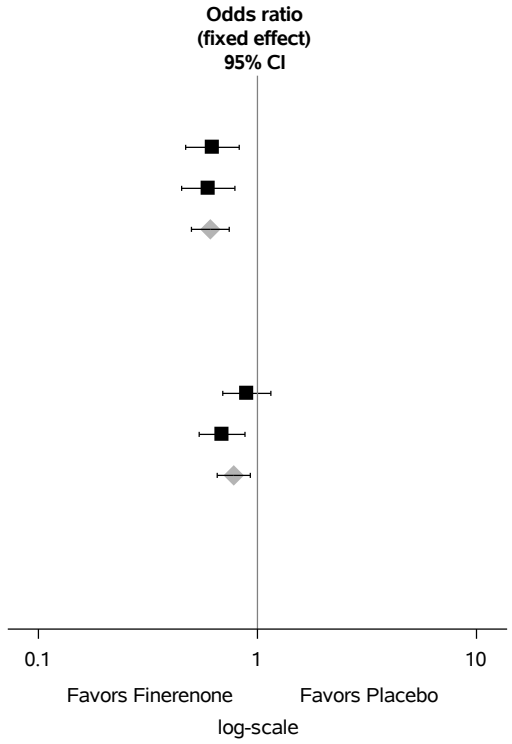
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	13 / 209	15 / 213	11.6	0.88 [0.41,1.89]	
FIGARO-DKD	86 / 1720	138 / 1698	88.4	0.59 [0.45,0.79]	
Total	99 / 1929	153 / 1911		0.62 [0.48,0.81]	Z=-3.57, p=0.0004
Heterogeneity:	Q=0.86 (df=1)	p=0.3542	I^2=0.0%		
Very High					
FIDELIO-DKD	199 / 2618	258 / 2618	61.0	0.75 [0.62,0.91]	
FIGARO-DKD	121 / 1963	170 / 1960	39.0	0.69 [0.54,0.88]	
Total	320 / 4581	428 / 4578		0.73 [0.63,0.85]	Z=-4.12, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5938	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.06 (df=1)	p=0.3043	I^2=5.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.143.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

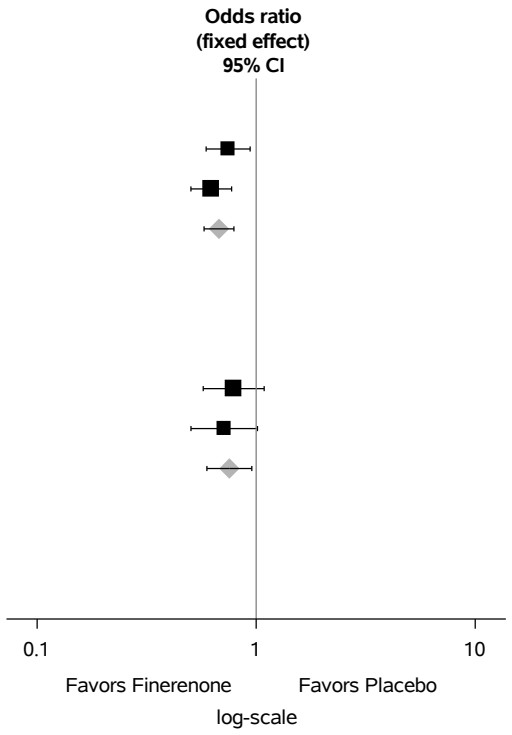
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	87 / 1301	134 / 1299	49.7	0.62 [0.47,0.83]	
FIGARO-DKD	85 / 1673	136 / 1651	50.3	0.60 [0.45,0.79]	
Total	172 / 2974	270 / 2950		0.61 [0.50,0.74]	Z=-4.89, p=<.0001
Heterogeneity:	Q=0.05 (df=1)	p=0.8283	I^2=0.0%		
Absent					
FIDELIO-DKD	125 / 1526	139 / 1532	47.6	0.89 [0.69,1.15]	
FIGARO-DKD	122 / 2010	172 / 2007	52.4	0.69 [0.54,0.88]	
Total	247 / 3536	311 / 3539		0.78 [0.66,0.93]	Z=-2.80, p=0.0050
Heterogeneity:	Q=2.13 (df=1)	p=0.1442	I^2=53.1%		
Subgroup Heterogeneity:	Q=3.34 (df=1)	p=0.0675	I^2=70.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.143.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

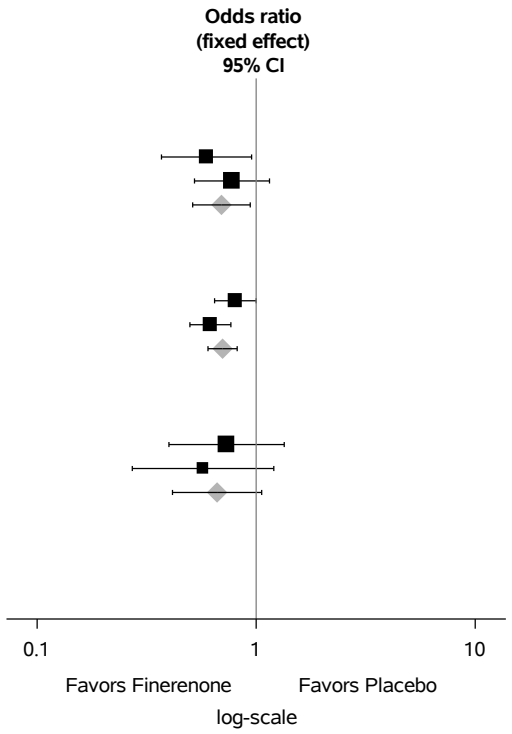
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	139 / 1879	180 / 1858	46.1	0.74 [0.59,0.94]	
FIGARO-DKD	149 / 2643	228 / 2608	53.9	0.62 [0.50,0.77]	
Total	288 / 4522	408 / 4466		0.68 [0.58,0.79]	Z=-4.88, p=<.0001
Heterogeneity:	Q=1.22 (df=1)	p=0.2697	I^2=17.9%		
> 4.5					
FIDELIO-DKD	73 / 948	93 / 973	54.3	0.79 [0.57,1.09]	
FIGARO-DKD	58 / 1040	80 / 1048	45.7	0.71 [0.50,1.01]	
Total	131 / 1988	173 / 2021		0.75 [0.60,0.96]	Z=-2.34, p=0.0192
Heterogeneity:	Q=0.17 (df=1)	p=0.6808	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4517	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.143.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

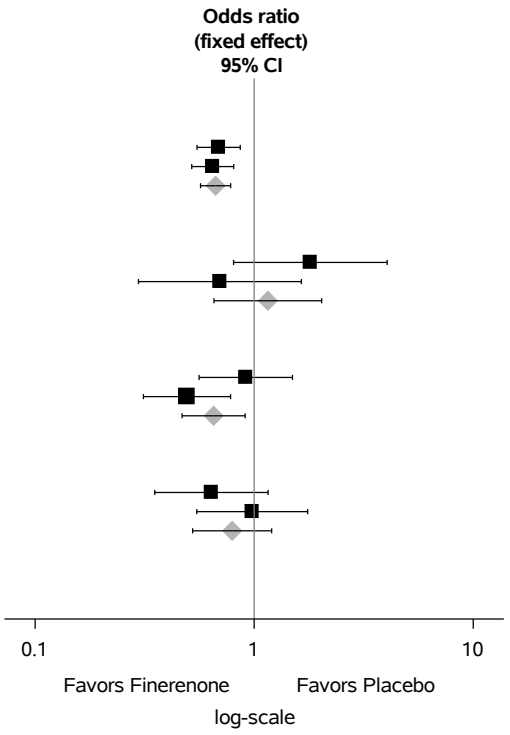
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	29 / 788	47 / 777	40.9	0.59 [0.37,0.95]	
FIGARO-DKD	46 / 1187	59 / 1194	59.1	0.78 [0.52,1.15]	
Total	75 / 1975	106 / 1971		0.69 [0.51,0.94]	Z=-2.36, p=0.0180
Heterogeneity:	Q=0.72 (df=1)	p=0.3947	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	160 / 1897	197 / 1916	49.2	0.80 [0.65,1.00]	
FIGARO-DKD	148 / 2389	227 / 2351	50.8	0.62 [0.50,0.77]	
Total	308 / 4286	424 / 4267		0.70 [0.60,0.82]	Z=-4.51, p=<.0001
Heterogeneity:	Q=2.81 (df=1)	p=0.0934	I^2=64.5%		
>= 160					
FIDELIO-DKD	23 / 141	29 / 138	60.1	0.73 [0.40,1.34]	
FIGARO-DKD	13 / 107	22 / 113	39.9	0.57 [0.27,1.20]	
Total	36 / 248	51 / 251		0.66 [0.41,1.06]	Z=-1.72, p=0.0859
Heterogeneity:	Q=0.26 (df=1)	p=0.6133	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=2)	p=0.9734	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.143.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

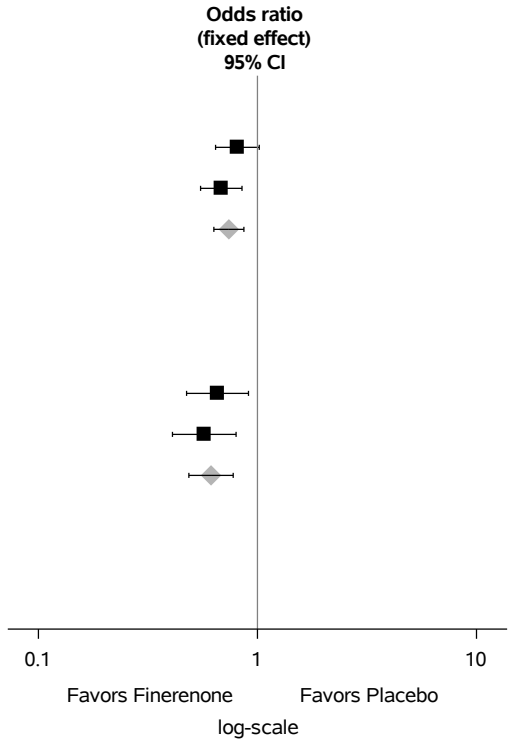
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	139 / 1773	199 / 1809	48.5	0.69 [0.55,0.86]	
FIGARO-DKD	142 / 2668	208 / 2601	51.5	0.65 [0.52,0.81]	
Total	281 / 4441	407 / 4410		0.67 [0.57,0.78]	Z=-5.02, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.7004	I^2=0.0%		
Black					
FIDELIO-DKD	19 / 139	10 / 124	52.9	1.80 [0.80,4.05]	
FIGARO-DKD	9 / 113	16 / 145	47.1	0.70 [0.30,1.64]	
Total	28 / 252	26 / 269		1.15 [0.66,2.03]	Z=0.50, p=0.6189
Heterogeneity:	Q=2.50 (df=1)	p=0.1135	I^2=60.1%		
Asian					
FIDELIO-DKD	32 / 717	35 / 721	46.6	0.92 [0.56,1.50]	
FIGARO-DKD	29 / 716	58 / 736	53.4	0.49 [0.31,0.78]	
Total	61 / 1433	93 / 1457		0.65 [0.47,0.91]	Z=-2.52, p=0.0117
Heterogeneity:	Q=3.26 (df=1)	p=0.0711	I^2=69.3%		
Others					
FIDELIO-DKD	22 / 198	29 / 177	48.9	0.64 [0.35,1.16]	
FIGARO-DKD	27 / 186	26 / 176	51.1	0.98 [0.55,1.75]	
Total	49 / 384	55 / 353		0.79 [0.52,1.20]	Z=-1.09, p=0.2750
Heterogeneity:	Q=1.02 (df=1)	p=0.3131	I^2=1.7%		
Subgroup Heterogeneity:	Q=3.88 (df=3)	p=0.2745	I^2=22.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.143.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

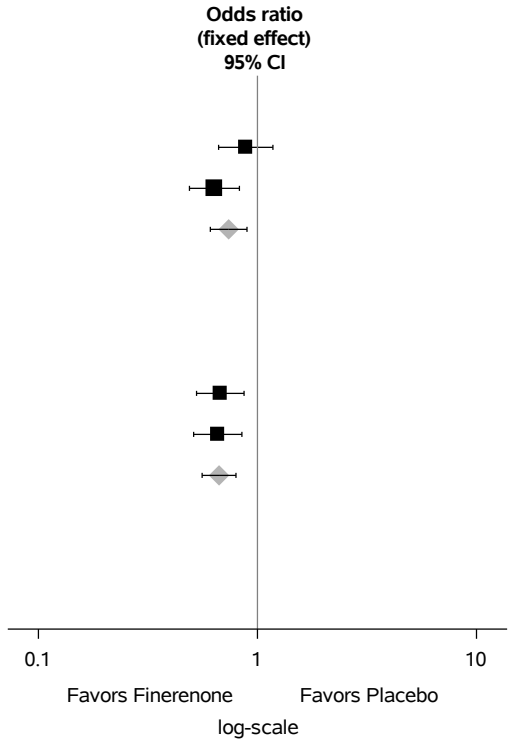
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	142 / 1949	179 / 2024	47.3	0.81 [0.64,1.02]	
FIGARO-DKD	147 / 2527	213 / 2571	52.7	0.68 [0.55,0.85]	
Total	289 / 4476	392 / 4595		0.74 [0.63,0.87]	Z=-3.73, p=0.0002
Heterogeneity:	Q=1.10 (df=1)	p=0.2941	I^2=9.2%		
Female					
FIDELIO-DKD	70 / 878	94 / 807	51.4	0.66 [0.47,0.91]	
FIGARO-DKD	60 / 1156	95 / 1087	48.6	0.57 [0.41,0.80]	
Total	130 / 2034	189 / 1894		0.61 [0.49,0.77]	Z=-4.11, p=<.0001
Heterogeneity:	Q=0.34 (df=1)	p=0.5583	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.71 (df=1)	p=0.1914	I^2=41.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.143.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set

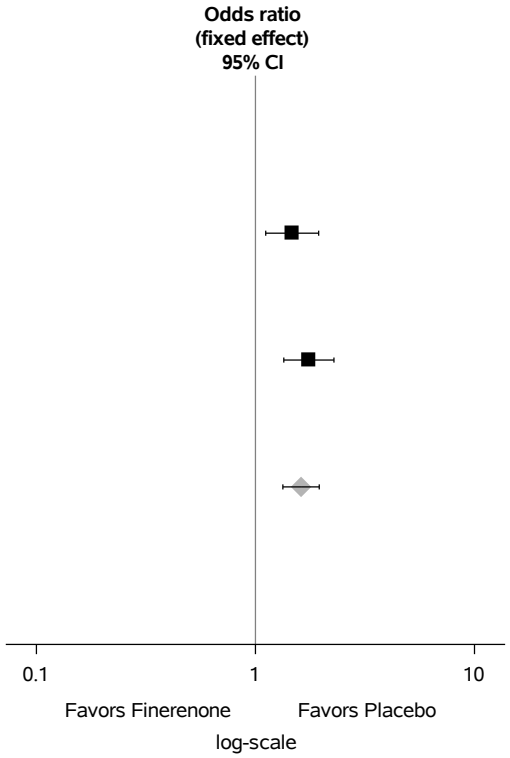
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	99 / 1201	108 / 1171	45.8	0.88 [0.66,1.18]	
FIGARO-DKD	99 / 1752	151 / 1755	54.2	0.64 [0.49,0.83]	
Total	198 / 2953	259 / 2926		0.74 [0.61,0.90]	Z=-3.08, p=0.0021
Heterogeneity:	Q=2.77 (df=1)	p=0.0962	I^2=63.9%		
>= 65					
FIDELIO-DKD	113 / 1626	165 / 1660	50.8	0.68 [0.53,0.87]	
FIGARO-DKD	108 / 1931	157 / 1903	49.2	0.66 [0.51,0.85]	
Total	221 / 3557	322 / 3563		0.67 [0.56,0.80]	Z=-4.45, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8829	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4506	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

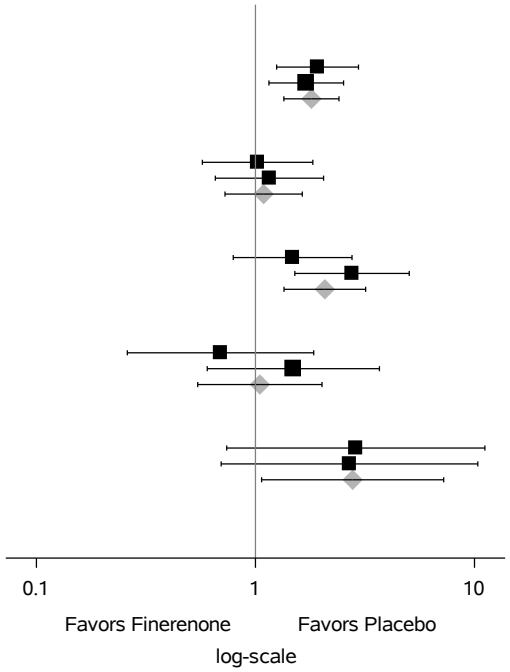
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	126 / 2827	87 / 2831	47.3	1.47 [1.11,1.94]	
FIGARO-DKD	156 / 3683	90 / 3658	52.7	1.75 [1.35,2.28]	
Total	282 / 6510	177 / 6489		1.62 [1.33,1.96]	Z=4.92, p=<.0001
Heterogeneity:	Q=0.80 (df=1)	p=0.3697	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.144.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

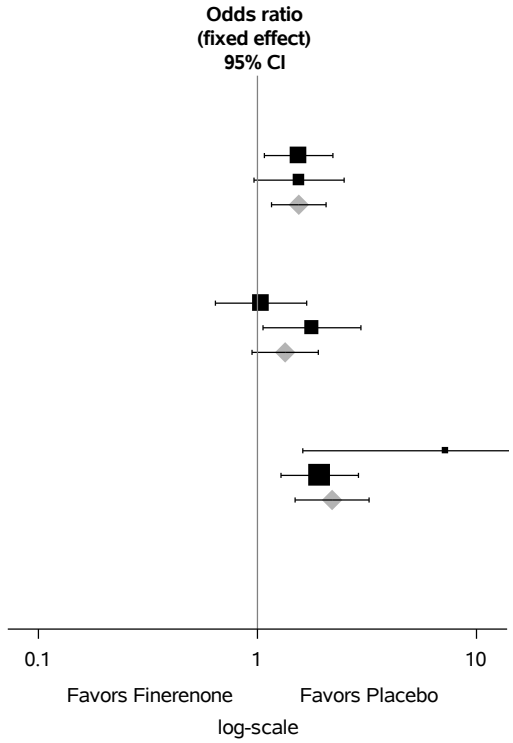
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	62 / 1178	33 / 1174	45.4	1.92 [1.25,2.95]	
FIGARO-DKD	69 / 1752	41 / 1747	54.6	1.71 [1.15,2.53]	
Total	131 / 2930	74 / 2921		1.80 [1.35,2.41]	Z=3.98, p=<.0001
Heterogeneity:	Q=0.16 (df=1)	p=0.6896	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 466	24 / 476	49.0	1.02 [0.57,1.83]	
FIGARO-DKD	27 / 559	23 / 548	51.0	1.16 [0.66,2.05]	
Total	51 / 1025	47 / 1024		1.09 [0.73,1.64]	Z=0.42, p=0.6779
Heterogeneity:	Q=0.09 (df=1)	p=0.7637	I^2=0.0%		
Asia					
FIDELIO-DKD	25 / 790	17 / 786	48.2	1.48 [0.79,2.76]	
FIGARO-DKD	40 / 811	15 / 813	51.8	2.76 [1.51,5.04]	
Total	65 / 1601	32 / 1599		2.07 [1.35,3.19]	Z=3.33, p=0.0009
Heterogeneity:	Q=2.00 (df=1)	p=0.1576	I^2=49.9%		
Latin America					
FIDELIO-DKD	7 / 294	10 / 294	46.0	0.69 [0.26,1.85]	
FIGARO-DKD	12 / 424	8 / 417	54.0	1.49 [0.60,3.68]	
Total	19 / 718	18 / 711		1.05 [0.54,2.01]	Z=0.14, p=0.8896
Heterogeneity:	Q=1.26 (df=1)	p=0.2607	I^2=20.9%		
Others					
FIDELIO-DKD	8 / 99	3 / 101	49.7	2.87 [0.74,11.16]	
FIGARO-DKD	8 / 137	3 / 133	50.3	2.69 [0.70,10.36]	
Total	16 / 236	6 / 234		2.78 [1.07,7.23]	Z=2.09, p=0.0364
Heterogeneity:	Q=0.00 (df=1)	p=0.9458	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.37 (df=4)	p=0.0790	I^2=52.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

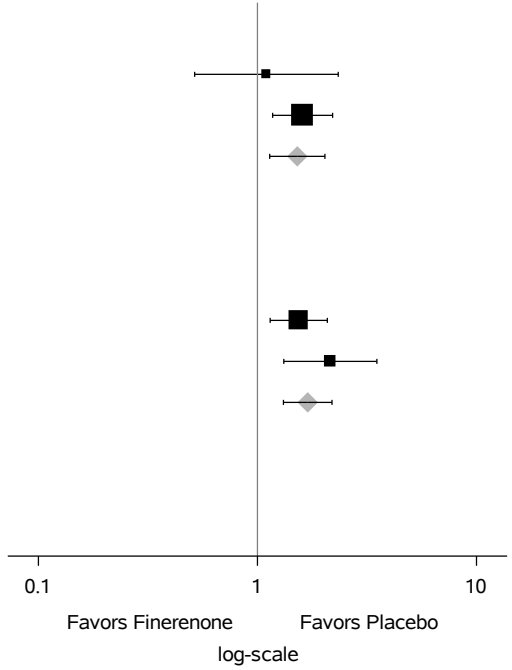
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	78 / 1556	51 / 1541	63.4	1.54 [1.08,2.21]	
FIGARO-DKD	46 / 637	30 / 627	36.6	1.55 [0.96,2.49]	
Total	124 / 2193	81 / 2168		1.54 [1.16,2.06]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.00 (df=1)	p=0.9880	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	34 / 1069	53.5	1.04 [0.64,1.68]	
FIGARO-DKD	41 / 720	24 / 729	46.5	1.77 [1.06,2.97]	
Total	76 / 1781	58 / 1798		1.34 [0.94,1.90]	Z=1.64, p=0.1012
Heterogeneity:	Q=2.22 (df=1)	p=0.1358	I^2=55.1%		
>= 60					
FIDELIO-DKD	13 / 210	2 / 221	6.9	7.23 [1.61,32.42]	
FIGARO-DKD	69 / 2326	36 / 2302	93.1	1.92 [1.28,2.89]	
Total	82 / 2536	38 / 2523		2.19 [1.49,3.23]	Z=3.96, p=<.0001
Heterogeneity:	Q=2.82 (df=1)	p=0.0932	I^2=64.5%		
Subgroup Heterogeneity:	Q=3.58 (df=2)	p=0.1669	I^2=44.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

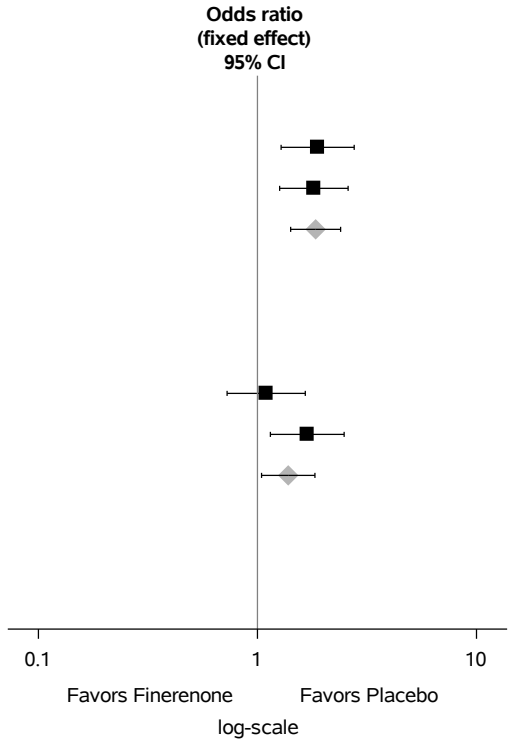
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	15 / 209	14 / 213	14.9	1.10 [0.52,2.34]	
FIGARO-DKD	105 / 1720	66 / 1698	85.1	1.61 [1.17,2.20]	
Total	120 / 1929	80 / 1911		1.52 [1.14,2.03]	Z=2.83, p=0.0047
Heterogeneity:	Q=0.83 (df=1)	p=0.3621	I^2=0.0%		
Very High					
FIDELIO-DKD	111 / 2618	73 / 2618	72.6	1.54 [1.14,2.08]	
FIGARO-DKD	51 / 1963	24 / 1960	27.4	2.15 [1.32,3.51]	
Total	162 / 4581	97 / 4578		1.70 [1.31,2.19]	Z=4.06, p=<.0001
Heterogeneity:	Q=1.29 (df=1)	p=0.2568	I^2=22.2%		
Subgroup Heterogeneity:	Q=0.31 (df=1)	p=0.5799	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

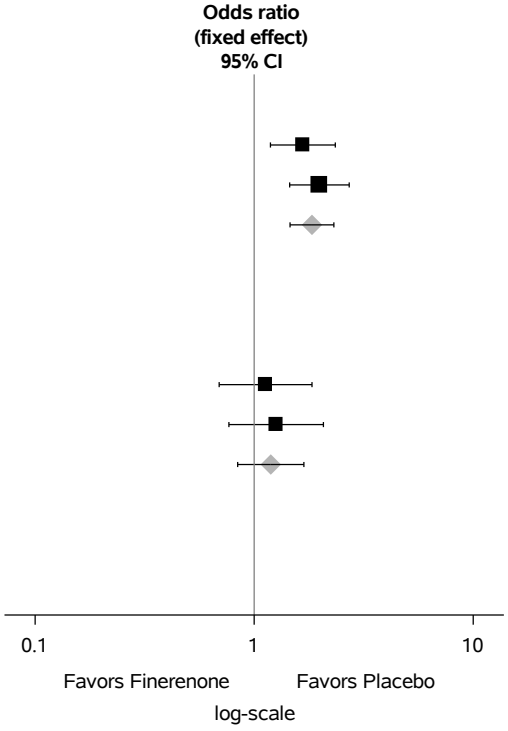
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	77 / 1301	42 / 1299	46.7	1.88 [1.28,2.76]	
FIGARO-DKD	86 / 1673	48 / 1651	53.3	1.81 [1.26,2.59]	
Total	163 / 2974	90 / 2950		1.84 [1.42,2.40]	Z=4.57, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8829	I^2=0.0%		
Absent					
FIDELIO-DKD	49 / 1526	45 / 1532	47.1	1.10 [0.73,1.65]	
FIGARO-DKD	70 / 2010	42 / 2007	52.9	1.69 [1.15,2.49]	
Total	119 / 3536	87 / 3539		1.38 [1.04,1.83]	Z=2.26, p=0.0238
Heterogeneity:	Q=2.24 (df=1)	p=0.1342	I^2=55.4%		
Subgroup Heterogeneity:	Q=2.16 (df=1)	p=0.1416	I^2=53.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

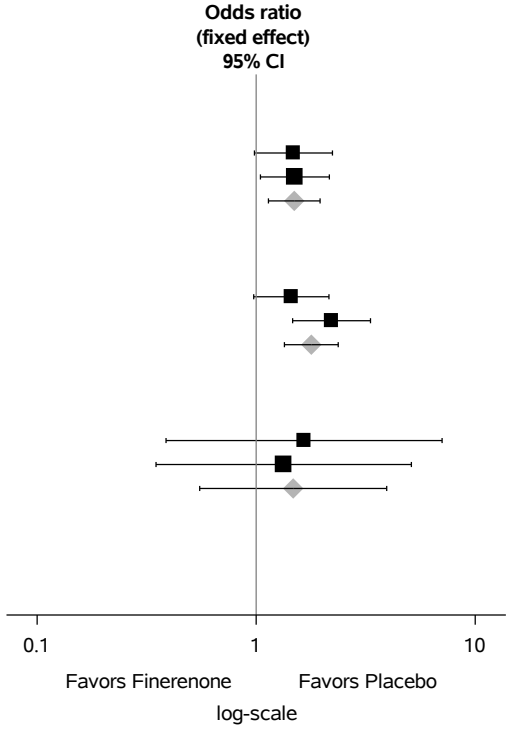
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	91 / 1879	55 / 1858	45.7	1.67 [1.19,2.35]	
FIGARO-DKD	120 / 2643	61 / 2608	54.3	1.99 [1.45,2.72]	
Total	211 / 4522	116 / 4466		1.84 [1.46,2.31]	Z=5.17, p=<.0001
Heterogeneity:	Q=0.54 (df=1)	p=0.4608	I^2=0.0%		
> 4.5					
FIDELIO-DKD	35 / 948	32 / 973	50.9	1.13 [0.69,1.84]	
FIGARO-DKD	36 / 1040	29 / 1048	49.1	1.26 [0.77,2.07]	
Total	71 / 1988	61 / 2021		1.19 [0.84,1.69]	Z=0.98, p=0.3255
Heterogeneity:	Q=0.10 (df=1)	p=0.7542	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.13 (df=1)	p=0.0421	I^2=75.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.144.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

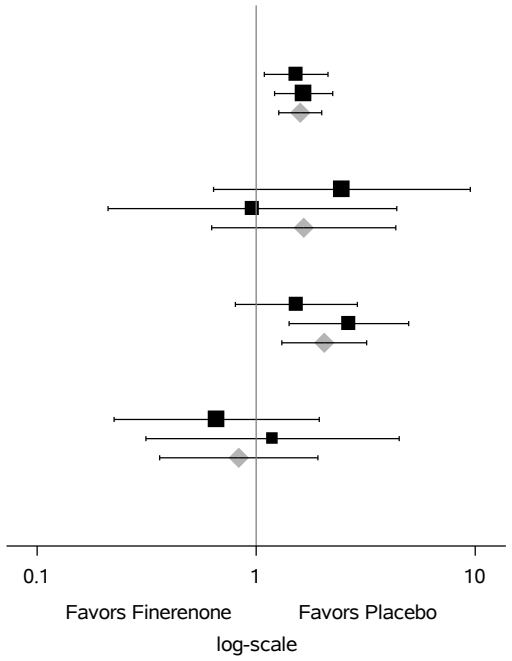
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	60 / 788	41 / 777	43.8	1.48 [0.98,2.23]	
FIGARO-DKD	76 / 1187	52 / 1194	56.2	1.50 [1.05,2.16]	
Total	136 / 1975	93 / 1971		1.49 [1.14,1.96]	Z=2.89, p=0.0039
Heterogeneity:	Q=0.00 (df=1)	p=0.9563	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	61 / 1897	43 / 1916	51.7	1.45 [0.97,2.15]	
FIGARO-DKD	75 / 2389	34 / 2351	48.3	2.21 [1.47,3.33]	
Total	136 / 4286	77 / 4267		1.79 [1.35,2.37]	Z=4.02, p=<.0001
Heterogeneity:	Q=2.12 (df=1)	p=0.1453	I^2=52.9%		
>= 160					
FIDELIO-DKD	5 / 141	3 / 138	46.1	1.65 [0.39,7.06]	
FIGARO-DKD	5 / 107	4 / 113	53.9	1.34 [0.35,5.11]	
Total	10 / 248	7 / 251		1.48 [0.55,3.94]	Z=0.78, p=0.4378
Heterogeneity:	Q=0.05 (df=1)	p=0.8320	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.84 (df=2)	p=0.6569	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.144.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

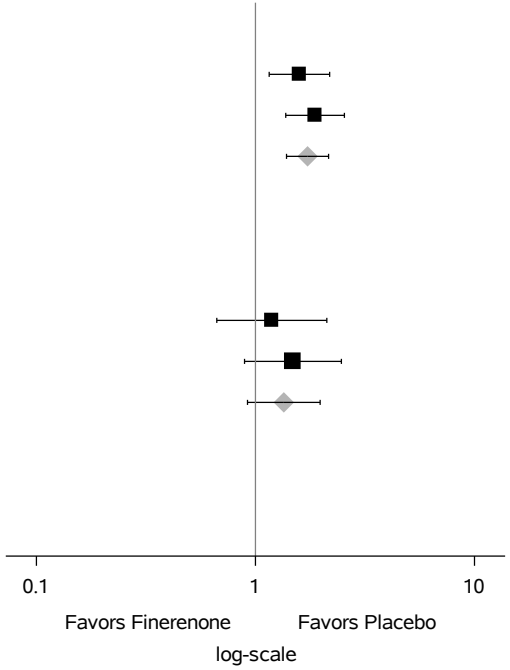
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	88 / 1773	60 / 1809	45.5	1.52 [1.09,2.13]	
FIGARO-DKD	113 / 2668	68 / 2601	54.5	1.65 [1.21,2.24]	
Total	201 / 4441	128 / 4410		1.59 [1.27,1.99]	Z=4.02, p=<.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7329	I^2=0.0%		
Black					
FIDELIO-DKD	8 / 139	3 / 124	55.8	2.46 [0.64,9.50]	
FIGARO-DKD	3 / 113	4 / 145	44.2	0.96 [0.21,4.38]	
Total	11 / 252	7 / 269		1.65 [0.63,4.34]	Z=1.01, p=0.3111
Heterogeneity:	Q=0.83 (df=1)	p=0.3637	I^2=0.0%		
Asian					
FIDELIO-DKD	24 / 717	16 / 721	49.0	1.53 [0.80,2.90]	
FIGARO-DKD	35 / 716	14 / 736	51.0	2.65 [1.41,4.97]	
Total	59 / 1433	30 / 1457		2.05 [1.31,3.19]	Z=3.15, p=0.0017
Heterogeneity:	Q=1.45 (df=1)	p=0.2277	I^2=31.3%		
Others					
FIDELIO-DKD	6 / 198	8 / 177	60.4	0.66 [0.22,1.94]	
FIGARO-DKD	5 / 186	4 / 176	39.6	1.19 [0.31,4.50]	
Total	11 / 384	12 / 353		0.83 [0.36,1.91]	Z=-0.43, p=0.6666
Heterogeneity:	Q=0.45 (df=1)	p=0.5016	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.53 (df=3)	p=0.3165	I^2=15.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.144.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

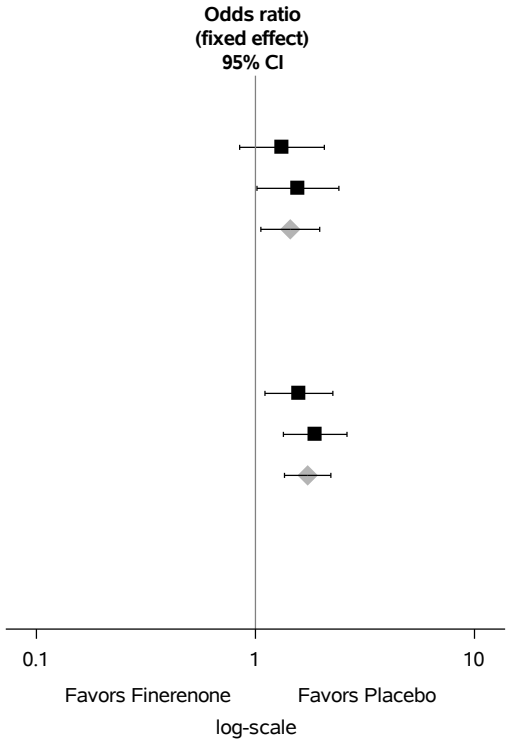
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	99 / 1949	66 / 2024	48.5	1.59 [1.16,2.18]	
FIGARO-DKD	117 / 2527	65 / 2571	51.5	1.87 [1.38,2.55]	
Total	216 / 4476	131 / 4595		1.73 [1.39,2.16]	Z=4.86, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4662	I^2=0.0%		
Female					
FIDELIO-DKD	27 / 878	21 / 807	43.7	1.19 [0.67,2.12]	
FIGARO-DKD	39 / 1156	25 / 1087	56.3	1.48 [0.89,2.47]	
Total	66 / 2034	46 / 1894		1.35 [0.92,1.97]	Z=1.53, p=0.1259
Heterogeneity:	Q=0.32 (df=1)	p=0.5717	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.23 (df=1)	p=0.2673	I^2=18.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.144.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set

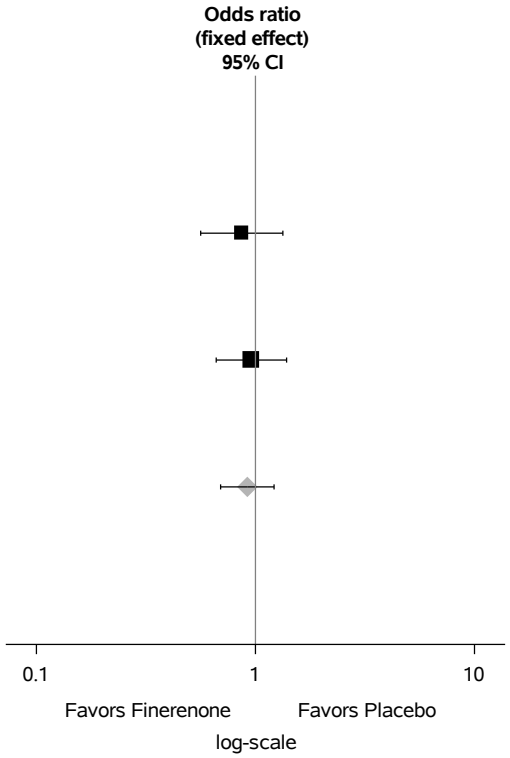
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	47 / 1201	35 / 1171	48.3	1.32 [0.85,2.06]	
FIGARO-DKD	54 / 1752	35 / 1755	51.7	1.56 [1.02,2.40]	
Total	101 / 2953	70 / 2926		1.44 [1.06,1.97]	Z=2.32, p=0.0203
Heterogeneity:	Q=0.28 (df=1)	p=0.5962	I^2=0.0%		
>= 65					
FIDELIO-DKD	79 / 1626	52 / 1660	46.7	1.58 [1.11,2.26]	
FIGARO-DKD	102 / 1931	55 / 1903	53.3	1.87 [1.34,2.62]	
Total	181 / 3557	107 / 3563		1.73 [1.36,2.21]	Z=4.41, p=<.0001
Heterogeneity:	Q=0.47 (df=1)	p=0.4928	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3631	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.145: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set

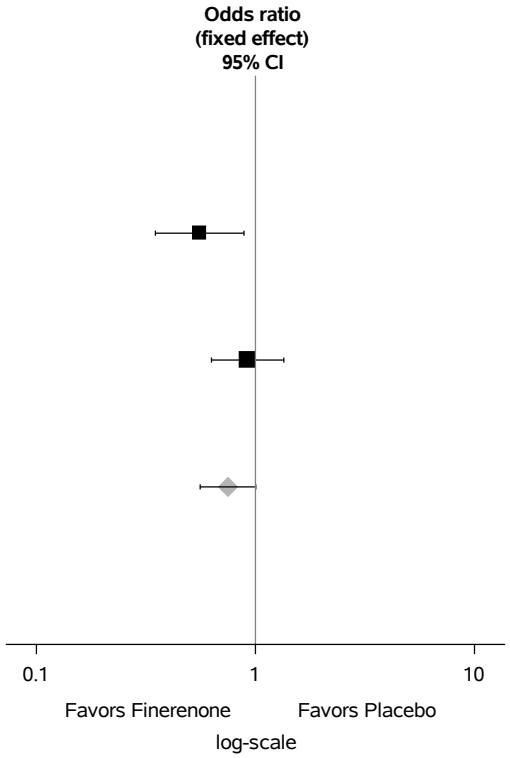
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	39 / 2827	45 / 2831	42.3	0.87 [0.56,1.33]	
FIGARO-DKD	56 / 3683	58 / 3658	57.7	0.96 [0.66,1.39]	
Total	95 / 6510	103 / 6489		0.92 [0.69,1.22]	Z=-0.60, p=0.5510
Heterogeneity:	Q=0.12 (df=1)	p=0.7272	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.146: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

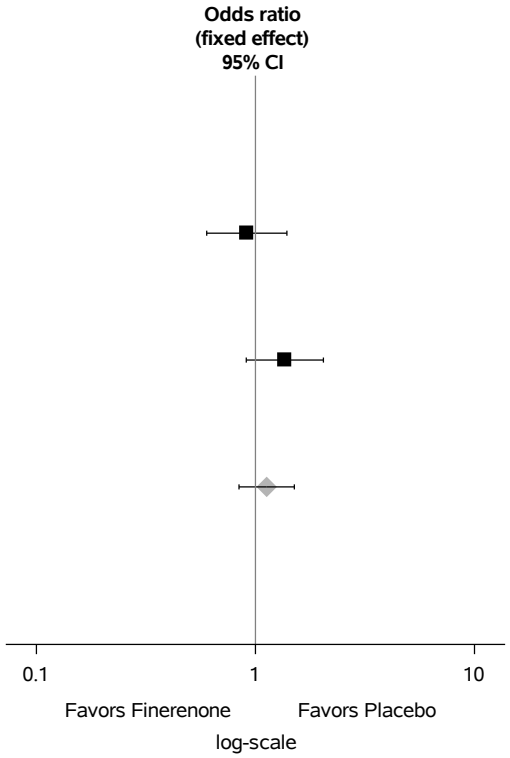
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2827	50 / 2831	40.0	0.56 [0.35,0.89]	
FIGARO-DKD	52 / 3683	56 / 3658	60.0	0.92 [0.63,1.35]	
Total	80 / 6510	106 / 6489		0.75 [0.56,1.00]	Z=-1.94, p=0.0528
Heterogeneity:	Q=2.70 (df=1)	p=0.1002	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.147: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set

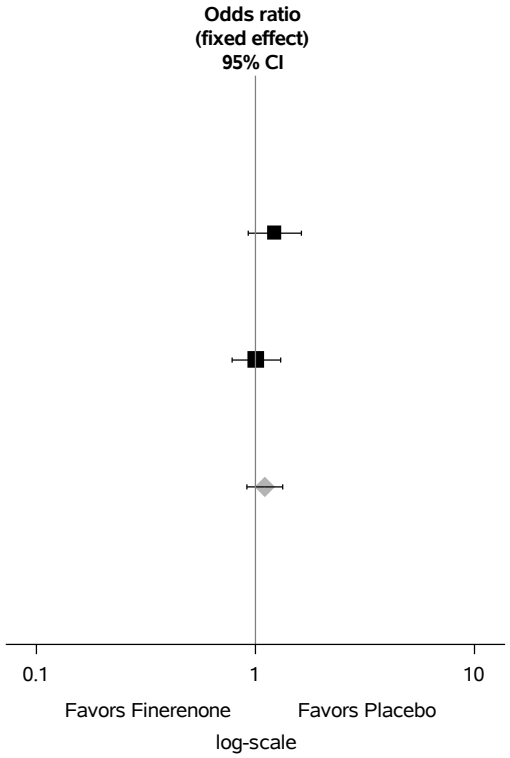
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	46 / 2831	48.1	0.91 [0.60,1.39]	
FIGARO-DKD	56 / 3683	41 / 3658	51.9	1.36 [0.91,2.04]	
Total	98 / 6510	87 / 6489		1.13 [0.84,1.50]	Z=0.79, p=0.4270
Heterogeneity:	Q=1.80 (df=1)	p=0.1802	I^2=44.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.148: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

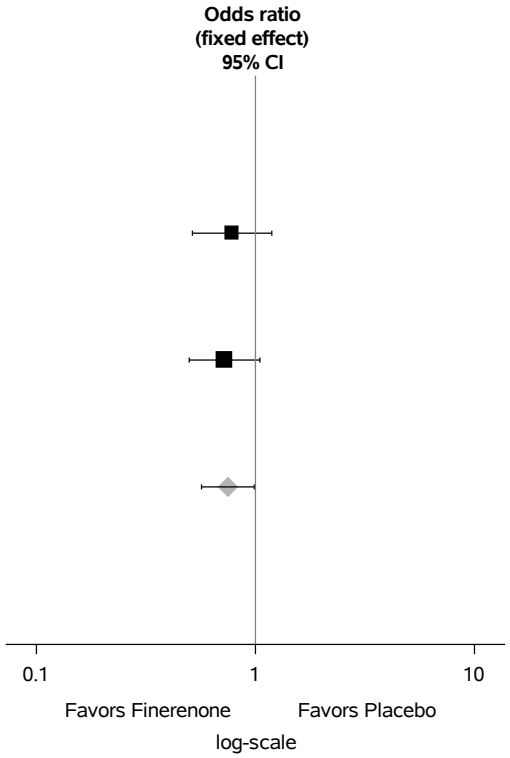
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2827	93 / 2831	45.5	1.23 [0.93,1.62]	
FIGARO-DKD	123 / 3683	121 / 3658	54.5	1.01 [0.78,1.30]	
Total	236 / 6510	214 / 6489		1.10 [0.91,1.33]	Z=1.02, p=0.3066
Heterogeneity:	Q=1.01 (df=1)	p=0.3159	I^2=0.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.149: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

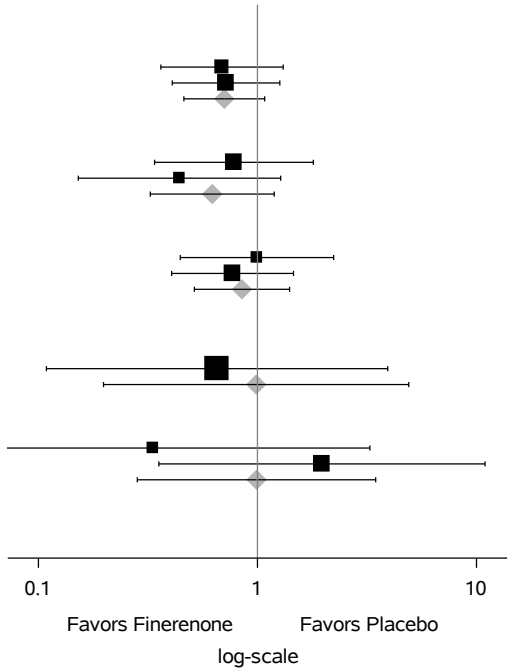
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	51 / 2831	44.2	0.78 [0.52,1.19]	
FIGARO-DKD	49 / 3683	67 / 3658	55.8	0.72 [0.50,1.05]	
Total	89 / 6510	118 / 6489		0.75 [0.57,0.99]	Z=-2.05, p=0.0405
Heterogeneity:	Q=0.08 (df=1)	p=0.7808	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.149.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

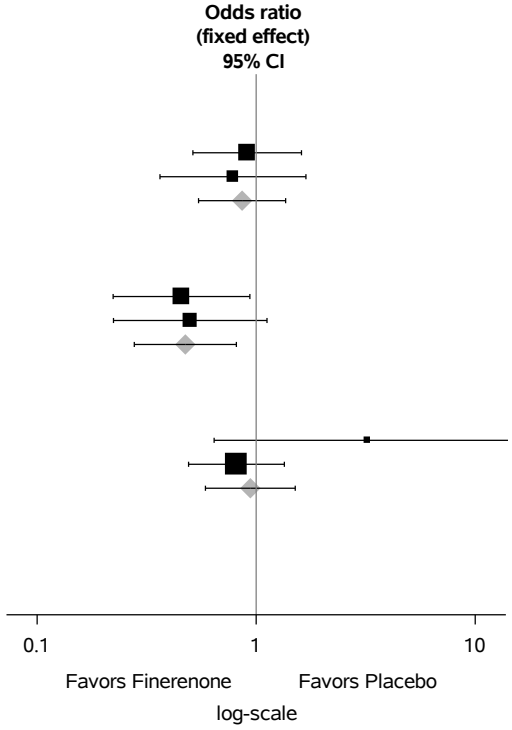
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1178	23 / 1174	43.6	0.69 [0.36,1.31]	
FIGARO-DKD	21 / 1752	29 / 1747	56.4	0.72 [0.41,1.27]	
Total	37 / 2930	52 / 2921		0.71 [0.46,1.08]	Z=-1.61, p=0.1076
Heterogeneity:	Q=0.01 (df=1)	p=0.9232	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 466	13 / 476	61.9	0.78 [0.34,1.80]	
FIGARO-DKD	5 / 559	11 / 548	38.1	0.44 [0.15,1.28]	
Total	15 / 1025	24 / 1024		0.62 [0.32,1.19]	Z=-1.43, p=0.1528
Heterogeneity:	Q=0.69 (df=1)	p=0.4063	I^2=0.0%		
Asia					
FIDELIO-DKD	12 / 790	12 / 786	38.7	0.99 [0.44,2.23]	
FIGARO-DKD	17 / 811	22 / 813	61.3	0.77 [0.41,1.46]	
Total	29 / 1601	34 / 1599		0.85 [0.52,1.40]	Z=-0.64, p=0.5238
Heterogeneity:	Q=0.24 (df=1)	p=0.6255	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 294	0 / 294	0.0	143E9 [143E9,143E9]	
FIGARO-DKD	2 / 424	3 / 417	100.0	0.65 [0.11,3.93]	
Total	3 / 718	3 / 711		0.99 [0.20,4.91]	Z=-0.02, p=0.9864
Heterogeneity:	Q=0.20 (df=1)	p=0.6537	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 99	3 / 101	36.1	0.33 [0.03,3.26]	
FIGARO-DKD	4 / 137	2 / 133	63.9	1.97 [0.35,10.94]	
Total	5 / 236	5 / 234		0.99 [0.28,3.47]	Z=-0.02, p=0.9875
Heterogeneity:	Q=1.49 (df=1)	p=0.2216	I^2=33.1%		
Subgroup Heterogeneity:	Q=0.94 (df=4)	p=0.9192	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.149.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

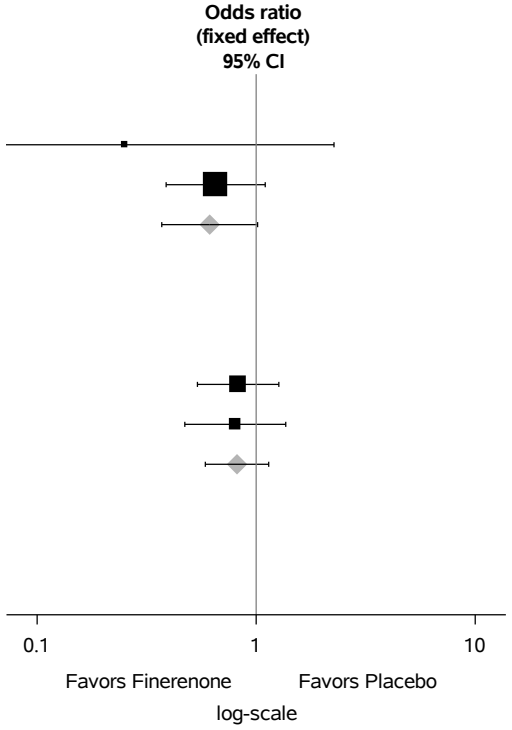
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	23 / 1556	25 / 1541	64.4	0.91 [0.51,1.61]	
FIGARO-DKD	12 / 637	15 / 627	35.6	0.78 [0.36,1.69]	
Total	35 / 2193	40 / 2168		0.86 [0.55,1.36]	Z=-0.63, p=0.5261
Heterogeneity:	Q=0.09 (df=1)	p=0.7591	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	24 / 1069	55.8	0.46 [0.22,0.94]	
FIGARO-DKD	9 / 720	18 / 729	44.2	0.50 [0.22,1.12]	
Total	20 / 1781	42 / 1798		0.47 [0.28,0.81]	Z=-2.72, p=0.0065
Heterogeneity:	Q=0.03 (df=1)	p=0.8678	I^2=0.0%		
>= 60					
FIDELIO-DKD	6 / 210	2 / 221	8.9	3.22 [0.64,16.14]	
FIGARO-DKD	28 / 2326	34 / 2302	91.1	0.81 [0.49,1.34]	
Total	34 / 2536	36 / 2523		0.94 [0.59,1.51]	Z=-0.25, p=0.7989
Heterogeneity:	Q=2.56 (df=1)	p=0.1093	I^2=61.0%		
Subgroup Heterogeneity:	Q=4.02 (df=2)	p=0.1337	I^2=50.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.149.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

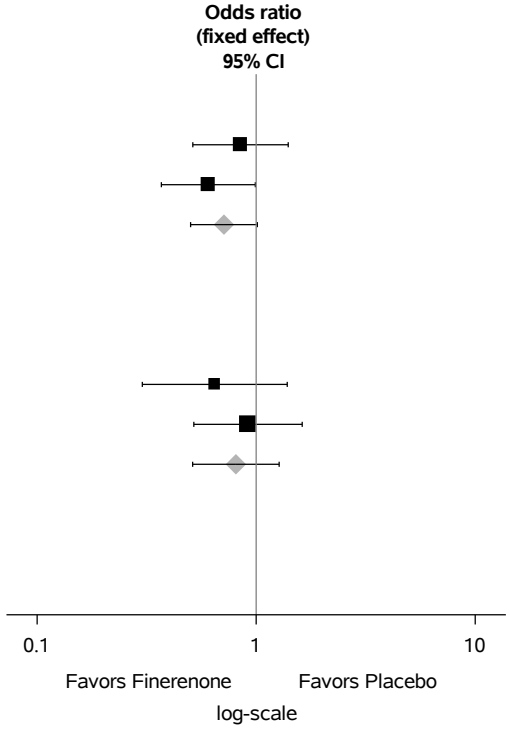
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	4 / 213	5.3	0.25 [0.03,2.27]	
FIGARO-DKD	24 / 1720	36 / 1698	94.7	0.65 [0.39,1.10]	
Total	25 / 1929	40 / 1911		0.61 [0.37,1.02]	Z=-1.90, p=0.0573
Heterogeneity:	Q=0.69 (df=1)	p=0.4065	I^2=0.0%		
Very High					
FIDELIO-DKD	39 / 2618	47 / 2618	60.6	0.83 [0.54,1.27]	
FIGARO-DKD	25 / 1963	31 / 1960	39.4	0.80 [0.47,1.36]	
Total	64 / 4581	78 / 4578		0.82 [0.59,1.14]	Z=-1.19, p=0.2357
Heterogeneity:	Q=0.01 (df=1)	p=0.9311	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.87 (df=1)	p=0.3515	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.149.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

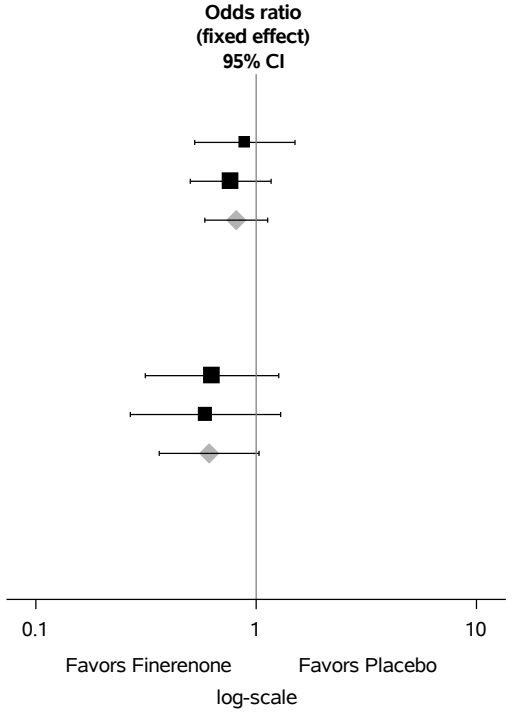
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	29 / 1301	34 / 1299	49.2	0.85 [0.51,1.40]	
FIGARO-DKD	26 / 1673	42 / 1651	50.8	0.60 [0.37,0.99]	
Total	55 / 2974	76 / 2950		0.71 [0.50,1.01]	Z=-1.89, p=0.0586
Heterogeneity:	Q=0.89 (df=1)	p=0.3461	I^2=0.0%		
Absent					
FIDELIO-DKD	11 / 1526	17 / 1532	35.9	0.65 [0.30,1.39]	
FIGARO-DKD	23 / 2010	25 / 2007	64.1	0.92 [0.52,1.62]	
Total	34 / 3536	42 / 3539		0.81 [0.51,1.27]	Z=-0.92, p=0.3582
Heterogeneity:	Q=0.52 (df=1)	p=0.4715	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6687	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.149.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

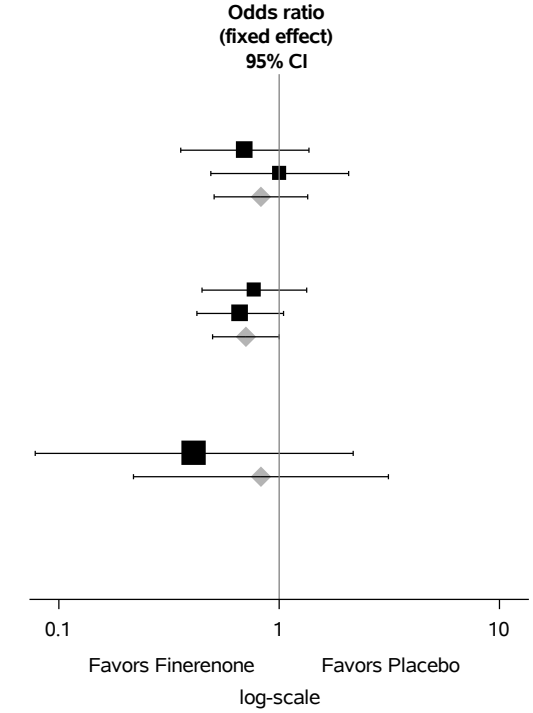
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	27 / 1879	30 / 1858	39.4	0.89 [0.53,1.50]	
FIGARO-DKD	39 / 2643	50 / 2608	60.6	0.77 [0.50,1.17]	
Total	66 / 4522	80 / 4466		0.81 [0.58,1.13]	Z=-1.24, p=0.2141
Heterogeneity:	Q=0.19 (df=1)	p=0.6667	I^2=0.0%		
> 4.5					
FIDELIO-DKD	13 / 948	21 / 973	55.9	0.63 [0.31,1.27]	
FIGARO-DKD	10 / 1040	17 / 1048	44.1	0.59 [0.27,1.29]	
Total	23 / 1988	38 / 2021		0.61 [0.36,1.03]	Z=-1.85, p=0.0647
Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=1)	p=0.3675	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.149.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

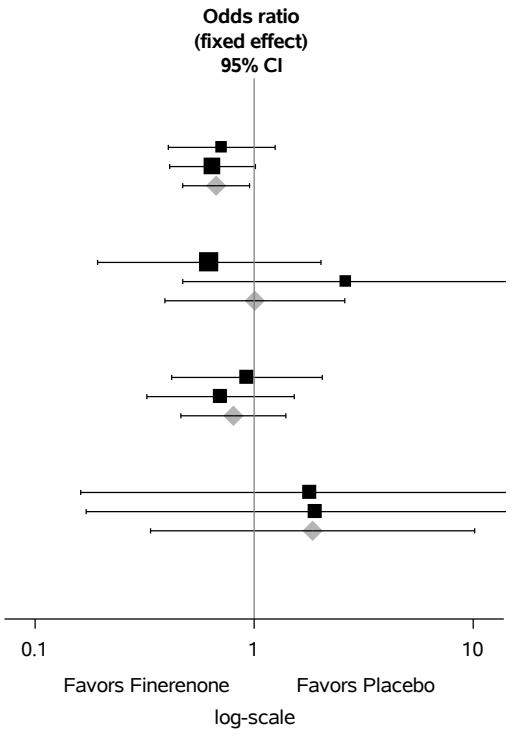
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	21 / 777	53.6	0.70 [0.36,1.37]	
FIGARO-DKD	15 / 1187	15 / 1194	46.4	1.01 [0.49,2.07]	
Total	30 / 1975	36 / 1971		0.83 [0.51,1.35]	Z=-0.76, p=0.4444
Heterogeneity:	Q=0.53 (df=1)	p=0.4675	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	23 / 1897	30 / 1916	40.7	0.77 [0.45,1.33]	
FIGARO-DKD	32 / 2389	47 / 2351	59.3	0.67 [0.42,1.05]	
Total	55 / 4286	77 / 4267		0.71 [0.50,1.00]	Z=-1.95, p=0.0508
Heterogeneity:	Q=0.17 (df=1)	p=0.6832	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 141	0 / 138	0.0	222E9 [222E9,222E9]	
FIGARO-DKD	2 / 107	5 / 113	100.0	0.41 [0.08,2.17]	
Total	4 / 248	5 / 251		0.83 [0.22,3.13]	Z=-0.28, p=0.7793
Heterogeneity:	Q=0.68 (df=1)	p=0.4106	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=2)	p=0.8677	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.149.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

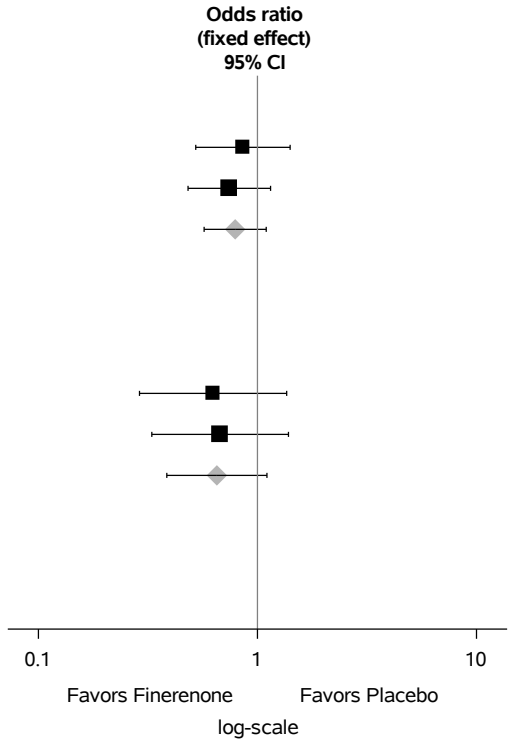
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1773	30 / 1809	39.2	0.71 [0.41,1.25]	
FIGARO-DKD	32 / 2668	48 / 2601	60.8	0.65 [0.41,1.01]	
Total	53 / 4441	78 / 4410		0.67 [0.47,0.95]	Z=-2.23, p=0.0257
Heterogeneity:	Q=0.07 (df=1)	p=0.7937	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	7 / 124	68.1	0.62 [0.19,2.02]	
FIGARO-DKD	4 / 113	2 / 145	31.9	2.62 [0.47,14.59]	
Total	9 / 252	9 / 269		1.01 [0.39,2.59]	Z=0.01, p=0.9885
Heterogeneity:	Q=1.84 (df=1)	p=0.1753	I^2=45.6%		
Asian					
FIDELIO-DKD	12 / 717	13 / 721	48.9	0.93 [0.42,2.05]	
FIGARO-DKD	11 / 716	16 / 736	51.1	0.70 [0.32,1.52]	
Total	23 / 1433	29 / 1457		0.80 [0.46,1.40]	Z=-0.78, p=0.4375
Heterogeneity:	Q=0.24 (df=1)	p=0.6229	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 198	1 / 177	50.0	1.80 [0.16,19.98]	
FIGARO-DKD	2 / 186	1 / 176	50.0	1.90 [0.17,21.17]	
Total	4 / 384	2 / 353		1.85 [0.34,10.16]	Z=0.71, p=0.4797
Heterogeneity:	Q=0.00 (df=1)	p=0.9736	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.90 (df=3)	p=0.5930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.149.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

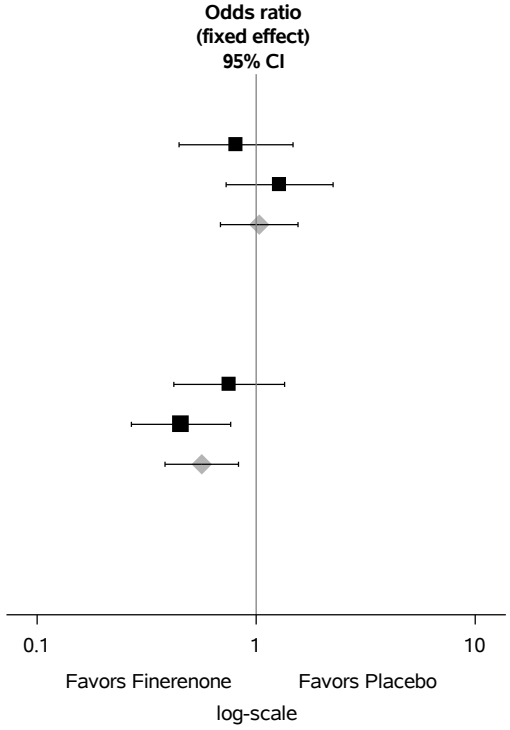
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	29 / 1949	35 / 2024	43.3	0.86 [0.52,1.41]	
FIGARO-DKD	36 / 2527	49 / 2571	56.7	0.74 [0.48,1.15]	
Total	65 / 4476	84 / 4595		0.79 [0.57,1.10]	Z=-1.41, p=0.1597
Heterogeneity:	Q=0.18 (df=1)	p=0.6702	I^2=0.0%		
Female					
FIDELIO-DKD	11 / 878	16 / 807	46.3	0.63 [0.29,1.36]	
FIGARO-DKD	13 / 1156	18 / 1087	53.7	0.68 [0.33,1.39]	
Total	24 / 2034	34 / 1894		0.65 [0.39,1.10]	Z=-1.59, p=0.1120
Heterogeneity:	Q=0.02 (df=1)	p=0.8906	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=1)	p=0.5423	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.149.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

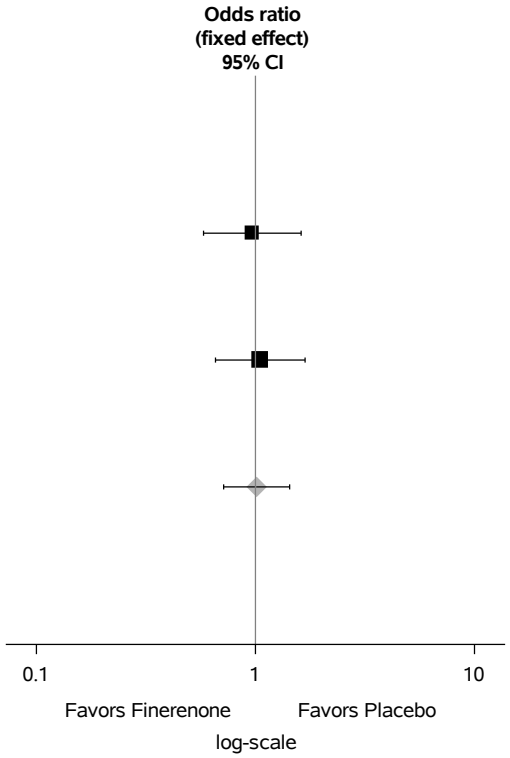
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	20 / 1201	24 / 1171	46.9	0.81 [0.44,1.47]	
FIGARO-DKD	28 / 1752	22 / 1755	53.1	1.28 [0.73,2.25]	
Total	48 / 2953	46 / 2926		1.03 [0.69,1.55]	Z=0.15, p=0.8772
Heterogeneity:	Q=1.19 (df=1)	p=0.2747	I^2=16.2%		
>= 65					
FIDELIO-DKD	20 / 1626	27 / 1660	44.5	0.75 [0.42,1.35]	
FIGARO-DKD	21 / 1931	45 / 1903	55.5	0.45 [0.27,0.77]	
Total	41 / 3557	72 / 3563		0.56 [0.38,0.83]	Z=-2.90, p=0.0037
Heterogeneity:	Q=1.61 (df=1)	p=0.2042	I^2=38.0%		
Subgroup Heterogeneity:	Q=4.44 (df=1)	p=0.0350	I^2=77.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.150: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

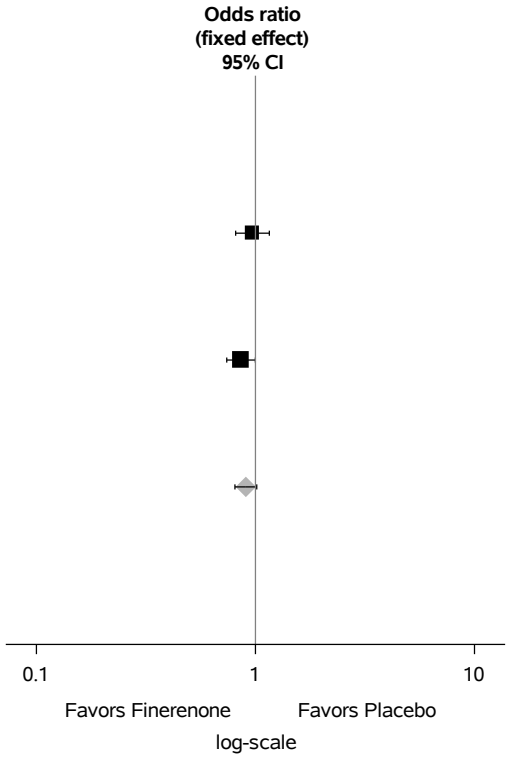
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	30 / 2831	45.7	0.97 [0.58,1.62]	
FIGARO-DKD	36 / 3683	34 / 3658	54.3	1.05 [0.66,1.69]	
Total	65 / 6510	64 / 6489		1.01 [0.72,1.43]	Z=0.07, p=0.9433
Heterogeneity:	Q=0.06 (df=1)	p=0.8139	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.151: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

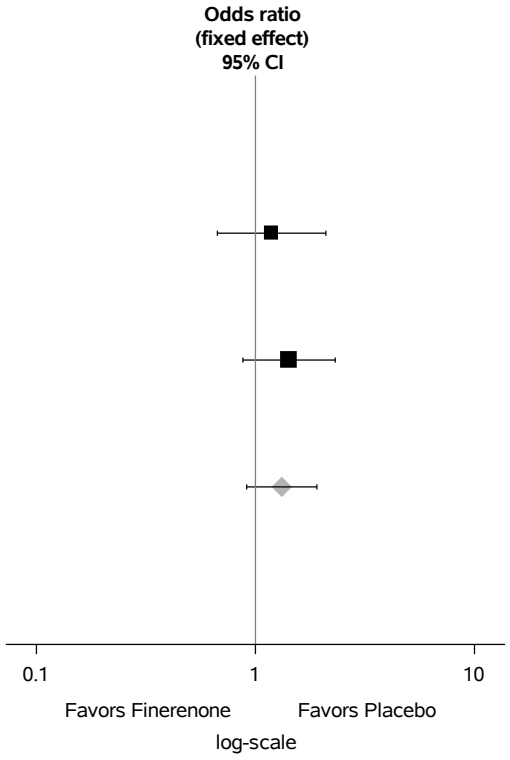
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	267 / 2827	275 / 2831	41.9	0.97 [0.81,1.16]	
FIGARO-DKD	356 / 3683	405 / 3658	58.1	0.86 [0.74,1.00]	
Total	623 / 6510	680 / 6489		0.90 [0.81,1.01]	Z=-1.73, p=0.0838
Heterogeneity:	Q=1.03 (df=1)	p=0.3099	I^2=3.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.152: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set

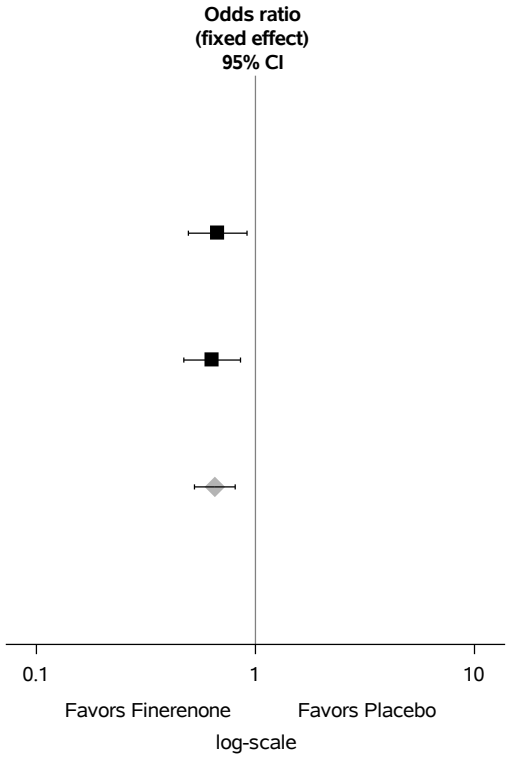
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2827	22 / 2831	42.0	1.19 [0.67,2.10]	
FIGARO-DKD	40 / 3683	28 / 3658	58.0	1.42 [0.88,2.31]	
Total	66 / 6510	50 / 6489		1.32 [0.91,1.91]	Z=1.47, p=0.1418
Heterogeneity:	Q=0.23 (df=1)	p=0.6315	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.153: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

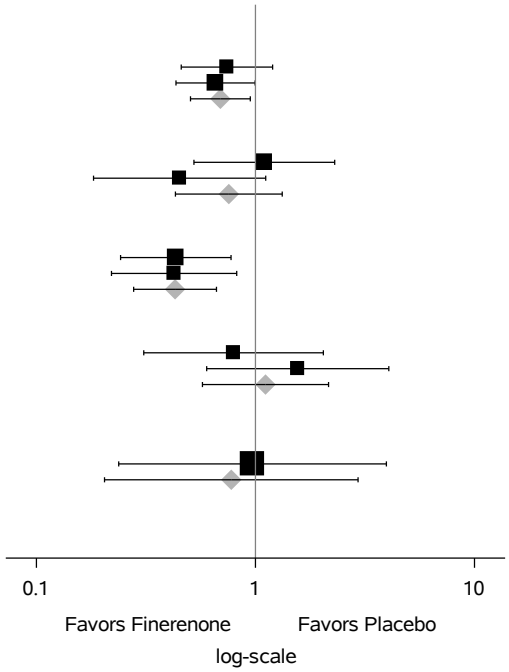
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2827	103 / 2831	48.3	0.67 [0.49,0.92]	
FIGARO-DKD	73 / 3683	113 / 3658	51.7	0.63 [0.47,0.85]	
Total	143 / 6510	216 / 6489		0.65 [0.53,0.81]	Z=-3.91, p=<.0001
Heterogeneity:	Q=0.07 (df=1)	p=0.7898	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.153.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

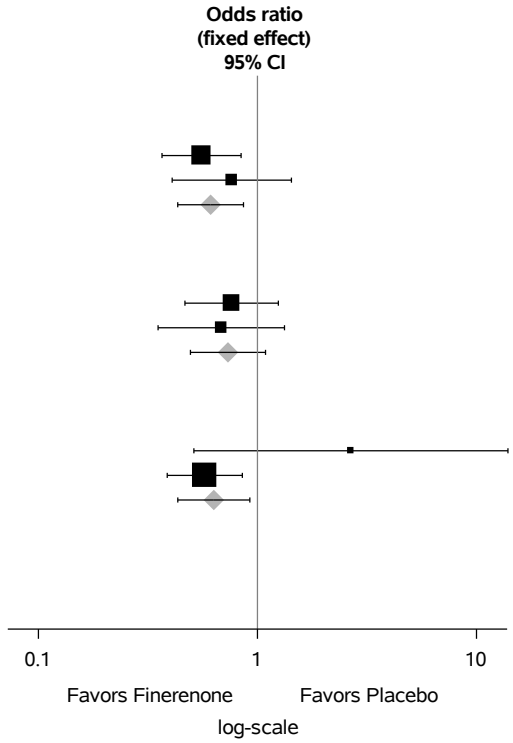
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	30 / 1178	40 / 1174	42.8	0.74 [0.46,1.20]	
FIGARO-DKD	38 / 1752	57 / 1747	57.2	0.66 [0.43,1.00]	
Total	68 / 2930	97 / 2921		0.69 [0.51,0.95]	Z=-2.30, p=0.0215
Heterogeneity:	Q=0.14 (df=1)	p=0.7122	I^2=0.0%		
North America					
FIDELIO-DKD	15 / 466	14 / 476	59.9	1.10 [0.52,2.30]	
FIGARO-DKD	7 / 559	15 / 548	40.1	0.45 [0.18,1.11]	
Total	22 / 1025	29 / 1024		0.76 [0.43,1.32]	Z=-0.98, p=0.3282
Heterogeneity:	Q=2.23 (df=1)	p=0.1352	I^2=55.2%		
Asia					
FIDELIO-DKD	17 / 790	38 / 786	56.2	0.43 [0.24,0.77]	
FIGARO-DKD	13 / 811	30 / 813	43.8	0.43 [0.22,0.82]	
Total	30 / 1601	68 / 1599		0.43 [0.28,0.66]	Z=-3.80, p=0.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9680	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 294	10 / 294	50.7	0.79 [0.31,2.04]	
FIGARO-DKD	11 / 424	7 / 417	49.3	1.56 [0.60,4.06]	
Total	19 / 718	17 / 711		1.11 [0.57,2.16]	Z=0.31, p=0.7548
Heterogeneity:	Q=0.97 (df=1)	p=0.3252	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	4 / 137	4 / 133	100.0	0.97 [0.24,3.96]	
Total	4 / 236	5 / 234		0.78 [0.20,2.94]	Z=-0.37, p=0.7086
Heterogeneity:	Q=0.10 (df=1)	p=0.7555	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.48 (df=4)	p=0.1662	I^2=38.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.153.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

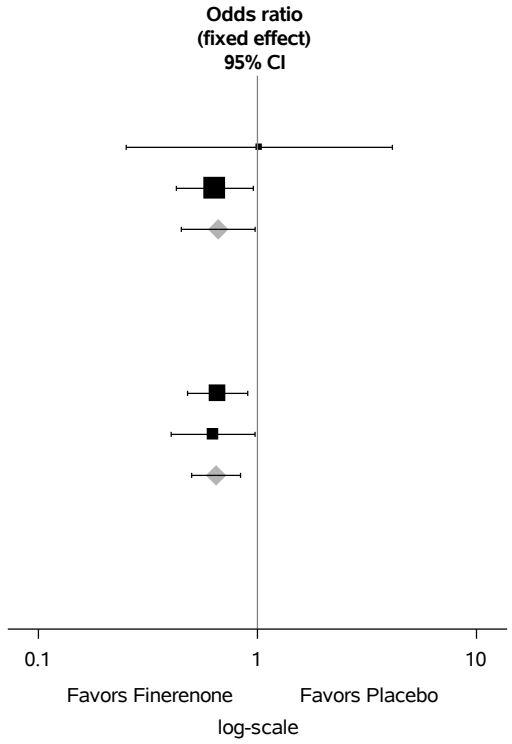
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	36 / 1556	63 / 1541	69.5	0.56 [0.37,0.84]	
FIGARO-DKD	18 / 637	23 / 627	30.5	0.76 [0.41,1.43]	
Total	54 / 2193	86 / 2168		0.61 [0.43,0.86]	Z=-2.79, p=0.0052
Heterogeneity:	Q=0.69 (df=1)	p=0.4073	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	38 / 1069	64.7	0.76 [0.47,1.25]	
FIGARO-DKD	15 / 720	22 / 729	35.3	0.68 [0.35,1.33]	
Total	44 / 1781	60 / 1798		0.73 [0.49,1.09]	Z=-1.54, p=0.1238
Heterogeneity:	Q=0.07 (df=1)	p=0.7961	I^2=0.0%		
>= 60					
FIDELIO-DKD	5 / 210	2 / 221	5.4	2.67 [0.51,13.92]	
FIGARO-DKD	40 / 2326	68 / 2302	94.6	0.57 [0.39,0.85]	
Total	45 / 2536	70 / 2523		0.63 [0.43,0.92]	Z=-2.37, p=0.0176
Heterogeneity:	Q=3.15 (df=1)	p=0.0760	I^2=68.2%		
Subgroup Heterogeneity:	Q=0.50 (df=2)	p=0.7778	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.153.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

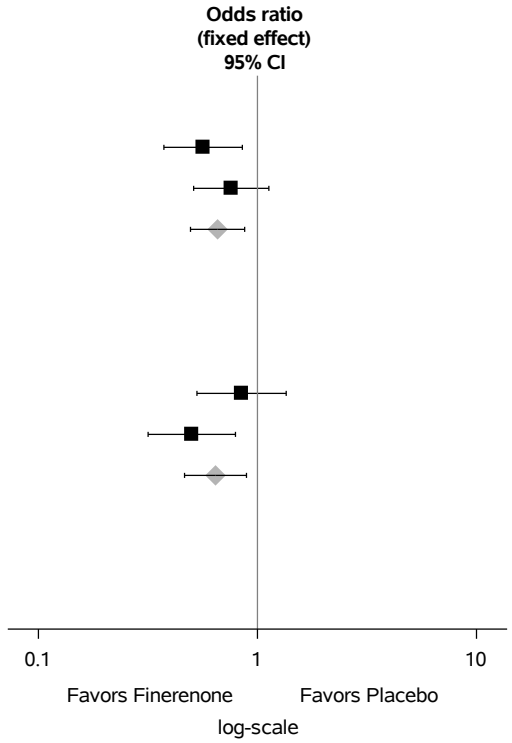
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	4 / 213	7.7	1.02 [0.25,4.13]	
FIGARO-DKD	40 / 1720	61 / 1698	92.3	0.64 [0.43,0.96]	
Total	44 / 1929	65 / 1911		0.66 [0.45,0.98]	Z=-2.08, p=0.0372
Heterogeneity:	Q=0.40 (df=1)	p=0.5295	I^2=0.0%		
Very High					
FIDELIO-DKD	66 / 2618	99 / 2618	66.0	0.66 [0.48,0.90]	
FIGARO-DKD	33 / 1963	52 / 1960	34.0	0.63 [0.40,0.97]	
Total	99 / 4581	151 / 4578		0.65 [0.50,0.84]	Z=-3.32, p=0.0009
Heterogeneity:	Q=0.03 (df=1)	p=0.8631	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9252	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.153.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

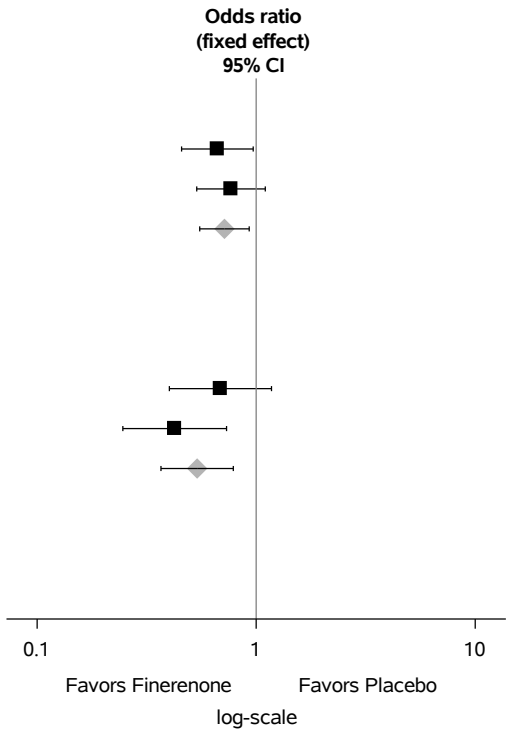
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	37 / 1301	64 / 1299	47.9	0.56 [0.37,0.85]	
FIGARO-DKD	45 / 1673	58 / 1651	52.1	0.76 [0.51,1.13]	
Total	82 / 2974	122 / 2950		0.66 [0.49,0.87]	Z=-2.89, p=0.0039
Heterogeneity:	Q=1.03 (df=1)	p=0.3104	I^2=2.8%		
Absent					
FIDELIO-DKD	33 / 1526	39 / 1532	48.9	0.85 [0.53,1.35]	
FIGARO-DKD	28 / 2010	55 / 2007	51.1	0.50 [0.32,0.79]	
Total	61 / 3536	94 / 3539		0.64 [0.46,0.89]	Z=-2.65, p=0.0080
Heterogeneity:	Q=2.44 (df=1)	p=0.1181	I^2=59.1%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.153.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

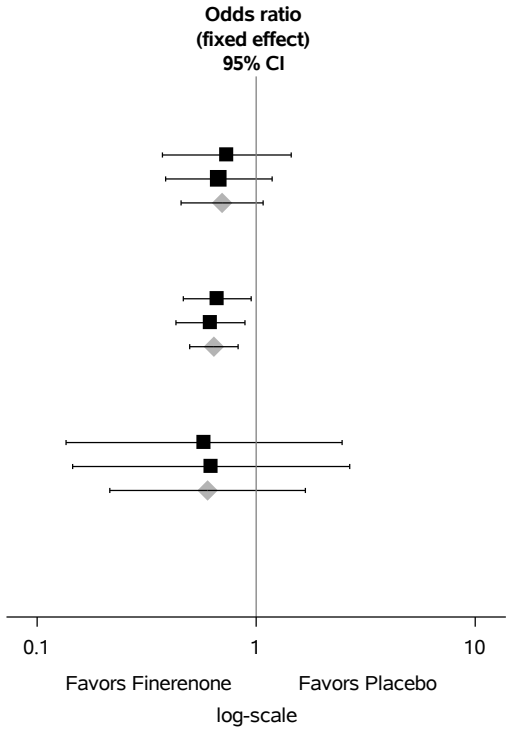
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	47 / 1879	69 / 1858	47.8	0.67 [0.46,0.97]	
FIGARO-DKD	54 / 2643	69 / 2608	52.2	0.77 [0.54,1.10]	
Total	101 / 4522	138 / 4466		0.72 [0.55,0.93]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.29 (df=1)	p=0.5904	I^2=0.0%		
> 4.5					
FIDELIO-DKD	23 / 948	34 / 973	50.8	0.69 [0.40,1.17]	
FIGARO-DKD	19 / 1040	44 / 1048	49.2	0.42 [0.25,0.73]	
Total	42 / 1988	78 / 2021		0.54 [0.37,0.79]	Z=-3.20, p=0.0014
Heterogeneity:	Q=1.52 (df=1)	p=0.2179	I^2=34.1%		
Subgroup Heterogeneity:	Q=1.49 (df=1)	p=0.2218	I^2=33.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.153.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

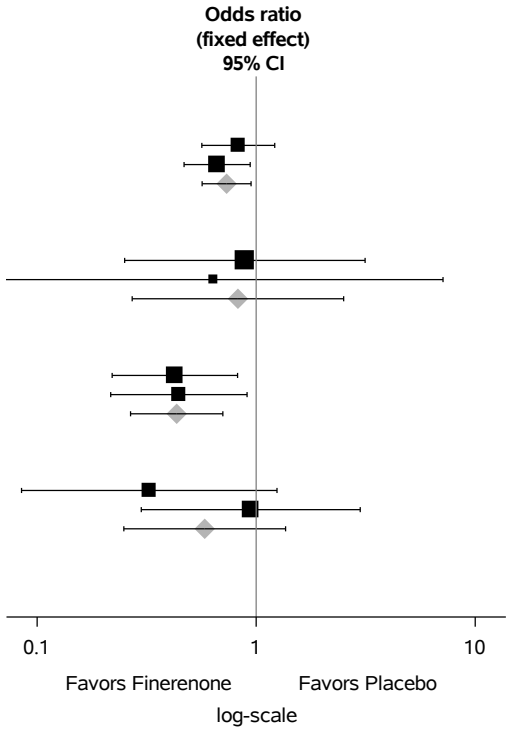
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	15 / 788	20 / 777	40.6	0.73 [0.37,1.45]	
FIGARO-DKD	21 / 1187	31 / 1194	59.4	0.68 [0.39,1.18]	
Total	36 / 1975	51 / 1971		0.70 [0.45,1.08]	Z=-1.63, p=0.1035
Heterogeneity:	Q=0.03 (df=1)	p=0.8523	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	52 / 1897	78 / 1916	50.8	0.66 [0.46,0.95]	
FIGARO-DKD	49 / 2389	77 / 2351	49.2	0.62 [0.43,0.89]	
Total	101 / 4286	155 / 4267		0.64 [0.50,0.83]	Z=-3.42, p=0.0006
Heterogeneity:	Q=0.08 (df=1)	p=0.7835	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 141	5 / 138	50.2	0.58 [0.14,2.47]	
FIGARO-DKD	3 / 107	5 / 113	49.8	0.62 [0.15,2.67]	
Total	6 / 248	10 / 251		0.60 [0.21,1.68]	Z=-0.97, p=0.3302
Heterogeneity:	Q=0.01 (df=1)	p=0.9433	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=2)	p=0.9319	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.153.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

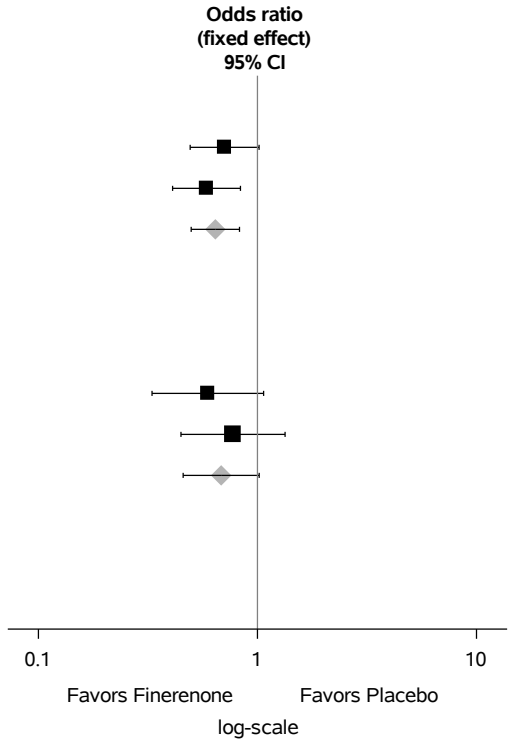
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	49 / 1773	60 / 1809	45.1	0.83 [0.56,1.22]	
FIGARO-DKD	55 / 2668	80 / 2601	54.9	0.66 [0.47,0.94]	
Total	104 / 4441	140 / 4410		0.73 [0.57,0.95]	Z=-2.37, p=0.0178
Heterogeneity:	Q=0.71 (df=1)	p=0.3995	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 139	5 / 124	78.5	0.89 [0.25,3.14]	
FIGARO-DKD	1 / 113	2 / 145	21.5	0.64 [0.06,7.13]	
Total	6 / 252	7 / 269		0.83 [0.27,2.51]	Z=-0.34, p=0.7351
Heterogeneity:	Q=0.06 (df=1)	p=0.8123	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 717	30 / 721	54.2	0.43 [0.22,0.82]	
FIGARO-DKD	11 / 716	25 / 736	45.8	0.44 [0.22,0.91]	
Total	24 / 1433	55 / 1457		0.43 [0.27,0.70]	Z=-3.38, p=0.0007
Heterogeneity:	Q=0.01 (df=1)	p=0.9320	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	8 / 177	42.3	0.33 [0.08,1.24]	
FIGARO-DKD	6 / 186	6 / 176	57.7	0.94 [0.30,2.99]	
Total	9 / 384	14 / 353		0.58 [0.25,1.36]	Z=-1.25, p=0.2123
Heterogeneity:	Q=1.40 (df=1)	p=0.2362	I^2=28.7%		
Subgroup Heterogeneity:	Q=3.75 (df=3)	p=0.2903	I^2=19.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.153.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

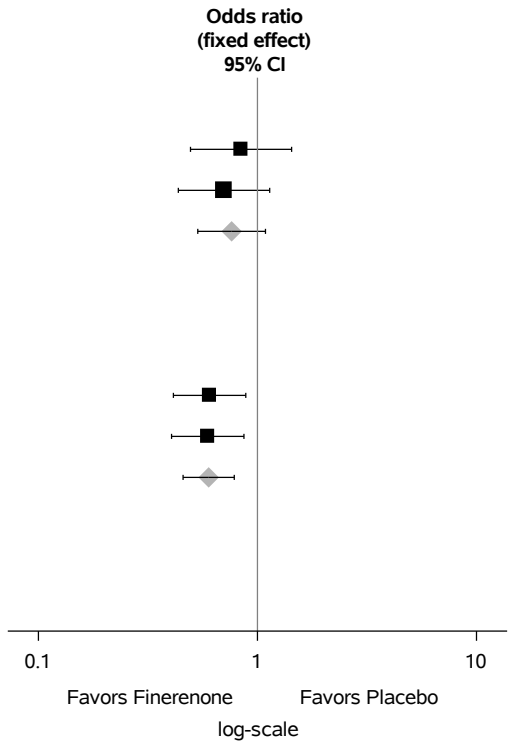
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	51 / 1949	74 / 2024	49.2	0.71 [0.49,1.02]	
FIGARO-DKD	49 / 2527	84 / 2571	50.8	0.59 [0.41,0.84]	
Total	100 / 4476	158 / 4595		0.64 [0.50,0.83]	Z=-3.42, p=0.0006
Heterogeneity:	Q=0.54 (df=1)	p=0.4635	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 878	29 / 807	46.5	0.59 [0.33,1.07]	
FIGARO-DKD	24 / 1156	29 / 1087	53.5	0.77 [0.45,1.34]	
Total	43 / 2034	58 / 1894		0.68 [0.46,1.02]	Z=-1.87, p=0.0613
Heterogeneity:	Q=0.42 (df=1)	p=0.5173	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.7998	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.153.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

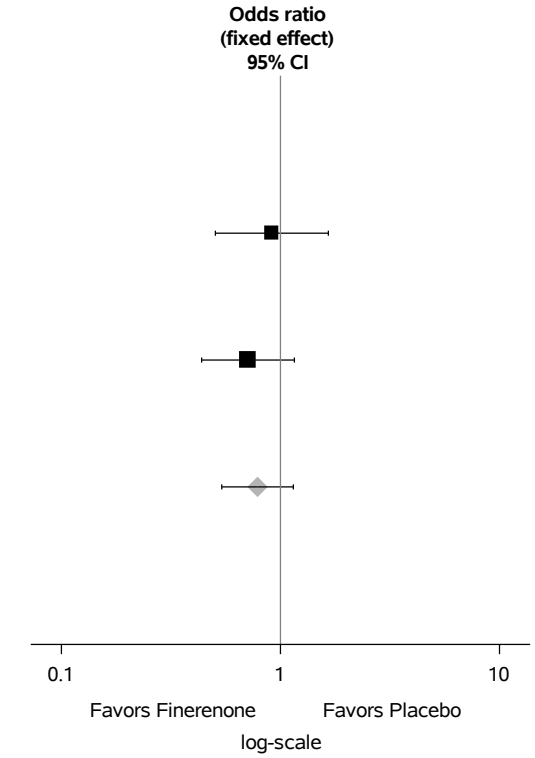
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	26 / 1201	30 / 1171	45.0	0.84 [0.49,1.43]	
FIGARO-DKD	29 / 1752	41 / 1755	55.0	0.70 [0.44,1.14]	
Total	55 / 2953	71 / 2926		0.76 [0.53,1.09]	Z=-1.50, p=0.1349
Heterogeneity:	Q=0.24 (df=1)	p=0.6242	I^2=0.0%		
>= 65					
FIDELIO-DKD	44 / 1626	73 / 1660	50.0	0.60 [0.41,0.88]	
FIGARO-DKD	44 / 1931	72 / 1903	50.0	0.59 [0.41,0.87]	
Total	88 / 3557	145 / 3563		0.60 [0.46,0.78]	Z=-3.74, p=0.0002
Heterogeneity:	Q=0.01 (df=1)	p=0.9434	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.12 (df=1)	p=0.2889	I^2=11.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.154: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set

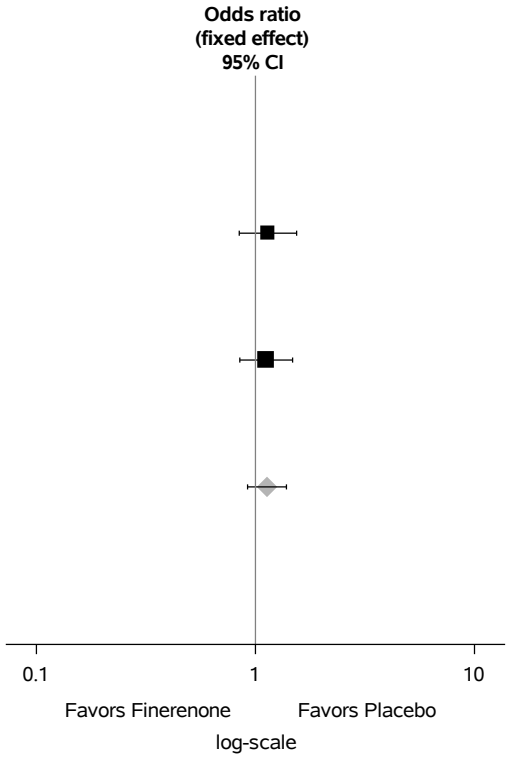
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	23 / 2831	40.3	0.91 [0.50,1.65]	
FIGARO-DKD	28 / 3683	39 / 3658	59.7	0.71 [0.44,1.16]	
Total	49 / 6510	62 / 6489		0.79 [0.54,1.14]	Z=-1.26, p=0.2095
Heterogeneity:	Q=0.41 (df=1)	p=0.5220	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.155: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

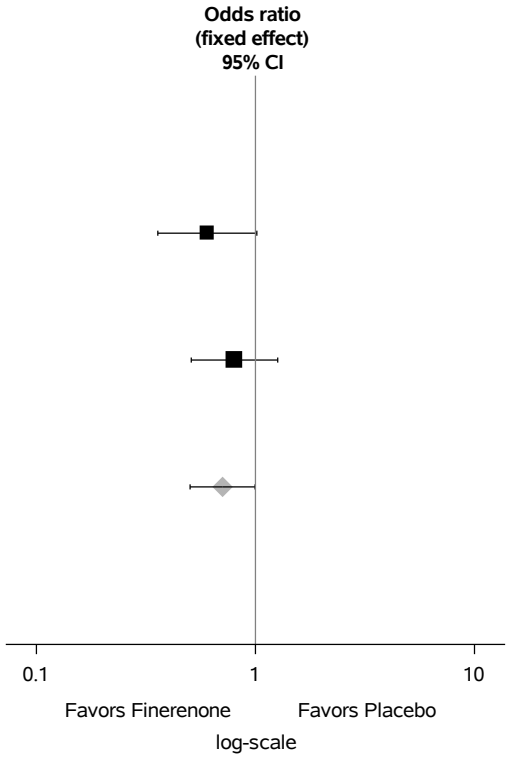
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	93 / 2827	82 / 2831	45.8	1.14 [0.84,1.54]	
FIGARO-DKD	109 / 3683	97 / 3658	54.2	1.12 [0.85,1.48]	
Total	202 / 6510	179 / 6489		1.13 [0.92,1.38]	Z=1.17, p=0.2439
Heterogeneity:	Q=0.01 (df=1)	p=0.9300	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.156: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

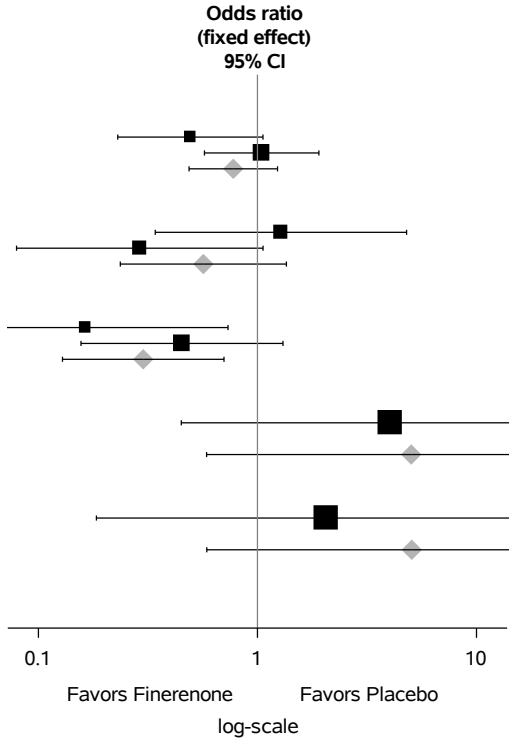
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2827	38 / 2831	43.3	0.60 [0.36,1.01]	
FIGARO-DKD	34 / 3683	42 / 3658	56.7	0.80 [0.51,1.26]	
Total	57 / 6510	80 / 6489		0.71 [0.50,1.00]	Z=-1.98, p=0.0472
Heterogeneity:	Q=0.66 (df=1)	p=0.4178	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.156.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

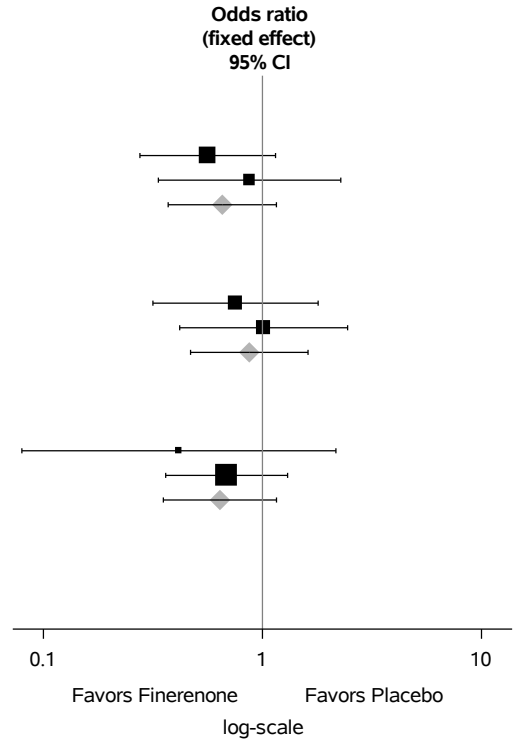
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	10 / 1178	20 / 1174	38.3	0.49 [0.23,1.06]	
FIGARO-DKD	22 / 1752	21 / 1747	61.7	1.05 [0.57,1.91]	
Total	32 / 2930	41 / 2921		0.78 [0.49,1.24]	Z=-1.07, p=0.2844
Heterogeneity:	Q=2.29 (df=1)	p=0.1306	I^2=56.2%		
North America					
FIDELIO-DKD	5 / 466	4 / 476	49.0	1.28 [0.34,4.80]	
FIGARO-DKD	3 / 559	10 / 548	51.0	0.29 [0.08,1.06]	
Total	8 / 1025	14 / 1024		0.57 [0.24,1.36]	Z=-1.28, p=0.2017
Heterogeneity:	Q=2.49 (df=1)	p=0.1149	I^2=59.8%		
Asia					
FIDELIO-DKD	2 / 790	12 / 786	33.4	0.16 [0.04,0.73]	
FIGARO-DKD	5 / 811	11 / 813	66.6	0.45 [0.16,1.31]	
Total	7 / 1601	23 / 1599		0.30 [0.13,0.70]	Z=-2.77, p=0.0056
Heterogeneity:	Q=1.20 (df=1)	p=0.2736	I^2=16.6%		
Latin America					
FIDELIO-DKD	4 / 294	1 / 294	100.0	4.04 [0.45,36.38]	
FIGARO-DKD	1 / 424	0 / 417	0.0	989E8 [989E8,989E8]	
Total	5 / 718	1 / 711		5.04 [0.59,43.29]	Z=1.47, p=0.1409
Heterogeneity:	Q=0.04 (df=1)	p=0.8445	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 99	1 / 101	100.0	2.06 [0.18,23.11]	
FIGARO-DKD	3 / 137	0 / 133	0.0	127E9 [127E9,127E9]	
Total	5 / 236	1 / 234		5.07 [0.59,43.71]	Z=1.48, p=0.1401
Heterogeneity:	Q=0.53 (df=1)	p=0.4660	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.68 (df=4)	p=0.0305	I^2=62.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.156.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

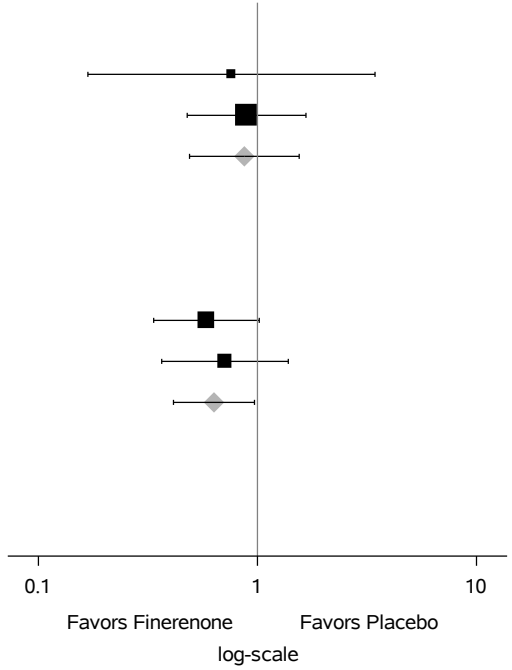
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	12 / 1556	21 / 1541	64.4	0.56 [0.28,1.15]	
FIGARO-DKD	8 / 637	9 / 627	35.6	0.87 [0.33,2.28]	
Total	20 / 2193	30 / 2168		0.66 [0.37,1.16]	Z=-1.45, p=0.1460
Heterogeneity:	Q=0.52 (df=1)	p=0.4705	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	12 / 1069	50.8	0.75 [0.32,1.80]	
FIGARO-DKD	10 / 720	10 / 729	49.2	1.01 [0.42,2.45]	
Total	19 / 1781	22 / 1798		0.87 [0.47,1.61]	Z=-0.44, p=0.6606
Heterogeneity:	Q=0.22 (df=1)	p=0.6399	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	5 / 221	13.1	0.42 [0.08,2.16]	
FIGARO-DKD	16 / 2326	23 / 2302	86.9	0.69 [0.36,1.30]	
Total	18 / 2536	28 / 2523		0.64 [0.35,1.16]	Z=-1.47, p=0.1407
Heterogeneity:	Q=0.31 (df=1)	p=0.5782	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=2)	p=0.7356	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.156.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

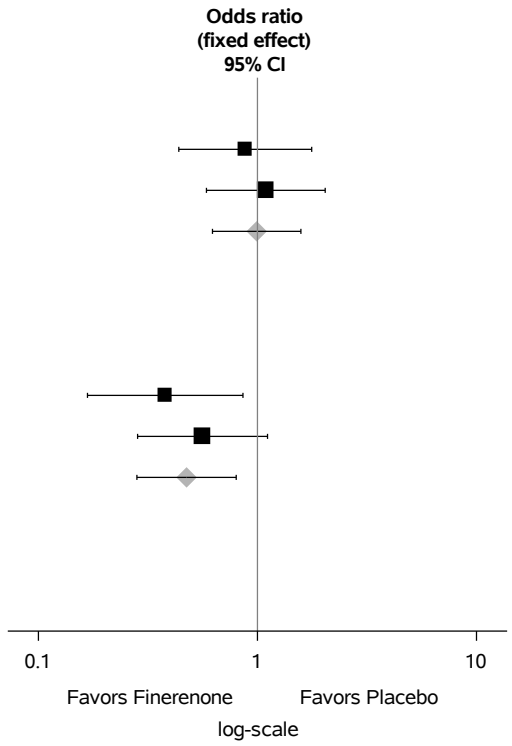
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	4 / 213	14.6	0.76 [0.17,3.44]	
FIGARO-DKD	19 / 1720	21 / 1698	85.4	0.89 [0.48,1.67]	
Total	22 / 1929	25 / 1911		0.87 [0.49,1.55]	Z=-0.47, p=0.6398
Heterogeneity:	Q=0.04 (df=1)	p=0.8487	I^2=0.0%		
Very High					
FIDELIO-DKD	20 / 2618	34 / 2618	59.0	0.59 [0.34,1.02]	
FIGARO-DKD	15 / 1963	21 / 1960	41.0	0.71 [0.37,1.38]	
Total	35 / 4581	55 / 4578		0.63 [0.41,0.97]	Z=-2.10, p=0.0354
Heterogeneity:	Q=0.19 (df=1)	p=0.6593	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=1)	p=0.3825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.156.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

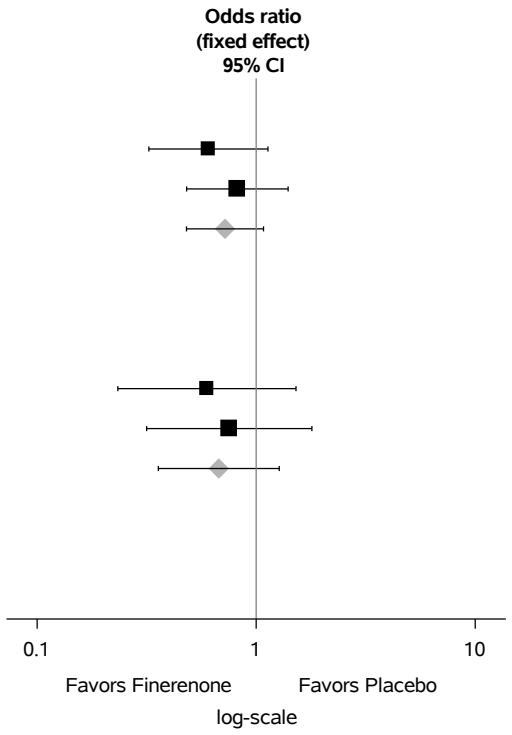
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 1301	17 / 1299	44.4	0.88 [0.44,1.77]	
FIGARO-DKD	21 / 1673	19 / 1651	55.6	1.09 [0.58,2.04]	
Total	36 / 2974	36 / 2950		0.99 [0.62,1.58]	Z=-0.03, p=0.9726
Heterogeneity:	Q=0.20 (df=1)	p=0.6511	I^2=0.0%		
Absent					
FIDELIO-DKD	8 / 1526	21 / 1532	41.1	0.38 [0.17,0.86]	
FIGARO-DKD	13 / 2010	23 / 2007	58.9	0.56 [0.28,1.11]	
Total	21 / 3536	44 / 3539		0.47 [0.28,0.80]	Z=-2.80, p=0.0051
Heterogeneity:	Q=0.52 (df=1)	p=0.4697	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.27 (df=1)	p=0.0387	I^2=76.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.156.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1879	26 / 1858	42.1	0.61 [0.32,1.13]	
FIGARO-DKD	25 / 2643	30 / 2608	57.9	0.82 [0.48,1.40]	
Total	41 / 4522	56 / 4466		0.72 [0.48,1.08]	Z=-1.59, p=0.1127
Heterogeneity:	Q=0.53 (df=1)	p=0.4680	I^2=0.0%		
> 4.5					
FIDELIO-DKD	7 / 948	12 / 973	46.2	0.60 [0.23,1.52]	
FIGARO-DKD	9 / 1040	12 / 1048	53.8	0.75 [0.32,1.80]	
Total	16 / 1988	24 / 2021		0.68 [0.36,1.27]	Z=-1.21, p=0.2256
Heterogeneity:	Q=0.13 (df=1)	p=0.7182	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8653	I^2=0.0%		

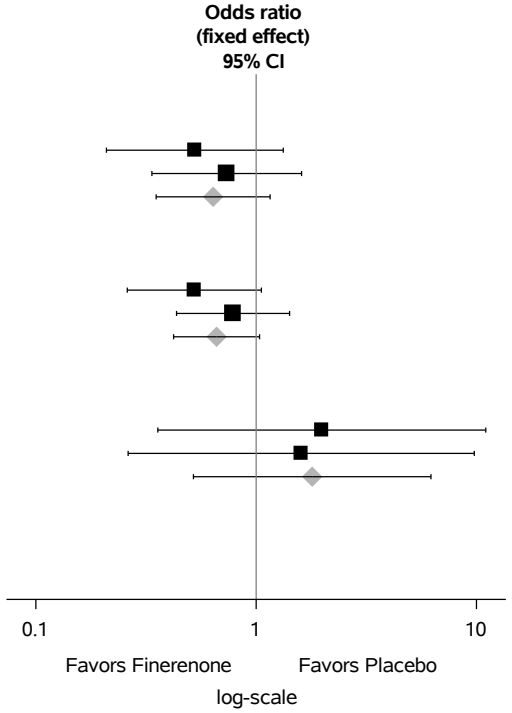


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.156.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Investigations (SOC with Incidence >=1%)

Safety Analysis Set

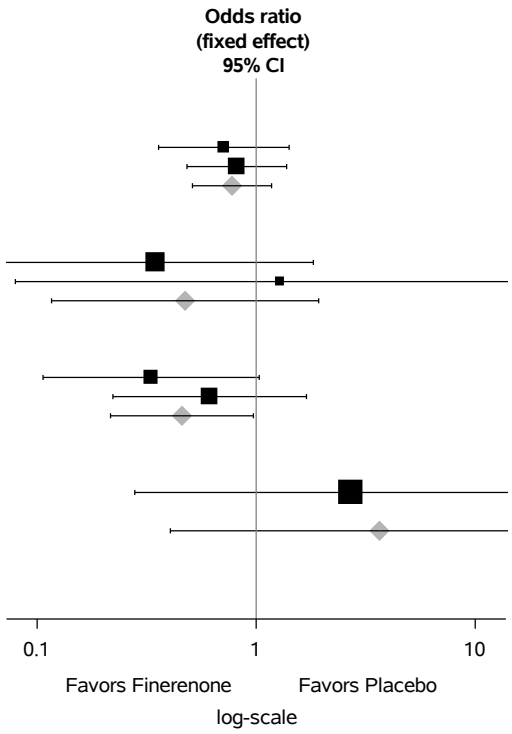
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	7 / 788	13 / 777	41.7	0.53 [0.21,1.33]	
FIGARO-DKD	11 / 1187	15 / 1194	58.3	0.74 [0.34,1.61]	
Total	18 / 1975	28 / 1971		0.64 [0.35,1.16]	Z=-1.48, p=0.1387
Heterogeneity:	Q=0.29 (df=1)	p=0.5893	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 1897	23 / 1916	41.5	0.52 [0.26,1.06]	
FIGARO-DKD	20 / 2389	25 / 2351	58.5	0.79 [0.44,1.42]	
Total	32 / 4286	48 / 4267		0.66 [0.42,1.04]	Z=-1.81, p=0.0710
Heterogeneity:	Q=0.75 (df=1)	p=0.3865	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	2 / 138	52.7	1.99 [0.36,11.02]	
FIGARO-DKD	3 / 107	2 / 113	47.3	1.60 [0.26,9.77]	
Total	7 / 248	4 / 251		1.80 [0.52,6.21]	Z=0.92, p=0.3553
Heterogeneity:	Q=0.03 (df=1)	p=0.8656	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.37 (df=2)	p=0.3062	I^2=15.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.156.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

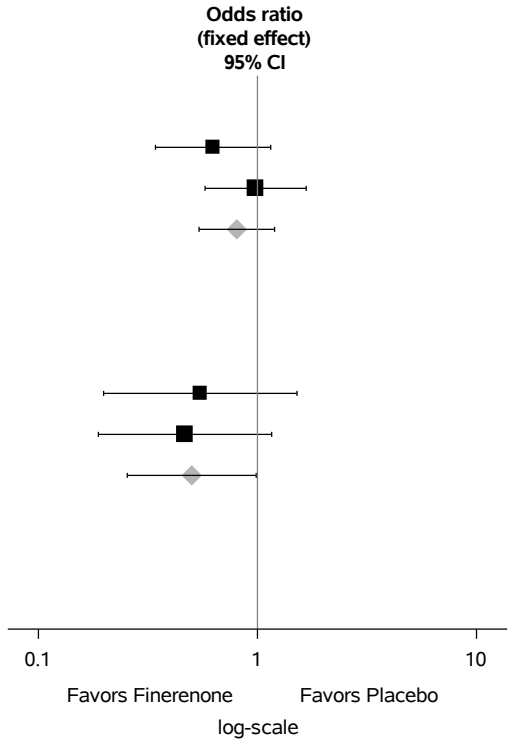
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1773	20 / 1809	36.8	0.71 [0.36,1.41]	
FIGARO-DKD	26 / 2668	31 / 2601	63.2	0.82 [0.48,1.38]	
Total	40 / 4441	51 / 4410		0.78 [0.51,1.18]	Z=-1.20, p=0.2315
Heterogeneity:	Q=0.10 (df=1)	p=0.7571	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 139	5 / 124	73.8	0.35 [0.07,1.82]	
FIGARO-DKD	1 / 113	1 / 145	26.2	1.29 [0.08,20.78]	
Total	3 / 252	6 / 269		0.47 [0.12,1.93]	Z=-1.04, p=0.2969
Heterogeneity:	Q=0.63 (df=1)	p=0.4278	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 717	12 / 721	44.5	0.33 [0.11,1.03]	
FIGARO-DKD	6 / 716	10 / 736	55.5	0.61 [0.22,1.70]	
Total	10 / 1433	22 / 1457		0.46 [0.22,0.97]	Z=-2.04, p=0.0418
Heterogeneity:	Q=0.63 (df=1)	p=0.4281	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	100.0	2.71 [0.28,26.27]	
FIGARO-DKD	1 / 186	0 / 176	0.0	832E8 [832E8,832E8]	
Total	4 / 384	1 / 353		3.65 [0.41,32.90]	Z=1.16, p=0.2479
Heterogeneity:	Q=0.07 (df=1)	p=0.7961	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.92 (df=3)	p=0.2698	I^2=23.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.156.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

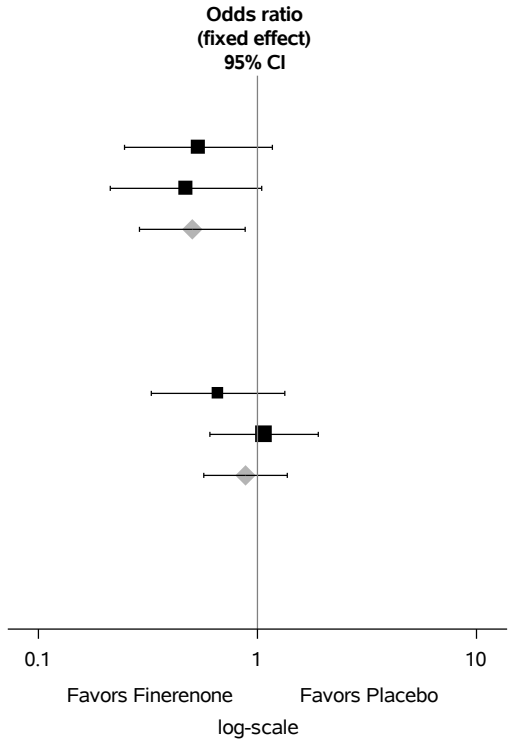
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1949	28 / 2024	43.5	0.63 [0.34,1.15]	
FIGARO-DKD	27 / 2527	28 / 2571	56.5	0.98 [0.58,1.67]	
Total	44 / 4476	56 / 4595		0.80 [0.54,1.20]	Z=-1.07, p=0.2839
Heterogeneity:	Q=1.18 (df=1)	p=0.2769	I^2=15.4%		
Female					
FIDELIO-DKD	6 / 878	10 / 807	44.5	0.55 [0.20,1.52]	
FIGARO-DKD	7 / 1156	14 / 1087	55.5	0.47 [0.19,1.16]	
Total	13 / 2034	24 / 1894		0.50 [0.25,0.99]	Z=-2.00, p=0.0458
Heterogeneity:	Q=0.05 (df=1)	p=0.8174	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.40 (df=1)	p=0.2372	I^2=28.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.156.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Investigations (SOC with Incidence >=1%)
Safety Analysis Set

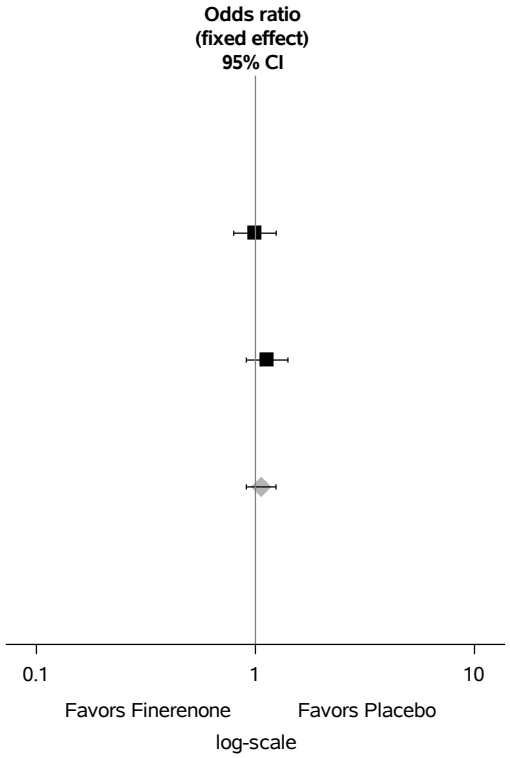
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1201	18 / 1171	51.2	0.54 [0.25,1.17]	
FIGARO-DKD	9 / 1752	19 / 1755	48.8	0.47 [0.21,1.05]	
Total	19 / 2953	37 / 2926		0.50 [0.29,0.88]	Z=-2.42, p=0.0157
Heterogeneity:	Q=0.05 (df=1)	p=0.8174	I^2=0.0%		
>= 65					
FIDELIO-DKD	13 / 1626	20 / 1660	39.7	0.66 [0.33,1.33]	
FIGARO-DKD	25 / 1931	23 / 1903	60.3	1.07 [0.61,1.90]	
Total	38 / 3557	43 / 3563		0.88 [0.57,1.37]	Z=-0.56, p=0.5758
Heterogeneity:	Q=1.10 (df=1)	p=0.2941	I^2=9.2%		
Subgroup Heterogeneity:	Q=2.40 (df=1)	p=0.1214	I^2=58.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.157: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

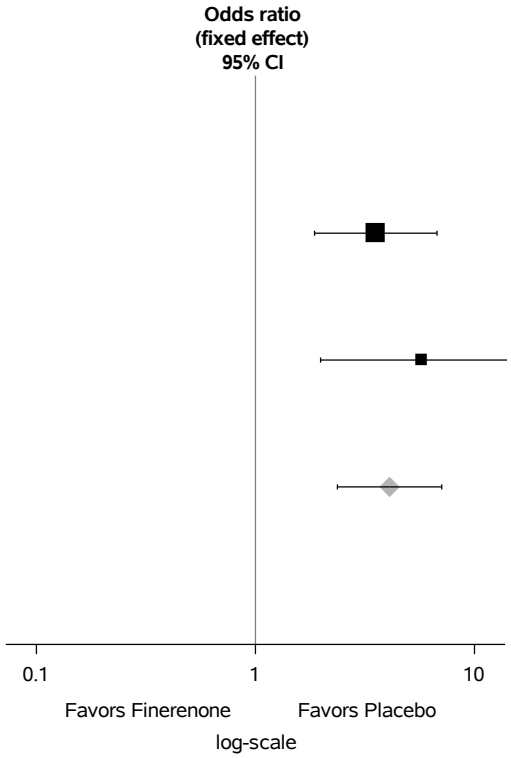
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	163 / 2827	164 / 2831	48.9	1.00 [0.80,1.24]	
FIGARO-DKD	180 / 3683	159 / 3658	51.1	1.13 [0.91,1.41]	
Total	343 / 6510	323 / 6489		1.06 [0.91,1.24]	Z=0.76, p=0.4478
Heterogeneity:	Q=0.64 (df=1)	p=0.4222	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.158: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

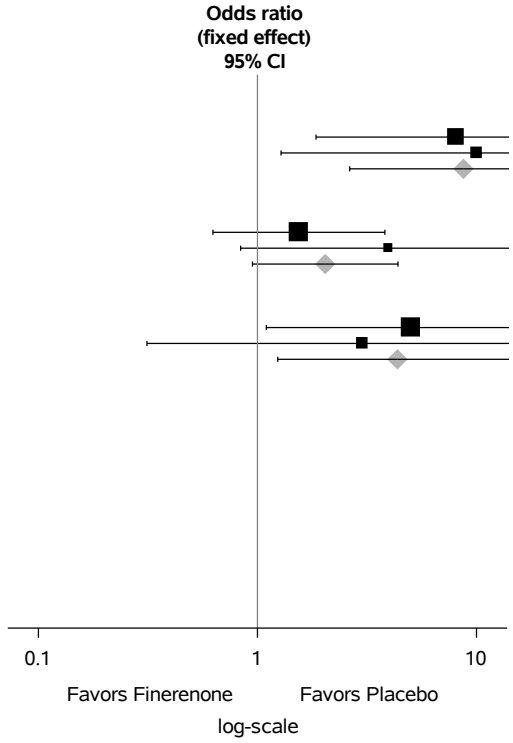
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2827	12 / 2831	73.2	3.54 [1.86,6.74]	
FIGARO-DKD	23 / 3683	4 / 3658	26.8	5.74 [1.98,16.62]	
Total	65 / 6510	16 / 6489		4.09 [2.37,7.09]	Z=5.04, p=<.0001
Heterogeneity:	Q=0.58 (df=1)	p=0.4453	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.158.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

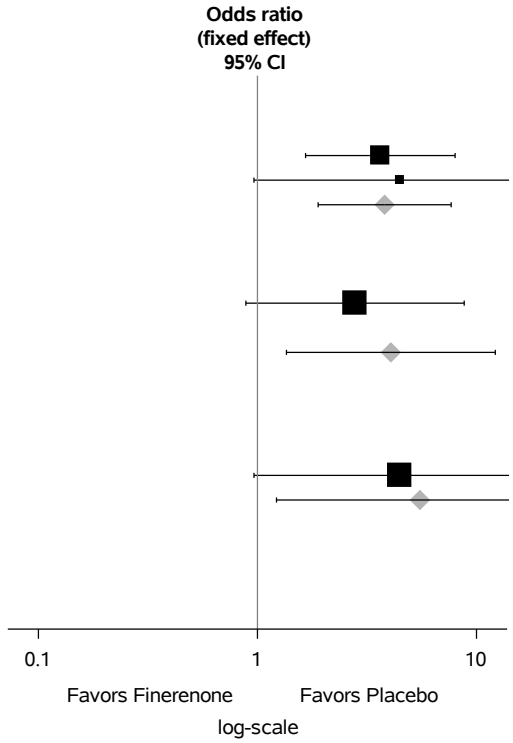
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1178	2 / 1174	66.1	8.07 [1.85,35.17]	
FIGARO-DKD	10 / 1752	1 / 1747	33.9	10.02 [1.28,78.38]	
Total	26 / 2930	3 / 2921		8.72 [2.64,28.85]	Z=3.55, p=0.0004
Heterogeneity:	Q=0.03 (df=1)	p=0.8664	I^2=0.0%		
North America					
FIDELIO-DKD	12 / 466	8 / 476	74.7	1.55 [0.63,3.82]	
FIGARO-DKD	8 / 559	2 / 548	25.3	3.96 [0.84,18.75]	
Total	20 / 1025	10 / 1024		2.04 [0.95,4.38]	Z=1.83, p=0.0679
Heterogeneity:	Q=1.06 (df=1)	p=0.3026	I^2=5.9%		
Asia					
FIDELIO-DKD	10 / 790	2 / 786	68.9	5.03 [1.10,23.01]	
FIGARO-DKD	3 / 811	1 / 813	31.1	3.01 [0.31,29.04]	
Total	13 / 1601	3 / 1599		4.35 [1.24,15.32]	Z=2.29, p=0.0219
Heterogeneity:	Q=0.14 (df=1)	p=0.7130	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	0 / 294	0.0	105E9 [105E9,105E9]	
FIGARO-DKD	0 / 424	0 / 417	0.0	-	
Total	2 / 718	0 / 711		259E9 [259E9,259E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 99	0 / 101	0.0	117E9 [117E9,117E9]	
FIGARO-DKD	2 / 137	0 / 133	0.0	228E9 [228E9,228E9]	
Total	4 / 236	0 / 234		978E8 [978E8,978E8]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.24 (df=4)	p=0.3744	I^2=5.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.158.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

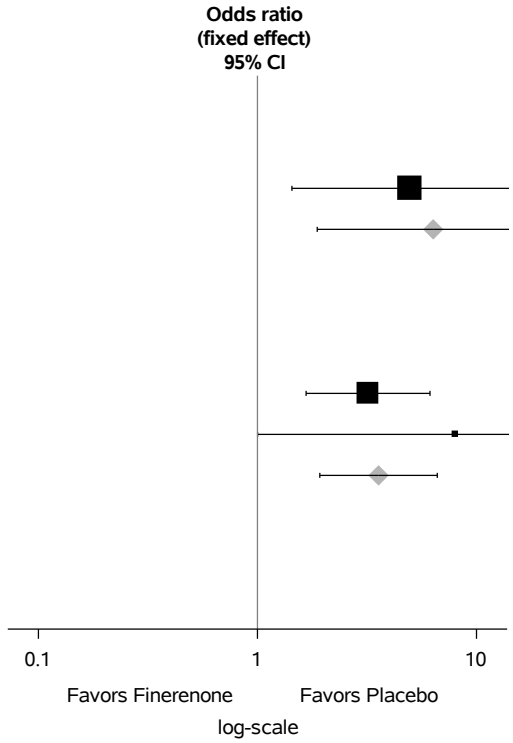
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	29 / 1556	8 / 1541	79.3	3.64 [1.66,7.99]	
FIGARO-DKD	9 / 637	2 / 627	20.7	4.48 [0.96,20.81]	
Total	38 / 2193	10 / 2168		3.81 [1.89,7.66]	Z=3.75, p=0.0002
Heterogeneity:	Q=0.06 (df=1)	p=0.8136	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	4 / 1069	100.0	2.79 [0.89,8.79]	
FIGARO-DKD	5 / 720	0 / 729	0.0	108E9 [108E9,108E9]	
Total	16 / 1781	4 / 1798		4.07 [1.36,12.19]	Z=2.50, p=0.0123
Heterogeneity:	Q=0.41 (df=1)	p=0.5199	I^2=0.0%		
>= 60					
FIDELIO-DKD	2 / 210	0 / 221	0.0	148E9 [148E9,148E9]	
FIGARO-DKD	9 / 2326	2 / 2302	100.0	4.47 [0.96,20.70]	
Total	11 / 2536	2 / 2523		5.52 [1.22,24.92]	Z=2.22, p=0.0264
Heterogeneity:	Q=0.07 (df=1)	p=0.7873	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=2)	p=0.9088	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.158.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

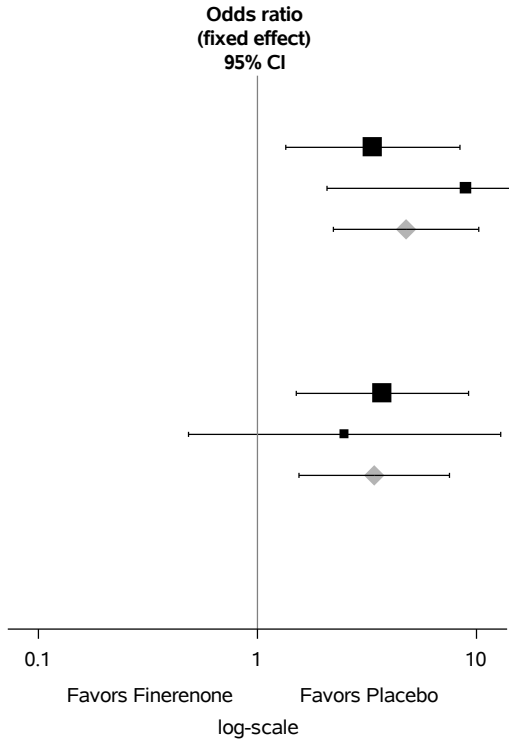
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	0 / 213	0.0	111E9 [111E9,111E9]	
FIGARO-DKD	15 / 1720	3 / 1698	100.0	4.97 [1.44,17.20]	
Total	19 / 1929	3 / 1911		6.34 [1.87,21.48]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.15 (df=1)	p=0.7000	I^2=0.0%		
Very High					
FIDELIO-DKD	38 / 2618	12 / 2618	91.1	3.20 [1.67,6.13]	
FIGARO-DKD	8 / 1963	1 / 1960	8.9	8.02 [1.00,64.15]	
Total	46 / 4581	13 / 4578		3.57 [1.93,6.62]	Z=4.04, p=<.0001
Heterogeneity:	Q=0.69 (df=1)	p=0.4059	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.68 (df=1)	p=0.4099	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.158.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

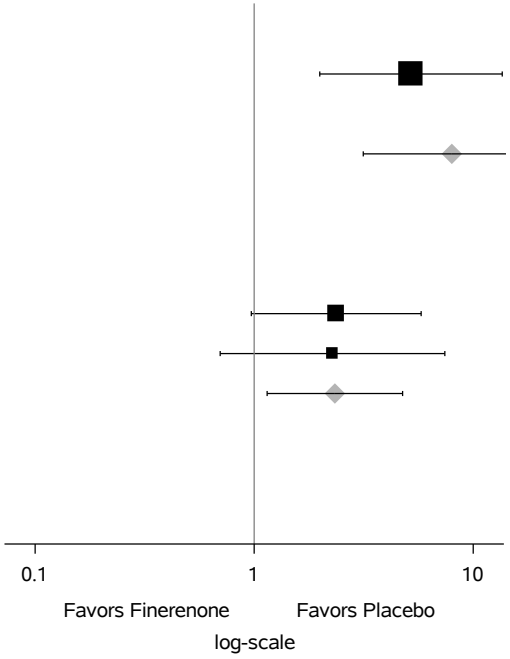
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	20 / 1301	6 / 1299	71.8	3.36 [1.35,8.41]	
FIGARO-DKD	18 / 1673	2 / 1651	28.2	8.97 [2.08,38.71]	
Total	38 / 2974	8 / 2950		4.77 [2.22,10.24]	Z=4.01, p=<.0001
Heterogeneity:	Q=1.27 (df=1)	p=0.2590	I^2=21.5%		
Absent					
FIDELIO-DKD	22 / 1526	6 / 1532	76.7	3.72 [1.50,9.20]	
FIGARO-DKD	5 / 2010	2 / 2007	23.3	2.50 [0.48,12.90]	
Total	27 / 3536	8 / 3539		3.41 [1.55,7.53]	Z=3.04, p=0.0024
Heterogeneity:	Q=0.17 (df=1)	p=0.6774	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5509	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.158.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

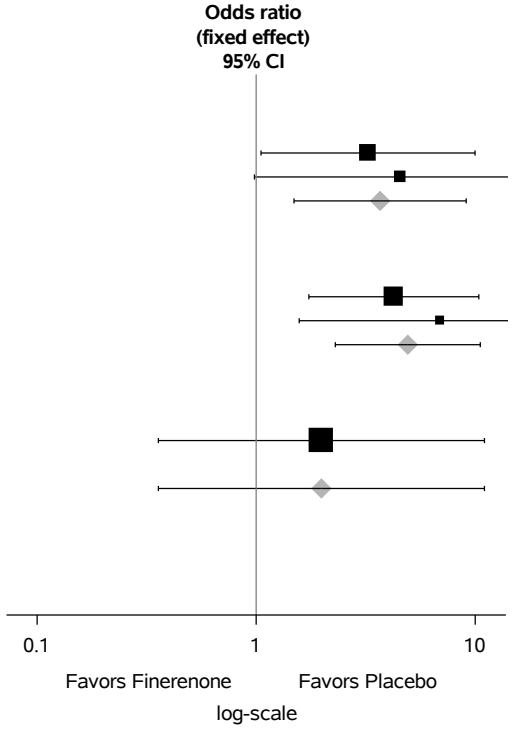
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	26 / 1879	5 / 1858	100.0	5.20 [1.99,13.57]	
FIGARO-DKD	14 / 2643	0 / 2608	0.0	823E8 [823E8,823E8]	
Total	40 / 4522	5 / 4466		7.99 [3.15,20.26]	Z=4.37, p=<.0001
Heterogeneity:	Q=0.77 (df=1)	p=0.3807	I^2=0.0%		
> 4.5					
FIDELIO-DKD	16 / 948	7 / 973	63.6	2.37 [0.97,5.78]	
FIGARO-DKD	9 / 1040	4 / 1048	36.4	2.28 [0.70,7.42]	
Total	25 / 1988	11 / 2021		2.34 [1.15,4.76]	Z=2.33, p=0.0196
Heterogeneity:	Q=0.00 (df=1)	p=0.9588	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.23 (df=1)	p=0.0398	I^2=76.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.158.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

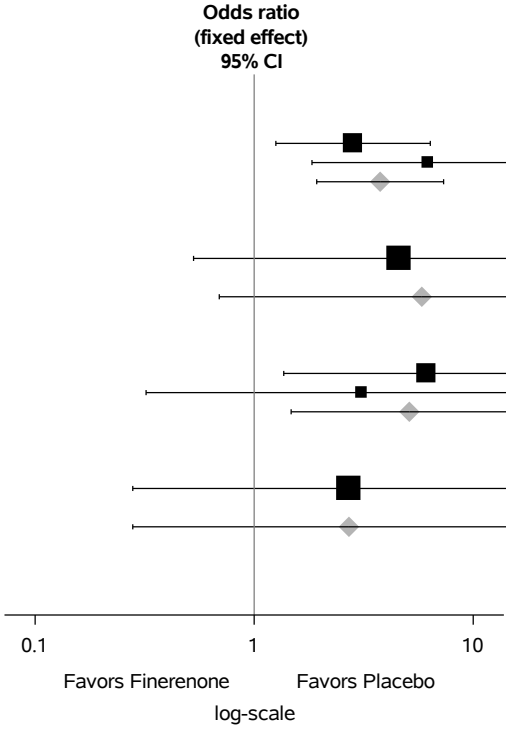
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	13 / 788	4 / 777	65.0	3.24 [1.05,9.99]	
FIGARO-DKD	9 / 1187	2 / 1194	35.0	4.55 [0.98,21.12]	
Total	22 / 1975	6 / 1971		3.68 [1.49,9.10]	Z=2.82, p=0.0048
Heterogeneity:	Q=0.12 (df=1)	p=0.7260	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	25 / 1897	6 / 1916	73.4	4.25 [1.74,10.39]	
FIGARO-DKD	14 / 2389	2 / 2351	26.6	6.92 [1.57,30.50]	
Total	39 / 4286	8 / 4267		4.92 [2.30,10.55]	Z=4.10, p=<.0001
Heterogeneity:	Q=0.31 (df=1)	p=0.5797	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 141	2 / 138	100.0	1.99 [0.36,11.02]	
FIGARO-DKD	0 / 107	0 / 113	0.0	-	
Total	4 / 248	2 / 251		1.99 [0.36,11.02]	Z=0.78, p=0.4329
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.96 (df=2)	p=0.6190	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.158.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

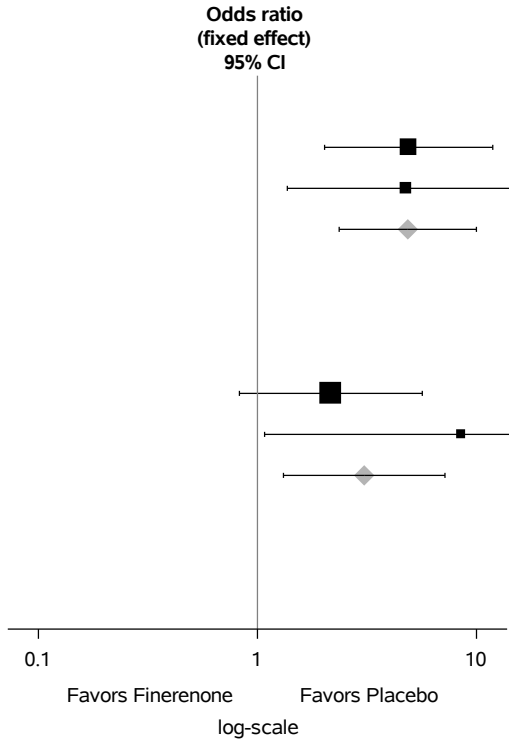
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	8 / 1809	69.3	2.83 [1.26,6.37]	
FIGARO-DKD	19 / 2668	3 / 2601	30.7	6.21 [1.84,21.02]	
Total	41 / 4441	11 / 4410		3.76 [1.93,7.33]	Z=3.89, p=<.0001
Heterogeneity:	Q=1.12 (df=1)	p=0.2891	I^2=11.0%		
Black					
FIDELIO-DKD	5 / 139	1 / 124	100.0	4.59 [0.53,39.83]	
FIGARO-DKD	1 / 113	0 / 145	0.0	137E9 [137E9,137E9]	
Total	6 / 252	1 / 269		5.83 [0.69,48.99]	Z=1.62, p=0.1047
Heterogeneity:	Q=0.05 (df=1)	p=0.8287	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 717	2 / 721	69.5	6.12 [1.36,27.44]	
FIGARO-DKD	3 / 716	1 / 736	30.5	3.09 [0.32,29.80]	
Total	15 / 1433	3 / 1457		5.11 [1.47,17.70]	Z=2.57, p=0.0101
Heterogeneity:	Q=0.24 (df=1)	p=0.6212	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 198	1 / 177	100.0	2.71 [0.28,26.27]	
FIGARO-DKD	0 / 186	0 / 176	0.0	-	
Total	3 / 384	1 / 353		2.71 [0.28,26.27]	Z=0.86, p=0.3902
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=3)	p=0.9373	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.158.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

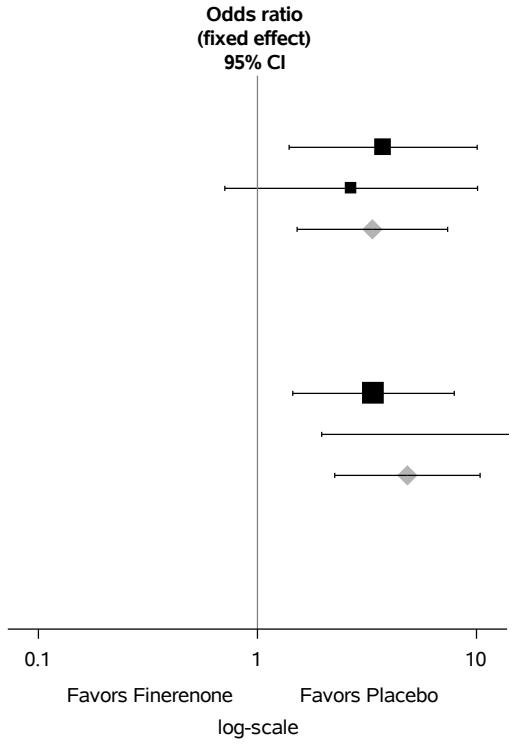
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	28 / 1949	6 / 2024	66.6	4.90 [2.03,11.87]	
FIGARO-DKD	14 / 2527	3 / 2571	33.4	4.77 [1.37,16.61]	
Total	42 / 4476	9 / 4595		4.86 [2.36,9.99]	Z=4.29, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9718	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 878	6 / 807	82.2	2.16 [0.83,5.66]	
FIGARO-DKD	9 / 1156	1 / 1087	17.8	8.52 [1.08,67.37]	
Total	23 / 2034	7 / 1894		3.07 [1.31,7.18]	Z=2.59, p=0.0096
Heterogeneity:	Q=1.45 (df=1)	p=0.2290	I^2=30.9%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4201	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.158.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set

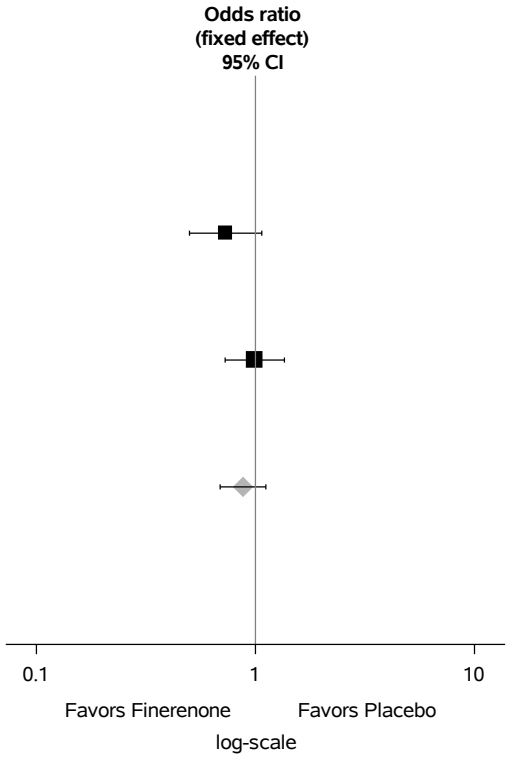
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	19 / 1201	5 / 1171	64.4	3.75 [1.40,10.07]	
FIGARO-DKD	8 / 1752	3 / 1755	35.6	2.68 [0.71,10.11]	
Total	27 / 2953	8 / 2926		3.35 [1.52,7.38]	Z=2.99, p=0.0028
Heterogeneity:	Q=0.16 (df=1)	p=0.6906	I^2=0.0%		
>= 65					
FIDELIO-DKD	23 / 1626	7 / 1660	85.1	3.39 [1.45,7.92]	
FIGARO-DKD	15 / 1931	1 / 1903	14.9	14.89 [1.96,112.84]	
Total	38 / 3557	8 / 3563		4.84 [2.25,10.39]	Z=4.04, p=<.0001
Heterogeneity:	Q=1.86 (df=1)	p=0.1726	I^2=46.2%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5116	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.159: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

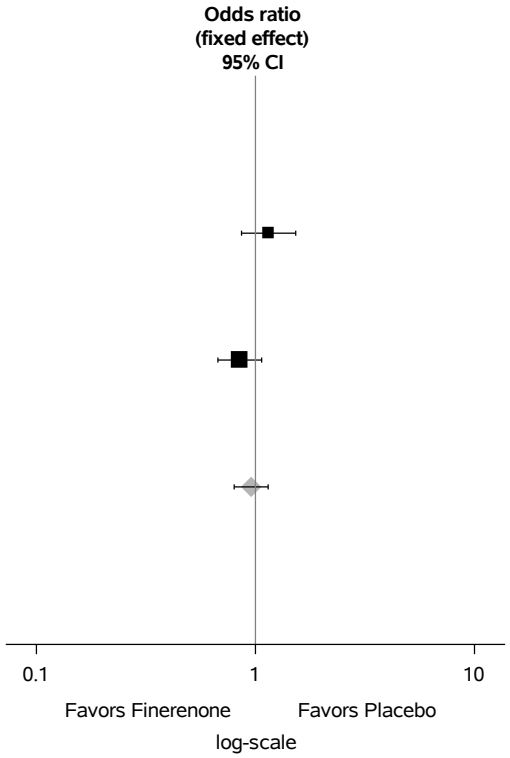
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	64 / 2831	40.2	0.73 [0.50,1.07]	
FIGARO-DKD	81 / 3683	81 / 3658	59.8	0.99 [0.73,1.36]	
Total	128 / 6510	145 / 6489		0.88 [0.69,1.12]	Z=-1.07, p=0.2855
Heterogeneity:	Q=1.49 (df=1)	p=0.2216	I^2=33.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.160: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

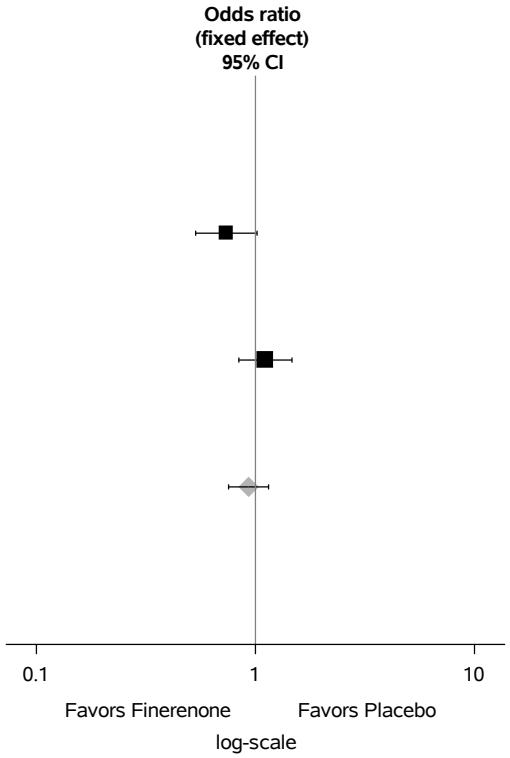
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	105 / 2827	92 / 2831	39.4	1.15 [0.86,1.53]	
FIGARO-DKD	141 / 3683	164 / 3658	60.6	0.85 [0.67,1.07]	
Total	246 / 6510	256 / 6489		0.96 [0.80,1.14]	Z=-0.50, p=0.6198
Heterogeneity:	Q=2.63 (df=1)	p=0.1046	I^2=62.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.161: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

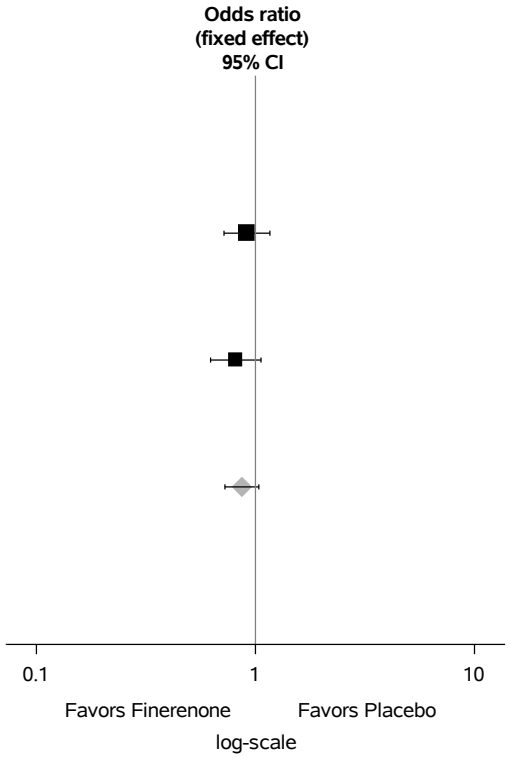
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	66 / 2827	89 / 2831	42.8	0.74 [0.53,1.02]	
FIGARO-DKD	107 / 3683	96 / 3658	57.2	1.11 [0.84,1.47]	
Total	173 / 6510	185 / 6489		0.93 [0.75,1.15]	Z=-0.67, p=0.5002
Heterogeneity:	Q=3.55 (df=1)	p=0.0595	I^2=71.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.162: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

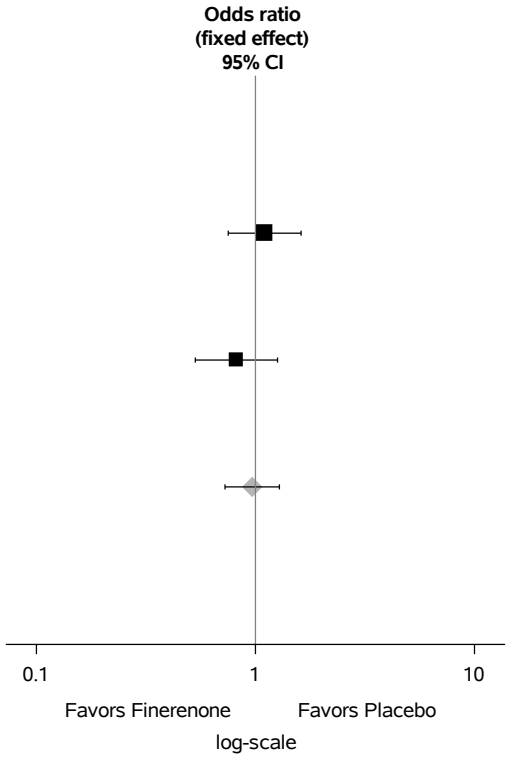
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	133 / 2827	145 / 2831	54.7	0.91 [0.72,1.16]	
FIGARO-DKD	103 / 3683	125 / 3658	45.3	0.81 [0.62,1.06]	
Total	236 / 6510	270 / 6489		0.87 [0.73,1.04]	Z=-1.57, p=0.1167
Heterogeneity:	Q=0.41 (df=1)	p=0.5207	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.163: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

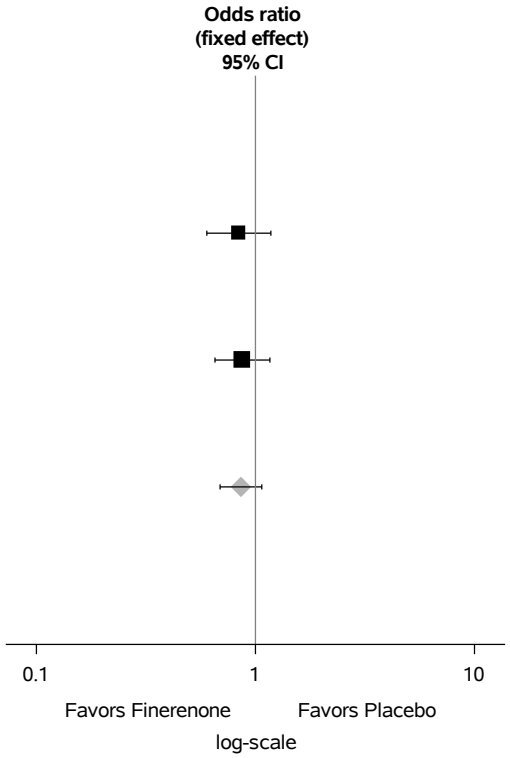
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	56 / 2827	51 / 2831	56.0	1.10 [0.75,1.62]	
FIGARO-DKD	38 / 3683	46 / 3658	44.0	0.82 [0.53,1.26]	
Total	94 / 6510	97 / 6489		0.97 [0.73,1.29]	Z=-0.23, p=0.8149
Heterogeneity:	Q=1.02 (df=1)	p=0.3135	I^2=1.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.164: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

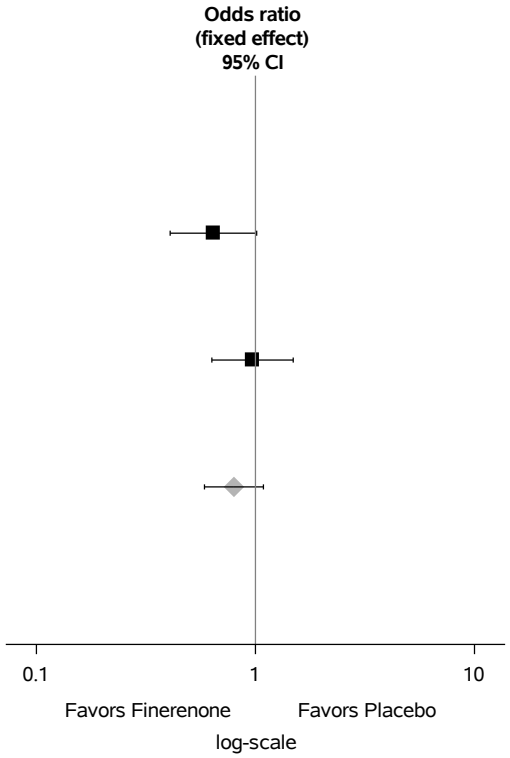
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	64 / 2827	76 / 2831	42.4	0.84 [0.60,1.18]	
FIGARO-DKD	89 / 3683	101 / 3658	57.6	0.87 [0.65,1.16]	
Total	153 / 6510	177 / 6489		0.86 [0.69,1.07]	Z=-1.37, p=0.1714
Heterogeneity:	Q=0.03 (df=1)	p=0.8669	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.165: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

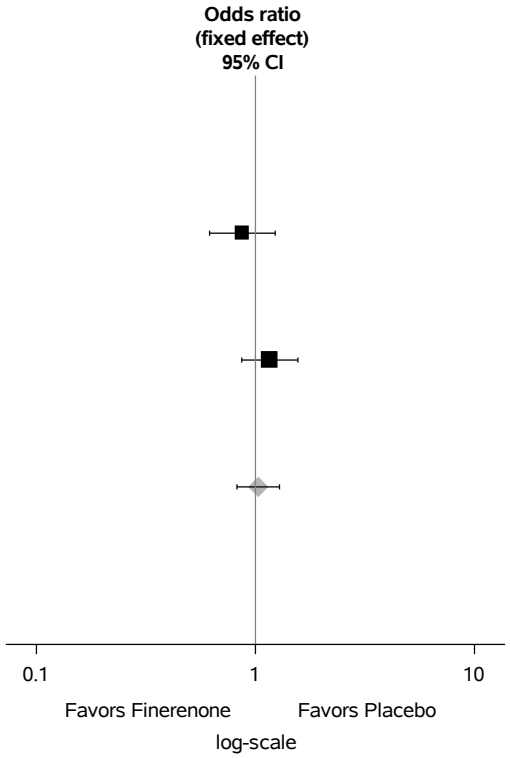
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2827	48 / 2831	46.9	0.64 [0.41,1.01]	
FIGARO-DKD	42 / 3683	43 / 3658	53.1	0.97 [0.63,1.49]	
Total	73 / 6510	91 / 6489		0.80 [0.59,1.09]	Z=-1.43, p=0.1527
Heterogeneity:	Q=1.67 (df=1)	p=0.1966	I^2=40.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.166: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set

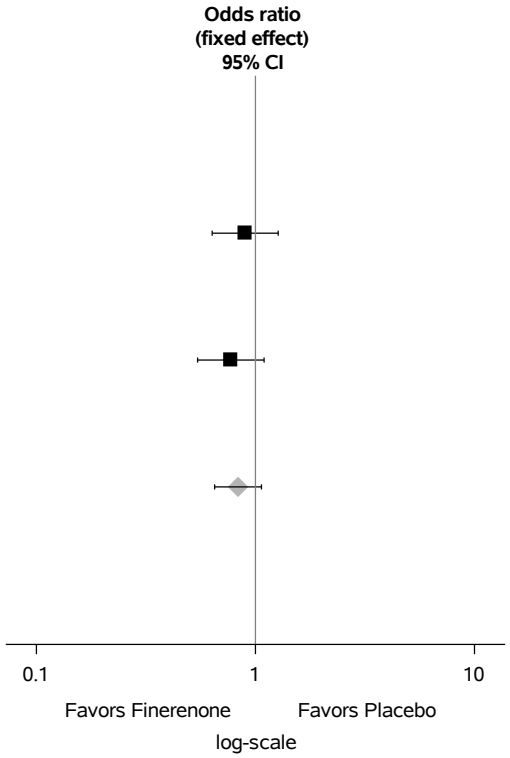
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	71 / 2831	42.3	0.87 [0.62,1.23]	
FIGARO-DKD	98 / 3683	84 / 3658	57.7	1.16 [0.87,1.56]	
Total	160 / 6510	155 / 6489		1.03 [0.82,1.29]	Z=0.26, p=0.7986
Heterogeneity:	Q=1.55 (df=1)	p=0.2128	I^2=35.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.167: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

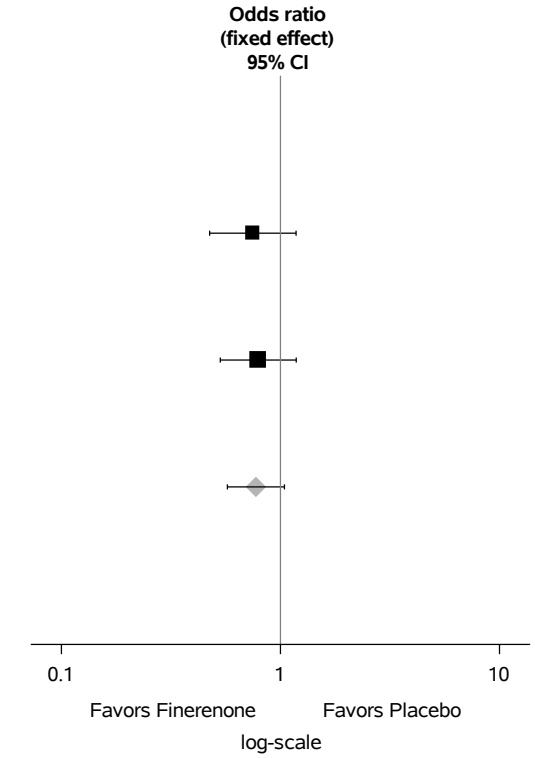
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2827	69 / 2831	50.4	0.90 [0.63,1.27]	
FIGARO-DKD	57 / 3683	73 / 3658	49.6	0.77 [0.54,1.09]	
Total	119 / 6510	142 / 6489		0.83 [0.65,1.06]	Z=-1.46, p=0.1447
Heterogeneity:	Q=0.36 (df=1)	p=0.5486	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.168: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set

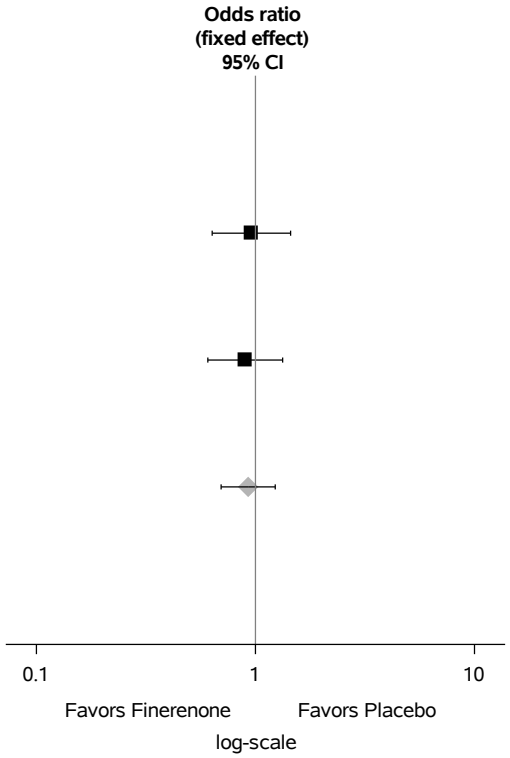
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2827	44 / 2831	43.5	0.75 [0.47,1.18]	
FIGARO-DKD	44 / 3683	55 / 3658	56.5	0.79 [0.53,1.18]	
Total	77 / 6510	99 / 6489		0.77 [0.57,1.04]	Z=-1.69, p=0.0917
Heterogeneity:	Q=0.03 (df=1)	p=0.8532	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.169: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

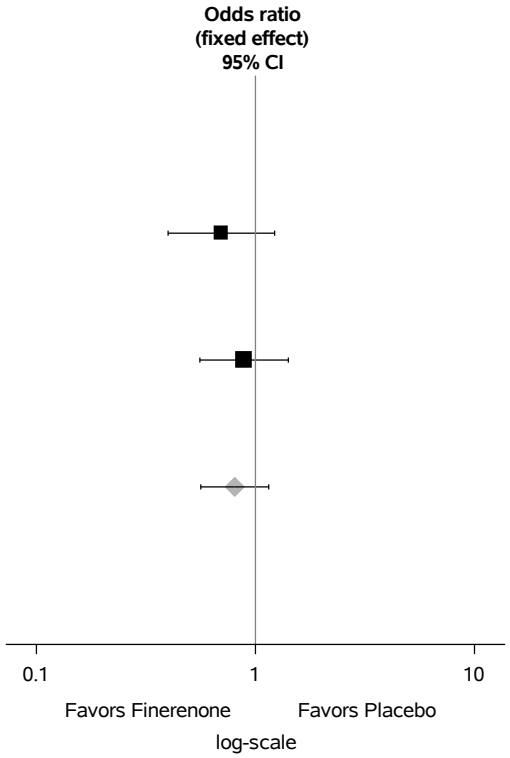
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2827	47 / 2831	47.7	0.96 [0.63,1.45]	
FIGARO-DKD	48 / 3683	53 / 3658	52.3	0.90 [0.61,1.33]	
Total	93 / 6510	100 / 6489		0.93 [0.70,1.23]	Z=-0.53, p=0.5976
Heterogeneity:	Q=0.05 (df=1)	p=0.8241	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.170: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set

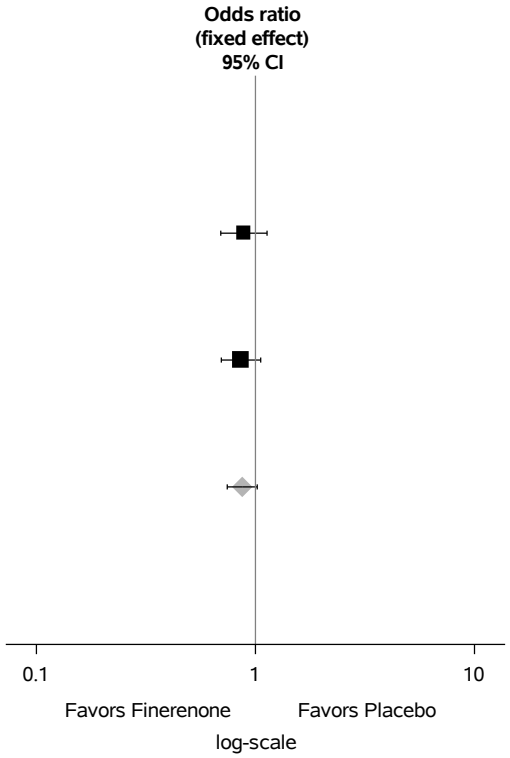
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2827	30 / 2831	40.8	0.70 [0.40,1.22]	
FIGARO-DKD	34 / 3683	38 / 3658	59.2	0.89 [0.56,1.41]	
Total	55 / 6510	68 / 6489		0.80 [0.56,1.15]	Z=-1.19, p=0.2323
Heterogeneity:	Q=0.41 (df=1)	p=0.5194	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.171: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set

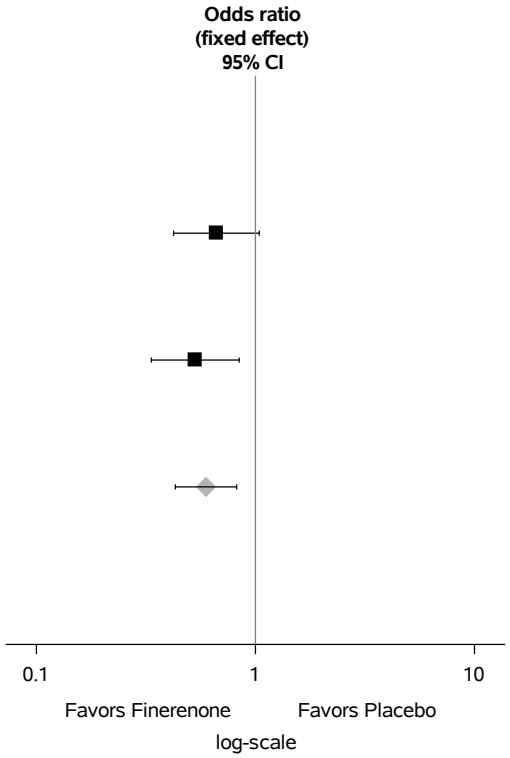
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2827	145 / 2831	42.0	0.89 [0.69,1.13]	
FIGARO-DKD	177 / 3683	203 / 3658	58.0	0.86 [0.70,1.06]	
Total	306 / 6510	348 / 6489		0.87 [0.74,1.02]	Z=-1.73, p=0.0839
Heterogeneity:	Q=0.03 (df=1)	p=0.8523	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.172: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

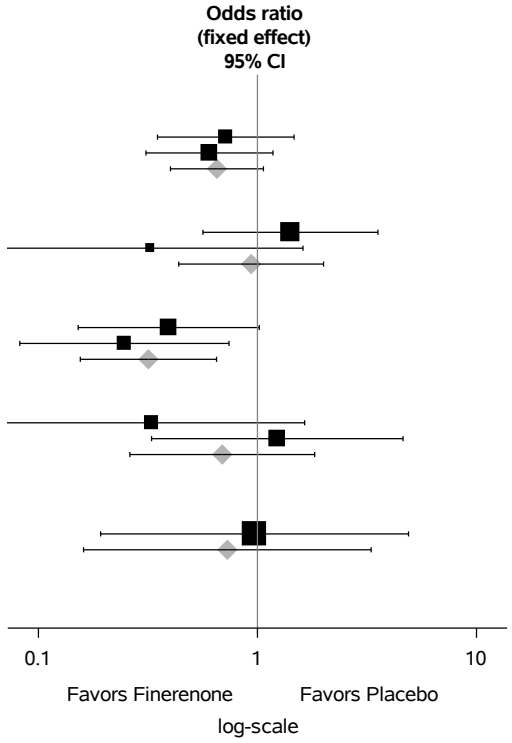
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2827	48 / 2831	51.2	0.66 [0.42,1.04]	
FIGARO-DKD	28 / 3683	52 / 3658	48.8	0.53 [0.33,0.84]	
Total	60 / 6510	100 / 6489		0.59 [0.43,0.82]	Z=-3.16, p=0.0016
Heterogeneity:	Q=0.46 (df=1)	p=0.4984	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.172.1: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

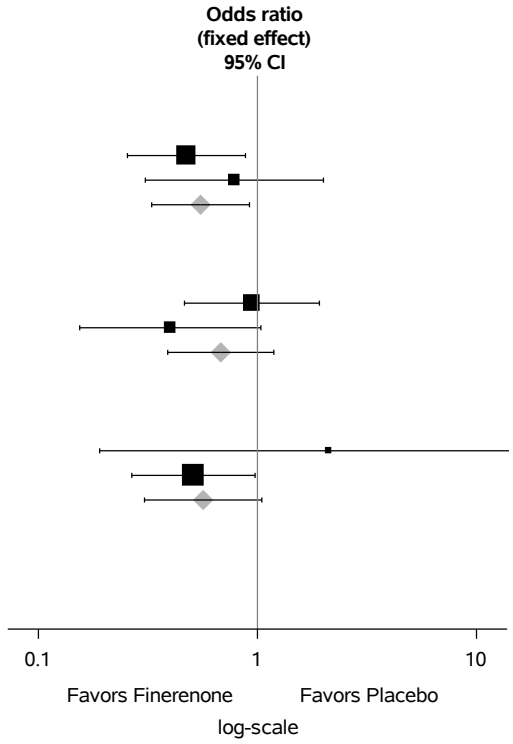
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	13 / 1178	18 / 1174	46.4	0.72 [0.35,1.47]	
FIGARO-DKD	14 / 1752	23 / 1747	53.6	0.60 [0.31,1.18]	
Total	27 / 2930	41 / 2921		0.65 [0.40,1.06]	Z=-1.71, p=0.0876
Heterogeneity:	Q=0.12 (df=1)	p=0.7320	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 466	8 / 476	75.3	1.41 [0.56,3.55]	
FIGARO-DKD	2 / 559	6 / 548	24.7	0.32 [0.07,1.61]	
Total	13 / 1025	14 / 1024		0.94 [0.44,2.00]	Z=-0.17, p=0.8648
Heterogeneity:	Q=2.45 (df=1)	p=0.1176	I^2=59.2%		
Asia					
FIDELIO-DKD	6 / 790	15 / 786	57.2	0.39 [0.15,1.02]	
FIGARO-DKD	4 / 811	16 / 813	42.8	0.25 [0.08,0.74]	
Total	10 / 1601	31 / 1599		0.32 [0.16,0.65]	Z=-3.14, p=0.0017
Heterogeneity:	Q=0.40 (df=1)	p=0.5296	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 294	6 / 294	40.3	0.33 [0.07,1.64]	
FIGARO-DKD	5 / 424	4 / 417	59.7	1.23 [0.33,4.62]	
Total	7 / 718	10 / 711		0.69 [0.26,1.83]	Z=-0.75, p=0.4555
Heterogeneity:	Q=1.55 (df=1)	p=0.2125	I^2=35.7%		
Others					
FIDELIO-DKD	0 / 99	1 / 101	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	3 / 137	3 / 133	100.0	0.97 [0.19,4.89]	
Total	3 / 236	4 / 234		0.73 [0.16,3.30]	Z=-0.41, p=0.6816
Heterogeneity:	Q=0.12 (df=1)	p=0.7289	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.59 (df=4)	p=0.3322	I^2=12.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.172.2: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

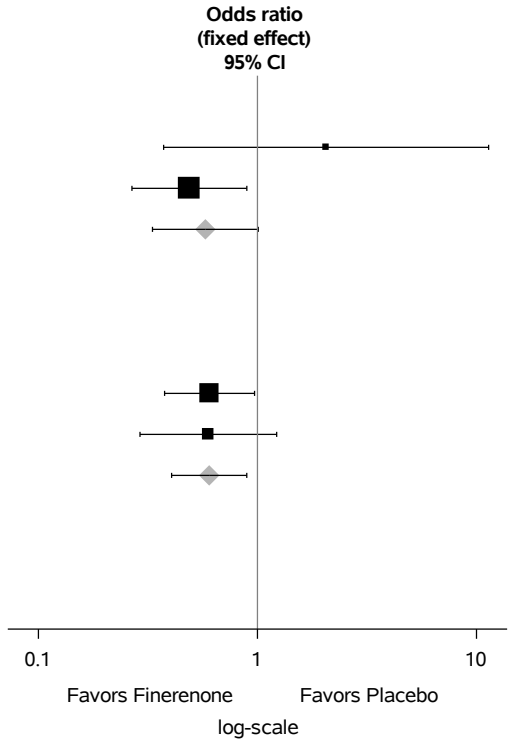
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	15 / 1556	31 / 1541	69.5	0.47 [0.25,0.88]	
FIGARO-DKD	8 / 637	10 / 627	30.5	0.78 [0.31,2.00]	
Total	23 / 2193	41 / 2168		0.55 [0.33,0.92]	Z=-2.28, p=0.0226
Heterogeneity:	Q=0.77 (df=1)	p=0.3792	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	15 / 1061	16 / 1069	64.3	0.94 [0.46,1.92]	
FIGARO-DKD	6 / 720	15 / 729	35.7	0.40 [0.15,1.04]	
Total	21 / 1781	31 / 1798		0.68 [0.39,1.19]	Z=-1.35, p=0.1756
Heterogeneity:	Q=2.01 (df=1)	p=0.1561	I^2=50.3%		
>= 60					
FIDELIO-DKD	2 / 210	1 / 221	6.8	2.12 [0.19,23.50]	
FIGARO-DKD	14 / 2326	27 / 2302	93.2	0.51 [0.27,0.98]	
Total	16 / 2536	28 / 2523		0.57 [0.30,1.05]	Z=-1.81, p=0.0697
Heterogeneity:	Q=1.25 (df=1)	p=0.2636	I^2=20.0%		
Subgroup Heterogeneity:	Q=0.34 (df=2)	p=0.8446	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.172.3: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

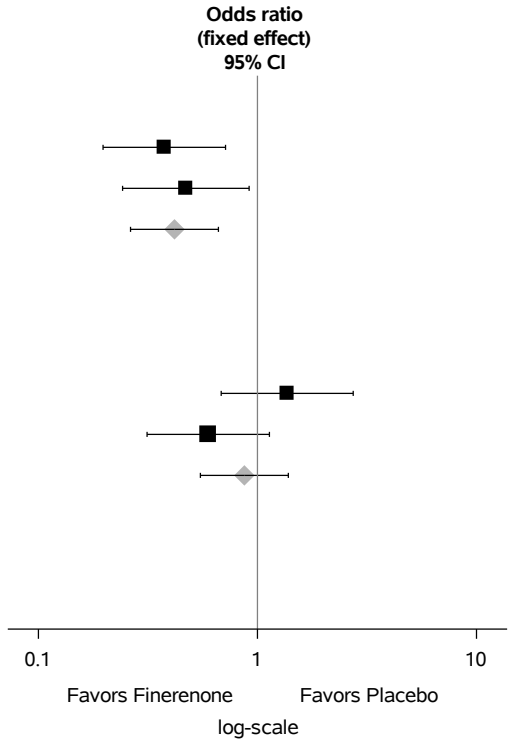
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	2 / 213	11.1	2.06 [0.37,11.36]	
FIGARO-DKD	16 / 1720	32 / 1698	88.9	0.49 [0.27,0.89]	
Total	20 / 1929	34 / 1911		0.58 [0.33,1.01]	Z=-1.93, p=0.0536
Heterogeneity:	Q=2.42 (df=1)	p=0.1198	I^2=58.7%		
Very High					
FIDELIO-DKD	28 / 2618	46 / 2618	69.8	0.60 [0.38,0.97]	
FIGARO-DKD	12 / 1963	20 / 1960	30.2	0.60 [0.29,1.22]	
Total	40 / 4581	66 / 4578		0.60 [0.41,0.89]	Z=-2.52, p=0.0118
Heterogeneity:	Q=0.00 (df=1)	p=0.9762	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9082	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.172.4: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

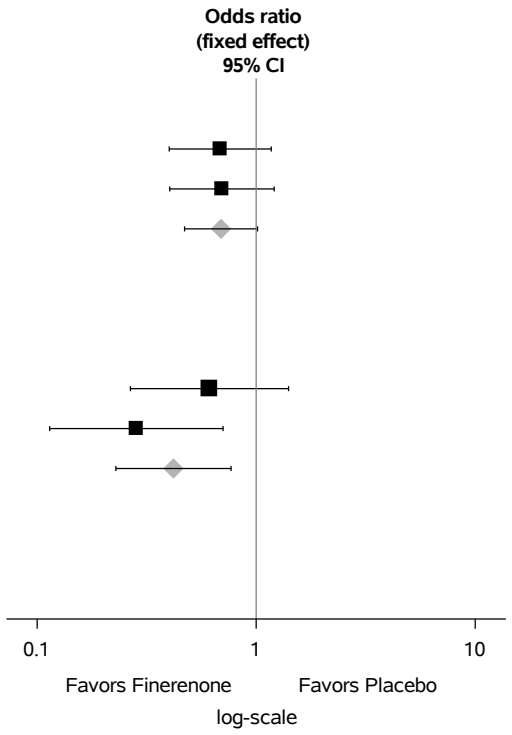
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1301	34 / 1299	51.6	0.38 [0.20,0.71]	
FIGARO-DKD	13 / 1673	27 / 1651	48.4	0.47 [0.24,0.92]	
Total	26 / 2974	61 / 2950		0.42 [0.26,0.66]	Z=-3.70, p=0.0002
Heterogeneity:	Q=0.23 (df=1)	p=0.6313	I^2=0.0%		
Absent					
FIDELIO-DKD	19 / 1526	14 / 1532	46.2	1.37 [0.68,2.74]	
FIGARO-DKD	15 / 2010	25 / 2007	53.8	0.60 [0.31,1.13]	
Total	34 / 3536	39 / 3539		0.87 [0.55,1.38]	Z=-0.58, p=0.5594
Heterogeneity:	Q=2.96 (df=1)	p=0.0855	I^2=66.2%		
Subgroup Heterogeneity:	Q=4.85 (df=1)	p=0.0276	I^2=79.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.172.5: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	23 / 1879	33 / 1858	51.2	0.69 [0.40,1.17]	
FIGARO-DKD	22 / 2643	31 / 2608	48.8	0.70 [0.40,1.21]	
Total	45 / 4522	64 / 4466		0.69 [0.47,1.01]	Z=-1.89, p=0.0594
Heterogeneity:	Q=0.00 (df=1)	p=0.9634	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 948	15 / 973	54.6	0.61 [0.27,1.41]	
FIGARO-DKD	6 / 1040	21 / 1048	45.4	0.28 [0.11,0.71]	
Total	15 / 1988	36 / 2021		0.42 [0.23,0.77]	Z=-2.81, p=0.0049
Heterogeneity:	Q=1.50 (df=1)	p=0.2205	I^2=33.4%		
Subgroup Heterogeneity:	Q=1.87 (df=1)	p=0.1712	I^2=46.6%		

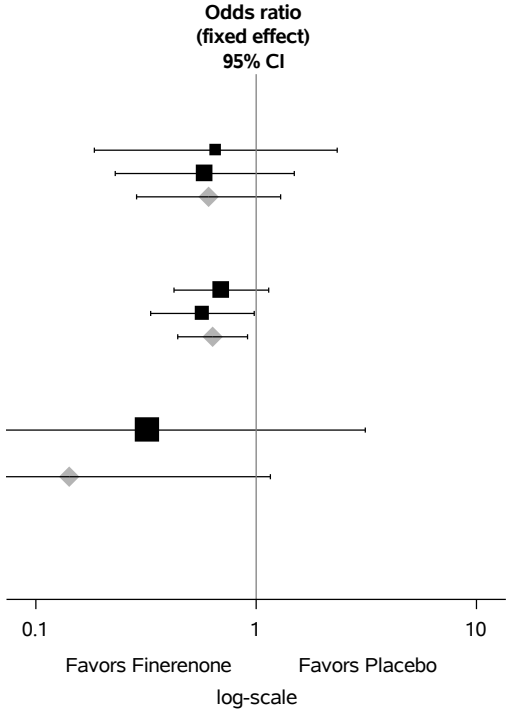


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.172.6: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)

Safety Analysis Set

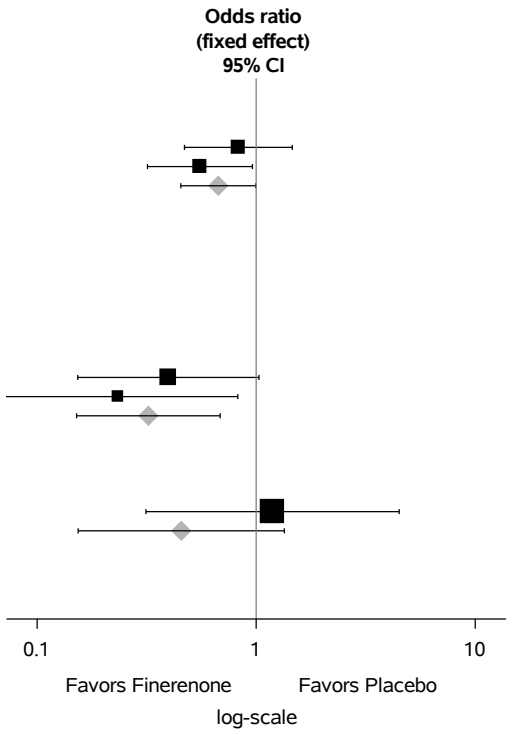
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 788	6 / 777	35.2	0.66 [0.18,2.33]	
FIGARO-DKD	7 / 1187	12 / 1194	64.8	0.58 [0.23,1.49]	
Total	11 / 1975	18 / 1971		0.61 [0.29,1.29]	Z=-1.29, p=0.1955
Heterogeneity:	Q=0.02 (df=1)	p=0.8862	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	27 / 1897	39 / 1916	54.5	0.69 [0.42,1.14]	
FIGARO-DKD	21 / 2389	36 / 2351	45.5	0.57 [0.33,0.98]	
Total	48 / 4286	75 / 4267		0.63 [0.44,0.91]	Z=-2.44, p=0.0145
Heterogeneity:	Q=0.28 (df=1)	p=0.5973	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 141	3 / 138	100.0	0.32 [0.03,3.13]	
FIGARO-DKD	0 / 107	4 / 113	0.0	0.00 [0.00,86E295]	
Total	1 / 248	7 / 251		0.14 [0.02,1.16]	Z=-1.82, p=0.0685
Heterogeneity:	Q=0.50 (df=1)	p=0.4803	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.90 (df=2)	p=0.3876	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.172.7: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

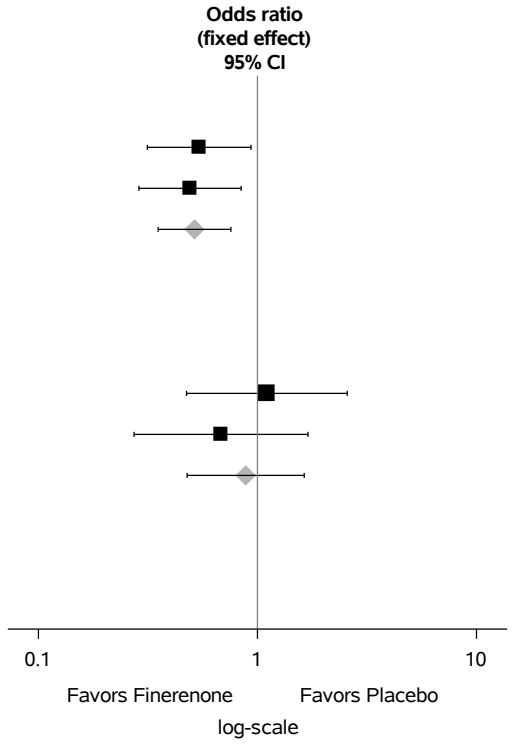
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1773	27 / 1809	48.7	0.83 [0.47,1.46]	
FIGARO-DKD	20 / 2668	35 / 2601	51.3	0.55 [0.32,0.96]	
Total	42 / 4441	62 / 4410		0.67 [0.45,1.00]	Z=-1.98, p=0.0476
Heterogeneity:	Q=1.00 (df=1)	p=0.3171	I^2=0.1%		
Black					
FIDELIO-DKD	4 / 139	0 / 124	0.0	168E9 [168E9,168E9]	
FIGARO-DKD	0 / 113	0 / 145	0.0	-	
Total	4 / 252	0 / 269		471E9 [471E9,471E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	6 / 717	15 / 721	63.6	0.40 [0.15,1.03]	
FIGARO-DKD	3 / 716	13 / 736	36.4	0.23 [0.07,0.82]	
Total	9 / 1433	28 / 1457		0.32 [0.15,0.68]	Z=-2.94, p=0.0032
Heterogeneity:	Q=0.43 (df=1)	p=0.5104	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 198	6 / 177	0.0	0.00 [0.00,9E296]	
FIGARO-DKD	5 / 186	4 / 176	100.0	1.19 [0.31,4.50]	
Total	5 / 384	10 / 353		0.45 [0.15,1.35]	Z=-1.42, p=0.1545
Heterogeneity:	Q=2.00 (df=1)	p=0.1577	I^2=49.9%		
Subgroup Heterogeneity:	Q=3.02 (df=3)	p=0.3880	I^2=0.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure 2.2.172.8: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

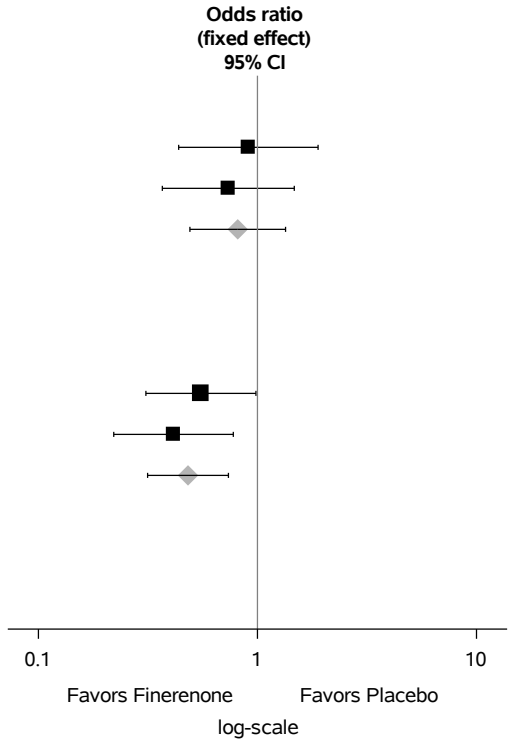
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	20 / 1949	38 / 2024	49.3	0.54 [0.31,0.93]	
FIGARO-DKD	20 / 2527	41 / 2571	50.7	0.49 [0.29,0.84]	
Total	40 / 4476	79 / 4595		0.52 [0.35,0.76]	Z=-3.39, p=0.0007
Heterogeneity:	Q=0.06 (df=1)	p=0.8059	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 878	10 / 807	54.0	1.10 [0.47,2.57]	
FIGARO-DKD	8 / 1156	11 / 1087	46.0	0.68 [0.27,1.70]	
Total	20 / 2034	21 / 1894		0.88 [0.48,1.64]	Z=-0.39, p=0.6933
Heterogeneity:	Q=0.58 (df=1)	p=0.4475	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.11 (df=1)	p=0.1459	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.172.9: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set

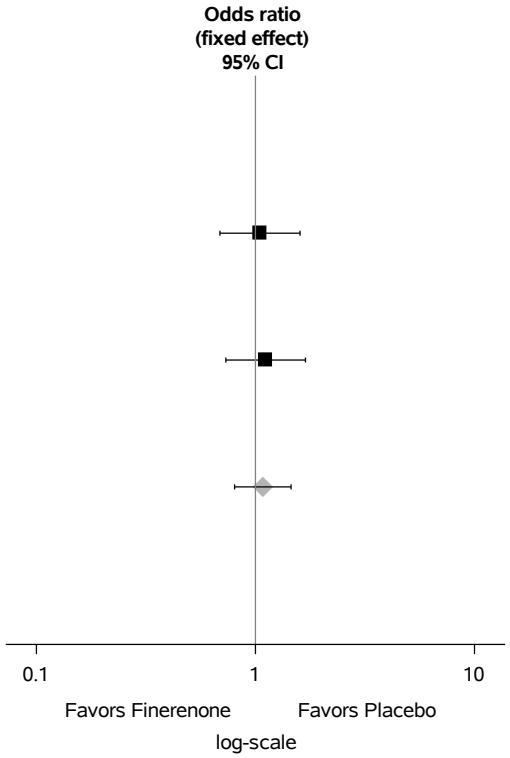
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	14 / 1201	15 / 1171	47.2	0.91 [0.44,1.89]	
FIGARO-DKD	14 / 1752	19 / 1755	52.8	0.74 [0.37,1.47]	
Total	28 / 2953	34 / 2926		0.81 [0.49,1.34]	Z=-0.81, p=0.4191
Heterogeneity:	Q=0.17 (df=1)	p=0.6818	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 1626	33 / 1660	54.1	0.55 [0.31,0.98]	
FIGARO-DKD	14 / 1931	33 / 1903	45.9	0.41 [0.22,0.78]	
Total	32 / 3557	66 / 3563		0.48 [0.32,0.74]	Z=-3.37, p=0.0008
Heterogeneity:	Q=0.44 (df=1)	p=0.5087	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.42 (df=1)	p=0.1197	I^2=58.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure 2.2.173: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set

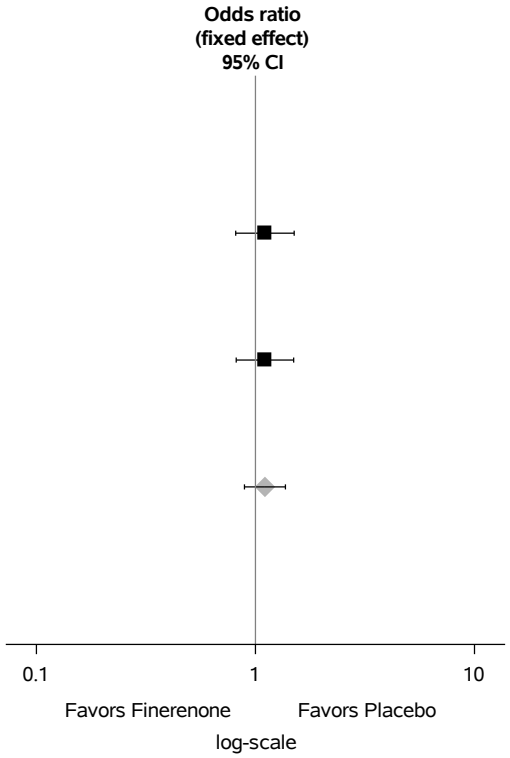
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2827	43 / 2831	49.7	1.05 [0.69,1.60]	
FIGARO-DKD	47 / 3683	42 / 3658	50.3	1.11 [0.73,1.69]	
Total	92 / 6510	85 / 6489		1.08 [0.80,1.45]	Z=0.51, p=0.6090
Heterogeneity:	Q=0.04 (df=1)	p=0.8447	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.174: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set

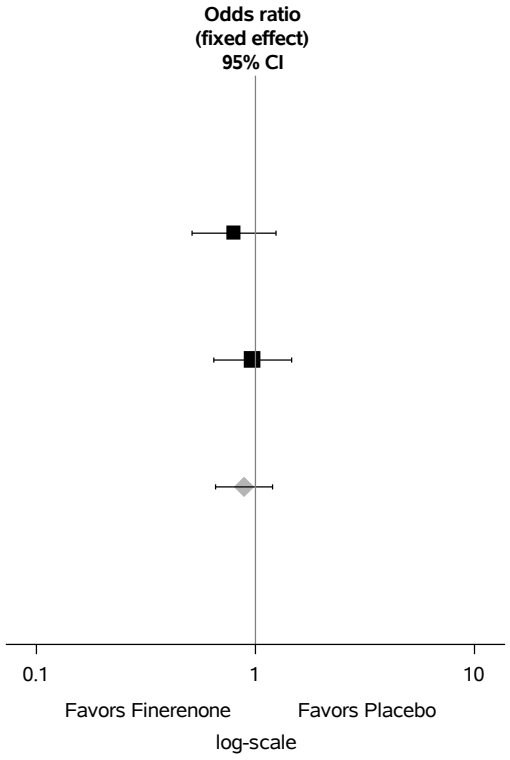
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	88 / 2827	80 / 2831	49.1	1.10 [0.81,1.50]	
FIGARO-DKD	91 / 3683	82 / 3658	50.9	1.10 [0.82,1.49]	
Total	179 / 6510	162 / 6489		1.10 [0.89,1.37]	Z=0.91, p=0.3644
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.175: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set

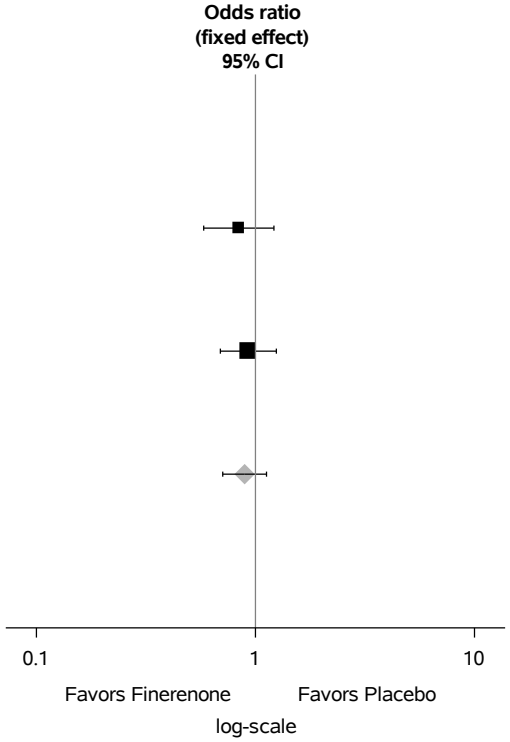
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	45 / 2831	46.2	0.80 [0.51,1.24]	
FIGARO-DKD	46 / 3683	47 / 3658	53.8	0.97 [0.65,1.46]	
Total	82 / 6510	92 / 6489		0.89 [0.66,1.20]	Z=-0.78, p=0.4339
Heterogeneity:	Q=0.41 (df=1)	p=0.5227	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.176: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set

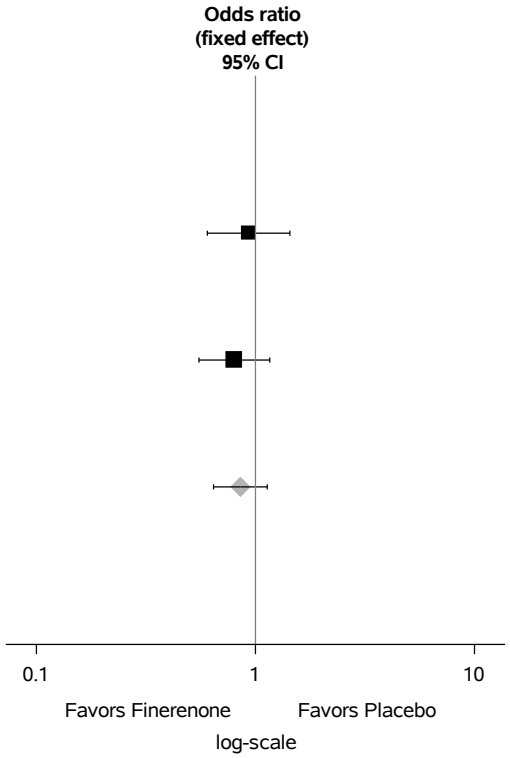
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2827	63 / 2831	38.9	0.84 [0.58,1.21]	
FIGARO-DKD	88 / 3683	94 / 3658	61.1	0.93 [0.69,1.25]	
Total	141 / 6510	157 / 6489		0.89 [0.71,1.12]	Z=-0.97, p=0.3326
Heterogeneity:	Q=0.17 (df=1)	p=0.6769	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.177: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set

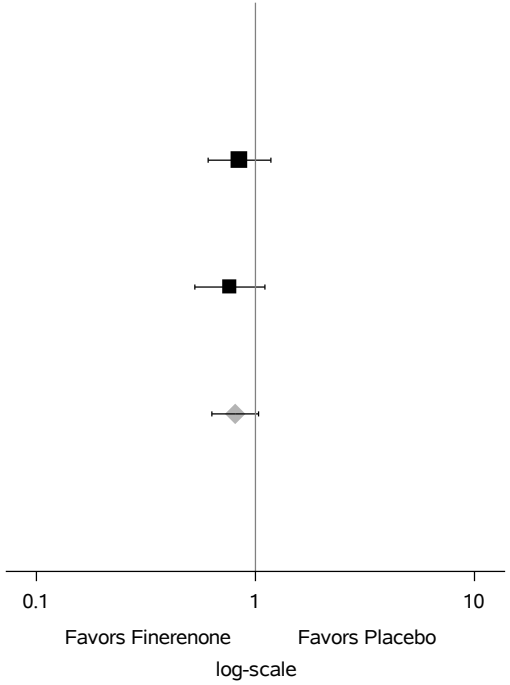
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2827	43 / 2831	42.4	0.93 [0.60,1.44]	
FIGARO-DKD	51 / 3683	63 / 3658	57.6	0.80 [0.55,1.16]	
Total	91 / 6510	106 / 6489		0.85 [0.64,1.13]	Z=-1.10, p=0.2716
Heterogeneity:	Q=0.26 (df=1)	p=0.6079	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.178: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set

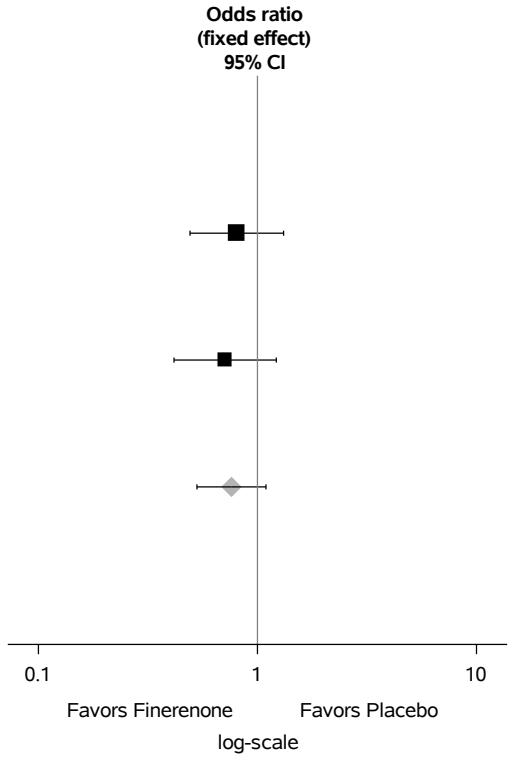
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 2827	79 / 2831	55.5	0.85 [0.61,1.18]	
FIGARO-DKD	51 / 3683	66 / 3658	44.5	0.76 [0.53,1.10]	
Total	118 / 6510	145 / 6489		0.81 [0.63,1.03]	Z=-1.70, p=0.0894
Heterogeneity:	Q=0.16 (df=1)	p=0.6881	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.179: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set

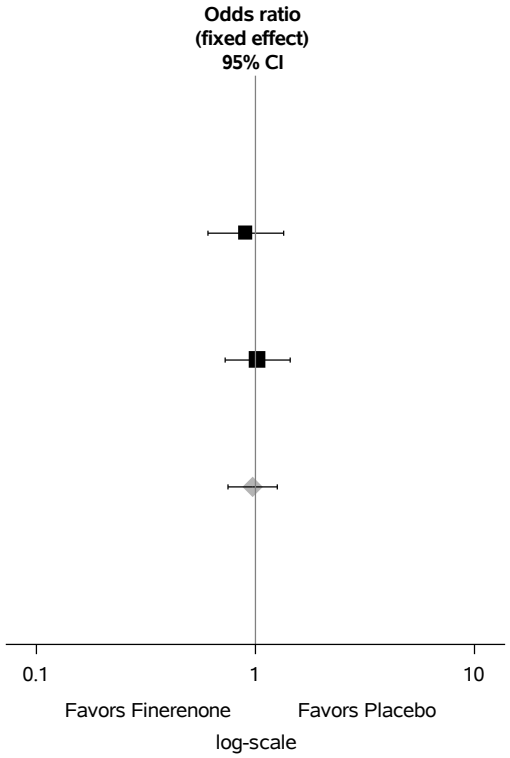
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	29 / 2827	36 / 2831	54.4	0.80 [0.49,1.32]	
FIGARO-DKD	23 / 3683	32 / 3658	45.6	0.71 [0.42,1.22]	
Total	52 / 6510	68 / 6489		0.76 [0.53,1.09]	Z=-1.48, p=0.1399
Heterogeneity:	Q=0.11 (df=1)	p=0.7423	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.180: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set

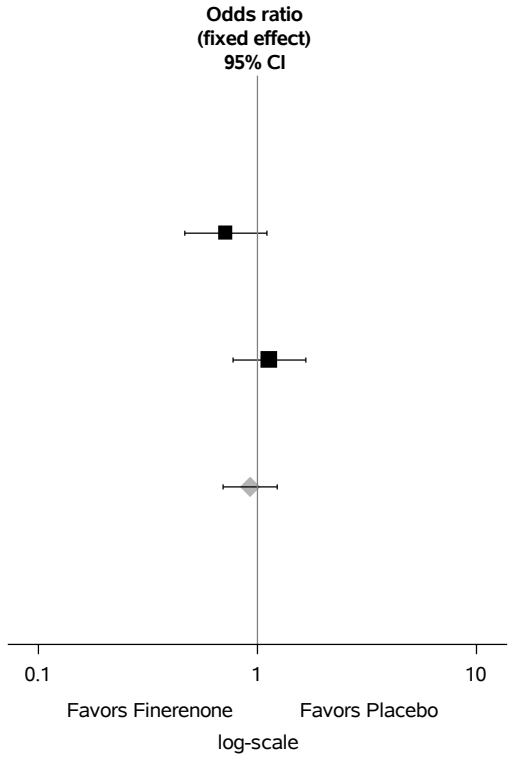
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2827	52 / 2831	42.5	0.90 [0.61,1.35]	
FIGARO-DKD	68 / 3683	66 / 3658	57.5	1.02 [0.73,1.44]	
Total	115 / 6510	118 / 6489		0.97 [0.75,1.26]	Z=-0.22, p=0.8229
Heterogeneity:	Q=0.22 (df=1)	p=0.6407	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure 2.2.181: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2827	50 / 2831	44.0	0.72 [0.47,1.10]	
FIGARO-DKD	57 / 3683	50 / 3658	56.0	1.13 [0.77,1.66]	
Total	93 / 6510	100 / 6489		0.93 [0.70,1.23]	Z=-0.53, p=0.5964
Heterogeneity:	Q=2.42 (df=1)	p=0.1195	I^2=58.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDIGO=Kidney Disease: Improving Global Outcomes, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.